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ACCESS TO COVID-19 TOOLS

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REPORT OF ACCESS TO COVID-19 TOOLS ACCELERATOR FACILITATION COUNCIL WORKING GROUP ON DIAGNOSTICS AND THERAPEUTICS

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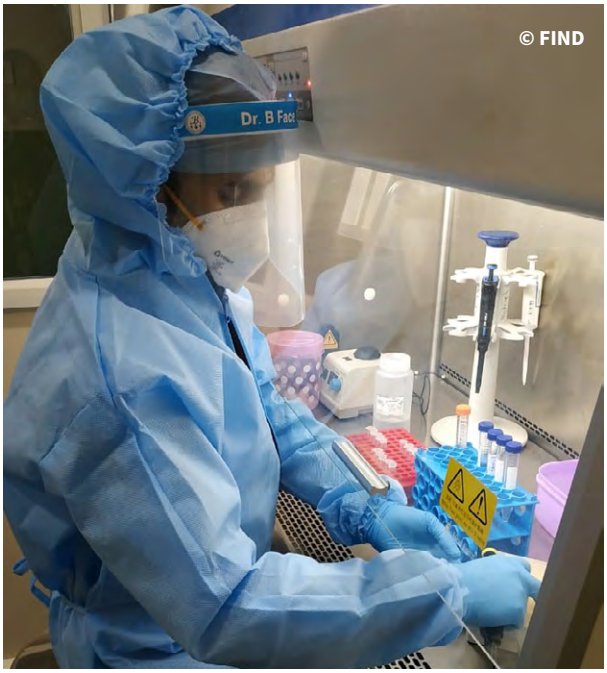
EXECUTIVE SUMMARY



The COVID-19 pandemic requires a complete public health response that spans non-pharmaceutical interventions and medical countermeasures to mitigate the impact of the virus on lives and livelihoods. Despite this need, equitable roll-out of COVID-19 diagnostics and therapeutics continues to be inadequate and threatens to undo public health gains achieved throughout the pandemic. With limited attention on procurement, delivery models and in-country planning, low-income and lower middle-income countries, are disproportionally affected, placing equitable access at risk.

Testing rates, already low in low-income and lower-middle-income countries, have fallen everywhere since the beginning of 2022. As a result, the world lacks a complete understanding of the full evolution of the pandemic and emerging variants. The delay and shortfall in community-based diagnostics and self-testing with antigen rapid diagnostic tests is particularly concerning. This risks compromising the rollout of new lifesaving outpatient oral antivirals, which are most effective at reducing hospitalisation and death when given within 5 days of symptom onset, and thus reliant on targeted and effective testing to identify early those at risk of severe disease progression. Alongside the challenges of getting treatments to the right people in the right timeframe, realizing the full potential of these new medicines also continues to be hampered by limited access to these products for LMICs, unaffordable prices, delays in adopting test-to-treat strategies, lack of guidance, and a limited ability to deploy these medicines to the primary care and community level. Furthermore, most LMICs are making challenging resource allocation decisions within scarce resource environments and the priority given to COVID-19 diagnostics and therapeutics will therefore depend on broader health demands. The case for supporting greater efficiencies through integration of COVID-19 interventions with existing primary health care systems is strong.

Affordability is an important aspect that will impact availability and equitable distribution of therapeutics and diagnostics. It is critical that affordable diagnostics and therapeutics are not treated as siloed interventions, and to recognise the importance of the broader ecosystem in enabling their development, such as a strong R&D and clinical trials infrastructure. Strengthening primary health care systems is necessary for the rollout of medical countermeasures and general pandemic response. As such, we need to consider medical countermeasures within the wider context of primary health care systems and universal health coverage. National and local ownership and co-investment, alongside strong regional level support, are essential if integrated diagnostics and treatment approaches are to have sustained impact.

This report's central premise is that diagnostics and therapeutics, and associated test to treat strategies, are fundamental components of the pandemic response, both for COVID-19 and for future health threats. Addressing this is as much a structural problem as a technical one: diagnostics and therapeutics are often considered different markets with independent stakeholders. But integration of diagnostics and therapeutics including test to treat strategies in primary health care systems, along with vaccines and public health measures, is a core part of pandemic response. Two and a half years into the COVID-19 pandemic, this report reflects on the main challenges and key solutions on the road to equitable access to diagnostics and therapeutics.

Our Approach

This report draws from experience gained through the Access to COVID-19 Tools (ACT) Accelerator Diagnostics and Therapeutics pillars, and also includes the perspectives of collaborating stakeholders (countries, civil society representatives and the private sector). To ensure a consistent analysis, each pillar evaluated - as of July/August 2022 - the state of play across three areas:

a. regulation, manufacturing and supply;

b. sustainable markets and demand; and

c. in-country delivery and health system approaches.

Equitable access and effective uptake of tests and treatments are complex issues. For both diagnos-tics and therapeutics, recurring challenges have been identified:

- Regulation: slow or incomplete at global level, regional level and in countries.
- Manufacturing: highly concentrated in a few countries and manufacturers, with variable diagnostic product quality.
- Allocation: lack of volumes reserved for low- and middle-income countries, including upper-middle income countries (UMICs).
- Funding: delays in mobilizing funds in a timely manner, and scarce and uncertain funding for development of medical countermeasures, with vaccines receiving most attention and funding.
- Access & Deployment: global, regional and national efforts to promote equitable access to medical countermeasures have had variable implementation and accountability. This has not resulted in equitable or affordable access.
- Forecasting: dynamic and unpredictable nature of the pandemic has led to challenges in demand forecasting. Determinants of local demand and fragmented international response have hindered efficient planning.
- Demand: evidence suggests diagnostics and therapeutics continue to be crucial for those at highest risk of progression to severe disease, but awareness and demand remain low.

Building on these findings, this report proposes sixteen recommended actions to address what have been identified as key structural challenges and specifies a potential owner for each action. The report offers a potential high-level roadmap of where efforts should be concentrated to support country-level decision-making.

The recommended actions follow two different time frames:

- Six recommended actions are in the context of the six-month ACT-A plan (October 2022 to March 2023). These actions are relevant during the next period of the ACT-Accelerator's work and thus focus on the downstream part of the value chain. It is recommended that the ACT-Accelerator Tracking and Accelerating Progress Working Group - or the mechanism that will continue to track and monitor ACT-A's work - together with the G20 & G7 health track, review the implementation of the recommended actions.
- Ten recommended actions are made in the context of long-term COVID-19 control and the broader Pandemic Prevention Preparedness and Response (PPR) agenda. Therefore, these actions span across the value chain (upstream and downstream).[1] This report's long-term recommendations consider ongoing proposals to strengthen the Global Health Architecture, as identified in the WHO White Paper and the G20 health track, as well as the new Financial Intermediary Fund (FIF) for pandemic prevention preparedness and response and the Pact for Pandemic Readiness launched by the German G7 Presidency, which will help ensure the world is better prepared for future pandemics.

[1] At the time of this report, the design and operating principles of funding streams and implementing partners to support a future medical countermeasures' platform have not been finalized.

2

RECOMMENDED ACTIONS

2.1 Recommended actions between now and the end of March 2023:

Sustainable markets & procurement

Recommended action 1, Page 21: Countries should assess their national diagnostic strategies in line with WHO diagnostics and surveillance/monitoring guidelines including with respect to self-testing. This is to achieve sufficient testing required for the rollout of targeted test to treat strategies, surveillance to spot outbreaks and assess new variants, within wider health system priorities. National diagnostic strategies should have flexibility to adapt to the evolving nature of the pandemic and utilize local intelligence to forecast procurement needs.

Recommended action 2, Page 22: To support sufficient supply of COVID-19 treatments and diagnostics for LMICs in the near term, the ACT-A Diagnostic & Therapeutics pillars should develop a plan for optimal use of existing resources and funding, and update funding priorities for the next 6 months. It is important for ACT-A agencies and partners to clearly communicate with countries on the availability of products; the benefits and logistics of test to treat; and funding channels.

Recommended action 3, Page 20: All countries are recommended to support the fulfilment of country COVID-19 Diagnostic & Therapeutics needs. G20 and donor countries are recommended to support LICs/LMICs, including through funding the ACT-A Diagnostic & Therapeutics pillars. Furthermore, paired with domestic resources, concessional financing from World Bank (WB) and other multilateral development banks should be effectively used for strengthening diagnostics and therapeutics systems, procurement, and service delivery. These investments could have a legacy impact and can be used to support and strengthen primary health care systems and routine surveillance for all diseases with outbreak, epidemic and pandemic potential.

Recommended action 4, Page 24: Efforts by ACT-A to secure expanded and affordable access to originator products, including from Merck Sharp & Dohme & Pfizer in advance of generics coming online are essential for LMICs. Collaboration between industry partners and ACT-A is required to bring the current discussion on equitable access to new therapeutics to a positive conclusion swiftly. In parallel, industry partners to work with countries and health agencies to maximize affordability to all LMICs, including upper-middle income countries. Finally, as part of the future medical counter-measures platform, partners and health agencies could examine the role price transparency, tiered pricing, and expansion of licensed generic suppliers play in maximizing affordability and availability for all LMICs.

In-country delivery & technical assistance

Recommended action 5, Page 20: Support from ACT-A partners and concessional financing could significantly influence and facilitate uptake of crucial diagnostics and treatments. Multilateral Development Banks (MDBs) and ACT-A partners should continue to work with countries and support procurement and delivery of COVID-19 treatments and diagnostics. This is core to achieving effective targeted test-to-treat strategies in all countries. Progress on implementation of roll out of test to treat strategies should be reported to the ACT-A Facilitation Council, Global Action Plan on COVID-19 and G20 Health Track.

Recommended action 6, Page 29: Building on emerging evidence from COVID-19 test to treat pilots, countries should consider integrating sustainable test to treat strategies into primary healthcare and community level systems. These strategies should also aim to increase community test to treat health literacy and engagement.

2.2 Long-term COVID-19 control & strengthening of prevention, preparedness and response (PPR):

Regulation & manufacturing

Recommended action 7, Page 25: In order to ensure diagnostics & treatments are made available in a timely manner, WHO should continue to ramp-up support to countries and regional groups in their efforts to

harmonize and expedite the review processes for national registration/approval of generic and originator products. Stringent Regulatory Authorities play a role, according to existing procedures previously defined.

Recommended action 8, Page 18: The COVID-19 pandemic has highlighted the urgent need to strengthen the regulatory systems for diagnostics products; as such, sufficient resources should be provided to WHO to address regulatory challenges and bottlenecks, including funding for strengthening regulatory harmonization, oversight, and specifications, and providing adequate human resources.

Recommended action 9, Page 25: To further strengthen pandemic preparedness it is important for WTO (World Trade Organization), WHO and Medicines Patent Pool (MPP) to build and strengthen strategies for generic licensing and technology transfer for therapeutics, including relevant TRIPS procedures, with input from industry partners and stakeholders. The aim of this is to accelerate access of novel products for all LMICs and increase diversified manufacturing. To further reinforce these interventions, the C-TAP could be expanded into a longer-term project to expand access to tools.

Recommended action 10, Page 18: To address the uneven balance of testing supply and manufacturing between LMICs and high-income countries and between regions, the G20, interested countries, and regional groups, in collaboration with WHO, FIND and MDBs, should identify and support efforts to increase local development of sustainable manufacturing capacity, including through technology transfer and improving skills and infrastructure, especially in underserved regions.

