



Nagasaki Outcome Statement

Accelerating For Neglected Tropical Diseases (NTDs)

Nagasaki Outcomes Statement

In May 2023, Japan hosted the G7 Health Ministers' Meeting in Nagasaki and the G7 Leaders' Summit Meeting in Hiroshima highlighting the importance of undertaking efforts on human security and Universal Health Coverage (UHC) as central to the Japanese Government's vision for the Summit. On May 12th, the eve of the G7 Health Ministers' Meeting, multi-sectoral stakeholders gathered in Nagasaki to discuss "Accelerating Research and Development (R&D), Access and Delivery for Neglected Tropical Diseases (NTDs)." The result of that event, hosted by the Global Health Innovative Technology Fund (GHIT Fund), Nagasaki University and Uniting to Combat NTDs, is this Nagasaki Outcome Statement which builds on and reaffirms the "Kigali Declaration on NTDs." The Nagasaki Outcome Statement aims to accelerate the implementation of the Kigali Declaration by outlining how R&D, access, and delivery for NTDs are critical to achieving G7's ambitions on UHC and pandemic preparedness.

We commend G7 Leaders for including NTDs in the G7 Leaders' communiqué, and for prioritizing UHC and pandemic preparedness. We ask:

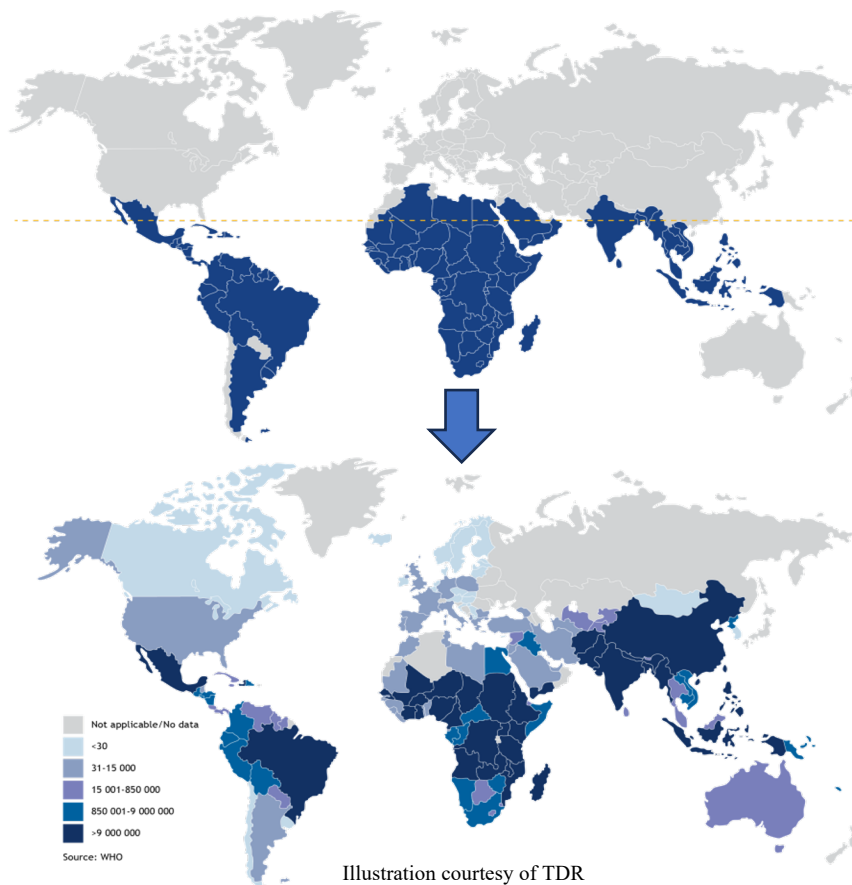
1. G7 Leaders to renew their commitment to end NTDs, which they first outlined in the London Declaration in 2012, affirmed in the Kigali Declaration in 2022 and more recently, affirmed in the Nagasaki G7 Health Ministers' Communique and Hiroshima G7 Leaders Communique, by translating these commitments into ongoing political prioritization, bold action, and investments.
2. The G7 should support long-term, sustainable financing for not-for-profit/alternative models of R&D, for example, Product Development Partnerships (PDPs), as well as strategies and partnerships to ensure access to, and delivery of, the resulting products. Japan has been a leader in this by supporting novel funding mechanisms for NTD research and development like the GHIT Fund and access initiatives through the UNDP-led Access and Delivery Partnership (ADP) and continues to lead by example, with the pledge of \$200 million to the GHIT Fund announced by PM Kishida in Hiroshima.
3. G7 Leaders to further prioritize NTDs and to champion NTDs at future G7, G20 Summits and other high-level political fora like the UNGA, and to ensure that NTDs and other infectious diseases are included in new commitments being made, particularly funding for UHC, pandemic preparedness, and climate change to capitalize on the synergistic and cost-effective outcomes that will be achieved.
4. We commend the G7 Health Ministers for their pledge to support low- and middle-income countries, to ensure that these countries have the resources they need to address the NTD crisis and prevent future outbreaks. The G7 should leverage their resources to support sustainable research networks rooted in NTD-endemic countries, developing new health tools that can be used at the primary health care (PHC) level promoting south-south collaboration and capacity building, ultimately accelerating R&D and equitable access to health solutions for NTDs.
5. The G7 is well positioned, as a group containing some major funders to institutions like the Global Fund, to leverage some of the access initiatives created by these institutions like Pooled Procurement Mechanisms (PPMs), to be also used for the procurement of NTD health technologies. This is also in line with the one of the key pillars of the NTD road map which calls for a multi-sectoral and integrated approach to managing NTDs.
6. We urge G7 Leaders to continue supporting the World Health Organization (WHO) Global NTD program and all WHO member states to ensure that NTDs are not 'neglected', even within the WHO. We commend the WHO Global NTD Program on their current efforts steering the NTD road map and developing a costed implementation plan. We call on G7 Leaders to increase investments in research and innovation for new vaccines, drugs, and diagnostics, to help reach the goals set out in WHO's NTD road map, as well as financing to ensure access of these innovations and technologies to the most vulnerable populations affected by NTDs.

