OPEN LETTER

How can we make better health decisions a Best Buy for all?
[version 1; peer review: 2 approved, 1 approved with reservations]

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Abstract
The World Health Organization (WHO) resolution calling on Member States to work towards achieving universal health coverage (UHC) has increased the need for prioritizing health spending. Such need will soon accelerate as low- and middle-income countries transition from external aid. Countries will have to make difficult decisions on how best to integrate and finance previously donor-funded technologies and health services into their UHC packages in ways that are equitable, and operationally and financially sustainable.

The International Decision Support Initiative (iDSI) is a global network of health, policy and economic expertise which supports countries in making better decisions about how best and how much to spend public money on healthcare. iDSI core partners include Center For Global Development, China National Health Development Research Center, Clinton Health Access Initiative, Health Intervention and Technology Assessment Program, Thailand / National Health Foundation, Imperial College London, Kenya Medical Research Institute, and the Norwegian Institute of Public Health. In May 2019, iDSI convened a roundtable entitled Why strengthening health systems to make better decisions is a Best Buy.

The event brought together members of iDSI, development partners and other organizations working in the areas of evidence-informed priority-setting, resource allocation and purchasing. The roundtable participants identified key challenges and activities that could be undertaken by the broader health technology assessment (HTA)
community to further country-led capacity building, as well to foster deeper collaboration between the community itself.

HTA is a tool which can assist governments and development partners with evaluating alternative investment options in a defensible and accountable fashion. The definition and scope of HTA, and what it can achieve and support, can be presented more clearly and cohesively to stakeholders. Organizations engaging in HTA must develop deeper collaboration, and integrate existing collaborations, to ensure progress in developing HTA institutionalization globally is well organized and sustainable.

Keywords
health technology assessment, global health, healthcare, financing, healthcare financing, economic evaluation, international development, donor, donor transition, international decision support initiative, health services, universal health coverage, health system, health system strengthening, HTA institutionalization, evidence-informed priority setting, priority setting, resource allocation, purchasing

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Introduction

The World Health Organization (WHO) resolution calling on Member States to work towards achieving universal health coverage (UHC) has increased the need for prioritizing health spending\(^1\). Such need will soon accelerate as low- and middle-income countries (LMICs) transition from external aid. By 2022, 24 countries are projected to be in simultaneous transition from external financing\(^2\). Countries will have to make difficult decisions on how best to integrate and finance previously donor-funded technologies and health services into their UHC packages, including identifying and balancing trade-offs between competing health priorities to ensure that high-quality, affordable access to healthcare is provided to the population in ways that are equitable and operationally and financially sustainable.

But how might priority-setting best be done? Health technology assessment (HTA) is a multi-disciplinary exercise in assessing the clinical and cost-effectiveness of health services and technologies, and their broader impact to inform priority setting, resource allocation and purchasing\(^3\). The WHO has argued that HTA should be a clear part of the priority-setting process and is an important means through which UHC can be achieved and secured. The WHO defines the scope of technologies which can be evaluated using HTA as "medicines, medical devices, vaccines, procedures and systems"\(^4\).

The International Decision Support Initiative (iDSI) is a global network of health, policy and economic expertise which supports countries in making better decisions about how best and how much to spend public money on healthcare\(^5\). Funders of the network include the Bill & Melinda Gates Foundation (BMGF) and the UK Department for International Development (DFID). In May 2019, iDSI convened a roundtable\(^6\) discussion in London, UK, entitled Why strengthening health systems to make better decisions is a Best Buy. The event brought together members of the iDSI network, development partners and other organizations working in the areas of evidence-informed priority-setting, resource allocation and purchasing. Discussions explored the priority-setting challenges that governments in Africa and Asia face and how HTA can be a means of strengthening health systems, why investing in evidence-informed priority-setting is a Best Buy for development partners, and how organizations working in this area could work together to add further value. The roundtable participants identified key challenges and activities that could be undertaken by the broader HTA community to further country-led capacity building for priority setting and HTA, as well as to foster deeper collaboration between the community itself.

Why is HTA not yet routinely adopted as a tool for strengthening health systems for UHC?

