

# Six Reasons Why the Global Fund Should Adopt Health Technology Assessment

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## Introduction

With aid budgets shrinking and even low-income countries increasingly faced with cofinancing requirements,<sup>[1]</sup> this is the right time for global health funders such as the Global Fund and their donors to formally introduce Health Technology Assessment (HTA), both at the central operations level and at the national or regional level in recipient countries. HTA—the systematic assessment of the comparative effectiveness and cost of health technologies—provides the economic and clinical evidence needed for decisions about what products to purchase to achieve value for money. Operationalising HTA as a routine component of the Fund’s model must be a [top priority](#) for its incoming executive director, expected [to be announced](#) on November 14.

CGD colleagues and others have been urging global health funders like the Global Fund to adopt HTA for several years, but there has been little progress to date.<sup>[2]</sup> Given increasing pressure to maximize results, demonstrate impact, and minimize waste, formally adopting HTA is now more important than ever. We hope the incoming executive director will acknowledge that doing so is key to achieving better value for money across the Fund’s portfolio, and especially for the \$2 billion it spends annually on health commodities.

In this CGD Note, we explain why introducing HTA is a good idea. Specifically, we outline six benefits that the application of HTA could bring to the Global Fund, the countries it supports, and the broader global health community.

HTA would:

1. Help the Global Fund make a stronger and easier-to-defend case for its global impact
2. Enhance data transparency and improve data quality
3. Strengthen the engagement process with product manufacturers by signalling willingness to pay for innovation, moving away from cost minimisation, and exploring innovative public-private risk-sharing schemes for evidence generation
4. Help strengthen and streamline the WHO Prequalification process, and in turn build local capacity to apply WHO norms and guidance in the country context
5. Help make a well-substantiated case for additional, dedicated funding for upstream R&D and innovation
6. Empower country payers to make their own decisions by effectively engaging the private sector, and encourage regional partnerships

## How HTA could drive smarter policy decisions at the Global Fund

When decision makers are confronted with questions about adopting new health products, they tend to apply HTA in an ad hoc way or as a one-off exercise, if at all. Repeating this process every time a new health technology is introduced is inefficient. It is long overdue for funders to agree on the standards, processes, and methods for generating the evidence, explicitly including economic evidence, needed to inform resource allocation—a critical component of HTA and a common practice in healthcare markets in many high- and middle-income countries.

The Global Fund’s [new strategy](#) for 2017-2022 makes extensive reference to value for money.<sup>[3]</sup> Further, the UK’s Department for International Development (DFID) [introduced value for money](#) as a conditionality, both centrally and at a country level, in its first ever [performance agreement](#) with the Fund during last year’s replenishment. Given the political will, there *are* opportunities within the Global Fund’s complex processes to think about—and generate—value for money (for practical recommendations on how the Global Fund can incorporate value for money, see [here](#) and [here](#)). In fact, there is now a dedicated team thinking about how to operationalise HTA across the Fund’s investment cycle.

Introducing HTA as a routine component of its operating model would bring a number of benefits to the Fund, the countries it supports, and the broader global health market and community of stakeholders.

## 1. HTA would make it easier for the Fund to demonstrate (and defend) its impact.

Systematic, publicly available, and reproducible analyses of the trade-offs between alternative investment decisions—at least for big-ticket items where most of the quick wins can be achieved—will make it easier to source, synthesise, and extrapolate return-on-investment estimates. Such analyses will also help demonstrate (as well as independently verify) the Fund’s value on a case-by-case basis and on aggregate. Moreover, HTA can enable different partners to engage with available data and make defensible decisions about new health technologies. In doing so, it can also address equity concerns by making distributional impacts of allocation decisions explicit and open to scrutiny.

A recent analysis by [RAND](#) in the UK provides a useful example. The study found that implementing a small subset (10 in total) of the national guidance products developed over the lifetime of the HTA programme would bring about £3billion in benefits over a single year. A [more detailed analysis](#) of the process through which HTA impacts practice revealed additional, less-easy-to-quantify—but equally important—benefits, such as cultural change, international reputation, and direct policy change.

In Thailand, the national HTA programme, HITAP, generated US\$6 million purchasing power parity in savings through one HTA study and a resulting [policy change](#) in 2007 on national prevention of cervical cancer. This was more than enough to cover HITAP’s operating costs that year. A 2010 evaluation of a new drug regimen for preventing maternal-to-child transmission of HIV found that it would avert more than 100 paediatric HIV infections and save US\$2.6 million for each child saved. And price negotiations with innovator companies seeking inclusion of their products (including ARVs, anticoagulants, and the flu vaccine) on the country’s universal coverage list resulted in almost US\$800 million in savings over five years.

As a first step toward this end, the Global Fund should put in the public domain (and invite independent verification of) the data and methods underpinning its claim that investments in improved procurement practices, including the expansion of its pooled procurement mechanism, yielded savings of more than [US\\$650 million](#) over four years.

