UNITING EFFORTS
FOR INNOVATION, ACCESS & DELIVERY

Uniting Efforts for Innovation, Access and Delivery: A Global Dialogue

Meeting report

30-31 January 2019
Bangkok, Thailand

GHIT Fund
Global Health Innovative Technology Fund

THE ACCESS AND DELIVERY PARTNERSHIP
New Health Technologies for TB, Malaria and NTDs

Contents

Foreword

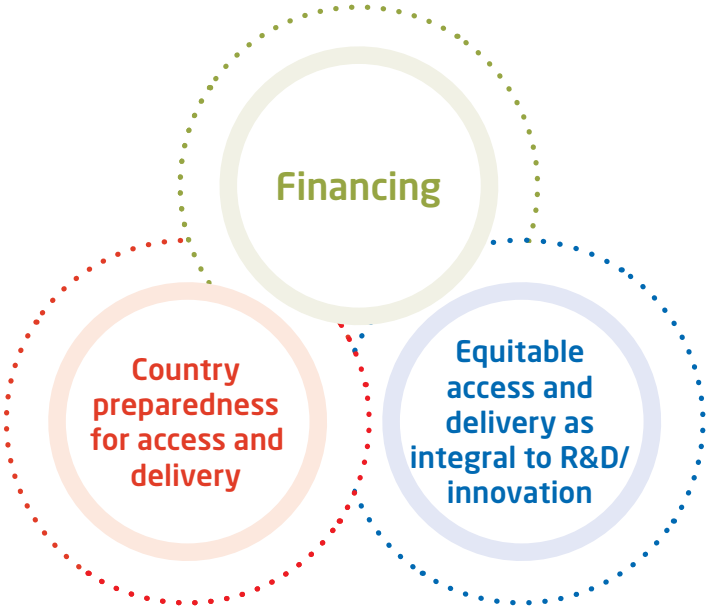
In January 2019, at the invitation of the Government of Japan, the UNDP-led Access and Delivery Partnership (ADP) and the Global Health Innovative Technology Fund (GHIT Fund), over 100 representatives from biomedical, funder, innovator and access constituencies met in Bangkok, Thailand at *Uniting Efforts for Innovation, Access and Delivery: a Global Dialogue*.[1]

The goal of the meeting was to launch a platform to improve the innovation, access and delivery of medicines, vaccines, diagnostics and other health technologies for unmet health needs in low- and middle-income countries (LMICs).

There are limited opportunities for funders, innovators and access and delivery stakeholders to discuss common challenges and needs, and to jointly identify solutions. The participants in this first dialogue were purposefully selected to represent these three groups of actors, each with unique perspectives and roles.

Countries face a variety of health challenges and needs, including multiple infectious diseases, the impact of which is amplified by demographic, epidemiological and climate-related changes, as well as a growing burden of non-communicable diseases. Although significant advances have been made in both innovation and expanding access to health technologies, critical gaps still exist. Even when new prevention, diagnosis or treatment technologies are developed, they frequently remain out of reach for people who need them most, and many are being left behind.

The interdependence between health and development is clearly articulated in the 2030 Agenda for Sustainable Development (2030 Agenda) and its 17 Sustainable Development Goals (SDGs).[2] SDG target 3.8 focuses on achieving universal health coverage (UHC), including equitable access to quality essential health care services and to safe, effective, quality and



Key themes identified during the global dialogue

1 The first global dialogue took place in Bangkok, Thailand, from 30 to 31 January 2019. More information is available at: https://www.unitingeffortsforhealth.org/

2 Sustainable Development Goals (2015): http://www.undp.org/content/undp/en/home/sustainable-development-goals.html

affordable essential medicines and vaccines. The global dialogue aimed to align innovation, access and delivery with the UHC target, and was focused on malaria, tuberculosis (TB) and neglected tropical diseases (NTDs) – diseases that impede human and economic development among the world's poorest populations.

There are multiple decisions, actors, institutional interactions, advances and setbacks between the start of research and development (R&D) to address a specific disease or health issue, and the ultimate use of resulting new health products by affected communities and individuals. The entire value chain acts as a complex adaptive system, where an unexpected turn of events or an emerging challenge at one stage can have substantive impact elsewhere in the system.

The global dialogue provided the opportunity to establish a collaborative platform to share experiences and common challenges, identify good practices and explore opportunities for future collaboration. While this first dialogue was an experiment for those involved, a good degree of 'listening to understand' and unity were seen. Feedback received from participants highlighted the potential benefits of early collaboration between innovators and end users, as well as the critical importance of multi-stakeholder collaboration in global health.

This is just the beginning, and continuing dialogue among initial participants – and other key stakeholders – will take place in expanded conversations in the future. Dialogues can occur in different forms and moments, and the three organizing partners are committed to supporting the continuation and expansion of this new space for exchange of perspectives, with a focus on driving and achieving concrete outcomes.

We hope this brief report reflects the rich and productive discussions that took place in Bangkok, and serves as guidance and inspiration for subsequent dialogue, as well as for other global health initiatives.

Sumi Manabu
Director
Global Health Policy Division
Ministry of Foreign Affairs
of Japan

BT Slingsby
CEO and Executive Director
GHIT Fund

Mandeep Dhaliwal
Director
HIV, Health and Development
UNDP

Introduction
Why a global dialogue?

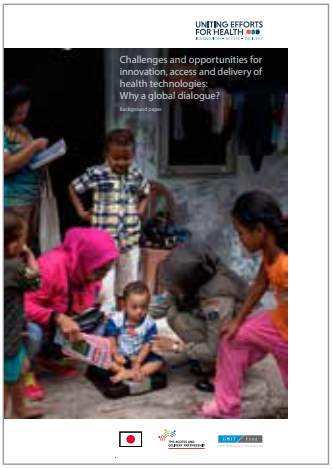
Health is the foundation of prosperity and security. Strong, sustainable and resilient health systems are the basis for prosperous and stable societies.[3,4] Although the world has seen tremendous health progress in recent years, millions of people still have limited access to the medicines, diagnostics and vaccines they need to survive and thrive. Diseases affecting the world's poorest people, such as neglected tropical diseases (NTDs), have often failed to attract required attention and funding. Even when treatments are developed, they are often not available at the country level, remaining out of reach for the people who need them most.

