

COVID-19 testing

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Key points

- WHO recommends that its Member States continue to offer testing for COVID-19 in line with
 three main objectives as part of COVID-19 management and control: reduce morbidity and
 mortality through linkage to prompt care and treatment, track the evolution of the SARS-CoV-2
 virus and reduce the risk of emergence and spread of new SARS-CoV-2 variants that could
 cause upsurges of cases threatening health system capacities.
- The WHO Director-General's standing recommendations for COVID-19 encourage countries to support and enhance equitable access to safe, effective and quality-assured COVID-19 diagnostics for all communities, including through mechanisms such as resource mobilization and technology transfer, as appropriate.
- Testing of suspected cases early in the disease course–especially among people at increased risk for hospitalization or severe COVID-19–facilitates access to supportive care and COVID-19 therapeutics.
- Testing is a critical tool for tracking the evolution of the epidemic and the SARS-CoV-2 by submitting data on sentinel, wastewater and animal surveillance to SARS-CoV-2 surveillance systems.
- COVID-19 testing and reporting strategies should be linked to genomic surveillance and phenotypic assessment.
- As countries shift to comprehensive, long-term management of COVID-19 within broader disease prevention and control programmes, they should remain prepared to rapidly expand testing in the event of surges caused by new SARS-CoV-2 variants that may strain health system capacities.

Introduction

Nearly five years since the first SARS-CoV-2 infections were reported, the global COVID-19 situation has changed substantially. With widespread immunity from both vaccination and prior infection, currently circulating variants are now associated with lower severe disease rates and fewer hospitalizations. As a result, most countries have lifted public health and social measures and have moved to end their national COVID-19 emergencies. In this context, many around the world wish to move on and forget their experiences with the COVID-19 pandemic.

COVID-19 continues to circulate widely, however, presenting significant challenges to health systems worldwide. Tens of thousands of people are infected or re-infected with SARS-CoV-2 each week. From mid-September to mid-October 2024, WHO received reports of more than 296 000 confirmed cases of COVID-19 (see the WHO COVID-19 Dashboard). This figure is certainly an underestimate, as there has been a persistent decline in COVID-19 surveillance and reporting, and wastewater surveillance indicates that circulation is 2–20 times higher than the case numbers that are reported.

It is vital that countries sustain the public health response to COVID-19 amid ongoing illness and death and the emergence of SARS-CoV-2 variants, adapting it to the requirements based on the current COVID-19 situation and risk. Countries are increasingly balancing COVID-19 prevention and response activities with other social and economic priorities.

On 9 August 2023, the WHO Director-General of published <u>standing recommendations to support ongoing efforts for the prevention and control of COVID-19</u> in accordance with provisions of Articles 16 to 18, and 50 to 53 of the International Health Regulations (2005) (IHR). These standing recommendations are in effect for all States Parties (WHO Member States plus Liechtenstein and the Holy See) until 30 April 2025 (1).

The updated WHO <u>Strategic Preparedness and Response plan for 2023-2025</u> is designed to help countries end the emergency phase of the pandemic and shift to comprehensive, long-term management of COVID-19 within broader disease prevention and control programmes.

As countries continue to strengthen COVID-19 programmes within their public health systems, two objectives remain critical: 1) reducing the risk of emergence of and controlling the circulation of SARS-CoV-2 variants with increased growth rates and immune escape, with a particular focus on reducing infection in high-risk and vulnerable populations; and 2) diagnosing and treating COVID-19 to reduce mortality, acute severe disease morbidity and long-term sequelae.

Purpose of this document

In 2022 and 2023, WHO released a package of policy briefs designed to help countries formulate policies to manage SARS-CoV-2 transmission, particularly in high-risk and vulnerable populations, and to reduce morbidity, mortality and long-term sequelae from COVID-19. The policy briefs have been updated to reflect the current situation and risk of COVID-19, the approaches outlined in the September 2023 WHO document Ending the COVID-19 emergency and transitioning from emergency phase to longer-term disease management: Guidance on calibrating the response (2) and the Director-General's Standing Recommendations for COVID-19 (1).

This policy brief is intended for national and sub-national policy and decision makers in ministries of health other governments agencies and partners engaged in and responsible for the health of the populations they serve. It provides a concise overview of the key recommended actions for Member States to take based on WHO COVID-19 technical guidance and strategies.

Essential actions for Member States to consider in updating COVID-19 testing policies

It remains important to sustain fit-for-purpose testing systems and strategies that strive to support three main objectives for the management of COVID-19: (1) enable timely and appropriate clinical management of COVID-19 for those at highest risk of severe disease (3, 4); (2) track epidemiological trends and the circulation and evolution of the virus to detect increases in incidence and the emergence and public health impact of SARS-CoV-2 variants (5, 6); and (3) reduce the spread of new SARS-CoV-2 variants during surges of cases that threaten the capacities of health systems.

