VALIDATE
VALues In Doing Assessments of health TEchnologies

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HTAi HEALTH TECHNOLOGY ASSESSMENT iNTERNATIONAL

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VALIDATE – concepts, methodology and applications

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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, unitended, 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 types of impact that need to be addressed in HTA:
- safety
- clinical effectiveness
- cost-effectiveness
- ethical, legal and social implications (aka ELSI)

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

Downside:
suggestive of two distinct ways of learning about a health technology:
1. through empirical research (safety, clinical- and cost-effectiveness)
2. through normative inquiry (ELSI)

OBJECTIVE REALITY

SUBJECTIVE INTERPRETATION

Leaving decision makers uncertain as to how to take into account ethical issues (if at all)

In reality, however, _all_ aspects have _both_, an _empirical_ and a _normative_ (or value) dimension.

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

Clinical effectiveness: the sort of 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 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)
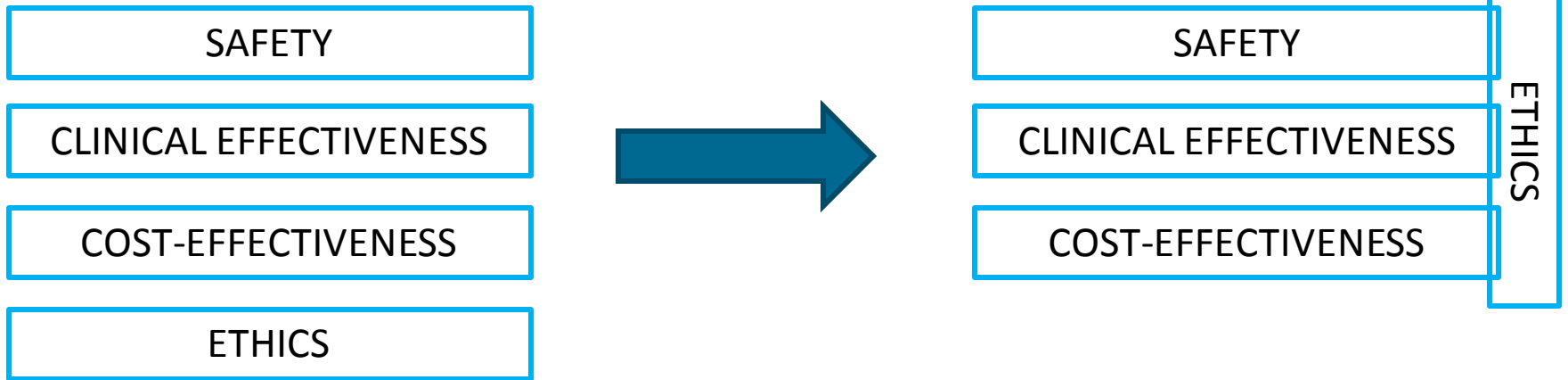
ELSI:

a distinct, separate category???

The VALIDATE move:

SAFETY	
CLINICAL EFFECTIVENESS	
COST-EFFECTIVENESS	
ETHICS	

→

SAFETY	ETHICS
CLINICAL EFFECTIVENESS	
COST-EFFECTIVENESS	

About what sort of things can we obtain reliable knowledge?

Empirical inquiry

What sort of things may happen when we would start using this technology?

What sort of things *matter* to us, and for what reason?

What sort of things might happen?

Sources

- Read the literature:
  - What causes the problem?
  - How does the intervention work and how does it mesh with the processes that cause and sustain the disease?
  - What sort of outcomes have already been reported?
- Talk to people:
  - Experts
  - Health professionals
  - Patients and their carers (experiential knowledge)
  - Decision makers

What sort of things matter and why?

Sources: literature, informants

- Focus on *what* (people are trying to achieve or to avoid) and *why*
- Should reveal what *general* values are considered important (e.g., fairness, autonomy, fellowship or cohesion) *and how they are brought to bear on the practice of health care* (how they are *specified*)

What sort of things can we come to know?

- Different types of knowledge (e.g., scientific knowledge, experiential knowledge, moral knowledge)
- Different research methodologies (e.g., quantitative research, qualitative research, phenomenology)

HTA is not a matter of collecting *the* facts, but a matter of collecting facts that are considered to be

- (1) plausibly associated with the use of a health technology in a specific context,
- (2) relevant in view of values to which we are committed, and
- (3) amenable to methods of inquiry that are held to produce reliable knowledge and understanding.

