

30 January 2022

To: Dr. Tedros Adhanom Ghebreyesus, Director General, WHO

Open Letter to the World Health Organisation

Re: COVID Won't Wait—The Urgent Need for Access to Self-Testing

Dear Dr. Tedros,

We are writing as concerned members of civil society, clinicians, advocates, and communities affected by COVID-19, to urge the World Health Organisation (WHO) to rapidly recommend self-testing for COVID-19 and request your leadership in more broadly improving access to diagnostics for COVID-19. **We specifically call on WHO to expedite the finalisation and release of a self-testing guideline for SARS-CoV-2 infection that includes a strong recommendation in favour of widespread access to self-testing. We understand that the Guideline Development Process is ongoing but emphasise the urgency of making an immediate statement in favour of this important tool for COVID-19 control in the interim.**ⁱ

Although low- and middle-income countries (LMICs) represent nearly 85% of the global population, only 40% of tests for COVID-19 have been used in LMICs.ⁱⁱ As a result, the reported average daily testing rate of high-income countries is, per capita, nearly 10 times higher than that of middle-income countries and close to 100 times higher than that of low-income countries.ⁱⁱⁱ In Africa alone, 85% of COVID-19 infections are going undetected according to WHO AFRO.^{iv} This inequity in access to the diagnostic tools that trigger life-saving individual and public health measures is part of the same 'medical apartheid' that has plagued the rollout of COVID-19 vaccines.

Below are three major reasons that access to diagnostics broadly, and rapid antigen detection testing (RADTs) for self-testing in particular, needs to be urgently accelerated:

1. Individuals have a fundamental right to 'know their status'

Instead of learning the lessons of HIV and centering the fundamental right of people to know their own status, in its interim guidance and other statements, WHO has placed undue weight on concerns that self-testing will lead to more false negatives, unreported results, inferior disease surveillance, and reduced opportunities for facilitating entry into case management. This risk averse approach ignores the lessons of HIV on the importance of empowering individuals with health status knowledge as well as the harm to national responses and individual health that can result from exaggerated caution. In that case, a reluctance to recommend self-testing even after treatments became available and tests became more accurate continued due to a comparable insistence from WHO and national authorities on an overwhelming quantity of evidence to counter concerns such as the need to link people to care and confirmatory testing.^{v vi vii}

Instead of bluntly recommending against self-testing, WHO should address its specific concerns directly with complementary recommendations that ensure countries pair access to self-tests with knowledge that empowers people to properly collect their sample, notify positive test results to public health bodies, and understand the risk of false negatives. Additionally, WHO should recommend that health authorities incentivise people to report their results and engage with the health system by offering supportive care, treatment options, and PPE to all who do. With COVID-19 self-testing, the complexity of addressing the risk of false negatives and other concerns cannot just be met with silence, it has to be met with nuanced public health messaging that improves access to health knowledge while mitigating its risks.^{viii}

2. Self-testing is critical to prevent onward transmission and to empower individuals to protect their families and communities

Self-testing has the capacity of greatly expanding the number of people who know that they have contracted COVID-19 and are likely to be infectious to others. Not only will expanded access to self-tests help ensure that more people are tested but it will also allow more people to be isolated while infectious and, thereby, safeguard family members, work colleagues, and vulnerable members of the community. Access to self-tests promises particularly significant benefits in resource-limited and geographically remote settings that lack sufficient PCR testing capacity. Even in areas with PCR testing capacity, self-testing may increase uptake among marginalised populations less able or likely to engage with the health system because of stigma, discrimination or unaffordability.

The benefits of self-tests can be seen in a range of high-income countries that have made RADTs widely available: where self-testing has been a mainstay of the response to COVID-19, individuals and households have been able protect themselves and schools, businesses and community organisations have been able to make informed decisions about opening, gathering and operating. Anecdotal evidence indicates that people in high-income countries manage their concern for infecting others by combining self-testing with self-isolation and similar self-initiated public health strategies are likely to be pursued by people in LMICs.^{ix} Testing literacy will promote isolation if it includes information about (1) reporting positive tests, (2) understanding symptoms of COVID-19 infection and their progression, (3) understanding the personal age and health factors that increase the risk of worse outcomes, (4) connecting to care and having health status ascertained, and (5) understanding the protocols and time periods for isolation, masking, and possibly re-testing.

3. Self-testing is a necessary tool to enable rapid linkage to care and initiation of outpatient treatment to prevent hospitalisation and death, especially among those at high risk of disease progression

With ‘test and treat’ strategies for COVID-19 further demonstrating the benefit of knowledge of status in high-income countries, the lethal and immoral consequences of access inequities seen with vaccines is recurring in the case of diagnostics. Just as we reject vaccine inequity, we cannot silently tolerate a situation in which access to widespread testing, along with linkage to care and treatment, becomes the norm in the populations of wealthier countries, while diagnostic access—and its related benefits—are missing in LMICs.

Access to care and treatment, including promising oral antivirals and immune suppressants, will falter without more widespread community-based and household level testing, which could be greatly facilitated by provision of self-testing.^x Testing—which should be a gateway to COVID-19 care and treatment—is instead a bottleneck—and this difficulty is exacerbated further when testing strategies do not extend to the household level through self-testing.