Call to Action for the Global Community

1. Increase visibility of NTDs from the community level, at country, regional and global levels to highlight the socio-economic impact of NTDs and embrace the ownership and political will that is required to drive the change needed.
2. Endemic countries to take more political leadership and, together with partners, implement cost-effective approaches through evidence-based targeting of interventions and ensure efficient use of resources by leveraging and increasing existing resource mobilization, sustainable procurement, and service delivery platforms for the delivery of integrated, cross-sectoral people-centered services for NTDs.
3. Develop innovative funding mechanisms to mobilize substantial funding for NTD control and elimination - these mechanisms must be additive to existing funding flows. Investment cases to make a clear and compelling case for investment in R&D need to be developed.
4. Resource mobilization for the most severely underfunded NTDs, as well as the new NTDs that have been or will be added to WHO list of NTDs, and where we know that even a little investment will fast-track countries' ability to achieve NTD road map/elimination targets (e.g. VL), should be prioritized.
5. All R&D actors and partners, including funders, PDPs, private sector, and others, need to promote knowledge and technology sharing more openly and more transparently, by encouraging sharing of research knowledge, data, and costs throughout the R&D process to improve efficiency in R&D and access.
6. Re-evaluate all the steps across the access value chain (AVC) from innovation to access and delivery and explore ways to improve and accelerate the process to foster a seamless end-to-end ecosystem.
7. Connect, coordinate, and create a multisectoral approach, enabling end-to-end ecosystem for the acceleration of R&D, access and delivery with other interventions that intersect with animal health, WASH, climate change, pandemic preparedness, etc. There is need for greater donor collaboration across R&D, access, and delivery.

