

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

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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.

*Nazila Assasi et al (2014) “Methodological guidance documents for evaluation of ethical considerations in health technology assessment: a systematic review.” Expert Rev. Pharmacoecon. Outcomes Res. 14(2): 203–220

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.

2. Reporting on method: key steps in doing a systematic review of ethics issues in HTA

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)

Example: Droste et al (2011) “Ethical issues in autologous stem cell transplantation (ASCT) in advanced breast cancer: A systematic review of the literature”

- › a **systematic review of literature on ethical issues related to ASCT**
- › **assigned issues to B. Hofmann’s framework**

Table 4 Number of publications with arguments related to the dimensions and questions of Hofmann’s question list

Dimension/Question	Number of publications with related arguments (N = 102)
Moral issues	81
Q1 What are the morally relevant consequences of the implementation of the technology?	18
Q2 Does the implementation or use of the technology challenge patient autonomy?	24
Q3 Does the technology violate or interfere with basic human rights in any way?	2
Q4 Does the technology challenge human integrity?	9
Q5 Does the technology challenge human dignity?	4
Q6 Will there be a moral obligation related to the implementation and use of a technology?	11
Q7 Does the technology challenge social values and arrangements?	3
Q8 Does the widespread use of the technology change our conception of certain persons?	0
Q9 Does the technology contest religious, social or cultural convictions?	1

2. Reporting the results: SR of normative lit (McCullough model)

Example: McCullough et al (2007) Constructing a Systematic Review for Argument-Based Clinical Ethics Literature: The Example of Concealed Medications

- › **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.)**

2. Reporting the results: SR of normative lit (McCullough model)

Example: McCullough et al (2007) Constructing a Systematic Review for Argument-Based Clinical Ethics Literature: The Example of Concealed Medications – cont'd

TABLE 1 Critical Analysis of Papers on Concealed Medications

	Patient Population	Focused Question	Literature Search	Ethical Analysis and Argument	Conclusions	Clinical Application	Overall Score	Position Taken
Griffith & Bell, 1996	History of possible temporal lobe epilepsy and current elevated mood	1	0	0	1	1	3.0	Concealed medication in the case considered was not unethical
Treloar, Philpot, & Beats, 2001	Not clearly specified	0	0	1/2	1	1	2.5	Permissible with safeguards to prevent abuse
Honkanen, 2001	Dementia	0	0	0	1	1	2	"Underground" mediation not ethically justifiable; medication may be justifiable with surrogate consent
Stroup, Swartz, & Appelbaum, 2002	Schizophrenia	1/2	0	1	1	1	3.5	Not usually justifiable; consider advance directives and other approaches
Welsh & Deahl, 2002	Not clearly specified	1	0	1/2	1	1	3.5	Best-interest judgments are not just clinical but also societal and legal
Whitty & Devitt, 2005	Severe mental illness	1	0	1/2	1	1	3.5	In absence of a single rule applied to all cases, adopt a multidisciplinary approach
Ahern & van Tosh, 2005	Not clearly specified	0	0	0	1	1	2.0	Never ethically permissible

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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