Many key roadmaps for the scale up of interventions to achieve the health-related Sustainable Development Goals (SDGs)[5] underscore the need to increase coordination between research and development (R&D) for new health technologies and access and delivery platforms.

The prospect of new health technologies – including those emerging from the Global Health Innovative Technology (GHIT) Fund and other product development partnerships (PDPs) – and ongoing national and global efforts to pursue universal health coverage (UHC), provide an opportunity for stronger collaboration, learning and coordination among different actors and stakeholders at all levels across the entire innovation, access and delivery value chain.

In response, the Government of Japan, the UNDP-led Access and Delivery Partnership (ADP) and the GHIT Fund launched a platform, *Uniting Efforts for Innovation, Access and Delivery*. The platform aims to foster dialogue and collaboration between key stakeholders involved in innovation, access and delivery of health technologies, especially for NTDs, malaria and tuberculosis (TB). The purpose of the platform is to address access and delivery gaps so that patients can access new health products as efficiently and effectively as possible. For this purpose, it is important to involve both access and delivery actors as well as stakeholders working in innovation and funding, because all actors should pay greater attention to access and delivery processes and obstacles through all R&D and health technology stages.

As the background paper[6] prepared for the first global dialogue explained the underlying complexity across the innovation, access and delivery value chain has led to fragmentation of goals and strategies, emergence of operational silos, and misalignment of understanding, knowledge and incentives, which together impede overall progress. Poor alignment and coordination between innovation, access and delivery segments of the value chain can act as a disincentive to investment, and further weaken returns and opportunities for success in reaching people in need. There are also important good practices, lessons learned and opportunities that need to be acknowledged, amplified and seized.



To achieve the 2030 Agenda, including UHC, it is imperative that we explore new ways for key actors to work together. The first meeting aimed at contributing to the achievement of five related objectives:

3 Government of Japan. Basic Design for Peace and Health (2015). Available at: http://www.mofa.go.jp/files/000110234.pdf

4 G7 Ise-Shima Vision for Global Health (2016). Available at: http://www.mofa.go.jp/files/000160273.pdf

5 Berlin Declaration of the G20 Health Ministers (2017). Available at: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/G/G20-Gesundheitsministertreffen/G20_Health_Ministers_Declaration_engl.pdf

6 Suerie Moon (2019). Challenges and opportunities for innovation, access and delivery of health technologies: Why a global dialogue? Background paper. Available at: https://www.unitingeffortsforhealth.org/backgrounder

Learning

The dialogue provided a platform for stakeholders to learn from each other's successes in addressing shared challenges, accelerate identification of effective practices and drive the articulation of shared principles. Participants identified many opportunities that exist for this type of exchange and learning.

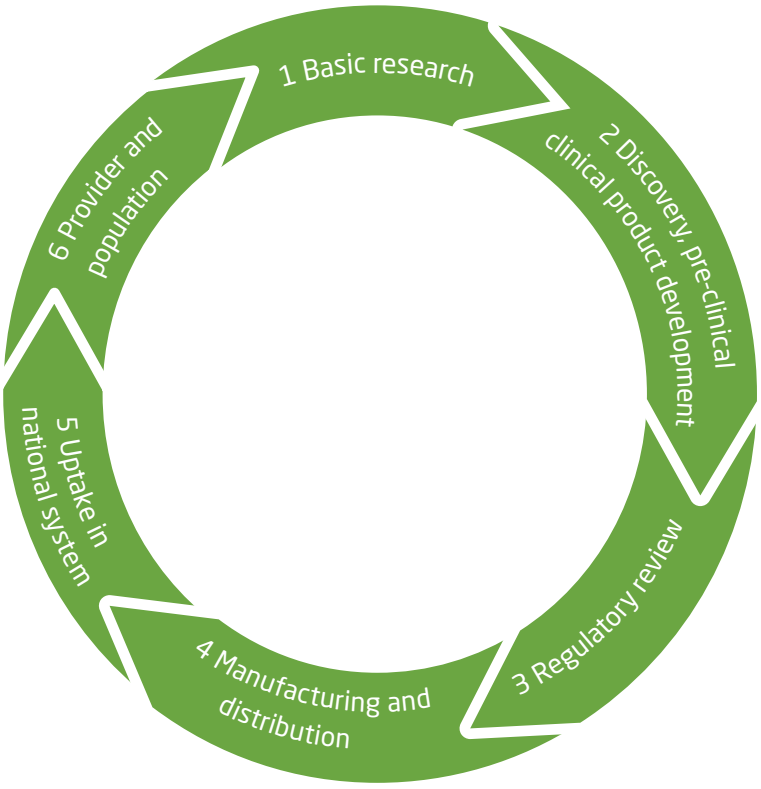


Figure 1. Stages of the health technology innovation–access–delivery continuum

Coordinated action

Numerous issues identified during the meeting can greatly benefit from more coordinated action among actors. This was the most consistent theme emerging from discussions, and the apparent willingness and appetite for this to take place was a significant and positive force for change.

Greater coordination between product developers, non-profit agencies, policymakers, health workers and end users of new health technologies will ensure that products are well adapted for use at country and local levels, introduced and delivered in a timely manner and acceptable to patients. Similarly, coordination across stages – between earlier-stage product developers and later-stage procurement and implementation agencies, for example – can facilitate the more efficient uptake of new technologies. Added coordination among funders, both in R&D stages and nearing market introduction, will allow faster delivery of health technologies in a more sustainable manner. To accomplish this, aligning incentives among key stakeholders will be critical. A coordinated co-funding strategy could be a mechanism to incentivize greater impact and to share risk among funders.

Collective action

Participants identified numerous challenges that would benefit from more collective action. For example, joint adoption of certain approaches – such as enhanced target product profiles (TPPs), institutionalizing implementation research and development of investment cases for specific NTDs – could accelerate progress and progressive policies. At the same time, joint action by major funders could improve transparency and efficiency. Harmonization of legislation and/or national regulatory requirements could accelerate access, decrease costs to developers and expedite the introduction of new health technologies, while ensuring safety. Agreeing upon priority areas for research – whether for basic research, product development or implementation/ delivery research – could also reduce the risk of duplication, facilitate progress tracking and help ensure major gaps do not go unfilled. Finally, joint endorsement of a set of principles could help to align actors and advance initiatives to develop norms for innovation and access.

