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

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


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

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

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)

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)

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
Promoting value-based decision making: FHES Approach

* Offers another option for HTA process that lives up to criteria listed above

* Multi-step process

* Intended for systems-levels decisions in health care
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 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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