World Health Organization

HTA value based pricing vs fair pricing. Which delivers universal health coverage?

ISPOR Europe
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www.who.int

"Health is a human right. No one should get sick or die just because they are poor, or because they cannot access the services they need." – Dr Tedros

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UHC is a key component of the SDGs

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The Sustainable Development Goals, aka the Global Goals, are a universal call to action 2015-2030 to end poverty, protect the planet and ensure that all people enjoy peace and prosperity

SDG 3 focuses on: Health throughout the life course and UHC by strengthening health systems

- achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all
- support research and development of vaccines and medicines for communicable and non-communicable diseases that primarily affect developing countries,
- provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration which affirms the right of developing countries to use to the full the provisions in the TRIPS agreement regarding flexibilities to protect public health and, in particular, provide access to medicines for all

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SDG3: Achieve Universal Health Coverage, Including Access to Quality Essential Services

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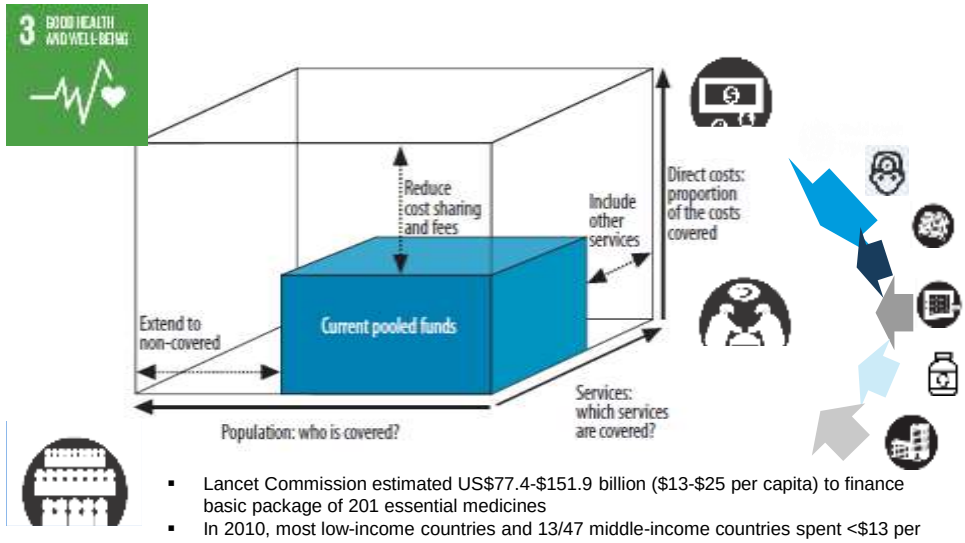
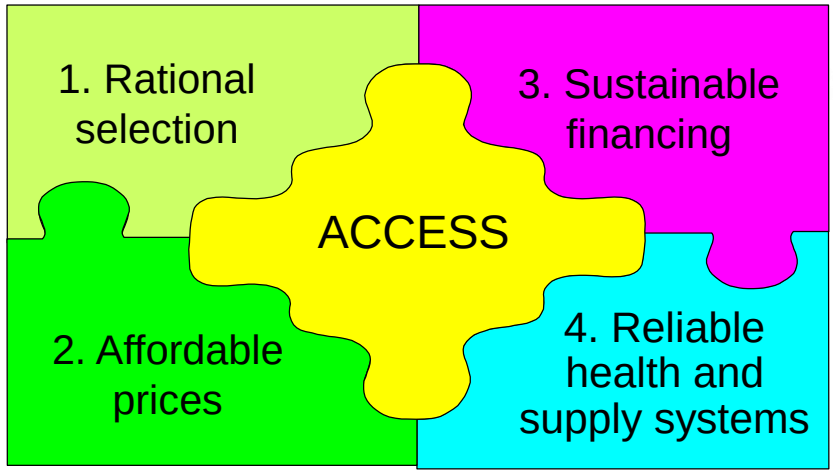


- Lancet Commission estimated US$77.4-$151.9 billion ($13-$25 per capita) to finance basic package of 201 essential medicines
- In 2010, most low-income countries and 13/47 middle-income countries spent <$13 per capita on pharmaceuticals

