



Policy Brief

# **SUSTAINABLE COUNTRY ACCESS TO MEDICAL TECHNOLOGIES: LESSONS LEARNED DURING THE COVID-19 PANDEMIC**

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*Task Force 6*

**Global Health Security and Covid 19**



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# Abstract

Access to quality-assured and affordable medical technologies is a human right and required for successfully confronting future and contemporary health problems. COVID-19 has exposed the inequities across the world of access to vaccines, treatments and diagnostics. Research & development is extremely important in their production. Manufacturing should be more diversified to enhance health system resilience. Barriers to intellectual property rights need to be overcome. COVID-19 treatment and diagnostics also need to be covered by TRIPS flexibilities like the vaccines. Legal mechanisms need to be extended so that all future and contemporary medical technologies are covered by TRIPS flexibilities. Financing has delayed global vaccine coverage and new innovative financial mechanisms are being created to address this. Community involvement underpins the success or failure of interventions: it requires ongoing effective communication between professionals and the public. Alignment between 'national', 'regional' and 'global' policies is required for coordinated action against contemporary public health threats to be successful.

# Challenges

By the end of October 2022, 17.6 million (14.3-21.3 million) people were estimated to have died from COVID-19, of whom 7.1 million were recorded cases (IHME COVID-19 Projections, 2022). As the COVID-19 Pandemic continues, countries are struggling to cope with its consequences alongside other significant challenges, including climate change, development of sustainable sources of energy, ecological destruction and changing ecological habitats, worsening global economic conditions, reduced overseas development assistance, national or regional insurrections or wars, and famine - issues that all affect the fiscal space of low-and middle-income countries (LMICs).

## 1.1 COVID-19 Response

The COVID-19 response has been the largest and fastest in the history of some national and international agencies. The initial focus was on saving lives by funding the provision of critical lifesaving equipment to countries, protecting livelihoods through cash transfer and safety-net programs to off-set the massive economic losses generated by lockdowns. As soon as vaccines became available, the focus changed to vaccine delivery.

While in many countries the number of people infected with COVID-19 is again rising due to the circulation of new variants, associated morbidity and mortality among infected populations has, on the whole, decreased. Even if COVID-19 becomes an endemic infection and it is not eliminated, it may not lead to such high morbidity and mortality rates, and such large disruptions to societies and economies, as seen over the last few years.

The rapid production of effective vaccines, medicines and diagnostics played an important part in this response. National and global leadership was required for the development of effective, efficient, equitable and acceptable national and global responses to the COVID-19 Pandemic. The sharing of information and effective and timely communication within and between scientific communities, politicians, policy-makers, public health officials, the business sector and civil society was instrumental to effective and efficient COVID-19 responses. Guidelines needed to be developed, updated, revised and implemented based on available scientific evidence, which included sharing of genetic information and running international clinical trials.

## 1.2 Strengthening Healthcare Systems

The COVID-19 Pandemic exposed the fault lines in healthcare systems in every country - especially in LMICs - and the inequities in access to lifesaving medical technologies, especially among marginalized populations. Health system strengthening is required in many countries across all health sectors, especially primary health care. This requirement has long been widely recognized, both to deal with future and contemporary major health problems. Sustained access to quality-assured and affordable new medical technologies is a major requirement for addressing these public health problems and for building health system resilience.

Roll-out of accepted medical technologies and other public health interventions needs to reach all populations within countries. Roll-out should be effective and efficient, equitably distributed and acceptable to both users and providers. This has not been achieved to date

in the roll-out of COVID-19 vaccines, with lower coverage rates within rural compared to urban centres, and high income versus LMICs respectively.