Background

Neglected tropical diseases (NTDs)¹ are a group of 20 diseases that affect more than 1.6 billion people globally every year, disproportionately affecting poor communities. The overlap between countries with the highest NTD burden and lowest GDP is notable; it includes populations in both low- and middle-income countries. Addressing NTDs is an equity issue. Success positively impacts the lives of the most disadvantaged communities globally. In the past, NTDs disproportionately affected poor communities particularly in low-income countries (LICs), however, this trend is changing and moving from ‘tropical areas’ to affecting poor communities in middle-income and high-income countries, as illustrated below.



NTDs are under-researched, under-treated and under-funded, despite the huge needs in terms of health technologies like diagnostics, vaccines, and therapeutics. One of the reasons for this is that they are not prioritized for interventions, with a risk of even further de-prioritization post-COVID as countries focus on other health and non-health prioritization. These diseases cause untold suffering, can disable, disfigure, and be fatal. In addition to the human toll, NTDs have a significant economic impact, resulting in billions of dollars in associated costs and lost productivity each year.

Incredible progress has been made; 49 countries have eliminated at least one NTD, with several countries having eliminated two, three or four NTDs, and in 2020, 600 million fewer people required interventions against NTDs than in 2010. Some low-cost interventions for NTDs exist, are affordable to implement in low-income settings, and yield a robust return on investment.

¹ https://www.who.int/health-topics/neglected-tropical-diseases#tab=tab_1 NTDs include: Buruli ulcer, Chagas disease, dengue and chikungunya, dracunculiasis (Guinea-worm disease), echinococcosis, foodborne trematodes, human African trypanosomiasis (sleeping sickness), leishmaniasis, leprosy (Hansen’s disease), lymphatic filariasis, mycetoma, chromoblastomycosis and other deep mycoses, onchocerciasis (river blindness), podoconiosis, rabies, scabies and other ectoparasites, schistosomiasis, soil-transmitted helminthiases, snakebite envenoming, taeniasis/cysticercosis, trachoma, and yaws and other endemic treponematoses.

Drug donations for interventions like preventive chemotherapy, for example, have been particularly efficacious and cost-effective, with over 19 billion tablets donated by the pharmaceutical industry to deliver the WHO NTD road map so far.

Availability and access to NTD health technologies; diagnostics, therapeutics, and vaccines, remains limited and setbacks caused by the COVID-19 pandemic and global economic slowdowns are threatening the progress made to date. Unless sustained action is taken, there is a real risk of a reversal of gains and more people being pushed into poverty due to preventable diseases. Increasing investments in R&D, access, and delivery for NTDs makes good financial sense. Investing in NTD programs is critical to achieving the G7 priorities of UHC and pandemic preparedness, prevention, and response (Pandemic PPR) efforts. There is a need to increase the visibility of NTDs, highlight the importance of R&D and demonstrate the social impact of the health technologies. “It’s not just an economic model”, says one of the participants at the Nagasaki event.

From London to Kigali, carrying the momentum in Nagasaki

In January 2012, stakeholders came together to sign the London Declaration on NTDs, to commit to controlling, eliminating or eradicating 10 diseases by 2020. The Kigali Declaration on Neglected Tropical Diseases rebuilt the momentum by putting individuals, communities, and countries at the center of the NTD response. Launched alongside the 26th Commonwealth Heads of Government Meeting in June 2022, the Declaration has already galvanized substantial commitment with USD1.7 billion in financial commitments. Continuous engagement and reminders to the coalition of the commitments made is necessary to ensure continued momentum.

In May 2023, Japan hosted the G7 Health Ministers’ Meeting in Nagasaki and the G7 Leaders’ Summit Meeting in Hiroshima highlighting the importance of undertaking efforts on human security and UHC as central to the Japanese Government’s vision for the Summit. Prime Minister Kishida highlighted in the Lancet commentary Japan’s global health priorities reaffirming the nation’s commitment to human security and UHC and emphasized three important areas in support of this vision²:

1. First, the need to strengthen the global health architecture to prepare for public health emergencies for fast deployment of medical countermeasures when it is needed most.
2. Advancement of UHC toward the post-COVID-19 era. Japan is a long-standing and dedicated promoter of global advancement of UHC. A key element that underpins UHC is that health systems must be able to effectively respond to and overcome health challenges to meet the Sustainable Development Goals (SDGs), including infectious diseases such as HIV/AIDS, tuberculosis, malaria, and NTDs as indicated both in the G7 Health Ministers’ and Leaders’ Communiqués.
3. Promotion of health technology innovation and having equitable access to those innovations. The global response to COVID-19 shows that remarkable progress in research and development can be achieved to address global public health threats. However, striking inequities in access to COVID-19 tools persisted despite major global efforts and this is also seen in other diseases like NTDs.