Confusion over definitions and terms

A notable challenge to the institutionalization of priority setting and HTA identified in the roundtable discussion was a frequent lack of understanding of the vocabulary of HTA and its method among stakeholders in healthcare decision-making processes. This challenge is not surprising, given the HTA community itself is still struggling with definitions. In 2019, a task group was set up with open consultation of HTA definition, a step forward to resolve this challenge, brought together several organisations working on HTA and the WHO to develop an updated definition that consolidates and simplifies the multiple existing definitions to reflect "current and emerging realities of HTA"\(^7\). The task group proposed the definition:

- A multidisciplinary process that uses explicit and scientifically robust methods to assess the value of using a health technology at different points in its lifecycle.

  The process is comparative, systematic, transparent and involves multiple stakeholders. The purpose is to inform health policy and decision-making to promote an efficient, sustainable, equitable and high-quality health system\(^8\).

Participants of the roundtable noted that conceptualising priority-setting and HTA and explaining such concepts to the wider global health community must go beyond agreeing on the definition. It should include outlining what is included in the scope of HTA, as well as the priority setting process, which may include terms of engagement with stakeholders and the identification of topics for evidence review. HTA should be viewed as more than a merely technocratic exercise. It can at its best be a bridge to join professional technical assessment and professional policy decision-making in a fully integrated whole.

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\(^1\) Members of the iDSI roundtable included: Anthony J. Culyer (Chair), University of York, York, UK; Peter Baker, Global Health and Development Group (GHD), Imperial College London, London, UK; Maria Vittoria Bufali, University of Strathclyde, Glasgow, UK; Francoise Cluzeau, Global Health and Development Group (GHD), Imperial College London, London, UK; Kalipso Chalkidou, Center for Global Development (CGD); Global Health and Development Group (GHD), Imperial College London, London, UK; Sannah Minna Dubak, Health Intervention and Technology Assessment Program (HITAP) Thailand (Asia HTA Consortium), Nonthaburi, Thailand; Austen Davis, Norwegian Agency for Development Cooperation (Norad), Oslo, Norway; Samantha Diamond, Clinton Health Access Initiative (CHAI), Boston, USA; Sayai Ehlers, Global Health and Development Group (GHD), Imperial College London, London, UK; Sarah Garner, World Health Organization (WHO), Geneva, Switzerland; Amanda Glassman MSc, Center For Global Development (CGD); Javier Guzman, Management Sciences for Health, Medford, Massachusetts, USA; Martha Gyansa Lutterodt, Ministry of Health Ghana, Accra, Ghana; Raph Harley, Clinton Health Access Initiative (CHAI), Pretoria, South Africa; Wanrudee Itharawatchai, Health Intervention and Technology Assessment Program (HITAP) Thailand (Asia HTA Consortium), Nonthaburi, Thailand; Kjell- Arne Johansson, University of Bergen, Bergen, Norway; Jo Keatinge, Department for International Development (DFID), East Kilbride, UK; Ryan Li, Global Health and Development Group (GHD), Imperial College London, London; Rob Lloyd, Itad, Brighton, UK; Ingrid Milteige, University of Bergen, Bergen, Norway; Robyn Millar, University of Strathclyde, Glasgow, UK; Niki O’Brien, Global Health and Development Group (GHD), Imperial College London, London, UK; Trygve Ottersen, Norwegian Institute of Public Health (NIPH), Oslo, Norway; Francis Ruiz, Global Health and Development Group (GHD), Imperial College London, London, UK; Ingvil Saeterdal, Norwegian Institute of Public Health (NIPH), Oslo, Norway; Anna Vassall, London School of Hygiene and Tropical Medicine, London, UK; Damian Walker, Bill & Melinda Gates Foundation (BMGF), Seattle, USA; David Wilson, Bill & Melinda Gates Foundation (BMGF), Seattle, USA; Kun Zhou, China National Health Development Research Center (CNHDRC), Beijing, China.
Assessment tools must be designed to address the nature of the decisions that need to be taken and the policy decision-making process to ensure critical political elements are taken into account in the tool's design. This becomes much more than a matter of a definition of HTA, for it includes a role for context, scope, and process. HTA, then, is both the portfolio of analytical tools for assessment (the “assessment” tools) and the broader range of topics that define context, objectives, barriers, conflicting interests, that, taken together, amount to a kind of “political economy” of healthcare prioritization. On this view, while the technical attributes of “assessment”, like the meanings of opportunity cost, evidence, effectiveness or model building, are common to all practical applications of HTA, in any specific application, the objectives, the weights attached to them, the scope and outcomes and the historical and cultural context which may make decisions and their implementation more or less possible, are particular to that application. In this sense, “one size does not fit all”, there is no universally correct “perspective” of a study and “cost-effectiveness” is a function of local circumstances: what is cost-effective in one place may or may not be cost effective in another. Roundtable participants noted that once consensus is reached in defining HTA, greater efforts must be made to communicate the agreed definition clearly and definitively to relevant stakeholders while concurrently connecting stakeholders to facilitate knowledge and information sharing required as part of such a multidisciplinary endeavour.