Recommended action 11, Page 30: G20, interested countries, and regional groups, with support from WHO, Unitaid, MPP and MDBs, to conduct market assessments, evaluate feasibility and create sustainable funding streams to establish regional therapeutics manufacturing hubs. These can draw lessons from, or in tandem with, the network of manufacturers producing generic COVID-19 antivirals, the mRNA Technology Transfer hub, the Global Training Hub for Biomanufacturing sponsored by WHO, and the G20 initiative on global manufacturing and research hub, to support diversified, sustainable local manufacturing in underserved regions.

Sustainable markets & procurement

Recommended action 12, Page 11: In line with the implementation of WHO White Paper "10 proposals to build a safer world together", a future comprehensive medical countermeasures platform could be developed, drawing upon lessons from the COVID-19 pandemic and ACT-A. A future medical countermeasures platform should consider upfront and at-risk financing and market shaping, including by front-loading commitments from donor countries and MDBs for rapid development, procurement and roll out of diagnostics, therapeutics and vaccines. Furthermore, the platform should spearhead pre-negotiated agreements/mechanisms for securing real-time equitable access to medical countermeasures for LMICs, including by promoting regionally diverse manufacturing, leveraging volume for pricing agreements and determining and aggregating demand based on country plans.

Recommended action 13, Page 13: Diagnostics agencies and industry partners to work with regional bodies to prioritize market shaping interventions for multi-pathogen tests, in order to reach sustainability. New diagnostic technologies, such as multi-pathogen tests together with existing diagnostic systems should be used to accelerate integrating COVID-19 diagnostics into primary health care services and increase pandemic preparedness.

Recommended action 14, Page 31: G20, donor countries, and MDBs to work towards fully funding mechanisms intended for pandemic preparedness (e.g. PPR FIF) and response (e.g. Future Countermeasure Platform) and do it together with co-investments from implementing countries. Donor countries should consider striking the right balance and not divert current funding flows from existing global health priorities, and instead contribute additional funding for PPR. This will contribute to increased national health security for all countries.

In-country delivery & technical assistance

Recommended action 15, Page 21: ACT-A and partners should support countries in identifying COVID-19 interventions that could be sustainably maintained long-term and integrated into wider primary health care systems. This will ensure effective implementation of targeted test-to-treat strategies and maintain and expand disease surveillance programs. Interventions identified will require adaptation of policy, guidelines and funding priorities, necessary for test-to-treat to work, as highlighted by the new COVID-19 testing strategy of Africa CDC.

Recommended action 16, Page 22: ACT-A agencies and key partners should support countries in strengthening laboratory capacity, including genomic sequencing. This should contribute to sustainable scale-up of national diagnostic capabilities, and strengthen the ability to identify variants of concern. Furthermore, strengthening of laboratory capacity should foster integrated COVID-19 and pandemic-prone pathogen surveillance, including through a one health approach, at the regional and global level to meet current health needs and increase pandemic preparedness.

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FOCUS, AIM AND APPROACH FOR THIS REPORT

This report of the Diagnostics and Therapeutics Working Group covers the current status of access to COVID-19 treatment & diagnostics in LIC/LMICs and provides recommendations to accelerate access through improving legal, financial, logistical and policy mechanisms, in the medium to longer-term.

3.1 High-level objectives

This report has two aims: firstly, to provide an overview of the status of the delivery of COVID-19 diagnostics and therapeutics, including challenges in regulation, manufacturing, markets, demand, in-country delivery and health systems. And secondly, to propose high-level recommended actions to support diagnostics and therapeutics in the mid to long-term, both for COVID-19 and future health threats.

The report's recommended actions are designed to be actionable, making targeted requests for support to specific audiences. At the same time, this report recognizes the special circumstances of the uncertain COVID-19 epidemiological situation and the current context around access to diagnostics and therapeutics.

3.2 Scope, membership and ways of working of the ACT-A Council Diagnostics and Therapeutics Working Group

Scope of this report

This report covers topics related to diagnostics and therapeutics in the context of addressing COVID-19 in the mid to long-term, and for PPR beyond COVID-19. On the subject of **Diagnostics**, this report will focus on community testing (including self-testing) and laboratory surveillance systems. On the subject of **Therapeutics**, this report will focus on oral outpatient treatments only, with the aim of providing a more comprehensive view for both COVID-19 and longer-term PPR issues. Oxygen is not included in the scope of this report, as it has its own unique set of challenges, different from those of most other treatments.

Membership and ways of working

This report was produced by the ACT-A Council Diagnostics and Therapeutics Working Group, as part of a highly consultative review process. The Working Group was set-up by the ACT-A Facilitation Council's Co-Chairs Norway and South Africa and has been co-chaired by South Africa and the United Kingdom (see Annex for membership details). It held 8 meetings, including 3 deep dives on diagnostics and 3 deep dives on therapeutics. In attendance were the co-chairs, the Working Group members, members of the Diagnostics and Therapeutics pillars, representatives of countries, and other participants. Beyond those meetings, the Working Group's Co-Chairs engaged in bilateral discussions with a wide range of stakeholders, including countries, the private sector, civil society organizations (CSOs), regulatory bodies, and health agencies (see Annex for bilateral discussions held).

3.3 Background, structure and objectives of the ACT-A Diagnostics and Therapeutics pillars

The ACT-A Diagnostic and Therapeutic Pillars provided key support to the ACT-A Facilitation Council Diagnostics and Therapeutics Working Group in the production of this report. This section provides a detailed overview of the background, structure, and objectives of these pillars.

ACT-A Diagnostics Pillar

Diagnostics are an essential tool to combat COVID-19 and were among the first resources deployed to support the global COVID-19 response. Diagnostic testing facilitates an understanding of transmission dynamics to enable governments and individuals to implement timely countermeasures, including non-pharmaceutical public health interventions, vaccination strategies and newly emerging treatments. Testing, therefore, continues to be one of the cornerstones of the COVID-19 response and indeed any future pandemic response.

To be more precise, testing enables the early identification and isolation of cases so that individuals can take decisions which may slow transmission, provide care to those affected, and protect health

and care systems.[2] Moreover, recent modelling efforts show that when COVID-19 testing is linked to timely treatment, rates of hospitalization and the proportion of deaths decreases as testing rates increase. As is well established, COVID-19 diagnostic testing can be conducted in multiple ways, using molecular testing, e.g., PCR, as well as using antigen-detecting rapid diagnostic tests (Ag-RDTs), which can offer more rapid testing and may be particularly impactful where laboratory capacity is limited and where treatment must be initiated within a short timeframe; for instance to qualify for oral antivirals, which must be started within 5 days of symptom onset. It is therefore important that easy-to-access and affordable or free testing, particularly rapid testing can and should be offered at the facility and community level.[3]

Given the importance of testing, the ACT-A Diagnostics Pillar was set up to improve equity of access to COVID-19 tests across the world, as part of the wider ACT-Accelerator partnership. The pillar is co-convened by FIND, the global alliance for diagnostics, and the Global Fund with WHO. The Diagnostics Pillar works alongside 50 global health partners with the objective to accelerate the development, production, and scale-up of equitable access to COVID-19 diagnostic tools and resources.

The ACT-A Diagnostics Pillar has several key objectives focused on addressing challenges hindering equitable diagnostics access and implementation in LMICs and LICs. These challenges include:

- Clear limitations of both lab-based molecular tests and near-patient rapid tests. Testing strategies solely reliant on lab-based testing can be slow, expensive and inefficient due to a lack to access to laboratory facilities, limited capacity, and delayed transport of specimens and results reporting, among other issues. Testing strategies based solely on rapid antigen tests will miss some cases, require investments in training, and are more difficult to integrate into surveillance efforts.
- An often-inadequate policy environment, coupled with slow regulatory approval. A lack of transparency on the regulatory process and timelines frequently results in access delays.
- A lack of evidence on cost-effective testing strategies.
- Substantial competition from high income countries (HIC) buyers, with HICs frequently crowding out LMICs and LICs.
- Preferred tests identified by HICs are often priced too high, making it difficult for LMICs and LICs to procure the tests.
- Fragmented transport networks and expensive sample collection, resulting in difficulty delivering testing to remote, and/or particularly low-income regions.
- Fluctuating and declining demand for tests has made it difficult for manufacturers to sustain manufacturing capacity. Even if tests themselves are fit for purpose, there is insufficient baseline manufacturing capacity for fit for-purpose tests to meet early demand, followed by huge fluctuations in supply and demand that drive inefficiencies and costs.

ACT-A Therapeutics Pillar

At the onset of the COVID-19 pandemic, little was known about effective therapeutic options for COVID-19. However, their promise and potential to transform outcomes related to the disease meant it was essential to take a coordinated approach to accelerating discovery, access and uptake of therapeutics. This resulted in the formation of the ACT-A Therapeutics Pillar, as part of the wider ACT-Accelerator partnership. ACT-A Therapeutics Pillar is co-convened by Wellcome, Unitaid and the Global Fund with WHO, and other ACT-A agencies, including UNICEF.

The ACT-A Therapeutics Pillar has several broad objectives. These objectives include advancing the COVID-19 therapeutic pipeline, securing meaningful, global, equitable access to priority treatments, and facilitating the introduction and scale-up of treatments in LMICs. The work of the pillar and its partners has brought about several key achievements in the supply of, and access to, COVID-19 therapeutics, including the introduction of oral antivirals for treatment of mild and /moderate cases. However, as the therapeutics

[2] Press Release COVID-19 Tests: https://www.findDiagnostics.org/newsroom/pr-22jan21.
[3] ACT-A Diagnostics OR Report: https://www.findDiagnostics.org/wp-content/uploads/2021/01/ACT-A-SARS-CoV-2-Ag-RDT-Operational-Research-Report.pdf.

landscape has changed, the work of the Pillar has had to evolve and adapt to continue to drive equitable access to therapeutics.

Before therapeutics were available, the Therapeutics Pillar worked to advance the pipeline of potential treatments. The COVID-19 Therapeutics Accelerator[4] is one example of an initiative that played a key role in advancing the R&D portfolio for COVID-19 therapeutics by providing quick, flexible, and targeted funding and technical assistance. As promising therapeutics emerged from the pipeline, the pillar worked and continues to work to secure equitable access for LMICs. An excellent example of a therapeutic class the Pillar has helped to support are oral antivirals for COVID-19. The development, guideline adoption and regulatory approval of these antivirals was a major milestone in the therapeutic landscape. It has enabled outpatient treatment of COVID-19 and can help to prevent hospitalization and save the lives of patients most at risk of developing severe COVID-19.[5]

[4] CTA, a philanthropic collaboration supporting efforts to research, develop and bring effective treatments against COVID-19 to market quickly and accessibly.
[5] COVID Collaborative. COVID GAP Accountability Report. Available from:https://covid19gap.org/assets/publications/COVID-GAP-Accountability-Report---May-2022.pdf (accessed 9 August 2022).