## 2. HTA would enhance data transparency and improve data quality.

To be legitimate and accepted by stakeholders, HTA requires that data used in analyses are in the public domain. Commercially sensitive information can still be shared with core stakeholders under nondisclosure agreements, for example, whilst other components are publicised. This is common practice for HTA agencies around the world, with agreement from large multinational companies. Further, companies like IMS Health operate a profit-making model of buying and selling commercial data on pharmaceuticals around the world with the right legal checks in place.

To make HTA analyses possible at central and country levels (as well as by independent researchers), the Global Fund would need to provide reliable, complete, comparable, and up-to-date data through its Price and Quality Reporting (PQR) mechanism. (While there are anecdotes about data issues related to the PQR, the only publicly available source we have been able to identify that points to errors and delays in data entry is the [2015 report](#) from the Fund’s Office of the Inspector General.)

In addition to increasing the legitimacy of decisions, making a convincing case about impact to funders, and empowering country teams, sharing data can also improve data quality, especially for cost data. For example, the UK government’s [Open Data](#) drive, through which it shared large volumes of information across sectors in the public domain, led to the identification of practice variation and potential waste in prescribing practices across the country.<sup>[4]</sup> In turn, when NICE publicised hospital reference costs during the early days of HTA it was able to improve accuracy through crowdsourcing better information from NHS providers.

## 3. HTA would improve the engagement process with product manufacturers.

A streamlined process and methodology for assessing the value of new health products compared to existing ones—including clearly set timelines, rules of engagement, and decision criteria—is needed as a first step. In addition, specifying the type of evidence (including economic evidence) needed to address the uncertainties of decision makers, within both the Global Fund and its partner countries, across the different stages of the investment case cycle will increase manufacturers’ confidence and accelerate the product selection process. This could be done through the use of evidence tables for product submissions, for example.<sup>[5]</sup>

Further, by establishing a track record of decisions on product adoption and procurement at given price points, the Fund will be signalling to manufacturers what it is willing to pay for incremental innovation. As a result, it will be in a stronger position to negotiate with first-in-class product manufacturers (where few or no competitor products exist) by using as its starting point a baseline informed by its own prior valuations, as opposed to an arbitrary ex-factory price set by the manufacturers. There will also be an impetus to pay for value where additional benefits can be proven, as opposed to a race-to-the-bottom triggered by cost-minimisation tactics.

Finally, through an HTA process, the Fund can drive better evidence generation ex ante, but also in parallel to product introduction through managed entry or risk-sharing schemes (or Medicare’s [Coverage with Evidence Development](#) approach). Such approaches are extensively used by payers in mature markets, where promising products are conditionally approved subject to further proof of their value added. These approaches are based on a shared burden of proof between manufacturers and regulators, and are widely accepted beyond the global health world. Adoption of a formal HTA process will most likely encourage manufacturers, including product development partnerships, to commission their own HTAs to inform the way they develop, test, and price their products.

## 4. HTA would help strengthen and streamline the WHO Prequalification process, and in turn build local capacity to apply WHO norms and guidance in the country context.

WHO Prequalification (PQ) has a central role in the Fund’s technology adoption decisions. Therefore, any attempt to introduce HTA would have to be closely coordinated with a revamped and strengthened (and better resourced, especially for currently neglected post-marketing surveillance studies) WHO PQ process. This could help build local capacity as countries contextualize norms and guidance

set at the global level to their own contexts. Also, as countries transition away from donor support, a legacy of HTA systems at the country or even the regional level can help to strength health systems.

The European Commission, for example, is now working to institutionalise [HTA across member states](#) in collaboration with the European Medicines Agency. The Fund and its donors can work to support WHO's expert panels by enhancing their role in norm-setting for an HTA process, for example. At the same time, the Fund can work with the WHO to demand greater transparency in the way these panels are constituted and interests are managed; clearer terms of reference that include strong economics expertise;<sup>[6]</sup> stricter rules on timeliness; and greater inclusiveness and transparency in the overall decision-making process (including data, methods, analyses, and decision criteria).

WHO's [Collaborative Regulatory process](#) may offer the right window of opportunity for such an attempt to connect the various players through a more cohesive process. This can also be an opportunity to reform what is an under-resourced, unresponsive, and rather prescriptive process, to one where manufacturers play a greater role in innovating (including bearing the cost of demonstrating value) in response to signals by purchasers such as the Global Fund and increasingly, country payers. This would contrast with an approach where manufacturers respond to detailed product specifications set out in expressions of interest based on WHO guidelines.

## 5. HTA would help make a well-substantiated case for additional, dedicated funding for upstream R&D and innovation.

A discussion is needed about what national healthcare budgets, supplemented by global financing, should be paying for, and who should be funding global R&D. In the UK, for example, [innovation](#) is influenced through clear and consistent signalling by the discerning national payer on what the NHS is willing to pay for, and the evidence that forms the basis of its decision (based on HTA analyses). In addition, the state invests in publicly funded R&D through universities and research institutes, and in turn offers a preferential tax regime for companies that produce and launch in the UK.<sup>[7]</sup> Funding for research and tax interventions does not come from the NHS budget, but from other public departments, such as the Department for Education and the Department for Business, Innovation and Skills.