Identification of issues requiring further dialogue and/or analysis

Global dialogues of this kind identify emerging issues and innovative ideas that may not yet be ripe for coordinated or collective action, but where further attention, dialogue or analysis is needed. Global dialogues can also help to set the agenda and identify participants for future discussions.

Community and network building

The global system of actors engaged in innovation, access and delivery of health technologies may function better if its constituent parts are connected through stronger networks. Active and authentic interactions around the meeting – both in the meeting rooms and outside – demonstrated that global dialogue can strengthen existing relationships and establishes new ones, building the trust required to collaborate for achieving positive outcomes.

"No single country, sector or organization can solve this problem. Let's work together, so that patients can access innovative health products as soon as possible. Everyone is part of the solution."

Sumi Manabu, Director,
Global Health Policy Division,
Ministry of Foreign Affairs of Japan

Key themes identified during the first global dialogue

This first global dialogue took place 30-31 January 2019 in Bangkok, Thailand, on the sidelines of the annual Prince Mahidol Award Conference (PMAC). The organizers were honoured to have two guest speakers in the pre-meeting event on 30 January: Dr Chieko Ikeda, Senior Assistant Minister for Global Health, Minister's Secretariat, Ministry of Health, Labour and Welfare, Government of Japan; and Dr Marie-Goretti Harakeye Ndayisaba, Head Social Affairs Department, African Union Commission.

The 31 January technical meeting opened with welcoming remarks from Dr Tenu Avafia, Team Leader, Human Rights, Key Populations, Health Technology Innovation and Access, UNDP; BT Slingsby, CEO and Executive Director of the GHIT Fund; and Sumi Manabu, Director, Global Health Policy Division, Ministry of Foreign Affairs of Japan.

This was followed by a summary presentation of the background paper by Dr Suerie Moon, Director of Research, Global Health Centre, Graduate Institute of Geneva. The rest of the meeting comprised panel discussions and working group sessions.[7]

The panel discussions focused on two cross-cutting themes: (1) ensuring returns on R&D investments: strategies and measures to ensure that investments result in positive impact for patients in need; and (2) country preparedness: the prerequisites and opportunities for access and delivery at country or regional levels. Panellists and moderators included representatives of the three meeting organizers, as well as PATH, Unitaid, the Special Programme for Research and Training in Tropical Diseases (TDR) at the World Health Organization (WHO), Global Tuberculosis Community Advisory Board/Section27, Merck, the Medicines for Malaria Venture, the Access to Medicine Foundation, the Commission of Science & Technology, Government of Tanzania, Drugs for Neglected Diseases initiative (DNDi), the African Union Development Agency-NEPAD, the Centre for Health Policy and Implementation Research of the University of Health and Allied Sciences of Ghana, and the National Agency for Drug and Food Control, Government of Indonesia.

The discussions covered a variety of issues, including challenges, opportunities and lessons learned related to ensuring a more effective and equitable approach to innovation, access and delivery of health technologies for unmet needs in LMICs.

7 Meeting agenda and presentations are available at: https://www.unitingeffortsforhealth.org/eventdetails

We must identify the mechanisms that can bring together actors to facilitate interlinkages between the various stages of the innovation, access and delivery continuum."

Dr Suerie Moon
Director of Research, Global Health Centre, Graduate Institute of Geneva

Some of the key themes discussed are summarized below:

a. Financing

The majority of R&D for malaria, TB and NTDs is funded by public and philanthropic sources based in high-income countries, with a significant minority from the private sector and disease-endemic countries.[8] In the absence of self-sustaining commercial markets, it is unclear how to increase total investments to meet the estimated US$2.5 billion annual R&D funding gap.[9] The financing requirements as well as decision making processes needed for introducing health technologies at country level were also considered, including the role of both development assistance and domestic resources. Dialogue participants considered these as well as good practices and lessons learned.

i) Issues and challenges

To achieve an ethical and human rights-based approach to health, more concerted attention and investment in implementing patient-focused R&D is required. This could be strengthened through longer-term research prioritization and planning, and by stronger coordination between investors to share and use the products and knowledge resulting from R&D investments.

There are considerable and well-recognized costs associated with meeting essential access and delivery requirements. However, there is no global initiative that systematically assesses and/or bears those costs. Most of the access and delivery interventions

8 Policy Cures Research. G-Finder Neglected Disease Research and Development: Reflecting on a Decade of Global Investment. 2017. Available at: https://www.policycuresresearch.org/wp-content/uploads/2019/01/Y10_G-FINDER_full_report.pdf

9 Suerie Moon (2019). Challenges and opportunities for innovation, access and delivery of health technologies: Why a global dialogue? Background paper. Available at: https://www.unitingeffortsforhealth.org/backgrounder

and costs are borne by governments, or in some contexts, patients and communities. Some participants raised the possibility that a proportion of R&D funding could be allocated to ensuring access and delivery of innovative interventions and health technologies. The funders at various stages of product development could coordinate and increase understanding of the entire path to market introduction, to identify possible financial gaps, such as for implementation research, which can sometimes be overlooked.

Unlike for other health challenges, few investment cases have been articulated for new NTD technologies now coming out of the pipeline. No financial mechanism exists to oversee, support or decrease inefficiencies in the purchasing of NTD-related health technologies.

National policymakers and other key stakeholders can work together to increase capacities for better transparency and effectiveness around prioritization, pricing and procurement as a means of driving wider participation and greater efficiency. This would also diminish the potential for corruption and other inefficiencies in relation to malaria, TB and NTD budgets and programme implementation.

ii) Good practices and lessons learned

Several exemplary initiatives were highlighted during the discussions, including:

- Evidence that implementation research, particularly in LMICs, can increase the efficiency of R&D investments. Participants cited case studies on TB in South Africa and the NTD programme in Ghana.
- In India, different stakeholders work together to increase transparency around prioritization in selection and procurement of health technologies.
- Several participants praised the WHO Global Observatory on Health R&D,[10] an initiative to help identify health R&D priorities based on public health needs, by consolidating, monitoring and analysing relevant information on the health R&D needs of LMICs.
- Coordinated funding partnerships, such as public–private partnerships, which pool and leverage funds from different sectors, could help initiate sustainable funding.

