



# Ethical criteria for priority setting in HTA

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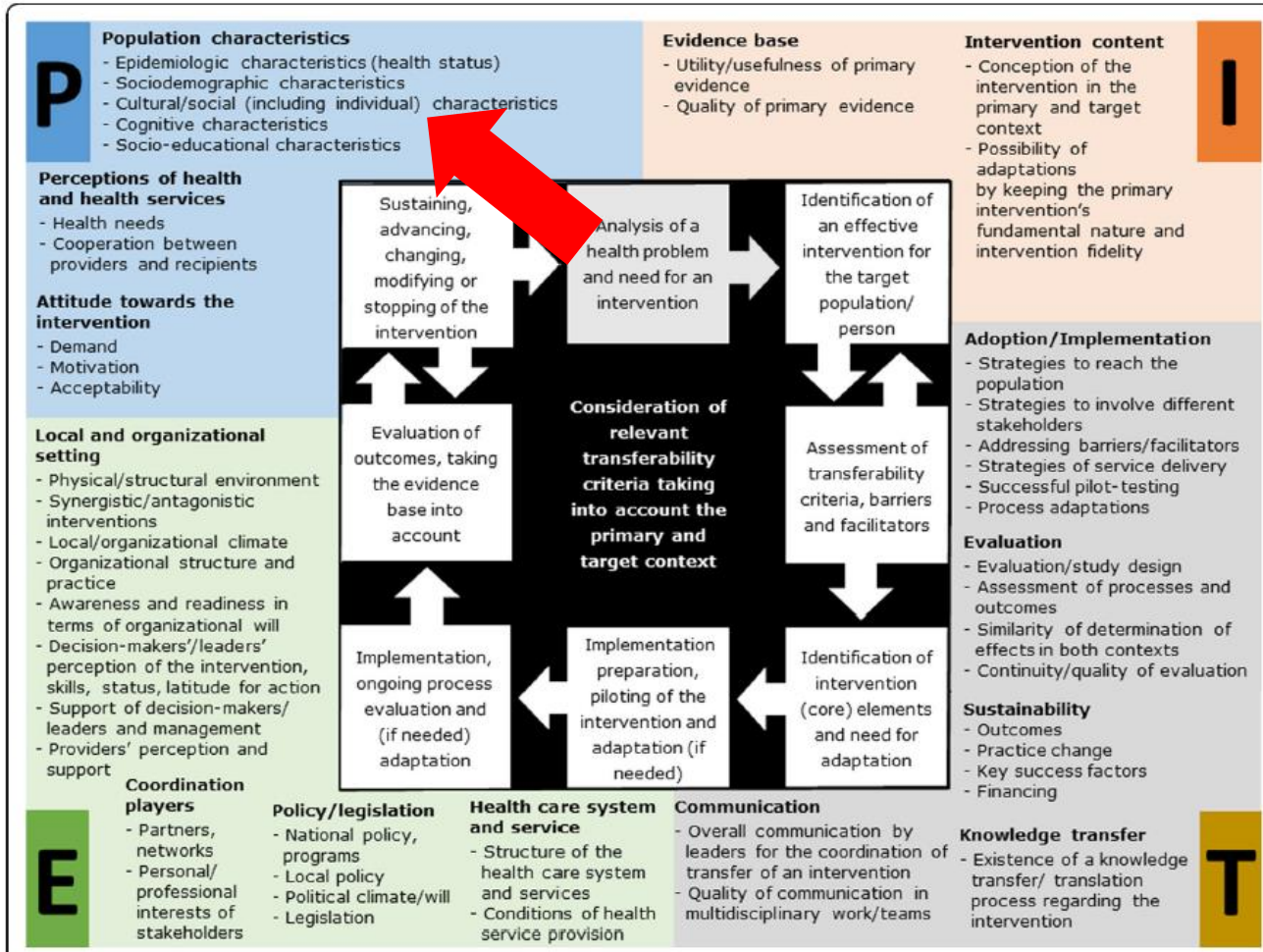
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**Prioritization in Public Health:  
new insights in the frame of Health Technology Assessment**  
*Dec 1st 2018, 9:40-11:10, Club CD 1*

## **This presentation in light of the workshop**

- How to allocate resources? How to set priorities (in light of scarce resources)?
  - An ethical perspective.
- Values and norms influence transferability (cf. Johan Hansen).
- What ethical norms, values, theories to inform decision making?
  - Incl. Accountability for Reasonableness (bridge to W. Ortwijs's presentation)