4

DIAGNOSTICS IN THE NEXT PHASE OF THE PANDEMIC & PREPARING FOR FUTURE HEALTH THREATS

4.1 Diagnostic regulation, guidance, manufacturing, and supply

COVID-19 diagnostic manufacturing and regulatory processes: progress to date and challenges

The COVID-19 pandemic resulted in unparalleled development and commercialization of diagnostics, evidenced by the more than 1,500 commercially available COVID-19 tests, with a wide-ranging performance and many from companies new to the in-vitro diagnostics (IVD) market. Much of this success was due to the unprecedented global demand for tests, facilitated by key stakeholders represented in the Diagnostics and Therapeutics Working Group. The Diagnostics Pillar has undertaken a wide range of actions to successfully progress diagnostic development, validation, regulation, policy, manufacturing, and supply (See Annex for more details). Nevertheless, challenges have been identified that should be addressed to further improve market dynamics, sustainable manufacturing and supply chains, and effective, efficient regulatory approval. This section will highlight the three, key overarching challenges identified in diagnostic regulation, manufacturing, and supply:

1. Price
2. Regulatory bottlenecks
3. Uneven distribution of supply

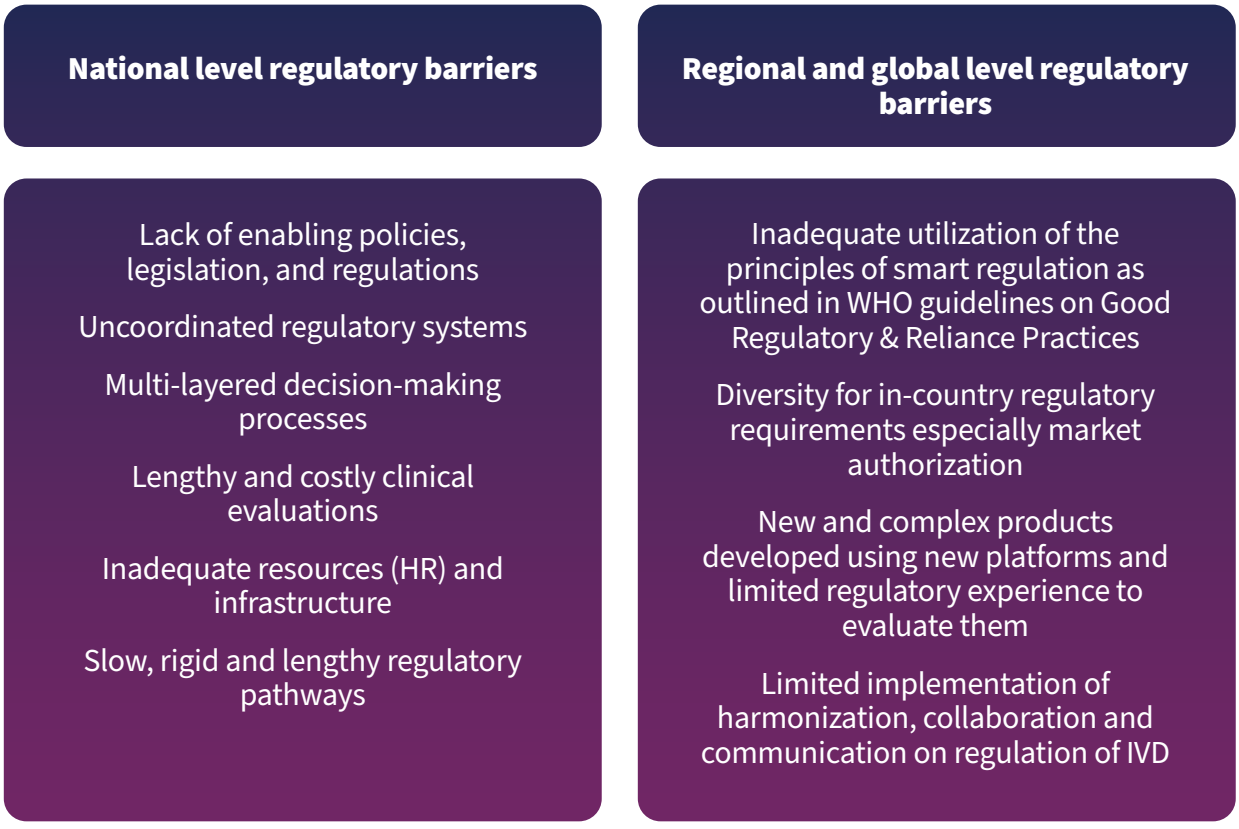
Price – through the support of ACT-A initiatives, price reductions of 30-50% were achieved early in the pandemic and led to significant cost savings. At the start of the pandemic, molecular tests were priced between US$20-30 for LICs and LMICs and are now less than US$15, while Ag-RDTs (both professional and self-tests) were priced above US$3 (in some settings, well above $3) and are now between US$1 and US$2 per test. Although progress has been made in lowering the price of tests, stakeholders have expressed the need to reduce prices further, citing prices below $US1 for Ag RDTs as the critical threshold for expanding greater access and uptake in LMICs. To achieve this price point, several interventions may be needed to ensure companies can still be profitable while safeguarding the production of high-performing and quality-assured tests. It is also important to note that funding from donors for diagnostics took time to materialize at the start of the pandemic. This impacted on LICs and LMICs ability to access diagnostic tests. In order to improve preparedness it is important that upfront and at-risk financing is available for the next pandemic. This would allow for faster procurement of diagnostics for LICs and LMICs at the start of a future outbreak.

Recommended action 12: In line with the implementation of WHO White Paper "10 proposals to build a safer world together", a future comprehensive medical counter-measures platform could be developed, drawing upon lessons from the COVID-19 pandemic and ACT-A. A future medical countermeasures platform should consider upfront and at-risk financing and market shaping, including by front-loading commitments from donor countries and MDBs for rapid development, procurement and roll out of diagnostics, therapeutics and vaccines. Furthermore, the platform should spearhead pre-negotiated agreements/mechanisms for securing real-time equitable access to medical countermeasures for LMICs, including by promoting regionally diverse manufacturing, leveraging volume for pricing agreements and determining and aggregating demand based on country plans.

Regulatory, guidance and quality bottlenecks – the level of product diversity and the number of suppliers in COVID-19 testing has been conducive to a competitive global market, but has also challenged manufacturers' ability to meet quality, safety and performance standards, and to conduct timely regulatory assessment. This is exemplified by the fact that 24 molecular and 11 Ag-RDTs (including 1 self-test) have been listed through the WHO Emergency Use Listing (EUL) procedure[6] among the 107 tests assessed by WHO. Many stakeholders have noted the challenges faced both by manufacturers in ensuring compliance with quality standards, and regulators in ensuring a timely assessment of much-needed products, in a regulatory context lacking harmonization and convergence. Challenges in ensuring sufficient capacity to assess the many products coming to market were amplified by manufacturers, many of which lacked any prior regulatory or global market experience, and provided incomplete regulatory submissions or provided submissions for poor quality products. Countries and key stakeholders, including WHO, could work to ensure that diagnostics regulation—specifically the emergency assessment procedures—leverages applicable aspects of the regulatory strategy for pandemic medicines and vaccines, where the benefit of accelerated EUL authorization may significantly outweigh the risks on which a slower, time- and labour-intensive regulatory process is based. This, however, requires both an increase in resources allocated to diagnostics assessment and adjustments to regulatory practice, based on the experience gained during the pandemic. Notably, several Stringent Regulatory Authorities (SRAs) streamlined the emergency listings process for SARS-CoV-2 tests and authorized hundreds of molecular tests and Ag-RDTs, with minimal negative consequences. Strengthening of reliance and recognition practice across the various assessment mechanisms should also be considered as good regulatory practice and an efficient tool for optimizing limited resources.

Figure 1 highlights national, regional and global regulatory barriers for access to in vitro diagnostics.

Figure 1: Key regulatory barriers at the national, regional, and global levels include:



[6] As of 22 August 2022, Aug 2022 as the time frame) per the FIND test directory (https://www.finddx.org/covid-19/test-directory/) based on WHO SRA definition (https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs) there are 219 molecular and 229 Ag-RDTs (including 90 self-tests) that are approved by at least one SRA recognized by the WHO.

Uneven distribution of supply – despite the significant global COVID-19 test market, test manufacturing capacity and supply chains remain highly centralized in a few countries. Early in the pandemic, supply was insufficient to meet demand, meaning that this limited supply of tests were quickly committed to countries that could afford fast procurement. In LMICs, fragile health systems and exclusive reliance on global supply chains for diagnostics left healthcare providers unable to access urgently needed tests. This contributed to a wide disparity in testing rates - while high-income countries, at the end of Q2 2022, conducted 2.01 tests per 1,000 people each day, LMICs only achieved rates of 0.04 tests per 1,000 people.[7] Many other factors underpin these low testing rates in LMICs and LICs, however access has been a persistent problem, Ag-RDTs and self-tests are important tools to increase access, and local manufacturing of these tests is a key component of a diagnostics access strategy.[8]

To support manufacturing, it is imperative to diversify COVID-19 diagnostic testing production capacity, and diagnostic production more generally, and further establish local and regional manufacturing capacity in LMICs. Currently, diagnostic manufacturing capacity is concentrated mainly in China and the Republic of Korea, and there is limited end-to-end local production capacity in LMICs, particularly in the Global South (Figure 2), as only a few countries in Africa and South America have significant production capacity (namely, Brazil, Kenya, Senegal, and South Africa). Further work to build local production capacity[9] must be prioritized to ensure LMICs are able to access timely local test supply without dependence on global supply chains. The Diagnostics Pillar has played a key-role in aiding manufacturers in Africa, Asia, and South America to expand production capacity, enable end-to-end manufacturing, and produce new diagnostics through technology transfer. While notable progress has been made, ongoing challenges have been identified by local manufacturers, including difficulties in recruiting sufficiently skilled personnel, export restrictions, unpredictable demand, and difficulties being cost competitive with larger, global manufacturers during the start-up period. Finally, depending on context, those additional LMIC-based production capabilities could be more impactful and more sustainable through the introduction of multi-pathogen tests and sustained support for the diagnostic tests essential for pandemic surveillance.

Recommended action 13: Diagnostics agencies and industry partners to work with regional bodies to prioritize market shaping interventions for multi-pathogen tests, in order to reach sustainability. New diagnostic technologies like multi-pathogen tests together with exist-ing diagnostic systems should be used to accelerate integrating COVID-19 diagnostics into primary health care services and increase pandemic preparedness.

[7] The SARS-COV-2 Test Tracker – 01 July 2022 Data https://www.findDiagnostics.org/covid-19/test-tracker.
[8] Press Release COVID-19 Tests: https://www.findDiagnostics.org/newsroom/pr-22jan21.
[9] There is a need to prioritize distributed manufacturing on therapeutics and diagnostics.

Regulatory, guidance and quality bottlenecks – the level of product diversity and the number of suppliers in COVID-19 testing has been conducive to a competitive global market, but has also challenged manufacturers' ability to meet quality, safety and performance standards, and to conduct timely regulatory assessment. This is exemplified by the fact that 24 molecular and 11 Ag-RDTs (including 1 self-test) have been listed through the WHO Emergency Use Listing (EUL) procedure[6] among the 107 tests assessed by WHO. Many stakeholders have noted the challenges faced both by manufacturers in ensuring compliance with quality standards, and regulators in ensuring a timely assessment of much-needed products, in a regulatory context lacking harmonization and convergence. Challenges in ensuring sufficient capacity to assess the many products coming to market were amplified by manufacturers, many of which lacked any prior regulatory or global market experience, and provided incomplete regulatory submissions or provided submissions for poor quality products. Countries and key stakeholders, including WHO, could work to ensure that diagnostics regulation—specifically the emergency assessment procedures—leverages applicable aspects of the regulatory strategy for pandemic medicines and vaccines, where the benefit of accelerated EUL authorization may significantly outweigh the risks on which a slower, time- and labour-intensive regulatory process is based. This, however, requires both an increase in resources allocated to diagnostics assessment and adjustments to regulatory practice, based on the experience gained during the pandemic. Notably, several Stringent Regulatory Authorities (SRAs) streamlined the emergency listings process for SARS-CoV-2 tests and authorized hundreds of molecular tests and Ag-RDTs, with minimal negative consequences. Strengthening of reliance and recognition practice across the various assessment mechanisms should also be considered as good regulatory practice and an efficient tool for optimizing limited resources.