Example: telecare for patients with mental conditions

- HTA Agency: National Health Care Institute of the Netherlands (ZIN)
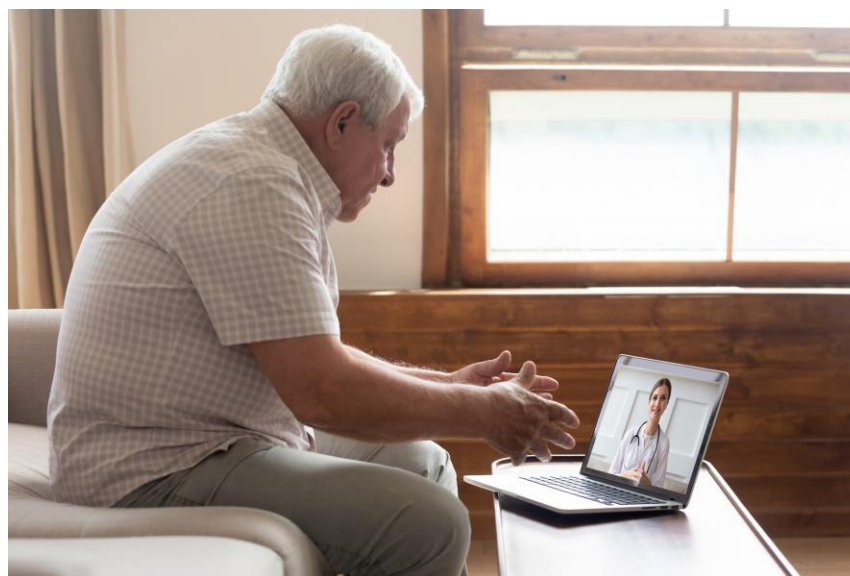
What sort of things might happen?

- Does the nature of mental care change? If so, in what way?
- Could it lead to overlooking things more often, to neglect?
- Is productivity increased?
- What happens to the burden of mental illness?
- Does it improve accessibility?
- Does it help to contain expenditures?
- Does it lead to a certain indifference on the part of the health care provider?
- Could telecare be a promising way of reducing the burden of mental illness, given our understanding of the key underlying causes?
- Etc.

What makes such things important?

- Recognition of the suffering that may be associated with mental illness
- Impact, for instance on people's capability
- Fairness, solidarity

How can we get to know these things better?

All sorts of studies may help to establish which of these claims and concerns are warranted, including randomised controlled trials and ethnographic studies of changes in the practic of mental care associated with the use of telecare, e.g.,

- Pols J, The heart of the matter: about good nursing and telecare. Health Care Analysis 2010; 18 (4): 374 – 388.
- Salisbury C et al, Effectiveness of an integrated telehealth service for patients with depression: a pragmatic randomised controlled trial of a complex intervention. The Lancet Psychiatry 2016; 3 (6): 515 – 525.
- Bountavongh M et al, Economic evaluation of home-based telebehavioural health care compared to in-person treatment delivery for depression. J Telemedicine Telecare 2018; 24 (2): 84 – 92.

What is the result of such HTA?

- Explain to the commissioning organisation which aspects (claims and concerns) may be considered relevant, and why.
- Explain how these aspects were identified, organised, prioritised, etc.
- Explain what the research team did in order to retrieve, critically appraise, and interpret the available evidence.
- Point out which of the claims and concerns seem to be warranted by the available evidence.
- Identify any uncertainties, conflicting evidence, gaps in knowledge, etc.
- Draw attention to possible conflicting values: reasons why we might want to go ahead with this technological development, and reasons why we might want to be holding back.
- Suggest possible ways of how such conflict might be resolved.

How does this differ from what is usually done in HTA?

- It distances itself from the standard, but ill-founded distinction between empirically verfiable aspects on the one hand, and ELSI on the other
- Instead, it examines of all claims and concerns their plausibility, relevance, and amenability to inquiry.
- It aims to clarify how technology changes the practice of health care from the perspective of shared values.
- It reveals the nature of any potential value conflicts, and how these might be resolved.

Thank you for your attention!