### 1.3 Intellectual Property Rights

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was used to ensure that HIV-related medical technologies were accessible to LMICs: on the 17th June 2022 it was agreed by the WTO that TRIPS flexibilities could be applied to SARS COV-2 vaccines (World Trade Organization, 2022). The proposal was limited to a single virus vaccine, involved a limited and temporary waiver of WTO rules, it did not address bilateral agreements nor agreements placed outside of WTO, and did not propose to change any national law. It did propose changes to WHO rules related to intellectual property. COVID-19 medicines and diagnostics were not covered, but negotiations are ongoing to extend the vaccine agreement to cover these medical technologies. The European Union came with a counterproposal, indicating that LMICs should issue compulsory licenses to access medical technologies. It is important, however, to note that when countries have tried to issue compulsory licenses in the past, they have been blocked by pharmaceutical companies. This happened in Bolivia and the Dominican Republic, and in Canada when these countries recently invoked TRIPS to issue compulsory licenses.

Traditionally, diagnostics have been undervalued and not enough investment has gone into this market. There is a need to incentivize the development, evaluation and manufacturing of diagnostics for diseases of public health importance. Given the spread and rate of transmission of COVID-19 and its variants, multiple versions of these medical technologies are currently available and many more are expected to come on the market. However, for other high-burden diseases like Ebola, when markets are small and investment more limited, other models need to be explored, other than being dependent on market forces.

The WTO deal included a request for a full waiver of all intellectual property (IP) elements: these related to patents, copyright right issues on related trade secrets, and confidential information that would allow manufacturing of medical technologies to be scaled up. Any future agreements ought to include obligations on countries to acquire intellectual property rights that can be used in the public interest during a pandemic and to share those rights with other members, which are part of the pandemic preparedness and response.

Governments can authorize or provide consent to allow the use of any patent by anyone, covering all patents in that country. Some countries have used this option, but none have done anything remotely close to the extent that the United States government has used

these government authorizations. Many of these contracts were not transparent in terms of permissions on intellectual property, pricing and quantities required. These issues are difficult to sort out in the middle of a pandemic when some nations are fending for themselves, and taking a more nationalistic approach.

## **1.4 Roll-out Medical Technologies**

Access to medical technologies also needs to include timely production and delivery. Regulatory approval and policy development needs to be done in a timely manner. The current access pathway for tests is too long. Tests are first reviewed by regulators to assess risk, then by policymakers to assess the incremental benefit against the level of acceptable risk. Policies are then developed, which need to be implemented on how to test, who should be tested, who should do the testing, and who should act on the results.

Countries should each develop a connected diagnostic system that starts from the National Reference Laboratories, down to community-based testing and self-testing. This should be part of the backbone of any healthcare system, to provide early alerts of unusual trends, enabling rapid deployment of public health measures, as well as monitoring the effectiveness of disease control interventions. Such a surveillance system should also be applied to other diseases that are not necessarily of an epidemic or pandemic nature.

## **1.5 Local Production and Sharing Technologies**

Some countries or regions may develop their manufacturing industry, complementing the importation of medical technologies. Local production plants can be stimulated by the development of regional 'hub and spoke' arrangements. This requires the harmonization of national regulations and agreements on benchmarks needed for the authorization of new products, as well as the employment and training of human resources for health.

In 2021, the WHO issued expressions of interest in sharing technology (World Health Organization, 2021). This technology was initially publicly funded and the knowledge around technology development included the work of public scientists at the NIH and researchers in Africa. WHO assisted the establishment of an 'hub' in South Africa, with 15 collaborating centres or 'spokes' across Africa, Asia and Latin America. This demonstrated that the Global South can develop the necessary technology for vaccine production, transfer the technology to scale up knowledge, and start scaling up manufacturing factories in the South.

## 1.6 Pandemic Prevention Preparedness and Response

Considering past pandemics, as soon as many were considered to be ‘over’, the world fell into a cycle of neglect and was surprised by the next pandemic, which raised similar issues and challenges. The G20 High Level Panel (Ministero dell’ Economia e delle, 2021), set up a new financial intermediary fund (FIF) as part of Pandemic Prevention Preparedness and Response (PPPR) led by the WHO and World Bank (World Health Organization, 2021 & The World Bank, 2022). FIF works closely with the WHO and other donor partners, while engaging widely with other stakeholders, including civil society. PPPR can also serve as a platform for advocacy as it is being set up to be able to operate as flexibly as possible.