# Context matters ≠ Ethical relativism



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Schloemer and Schröder-Bäck *Implementation Science* (2018) 13:88  
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Implementation Science

SYSTEMATIC REVIEW

Open Access

# Criteria for evaluating transferability of health interventions: a systematic review and thematic synthesis



Tamara Schloemer\*  and Peter Schröder-Bäck

## Why ethics should be part of health technology assessment

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From the heydays of HTA in the 1970s, it has been argued that ethics should be a part of HTA. Despite more than 30 years with repeated intentions, only few HTA reports include ethical analysis, and there is little agreement on methods for integrating ethics. This poses the question of why it is so important to integrate ethics in HTA? The article analyzes ten arguments for making ethics part of HTA. The validity of the arguments depend on what we mean by "integrating," "ethics," and "HTA." Some of the counterarguments explain why it has taken so long to integrate ethics in HTA and why there are so many ethical approaches. Nevertheless, some of the arguments for making ethics part of HTA appear to be compelling. Health care is a moral endeavor, and the vast potential of technology poses complex moral challenges. A thorough assessment of technology would include reflection on these moral aspects. Ethics provides such a moral reflection. Health technology is a way to improve the life of human individuals. This involves questions of what "the good life" is, and hence ethical issues. Trying to ignore such questions may inflict with the moral foundation of health care: to help people. Additionally, HTA is an *evaluation*, and as such also a reflection on values. Hence, there is a profound affinity between HTA and ethics. Accordingly, ethics cannot be "integrated" in HTA as ethics is already a constitutive part of HTA. However, ethics can be acknowledged and emphasized.

**Keywords:** Ethics, Methodology, Normative, Moral philosophy

## Ethical analysis to improve decision-making on health technologies

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**Abstract** Health technology assessment (HTA) is the multidisciplinary study of the implications of the development, diffusion and use of health technologies. It supports health-policy decisions by providing a joint knowledge base for decision-makers. To increase its policy relevance, HTA tries to extend beyond effectiveness and costs to also considering the social, organizational and ethical implications of technologies. However, a commonly accepted method for analysing the ethical aspects of health technologies is lacking.

This paper describes a model for ethical analysis of health technology that is easy and flexible to use in different organizational settings and cultures. The model is part of the EUnetHTA project, which focuses on the transferability of HTAs between countries.

The EUnetHTA ethics model is based on the insight that the whole HTA process is value laden. It is not sufficient to only analyse the ethical consequences of a technology, but also the ethical issues of the whole HTA process must be considered. Selection of assessment topics, methods and outcomes is essentially a value-laden decision. Health technologies may challenge moral or cultural values and beliefs, and their implementation may also have significant impact on people other than the patient. These are essential considerations for health policy. The ethics model is structured around key ethical questions rather than philosophical theories, to be applicable to different cultures and usable by non-philosophers.

Integrating ethical considerations into HTA can improve the relevance of technology assessments for health care and health policy in both developed and developing countries.

**DIMDI**

Deutsches Institut für Medizinische  
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Methoden zur Erfassung ethischer Aspekte  
und gesellschaftlicher Wertvorstellungen  
in Kurz-HTA-Berichten  
- eine internationale Bestandsaufnahme

Band 9

2003 DAHTA @ DIMDI

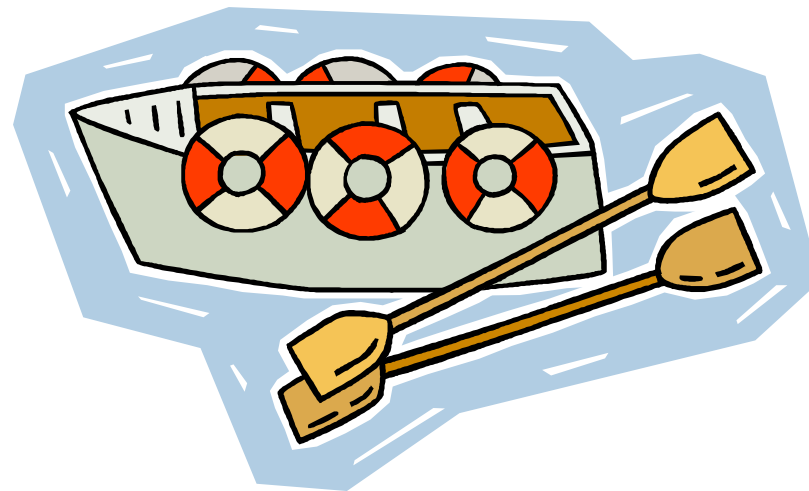
What ethical criteria for priority setting are currently being discussed and how plausible are they?