In order for outpatient therapies to be effective in reducing the risk of disease progression, hospitalisation, and death, we need widespread testing including self-testing and linkage to immediate treatment. At the same time, the availability of outpatient and inpatient treatment options, will be motivators for testing and, in this way, people can be provided access to COVID-19 clinical pathways. Because of this, testing and treatment strategies have to be seen as intertwined and mutually reinforcing with self-testing as critical to an effective testing strategy. In the same way that diagnosis precedes treatment, effective treatment strategies need to be underpinned by evidence-based testing strategies.

WHO's forthcoming guideline on COVID-19 diagnostics should recommend self-tests as a screening strategy on the basis of emerging yet strong evidence of the benefit to individual, community and population health and rights.^{xi} It is, in sum, increasingly clear WHO's interim position underweighted the potential of self-testing to increase the accessibility and timeliness of diagnosis for COVID-19 with this contributing to reduced transmission of the virus.

In the absence of urgent action by WHO, national health systems and individual people have already begun to use and rely on self-testing to increase national diagnostic capacity and to manage individual risk as a risk management tool for avoiding exposing others. No health systems should be waiting for WHO to overcome its conservative approach to the evidence. Accordingly, even in the absence of WHO guidance, countries need to act—in particular, if countries are buying antivirals, they need to ensure they have a testing strategy able to support their treatment strategy.

By acting with urgency now, WHO can help ensure supportive public health messaging and complementary strategies are properly designed and emphasised by national health authorities recommending self-testing and implementing programmes to make RADTs accessible. It will also allow the organisation to, by acting with ACT-A, provide crucially needed leadership for ensuring LMICs necessary conditions of equitable access on affordable terms to quality assured RADTs regardless of country income and by all populations within countries.

Any WHO guideline or other update to its interim guidance should be followed by rapid WHO pre-qualified or emergency use listing of quality assured self-tests. If this is not feasible, the guideline or other guidance should recommend that countries consider using self-tests approved by other stringent regulatory authorities. With the current timeline - it may well be that global health agencies and procurers will only be able to deploy self-tests in 2023. This is too late.

Thank you for considering our concerns and requests.

Sincerely,

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African Services Committee, United States

Aid for AIDS, Peru

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Aportes para el Desarrollo Humano, Peru

Arms To Lean On (ATLO), Kenya

Asoc agua Buena, Costa Rica

Asociación Asiris, Ecuador

Asociacion CCEFIRO, Peru

Asociación Civil Nupaz, Venezuela
 Asociación Construyendo Caminos de Esperanza frente a la injusticia, el rechazo y el olvido
 CCEFIRO, Peru
 Asociación Esperanza Viva en pro de personas con VIH en pobreza y pobreza extrema del territorio
 nacional CR, Costa Rica
 Asociación MANU, Costa Rica
 Asociación para la Prevención y Estudio del VIH/Sida, Guatemala
 Asociación por la Vida (ASOVIDA), Venezuela
 Asociación Viviendo Positivamente, Panama
 Asociación Aspidh Arcoiris Trans (ASPIDH), El Salvador
 Association des Femmes de l'Europe Méridionale, France
 Association for Protection of Human Rights and Community Development (APHRICOD), Nigeria
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 Foundation for Integrative AIDS Research (FIAR), United States
 Fundación Ecuatoriana Equidad, Ecuador
 Fundación Hábitat Verde, Bolivia
 Fundación por una sociedad empoderada, Argentina
 Fundación Mavid Carabobo, Venezuela
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 OPENMUJER, Venezuela
 Organic Health Care Service Ethiopian Residents Charity, Ethiopia
 Oxfam
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 Prevention Access Campaign, United States
 Proteja Amazonia, Brazil
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ⁱ <https://speakingofmedicine.plos.org/2022/01/24/covid-testing-equity-a-reflection-based-on-1-5-years-in-the-act-accelerator/>

ⁱⁱ <https://www.finddx.org/covid-19/test-tracker/>

ⁱⁱⁱ <https://www.finddx.org/covid-19/test-tracker/>

^{iv} [Six in seven COVID-19 infections go undetected in Africa | WHO | Regional Office for Africa](#)

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- ^v Julie E. Meyers, Wafaa M. El-Sadr, Allison Zerbe and Bernard M. Branson. 2013. Rapid HIV self-testing: long in coming but opportunities beckon. *AIDS* 27: 1687-1695.
- ^{vi} Sue Napierala Mavedzenge, Rachel Baggaley, and Elizabeth L. Corbett. 2013. A Review of Self-Testing for HIV: Research and Policy Priorities in a New Era of HIV Prevention. *Clinical Infectious Disease* 57: 126-138.
- ^{vii} Janne Krause, Friederike Subklew-Sehume, Chris Kenyon and Robert Colebunders. 2013. [Acceptability of HIV self-testing: a systematic literature review](#). *BMC Public Health* 13: 735.
- ^{viii} Lisa J. Krüger, et al. 2022. [Accuracy and ease-of-use of seven point-of-care SARS-CoV-2 antigen-detecting tests: A multi-centre clinical evaluation](#). *eBioMedicine* 75, 103774, ISSN 2352-3964, <https://doi.org/10.1016/j.ebiom.2021.103774>.
- ^{ix} <https://academic.oup.com/cid/article/71/12/3174/5866094?login=true>
- ^x WHO. 2021. Antigen-detection in the diagnosis of SARS-CoV-2 infection: Interim guidance.
- ^{xi} Paraskevi Goggolidou, et al. 2021. Self-Testing as an Invaluable Tool in Fighting the COVID-19 Pandemic. *Journal of Primary Care & Community Health*, 12. <https://doi.org/10.1177/2150132721104778>.