

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

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› Outline of the presentation

1. Guidelines: who are they for, benefits and drawbacks
2. Few general points about reporting on ethical issues in HTA
3. Reporting on method
4. Reporting the results
5. 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
- › Promotes consistency in terminology
- › Increases transparency
 - ... and therefore, also, reproducibility and transferability
- › 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?
 - “Our systematic review identified a range of approaches to aid consideration of ethical issues throughout the HTA process, yet no generally accepted way was found” (Assasi et al, 2014)
 - But... we could make the same case for (non-ethics) systematic reviews, 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?

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

- › Transparency
 - Perspective adopted (e.g. patient, health system, healthcare providers...)
 - Value conflicts among these stakeholders
- › Framework
 - Which framework was/was not adopted and why (Socratic, principlism, etc.)...
 - Choice contingent on: technology type, research question, expertise available, etc.
- › Usefulness of the output
 - What is the objective of the ethical analysis
 - What do the decision-makers want/need?
- › Output has to be context-sensitive:
 - Differences in: socio-cultural values, political ideologies, values underpinning the health system, etc.
- › Practical constraints
 - availability of required time/resources
 - availability of expertise

3. Reporting on method: key steps in doing a systematic review of ethical 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?

3. Reporting on method: key steps in doing a systematic review of ethical issues in HTA

1. Formulate the review question (SR of reasons vs. SR of normative literature)
2. Eligibility criteria (inclusion/exclusion)
3. Literature & ancillary search strategies
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)

4. Reporting the results 1 – 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. Hoffman’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

4. Reporting the results 1 – SR of reasons (Sofaer/Strech model)

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

Table 5 Summary of currently relevant ethical issues in ASCT in breast cancer patients

Ethical issue

Health technology

Harm: Introduction of ASCT into clinical practice took place without further evaluation in clinical trials.

Harm: Incidence of severe side effects, risk of mortality and some negative impact on quality of life in the survivors

Trust: The only two trials which showed benefit in overall survival were found to be fraudulent (Bezwoda fraud). This caused significant effects on further research and the doctor-patient relationship as well as a lack of trust in oncology and the trial investigators. In consequence ASCT in breast cancer remains a stigmatized technology and of great symbolic value.

Uncertainty: It is unknown to date whether there is any evidence of a benefit of ASCT for some subgroups of breast cancer patients and, if so, whether this group would benefit more from an existing alternative.

External validity: The trials are only representative for highly specialised centres.

Alternatives: Safer procedures than ASCT do exist

Patients

Last chance therapy in metastatic breast cancer: As a consequence of this status patients postpone preparing for death. Attention is drawing away from more appropriate efforts to minimize symptoms and enhance the quality of life for terminally ill patients and their families. Recent publications discuss the right of patients to aggressive, toxic and expensive treatment - even untested with insufficient evidence on effectiveness and safety if it is potentially life-saving or life-prolonging.

Patient autonomy: Patients were faced with the decision to consent to a hopefully life prolonging but also potentially fatal treatment. There are some suggestions that patients are insufficiently informed and patient understanding is not always ensured.

Technological imperative: ASCT with the potential to benefit women with a life-threatening disease raises new hope for patients and physicians.

4. Reporting the results 1 – 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: In patients with mental disorders (schizophrenia, dementia), is use of concealed medications in food or drink, rather than prescribing medications in the usual way or forcibly administering them, 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.)

4. Reporting the results 1 – 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

5. Interpretation of results

Reporting alone isn't enough – interpretation is also needed

- › Salience of arguments/issues identified in the evidence-gathering stage...
- › Main ethical disagreements identified
- › Evidence gaps and their importance
- › Linking of findings to context in which the decision is being made:
 - values underlying the health system
 - socio-cultural values in the jurisdiction of interest
 - political context (conservative, progressive, etc.)

5. Interpretation of results

Possible approach to presenting the interpretation (e.g. 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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