Responsible health system decision-making and HTA

Introduction

Decision-making in a health system that is informed by HTA is no different to any other type of healthcare decision-making that directly affects patients. Health systems that function within a liberal democracy generally strive to ensure people have the ability to achieve their health goals. Typically, the goals of a health system are:

- adequacy and equity in access,
- protection for citizens from detrimental financial impacts associated with payment for health services,
- freedom of choice for patients,
- appropriate autonomy (independence) for providers, and
- fiscal responsibility.

Ethical principles in health system decision-making

The goals outlined above reflect the underlying ethical principles common to many health systems. Four ethical principles in particular are usually specified in health system decision-making:

- **Respect for autonomy:** Recognising the rights of individuals to make informed, independent choices about healthcare, health promotion, and health protection. This leads to the concept of 'patient choice'. The ethical principle of respect for autonomy cannot, however, be applied universally or regardless of other social values.

- **Non-maleficence ('not doing harm'):** An obligation not to inflict harm (either physical or psychological). As any treatment or intervention can potentially have adverse consequences, it may be necessary to balance the benefits and harms (risks) when deciding whether an intervention is appropriate.
- **Beneficence ('doing good'):** An obligation to benefit individuals is closely related to non-maleficence. As no clinical or public health intervention is always beneficial for everyone, it is the balancing of benefits and harms that is usually more relevant.
- **Justice:** The provision of services in a fair and appropriate manner. This is a particular problem in healthcare because of the inevitable mismatch between demands and resources. There are two models of justice that relate to the fair and appropriate allocation of resources (called distributive justice), though there is no current consensus regarding which of these two models is best for decision making.
    - **Utilitarianism** seeks to maximise the amount of good that can be enjoyed by the community as a whole. Utilitarianism is a moral doctrine that assumes that the greatest happiness of the greatest number of people should be the guiding principle of conduct. Under this system, it is possible that minority interests can be overridden by the majority. It is also possible that factors such as age, personal responsibility, and urgency of need are overlooked.
- **Egalitarianism** is a moral doctrine that asserts the equality of **all** It suggests that each individual is entitled to their fair share of health resources. Because most medicines are prescribed by providers acting under rules and regulations, HTA recommendations are often more concerned with questions of **justice** and **autonomy** (although beneficence and non-maleficence are by no means ignored). In particular, those making

healthcare recommendations and decisions must consider what the 'fair and appropriate' balance of the use of health technology is, given constraints on resources.

Making decisions: Who, How, and Why?

Understanding the underlying ethical principles and recommendations for decision-making does not tell us how we can incorporate those principles into the decision-making process.

When conducting an appraisal of a technology, where societal values and ethical principles are considered in a recommendation, the best health systems aspire to use an approach that embraces these to the greatest extent possible. Rules that govern proceedings that may have far-reaching implications for society are therefore necessary if not an absolute requirement. They encompass procedural rights which include:

- the right to participate,
- the right to a fair and accountable proceeding, **and**
- the right to information.

These rights are explored in more detail below.

Right to participate: Stakeholder involvement

In the governance of health systems, stakeholder involvement has four major functions:

- to improve the quality of information concerning the population's values, needs, and preferences;
- to encourage public debate over the fundamental direction of the health system

- to ensure public accountability for the processes within and outcomes of the system; **and**

- to protect the public interest.[1]

Processes that attempt to aid decisions need to consider how different stakeholders can be involved in the process to ensure legitimacy of the decision. Decision-making processes are often overseen by a decision-making committee including individuals with different areas of expertise. The membership composition of a decision-making committee may be constrained by the possible impact of decisions, the resources available to support the committee, or the type of technology assessment being undertaken. Discussion frequently occurs about who should be involved in the decision-making committee and the potential conflicts of interest they may have. As everyone within a given health system is affected by decisions about the payment for and use of technologies, a fair approach to recommendations is needed that considers as many views as possible.

Table 1: Advantages and disadvantages of involving various stakeholders in the decision-making process.

Stakeholder	Advantages/disadvantages
Patient	Patients can shed light on what it is like to have the illness, but an individual patient may disproportionately represent the needs of their patient community against society at large.
Citizen	A citizen may have an unbiased view but may lack knowledge regarding specific technical or medical questions and issues.
Medical expert	A medical expert can provide clinical insight, but may disproportionately favour treating patients irrespective of cost.