The politics of HTA

Many countries have struggled with rationing of health services to serve population needs. In the absence of processes and methods for explicit rationing, decision-makers will find it easier to say ‘yes’ to health technologies including those that are novel and costly—decisions that may be politically favourable in the short run but prove financially unsustainable in the long run—and be reluctant to say ‘no’, with little consideration of effectiveness or cost-effectiveness. Evidence-informed priority-setting in comparison forces decision makers and their constituents to consider the trade-offs of any decision and helps decision maker justify what healthcare and resources are not to be included. HTA agencies across countries, notably the National Institute for Health and Care Excellence (NICE) in England, have driven up spending and put necessary pressure on health budgets. As such, it was noted in discussions that HTA need not only result in rejections. For example, HTA has been successfully used as a tool to inform price negotiations, procurement of commodities as well as in adjusting healthcare packages (i.e. what is provided to whom and under what circumstances?). It can thus drive governments’ and development partners’ Best Buys agendas, and such benefits must be more clearly communicated.

Lack of understanding about how policymakers and payers can use HTA

LMIC governments and healthcare payers have many needs for capacity and strengthened systems in priority-setting for UHC, and there is a proliferation of global initiatives and organisations providing technical assistance. However, when many different donor-funded organisations are providing technical assistance, often in an uncoordinated manner, this can overwhelm LMIC governments and healthcare payers whose capacities are typically already overstretched. Such disorganisation is exacerbated by the existence of multiple health packages, decision makers, donor funds, and insurance schemes in each country. A clearer narrative around priority setting, HTA and how it can assist governments in achieving UHC is overdue, as is communication between domestic and global organisations working in these areas. The roundtable discussed the need for developing a new publication which might build on discussions in *What’s In, What’s Out: Designing Benefits for Universal Health Coverage*, addressing the current issues facing the HTA movement, how to link priority setting to upstream financing and downstream payment, the possible means of engaging with governments and budget holders in practical activities such as procurement. Linking the exercise of HTA to realisable savings was flagged as a priority. We try to offer such examples of practical applications of HTA in Figure 1.

Country-owned applications of global and local evidence

Another major challenge relates to how traditional academic researchers and organizations whose roles are primarily in providing technical assistance can work together to serve partner LMICs in a responsive, demand-driven manner. For instance, these groups are required to work together in building capacity for the production and use of HTA evidence; and in understanding whether and how international evidence can be applicable locally. International development partners are investing in data collection and synthesis, notably through initiatives like the Disease Control Priorities Network (DCPN), funded by BMGF, which promotes and assists in the use of economic evaluation for priority setting at global and country levels. DCPN most recently published *Disease Control Priorities, Third Edition*, a review of evidence on cost-effective interventions to address the burden of disease in LMICs. However, the next phase of work for DCPN and other organizations in the HTA community, must bring together academics, data and technical assistance together to explore how evidence outputs can be applied in practical, locally-owned priority setting.

