Reporting on ethics in HTA: How to report on the methods, results and interpretation of ethics inquiry

“Introduction to Ethics in HTA” HTAi 2015 Preconference Workshop

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1. Guidelines in ethics for HTA?

2. Reporting on ethics issues in HTA:
   - Reporting on method
   - Reporting the results

1. Interpretation of the results
1. Guidelines in ethics for HTA – who are they for?

› Those familiar with HTA but not with ethics in HTA

› Those who have to evaluate the quality of systematic review which includes an ethics component

› Those with responsibility for implementing the findings of a systematic review which contains an ethics component
1. Benefits of guidelines in ethics for HTA

- Structures the analysis, increasing its readability
- Increases transparency
  - ... and therefore, also, reproducibility and transferability
- Promotes consistency in terminology
- Improves communication
  - Between agency/decision-maker/person carrying out the ethics analysis
  - By clarifying expectations regarding structure, content, output…
- Facilitates the quality assessment of the resulting analysis
1. Drawbacks of guidelines in ethics for HTA?

› **Standardisation where none is possible?**
  
  - There is a wide range of approaches to assessing ethics issues in HTA – how can a guideline help here?
  
  - But… we could make the same claim regarding systematic reviews more generally, yet guidelines do exist! (e.g. CRD’s guidance)
  
  - Standardisation need not prohibit flexibility of method and judgement (Duthie & Bond, 2011)

› **Would guidelines encourage a “race to the bottom”?**
  
  - stipulating a set of minimum criteria to be met may have the result that this “minimum” will become “the standard”
  
  - Has this been the case in other areas of systematic reviews?
1. Guidelines in ethics for HTA – but where do I find them?

A systematic review was recently done by our colleagues in Canada*, looking for the existing methodological guideline documents for ethics in HTA:

› Found 43 conceptual frameworks and/or guidelines
› From a variety of countries and international agencies
› Using various analytical methods
› And for a variety of purposes throughout the HTA process

Take home message: There are resources for you to use.

2. A few general points about reporting on ethical issues in HTA

› **Transparency**
  - Perspective adopted
  - Value conflicts

› **Framework**
  - Which framework was adopted and why

› **Usefulness of the output**
  - What do the decision-makers want/need?

› **Context-sensitivity:**
  - Differences in: socio-cultural values, political ideologies, values underpinning the health system, etc.
Two types of systematic reviews in ethics for HTA:

 › Systematic review of reasons (Sofaer/Strech model)
 › Systematic review of normative literature (McCullough et al model)

Difference in the question asked:

 › Systematic review of reasons asks an empirical question
   - E.g., what reasons have been given for the view that former drug trial participants should or should not be ensured post-trial access to trial drugs

 › Systematic review of normative literature asks a normative question
   - E.g., [P] In patients with mental disorders [I] is use of concealed medications in food/drink, [C] rather than prescribing medications in the usual way or forcibly administering them, [O] ethically justifiable?
2. Reporting on method: key steps in doing a systematic review of ethical issues in HTA

1. Formulate the review question
2. Eligibility criteria
3. Evidence gathering
4. Data extraction
5. Quality assessment
6. Reporting on the results
7. Interpretation of results

(References: Sofaer and Strech 2012; McCullough et al 2007; Hofmann et al 2014; adapted)
2. Reporting the results: SR of reasons (Sofaer/Strech model)


› a systematic review of literature on ethical issues related to ASCT

› assigned issues to B. Hofmann’s framework

<table>
<thead>
<tr>
<th>Dimension/Question</th>
<th>Number of publications with related arguments (N = 102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>81</td>
</tr>
<tr>
<td>Q2</td>
<td>18</td>
</tr>
<tr>
<td>Q3</td>
<td>24</td>
</tr>
<tr>
<td>Q4</td>
<td>2</td>
</tr>
<tr>
<td>Q5</td>
<td>9</td>
</tr>
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<td>Q6</td>
<td>4</td>
</tr>
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<td>Q7</td>
<td>11</td>
</tr>
<tr>
<td>Q8</td>
<td>3</td>
</tr>
<tr>
<td>Q9</td>
<td>0</td>
</tr>
</tbody>
</table>

› **PICO:** [P] In patients with mental disorders (schizophrenia, dementia), [I] is use of concealed medications in food or drink, [C] rather than prescribing medications in the usual way or forcibly administering them, [O] ethically justifiable?

› **Narrative discussion of the 7 publications that met their criteria + table of “critical analysis”**

› **N.B. did not assign their findings to a framework (e.g. B.Hofmann’s, principlist, etc.)**

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Focused Question</th>
<th>Literature Search</th>
<th>Ethical Analysis and Argument</th>
<th>Conclusions</th>
<th>Clinical Application</th>
<th>Overall Score</th>
<th>Position Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Griffith &amp; Bell, 1996</td>
<td>History of possible temporal lobe epilepsy and current elevated mood</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>Concealed medication in the case considered was not unethical</td>
</tr>
<tr>
<td>Trelor, Philpot, &amp; Beats, 2001</td>
<td>Not clearly specified</td>
<td>0</td>
<td>0</td>
<td>1/2</td>
<td>1</td>
<td>1</td>
<td>Permissible with safeguards to prevent abuse</td>
</tr>
<tr>
<td>Honkanen, 2001</td>
<td>Dementia</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>“Underground” mediation not ethically justifiable; medication may be justifiable with surrogate consent</td>
</tr>
<tr>
<td>Stroup, Swartz, &amp; Appelbaum, 2002</td>
<td>Schizophrenia</td>
<td>1/2</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3.5</td>
<td>Not usually justifiable; consider advance directives and other approaches</td>
</tr>
<tr>
<td>Welsh &amp; Deahl, 2002</td>
<td>Not clearly specified</td>
<td>1</td>
<td>0</td>
<td>1/2</td>
<td>1</td>
<td>3.5</td>
<td>Best-interest judgments are not just clinical but also societal and legal</td>
</tr>
<tr>
<td>Whitty &amp; Devitt, 2005</td>
<td>Severe mental illness</td>
<td>1</td>
<td>0</td>
<td>1/2</td>
<td>1</td>
<td>3.5</td>
<td>In absence of a single rule applied to all cases, adopt a multidisciplinary approach</td>
</tr>
<tr>
<td>Ahern &amp; van Tosh, 2005</td>
<td>Not clearly specified</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>Never ethically permissible</td>
</tr>
</tbody>
</table>
3. Interpretation of results

**Issues to consider:**

› Arguments/issues identified in the evidence-gathering stage

› Evidence gaps and their importance

› Main ethical disagreements identified

› Linking of findings to context
  - values underlying the health system
  - socio-cultural values in the jurisdiction of interest
  - stakeholder groups benefited/harmed by adoption of the health technology
  - political context (conservative, progressive, etc.)
3. Interpretation of results

Possible approach to interpreting the results in an executive summary:

› 10 arguments were identified in the literature
› Main disagreement was between arguments that [...] and arguments that [...] 
› The following 2 arguments are the most relevant to our jurisdictional context
  - Argument 1 [describe argument and relevance to context]
  - Argument 2 [describe argument and relevance to context]
› Value preference A supports adopting the position following from arg 1
› Value preference B supports adopting the position following from arg 2
THANK YOU!

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