Lessons from policy sciences for HTA

The VALIDATE approach

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VALIDATE
VALues In Doing Assessments of health TEchnologies

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Overview

VALIDATE and the current practice of HTA

Lessons from policy sciences:

- how well structured is the policy problem?

- what sort of policy analysis would work best here?

Method: reconstruction of stakeholders' interpretive frames

Example: pediatric cochlear implants

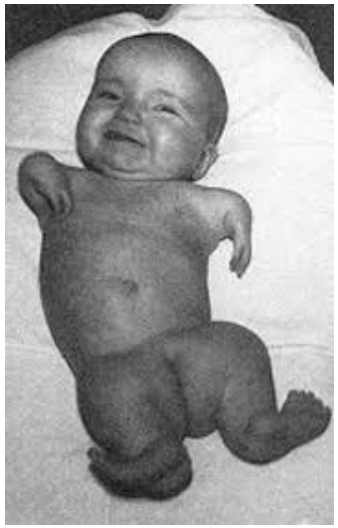
HTA: a type of policy science

"HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system."

O'Rourke, Oortwijn & Schuller, 2020

From its very inception, practitioners of HTA have been committed to the *comprehensive* study of the consequences associated with the use of health technologies

Presumably, this grew out of an increasing awareness, from the 1950s and onwards, that health technologies can have profound, unintended, and unforeseen consequences, that need to be taken into account when making decisions about the use of such technologies



This has led to the following aspects that need to be addressed in HTA:

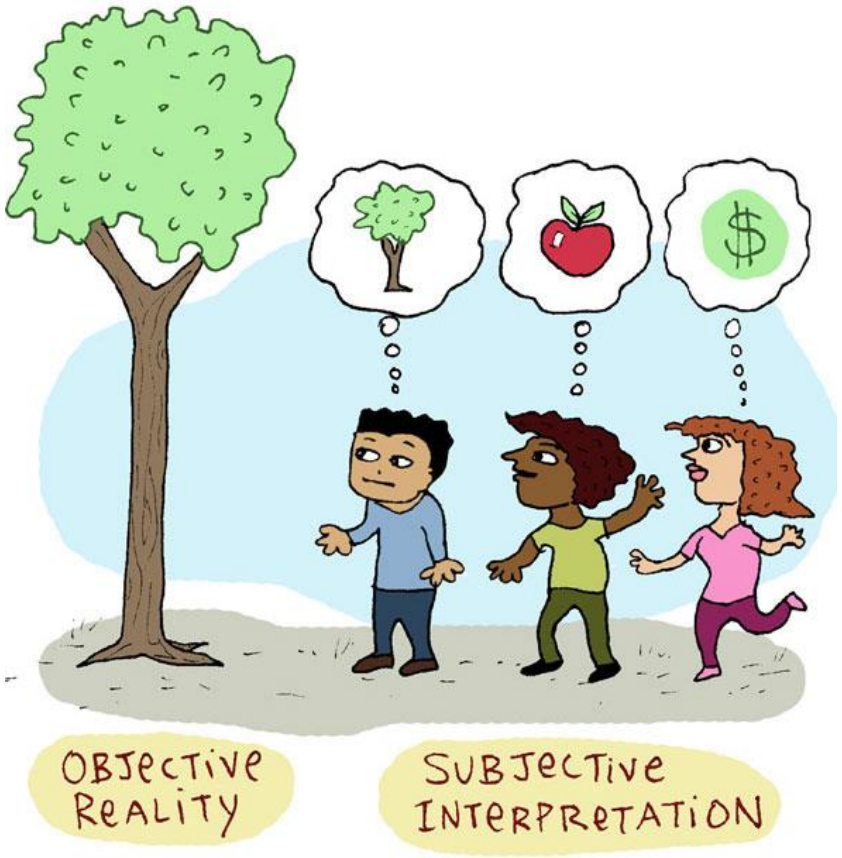
- safety
- clinical effectiveness
- cost-effectiveness
- ethical, legal and social implications (aka ELSI)

Although this approach has been important in pursuing comprehensiveness in HTA, there is a downside to it as well

Downside:

Suggests that there are facts (safety etc), on the one hand, and that there are values ('elsi'), on the other;

There are things that we can come to know about, and there are things that …..?


OBJECTIVE REALITY
SUBJECTIVE INTERPRETATION

Leaving decision makers at a loss as to how to take into account ethical issues of health technologies

The proposed distinction between empirical issues and ethical issues is, however, misconceived:

In reality, *all* aspects of health technologies have *both*, an *empirical* and a *normative* (or value) dimension.