Nucleic acid amplification tests (NAAT), such as real-time reverse-transcription polymerase chain reaction (rRT-PCR) tests, are the most sensitive and specific tests for diagnosing COVID-19 (7). Antigen-detection rapid diagnostic tests (Ag-RDTs) are recommended as a viable alternative to confirm SARS-CoV-2 infection, especially in settings where NAAT is unavailable or results are not timely (8). Although Ag-RDTs are less sensitive than NAAT, they offer rapid, inexpensive and user-friendly detection of the most infectious SARS-CoV-2 cases. Ag-RDTs are available for use by trained operators and by individuals through self-testing (9).

Ideally, COVID-19 testing services should be integrated with testing for other respiratory illnesses such as influenza and respiratory syncytial virus (RSV). The WHO Director-General's standing recommendations for COVID-19 encourage countries to support and enhance equitable access to safe, effective, and quality-assured COVID-19 diagnostics for all communities, including through mechanisms such as resource mobilization and technology transfer, as appropriate (1).

1. Test early in the course of COVID-19 to enable timely care and treatment

Testing suspected COVID-19 cases (10) early in the disease course–especially for people at increased risk for hospitalization or severe COVID-19 (3)–enables access to supportive care and available COVID-19 therapeutics, including antivirals (11, 12). Ensuring access to SARS-CoV-2 testing can also support individuals who experience persistent symptoms and who may have post COVID-19 condition (13). As the effectiveness of COVID-19-specific antivirals is highest when they are administered within the first few days of infection, COVID-19 testing should be integrated within relevant points of care across all levels of the health care system to enable prompt diagnosis. This may include, but is not limited to, primary health care, noncommunicable disease-specialized services, respiratory care, services for immunocompromised individuals and in health care settings for older individuals.

SARS-CoV-2 Ag-RDTs are simpler and faster to perform than NAAT and can be conducted outside of clinical and laboratory settings by trained operators, e.g. using the SARS-CoV-2 Antigen RDT Training Package (14) or by individuals as part of self-testing. Use of Ag-RDTs may enable prompt linkage to care and use of COVID-19 antivirals for individuals who test positive. Ag-RDTs will be most reliable in settings where SARS-CoV-2 prevalence is \geq 5%. When there is no transmission or low transmission, the positive predictive value of Ag-RDTs will be low, and in such settings NAATs are preferable for first line testing or for confirmation of Ag-RDT positive results.

To enhance case finding and ensure prompt clinical care, tailoring testing services for priority populations and settings, such as long-term care facilities and nursing homes [for definitions, see (5)], may also be considered. Where decentralized testing is implemented to facilitate early diagnosis and linkage to clinical care and treatment, it is important to have effective data capture systems in place for reporting confirmed cases to WHO.

2. Test to track the evolution of the epidemic and the SARS-CoV-2 virus

Testing is important for public health surveillance to maintain visibility on the continued circulation and evolution of SARS-CoV-2. WHO continues to recommend maintaining and strengthening surveillance to monitor epidemiological patterns, trends in morbidity and mortality, the impact of the disease burden on health care capacity and the evolution and circulation of SARS-CoV-2 variants (5, 6). To achieve these objectives, it is critical that testing data be integrated within multiple surveillance systems across human and animal health (see the WHO policy brief, COVID-19 surveillance) (15).

COVID-19 surveillance should be viewed within the larger context of other diseases, especially those caused by respiratory pathogens (such as influenza and respiratory syncytial virus). This can be done through surveillance for influenza-like-illness (ILI), acute respiratory infections (ARI) and severe acute respiratory infections (SARI) (16) including sampling and laboratory testing of all or a subset of cases from sentinel surveillance sites (17, 18). Leveraging existing national and global sentinel surveillance networks, such as the expanded Global Influenza Surveillance and Response System (e-GISRS) (19) and the Integrated Disease Surveillance and Response Strategy (IDSR), will continue to contribute to monitoring the spread and intensity of transmission of respiratory viruses as well as genetic evolution of SARS-CoV-2, and guide control measures (20–23).