Prime Minister Kishida also stressed the obstacles to this global health vision, and how ending ongoing major infectious diseases can help the world meet the SDGs. It is with this backdrop that, on May 12th, 2023, multi-sectoral stakeholders gathered in Nagasaki to discuss “Accelerating Research and Development, Access and Delivery for Neglected Tropical Diseases” with hopes of reminding us to “stop the neglect” and if anything, boost our investments in NTDs. The gathering jointly developed the Nagasaki Outcome Statement which calls for increased visibility of NTDs and the acceleration of R&D, access, and delivery for NTDs.

This Nagasaki Outcome Statement builds on and reaffirms the “Kigali Declaration on NTDs and aims to accelerate the implementation of the Kigali Declaration by outlining how R&D access and delivery for NTDs are critical to achieving G7’s ambitions on UHC and pandemic preparedness. It highlights the importance of:

² [https://doi.org/10.1016/S0140-6736\(23\)00014-4](https://doi.org/10.1016/S0140-6736(23)00014-4)

1. Accelerating R&D for NTDs
2. Accelerating access for medical interventions against NTDs
3. Connecting, coordinating and creating an enabling end-to-end ecosystem for the acceleration of R&D, access and delivery.

The above three pillars are in alignment with the G7 leaders' communique highlighting the importance of equity, inclusivity, efficiency, affordability, quality, accountability, agility, and speed for the medical countermeasures to be put in place³.

Accelerating R&D

The WHO NTD heat map (created in 2019) clearly shows a lack of tools for prevention, diagnosis and treatment that are simple, safe, and effective across all the NTDs.



Courtesy of WHO Global NTD Program⁴

This is due to wide-ranging reasons, including inadequate investment in R&D because of real and perceived lack of commercial returns, a lack of investment in strengthening health systems to deliver interventions for prevention, diagnosis, and treatment of NTDs, threatening progress towards sustainable disease elimination. NTDs are not considered 'attractive' by researchers and industry due to the lack of commercial gains and general lack of the 'pull incentives' to encourage innovators and product developers to invest in R&D with challenges at every step of the access value chain: From lack of funding for R&D, challenges

³ https://www.g7hiroshima.go.jp/documents/pdf/Leaders_Communique_01_en.pdf -p.25

⁴ Ending the neglect to attain the Sustainable Development Goals: A road map for neglected tropical diseases 2021–2030 (who.int)

with conducting high-quality clinical trial in endemic countries, complicated regulatory pathways, reflection in WHO and national treatment guidelines, fragmented markets, lack of sustainable procurement and delivery pathways, community acceptance of new technologies to lack of coordination with other existing programs.

Between 1975-1999, only 1.1% of the drugs developed were for neglected diseases that affected 12% of the population. What got us here won't get us where we need to be – despite considerable progress in reducing the burden, shrinking the map, and eliminating at least one NTD in 49 countries, the tools presently available are insufficient to drive through the gains to the elimination and eradication endpoints. Much more needs to be done to accelerate this progress.

The COVID-19 pandemic response enabled major scientific advances and the development of new vaccines, diagnostics, and treatments at unprecedented speed. There is a need to leverage this and sustainably invest in research and innovation infrastructure for other diseases like NTDs, to 'keep warm' this capacity and enable surge capacity to respond during intra-crisis times.

Open, collaborative R&D is a prerequisite to accelerate R&D. R&D partners including PDPs need to promote knowledge sharing more openly and more transparently, by encouraging sharing of research knowledge, data, and costs throughout the R&D process to improve efficiency in R&D. The PDP model, with its collaborative and open approach to R&D, has proven transformative in developing cost-effective health technologies for neglected diseases.