Manufacturers have also highlighted additional barriers specific to the regulatory approval processes, as specified in Figure 1.

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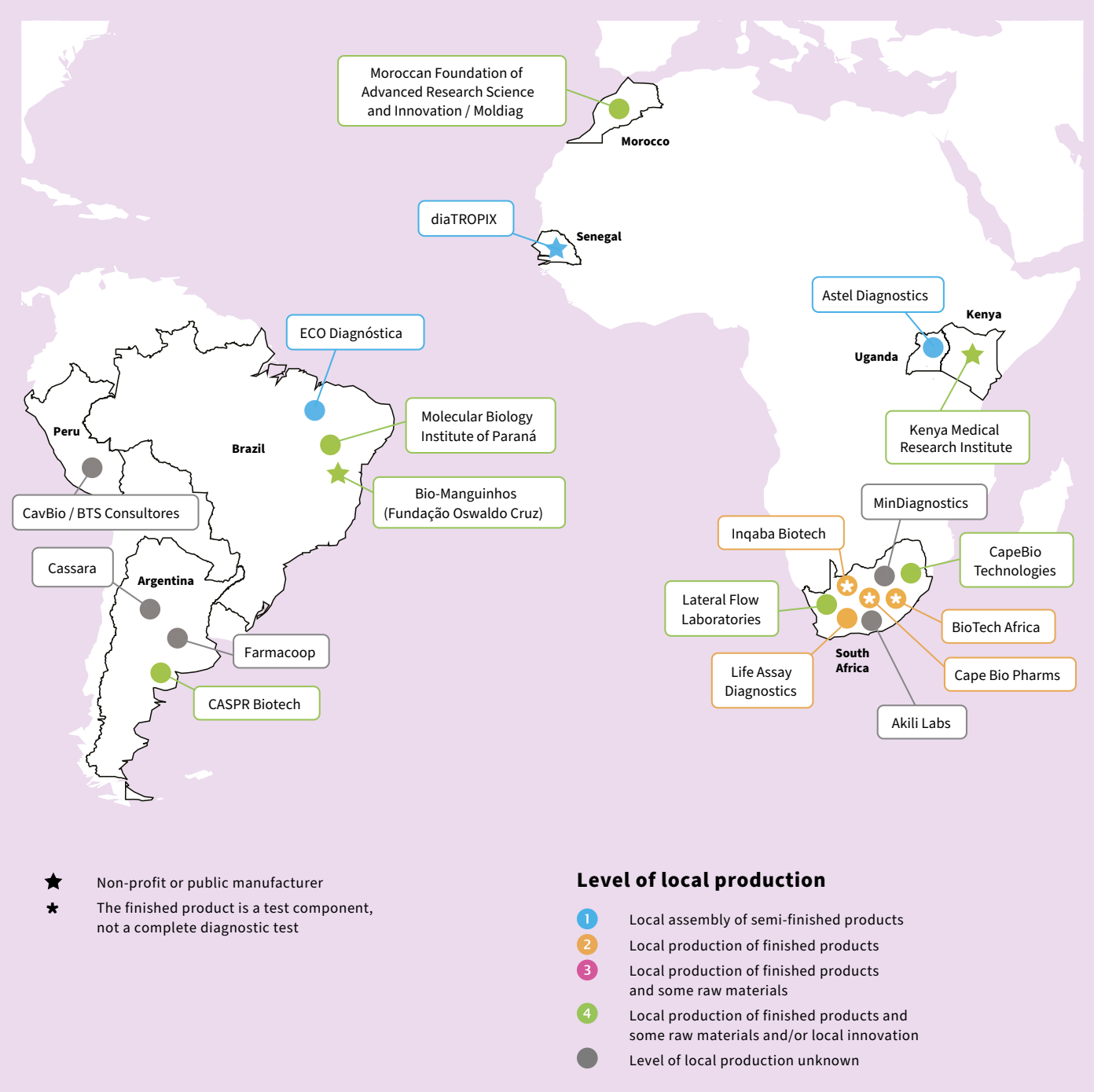
Figure 2. Local production capacity in South America and Africa[10]



Source: MSF Access Campaign Issue Brief, Local diagnostics to meet local health needs, 8 July 2021 https://msfaccess.org/improve-local-production-diagnostics

[10] There has been a growth production capacity in these regions since this map was published, including addition of Wama diagnostica, Brazil, an End to End manufacturer of AgRDTs.

To accelerate the supply and availability of diagnostic testing, the Diagnostics Pillar launched an Expression of Interest (EOI). The goal of this EOI was to bring additional well-performing, quality-assured, regulatory-approved, affordable, fit-for-purpose SARS-CoV-2 molecular and Ag-RDTs tests to market.[10] The impact of the interventions funded through the awards of the EOI included[13];

- Accelerating late-stage product development and optimization
- Facilitating technology transfer activities
- Conducting performance evaluation studies to support regulatory submissions
- Increasing production capacity
- Addressing supply chain challenges
- Strengthening local capacity for the development and deployment of new tests within national testing strategies
- Driving down prices
- Supporting the use of less invasive specimens to enable faster LMIC uptake

Through these efforts, the Diagnostics Pillar fast-tracked research & development, independent performance assessments and expanded manufacturing capacity, contributing to the expanded availability and use of molecular test kits and Ag-RDTs. These investments and activities have also contributed to the price reductions mentioned in the previous sections.

Further, to help address supply chain fragility in LMICs, the Diagnostic Pillar is supporting technology transfers[13] and scale-up of regional manufacturing capacities, with the goal of enabling more than 250 million low-cost, high-quality tests to be made available for LMICs. This expanded manufacturing capacity could also be used in the future to support the availability of affordable tests for other infectious diseases, including another for another potential pandemic.[14]

WHO's COVID-19 Technology Access Pool (C-TAP) is a good example of an important mechanism to enable the technology transfers described. C-TAP was launched during the pandemic and is a global platform for the developers of COVID-19 therapeutics, diagnostics and vaccines to voluntarily share their intellectual property and knowledge with quality-assured manufacturers through public health-driven and transparent licenses. The platform also provides support for technology transfer agreements to support local manufacturing, with Spain the first country to offer a diagnostics license to C-TAP. Technology transfer is particularly essential for local production capacity, as early in the COVID-19 pandemic, many LMICs did not have access to the necessary technology for COVID-19 diagnostics. The support and technical assistance provided through C-TAP partners is helping to expand the number of manufacturers globally that can produce life-saving COVID-19 products in line with international quality, safety and efficacy standards, while increasing availability and affordability for LMICs.[15] The Working Group also noted that the "Ministerial Decision on the TRIPs Agreement" was adopted on 17 June 2022.[16]

As described in this section, addressing high price points, regulatory bottlenecks and uneven distribution of supply through a series of recommendations could significantly impact the response to COVID-19 and future pandemics.

Summary: Priority areas and future advancements for the regulation, manufacturing, and supply of COVID-19 diagnostics moving forward

Despite the challenges described above, steady progress in the manufacturing, regulation and supply of diagnostics during the pandemic provides a foundation upon which more resilient and better prepared health systems can be built. Specifically, the Diagnostics Pillar's EoI to bring additional SARS-CoV-2 molecular and Ag-RDTs tests to market is a key initiative to address ongoing COVID-19 needs, while strengthening the LMIC response to future pandemics, so that more countries can be independent of supply chains in the Global North[17] (Figure 3).

[11,12,13] ACT Together Impact Report 20/21: www.findDiagnostics.org/wp-content/uploads/2021/04/ACT-Accelerator-IMPACT-REPORT-FINAL-220421.pdf.
[14] Press Release COVID-19 Tests: www.findDiagnostics.org/newsroom/pr-22jan21.
[15] www.who.int/initiatives/covid-19-technology-access-pool.
[16] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True .
[17] ACT Together Impact Report 20/21: www.findDiagnostics.org/wp-content/uploads/2021/04/ACT-Accelerator-IMPACT-REPORT-FINAL-220421.pdf.

Figure 3: ACT-A has accelerated the development, manufacturing and launch of COVID-19 tests improving equitable and timely access to diagnostics

Supported by ACT-A Diagnostics		Products	Total Capacity	Location	Priority Markets	Pricing/ Savings
Initiatives: • Late-stage product development • Performance evaluations • Regulatory support • Tech transfers • Improving fragil supply chains through boosting production capacity and stranghtening local capacity • Decreasing prices	4 manufacturers	COVID-19 Antigen RDTS *Professional Use*	314 million tests per year	Senegal India China Brazil S. Korea	LMICS	Achieved price reduction of tests ranging 30-50% PCR: Decreased from $20-30 to <$15 Ag-RDTs: Decreased from $5 to $1-2
	6 manufacturers	COVID-19 Antigen RDTS *Self Tests*	840 million tests per year			
	4 manufacturers	Point-of-care *molecular respiratory assays*	Capacity for multiple assay development process			

Moving forward, to continue to address the regulatory, manufacturing, and supply challenges, the Diagnostics Pillar will work with partners and key stakeholders, both globally and in-country, to sustain key initiatives launched during the pandemic. From a regulatory perspective, harmonizing and accelerating regulatory processes will be essential to ensure diagnostics are available in a timely manner. There is interest in developing WHO policy statements on use cases for diagnostic tests that would help manufacturers understand key products and their use, enabling industry to accelerate priority R&D programs and plan production capacity. It is important to note that WHO is already providing technical support to strengthen regulatory systems, facilitate regulatory coordination and collaboration, and support the development of policies and regulations. To this end, national regulatory agencies and key stakeholders can also help ameliorate regulatory barriers—for example, by establishing a sound legal framework based on international standards and best practices for sharing technical information and harmonizing emergency use processes, and by establishing a reciprocity mechanism to recognize regulatory decisions made by other SRAs. A fit-for-purpose, harmonized regulatory framework would facilitate timely access to quality, safe, and effective products.

Recommended action 8: The COVID-19 pandemic has highlighted the urgent need to strengthen the regulatory systems for diagnostics products; as such, sufficient resources should be provided to WHO to address regulatory challenges and bottlenecks, including funding for strengthening regulatory harmonization, oversight, and specifications, and providing adequate human resources.

From a manufacturing and supply perspective, it will be critical to provide continued support to help manufacturers further establish local production capacity for COVID-19 and related diagnostics. To this end, partners and manufacturers can work together to explore markets underserved by global manufacturers and support the linkage between procurement and supply security. Furthermore, all countries, supported by ACT-A agencies, must be transparent in forecasting their procurement needs. G7, G20, and other donor countries must be willing to support the fulfilment of these needs, especially for LICs/LMICs. Moreover, the C-TAP and diagnostics partners should support technology transfer arrangements, as these initiatives will be critical in facilitating and improving local production capacity.

Recommended action 10: To address the uneven balance of testing supply and manufacturing between LMICs and high-income countries and between regions, G20, interested countries, and regional groups, in collaboration with WHO, FIND and MDBs, should identify and support efforts to increase local development of sustainable manufacturing ca-pacity, including through improving skills and infrastructure, especially in underserved regions.