10 Available at: https://www.who.int/research-observatory/

b. Equitable access and delivery as integral considerations of R&D/ innovation

Discussions around integrating considerations of equitable access and delivery needs and challenges into the innovation process were central to the global dialogue. These discussions highlighted many common, cross-cutting perspectives among public funders, product development partnerships and the private sector, as well as among access and delivery stakeholders.

i) Issues and challenges

Promoting trust through transparency, ownership and dialogue

Many participants noted that a lack of meaningful involvement of communities, patients and LMICs as advocates and decision-makers in their own health needs undermines efficiency and accountability of health technology strategies aimed at ensuring that resulting products will be available, well-adapted and accessible to all in need. Lack of information on key aspects, including R&D costs, production, pricing and access strategies was also highlighted. This reinforces the perceived disconnect between innovators, funders and national public health needs and priorities.

Trust building through multi-stakeholder engagement, particularly among funders, innovators, health service providers and affected communities, is vital for the effective articulation of needs and the introduction and use of new technologies. The latter are often seen as unsuited for the context in which they will be used. As a result, they may not be optimally used and/or place tremendous strain on the existing health infrastructure.

> *"For our countries to benefit from new health technologies, we have to tackle system-wide challenges together, and convince policymakers to make use of available evidence to prioritize decisions and health policies."*
>
> *Khadija Yahya-Malima, Chief Research Officer, Commission of Science & Technology, Government of Tanzania*

Aligning priorities and incentives

There are differences in incentives for non-profit and for-profit actors. Some participants argued that commercial interests are prioritized over public health concerns. This misalignment of incentives should first be managed by identifying shared goals and a common value proposition from the earliest stages of health technology research. This might include the more effective and earlier use of target product profiles (TPPs), which allow all stakeholders to align respective incentives and perspectives through a common intent.

Discordance can be further minimized by integrating implementation research at the earliest stages of the R&D process, and through all relevant phases, including in the initial identification of public health needs and formulation of research questions.

A parallel problem is encountered as a result of the complexities with regard to regulatory review, including: diverse regulatory standards and processes across different countries, increasing the investment requirements for developers or manufacturers; limited experience in national regulatory authorities (NRAs) to review new health technologies that have not yet been approved elsewhere; and the potential for delays to the regulatory approval process.

Approaches that involve regulators from early stages of the R&D process have the potential to reduce the impact of these intricacies.

Gaps

Incomplete information and/or evidence about the use of new technologies in specific settings, without comparable standardization, as well as a paucity of specific health technologies (e.g. medicines for NTDs), can mean that inappropriate candidate medicines are sometimes selected for further development while potentially promising ones are abandoned. This incomplete picture underscores the lack of a critical pathway from basic science and R&D for new technologies, to their access and delivery – and awareness of who is doing what, in what phase. Although no one organization, sector or authority has the resources or mandate to provide stewardship across the entire innovation and access continuum, collective and coordinated action can help to achieve this.

ii) Good practices and lessons learned

Funders have an important role to play in addressing the disconnect between innovation and access and delivery considerations. Funding organizations and mechanisms can act as champions of "access and delivery as part of innovation", both in their own priority setting and planning, as well as by inspiring other funders through highlighting good practices and successes. Increasing transparency throughout the R&D chain can contribute to better policy in this area.

Accountability could be further promoted by the creation of norms and standards for R&D funding contracts – including around access, transparency of data, sharing of compounds, etc. – and would also encourage more shared incentives among diverse stakeholders. Application of such standards requires closer collaboration between all stakeholders and involvement of countries and access partners earlier in the R&D process.

Funders and product development partnerships (PDPs) vary in anticipating how future availability, affordability and accessibility of emerging products can be ensured. A good practice document on this would be a very useful contribution to the field.

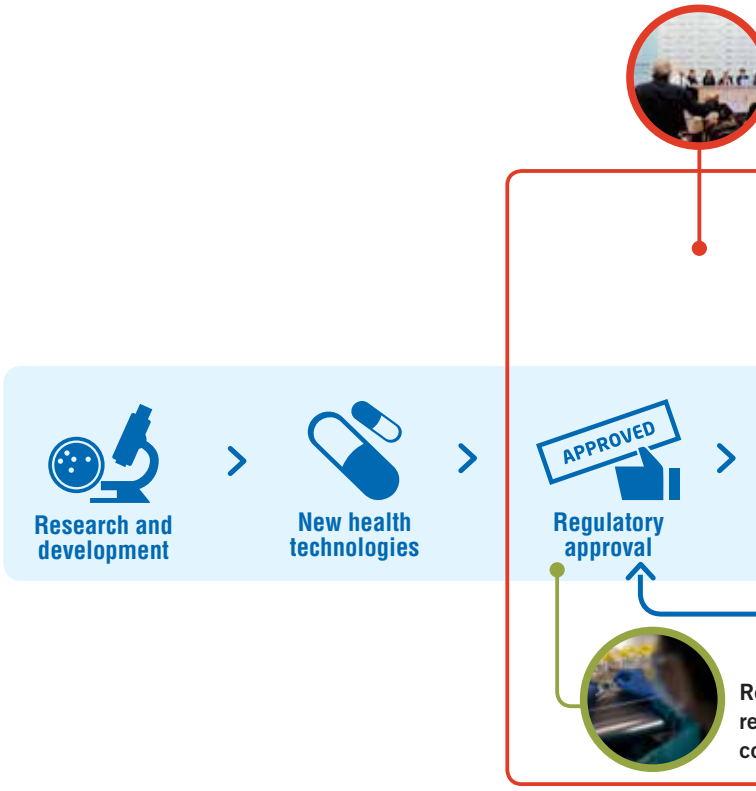
One of the most feasible solutions highlighted by participants was the opportunity to standardize and broaden the content of TPPs. If made more comprehensive, TPPs could help facilitate building of trust, aligning incentives and ensuring that priority gaps are identified, discussed and bridged. Building on previous experience with including technical criteria, 'new-generation' TPPs could integrate a broad range of issues, from acceptability and patient-centric approaches, to affordability and strategies for involvement of community advisory boards and local stakeholders at earlier stages with periodic updates.