Working towards sustainability and cohesion

The roundtable suggested that the WHO could be a “knowledge broker”, connecting decision-makers who require evidence or practical support to help them make difficult decisions with those who are in a position to provide such evidence or support. The WHO hosted Decide Health Decision hub, a platform established in June 2019 with the objective of hosting a virtual space to dedicated to supporting collaboration in the field of data-driven health decision making, through HTA, economic evaluation, investment cases or any other process encouraging fair and transparent decision making, could be an ideal platform to enable this. The roundtable endorsed the development of the platform and called for all partners to support the WHO in its coordination efforts. Strong leadership in the development of the HTA movement is crucial to the sustainability of HTA, as is long term financing in government ministries.
There is a secondary need to ensure that monitoring and evaluation mechanisms exist to measure and understand success. It was noted that the configuration of global health financing is changing, with an increasing reliance on concessional loans and less on donor funding as aid transition takes effect. As such, governments need to take responsibility for the development of strong and sustainable health systems. They need to recognize and seek out individuals and organizations with the skills to assist where gaps in knowledge and skills exist. In response to these needs, the roundtable endorsed the development of a unified Theory of Change for the major initiatives and organizations working in priority setting and HTA. Developing a Theory of Change involves working backward from a long-term goal, mapping out the causal pathways (including outputs and intermediate outcomes) toward that goal, and the assumptions—factors that would facilitate or impede the achievement of the goal\textsuperscript{14}. The proposed Theory of Change will outline a mutual goal related to HTA for UHC, with clear and measurable milestones and/or indicators to ensure successful and appropriate progression. The Theory of Change could build on the iDSI Theory of Change, outlining how facilitation of effective partnerships focused on institutional and technical capacity-building leads to institutionalization of evidence-informed priority-setting at the country level, ultimately resulting in better decision-making and sustainable health impact\textsuperscript{14}.

Next steps and conclusions
Next steps identified by the roundtable participants:

- Developing a new publication package building on content in *What’s In, What’s Out*, linking upstream to questions of premier estimation and budgeting, actuarial calculations and risk adjustment; and downstream to provider payment modalities and monitoring of quality in service delivery incl appropriate use of technology
- A written call for WHO to redouble its efforts as per the 2014 HTA WHA resolution to support countries in developing priority setting and HTA institutionalization and also to lead by example through introducing robust HTA processes in its own workings incl the development of STGs, disease specific targets and the EML as well as policy guidance documents
- Developing and converging towards a single Theory of Change for evidence informed priority setting, agreed by the major organizations working in the areas of priority setting and HTA to enhance coordination and alignment and minimize reporting requirements. Such work will be facilitated through the development of the WHO hosted Decide Health Decision hub, bringing together major HTA focused organizations
There is increasing pressure on governments to finance and achieve UHC. HTA is a tool which can assist governments and development partners with evaluating alternative investment options in a defensible and accountable fashion. The definition and scope of HTA, and what it can achieve and support, can be presented more clearly and cohesively to stakeholders. Organizations engaging in HTA must develop deeper collaboration, and integrate existing collaborations, to ensure progress in developing HTA institutionalization globally is well organized and sustainable.

Data availability
No data are associated with this study.

References

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The article summarizes discussions at a roundtable "Why strengthening health systems to make better decisions is a Best Buy." I did not participate the event and cannot comment on adequacy as a protocol of the discussions, my observations are based on the article alone.

The article builds up to three recommendations or "next steps" - a publication package to develop and document practice of health technology assessment (HTA), a "call for WHO to redouble its efforts [...] to support countries in developing priority setting," and development of a "single Theory of Change." These recommendations follow clearly from the discussion.

There are, however, a number of shortcomings which compromise the effectiveness of the letter:
1. The abstract is inadequate, and reads at first sight like an introduction. (Indeed, it turns out that is has been pasted and rearranged from the introduction.) This should be rewritten to communicate gist of discussions and recommendations.

2. The perspective - i.e., the dividing line between general remarks or exposition of a topic on one hand, and documentation of roundtable discussion on the other - is not always clear.