Access to essential medical products and UHC



All countries share problems in universal access to medicines and other health technologies

- **Inadequate financing** to ensure **universal access** to affordable essential medicines and health products
- **Inefficiencies** in procurement and managing supply chains
- **Limited use of effective pricing policies/ negotiating capacity** to get lowest possible prices for quality-assured products
- Problems of **substandard quality** medicines due to limited regulatory capacity and enforcement
- Wide-spread **inappropriate prescribing and use** - leading to drug resistance and suboptimal health outcomes

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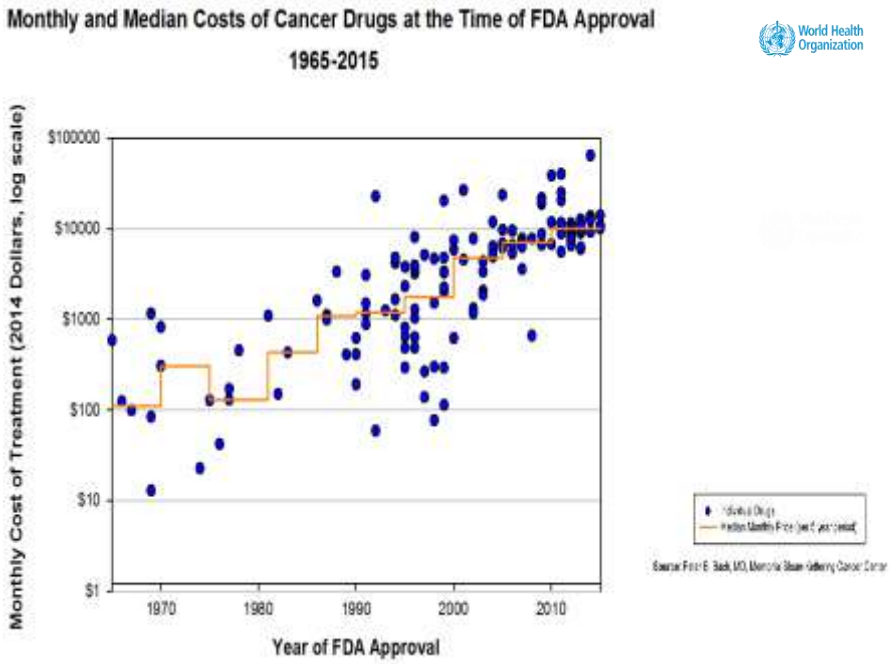
ACCESS TO NCD MEDICINES

Gaps in:

- Availability
  - 40% of countries have no general availability of cancer medicines
  - <10% of facilities in WHO survey contained entire basket of NCD medicines including opioids
- Affordability:
  - Large variation in price and/or co-pay for patients
  - Financial catastrophe rates (median) ~20-30%
- Acceptability
  - Inadequate formulations to optimize adherence (e.g. FDC)
  - Stigma common→ delays in care, low general adherence
- Quality
  - Poor supply chain governance
  - Weak quality assurance structures

Poorly functioning health systems exacerbate low access



Median prices of human insulin 100iu/ml 10ml vials are highly variable across income groups

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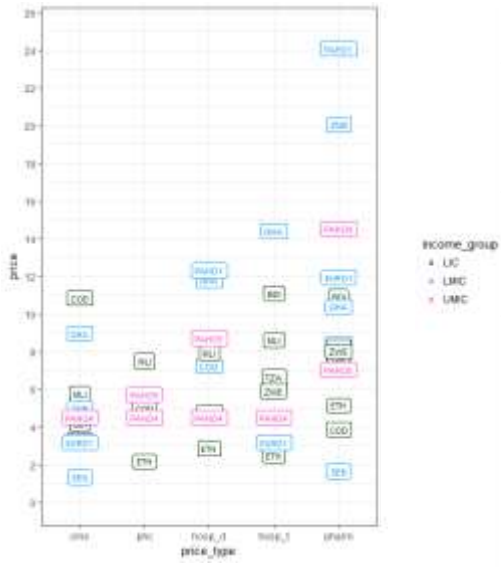
Prices are standardized to US Dollars; Countries excluded where data not available