The FIF brings additional dedicated resources for PPPR for LMICs, to allow for investments to be made at national, regional and global levels. Channelling these funds, will incentivize countries to make their own investments: about a third of annual FIF funding is anticipated to be provided through external financing, with the remaining two coming from domestic resources through country commitments.

Another objective of PPPR is to coordinate the many players in this crowded global health space, by channelling incentives and encouraging external partners to work together at country level to develop national country plans. High-level strengthening of country core capacities will be at the epicentre of this process and will seek to improve global disease surveillance, strengthen laboratory health workforce capacity, enhance community engagement and emergency communications and management. The health of the individual and the community are integrally linked to the broader natural, socio-economic and cultural environments.

Regulatory harmonization would enhance capacity for coordinated development and implementation of procurement systems and deployment of medical technologies, either imported or produced through local or regional manufacturing plants.

Preparations for any future pandemic will require the development and roll-out of new medical technologies, while countries will also need to seriously address the development and improvement of their healthcare infrastructure. As recently demonstrated by the global HIV-response, the immediate, acute response to a pandemic is likely to evolve into medium and long-term responses. However, in addition to coping with COVID-19, many countries are still coming to terms with their ‘old’ pandemics, including HIV, tuberculosis, malaria, non-communicable diseases among others, all of which have moved beyond ‘immediate’ into ‘medium- and long-term responses’.



The COVID-19 Pandemic has again demonstrated, that international organizations can step up when it comes to global response efforts. How can they work best with countries and regional partners to strengthen capacity to strengthen national health systems? Long-term intergenerational investment to improve health system capacity is required, a core focus of the World Bank. The Bank has an active portfolio of about US\$30 billion to support health system strengthening in over 100 countries.

## **1.7 Research & Development**

The future development of medical technologies will require rapid and relevant research and development, with pre-negotiated benefit sharing agreements, scalable manufacturing platforms, agreements for technology transfer, coordinated procurement and emergency supply chains, to ensure equitable access. This is one way to put in place integrated public and private sector mechanisms, that will allow all countries alike to be able to procure or produce medical technologies for contemporary or future crises.

## **1.8 Community Involvement**

For any major health problem, vulnerable groups in the affected countries need to be defined, identified and prioritized within national programs. This includes their active representation and involvement in program design, planning, implementation, monitoring and evaluating the response process. The formulation of rights-based communication and information strategies are required, like Risk Communication and Community Engagement (Centre for Communication Programs, 2022), that can represent the needs of vulnerable groups. Community engagement at each stage of the process needs to be based on local context and customs. Multi-sectoral action will be required to address community social welfare concerns and livelihood protection.

Within countries, regulatory frameworks need to be established that strategically integrate the development and implementation of health programs, clearly indicating the institutional roles across ministries and agencies, and providing inter-sectoral coordination and data management across all sectors. Active cross-sectoral engagement needs to be established with local actors, community health workers, and volunteers through the provision of training, adequate protection for front-line workers and resources. Such technical assistance could assist countries to better understand the different vulnerable groups in their society using detailed data, and prioritize support to those that need it most.

## 1.9 Human Rights.

Human rights, health rights, discrimination and intellectual property rights provide the basic principles governing why and how we need to respond as a global community. Health rights are fundamentally a human right and there is an inherent acceptance that timely access to lifesaving medical technologies is a health-right, including access to vaccines, medicines and diagnostics.

Timing of access to lifesaving interventions is important during a pandemic. Based on these four basic principles, discrimination needs to be addressed that exists within the current international system of trade rules, that denies timely responses. Despite all the promises and the existence of the TRIPS Agreement, which is meant to deal with such public health emergencies, what we saw in 2021 and 2022 was a situation of 'vaccine apartheid', and now we have, what some refer to as 'treatment and diagnostic apartheid'.

If we do not deal with the Intellectual Property (IP) barrier then we are not going to be able to address the pressing demand for access to medical technologies as a meaningful equity right. Civil Society, supported by other sections of society, plays an important role with the current discussions to extend TRIPS flexibilities to COVID-19 treatment and diagnostics.