3. In the section on "confusion over definitions and terms" (paragraph starting "Participants of the roundtable noted ..." until end of section) I am puzzled by the contrast between the "professional technical assessment and professional policy decision-making." This, and the following paragraph in which this theme is developed, lacks a clear health systems perspective which would usefully complement and connect the themes developed.

4. The section on "Theory of Change" appears out of context, because the article here conflates challenges in application of HTA and the perspective of institutions driving the HTA agenda and embedding it in a broader health policy agenda. I propose to separate these perspectives and objectives more clearly.
Is the rationale for the Open Letter provided in sufficient detail?
Yes

Does the article adequately reference differing views and opinions?
Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Economics, macroeconomics and public finance, global health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Daniel A. Ollendorf  
Center for the Evaluation of Value and Risk in Health (CEVR), Tufts Medical Center, Boston, MA, USA

This Open Letter is a clear and concise statement that places good context around the use of health technology assessment (HTA) to support prioritization and financing of resources. Given that this was a summary of a round table session, perhaps not all of the following suggestions can be taken up, but they are intended to help clarify the discussion somewhat:

1. HTA definition: it is unclear whether the term "lifecycle" refers to the product or the HTA process. If the product, my belief is that there is really only one point in the lifecycle in which the value is explicitly considered. Other points (e.g., early scientific advice) are focused on evidence generation.

2. Politics of HTA: The discussion of how HTA should not be considered merely a vehicle for saying "no" is an opportunity to describe examples of costly interventions that are shown to be
cost-effective given outsized benefits, cost-offsets, etc. This would more clearly show the benefit of value assessment as part of the HTA process.

3. Politics of HTA: Another example of use of HTA would be development of informative clinical guidelines (alluded to later).

4. Politics of HTA: This may not have been part of the discussions, but HTA’s independence (arm’s length relationship with government, multi-stakeholder approach) is one critical way to mitigate undue political influence.

5. Politics of HTA: “decision maker” should be “decision makers”.

6. Policymaker/payer use of HTA: In the preceding paragraph, NICE’s effects were described as increasing spending and putting “necessary pressure” on health budgets. This may be true in some instances in LMICs as well, and may not necessarily always result in “realisable savings”. Additional spending may be justified for health gain alone.

7. Working towards sustainability and cohesion: The goal of data-driven collaboration is a laudable one; are there examples outside of Decide that could be cited here?

8. Next steps and conclusions: In general, it is a good idea to spell out any acronyms that may not be clear to all readers, e.g. “HITA”, “WHA”, “EML”, “STGs”.

9. Next steps and conclusions: In the first bullet, it seems that “premier” should be “premium”?

Is the rationale for the Open Letter provided in sufficient detail?
Yes

Does the article adequately reference differing views and opinions?
Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Partly

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Clinical epidemiology, health economics, health technology assessment, pharmacoeconomics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.
Hector E. Castro
Pharmaceutical Economics & Financing, Management Sciences for Health, Arlington, VA, USA

The Open Letter is clear and relevant for the overall priority setting and health technology assessment community. A few comments below to potentially make the narrative more balanced:

- The confusion of terms is very relevant, perhaps could expand a little bit more on the confusion of methods? Not all countries apply the same principles for HTA, not all of them take the full CUA/CEA approach.

- The politics of HTA is of paramount importance for its successful implementation, however the paragraph seems a little bit short on the need to raise awareness among policymakers and get their buy in on more systematic priority setting processes. Also in many settings the historic lack of transparency of decision-making embedded in the context of health is being considered a human right has led to judicial intervention on behalf of the population posing an additional challenge to rational priority setting mechanisms.

- The section “Lack of understanding about how policymakers and payers can use HTA” mostly elaborates on the need for international coordination, but seems limited on the need to address the local capacity gaps of HTA “users” (i.e. policymakers, payers, etc.) so they can understand the potential use and limitations of HTA.

- Next steps and conclusions should include some notes on the need for capacity building of HTA users.

Is the rationale for the Open Letter provided in sufficient detail?
Yes

Does the article adequately reference differing views and opinions?
Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Yes
**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** HTA, Priority Setting, Health Sector Reform Universal Health Coverage, Global Health, Pharmaceuticals

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.