- Insulin prices are vary highly across income groups and facility types across the AFRO region
- Prices for insulin are lower in Lower-Middle Income Countries (LMICs) than in some Low-Income Countries (LICs)
- Prices for insulin in countries in the PAHO region are lower than many countries in the AFRO region in all facility types

The Forum has been conceived to:

- Facilitate discussion on strategies that could lead to a fairer price setting and a pricing system that is sustainable for health systems and for innovation.
- Hold preliminary discussions about the wanted but also unwanted consequences of the current business model including ideas about possible alternative business models.
- Explore approaches for high- and middle-income countries to remedy shortages of essential medicines that may be due to low profit margins.
- Expand current networks to include other relevant stakeholders and countries, to facilitate better exchange of experience.
- Identify research gaps, specific to the current innovation and pricing system, including the need for transparency of research and development (R&D) costs, production costs, and profit margins.

A fair price is one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines. In this context, fairness implies positive incentives/benefits for all stakeholders, including purchasers and those involved in the research and development and manufacture of medicines.

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Ministry of Health, Welfare and Sport

Fair Pricing Meeting summary points

- Governments need to be enabled to play a stronger role in negotiating prices and where appropriate, incentivizing needs-based R&D
- More cooperative approaches would be helpful, for example with governments sharing information on pricing, and gaining greater leverage when negotiating prices. More transparency on R&D costs.
- Governments should see funding for health as an investment that will contribute to greater economic benefits, for example by enabling more health sector jobs in the public and private sectors, in addition to keeping the population healthy.
- Value based pricing is not viable in many countries; affordability and total cost important. Used in isolation, it also has the potential to exclude other valuable price-negotiation tools such as tendering and price-volume agreements.
- There is a need to fully understand the concept and consequences of 'de-linkage' with respect to development of medicines.
- This was a first step: more discussion required.

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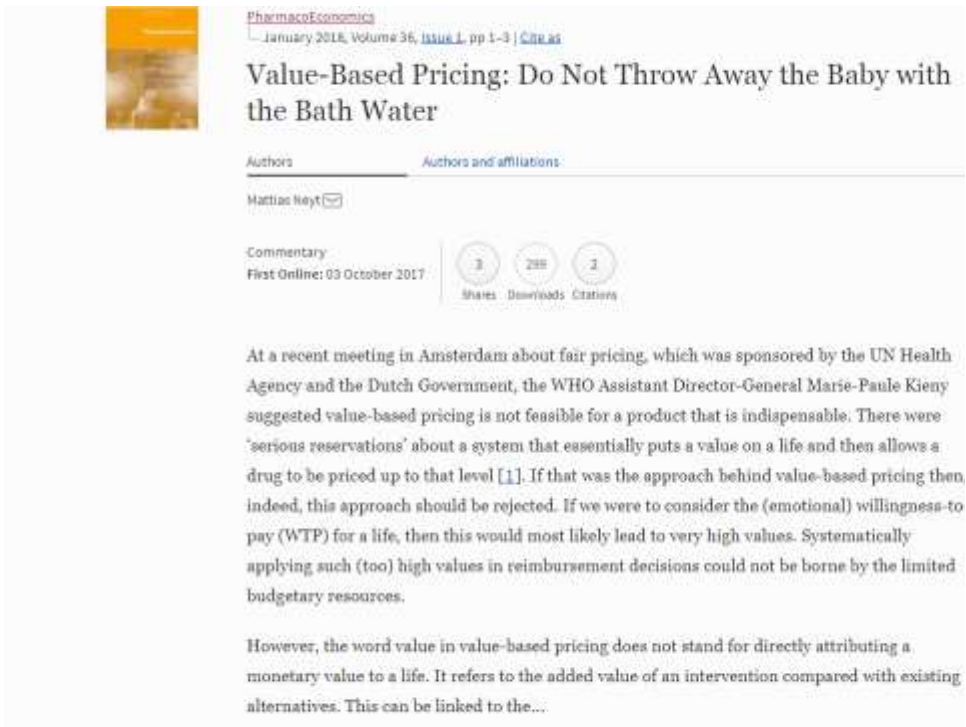