# How to divide the cake (when all are hungry)?



# Lifeboat

– Another thought experiment regarding priorities

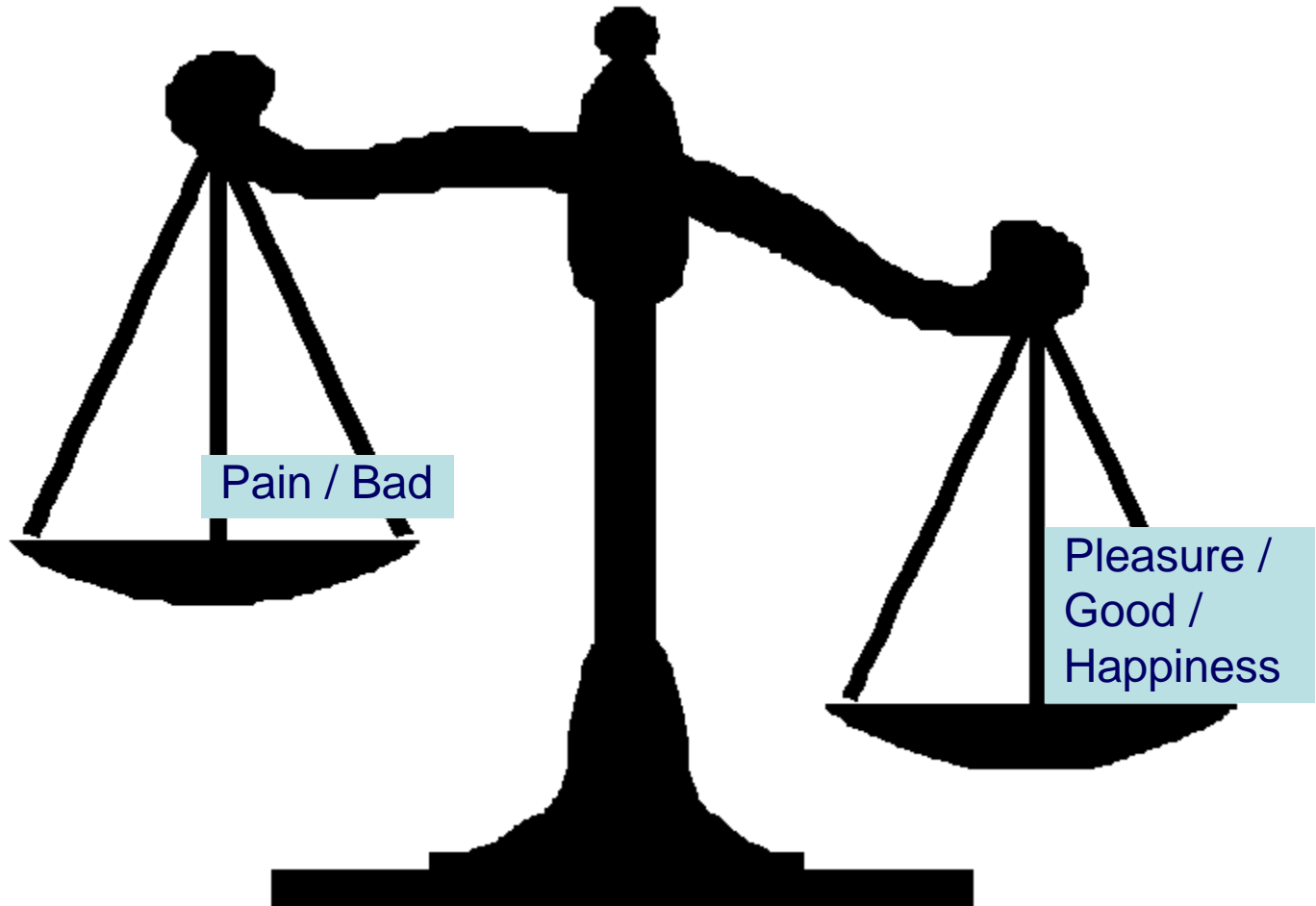


Childress J (1970) Who Shall Live When Not All Can Live? Soundings 53: 339-55



# Two perspectives discussed in the literature

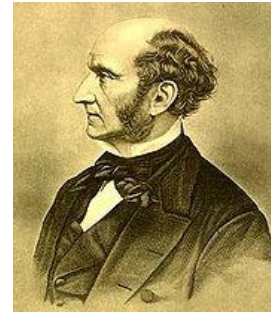
- Consequentialism
- Justice



## Consequentialism: Utilitarianism (in a nutshell)



Jeremy Bentham  
1748 - 1832



John St. Mill  
1806 - 1873

“Doing greatest possible good (to the greatest number)”



