



# COMMUNITY-BASED COVID-19 TEST-AND-TREAT

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## LEAD

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## Introduction

As the COVID-19 pandemic evolves, so must our responses. This requires us to draw on relevant, evidence-based strategies to prevent infections and deaths and enable our societies to function as they used to.

One such strategy is test-and-treat, which was introduced more than a decade ago to respond to HIV and has been hugely effective. The concept is simple: when someone is diagnosed, they are linked to care and offered immediate treatment if appropriate.

This approach has transformed the HIV epidemic – and it can transform the COVID-19 epidemic too.

Antiviral COVID-19 treatments now exist in pill or tablet form that can be cheaply produced and scaled up by a wide base of generic manufacturers and other therapies are likely.<sup>1</sup> These antivirals are easy to store and can be administered outside a hospital setting and also combined with outpatient medicines to reduce overactivation of the immune system. **But such treatment must be taken early, usually within five days of symptom onset. This makes effective testing critical.**

<sup>1</sup> Currently, these are the antiviral therapies Paxlovid and Molnupiravir, which are currently aimed at those most likely to become severely ill with COVID-19, namely older people and people with underlying health risks, such as obesity, diabetes, heart disease, and immuno-suppression. Molnupiravir is not advised for people who are pregnant or intending to get pregnant. Paxlovid is not advised for people taking the HIV antiretroviral Ritonavir. There are already some promising other candidates including oral immunomodulatory or anti-inflammatory therapies (such as fluvoxamine).

If people can access these treatments immediately after testing, they are less likely to get severely ill and will be infectious for a shorter period of time. As a result, these types of treatments are likely to reduce transmission, especially when accompanied by isolation and contact tracing. They might also reduce the risk of new mutations occurring, and the incidence and/or severity of long COVID.

Let us be clear: treatment is not a substitute for vaccination. But it is potentially lifesaving for people who are unable or unwilling to access vaccines or experience breakthrough infections. Given the vaccine apartheid that exists, access to community-based testing and immediate treatment is urgent.

This advocacy brief outlines civil society's vision for a community-based test-and-treat COVID-19 strategy and the steps needed to get there.

## HOW TO SCALE-UP AND INCREASE ACCESS TO COMMUNITY-BASED TESTING

There is no doubt that testing will need to be scaled-up to implement an effective test-and-treat strategy. But to do this, multiple barriers must be addressed.

Rapid antigen diagnostic tests give reasonably accurate results, especially true positives, in 15 minutes. But in low- and middle-income countries (LMICs), access to these tests, and uptake when available, is currently low.

It is highly likely that demand for community-based testing and self-testing will significantly increase when the new COVID treatments become widely available. **Making people aware of the need to test – and to test quickly, when symptoms appear, so that treatment has the best chance of working – is key to increasing uptake** (see the Health Literacy box).

**To broaden access, rapid COVID-19 tests should be freely available at the community or facility level**, not only in primary healthcare facilities but more broadly through community-based testing carried out by community health workers, peers, school nurses and others.



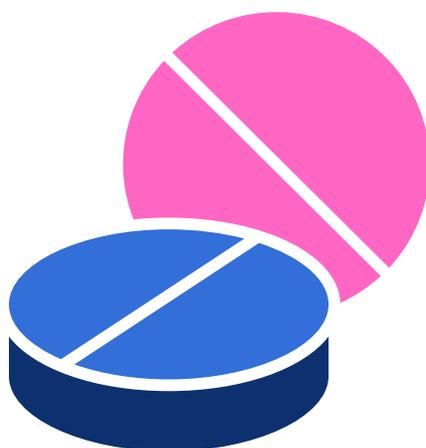
**This should be supplemented with self-testing.** Rapid tests have well-designed instructions and are easy to use. Self-testing is effectively used for pregnancy, HIV, malaria, HCV, and even flu – and people in high-income countries are already using rapid tests to self-test for COVID. The idea that people in LMICs will not know how to self-test, or will not respond appropriately to positive test results, is frankly insulting.

**Expanding testing supply.** Urgent efforts are needed to expand and diversify the global supply of rapid tests. It requires resource support, tech transfer, technical support, quicker regulatory approval, strengthened supply chains, and improved distribution channels.

**Reducing costs.** Both the price per test and testing costs borne by users are too high. Subsidising testing costs is needed. This will undoubtedly cost governments, but the payoff in terms of reduced health systems costs and decreased economic and social disruption will more than compensate.

**The World Health Organization must speed up its testing guidance and regulatory processes.** Still, WHO has not issued clear guidance on community-based- and self-testing, and is currently engaged in a lengthy, evidence-gathering process to inform such guidance. This needs to be challenged: guidance is needed now. WHO must also speed up emergency use listing of rapid diagnostic tests and facilitate faster national regulatory approval.

**Connecting testing to care.** People who test positive should be immediately connected to care so their individual clinical need can be further assessed. This is crucial for ensuring people can start treatment within the five-day window and according to treatment priorities. In some settings, community health workers could directly provide treatment, following strict screening, reporting, and treatment protocols.