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Value-Based Pricing: Do Not Throw Away the Baby with the Bath Water

Authors | Authors and affiliations

Mattias Neyt

Commentary
First Online: 03 October 2017

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At a recent meeting in Amsterdam about fair pricing, which was sponsored by the UN Health Agency and the Dutch Government, the WHO Assistant Director-General Marie-Paule Kieny suggested value-based pricing is not feasible for a product that is indispensable. There were 'serious reservations' about a system that essentially puts a value on a life and then allows a drug to be priced up to that level [1]. If that was the approach behind value-based pricing then indeed, this approach should be rejected. If we were to consider the (emotional) willingness-to pay (WTP) for a life, then this would most likely lead to very high values. Systematically applying such (too) high values in reimbursement decisions could not be borne by the limited budgetary resources.

However, the word value in value-based pricing does not stand for directly attributing a monetary value to a life. It refers to the added value of an intervention compared with existing alternatives. This can be linked to the...

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PharmacoEconomics
January 2018, Volume 36, Issue 1, pp 5–8 | Cite as

Value-Based Pricing: L'Enfant Terrible?

Authors | Authors and affiliations

Sarah Garner, Andrew Rintoul, Suzanne R. Hill

Open Access | Reply
First Online: 21 December 2017

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Concern over pricing of pharmaceuticals and other health technologies in both high- and low-income countries is not new. It has been high on the World Health Organization (WHO) agend for a number of years [1]. Affordability of products, both to individual patients and to health systems, is one of the main barriers to accessing many effective medicines. In high income countries this debate has been focused primarily on medicines for cancer and orphan diseases, but in 2014 the pricing of sofosbuvir expanded the issue much more broadly: here was a 'cost-effective' treatment for hepatitis C that was unaffordable to countries of any income. The price being asked on the basis of cost-effectiveness evaluations might be considered to be 'value based', but as described in Iyengar et al. [2], was completely unaffordable for countries to use to treat all eligible patients. So what has gone wrong with so-called value-based pricing (VBP)?

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- The outcome of the Forum is that there is much to do to agree on how a fairer pricing model can be achieved that ensures access to medicines without bankrupting progress towards universal health coverage.
- Comparative effectiveness assessment and budget impact evaluation by decision makers will remain critical tools going forward, and there we agree with Neyt and many others about using evidence to fully inform decisions.
- But equally important is the need to change the rhetoric about what constitutes a fair and sustainable price for all—and that must start with transparency of R&D costs and expected return on investment rather than just discussion of value.
- In the end, there is no value in a medicine that is too expensive and sits on the shelf.

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Could value based pricing lead to affordable access?

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"Value" assessment **may inform the pricing** of medicines …

BUT

its uncertainties **may lead to prices higher than the health system deems affordable.**

Some sources of uncertainties from VBP

Different technical approaches

in undertaking "value" assessments

Incomplete evidence

to inform judgements about "value" at the time of decision-making

Artificially high "value"

of a new medicine relative to an inefficient current practice, even though the absolute magnitude of benefits is low

Different conceptualizations and perceptions

of value

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Int J Technol Assess Health Care. 2018 Jan;34(2):163-171. doi: 10.1017/S0266462318000090. Epub 2018 Apr 10.
DECISION-COMPONENTS OF NICE'S TECHNOLOGY APPRAISALS ASSESSMENT FRAMEWORK. de Folter J[1], Trusheim M[2], Jonsson P[3], Garner S[4].

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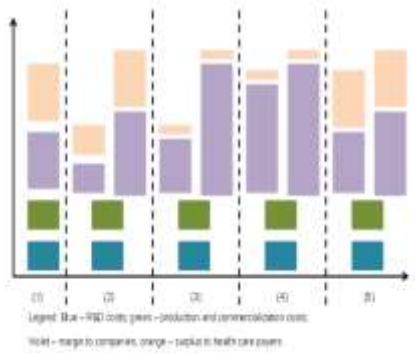
Value Based Pricing – European Commission EXPH



'"Value-based pricing" can lead to the reduction of prices for medicines with no or limited added value and increase the price for medicines with high value, which in turn may encourage manufacturers to focus their R&D on therapeutic medicines with superior value.