In the case of global health, the Global Fund and other donors often fund promising innovations through separate financing streams, such as [catalytic investments](#) to support market entry of new products. Two elements are essential to this process. First, nascent and limited national health budgets are protected from diversion away from proven technologies or expanding coverage to funding promising innovations at a price premium or at early-stage R&D (with detrimental impact in static efficiency). Second, the signals sent by payers (global in particular) to manufacturers emphasise that value for money matters and “excessive” innovation premiums will not be accepted. Otherwise, there is a risk of unsustainable inflationary pressures, as has been the case with [cancer drugs in the US](#) or the [Cancer Drugs Fund in the UK](#) (hence driving dynamic inefficiency).

## 6. HTA would empower country payers and encourage regional partnerships.

Country payers, in addition to being in charge of coverage decisions, will also be able to signal to manufacturers (product development partnerships, local companies, and multinationals) their countries' and populations' own priorities, given their budgets. They will have more legitimacy in negotiating prices with those manufacturers, just like high-income country governments do today, and could experiment with affordability-enhancing policies, such as tiered pricing or licensing-out arrangements. This is a necessary (albeit lengthy) step in the transition process of building local capacities. Nonetheless, it can help ensure that prices reach an equilibrium as cofinancing increases and external funds decrease. Such a delegation of power to purchase based on good information and within the Global Fund's governance framework may also lead to regional partnerships, where countries come together to collaborate on the analytics of HTA and to pool resources and know-how for joint procurement, as is the case with [European countries](#) and the Pan American Health Organization, which uses its [Strategic Fund](#) to place bulk orders for registered products.

## Increasing momentum for HTA

Almost 15 years ago, in an [insightful piece](#) about the affordability of medical innovation in the US market, Garber and Fuchs highlighted a dilemma: “making innovation affordable slows innovation.” Their finding reflects a tension that continues to torment the global health community today. To address the challenge of quality-improving and cost-inflating (rather than cost-reducing) innovation, as well as the tension between equitable and universal coverage on the one hand and financial sustainability on the other, the authors recommended setting up a National Centre for the Assessment of Medical Technologies (an HTA agency). By producing and disseminating knowledge on the comparative effectiveness and cost of technologies—information that payers, providers, and patients can use to make decisions—HTA helps bridge innovation with affordability.

Over the past years, several low- and middle-income countries have been following Garber and Fuchs's recommendations to set up mechanisms for assessing the comparative value of new health technologies. In [Brazil](#), [Mexico](#), and [Thailand](#), HTA drives investment decisions by national payers. China, Indonesia, the [Philippines](#), South Africa, [Ghana](#), and [India](#) all have budding HTA strategies, and/or new institutions either enshrined in law or included in their national health plans or insurance reform blueprints (see [here](#) and [here](#) for more country examples). In a 2015 [survey](#) on HTA among WHO member states, four out of five reported some HTA activity to inform policymaking.

The time is ripe for the Global Fund to take a leadership role in moving the HTA agenda forward. A key priority for the new executive director should be allocating resources towards a measurable proxy for stronger and more independent healthcare systems: evidence-informed purchasing mechanisms at country and regional levels.

## Further reading

- CGD Working Group. 2012. [Priority-Setting in Health: Building Institutions for Smarter Public Spending](#).
- CGD Working Group. 2013. [More Health for the Money](#).
- Chalkidou et al. 2016. Priority-Setting for Achieving Universal Health Coverage. *Bulletin of the World Health Organization* 94:462–467 (doi: <http://dx.doi.org/10.2471/BLT.15.155721>).
- Chalkidou et al. 2017. We Need a NICE for Global Development. *F1000Research* 6:1223 (doi: [10.12688/f1000research.11863.1](https://doi.org/10.12688/f1000research.11863.1)).
- Garber and Fuchs. 2003. [Medical Innovation: Promises & Pitfalls](#). Brookings Institute.
- Glassman and Kenny. 2015. [In Health Spending, Middle-Income Countries Face a Priorities Ditch, Not a Financing Ditch – But That Still Merits Aid](#). CGD Blog.
- Glassman. 2017. [Global Fund Executive Director Reboot](#). CGD Blog.
- Kanpirom et al. 2017. How Should Global Fund Use Value-for-Money Information to Sustain its Investments in Graduating Countries? *International Journal of Health Policy and Management* Article 6, Volume 6, Issue 9 (doi:[10.15171/ijhpm.2017.25](https://doi.org/10.15171/ijhpm.2017.25)).
- Teerawattananon et al. 2013. Health technology assessments as a mechanism for increased value for money: recommendations to the Global Fund. *Globalization and Health* 9:35 (doi: [10.1186/1744-8603-9-35](https://doi.org/10.1186/1744-8603-9-35)).

[1] The Global Fund's cofinancing requirements vary by income classification and disease burden, see [here](#) and [here](#).

[2] See the additional resources section.

[3] See operational objective 3 under strategic objective 1 and operational objective 1 under strategic objective 4.

[4] See [here](#) for an analysis of statin prescribing.

[5] Even completing table X [here](#) for all submissions would be a great start.

[6] See [here](#) for similar issues raised about limited impact of economic considerations on WHO's decision-making.

[7] See the example of the UK's [Patent Box](#).