4.2 Sustainable diagnostic markets and demand

Lessons learned from COVID-19 diagnostic markets and demand: progress to date and challenges

Since the pandemic began, there have been significant successes in increasing the availability of testing for countries most in need - 175.7m tests have been procured for 180 countries in need, with 140.1m tests delivered across 179 counties (Q1 2020 to Q2 2022) by agencies within the Diagnostic Purchasing Consortium – a UN initiative set up as part of the ACT-A Diagnostics Pillar. In addition, several organizations have funded the procurement of tests, including The Global Fund, which has awarded US$ 982m (as of Q2 2022) to countries for test procurement. Despite these successes, critical challenges have been identified in ensuring sustainable diagnostic coverage:

1. Fluctuating and declining demand
2. Mismatch between testing demand and its utility/ benefits
3. Targeted testing to support test to treat programmes

Fluctuating and declining demand – there has been unpredictable and fluctuating demand for COVID-19 tests - a hallmark of testing related to disease outbreaks and pandemics. The recent profound decline in COVID-19 testing rates globally is a major challenge. Though testing rates have fluctuated over time, based on the epidemiological context, they have declined 70-90% globally over the past several months. When COVID-19 activity is low, alternative testing target rates could be considered. The decline in testing rates (Figure 4) is most evident in HICs at

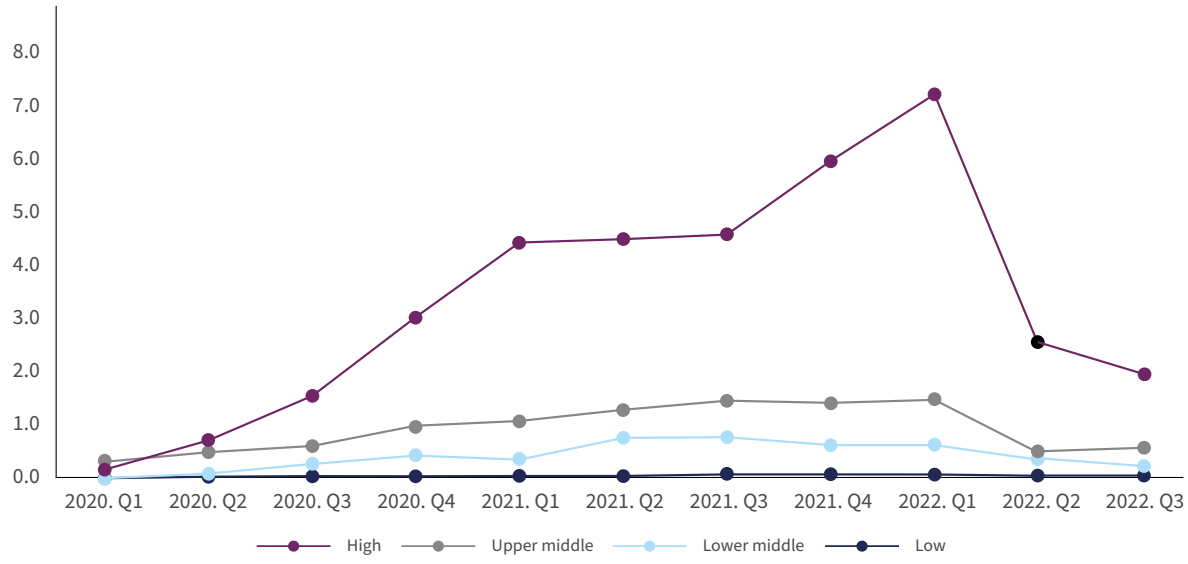
1.97 tests per day per 1,000 population, while rates are lowest in LICs with an average of .03 tests per day per 1,000 population as of Q3 2022.[18] Testing rates across the lower income groups (Lower Middle Income Countries and LICs) have persistently been much lower than the suggested minimum global testing target. Without sufficient testing, the world risks undoing the hard-earned public health gains achieved, furthermore timely and equitable access to the new oral antivirals are jeopardized. Without equitable and timely access to testing the world's understanding of patterns of virus transmission and evolution reduces.

In addition, the decline and unpredictability in testing rates presents enormous challenges for manufacturers, who require predictable product forecasts to support right-sized, efficient, and cost-effective human resource capacity, inventory levels and sourcing of reagents. In response to the decreasing demand for SARS-CoV-2 tests, some Ag-RDT manufacturers have already reported that they will either repurpose manufacturing capacity for other tests (potentially benefiting other infectious diseases management programs) or may shut down newly created manufacturing lines entirely.

Mismatch between testing demand and its utility/ benefits – Decline in demand for COVD-19 testing may not reflect the perceived value of COVID-19 testing among the general population. Despite the current climate for testing, 82% of individuals reported through the Diagnostics Access Survey (conducted by ACT-A Diagnostics Pillar) that they still value testing and believe that COVID testing is important to protect themselves and their communities. This same study also confirmed that interest in testing increases when people are told it could help connect them to safe and efficacious treatment.

Targeted testing to support test to treat programmes - Adequate testing is essential for test to treat strategies. The recent recommendation by WHO (April 2022) for use of the oral antiviral nirmatrelvir-ritonavir (Paxlovid) has demonstrated the need for sustained access to testing. This combination has been shown to reduce the risk of hospitalization by 85% in high-risk groups[19], including the unvaccinated, with the greatest impact when taken within 5 days of onset of symptoms. The impact of timely use of this treatment highlights the need to sustain testing availability in priority populations. Early testing and linkage to treatment also introduces opportunities to support patients and communities, including through contact tracing, providing social support for safe isolation during the infectious period, identifying people and communities for vaccination education and access, and identification of high-risk settings in the community that may benefit from additional mitigation efforts.

Figure 4. Tests per 1000 Population by Income Group Q1 2020 to Q3 2022



[18] FIND Test Tracker.
[19] Result based on clinical trial conditions –effectiveness studies in the field are required to develop both operational models and to understand constraints.

Recommended action 5: Support from ACT-A partners and concessional financing could significantly influence and facilitate uptake of crucial diagnostics and treatments. Multilateral Development Banks (MDBs) and ACT-A partners should continue to work with countries and support procurement and delivery of COVID-19 treatments and diagnostics. This is core to achieving effective targeted test-to-treat strategies in all countries. Progress on implementation of roll out of test to treat strategies should be reported to the ACT-A Facilita-tion Council, Global Action Plan on COVID-19 and G20 Health Track.

Looking forward: sustainable diagnostic markets and demand for COVID-19 and future health threats

For the reasons outlined above, attention to equitable testing access and demand remains critical. In the longer term, a sustainable market for COVID-19 diagnostics will require multifaceted support from stakeholders to avoid panic and neglect cycles. Although demand for COVID-19 testing may continue to ebb and flow with the epidemiology of the virus, countries can work to determine baseline testing levels to enable disease surveillance and targeted patient care/treatment. At the same time, those presenting with symptoms, COVID-19 or otherwise, should be encouraged to test for a range of illnesses. To sustain diagnostics manufacturing in the longer term, product diversification is an important consideration. Recognizing the intertwined nature of COVID-19 testing and treatment moving forward, the ACT-A Diagnostics and Therapeutics Pillars are working together to advocate for the role of testing and treatment in communities and with policymakers (discussed further in Section 6), and the Diagnostics Pillar is undertaking actions to help mitigate accessibility and demand-side challenges (see Annex for more details).

Beyond COVID-19, to build a sustainable, diversified and competitive diagnostics market and to strengthen the testing component of health systems, it will be essential to support preparedness to respond to future health threats, especially at the primary health care level. As for vaccines and therapeutics, advance purchase agreements for diagnostics tools, including tools that can be used for multiple pathogens, could be beneficial to help ensure predictable access irrespective of demand. Dedicated funding support for diagnostics will also be vital to support a sustainable and prepared diagnostic market that can respond quickly to future diagnostic needs. If the key challenges, described below in this section are addressed, significant progress could be made in ensuring sustainable demand for testing:

- Scaling access and improving equity in countries through strengthening lab systems, including expanding decentralized models of care (i.e., primary health care facilities) with a focus on providing a minimum package of tests with COVID-19, and moving away from stand-alone COVID-19 testing for respiratory illness, toward integrating COVID-19 testing into routine care for respiratory illness.
- Focusing on vulnerable and hard to reach populations through advocacy efforts, policy shifts, and prioritization of funds.
- Scaling access to self-testing in both the private and public sector.
- Better linking testing and treatment through packaging affordable testing with treatment services as part of test-to-treat programmes.

Recommended action 3: All countries are recommended to support the fulfilment of country COVID-19 Diagnostic & Therapeutics needs. G20 and donor countries are recommended to support LICs/LMICs, including through funding the ACT-A Diagnostic & Therapeutics pillars. Furthermore, paired with domestic resources, concessional financing from World Bank (WB) and other multilateral development banks should be effectively used for strengthening diagnostics and therapeutics systems, procurement, and service delivery. These investments could have a legacy impact and can be used to support and strengthen primary health care systems and routine surveillance for all diseases with outbreak, epidemic, and pandemic potential.

4.3 Diagnostics: in-country delivery and health system approaches

Lessons learned from COVID-19 diagnostics delivery: progress to date and challenges

Through the support of the ACT-A Diagnostics Pillar and its partners in-country and globally, significant strides have been made to scale up equitable access to COVID-19 diagnostics. As noted above, more than 175.7m COVID-19 tests (as of Q2 2022)[20] have been procured via the ACT-A Diagnostics Pillar. Furthermore, investing in laboratory systems and strengthening national surveillance systems, including laboratory and genomic surveillance, has allowed countries to be better prepared for new waves of COVID-19 and serve as a platform for resilient pandemic preparedness.

Investments in broader laboratory systems, including HR, data, governance bioinformatics and financing, will strengthen surveillance and contribute to initiatives such as the WHO Hub for Pandemic and Epidemic Intelligence has an important role to play in supporting countries, regions, and global actors to address future pandemic and epidemic risks with better access to data, better analytical capacities, and better tools and insights for decision making. Initiatives such as the International Pathogen Surveillance Network will also help bring pathogen surveillance capacity to speed and scale.

Integrating COVID-19 diagnostics into routine health service delivery systems will also help establish sustainable long-term COVID-19 management. To ensure COVID-19 testing approaches are feasible, interventions should be cost-effective compared with those offered for diseases with a similar health impact. Ongoing COVID-19 testing should also strengthen, not threaten, existing services, including multi-pathogen testing, provided by public health laboratories. It is also crucial that point-of-care testing and self-testing approaches for COVID-19 are supportive of surveillance systems, to be able to guide overall response activities. Successes from efforts to integrate COVID-19 testing into routine health service delivery and surveillance systems can also be leveraged to improve the readiness of health systems to respond to future health threats.

Recommended action 1: Countries should assess their national diagnostic strategies in line with WHO diagnostics and surveillance/monitoring guidelines, including with respect to self-testing.
This is to achieve sufficient testing required for the rollout of targeted test-to-treat strategies, surveillance to spot outbreaks and assess new variants, within wider health system priorities. National diagnostic strategies should have flexibility to adapt to the evolving nature of the pandemic and utilize local intelligence to forecast procurement needs.

Recommended action 15: ACT-A and partners should support countries in identifying COVID-19 interventions that could be sustainably maintained long-term and integrated into wider primary health care systems. This will ensure effective implementation of targeted test-to-treat strategies and maintain and expand disease surveillance programs. Interventions identified will require adaptation of policy, guidelines and funding priorities, necessary for test-to-treat to work, as highlighted by the new COVID-19 testing strategy of Africa CDC.