A concern emerges from this: the relative incentive to R&D, resulting from paying a price that approaches the value of benefits, transfers most of value generated to companies, affecting negatively the financial sustainability of health systems. There is difference between value-based pricing as a way to pay more for more benefits from innovation and prices approaching total value. Value-based pricing in the sense of the first part is a way to provide incentives for better innovation, while value based pricing in the sense of the latter element is a tool for exercise of market power.'

Source:https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/opinion_innovative_medicines_en.pdf page 17-18

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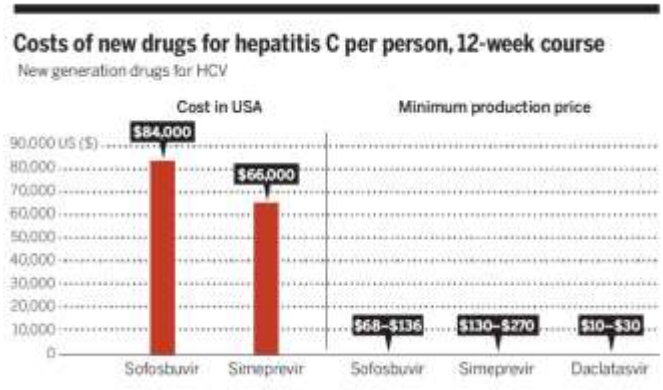
Cost of Production



Source: *Hill A, Cooke G. Science 2014: Vol. 345 no. 6193 pp. 141-142*

Hill A, Cooke G. Science 2014: Vol. 345 no. 6193 pp. 141-142

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Value-based pricing does not explicitly refer to costs of production

Three observations from *The Price of Sovaldi and its impact on the U.S. Health Care system* by Committee on Finance, United States Senate:

- **Production costs at commercial scale manufacturing are low**

  Pharmasset's internal company information suggests **0.9%-1.5% of the total costs**, if the treatment course were priced at US$50,000-US$30,000

- **R&D and other capital costs do not appear to inform pricing**

  "There was no concrete evidence in emails, meeting minutes or presentations that basic financial matters such as R&D costs or the multi-billion dollar acquisition of Pharmasset, the drug's first developer, factored into how Gilead set the price. Gilead knew **these prices would put treatment out of the reach of millions and cause extraordinary problems for Medicare and Medicaid**, but still the company went ahead."

- **Medicine prices evolve according to commercial goals**

  Pre-acquisition (<US$50,000 per course) to final launch price (US$84,000 per course)

? **How could value-based pricing ensure universal coverage without explicit reference to costs of production?**

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- Debates over value in health innovation have become increasingly dominated by cost-benefit assessments and "value-based pricing". This paper examines this prevailing narrative and its weaknesses and then presents an alternative framework for reimagining value.
- Drawing on literatures from the political economy of innovation, we argue that, in contrast to value-based pricing, value in health must be considered in the context of both value creation as a collective process amongst multiple public and private actors, as well as value extraction that often occurs due to trends such as financialization.
- Furthermore, in building an alternative framework of value, we ask three central questions that present areas for further research and public policy change: (1) What directions can innovation for health take to meet societal needs? (2) How can the divisions of innovative labor be structured to create value? and (3) How can the risks and rewards of innovation be distributed in way that sustains further value creation for health?
- In sum, this paper demystifies the prevailing narratives that often confound our understanding of value, while proposing alternative questions and pathways for public and private organizations, policymakers, and civil society to pursue.

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Achieving Fair Pricing of Medicines: Defining the concept of a fair price

Authors: Suerie Moon,[1,2] Stephanie Mariat,[3] Isao Kamae,[4] Hanne Bak Pedersen[3]

World Health

Factors to consider	Information and analysis needed
Sellers (supply-side)	
Cost of R&D	Usually not disclosed, various methodologies exist to estimate
Cost of manufacturing	Usually not disclosed, feasible to estimate
Fair profit	Aggregate profit disclosed but not product-specific; benchmarking feasible; entails normative judgment
Other costs (registration, administration, pharmacovigilance)	Usually not disclosed, feasible to estimate
Buyers (demand-side)	
Affordability	Further analytical work needed to identify concrete affordability ceilings for specific buyers
Value to individual and health system	HTA can contribute; methodologies needed to incorporate value within pricing under affordability constraint
Supply security	Information on volumes and producers needed to maintain competition and supply for specific product, feasible to collect

No value in expensive medicines sitting on the shelf

WHO is working with stakeholders to seek agreement on how a fairer pricing model can be achieved that ensures access to medicines without bankrupting progress towards universal health coverage.