COVID-19 testing and reporting strategies should be linked to genomic surveillance (24, 25) and phenotypic assessment (26). To ensure representativeness, sampling approaches should consider mechanisms

beyond sentinel surveillance through e-GISRS to enable sequencing of specimens from individuals who test positive using NAAT and Ag-RDT services, where feasible (27, 28). Genomic and phenotypic characterization data are needed to assess and analyse the risk posed by SARS-CoV-2 variants, including the effectiveness of countermeasures, such as vaccines and therapeutics. The WHO Coronavirus Network (CoViNet) has been established to facilitate timely and coordinated risk evaluations of variants and report these evaluations to the Technical Advisory Group on Viral Evolution (TAG-VE) (29) and the Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) (30). Both advisory groups continue to provide guidance to WHO as part of the COVID-19 response. Establishing and maintaining testing and genomic sequencing systems that are fit for purpose requires considerable political will, sustained financing and expertise (31). For this reason, a costing tool for genomic sequencing for SARS-CoV-2 has been developed.

Finally, while SARS-CoV-2 circulation is primarily driven by human-to-human transmission, SARS-CoV-2 is also a zoonotic virus. Although there is no evidence that SARS-CoV-2 infections in animals significantly impact human health, animal health or biodiversity, there is concern about the establishment of new animal reservoirs and potential virus evolution in novel hosts (32). The global scarcity of SARS-CoV-2 data on the extent of circulation in animals illustrates the need for increased animal susceptibility research, epidemiological follow-up on animal contacts of confirmed human COVID-19 cases and targeted surveillance in susceptible animals, including pets, livestock and wild animals (33). These activities require close collaboration across relevant sectors (e.g. public health, animal health, wildlife and environmental) following a One Health approach. CoViNet has adopted this approach and will facilitate the reporting of confirmed animal cases of SARS-CoV-2 infection through the World Animal Health Information System (34), and the sharing of genetic sequence data from animals in publicly available databases.

3. Test to reduce the spread of new circulating variants

As countries shift to comprehensive, long-term management of COVID-19 within broader disease prevention and control programmes, they should remain prepared to rapidly expand testing in the event of surges caused by new SARS-CoV-2 variants that may strain health system capacities.

Routine testing may be considered in priority settings (such as care facilities and long-term living facilities) to facilitate timely and appropriate clinical management for those at highest risk of severe disease. Further, individuals who regularly interact with high-risk individuals (e.g. in households or priority settings) should undergo testing, especially when symptomatic.

At the population level, compiling testing data can help assess the intensity of transmission and may also provide predictive insights into the demand for clinical care.

Conclusions

A sustained and strategic approach to testing is essential for supporting surveillance and clinical care for COVID-19. This approach can reduce the risk of new surges of SARS-CoV-2 variants and contribute to reducing COVID-19 mortality, morbidity and long-term sequelae.

Plans for updating

WHO will continue to monitor the situation closely for any changes that may affect this policy brief. WHO will issue necessary updates as evidence becomes available and is reviewed.

References

- World Health Organization. Standing recommendations for COVID-19 issued by the Director-General of the World Health Organization (WHO) in accordance with the International Health Regulations (2005) (IHR). 2023 Aug 9; Retrieved from https://www.who.int/publications/m/item/standing-recommendations-for-covid-19-issued-by-the-director-general-of-the-world-health-organization-(who)-in-accordance-with-the-international-health-regulations-(2005)-(ihr).
- 2. World Health Organization. Ending the COVID-19 emergency and transitioning from emergency phase to longer-term disease management: guidance on calibrating the response. 2023 Sep 4; Retrieved from https://www.who.int/publications/i/item/WHO-WHE-SPP-2023.2.
- 3. World Health Organization. Clinical management of COVID-19: Living Guideline. 2022 Jun 23; Retrieved from https://www.who.int/publications-detail-redirect/WHO-2019nCoV-clinical-2022-1.
- 4. World Health Organization. Considerations for implementing and adjusting public health and social measures in the context of COVID-19. 2021; Retrieved from https://www.who.int/publications-detail-redirect/WHO-2019nCoV-clinical-2022-1.
- 5. World Health Organization. Public health surveillance for COVID-19: interim guidance. 2022; Retrieved from https://www.who.int/publications/i/item/WHO-2019-nCoVSurveillanceGuidance-2022.2.
- 6. World Health Organization. Tracking SARS-CoV-2 Variants. 2022; Retrieved from https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/.
- 7. World Health Organization. Diagnostic testing for SARS-CoV-2. 2020; Retrieved from https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2.
- 8. World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection. 2021; Retrieved from https://www.who.int/publications/i/item/antigen-detection-in-thediagnosis-of-sars-cov-2infection-using-rapid-immunoassays.
- 9. World Health Organization. Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing. 2022; Retrieved from https://www.who.int/publications/i/item/WHO-2019-nCoV-Ag-RDTs-Self_testing-2022.1.
- 10. World Health Organization. WHO COVID-19: Case Definitions. 2022; Retrieved from https://www.who.int/publications/i/item/WHO-2019-nCoV-Surveillance_Case_Definition-2022.1.
- 11. World Health Organization. Therapeutics and COVID-19: living guideline. 2022; Retrieved from https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-therapeutics2022.4.
- 12. The COVID-19 Clinical Care Pathway. 2022; Retrieved from https://www.who.int/tools/covid-19-clinical-care-pathway.
- 13. World Health Organization. A clinical case definition of post COVID-19 condition by a Delphi consensus, 6 October 2021. 2021; Retrieved from https://www.who.int/publicationsdetail-redirect/WHO-2019-nCoV-Post_COVID-19_condition-Clinical_case_definition-2021.1.
- 14. World Health Organization. The SARS-CoV-2 Antigen RDT Training Package. 2022; Retrieved from https://extranet.who.int/hslp/content/sars-cov-2-antigen-rapid-diagnostic-testtraining-package.
- 15. WHO policy brief: COVID-19 surveillance. Retrieved from https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy_Brief-Surveillance-2023.1.
- 16. World Health Organization. Global Influenza Programme: Case definitions for influenza surveillance. 2018; Retrieved from https://www.who.int/teams/global-influenzaprogramme/surveillance-and-monitoring.
- 17. World Health Organization. Strengthening pandemic preparedness planning for respiratory pathogens: policy brief. 2022; Retrieved from https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy_briefpandemic_preparedness-2022.1.
- 18. World Health Organisation Regional Office for Europe, European Centre for Disease Prevention and Control. Operational considerations for respiratory virus surveillance in Europe. 2022; Retrieved from https://www.ecdc.europa.eu/en/publications-data/operational-considerationsrespiratory-virus-surveillance-europe.