Stakeholder	Advantages/disadvantages
Technology analysts	Analysts can provide insight into the complexities of the assessment, but it may be difficult for them to question the validity of the findings, specifically if they have conducted the analysis themselves.
Producer of technology	A technology producer (for instance, a pharmaceutical company) can provide special insight into the strengths and weaknesses of new technologies, but they will have a strong competing interest if the technology in question is not from their company or from a direct competitor's.

In other cases, the preliminary recommendations of a committee may be submitted to a larger public review or to request formal written comments from stakeholders. This is another way to increase involvement. Some have used citizens' juries — panels intended to reflect societal viewpoints — as an input into technology appraisal processes.[2]

All of these approaches must be carefully managed so as to prevent undue influence from any particular group. As with any form of political governance, there will be a heightened perception of fairness if restrictions are placed on who can participate in decision making, how they are chosen and how long they serve.

Right to a fair and accountable proceeding

The process of arriving at a recommendation must also reflect underlying principles of justice — in this case, procedural justice.

There are three key principles of an 'accountability for reasonableness' framework (fair process):

1. **Transparency about the grounds for** decisions — for HTA this might mean producing a summary document of reasons for a recommendation
2. **Appeals to rationales that all can accept as relevant to meeting health needs fairly** — for HTA, this might mean having a confidential draft available for comment or allowing appeal once a recommendation is made
3. **Procedures for revising decisions in light of challenges to them** — for HTA this might mean changing recommendations once stakeholder concerns have been heard and taken into account.

Right to information

Another best practice for creating recommendations is allowing people to view information even if they chose not to participate in the proceedings. Many HTA bodies now make the reports that led to their recommendations widely available on the internet and increasingly strive to explain why they have made the recommendations they have. However, this is not always the case and in some countries the use of HTA is still 'behind closed doors', with little transparency or possibility for wide stakeholder involvement.

[glossary_exclude]Conclusion

Once an HTA body is established, it becomes part of a larger political process that should ideally be considered with fairness and accountability. This means that the recommendations that are given and how they are made should be clear to everyone, and there should be a right to appeal them.

In addition to the WHO report ranking health system performance, there are several other important information resources to help us compare health systems and examine key indicators:

- The International Society for Pharmacoeconomics and

Outcomes Research (ISPOR) has created a 'Global Health Care Systems Road Map', which describes processes for medicine and medical technology adoption across various countries (http://www.ispor.org/HTARoadMaps/Default.asp)

- The WHO Regional Office for Europe (WHO/Europe) hosts a European Observatory on Health Systems and Policies that can be useful for looking at indicators and making comparisons (https://eurohealthobservatory.who.int/)
- The Organisation for Economic Co-operation and Development (OECD) website, although the information here requires some searching and may not be freely available (http://www.oecd.org/els/health-systems/)[/glossary_exclude]

[glossary_exclude]Further Resources

1. International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 'Global Health Care Systems Road Map'. Retrieved 11 February, 2016, from http://www.ispor.org/HTARoadMaps/Default.asp
2. WHO Regional Office for Europe (WHO/Europe) European Observatory on Health Systems and Policies. Retrieved 4 July, 2021, from https://eurohealthobservatory.who.int/
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4. World Health Organisation (2000). *The World Health Report 2000. Health Systems: Improving Performance*. Geneva: World Health Organisation. Retrieved 11 February, 2016, from http://www.who.int/whr/2000/en/
5. Health Equality Europe (2008). 'Understanding Health Technology Assessment'. Retrieved 4 July, 2021, from https://htai.org/wp-content/uploads/2018/02/PCISG-Resource-HEE_ENGLISH_PatientGuidetoHTA_Jun14.pdf[/glossary_exclude]

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2. Street, J., Duszynski, K., Krawczyk, S., Braunack-Mayer, A. (2014). 'The use of citizens' juries in health policy decision-making: A systematic review.' *Social Science & Medicine* (109), 1-9. Retrieved 11 February, 2016, from http://www.sciencedirect.com/science/article/pii/S027795 361400166X[/glossary_exclude]

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