# HOW TO MAKE TREATMENT WIDELY AVAILABLE

**Expanding manufacturing capacity.** Merck (which produces Molnupiravir) and Pfizer (which produces Paxlovid) have taken steps to expand their manufacturing capacity. They have also granted generic licenses so that other manufacturers can supply certain markets. But these generic licences do not cover enough LMICs. Merck and Pfizer retain exclusive supply rights to just under half of the global population,<sup>2</sup> and may not be able to supply enough treatments to meet demand, at least in the short term.<sup>3</sup> Activists are already mobilising around the idea of a defiance campaign to support independent producers and excluded under the TRIPS compulsory licensing procedures [countries](#). But the ACT-Accelerator, particularly Unitaid, could play its part by supporting coordinated compulsory licensing

**Reducing treatment costs:** Merck and Pfizer are free to set the price of their COVID-19 treatments.<sup>4</sup> To reduce costs, generic manufacturers that can operate in all LMICs should be supported to enter the market and compete against one another. Although production costs for these antivirals is still being decided, adjusted manufacturing and supply chains, along with economies-of-scale, could bring costs to below \$10-20 per course of treatment.

**Speeding up regulatory approval for medicines.** Emergency use authorisations from regulatory authorities and emergency use listing from WHO must be speeded up to ensure these new COVID treatments can be widely available.

**Estimating demand.** This is complicated because (i) the number of confirmed infections is likely to be a fraction of actual infections, especially in Africa and other places where testing rates are currently low (ii) treatment eligibility may change: antivirals access is currently restricted to people who are likely to get severely ill or die from COVID. But trials are happening on people with normal health risks and those who have been vaccinated. If regulatory authorities and/or WHO broaden access, demand could rise steeply.

Community-based service delivery. To be effective, COVID treatment must be available in primary healthcare facilities and community settings, alongside testing and ideally integrated with other service delivery.

<sup>2</sup>Merck's license with the Medicines Patent Pool covers 105 countries. This leaves more than 30 LMICs outside the license, which equates to 46% of the global population. Pfizer's license with the MPP covers 95 countries, and this leaves 47% of the global population outside.

<sup>3</sup>Both companies can enter into contract manufacturing agreements, including within their MPP licensees, but supply might still be less than demand, depending on how broad patient-use authorisation turns out to be.

<sup>4</sup>One troubling signal on treatment costs is that Merck charged Thailand \$300 for a course of Molnupiravir. This is disproportionately high, given that it is approximately 40% of what it first charged the US.

# HEALTH LITERACY

For test-and-treat to succeed, people and communities must be provided with culturally-tailored information on the importance of:

- (1) Regular testing, and early testing when COVID symptoms first appear (the 5-day window)
- (2) Reporting test results, especially positive results
- (3) Isolating and cooperating with contact tracing efforts
- (3) Connecting to care as quickly as possible to be assessed for treatment
- (4) Getting immediate access to COVID-19 treatments if eligible
- (5) Taking treatment as directed and completing the course to reduce the risk of resistance

This must be accompanied by training for all those involved in delivering test-and-treat.



## TESTING



## CONNECTION TO CARE



## TREATMENT

# RECOMMENDATIONS

## WHO

- Immediately develop clear use case guidance for community-based and self/home Ag RDT testing as the entry phase of T&T
- Accelerate WHO PQ and EUL of Ag RDTs, including self-tests
- Develop a test-and-treat framework emphasizing the importance of symptom awareness and early testing, isolation and other public health response for people testing positive, community-based connection to care for assessment of treatment eligibility and appropriateness, and rapid provision of therapeutics along with outpatient monitoring.
- Update Living Treatment Guidance to include proven antivirals and immune modulators and appropriate combination regimens.
- Establish clinical priorities in access to therapeutics
- Develop test-and-treat health literacy resources that emphasize the benefits of test-and-treat as well as any risks/uncertainties.

## FIND/Global Fund/UNICEF

- Better quantify need for Ag RDTs in a test-and-treat strategy, one that serves patients according to different treatment priorities.
- Accelerate development of more accurate and easy-to-use Ag RDTs.
- Expand the manufacturing base of qualified Ag RDT producers, including in LMICs and including through licensing and technology transfer.
- Pursue market strategies to reduce the costs to \$1 or less.
- Support community-based and patient-based campaigns for test-and-treat health literacy.
- Secure resources for expanded procurement of Ag RDTs.

## Donors

- Commit financial and technical support resources to support the scale-up of test-and-treat programming and the procurement of adequate supplies of tests and therapies.

## Wellcome Trust/Unitaid

- Encourage continued development of effective and simplified outpatient oral therapies and appropriate combination regimens to address different stages of outpatient disease and to reduce risk of resistance.
- Support expansion of the number of generic producers of outpatient therapies and their market entry.
- Support the expansion of the number of LMICs covered by originator voluntary licenses, including those already negotiated with the MPP by Pfizer and Merck.
- Support accelerated emergency use authorization/listing and regulatory approval of outpatient therapeutics, including at the national level.
- Secure commitments from Pfizer, Merck, and other qualified anti-viral manufacturers to meet immediate 2022 demand in LMICs.
- Support community-based and patient-based campaigns for test-and-treat health literacy.
- Secure resources for expanded procurement of outpatient therapeutics.

## Countries

- Adopt test-and-treat strategies at the country level.
- Support test-and-treat training for the health workforce and its community implementors, including community health workers and peer supporters. Treatment training should emphasize treatment priorities, contraindications, and treatment monitoring.
- Support development and dissemination of culturally and language appropriate test-and-treat health literacy resources for individuals and communities.
- Scale-up broad community-based, facility, and self-testing.
- Provide for immediate connection to care for those who test positive for assessment of eligibility for treatment.
- Ensure no-cost access to tests and recommended therapeutics.