An act is right  
*iff*

it raises net amount of the overall **good**.

# Utilitarian priority setting

- Happiness / the good is not (necessarily) health.
- Maximising subjective well-being (no preference for health / longevity per se).
- Prima facie: No priority for
  - depressed people,
  - people with bad risk profiles,
  - where intervention does not improve happiness much,
  - older people.
- Common diseases priority over rare diseases.
- Self-responsibility no value per se.
- Allocative efficiency!

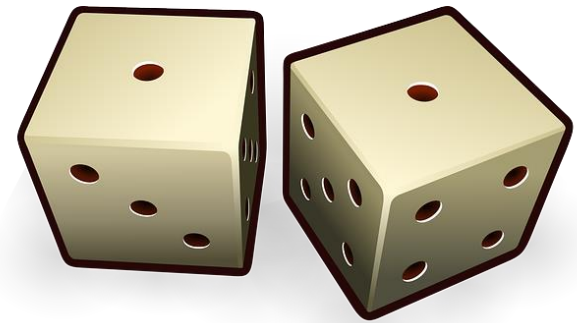
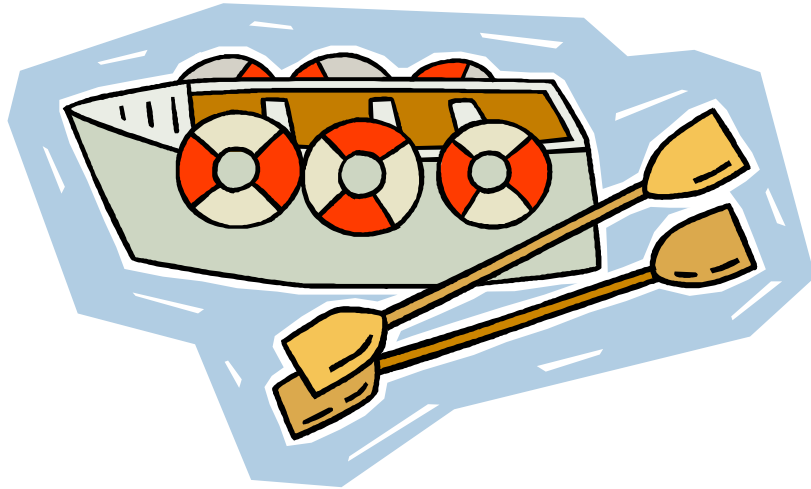
(Birnbacher, 2006)

„I) *Distributional indifference*: The utilitarian calculus tends to ignore inequalities in the distribution of happiness (only the sum-total matters – no matter how unequally distributed). We may be interested in general happiness, and yet want to pay attention not just to ‘aggregate’ magnitudes, but also to extents of inequalities in happiness.

II) *Neglect of rights, freedoms and other non-utility concerns*: The utilitarian approach attaches no intrinsic importance to claims of rights and freedoms (they are valued only indirectly and only to the extent they influence utilities). It is sensible enough to take note of happiness, but we do not necessarily want to be happy slaves or delirious vassals.

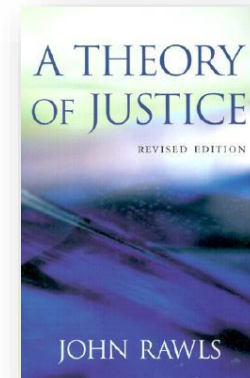
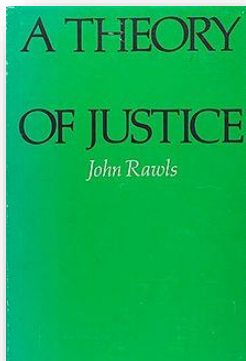
III) *Adaption and mental conditioning*: Even the view the utilitarian approach takes of individual well-being is not very robust, since it can easily swayed by mental conditioning and adaptive attitudes.“

Sen, Amartya: *Development as Freedom*.