Complementary opportunities also exist in the TPP development process for mutual learning and exchange to strengthen literacy and capacity around access and delivery challenges among innovators, and similarly among access-focused organizations. This could be extended to include joint demand forecasting and pipeline analysis.

c. Country preparedness for access and delivery

ADP's experience since 2013 confirms the need to focus on health systems strengthening, as well as on national and community-based preparedness for health technology introduction in LMICs through the whole access and delivery value chain.

Even where new health technologies are available, their timely and successful introduction and delivery within national health systems requires a variety of different interventions that were highlighted by several stakeholders, including LMIC governments and other experts. Strategies to ensure multi-sectoral, cross-sectoral governance – including both whole-of-government and whole-of-society engagement – at country level were highlighted as essential to improve effectiveness, which in turn, enables coordinated functioning of the policy, regulatory and delivery systems.



i) Issues and challenges

Acknowledging country-specific circumstances, participants highlighted some common challenges impeding the introduction of new health technologies, and the need for better coordination among the various entities involved in the value chain:

National prioritization and policymaking

It was noted that many LMICs are yet to establish robust evidence-based approaches to priority-setting and, as a result, programme planning and policy formulation are often influenced by incomplete consideration of data and/or country contexts. The attainment of harmonized and coherent health and related policies remains a challenge in many health settings.

Other common barriers identified were the lack of affordability of some new health technologies, including poor predictability of pricing and supplier costs, as well as the need to include new health technologies in national essential medicines lists and their incorporation in standard treatment guidelines and related training.

Implementation research

There was general agreement that strengthened and expanded national capacities for implementation research held the potential to support sound, contextualized prioritization and decision making.

Regulatory issues

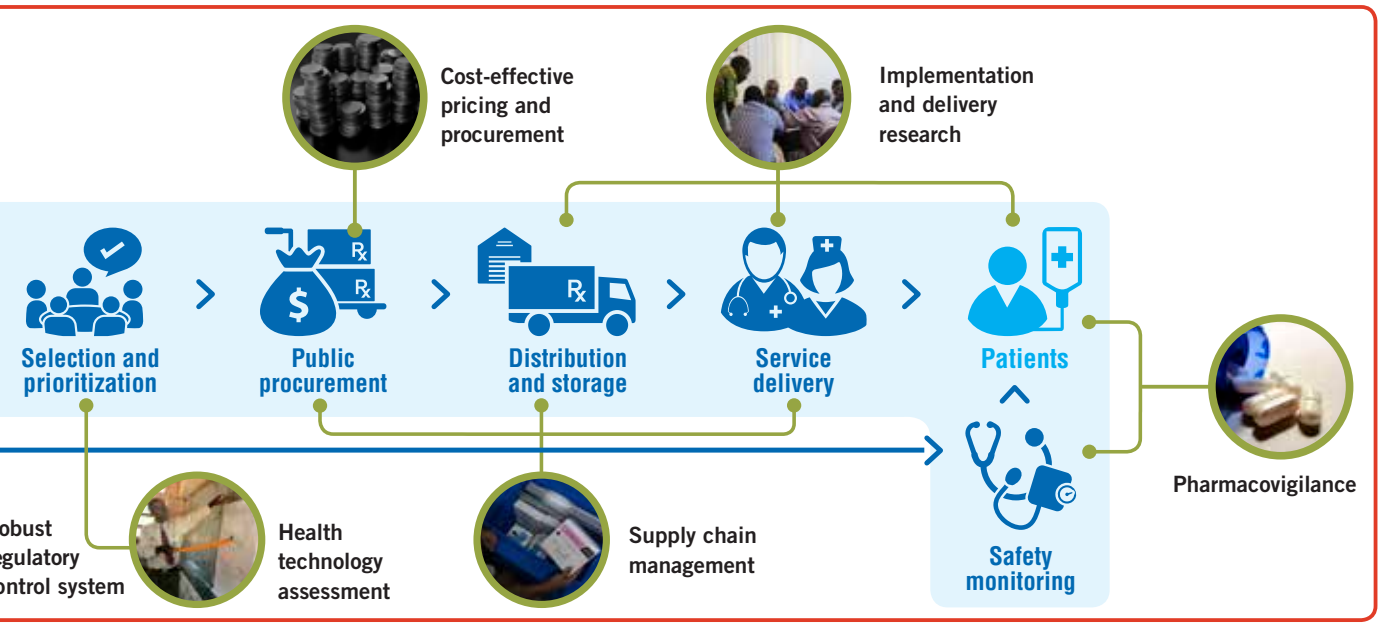
Participants highlighted widespread constraints related to fragmented and/or inefficient regulatory systems, including safety monitoring preparedness. Frequently cited challenges were the cost and burden of registration, pharmacovigilance and marketing of new technologies, and limited capacity – and regional collaboration – among regulators.

South-South and inter-country collaboration

In general, many opportunities are missed for interaction and collaboration between national, regional and global levels. One example raised by participants was the inadequate use of pooled procurement systems among countries.

Enabling policy and regulatory framework

The innovation, access and delivery value chain for new health technologies



Global context and shifts

The decrease in development assistance for health (e.g. transition from Global Fund and GAVi support) and inadequate mobilization of global and domestic resources were seen as substantial obstacles. At the same time, participants also mentioned siloed approaches, which continue to be pursued by some international partners.

Another barrier cited during discussions was countries experiencing intermittent global shortages of new health products.

Global and regional approaches, such as the African Union Model Law on Medical Products Regulation, have provided critical collaboration and learning opportunities and driven allocative and implementation efficiencies. Other key opportunities and potential coordination points remain to be fully developed, such as the WHO collaborative registration procedure aimed at accelerating WHO prequalification of new health technologies, and the new categorization of national regulatory authorities as 'WHO-listed' as they progress towards stringent regulatory authority status.

ii) Good practices and lessons learned

Since 2013, ADP has collaborated with stakeholders in a set of focus countries to: strengthen policy, regulatory harmonization and coherence; reinforce institutions for accelerating health technology introduction and access; and establish and contribute to regional and global platforms for health technology preparedness. In reflecting on some of the lessons learned, participants referred to various dimensions of the country-level implementation process.

