Guidelines for Incorporating the Societal Perspective and Wider Societal Benefits in Health Technology Assessment

Authors:

Baloghova K.^{1,2}, Pasztor B.^{1,3}, Klimes J.^{1,4}, Mlcoch T.^{1,5}, Decker B.^{1,5}, Kolek M.¹



¹Czech Society for Pharmacoeconomics and Health Technology Assessment, ²Independent HEOR Consultant, Zurich, Switzerland, ³AstraZeneca Czech Republic, ⁴Dpt of Social and clinical Pharmacy, Charles university in Prague, Czech Republic, ⁵VALUE OUTCOMES, Prague, Czech Republic

Introduction

Since 2022, a novel approach to the health technology assessment (HTA) of orphan drugs has been implemented in the Czech Republic, following the law adding the societal and governmental perspectives to the standard healthcare payers' perspective. The main objective of this guideline is to establish a standardised framework for incorporating the societal perspective, ensuring that consistent principles are applied in health economic analyses.

It is important to state that the societal perspective is not considered to be an extension of the healthcare payer's perspective and to be part of or be the same as the governmental perspective. Also, the societal perspective does not include pensions/societal payments as these are considered to be transfer payments, not opportunity cost/loss, and are usually part of the governmental perspective. We recommend that the authors of health economic analyses present and interpret their results separately from all

Methods

Following four conditions were identified to define the basic framework of health economic analyses from the societal perspective – see Table 1:

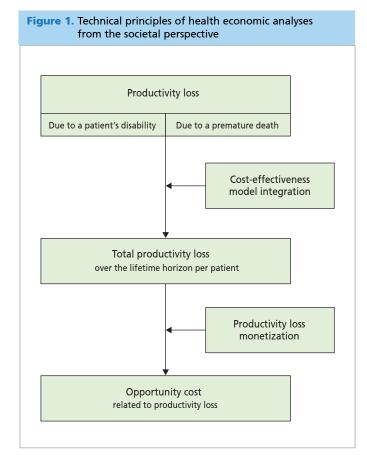
- 1. analyses from the societal perspective stand apart from and are independent from the analyses from both healthcare payer's and governmental perspective
- 2. the target population of analyses from the societal perspective ideally involves all the individuals affected by the primary disease, which is usually narrowed down to patients and their caregivers
- 3. the societal impact related to the primary disease and its treatment is expressed in terms of productivity loss
- 4. the societal impact is valued as opportunity cost

Table 1. Basic framework of analyses from the societal perspective Definition of the societal Analyses from the societal perspective in relation to other perspective stand apart from perspectives used in HTA and are independent from the analyses from healthcare payer's or governmental perspectives Ideally all individuals affected Target population by the particular disease, usually patients + caregivers Parameter of societal impact **Productivity loss** Value of societal impact Opportunity cost related to productivity loss

Results

Based on defined framework, following technical principles to perform economic analyses from the societal perspective were formulated:

- 1. the productivity loss due to patient's disability and the productivity loss due to premature death are measured and presented separately
- 2. the productivity loss is, if possible, integrated to the cost-effectiveness model of economic analysis from the healthcare payer's perspective
- 3. monetization of the productivity loss is calculated using the human
- 4. valuation of the productivity unit is performed via the top-down method based on the local macroeconomic data
- 5. uniform local data sources to calculate the productivity loss in general population are identified and listed



1A. Productivity loss due to patient's disability

Individual's productivity can be, regarding its economic benefit, divided into paid productivity, unpaid productivity and leisure activity. However, the societal impact of leisure activity is questionable as it does not have to be productive, financially rewarded or replaced. The societal impact of productivity change, paid or unpaid, depends on actions taken to compensate for the original loss – **Table S1** (see Supplement).

Regarding the character and permanence of productivity loss, we distinguish temporary absenteeism, permanent absenteeism and presenteeism. It is common that individuals transit between these states over time - see Figure 2.

Figure 2. Possible transitions between full productivity. absenteeism and presenteeism

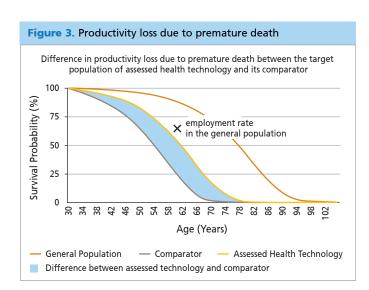
To measure/quantify the productivity loss, several approaches may be

- 1. questionnaire survey
- 2. published data
- 3. claims data
- 4. experts' estimation

It is important to acknowledge that the use of questionnaires to measure an individual's productivity change are not standardised and their outcomes may be associated with a significant level of uncertainty. Thus, similarly to health economic analyses from the healthcare payer's perspective, it is important to find a balance between complexity and technical precision of data collection on one hand and informative benefit and significance on the other.

1B. Productivity loss due to premature death

The productivity loss due to premature death is calculated as a difference between the probability of death within the general population and the probability of premature death within the target population, multiplied by the employment rate of the general population, adjusted by age and sex. This represents the productivity loss of 100 % in comparison with productivity of the general population - see Figure 3.