Looking forward: effective uses and approaches to diagnostics for COVID-19 and future health threats

Testing remains an integral part of the COVID-19 response. To achieve scale, sustainability and continued preparedness, the global community, with support from the ACT-A Diagnostics Pillar, must continue partnering to deliver on key diagnostics priorities. This will support containment of positive cases, swiftly identify patients who need medical care and support them to safely isolate. It will also help with identifying opportunities for community support, such as increased vaccination efforts or environmental mitigation, and continue to be a vital part of surveillance and the identification of new variants..[21] Modelling also shows that increasing access to healthcare-provided diagnostic testing at a minimum rate of 1 test per 1,000 people per day is essential for the timely identification of variants. Key use cases for COVID-19 testing are not necessarily interlinked, and can be summarized as follows:

[20] ACT-Accelerator: Quarterly Update Q2: 1 April – 30 June 2022 (who.int).
[21] https://pubmed.ncbi.nlm.nih.gov/35664998.

1. Integrated respiratory pathogen surveillance for SARS-CoV-2 along with RSV and influenza
2. COVID-19 case-detection for clinical management
3. Linkage with genomic surveillance to maintain visibility on the circulation and evolution of SARS-CoV-2
4. Phenotypic assessment of SARS-CoV-2 variants to understand their impact on medical countermeasures, nonpharmaceutical interventions, and public health and social measures

Looking ahead, it will be important to make COVID-19 testing more readily available through decentralized channels (e.g. at lower levels of the healthcare system), including expanding self-testing in both the public and private sectors. Attention also needs to be given to implementing timely test-to-treat strategies for high-risk and vulnerable populations, who would benefit most from treatment options, such as the effective oral antivirals that are now becoming more available.

Key priorities will be to support countries with enhancing laboratory capacity, including strengthening national networks, laboratory workforce and infrastructure, supply chain management, and regulatory frameworks.

Recommended action 16: ACT-A agencies and key partners should support countries in strengthening laboratory capacity, including genomic sequencing. This should contribute to sustainable scale-up of national diagnostic capabilities, and strengthen the ability to identify variants of concern. Furthermore, strengthening of laboratory capacity should foster integrated COVID-19 and pandemic-prone pathogen surveillance, including through a one health approach, at the regional and global level to meet current health needs and increase pandemic preparedness.

As discussed in section 5.1, establishing local production capacity that can produce a variety of tests for which there is local demand will also ensure that countries have timely access to COVID-19 diagnostics when needed. Countries may also require additional financing to secure stockpiles of essential tests to improve equitable access to supplies.

Recommended action 2: To support sufficient supply of COVID-19 treatments and diagnostics for LMICs in the near term, the ACT-A Diagnostic & Therapeutics pillars should develop a plan for optimal use of existing resources and funding, and update funding priorities for the next 6 months. It is important for ACT-A agencies and partners to clearly communicate with countries on the availability of products, the benefits and logistics of test-to-treat and funding channels.

5

THERAPEUTICS IN THE NEXT PHASE OF THE PANDEMIC & PREPARING FOR FUTURE HEALTH THREATS

5.1 Therapeutic regulation, guidance, manufacturing and supply

COVID-19 licensing, regulatory processes and manufacturing: progress to date and challenges

Global efforts by ACT-A agencies, national governments, private sector and other international organizations have led to the development and regulatory approval of oral antivirals for COVID-19, a major milestone in the therapeutic landscape, as this enables effective outpatient treatment of COVID-19. Oral antivirals can prevent hospitalization and save the lives of patients most at risk of developing severe illness, especially where vaccination rates are low.[22] In addition to other therapeutics that have been recommended for different use cases, the oral antivirals nirmatrelvir + ritonavir (Paxlovid) and molnupiravir are now recommended by WHO for patients with mild/moderate COVID-19 at highest risk of hospitalization.[23]

To support the production, supply and regulation of quality-assured therapeutics for COVID-19, WHO has established a number of prequalification pathways for COVID-19 therapeutics. The WHO Prequalification of Medicines Programme (PQP) helps ensure that medicines purchased by international procurement agencies for distribution in LMICs meet acceptable standards of quality, safety and efficacy. Manufacturers can submit their products for prequalification under four categories: innovator products, generic products with bioequivalence data, innovator biotherapeutics and biosimilar products.

As of 20 July 2022, innovator products of nirmatrelvir + ritonavir, remdesivir, molnupiravir and tocilizumab, and generic versions of dexamethasone, have received WHO prequalification. A further 5 finished pharmaceutical products and 16 active pharmaceutical ingredients are under assessment,[24] including generic molnupiravir and, notably, the first generic nirmatrelvir + ritonavir finished pharmaceutical product, which is expected to receive approval before the end of 2022.

In November 2020, 21 generic manufacturers joined MPP in an open pledge committing to making new COVID-19 treatments available. In October 2021, MPP signed a license agreement with Merck Sharp & Dohme to facilitate broad and affordable access to molnupiravir, and in November 2021 a similar agreement was signed with Pfizer for nirmatrelvir + ritonavir. Sublicensing agreements have since been signed with 23 generic manufacturers in 10 countries for molnupiravir and 38 manufacturers in 13 countries for nirmatrelvir + ritonavir. Generic companies are now in the product development stage, with frontrunner products already under assessment by the WHO PQP, and approvals expected before the end of 2022. In addition, MPP provides open access to information on the patent and licensing status of COVID-19 treatments and other selected essential medicines in LMICs through the website "MedsPAL". Another important initiative regarding intellectual property has been the WHO COVID-19 Technology Access Pool (C-TAP), which provides a platform for the sharing of intellectual property and knowledge for therapeutics and diagnostics.

ACT-A agencies are working with Merck Sharp & Dohme and Pfizer to ensure access to originator products until generics become available for LICs and eligible LMICs, as well as in the longer-term for LMICs that will not be able to access generic products.

[22] COVID Collaborative. COVID GAP Accountability Report. Available from: https://covid19gap.org/assets/publications/COVID-GAP-Accountability-Report---May-2022.pdf (accessed 9 August 2022).
[23] World Health Organization. Therapeutics and COVID-19: living guideline. Available from: https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.4 (accessed 9 August 2022).
[24] WHO PQ Status of COVID-10 Medicines and Active Pharmaceutical Ingredients (APIs).

Recommended action 4: Efforts by ACT-A to secure access to originator products, including from Merck Sharp & Dohme & Pfizer in advance of generics coming online are essential for LMICs. Collaboration between industry partners and ACT-A is required to bring the current discussion on equitable access to new therapeutics to a positive conclusion swiftly. In parallel, industry partners to work with countries and health agencies to maximize af-fordability to all LMICs, including upper-middle income countries. Finally, as part of the future medical countermeasures platform, partners and health agencies could examine the role price transparency, tiered pricing, and expansion of licensed generic suppliers play in maximizing affordability and availability for all LMICs.

While significant progress has been made in developing and securing access to COVID-19 therapeutics since the start of the pandemic, considerable challenges persist, including:

- **Affordability**, as a result of high prices on originator products and limited opportunities to negotiate prices.
- **Limited transparency** on price, available volumes, and commercial terms that hinder or delay access.
- **Generic access for all LMICs**, especially upper-middle-income countries, by continuing to expand the geographic coverage of licensing agreements.
- **Insufficient knowledge and materials sharing** to accelerate generic manufacturing.
- **Limited supply in the global market** as bilateral agreements between originators and high-income countries exhaust the majority of supply from originators while generics are not yet on the market[25].
- **Sustainability** of access programmes and donation mechanisms in the long-term.
- **Regulatory barriers**, as WHO prequalification does not automatically translate to marketing authorization in-country; as a result, there can be delays between prequalification and national approval.
- **Rapid development and implementation of clinical guidance** can be challenging to adopt in complex health systems, especially due to lack of capacity. Lack of awareness of new medicines also contributes to this challenge.

Priority areas for the regulation, guidance, manufacturing and supply COVID-19 therapeutics moving forward

The progress made to date in establishing regulatory mechanisms, treatment guidelines, manufacturing capacity and supply of COVID-19 therapeutics needs to be built upon to facilitate equitable access to therapeutics in LMICs. For future therapeutics R&D, stakeholders (e.g. agencies, industry partners) need to ensure alignment on target product profiles, in terms of use cases, regimens, modalities, and affordability. Whilst repurposing of pre-existing therapeutics for oral outpatient treatment of COVID-19 has shown partial success to date, trials are still ongoing. Further exploration of this area could be fruitful, however this should be carefully considered in the context of limited resources and the comparative potential for novel antiviral drug discovery to meet target product profiles. In addition, attention should be given to exploring therapeutics that have predictable delivery schedules, simpler treatment regimens, and efficacy in additional patient groups and standard risk populations[26]. Also important will be products that can be used in combination to minimize drug resistance, and those that have potential for treating respiratory viruses of pandemic potential more broadly.

To mitigate regulatory hurdles, harmonizing and accelerating regulatory processes should be a priority. Stakeholders are encouraged to work with the WHO regulatory team to support ongoing efforts on harmonizing WHO prequalification Emergency Use Listing and approval by stringent regulatory authorities, including for generic products. The WHO Prequalification Programme needs to be strengthened and capacitated to accelerate assessment of pandemic therapeutics. Through use of the WHO Collaborative Registration and other mechanisms, national regulatory approval processes also must be strengthened and accelerated with additional efforts to harmonize regulatory standards, procedures, mutual recognition, and reliance mechanisms. The process for

[25] For example, the first half year of Pfizer's production of nirmatrelvir+ritonavir was committed to HICs.
[26] For which risk is already so low that it is challenging to demonstrate impact.

developing guidance and use cases for therapeutics needs to be expedited, especially to reduce the time between emergency use listings, regulatory approvals and rollout of COVID-19 therapies.

Recommended action 7: In order to ensure diagnostics & treatments are made available in a timely manner, WHO should continue to ramp-up support to countries and regional groups in their efforts to harmonize and expedite the review processes for national registration/approval of generic and originator products. Stringent Regulatory Authorities, play a role, according to existing procedures previously defined.

To address issues of transparency and affordability, industry partners should work with countries and health agencies to maximise affordability. This will enable countries to plan and implement procurement, introduction and scale up of therapeutics accordingly.

Sufficient stocks of therapeutics also need to be available to LMICs, particularly during periods when COVID-19 cases are rising. Industry partners can support this effort by committing to reserve a proportion of real-time production of originator product at an affordable price for LMICs, and by continuing to expand the geographic coverage of licensing agreements. Increasing local manufacturing capacity also needs to be prioritized, so LMICs can produce therapeutics locally and regionally. Technology transfer to manufacturers in LMICs should be facilitated to expedite generic development, including to MPP's sublicensees as needed. In cases where it is appropriate, work can also be undertaken to establish stockpiles for urgent needs. To the extent possible, global health partners and industry should openly communicate about expected demand, noting that accurate demand forecasting is very challenging in the unpredictable and rapidly evolving epidemiological context.

Recommended action 9: To further strengthen pandemic preparedness it is im-portant for WTO, WHO and MPP to build and strengthen strategies for generic licensing and technology transfer for therapeutics, including relevant TRIPS procedures, with input from industry partners and stakeholders. The aim of this is to accelerate access of novel products for all LMICs and increase diversified manufacturing. To further reinforce these interventions, the C-TAP could be expanded into a longer-term project to expand access to tools.