Recommended follow-up actions

Dialogue participants identified specific possibilities for future actions at the global, regional and national levels. The range and breadth of discussions reiterated that the global health technology innovation–access–delivery continuum is a complex ecosystem with many opportunities for greater collaboration and increased efficiencies, as well as good practices and lessons learned.

Suggestions and consistent themes for next steps emerging from the first global dialogue included:

- Undertake earlier consultation and active promotion of linkages and issue literacy across the innovation–access–delivery continuum, with a view to strengthening trust and impact.
- Encourage joint action through articulation of shared principles across the innovation–access–delivery continuum.
- Develop investment cases for specific NTDs.
- Create strategies for consideration of access and delivery needs and challenges earlier in the R&D process.
- More open, longer-term planning in order to increase transparency and coordination 'dividends', particularly in relation to sources of funding and demand/needs forecasting.
- Improve identification and coordination of R&D and product development priorities. For example, better R&D mapping would enable more focused alignment with public health priorities, while helping to make the case for stronger R&D standards.
- Institutionalize implementation research at the national level.
- Support a more detailed understanding of financial and access and delivery gaps related to the most neglected disease portfolios.
- Enhance the use of TPPs, including expanded standards and more inclusive, multi-stakeholder approaches and processes.
- Strengthen multi-sectoral and South-South sharing of approaches at country and regional levels.
- Facilitate capacity building among key stakeholders on product development and launch strategies, health technology assessment, pooled procurement and contracting for NTDs.

Some participants highlighted that, as a next step, it is important to continue the focus on issues of mutual concern for funders, innovators and access stakeholders, rather than adopting a disease- or technology-specific approach.

Future dialogues will likely benefit from a selective focus on specific issues and/or goals. They may also address specific common bottlenecks for improving innovation, access and delivery. South-South learning could help identify and overcome such barriers.

The greatest challenge is not a shortage of solutions, but the collective willingness to implement, fund and jointly engage in known solutions. The fundamental question raised by the global dialogue is whether individuals and institutions working in disparate silos, convened around specific stages, diseases or regions, can be brought together to focus on the overall goal of strengthening and enhancing the discovery, development and delivery of new health technologies.

Continuing interaction among participants of the first global dialogue, and other key stakeholders will be useful for expanding these discussions.

To sustain an outcome-driven focus, future dialogues should continue to provide the space for genuine collaboration, accountability and trust to emerge among stakeholders. In this way, new levels of awareness and openness are critical outcomes of the dialogue.

It is vital that in defining the focus and scope of future dialogues, collective ownership is encouraged, so that an expanding set of stakeholders can coalesce around a shared set of goals and benefits. If this is done in an open and consultative way, a new paradigm of thinking and working together can become the norm.

For future dialogues, participants also raised the possibility of other knowledge-based outcomes, including the development of technical briefs covering some of the specific issues raised.

For updates on future dialogues and activities of the Uniting Efforts for Innovation, Access and Delivery initiative please visit **www.unitingeffortsforhealth.org**.

Future global dialogues: Participants' opinions

Through a post-meeting evaluation survey, participants provided suggestions for specific approaches and/or ideas to be considered during planning for future interactions of this kind, including:

"Bring together end-users country representatives and product developers to ensure end-user needs are reflected in target product profiles."

"A strong, sustained link among these broad stakeholder groups is essential."

"Get more countries, innovators and funders involved – engage new stakeholders."

"We need a 'deeper dive' into how to foster an effective 'end-to-end' approach."

"A cross-disease meeting on access and delivery is unique. Many disease-specific discussions focus on innovation, access and delivery."

"Please showcase best practices from access and delivery programmes – so we can replicate them in future programmes."

"Targeted smaller meetings, with the aim of identifying good practices in specific phases of innovation, access and delivery, could be valuable."

Annex 1:
Global Dialogue – Concept Note

Uniting Efforts for Innovation, Access and Delivery: A Global Dialogue

Location: Amari Watergate Hotel, Bangkok, Thailand
Date: 30 and 31 January 2019

Context

In September 2015, United Nations (UN) Member States adopted the comprehensive people-centered 2030 Agenda. This ambitious undertaking encompasses a set of universal and transformative Sustainable Development Goals (SDGs) and targets, including SDG 3, "Ensure healthy lives and promote well-being for all." The 2030 Agenda also highlights the need for synergies between the innovation of new health technologies – in this case defined to include medicines, diagnostics and vaccines – and enabling access to these health technologies in order to build on efforts of all countries to attain universal health coverage.[1]

Developing countries are facing a variety of health challenges and needs, including multiple infectious diseases, whose impact is amplified by demographic, epidemiological and climate-related changes and a growing burden of non-communicable diseases. Although significant advances have been made in both innovation and expanding access to health technologies, critical gaps exist and many people are being left behind in accessing the important technologies and knowledge generated over the last decades. For example, tuberculosis (TB) remains one the key killers in developing countries. In 2017, there was an estimated 10.4 million new TB cases, and TB remained one of the top 10 causes of death worldwide.[2] TB treatment has become complex with the emergence of multidrug resistance (MDR). In 2017, 3.5% of new TB cases and 18% of previous ones had MDR-TB.[3]

Since 2013, thanks to the generous support of the Government of Japan, the Global Health Innovative Technology Fund (GHIT Fund) and the UNDP-led Access and Delivery Partnership (ADP) have been working on two sides of the same coin: driving health technology innovation for TB, malaria, neglected tropical diseases (NTDs) and other neglected diseases on the one hand, and strengthening health systems to promote access and delivery, on the other. The prospect of new health technologies emerging from the GHIT Fund's portfolio of R&D investments between 2018 and 2023 provides an opportunity for even stronger collaboration between the Government of Japan, the GHIT Fund and ADP. In order to systematically address bottlenecks that impede the efficient uptake of new health technologies and deepen cooperation in this area, the Government of Japan, ADP and GHIT will work together to establish and contribute to national, regional and global platforms for technology delivery preparedness.

