Reporting on ethics in HTA: Methods, results and interpretation

Introduction to Ethics in HTA – HTAi 2017

Anna Mae Scott, CREBP, Bond University, Australia

Dario Sacchini, Università Cattolica del Sacro Cuore, Rome, Italy

3 topics to address:

1. Guidelines re: ethics for HTA?

2. Reporting on ethics issues in HTA:

    A. Method

    B. Results

3. Presenting the interpretation of the results

1. Guidelines re: ethics for HTA – for whom?

- **Those familiar with HTA but not with ethics in HTA**

- **Those evaluating the quality of a SR including an ethics component**
  - **E.g. updating an SR from another country**

- **Those implementing the findings of an SR containing an ethics component**

1. Guidelines re: ethics for HTA – benefits

- **Help to structure the analysis (thus, readability)**

- **Increase transparency (thus, reproducibility, transferability)**

- **Consistency in terminology**

- **Improve communication (ethicist/agency/ decision-makers)**

- **Facilitate quality assessment of the analysis**

1. Guidelines re: ethics for HTA – are there any?

SR of methodological guidelines for ethics in HTA:

- 43 conceptual frameworks and/or guidelines
- Various jurisdictions/agencies
- Variety of methods
- Various purposes (identification of ethics issues, QA, etc)

Take home message: Resources exist to help you.

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 points to keep in mind when reporting on ethical issues in HTA

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

- **Framework**
  - Which one adopted, why

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

- **Context-sensitivity**
  - Socio-cultural values, political ideologies, values underpinning the health system, etc.

2. Reporting on methods: key steps in doing a systematic review of ethical issues in HTA

1. Review question
2. Inclusion/exclusion criteria
3. Evidence searching
4. Data extraction
5. Quality assessment
6. Reporting on the results (more shortly)
7. Interpretation of results (more shortly)

(References: Sofaer and Strech 2012; McCullough et al 2007; Hofmann et al 2014; adapted)

2. Reporting the results: Example 1

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

- **SR of ethical issues related to ASCT; uses B. Hofmann's framework**

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

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

2. Reporting the results: Example 2

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

- **Question**:
  - **[P]** In patients with mental disorders
  - **[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 included 7 publications + 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: Example 2 cont'd

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

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	$\frac{1}{2}$	1	1	2.5	Permissible with safeguards to prevent abuse

3. Interpretation of results

<u>Issues to consider:</u>

- Arguments/issues identified: listing vs weighing

- Evidence gaps?

- Main ethical disagreements identified

- Linkage of findings to context
  - values of the health system
  - socio-cultural values
  - relevant stakeholder groups
  - political context

3. Interpretation of results

Approach to interpreting the results:

- E.g., 10 key ethical issues were identified in the literature

- Main disagreement was between arguments that […] and arguments that […]

- The following 2 arguments are the most relevant to our health system:
  - Arg 1 [describe & clarify relevance to context]
  - Arg 2 [describe & clarify 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

GRAZIE TANTE (Italian) /
THANKS HEAPS (Australian) / THANK YOU VERY MUCH (Queen's English)

Anna Mae Scott

ascott@bond.edu.au

Dario Sacchini

dario.sacchini@unicatt.it