Actions Needed:

- ⇒ Strengthen global partnerships to foster open, collaborative R&D to maximize knowledge and resource sharing.
- ⇒ Develop investment cases to make a clear and compelling case for investment in R&D and access to achieve the targets in the WHO NTD road map.
- ⇒ Develop a costed implementation plan of the NTD road map. The implementation plans should include new metrics for NTDs metrics that go beyond economic efficiency alone and consider equity and social impact to send a strong signal that the world is living up to its SDG promise of leaving no one behind.

Accelerating Access

We are in an important era of regionalization and there must be solidarity to support R&D as well as the systems and processes to ensure access and delivery to those tools. For instance, promoting manufacturing in lower-income countries can contribute to accessibility. Considerations for access should be integrated early in the R&D process. As observed with access to COVID-19 tools, particularly vaccines, tremendous efforts were made on R&D, but cracks appeared when the products were available, resulting in inequitable access. Post-COVID-19, the 100Day+ approach was adopted, an aspirational target to develop and deliver pandemic countermeasures within the shortest possible timeframe. Similar aspirations need to be applied to the development and delivery of NTD health technologies.

There is a critical gap in terms of procurement for NTD health technologies, beyond the donation model. There is a need to establish a sustainable not-for-profit procurement-based approach as a pull incentive to maintain interest of innovators and manufacturers for the NTD innovations. Opportunities may exist to expand existing mechanisms to include NTDs. This could include pooled procurement mechanisms at both regional and country levels.

Actions Needed:

- ⇒ Re-evaluate all the steps across the access value chain (AVC) from innovation to implementation and explore ways to improve and accelerate the process to foster a seamless end-to-end ecosystem.
- ⇒ Establish appropriate multidisciplinary partnerships from innovation to implementation with strong push and pull incentives for investment in discovery, and R&D to ensure a strong pipeline of new tool. Examples of pull incentives used in other diseases areas include, pooled procurement mechanisms (PPMs), advance market commitments, volume guarantees and other market shaping approaches to de-risk innovations and this should be explored for NTDs.

- ⇒ Integrate NTD innovations into the existing public health systems, funding systems and procurement mechanisms should be explored to reduce the costs through leveraging well-established systems and funding streams. While it is probably not feasible, nor is it desirable, to expect a vertical global funding mechanism for NTDs, there is a need to explore how existing global funding mechanisms could integrate NTDs.
- ⇒ Increase domestic and international funding for access and delivery for NTDs.

Political Will

The first step to solving any problem is acknowledging there is a problem. Without that acknowledgement, we will not have the political will for change as we have seen with other global health issues like HIV, TB, malaria, the COVID-19 pandemic, and climate change. Lack of prioritization of NTDs at national and global levels has led to decades of chronic low investments across the access value chain: from R&D all the way to last-mile delivery. The COVID-19 pandemic showed us, amongst other things, that our health systems are not fully prepared to handle global pandemics, particularly of the COVID-19 pandemic proportion.

NTDs provide us with a blueprint to work on. Primary health care (PHC) is a cornerstone in achieving universal health coverage (UHC), and G7 countries are well positioned to support NTD-endemic countries to develop new health tools that can be used at the PHC level. Strengthening our health systems and healthcare workforce to effectively address existing 'epidemics' like NTDs would provide us with a better fighting chance against future pandemics.

Actions Needed:

- ⇒ A regular and systematic check-in/follow-up at future G7 meetings (and other global fora) on NTDs and ensure that NTDs are high on the agenda to facilitate the opportunity for progress reports, advocacy, and future commitments.

Funding

One of the key questions is: *Who pays?* Who pays for the innovation, for R&D, for the clinical trials, for regulatory approval, for manufacturing, for procurement, for delivery to the patients and who pays for the economic losses patients and communities suffer because of NTDs? In contrast to other global diseases like HIV, TB, malaria, and more recently, the COVID-19 pandemic, there is insufficient investment in access and last-mile delivery for the limited tools that are currently available. This represents a critical obstacle to disease elimination.