Civil society elements were discussed at the UN Committee on the Elimination of Racial Discrimination Meeting in April 2022. The discussion reiterated the need for global vaccine equity, and similar language needs to be used for other major global health problems. The UN Human Rights Council in 2022 passed a resolution that access to medical technologies is the right of everyone for the enjoyment of the highest attainable standard of physical and mental health, and is something that should be promoted (OHCHR, 2022).

Human rights, health rights and decolonizing global health are part of understanding that every voluntary license that's announced, every technical hub that is established in the Global South, every kind of attempt to have technology transfer are deeply rooted in the rights around ability, capability and around race. Unfortunately, if governments insist not to use available flexibilities, which are contained in the TRIPS declaration or partially covered on the 17th of June WTO deal, countries may not get access to medical technologies.

If there is no true benefit in terms of sharing agreements post-trial, if there is no proper governance of how trials are to be conducted in LMICs, and if access is not guaranteed post-trial, then this is far from an equitable and fair process. A new IP regime ought to enable

both countries and manufacturers to widen commercial use of medical technologies and then send them across different countries, without any kind of export restrictions or threats.

## 1.10 Conclusion

In conclusion, there are many elements that need to be focused on by civil society and other sections of the population in countries, but if we only focus on the simple, easy things we are not going to be able to achieve sustainable access to quality-assured and affordable medical technologies for LMICs, and in particular for the most vulnerable populations in these countries.

# Recommendations

2.1 Access to medical technologies is a human right and sustainable access to quality-assured and affordable preventive or therapeutic medical technologies is a major requirement for successfully confronting contemporary and future pandemics. Access to these medical technologies will also enable local health conditions to be addressed, thereby strengthening country health care services and systems. A reduction in expenditure on medical technologies in countries, frees up fiscal space from their national budgets, that can be used to address other major public health and socio-economic challenges currently confronting countries.

2.2 Focus has often been on the supply of health technologies and particularly on increasing manufacturing capacity. However, lack of timely financing was responsible for a big part of the delay in terms of expanding vaccine coverage. Additional funding will be required and some of the global statutory and non-statutory institutions are creating the pathways whereby countries can be supported. For instance, the FIF initiative housed in the World Bank, is one example, whereby global funding for Pandemic Preparedness Prevention and Response will be provided but countries are still expected to bear the brunt of in-country funding.

2.3 The importance of research and development has again been stressed and how extremely important it is in the production of new products. Provisional orders should be put in place to make sure that access is embedded within agreed arrangements and funders should play a role here. Manufacturing should be more diversified to enhance health system resilience and responsiveness, but it also needs to be sustainable. The latter is something that has not been

discussed very often to date. Systems that are put in place for manufacturing, deployment, supply chains, can be used for producing routine immunizations, medicines and diagnostics for the other health problems that countries face.

2.4 Barriers to intellectual property rights need to be addressed and access to medical technologies needs to be recognized as an human and equity right. COVID-19 treatment and diagnostics need to be covered by TRIPS flexibilities similar to COVID-19 vaccines. Existing legal and process mechanisms that currently cover disease-specific medical technologies need to be extended to cover all contemporary and future vaccines, medicines, diagnostics and other relevant medical technologies as part of the TRIPS flexibilities.

2.5 Community involvement at country, regional and global levels underpin the success or failure of national, regional or global interventions. Communication between local or national scientists, healthcare professionals, business community representatives and the public are essential to keep all sectors of society focused on the same objectives of overcoming the acute health problem, as well dealing with other existing health or civil problems. Vulnerable populations need to be identified, engaged and may need to receive targeted interventions.

2.6 Ultimately countries need to take the lead in implementing relevant programs at country level, with the assistance of regional and global entities. Alignment needs to exist between 'national', 'regional' and 'global' aims, objectives and methods used to address these issues. This can overcome any element of lack of trust, accountability or ownership, as in a number of countries and some regions, not all stakeholders felt represented during the COVID-19 Response in the decisions made by global agencies. Country governance arrangements need to be regularly reviewed, evaluated and when required adjusted.

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