Uniting Efforts for Innovation, Access and Delivery: A Global Dialogue

Against this background, and as part of the scale-up phase of this ongoing collaboration, the Government of Japan, the GHIT Fund and ADP are uniting to

1 SDG targets of direct relevance to the project include: 3.3 By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases
3.8 Achieve universal health coverage, 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
3.b Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the fullest provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all

2 Global Tuberculosis Report (WHO, 2018): http://www.who.int/tb/publications/global_report/en/

3 Ibid

convene a platform for global dialogues to explore opportunities for deeper collaboration between key biomedical R&D funders, product development partnerships (PDPs), research institutes and access stakeholders (defined in this context to be entities involved in the selection, regulation, pricing, procurement and delivery of health technologies), focusing on diseases that predominantly affect developing countries, including TB, malaria and NTDs.

The purpose of this first meeting is to initiate a global dialogue between key stakeholders that are needed to accelerate innovation, access and delivery of essential health technologies, providing an opportunity for sharing experiences and knowledge, and exploring opportunities for future collaboration and deeper dialogues.

The global dialogue will take place in Bangkok in January 2019. The event will begin with a formal evening reception on Wednesday, 30 January and will be followed by a full-day working meeting on Thursday, 31 January 2019.

Participants and expected outcomes

The meeting will be by invitation only. Participants are expected to include representatives from:

- Select R&D funders, PDPs and research institutions, as well as access and delivery stakeholders working on or interested in diseases that predominantly affect LMICs.
- Government representatives from LMICs, including procurement and regulatory authorities within ministries of health, ministries of science and technology and research institutes.
- Select patients, civil society, academics, private sector representatives, experts and thought and opinion leaders.

This meeting and initiative aims to be useful to a broad variety of stakeholders who usually do not have pre-established forums for cross-sectoral dialogue, including for the following purposes:

- For R&D funders, the dialogue could increase visibility of R&D investments and priorities, increase return on investment by facilitating collaboration and efficiency, increase dissemination of knowledge and ability to showcase success and improve ability to evaluate impact on the R&D investments.
- For PDPs, the dialogue could help identify best practices to reduce cost and to increase efficiencies in biomedical research and strategies for development processes that would facilitate launch and adoption of resulting health technologies at the country level, as well as highlight potential opportunities and common challenges to overcome.
- For access stakeholders, the dialogue could help increase visibility of innovation, access and delivery needs at country level among R&D funders and innovators, as well as identify interventions and strategies to ensure health technologies will be developed and made available as needed.

Expected outcomes of the meeting include:

1. The initiation of a global dialogue to facilitate sharing and identification of experiences, best practices and challenges.
2. Identification of specific areas and opportunities for potential future dialogue, collaboration and partnerships to increase or leverage assets, capabilities and expertise.
3. Progress in the discussion of key areas to systematically address bottlenecks in key areas in order to accelerate both innovation and access and delivery of essential health technologies in LMICs.

Annex 2:
Global Dialogue – Participants

First name	Last name (A-Z)	Organization	Country
Ayushi	Agnihotri	Foundation for Innovative New Diagnostics (FIND)	Switzerland
Chutima	Akaleephan	Government of Thailand, International Health Policy Program IHPP, Ministry of Public Health	Thailand
Belynda	Amankwa	United Nations Development Programme (UNDP)	Ghana
Ibu Dwiana	Andayani	Government of Indonesia, National Agency for Drug and Food Control (BPOM)	Indonesia
Garry	Aslanyan	Special Programme for Research and Training in Tropical Diseases (TDR)	Switzerland
Deborah	Atherly	PATH Center for Vaccine Innovation and Access	USA
Tenu	Avafia	United Nations Development Programme (UNDP)	USA
Edwine	Barasa	KEMRI-Wellcome Trust	Kenya
Himani	Bhatnagar	United Nations Development Programme (UNDP)	Thailand
Prudchadee	Boonnak	United Nations Development Programme (UNDP)	Thailand
Grania	Brigden	The International Union Against TB and Lung Disease	Switzerland
Jeremy	Burrows	Medicines for Malaria Venture	Switzerland
Janet	Byaruhanga	New Partnership for Africa's Development Planning and Coordinating Agency (NEPAD Agency)	South Africa
Hector	Castro	Management Sciences for Health	USA
Dechen	Choiphel	Government of Bhutan, Ministry of Health	Bhutan
Saudamini	Dabak	Health Intervention and Technology Assessment Program (HITAP)	Thailand
Rittika	Datta	Asia Pacific Leaders Malaria Alliance	Singapore
Damiano	de Felice	Access to Medicine Foundation	Netherlands
Eugenio	de Hostos	PATH	USA
Todd	Dickens	PATH	USA
Fumiya	Domoto	Astellas Pharma	Japan
Amadou	Doucouré	Government of Senegal, Directorate of Disease Control (DLM), Ministry of Health and Social Planning	Senegal
Tim	France	Inis Communication	UK
Masami	Fujita	National Center for Global Health and Medicine	Japan
Jennifer	Furin	DR-TB Scale-up Treatment Action Team	UK
Gladwell	Gathecha	MOH - DNCD	Kenya
Edith	Gavor	Government of Ghana, Ministry of Health	Ghana
Janet	Ginnard	UNITAID	Switzerland
Spring	Gombe-Götz	Drugs for Neglected Diseases initiative (DNDi)	Switzerland