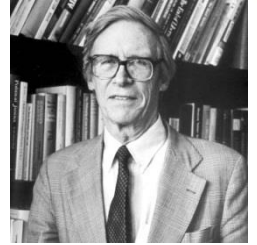


Childress J (1970) Who Shall Live When Not All Can Live? Soundings 53: 339-55

# The famous anti-utilitarian & anti-libertarian contractualist: John Rawls (A Theory of Justice, 1971)



# The famous anti-utilitarian contractualist: John Rawls (1971)



1.\* Each person has an equal claim to a fully adequate scheme of basic rights and liberties, which scheme is compatible with the same scheme for all; and in this scheme the equal political liberties, and only those liberties, are to be guaranteed their fair value.

2.\* Social and economic inequalities are to satisfy two conditions: first, they are to be attached to positions and offices open to **all** under conditions of fair **equality of opportunity**; and second, they are to be to the greatest benefit of the least advantaged members of society.

\* lexically ordered.



## Rawls for health (care): Norman Daniels' „Just Health“ (2008) (in a nutshell)

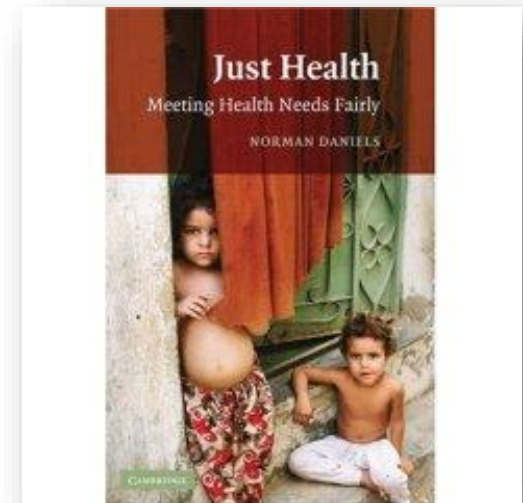
Public Institutions are obliged to promote **fair equality of opportunity** (cf. John Rawls' *Theory of Justice*).



**Health** significantly contributes to the **opportunity range**.



Justice requires to **protect health** and to meet **health needs**.



# Nussbaum's capabilities approach of justice

For Nussbaum health is one of several capabilities that people need to have in terms of developing **a good life**.

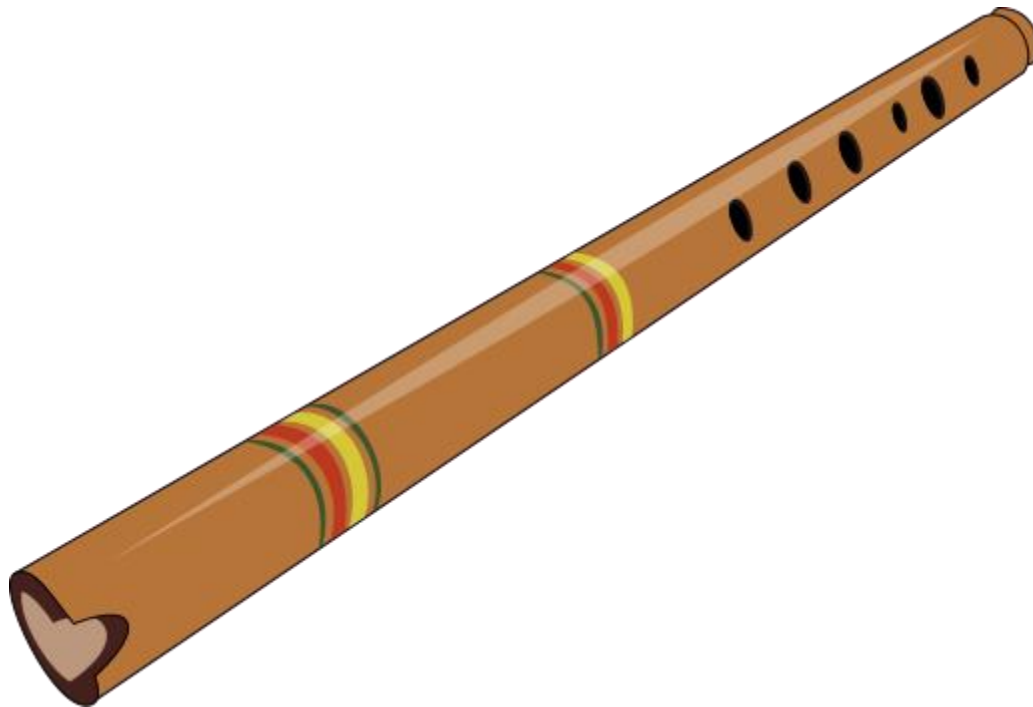
“First, the claim that the freedom to achieve well-being is of primary moral importance, and second, that freedom to achieve well-being is to be understood in terms of people's capabilities, that is, their **real opportunities** to do and be what they have reason to value”.