Safety: the sort of (empirically ascertainable) outcomes that we wish to avoid because of our commitment to avoiding harm (non-maleficence)

Clinical effectiveness: the sort of (empirically ascertainable) outcomes that we wish to achieve because of our commitment to doing good (beneficence), e.g., prolonging life, alleviating suffering, restoring functioning, etc.

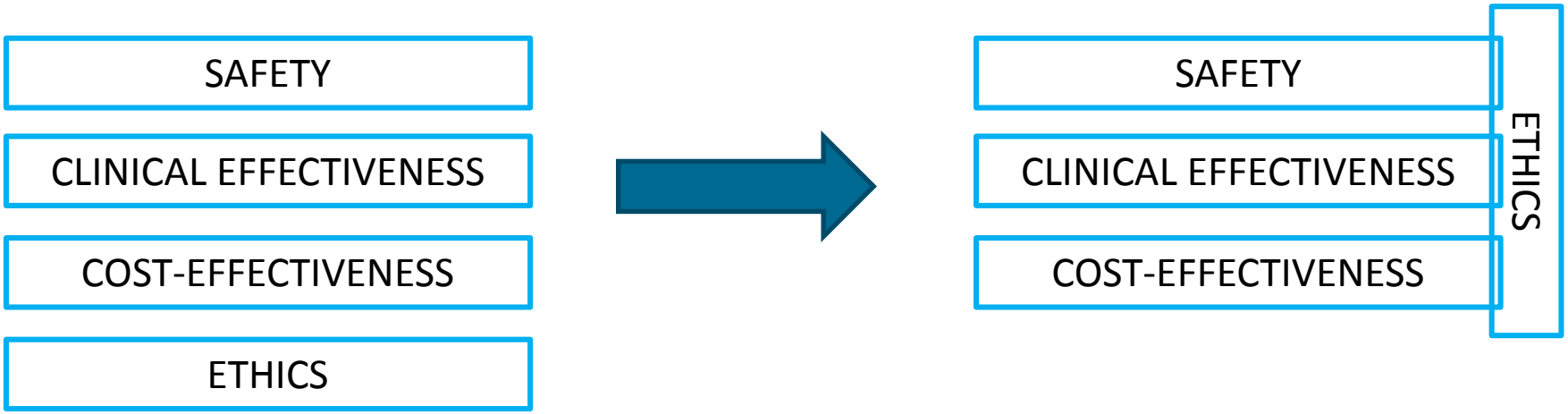
Cost-effectiveness: the sort of (empirically ascertainable) outcomes that we wish to achieve because of our commitment to distributive justice / fairness (e.g., proportionality between resource commitment and reduction in burden of illness)

Likewise: is there *any evidence to suggest* that use of technology X helps patients, for instance, to better maintain their autonomy?

ELSI:

goodbye to splendid isolation

The VALIDATE move:



Instead of various 'aspects':

Claims and concerns regarding health technologies

With respect to each claim and concern we can ask two questions:

- *Is it true?*
- *Does it matter?*

How? By reconstructing stakeholders' interpretive frames:

- Judgment of a specific health technology
- Problem definition
- Background theory *(why is it plausible?)*
- Ethical commitments *(why does it matter?)*

Resulting in a classification of policy problems

Agreement on what is considered desirable	HIGH	Moderately structured	Well structured
	LOW	Ill structured	Moderately structured
		LOW	HIGH
		Agreement on what is considered possible	

Implications for the sort of inquiry that is appropriate

- Well-structured problems: means-ends analysis (e.g., some type of cost-benefit analysis)
- Otherwise: problem structuring (resulting in greater agreement on the nature of the questions to be addressed and on how this will be done)

Example: pediatric cochlear implants

For some stakeholders, pediatric CI was acceptable only if hearing parents would be supported in using Sign Language in the communication with their deaf child

Should this view be taken seriously? (1)

Reconstruction of interpretive frame:

Judgment of pediatric CI

Problem definition: deaf children usually do not get the sort of input that they can use for their cognitive, social and emotional development

Background theory: sign language is unlikely to hinder subsequent acquisition of spoken language

Ethical commitment: recognition of Deaf culture

Should this view be taken seriously? (2)

Evaluation of interpretive frame:

- Does it matter: Specification of the principle of the basic equality of human beings? If so, may commitment to such principle be presumed in the relevant community?
- Is it true: Is there any evidence to suggest that sign language and spoken language can be mutually supportive?
- Implications for the evidence collection!

- Taking stakeholders' views on a health technology seriously
- By clarifying background theories and ethical commitments that give rise to problem perception and judgement of options for resolution
- Is it true? Does it matter?
- What are the implications for the evidence collection?

VALIDATE:
Scoping: what issues need to be addressed and how?
Integral and *constitutive* role for stakeholders in HTA

Thank you for your attention!

https://validatehta.eu