First name	Last name (A-Z)	Organization	Country
Ashoo	Grover	Government of India, Indian Council of Medical Research (ICMR)	India
R.S	Gupta	Government of India, National AIDS Control Organization	India
Fabian	Gusovsky	Eisai	USA
Margaret	Gyapong	University of Health and Allied Sciences	Ghana
Christine	Halleux	Special Programme for Research and Training in Tropical Diseases (TDR)	Switzerland
Marie-Goretti	Harakeye Ndayisaba	African Union Commission	Ethiopia
Ade Irma	Haryani	Government of Indonesia, National Agency of Drugs and Food Control	Indonesia
Abdirahman	Hassan	Kenya National Assembly	Kenya
Budi	Hidayat	Government of Indonesia, Ministry of Health	Indonesia
Eiji	Hinoshita	National Center for Global Health and Medicine (NCGM)	Japan
Fumiko	Hirabayashi	Nagasaki University, Drugs for Neglected Diseases initiative (DNDi) Japan	Japan
Kenji	Hirayama	Nagasaki University, NEKKEN - Institute of Tropical Medicines	Japan
Toshihiro	Horii	Osaka University	Japan
Dairiku	Hozumi	IntraHealth International	USA
Kazuyo	Ichimori	Nagasaki University, Institute of Tropical Medicines Japan Alliance on Global NTDs	Japan
Chieko	Ikeda	Government of Japan, Ministry of Health, Labour and Welfare	Japan
Daisuke	Imoto	Drugs for Neglected Diseases initiative (DNDi) Japan	Japan
Wanrudee	Isaranuwatchai	Health Intervention and Technology Assessment Program (HITAP)	Thailand
Mukesh	Kapila	Defeat-NCD Partnership	Switzerland
Yasushi	Katsuma	Waseda University, Institute for Global Health Policy Research	Japan
Paul	Kazyoba	Government of Tanzania, National Institute for Medical Research	Tanzania
Naoto	Keicho	Research Institute of Tuberculosis, Japan - Anti Tuberculosis Association	Japan
Goichiro	Kimura	First Secretary (Health and Welfare), Embassy of Japan in Thailand	Thailand
Elly	Kourany-Lefoll	Merck	Switzerland
Gaelle	Krikorian	Access Campaign, Médecins Sans Frontières	France
Osamu	Kunii	The Global Fund to Fight AIDS, Tuberculosis and Malaria	Switzerland
Marie	Lamy	Asia Pacific Leaders Malaria Alliance	Singapore
Fabian	Lefrancois	United Nations Development Programme (UNDP)	Switzerland
Marcus	Low	Global Tuberculosis Community Advisory Board and SECTION27	South Africa
Yodi	Mahendradhata	Universitas Gadjah Mada	Indonesia
Tomohiko	Makino	Japan International Cooperation Agency (JICA)	Thailand
Rahab	Mbau	KEMRI – Wellcome Trust	Kenya

First name	Last name (A-Z)	Organization	Country
Suerie	Moon	Graduate Institute of International and Development Studies	Switzerland
Taeko	Moriyasu	Japan Alliance on Global NTDs	Japan
Kawaye	Mphatso	Government of Malawi, Pharmacy, Medicines and Poisons Board	Malawi
Daudi	Msasi	Government of Tanzania, Ministry of Health	Tanzania
Moses	Mulumba	Center for Health, Human Rights and Development	Uganda
Ian	Mungall	United Nations Development Programme (UNDP)	Thailand
Charles	Mwansambo	Government of Malawi, Ministry of Health	Malawi
Chikumbutso	Namelo	Government of Malawi, Ministry of Justice	Malawi
Njery	Nancy	Government of Kenya, Ministry of Health	Kenya
Ichwan	Nasution	Government of Indonesia, National Procurement Agency (LKPP)	Indonesia
Youssoupha	Ndiaye	Government of Senegal, Directorate of Planning, Research and Statistics (DPRS), Ministry of Health and Social Action	Senegal
Sophie	Newland	PATH	USA
Christophe	Ngendahayo	International Federation of Medical Students' Associations (IFMSA)	Rwanda
Matar	Niang	Government of Senegal, National Procurement Pharmacy (PNA)	Senegal
Francis	Ntangaaza	Centers for Health Access	Uganda
Olumide	Ogundahunsi	Special Programme for Research and Training in Tropical Diseases (TDR)	Switzerland
Cecilia	Oh	United Nations Development Programme (UNDP)	Thailand
Kuniko	Oka Ezoe	United Nations Development Programme (UNDP)	USA
Les	Ong	United Nations Development Programme (UNDP)	Thailand
Windné Emile	Ouedraogo	Government of Burkina Faso, Ministry of Health	Burkina Faso
Manish	Pant	United Nations Development Programme (UNDP)	India
Aimee	Patel	Health Intervention and Technology Assessment Program (HITAP)	Thailand
Jean-Michel	Piedagnel	Drugs for Neglected Diseases initiative (DNDi) South East Asia	Malaysia
Agus	Purwadianto	Government of Indonesia, Ministry of Health	Indonesia
A.	Ramkishan	Government of India, Central Drugs Standard Control Organization (Kolkata)	India
Judit	Rius Sanjuan	United Nations Development Programme (UNDP)	USA
Yuli	Saputri	National Agency of Drug and Food Control (NADFC) (BPOM)	Indonesia
SE	Sartini	Government of Indonesia, Directorate of Drug Registration - National Agency of Drug and Food Control (NADFC)	Indonesia
Sudigdo	Sastroasmoro	Government of Indonesia, Ministry of Health	Indonesia
Takanobu	Sato	Nobelpharma Co., Ltd.	Japan
Takanori	Sato	Takeda Pharmaceutical Company	Japan
Hana	Shibayama	Government of Japan, Ministry of Foreign Affairs (MOFA)	Japan

First name	Last name (A-Z)	Organization	Country
Kenji	Shibuya	University of Tokyo	Japan
Hiiti	Sillo	World Health Organization (WHO)	Switzerland
BT	Slingsby	Global Health Innovative Technology (GHIT) Fund	Japan
Netnapis	Suchonwanich	Health Intervention and Technology Assessment Program (HITAP)	Thailand
Yosuke	Sugiyama	Takeda Pharmaceutical Company	Japan
Manabu	Sumi	Government of Japan, Ministry of Foreign Affairs (MOFA)	Japan
Yot	Teerawattananon	Health Intervention and Technology Assessment Program (HITAP)	Thailand
Robert	Terry	Special Programme for Research and Training in Tropical Diseases (TDR)	Switzerland
Beena	Thomas	Government of India, National Institute for Research in Tuberculosis	India
Hayato	Urabe	Global Health Innovative Technology (GHIT) Fund	Japan
Marcela	Vieira	Graduate Institute of International and Development Studies	Switzerland
Elizabeth	Wilskie	PATH	USA
Ratchanekorn	Wutirat	Inis Communication	Thailand
Khadija	Yahya-Malima	Government of Tanzania, Commission of Science & Technology (COSTECH)	Tanzania
Inthira	Yamabhai	Government of Thailand, International Health Policy Program IHPP, Ministry of Public Health	Thailand

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