Most of the access relies on donation programs, which plays a pivotal role. However, this approach is insufficient to address all the NTDs, all the technologies and the intervention models required to prevent, diagnose, and treat NTDs. There have been many examples of innovative financing approaches for global health outcomes (IFFIm, AMC, AmFam, malaria bonds debt to health SWAPs). Yet, there has been limited consideration of their potential application to NTDs.

Actions Needed:

- ⇒ Mobilize innovative funding mechanisms to catalyze NTD elimination efforts - these mechanisms must also be additive and must not replace existing funding flows.
- ⇒ Increase and sustain domestic and international funding for R&D, access, and delivery for NTDs.
- ⇒ Expand the remit of existing global funding mechanisms, like Global Fund, to include NTDs.
- ⇒ Improve coordination, planning, and incentivizing across existing donors throughout the NTD access value chain.

Coordination

NTDs are prime for mainstreaming within health systems, for example in service delivery, health information and surveillance systems, etc., but we must also look at non-health sectors to optimize UHC and human security aims. For example, some NTDs, including yaws, lymphatic filariasis, schistosomiasis, and dengue, have interventions that intersect with animal health and with WASH programs. Climate change and One Health are research priorities that are integral to achieving elimination and control of NTDs. In practice, collaborating with animal, environment and climate entities should translate to increased research of NTDs such as dracunculiasis, leishmaniasis, and rabies, that is conducted in collaboration with agriculture, livestock, wildlife, and environment research programs.

Actions Needed:

- ⇒ Establish collaborative research networks for NTDs between the public and private sector and PDPs. The critical NTD-related research studies that are ongoing in wealthy countries should be collaborated with endemic country researchers and disease programs to translate research to practice. This would also increase the visibility of research groups and researchers in endemic countries who often have lower levels of funding and less access to new research findings.
- ⇒ Establish a regular global NTDs convening that brings together all the stakeholders involved along the AVC - this could be modeled after the International AIDS Society (IAS) or the International Union Against TB and Lung Diseases (TB Union) or incorporated into the currently existing NNN (NTDs NGO Network) Platform or the Uniting Efforts for Innovation, Access and Delivery Platform which brings together a broad range of stakeholders that can facilitate an end-to-end approach. These convenings must be accessible to endemic countries and communities.

Conclusion

We all share a common vision in our fight against NTDs. Urgent action is required to accelerate progress and end the neglect. An investment in NTDs is an investment in human security, SDGs, UHC and pandemic preparedness. The G7 has a well-established history of taking important action against pressing global health issues and has notably prioritized neglected and poverty-related diseases during past summits.

We applaud the G7's commitment to strengthening global capacity to prevent, prepare for, and respond to future global health emergencies, especially through the G7 Pact for Pandemic Readiness endorsed in Elmau in 2022. When the G7 acts together, they can achieve ambitious goals. We believe that the G7 has a critical role to play in renewing support to end NTDs, and in ensuring that this support is backed by concrete actions and financial commitments. And when the G7 acts together with the global community, we can make a difference.

Endorsements

This Nagasaki Outcome Statement (July 2023) is endorsed by the following organizations:

For organizations who would like to endorse the Statement, please send an email to g7_summit_ntd_event@tm.nagasaki-u.ac.jp



The [Access and Delivery Partnership](#) (ADP) works with low- and middle-income countries to ensure life-saving medicines and health technologies reach the people who need them. We support countries to strengthen and harmonize policies and systems and build the capacities of key people and institutions to drive the necessary reforms for sustainable, country-led progress towards universal health coverage. ADP is supported by the Government of Japan and led by the United Nations Development Programme, in collaboration with the World Health Organization, the Special Programme for Research and Training in Tropical Diseases and PATH.

This Nagasaki Outcome Statement (July 2023) is also endorsed by the following individuals:

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By endorsing, the individuals and organizations undertake to continue engaging and supporting the global efforts to deliver the NTD Roadmap and SDG goals and targets on NTDs. As such, the group will convene regularly to assess progress and discuss areas that need more attention.

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