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5.2 Sustainable markets and demand for COVID-19 therapeutics

Lessons learned around sustainable markets and demand for COVID-19 therapeutics: progress to date and challenges

Therapeutics became available to LMICs at a time when the worst impacts of COVID-19 had begun to decline and access to nirmatrelvir + ritonavir remains limited in LMICs. High originator prices, competition for resources, decentralized funding approaches, a lack of transparent pricing and terms, as well as clear means of reaching target patient populations within the treatment window, creates a complex environment for implementation and demand. UNICEF and WHO are actively supporting over 30 countries to access therapeutics, while The Global Fund, the World Bank and Asian Development Bank have reported minimal requests from LMIC for support for therapeutics.

Several barriers are driving this low demand for COVID-19 therapeutics, against a backdrop of competing health priorities. Firstly, awareness of the value and importance of outpatient therapeutics and test-to-treat strategies in many LMICs is low, including among government officials, health workers and communities. Secondly, high prices and a lack of price transparency make it difficult for countries to introduce new products, resulting in expensive therapeutics having a high opportunity cost. As such, only LMICs that negotiated bilaterally with manufacturers have gained access to these products, with few reported deals at the current time. As more affordable generic products enter the market, there may be a shift in demand and public procurement. Thirdly, the use of oral antivirals is highly dependent on linkages to care, as treatment needs to be initiated within the first five days of symptoms. Consequently, a lack of rapid access to diagnostics and linkage to treatment in communities poses an additional barrier for uptake. Fourthly there is a disconnect between WHO prequalification of product and national-level marketing authorizations which can delay uptake at the country level.

In order to support test-to-treat, countries will need to have models and information to support test-to-treat approaches and operate them on a continual basis, including at low levels when need and demand are low. This is important for ongoing engagement of populations and to improve health-seeking behaviours of high-risk patients, but it will be even more important in being prepared for a rapid scale-up, if and when needed.

Establishing a sustainable therapeutics market has been a challenge, as potential demand for oral antivirals is unclear. To address this, WHO's Essential Supplies Forecasting Tool (EFST) has been recently modified to support governments and partners with forecasting the necessary volume of COVID-19 antivirals and other therapeutics, associated diagnostics, and consumables. The EFST has been updated to provide further country support, particularly to accommodate the use of national data to allow for more accurate and supportive plans.

Additionally, clinical guidelines, treatment eligibility and prioritization criteria, staffing norms, an essential medicines list, differentiated delivery strategies within different components of primary care (outpatient clinics, chronic care clinics, TB clinics etc), and more are also needed to support counties to roll out treatments. WHO is supporting this work by providing global clinical guidelines, which can be adapted at the country level, but this work could be accelerated.

A key lesson to take forward is that demand must be created through stronger testing systems, knowledge of and advocacy for safe, effective, and deployable therapies. Special attention should be paid to building community awareness and demand through treatment and test-to-treat literacy, as well as with information about the availability and prices of products.

Mid- to long-term supply and demand projections for COVID-19 therapeutics and potential future threats

Demand for COVID-19 antivirals in 2023 has been estimated using three different models developed by WHO and ACT-A partners. Based on 2022 demand levels and the current epidemiological situation, there is a large discrepancy between estimated demand and the real need for treatments. This is ranging from demand of 31 million treatment courses to an unconstrained[27] need for 223 million treatments in 2023 across 138 eligible LMICs. However, it is likely that actual demand will continue to be much lower than estimated, as reflected in reports by the Therapeutics Pillar and the World Bank and Asia Development Bank.

[27] 'Unconstrained need' is the total number of cases in LMICs in the next 12 months, regardless of a country's testing capacity, interest in the product, or capacity to roll it out.

Based on current models, there is an estimated need of 750 million tests[28] to treat all eligible people (those meeting the high-risk criteria) who would become infected in the next year. Three demand-related bottlenecks were identified and additional models were used to test potential options. The three bottlenecks included:

1. **Health seeking behaviour.** Eligible patients must start treatment within 5 days of symptom onset, but available studies show than less than 50% seek care within this window. Data from peak periods in the pandemic were included, suggesting that advocacy campaigns were already at high levels.
2. **Diagnostic capacity.** Information on diagnostic capacity is inconsistently available across LMICs, particularly information on availability by subnational geographic zones. Rapid tests may be a solution to this issue.
3. **Financing.** High costs of innovator products, decentralized funding support, and unfavourable market dynamics for some products have limited uptake. Imminent availability of generic products may ease this problem.

To identify options for health seeking behaviour bottlenecks, the models first identified a testing rate of 100 tests per population of 100,000 would be required[29] for an effective national test-to-treat programme. Current testing rates, however, are actually much lower in LMICs so additional scenarios were modelled.

The scenario of testing all high-risk people who seek outpatient care for any reason seemed to offer a solution for most countries[30]. The model concluded that people generally seek outpatient care in sufficient numbers to support test-to-treat programmes. Also, those who seek outpatient care are more likely to be people who have risk factors. The approach does not capture people in subnational regions or countries that have low levels of outpatient visits. These settings would require other options, such as voluntary testing at schools, churches, transportation hubs and others gathering places.

As described in the diagnostics section, targeted testing of the population – including through community-based testing and self-testing – could reach sufficient people to make test-to-treat approaches feasible under the current epidemiological situation for COVID-19. Sharing the findings from modelling work on the number of lives that could be saved with COVID-19 therapeutics may also be useful to help countries recognize the value of such treatments and drive demand. Countries should also consider developing rapid scale-up plans to anticipate future spikes in COVID-19 cases, such as those that could result from new variants, efforts that would also likely support testing platforms for other or emerging pathogens. For future pandemic preparedness, consideration should be given to the lessons learned from the COVID-19 pandemic, especially the systems needed to scale up therapeutics and necessary investments in public health platforms.

5.3 Therapeutics in-country delivery and health system approaches

Lessons learned from COVID-19 therapeutic delivery: progress to date and challenges

ACT-A Therapeutics Pillar partners have made important progress in increasing the availability of priority therapeutics in LMICs. Treatments for hospitalized patients, including oxygen, were available before oral antivirals, but were in short supply. This was due to several factors, including but not limited to, low rates of donor-financing early in the pandemic. As the pandemic progressed, and financing increased, ACT-A partners secured supplies of tocilizumab to support countries with unmet needs and signed landmark agreements with medical oxygen suppliers to increase accessibility for LMICs.

As oral outpatient treatments came to market, ACT-A partners have worked to secured supply agreements with producers of originators, Merck Sharp & Dohme and Pfizer, to make treatment courses available to LMICs, with the WHO has established an allocation mechanism for timely and equitable distribution of treatments based on country demand. Access to originator product is critical to catalyse the market, initiate product introduction and preparations for scale up, and supply product until generics are on the market (for those who will be able to access them through the MPP licensing agreements). As described above, there have recently been promising developments in

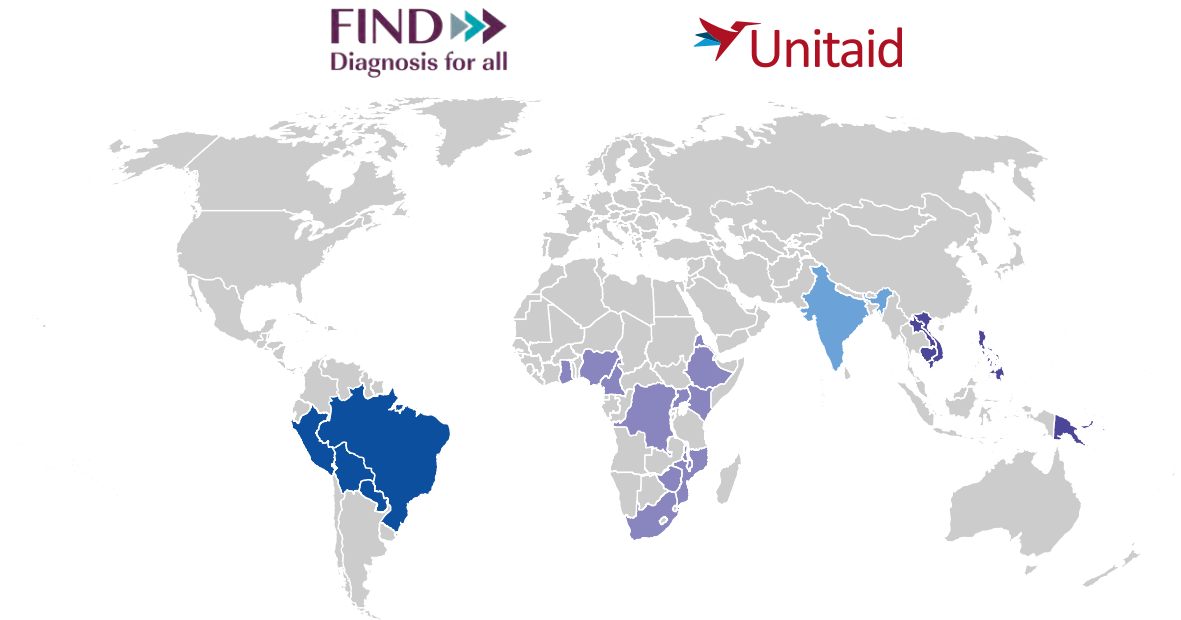
[28] WHO presentation to the Dx/Tx Working Group.
[29] WHO presentation to the Dx/Tx Working Group and a paper pending publication from the University of Amsterdam.
[30] WHO presentation to the Dx/Tx Working Group.

generic oral antivirals. The first generic nirmatrelvir + ritonavir from India-based manufacturer Hetero is now under assessment by WHO PQP, along with three generic molnupiravir products, and could become available for procurement by December 2022 for eligible LMICs. UNICEF has proactively entered into over 10 conditional supply agreements with generic manufacturers for the supply of molnupiravir, and ACT-A partners are actively monitoring progress with generic nirmatrelvir + ritonavir to ensure rapid rollout once WHO prequalification is obtained. The Clinton Health Access Initiative (CHAI) and other partners have secured an agreement with several generic producers of nirmatrelvir + ritonavir to sell for less than $25 per course of treatment, conditioned on sufficient volumes.[31]

In anticipation of oral outpatient treatments coming to market and to accelerate the uptake of lifesaving testing and treatment solutions as they became a reality, ACT-A partners launched early test-and-treat pilot programmes in 2021. FIND and Unitaid granted US$ 50 million to seven implementing partners to support test-and-treat pilot initiatives across 22 countries (Figure 5) focused on:

- evidence generation on acceptability, feasibility and effectiveness of COVID-19 ser-vices and delivery models;
- supply chain strengthening and catalytic procurement;
- creating an enabling environment for policy and guideline development;
- demand creation; and
- effective transition and scale-up through linkages with national programmes and addi-tional funding sources.

Figure 5. Location of the test-and-treat pilot initiatives supported by FIND and Unitaid



[31] https://unitaid.org/news-blog/unitaid-welcomes-new-agreements-from-chai-to-accelerate-access-to-affordable-covid-19-antiviral-nirmatrelvir-ritonavir-in-low-and-middle-income-countries/#en.

Although these advances represent important milestones in the COVID-19 response, challenges in effectively rolling out therapeutics remain. Barriers hindering the introduction of oral antivirals include: i) limited access to the products themselves and a complex and evolving landscape of treatments and costs; ii) low diagnostic use and low risk perception; and iii) limited community engagement.

While the pilots have laid the groundwork to enable rollout of effective test-to-treat strategies, they have also demonstrated that affordable treatments, full price transparency, and clarity on available funding and sustainability is instrumental for catalysing therapeutic demand and uptake.

