

Ethical, social, and legal issues (ELSI) in HTA

Introduction

Assessing the impact of any technology requires comprehensive information that reflects what is likely to happen in a health system or society. Good analysis requires the use of expert advice and methods from the various disciplines that are used as inputs.

Health technology assessment (HTA) bodies must take a broad range of issues into account during their analyses, including ethical, social, and legal issues that arise from the use (or non-use) of health technologies.

Ethical issues in HTA

Ethical issues arising from health technologies have become more prominent over the last several decades. This is due to a combination of factors including:

- increasingly complex systems for delivering increasingly complex care
- a reappraisal of the assumption that all technology is good
- recognition of the difficult choices that must be made in allocating resources for health

In the field of HTA, ethical issues arise in particular around the following areas:

- Use of technology
- Conduct of research
- Allocating resources

Use of technology

The practice of HTA focuses on responding to existing or emerging technologies. How a technology is used will determine the scope of the ethical issues associated with that technology. If a technology is used in a different way or setting, the scope of ethical issues associated with it will likely vary. For example, genetic testing to see how likely an individual might be to develop a disease has potentially different ethical implications in healthy adults than in unborn babies (prenatal testing).

While guidelines from an HTA bodies may define medically appropriate care, individual practitioners and patients are the ultimate decision-makers regarding whether a technology will be used or not in a particular case. Assessing a technology can provide important information about the balance between beneficence (benefit) and non-maleficence (doing no harm).

Using technologies that provide no benefit would be inconsistent with the principle of beneficence. HTA reports can identify situations where the use or the absence of use of technology may run counter to the principle of justice and give appropriate recommendations for its use. The same principles that are relevant to research in humans are also relevant to technology use.

Conducting research

HTA involves gathering information and in some cases conducting original research, not just about the science that underlies and supports a health technology, but also about the preferences or values of patients who may use it. Some HTA organisations may explore patient preferences or values directly through qualitative methods. This is particularly relevant for technologies with both significant desirable and adverse health effects that must be weighed in decisions about

using the technology. From an ethics perspective, research on patient preferences is no different from research on health effects. Therefore, it must conform to the standards for doing research, and be consistent with the principles as laid out in the Declaration of Helsinki of respect for persons, beneficence, and justice.

Allocating resources

HTA assessments are often used to make decisions about the allocation of resources pertaining to healthcare. When allocating resources, care must be taken to distinguish between equal access and equitable access:

- In discussions of resource allocation, equity has come to mean fair allocation
- The distinction between equal and equitable access depends on whether allocation should reflect the need of the individual patient (equity) or equal access by all (equal)
- The principle of equal allocation can lead to an inequitable distribution of health resources if those resources are limited. For example: If a certain pill is distributed equally, everyone in the population receives one pill regardless of their need. However, there may be some in the population who need ten of the pills, but who would be unable to get them because of the limited amount of pills available. Equitable distribution seeks to ensure that those who most require the health technology can access it.

Considerations for ethical analysis

Over the past few years there have been major developments in structures supporting ethical analysis. Checklists have been developed by academics involved in HTA in order to help structured consideration of ethical issues and are used by many HTA agencies, and are helpful for patient groups (see,

for instance, Hofmann et al. (2014) listed under Further Resources).

Social issues in HTA

Society and culture shape both ethical norms and how decisions are made, meaning that decisions about the same technology may differ in different places. It is important to remember that ethical and social issues may not be the same. Some aspects of social outcomes, such as anxiety associated with technology use or human integrity, may overlap with clinical and ethical outcomes.

Social effects can be researched by a review of existing literature or through original study. However, the studies carried out to understand what social effects may occur do not borrow from epidemiology but rather from other disciplines – such as sociology, medical anthropology, and society and technology. These studies are typically qualitative. Often, they try to discover which outcomes are relevant, rather than identifying the outcomes ahead of time. These studies rely on patient experiences in order to understand the social and cultural effects of new technologies, this is a growing area where patients can play a real role in shaping existing HTA processes.

Legal issues in HTA

Legal systems vary the world over, but certain aspects of technology use may draw the attention of legal systems regardless of their cultural basis. At the level of professional practice, ethics and the law are linked because unethical practice is illegal. Illegal practice can lead to criminal or civil proceedings against individual healthcare practitioners and also the institutions and organisations where they work.

In general, legal aspects that are relevant to HTA relate to responsibility and its legal counterpart, liability. HTA bodies need to consider legal issues and a framework for considering them is important in any assessment of a health technology.

Additionally, HTA bodies must be aware that stakeholders who disagree with an assessment's conclusions may turn to the courts. Therefore, an HTA body that does not take reasonable steps to ensure a high quality assessment may itself be at risk of legal action for failing to perform a responsible assessment.

Ethical, Legal, and Social Issues (ELSI) checklist

EUnetHTA developed the ELSI checklist, which can be helpful in assessing the ethical, legal and social issues in effectiveness assessment. This can be used along with the HTA Core Model[®].

1. Ethical

1. Does the introduction of the new medicine and its potential use/non-use instead of the defined, existing comparator(s) give rise to any new ethical issues?
2. Does comparing the new medicine to the defined, existing comparators point to any difference that may be ethically relevant?

2. Organisational

1. Does the introduction of the new medicine and its potential use/non-use instead of the defined, existing comparators point to any differences that may be organisationally relevant?
2. Does comparing the new medicine to the defined, existing comparator(s) point to any differences

that may be organisationally relevant?

3. Social

1. Does the introduction of the new medicine and its potential use/non-use instead of the defined existing comparator(s) give rise to any new social issues?
2. Does comparing the new medicine to the defined, existing comparator(s) point to any differences that may be socially relevant?

4. Legal

1. Does the introduction of the new medicine and its potential use/non-use instead of the defined, existing comparator(s) give rise to any legal issue?
2. Does comparing the new medicine to the defined, existing comparators point to any differences that may be legally relevant?