- Comparative effectiveness assessment through HTA and budget impact evaluation will remain critical tools

BUT

- Affordability needs to be at the centre of any decision to invest or disinvest
- Transparency of R&D costs and expected return on investment should also be part of the discussion rather than just discussion of value
- WHO does not support using cost effective thresholds as the sole basis of decision making. *(see Bulletin World Health Organ* 2016;94:925–930)

Policy & practice

World Health Organization

Cost–effectiveness thresholds: pros and cons

Melanie Y Bertram,[a] Jeremy A Lauer,[a] Kees De Joncheere,[a] Tessa Edejer,[a] Raymond Hutubessy,[a] Marie-Paule Kieny[a] & Suzanne R Hill[b]

Abstract Cost–effectiveness analysis is used to compare the costs and outcomes of alternative policy options. Each resulting cost–effectiveness ratio represents the magnitude of additional health gained per additional unit of resources spent. Cost–effectiveness thresholds allow cost–effectiveness ratios that represent good or very good value for money to be identified. In 2001, the World Health Organization's Commission on Macroeconomics and Health suggested cost–effectiveness thresholds based on multiples of a country's per-capita gross domestic product (GDP). In some contexts, in choosing which health interventions to fund and which not to fund, these thresholds have been used as decision rules. However, experience with the use of such GDP-based thresholds in decision-making processes at country level shows them to lack country specificity and this – in addition to uncertainty in the modelled cost–effectiveness ratios – can lead to the wrong decision on how to spend health-care resources. Cost–effectiveness information should be used along side other considerations – e.g. budget impact and feasibility considerations – in a transparent decision-making process, rather than in isolation based on a single threshold value. Although cost–effectiveness ratios are undoubtedly informative in assessing value for money, countries should be encouraged to develop a context-specific process for decision-making that is supported by legislation, has stakeholder buy-in, for example the involvement of civil society organizations and patient groups, and is transparent, consistent and fair.

Abstracts in عربي, 中文, Français, Русский and Español at the end of each article

What are cost–effectiveness thresholds?

The main results of a cost–effectiveness analysis – in which the costs and outcomes of alternative policy options are compared – are cost–effectiveness ratios. In the field of health, a cost–effectiveness ratio usually represents the amount of additional health gained for each additional unit of resources spent. The makers of health policy initially used cost–effectiveness analyses for priority setting, in their attempts to ensure that the greatest possible health benefits were achieved given the available budget. Many countries currently use cost–effectiveness analyses and the resultant cost–effectiveness ratios to guide their decisions on resource allocation and to compare the efficiencies of alternative health interventions.

A cost–effectiveness threshold is generally set so that the interventions that appear to be relatively good or very good value for money can be identified. There are several types of threshold. In health-related analyses, a willingness-to-pay

Recent claims about the misapplication of cost–effectiveness thresholds are well founded. However, we find that the implication that the World Health Organization's (WHO's) Commission on Macroeconomics and Health's cost–effectiveness thresholds are intended to be used as the explicit criteria for health decisions at national level – ignoring all other policy-relevant evidence – is incorrect.

Thresholds based on gross domestic product

The most commonly cited cost–effectiveness thresholds are those based upon a country's per-capita gross domestic product (GDP) and the Commission on Macroeconomics and Health's corresponding estimate of the economic value of a year of healthy life.[1] As ill health has a negative economic impact, investments in health can contribute to economic development. The commission, in trying to encourage investment in health, has suggested that all countries should map out a path to universal access to essential health services.

Bull World Health Organ 2016;94:925–930| doi: http://dx.doi.org/10.2471/BLT.15.164418


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