Leveraging lessons learned from test-to-treat pilots

Programme implementors are testing different models to identify high-risk populations and integrate COVID-19 services into existing clinical pathways, while meaningfully engaging civil society and communities, and investing in country readiness to respond to future health emergencies. These pilots are generating valuable lessons on how to best support country-led test-and-treat initiatives, to which ACT-A partners have swiftly responded.

i. Coordinated support and linkages to larger scale financing are required. In May 2022, ACT-A partners (Unitaid, the Global Fund, USAID) committed an additional USD 125m to expand test-and-treat approaches, working together with WHO/WHE. The Therapeutics Pillar established a Coordination Group (which includes the Bill & Melinda Gates Foundation, Clinton Health Access Initiative, Duke, the Global Fund, UNICEF, FIND, Unitaid, USAID, and WHO Health Emergencies Programme/Health Systems and Response Connector) to coordinate the expansion of test-and-treat pro-jects, ensuring the complementarity of programmes and linking pilots to larger-scale financing and procurement, via the Global Fund's COVID-19 Response Mechanism, UNICEF, and the WHO Partners Platform. These projects will leverage the C-19 Clinical Care Readiness framework & planning tool currently in development by WHO, to help countries assess their clinical capacities and readiness. The tool will also generate tailored action plans for countries, based on inputted information, however more work is needed to ensure this support and linkages are sustained.

ii. Prioritization of long-term readiness and preparedness. Identifying high-risk patients is resource-intensive, complex and requires adaptations to clinical pathways. With the support of test-and-treat project implementors, countries are adapting to the current epidemiological environment by piloting different models to identify high-risk populations and integrate COVID-19 test-and-treat into existing clinical pathways (e.g. elder health services, noncommunicable diseases, HIV, tuberculosis). Through tailored approaches specific to their context, countries are enhancing their ability to respond to future waves and to provide treatment in an endemic environment. Part of the addi-tional US$ 125 million in funding will be used to expand the support for implementa-tion of these models.

iii. Meaningful community engagement and test-to-treat health literacy. Local communities and civil society organizations play a critical role in health literacy, raising awareness for test-to-treat approaches. Engagement of communities is essential to make test-to-treat strategies successful. FIND and Unitaid are providing an additional US$ 2 million to support 21 organizations in 19 countries to develop and implement advocacy strategies that will improve uptake of test-to-treat approaches to combat COVID-19. A community of practice for these partners has also been established to facilitate shared learnings and collaboration. Although this has been successful, more work is needed to generate and sustain meaningful community engagement.

Recommended action 6: Building on emerging evidence from COVID-19 test to treat pilots, countries should consider integrating sustainable testing & treatment strategies into primary healthcare and community level systems. These strategies should also aim to increase community test to treat health literacy and engagement.

Future considerations for therapeutic delivery and addressing health system challenges for the COVID-19 and future pandemic preparedness, readiness and response

It is essential that the advancements achieved during COVID-19 are leveraged and expanded upon to strengthen health system capacity for pandemic preparedness, readiness, and response. The progress made in developing COVID-19 therapeutics has the potential to advance the therapeutic landscape for other health threats. In particular, breakthroughs in oral antivirals for COVID-19 could help pave the way to develop antivirals that are effective for the treatment of other respiratory viruses of pandemic potential. This work could be undertaken and facilitated by interested countries, with funding derived from these stakeholders.

To advance the therapeutic landscape for COVID-19, key areas for further exploration include novel combination therapies, simpler treatment regimens, and therapeutics that are safe and effective for broader patient populations. As the therapeutics landscape continues to evolve, it is essential to plan for equitable access to products early on as they emerge. Early engagement and cooperation between the biopharmaceutical industry, global health agencies and countries is fundamental to effective, global pandemic preparedness and response.

Moreover, it will be critical to continue efforts to diversify therapeutic manufacturing capacity, particularly in LMICs, to help strengthen regional health security and pandemic preparedness. Building local manufacturing capacity can help LMICs overcome supply chain issues and export bans and can have wider effects on economic development and resilience. Support to diversify manufacturing capacity will need to have high-level political and resource buy-in, supported by both governments and global partners. As countries transition to an endemic COVID-19 response, countries and supporting partners should continue to work towards integrating COVID-19 testing and treatment into routine health service delivery systems for sustainable, long-term management of COVID-19.

Recommended action 11: G20, interested countries, and regional groups, with support from WHO, Unitaid, MPP and MDBs, to conduct market assessments, evaluate feasi-bility and create sustainable funding streams to establish regional therapeutics manufacturing hubs. These can draw lessons from, or in tandem with, the network of manufacturers pro-ducing generic COVID-19 antivirals, mRNA Technology Transfer hub, the GlobalTraining Hub for Biomanufacturing sponsored by WHO, and the G20 initiative on global manufacturing and research hub to support diversified, sustainable local manufacturing in underserved regions.

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WAY FORWARD: RECOMMENDED ACTIONS AND SUGGESTIONS FOR BUILDING RESILIENT DIAGNOSTIC AND THERAPEUTICS SYSTEMS

This paper has been produced through a highly collaborative process, engaging key stakeholders across relevant healthcare domains and country settings. The recommended actions are designed to serve as a handover product to various political fora and highlight challenges they can help solve. For this reason, each recommended action has an owner and clear actions ascribed to each owner. These recommended actions and their implementation should be reviewed by the G20 and G7 health tracks, and the ACT-Accelerator Facilitation Council, to ensure progress is achieved in meeting diagnostic and treatment goals.

The G20 has a crucial role to play here, having already taken action to integrate these lessons, including through the Financial Intermediary Fund (FIF) for Pandemic Preparedness, Prevention, and Response; and ii) Developing Finance and Health coordination arrangements for Pandemic Preparedness, Prevention, and Response. This report is also intended to support these recent developments.

It must be noted that the pandemic is not over and issues of access to COVID-19 therapeutics and diagnostics must be addressed. For these actions to have maximum impact, it is vital that countries fully fund current and future PPR needs. Whilst acknowledging the focus of this report is on COVID-19, it is now essential that these lessons are integrated into health and regulatory systems to prepare for future pandemic threats. Diagnostics and therapeutics are a key component of pandemic preparedness and response, both now and in the future and ensuring that all interventions have the adequate resources will influence our success in protecting human health.

Recommended action 14: G20, donor countries, and MDBs to work towards fully funding mechanisms intended for pandemic preparedness (e.g. PPR FIF) and response (e.g. Future Countermeasure Platform) and do it together with co-investments from implementing countries. Donor countries should consider striking the right balance and not divert current funding flows from existing global health priorities, and instead contribute additional funding for PPR. This will contribute to increased national health security for all countries.

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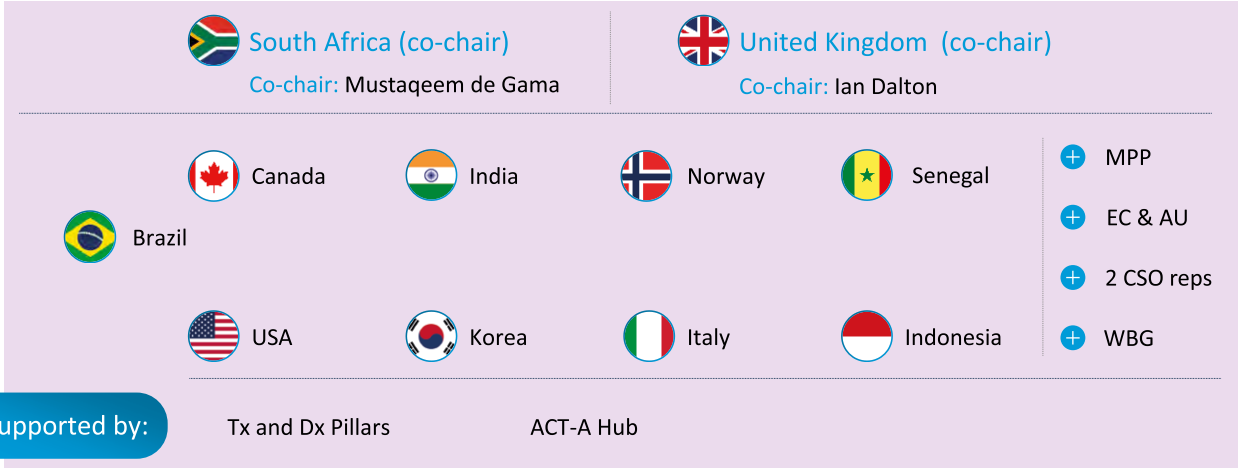
ANNEX

Figure 6: Membership of Diagnostics and Therapeutics Working Group



List of bilateral discussion participants

- Brazil
- Korea
- Canada
- ACT-A hub
- India
- Norway
- USA
- IFPMA
- MPP
- CSO reps
- Abbott
- DIATROPIX
- World Bank
- WHO
- Indonesia

Summary of Findings for COVID-19 Access Survey conducted by the ACT-A Diagnostics Pillar

Results from a COVID-19 Diagnostics Access Survey conducted by the ACT-A Diagnostics Pillar across 22 countries with over 5,000 respondents completed in April and May of 2022 found broad support for COVID-19 testing among communities. Highlights from the survey are highlighted below[32]:

- Despite the current climate, 82% of individuals reported still value testing and believe that COVID testing is important to protect themselves and their communities
- The majority (81%) of respondents stated they would be more willing to get tested if linked to treatment
- Affordability is a key consideration – 65% of respondents reported being more willing to get tested if it were free
- Among respondents, 64% reported wanting to get tested for COVID-19 in the past month (April and May 2022). Key reasons for wanting to get tested were because of COVID-19 symptoms (39%), work requirements (29%), exposure to COVID-19 (25%), and travel requirements (20%).

Actions taken by Diagnostics Pillar to accelerate supply of diagnostics

Overview of Diagnostics Consortium

As part of the ACT-A Diagnostics Pillar, in early 2020, the United Nations Crisis Management Team established a COVID-19 supply chain system (CSCS) to coordinate the procurement and distribution of essential supplies for countries' COVID-19 responses. The CSCS subsequently established a Diagnostics Purchasing Consortium to address the supply chain issues early in the pandemic, where essential testing supplies were retained-in or diverted to high-income countries. The Diagnostics Consortium improved coordination across agencies and partners to support access to diagnostics in LMICs by approaching the market with a united voice and limiting competition in the diagnostics market. In addition, the Consortium has worked to secure product volumes while reducing the inefficient and inequitable allocation of limited supplies. All activities and decisions made by the Consortium are based on the principles of equity, transparency, inclusiveness, consistency, and accountability.

Actions taken by Diagnostics pillar to increase diagnostics demand

In order to generate this greater demand for testing, approaches could be taken to ensure testing is more accessible. To mitigate accessibility demand challenges, the Diagnostics Pillar is currently undertaking the following efforts:

- Scaling access and improving equity in countries through strengthening lab systems, including expanding decentralized models of care (i.e., primary health care facilities) with a focus on providing a minimum package of tests with COVID-19 and integrating COVID-19 diagnostics into the larger health system (i.e., bi-directional screening).
- Focusing on vulnerable and hard to reach populations through advocacy efforts, poli-cy shifts, and prioritization of funds.
- Scaling self-testing both in the private and public sector to ensure communities that re-quire, and value testing can test when needed.
- Better linking testing and treatment through packaging affordable testing with treatment services as part of test-and-treat programmes.

[32] COVID-19 Access to Testing survey conducted in April and May 2022 to better assess how the accessibility, feasibility, affordability, and acceptability of COVID-19 testing. Survey included >5000 respondents from 22 countries.

ACT-A co-convening partners:

Working with goverments, civil society and industry