(Robeyns, 2011; cf. Sorensen, Schröder-Bäck, Brand 2012). [emphases added]

Priority for Health Literacy and enabling self-responsibility.

# Two perspectives

- Consequentialism
  - Best outcomes matter
  - Aggregation is ok
  - Efficiency has moral value
  - No priority to the worst off
- Justice
  - Focus on the rights and (real / fair) opportunities of every person
  - Priority to the worst off
  - Still no algorithm for dividing the cake



# Procedural justice and ethics

“The problem of fair allocation becomes a problem of procedural justice because there is no consensus on which principles should govern fair deliberation, and that even if there were consensus on those principles, reasonable disagreement would remain regarding how to apply them’. [...]

Procedural-based justice: deems an outcome just if the outcome results from a just process”

Wilson, Y.Y. (2018). Distributive justice and priority setting in health care. *The American Journal of Bioethics*, 18(3), 53-54.

→ Thus more focus on procedural aspects in ethical evaluation! →

## Procedural justice

- ... as ethical minimum – given resources are limited and other sectors (e.g. education) also need resources!
- Involve a decision making process:
  - “public (fully transparent) about the grounds for its decisions;
  - the decision must rest on reasons that stakeholders can agree are relevant;
  - decisions should be revisable in light of new evidence and arguments;
  - and there should be assurance through enforcement that these conditions (publicity, relevance, and revisability) are met.”

(Daniels [& Sabin] 2008: Accountability for Reasonableness)

## Relevance

- Develop a rationale for each priority-setting decision
- Use explicit decision criteria related to the mission, vision and values
- Collect data related to each criterion
- Consult with internal/external stakeholders to ensure relevance of decision criteria and to collect relevant information.
- Make decisions using a multidisciplinary group of people.

## Publicity

- Communicate the decision and its rationale.
- Use an effective communication strategy to engage internal/external stakeholders around priority-setting goals, criteria, processes and decisions.

## Revision

- Incorporate opportunities for iterative decision review.
- Develop a formal decision-review process based on explicit decision review criteria

## Enforcement

- Lead by example
- Evaluate and improve the priority-setting process.

## Empowerment (Possible additional condition)

- Support people with leadership development and change management strategies.

Gibson, J.L., Martin, D.K. and Singer, P.A. (2005). Evidence, economics and ethics – Resource allocation in health services organisations. *Healthcare quarterly*, 8(2), 50- 58.

## **Stepwise guide for ethical evaluation processes in HTA (Assasi et al. 2016)**

- 1) Define objectives and scope of the evaluation
- 2) Identify stakeholders (who might be affected?)
- 3) Assess organizational capacity (who is in the evaluating organisation, is there ethical expertise etc.?)
- 4) Framing ethical evaluations (identify ethical issues)
- 5) Ethical analysis (develop argument)
- 6) Deliberation (discuss with others and check plausibility)
- 7) Knowledge exchange and translation (aim at target audience)



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# Conclusions

- Ethics helps to give answers to the question: What shall we do? How shall we prioritise? Arguments and justifications are to be developed - based on moral norms and values - that are designed to convince others.
- Acknowledging value pluralism, it would not be helpful to develop arguments only based on one ethical theory (e.g. utilitarianism).
- Suspicion: Ethics is arbitrary and discretionary. Our answer: No! One has to develop convincing arguments and can refer to different theories and midlevel principles!
- HTAs shall consider ethical aspects of priority setting and shall include different ethical perspectives – including perspectives from procedural justice.
- The AfR account of Daniels / Sabin is helpful – but only a minimum requirement from the ethical point of view. Procedures alone won't do the job!
- The integration of ethics into HTA processes is a topic of further discussion (cf. Hofmann, Oortwijn et al. 2015; Assasi et al. 2016).

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