

# Assessing What Matters in HTA: System's Level Decision Making in the Fraser Health Authority

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# Ethics in HTA: Continuing the Conversation

1. Improving ethics analysis in HTA
2. Assessing quality of ethics analysis
3. Availability of ethics expertise in Canada
4. Case studies in ethics analysis
5. System-level values-based decision making

# A “Values-Based” Decision

Usually refers to...

- \* Costs and benefits are weighed in health care policy
- \* Better value = improved clinical outcomes, quality, and/or patient satisfaction per dollar spent

We mean...

- \* Supports integrity
- \* Integrity = intentional and deliberate living of values in decisions, actions, and attitudes

Jiwani B. Good decisions: A map to the best system-level decision all things considered. Surrey, BC: Fraser Health Ethics Services, 2011.

# The THIN View

- \* Facts and values logically unconnected
- \* Ethical issues are separate from assessment of effectiveness, safety, cost-effectiveness
- \* Addresses a narrow range of questions
- \* Insufficient opportunity (space, attention) to discuss tensions among values at play
- \* Implicit prioritization of values which may or may not reflect what is of greatest importance

Ashcroft RE. Health technology assessment. In: Ruth Chadwick, ed. The concise encyclopedia of the ethics of new technologies. Academic Press, 2001.

Braunack-Mayer AJ. Ethics and health technology assessment: Handmaiden and/or critic? *Int J Technol Assess Health Care* 2006;22(3):307-12.

# Example Frameworks

## **OHTAC Decision Determinants**

- \* Invariant substantive values
- \* Ethics is “consistency with values and ethics”
- \* Context-free and context-sensitive evidence
- \* Ethics “stands alone”, i.e., not meant to influence how other criteria are defined and understood
- \* Revision of decision process and appraisal criteria may be closer to “thick” view

Johnson et al. Health technology assessment: A comprehensive framework for evidence-based recommendations in Ontario. *J Technol Assess Health Care* 2009;25(2):141-50.

# Example Frameworks

## **EVIDEM (MCDA)**

- \* Universal and contextual criteria
- \* Ethical considerations “optional”
- \* Ethics “stands alone”, i.e., not meant to influence how other criteria are defined and understood
- \* Little guidance on systematic reflection apart from ranking

EVIDEM Collaboration. Decision criteria: Conceptual background, definitions, design and instructions. EVIDEM v2.2. December 2012. Available: [Evidem.org](http://Evidem.org)

# The **THICK** View

- \* Acknowledges ethical issues in:
  - \* HTA processes
  - \* HTA itself
  - \* Technology design and use
- \* More fully supports robust decision making
- \* Hofmann's (2005) questions, EUnetHTA core model, approaches in Sweden (SBU) and France (HAS)

Hoffman B. Why ethics should be a part of health technology assessment.  
Int J Technol Assess Health Care 2008;24(4):423-9.

# Hofmann's Axiological Approach

33 (now 32) core questions belong to the following groups:

1. General moral issues (1-16)
2. Moral issues related to stakeholders (17-20)
3. Moral issues related to health technology (21-23)
4. Moral issues related to HTA methodology (24-28)
5. Moral issues related to the activity of HTA itself (29-33)

Hofmann B. Toward a procedure for integrating moral issues in HTA. *Int J Technol Assess Health Care* 2005;21(3):312-18.



# EUnetHTA Core Model

Every HTA should be performed considering the following ethical issues:

1. **Process:** Forces and values motivating assessment at this stage, interests of technology producers, and expert group involved
2. **HTA itself:** Endpoints, issues related to meta-analysis and included studies, and scope of HTA and choice of research methods
3. **Technology:** Related morally contentious technologies

# For ethics analysis in HTA to contribute meaningfully...

1. Openness to the (process and results of the) ethics analysis
2. Able to incorporate a variety of morally relevant values and principles, balanced as context demands
3. Protected time for conversation about ethical issues and implications
4. Commitment to respectful engagement with the issues



# The Process – 15 steps



- 1 – Establish the Team
- 2 – **Select the key question**
- 3 – **Look at the evidence**
- 4 – **Consider what is important**
- 5 – **Brainstorm Options**
- 6 – Analyze options
- 7 – **The Preliminary Decision**
- 8 – Engagement
- 9 – The Decision

- 10 – Communication Strategy
- 11 – Education Plan
- 12 – Downstream Support Plan
- 13 – Evaluation & Sustainability Plan
- 14 – Ongoing Feedback Plan
- 15 – Implement the Decision

# FHES process in action: Drug undersupply

- \* Step 1: Gathering the team

- \* Team included health care decision-makers, content experts, group of health ethicists from BC

- \* Step 2: The key question:

*What allocation criteria should be used to allocate scarce injectable opioids, if the need for the drug outweighs supply?*



# FHES process in action: Drug undersupply

- \* Step 3 – Gathering the facts
  - \* The reality of drug undersupply
  - \* Severity of drug shortages
  - \* Causes of drug undersupply
  - \* Impact of drug shortages
  - \* 2012 – Experience with this drug manufacturer
  - \* Vulnerable Populations
  - \* Decision-making authority and the law
  - \* Drug supply chain



# FHES process in action: Drug undersupply

- \* Step 4 – What is important as we allocate:
  - \* That we maximize patients' quality of life
  - \* That we minimize patients' pain and suffering
  - \* That we support patients' autonomy and dignity
  - \* That we respect dying as a crucial phase of life
  - \* That we protect vulnerable patients, particularly those who do not have the capacity to make sense of their pain



# FHES process in action: Drug undersupply

## \* Step 7 - Preliminary Decision - criteria

- \* 1. Those who are terminally ill, experiencing severe pain and in the dying process; Those who need opioid to undergo a life-saving procedure
- \* 2. Those who require urgent and emergent health care procedures
- \* 3. those who are experience severe physical pain and suffering
- \* 4. Those in need of elective health care procedures



# FHES process in action: Drug undersupply

- \* **Step 8 – Engagement**

- \* Document summarizing the facts, values, and proposed response was circulated to those involved in the process for feedback

- \* **Step 9 – The Decision**

- \* Feedback was collected and received, and informed the policy going forward

# Key Features of FHES process

- \* **Encompassing** – considers the whole activity to be one of moral/ethical deliberation
- \* **Inclusive** – asks questions about who should become involved
- \* **Deliberative** – requires that people come together in various forms to consider the facts and values
- \* **Recursive** – open to changing the decision with the arrival of new information/values
- \* **Solutions oriented** – systematically designed to work toward a decision

# FHES Method

- \* A feasible process
- \* Structures respectful engagement and time for the ethics conversation
- \* Elicits key values (rather than assuming which values will be relevant)
- \* Provides systematic methods for values prioritization
- \* Allows for thick conception of ethics

# On-going Challenges

- \* FHES systems level tool is not designed with HTA in; some modifications may be required to put it to use in an HTA context
- \* Arriving at consensus about the role of ethics expertise in HTA
- \* Balancing thoroughness with practical limitations

# The Systems Level Tool

<http://www.incorporatingethics.ca/view-good-decisions.php>

# THANK YOU

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