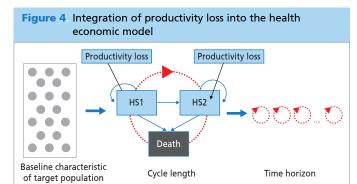


We recommend that the authors of health economic analyses from the societal perspective present and interpret the productivity loss due to patient's disability and the productivity loss due to premature death separately. The recommended unit for the productivity loss is a patient-hour.

2. Integration of productivity loss into the health economic model

Productivity loss can be understood as a new attribute of the health economic model used in health economic analyses from the healthcare paver's perspective when each health state can be described by corresponding decline of productivity – see Figure 4. Using the health economic model allows us to capture the expected dynamics of productivity change over time with respect to presumed disease development. However, it is important to understand that this does not mean just adding indirect cost to the health economic analysis from the healthcare payer's perspective, rather bringing new information to the decision-making process via new analysis.

In case of productivity loss due to premature death we recommend that the authors calculate the productivity loss of 100 % – see section 1B.



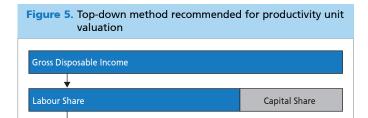
3. Monetization of productivity loss

Generally, two basic approaches to monetize productivity loss were explored: human capital approach (HCA) and friction cost approach (FCA). Since it may be reasonable to estimate both permanent and temporary productivity change, paid or unpaid, and it is possible to capture its development over the lifetime horizon via its linking to the health economic model, the human capital approach is recommended.

Table 2. Comparison of HCA and FCA		
	HCA	FCA
Definition of societal loss	Productivity loss during the entire time when individual's productivity is reduced	Productivity loss during the friction period
Consideration of hiring a replacement employee	No	Yes
Cost of staff replacement	No	Yes
Potential chaining of production loss	No	Yes

4. Productivity unit valuation

Top-down method is recommended to value the productivity unit based on the labour share of gross disposable income (GDI).



5. Unified data source

Productivity Unit

For the purpose of consistency of health economic analyses from the societal perspective, different relevant data sources related to productivity of the general population were identified and listed. To estimate productivity of the general population we recommend considering the employment rate within all age groups, including individuals aged 15-18 and 65+ years.

Discussion

In literature, the societal perspective of health economic analysis is between different stakeholders is not uncommon. Therefore, at the beginning, it is essential to define the terms "society", "societal" and where the societal perspective stands, especially regarding the healthcare payer's perspective, and to ensure that this is understood properly. During the guideline development, the society was narrowed down to patients and their caregivers and the productivity loss was set as a basic parameter of the societal impact of assessed technology. However, as the real impact might be wider, further discussion on how to capture its other aspects is needed.

Conclusions

Consistent methodological approach of health economic analyses is crucial for meaningful comparison of its results within groups of drugs (vertically), across different diagnoses (horizontally) and over time. Incorporating the societal perspective into the HTA brings additional information to the decision-making process and allows us to consider the societal impact of assessed technology. Because of its clarity and applicability, this methodological guideline could be adopted across countries, providing a standardised approach to ensure consistent and comparable results in healthcare decision-making.

LITERATURE

- 1 Garrison LP Jr, Mansley EC, Abbott TA 3rd, Bresnahan BW, Hay JW, Smeeding J. Value Health. 2010 Jan-Feb;13(1):8-13. doi: 10.1111/j.1524-4733.2009.00660.x. Epub 2009 Oct 23. PMID: 19883405.
- 2 Hubens K, Krol M, Coast J, Drummond MF, Brouwer WBF, Uyl-de Groot CA, Hakkaart-van Roijen L. Value Health 2021 Nov;24(11):1686-1699. doi: 10.1016/j.jval.2021.05.002. Epub 2021 Sep 17. PMID: 34711370.
- 3 Bouwmans C, Krol M, Severens H, Koopmanschap M, Brouwer W, Hakkaart-van Roijen L. Value Health. 2015 Sep;18(6):753-8. doi: 10.1016/j.jval.2015.05.009. Epub 2015 Aug 20. PMID: 26409601. 4 Severens JL, Mulder J, Laheij RJ, Verbeek AL. Soc Sci Med. 2000 Jul;51(2):243-9. doi: 10.1016/s0277-9536(99)00452-5
- 5 NICE. NICE health technology evaluations: the manual, Process and methods. 2022. [Online]. Available: https://v 6 Pike J, Grosse SD. Appl Health Econ Health Policy. 2018 Dec; 16(6):765-778. doi: 10.1007/s40258-018-0416-4. PMID:
- 30094591; PMCID: PMC6467569. 7 Guerriero M. The Labor Share of Income Around the World: Evidence from a Panel Dataset. ADBI Working Paper 920
- 8 Czech Society for Pharmacoeconomics and Health Technology Assessment. Recommended Practices for Health-Economic Assessments in the Czech Republic: Czech Society for Pharmacoeconomics and Health Technology Assessment (CFES). 2020. [Online]. Available: https://farmakoekonomika.cz/812-2/. 9 Severens JL, Milne RJ. Value Health. 2004 Jul-Aug;7(4):397-401. doi: 10.1111/j.1524-4733.2004.74002.x. PMID: 15449631.

Corresponding author:

karolina.baloghova@gmail.com ISPOR EUROPE 2023, November, Copenhagen, Denmark