- 19. World Health Organization. Global Influenza Surveillance and Response System (GISRS). 2020; Retrieved from https://www.who.int/initiatives/global-influenza-surveillance-and-response-system.
- 20. World Health Organization Regional Office for Africa. Guide for National Public Health Laboratory Networking to Strengthen Integrated Disease Surveillance and Response (IDSR). Retrieved from https://www.afro.who.int/publications/guide-national-public-health-laboratory-networking-strengthen-integrated-disease.
- 21. World Health Organization Regional Office for Africa. Integrated Disease Surveillance and Response Technical Guidelines, Booklet One: Introduction Section, 3rd ed. 2019 Jan 1.
- 22. World Health Organization Regional Office for Africa. Integrated disease surveillance and response technical guidelines: Booklet Two: sections 1, 2, and 3, 3rd ed. 2019 Jan 1; Retrieved from https://www.who.int/publications/i/item/WHO-AF-WHE-CPI-01-2019.
- 23. World Health Organization Regional Office for Africa. Integrated Disease Surveillance and Response Technical Guidelines: Booklet Three: Sections 4, 5, 6, and 7, 3rd ed. 2019; Retrieved from https://iris.who.int/handle/10665/312362.
- 24. World Health Organization. Guidance for surveillance of SARS-CoV-2 variants: Interim guidance, 9 August 2021.
- 25. World Health Organization. Operational considerations to expedite genomic sequencing component of GISRS surveillance of SARS-CoV-2. 2021; Retrieved from https://www.who.int/publications/i/item/WHO-2019-nCoV-genomic-sequencing-GISRS-2021.1.
- 26. World Health Organization Regional Office for Europe, European Centre for Disease Prevention and Control. Methods for the detection and characterisation of SARS-CoV-2 variants second update. 2022; Retrieved from https://www.ecdc.europa.eu/en/publications-data/methodsdetection-and-characterisation-sars-cov-2-variants-second-update.
- 27. World Health Organization. SARS-CoV-2 genomic sequencing for public health goals: Interim guidance. 2021; Retrieved from https://www.who.int/publications/i/item/WHO-2019nCoV-genomic sequencing-2021.1.
- 28. World Health Organization. Genomic sequencing of SARS-CoV-2: a guide to implementation for maximum impact on public health. 2021; Retrieved from https://www.who.int/publications/i/item/9789240018440.
- 29. World Health Organization. Technical Advisory Group on SARS-CoV-2 Virus Evolution. Retrieved from https://www.who.int/groups/technical-advisory-group-on-sars-cov-2-virusevolution.
- 30. World Health Organization. Technical Advisory Group on COVID-19 Vaccine Composition. Retrieved from https://www.who.int/groups/technical-advisory-group-on-covid-19vaccine-composition-(tag-co-vac).
- 31. World Health Organization. Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032. 2022; Retrieved from https://www.who.int/publications/i/item/9789240046979.
- 32. World Health Organization. 38. SARS-CoV-2 in animals used for fur farming: GLEWS+ risk assessment,. 2021; Retrieved from https://www.who.int/publications/i/item/WHO-2019-nCoV-fur-farmingrisk-assessment-2021.1.
- 33. World Health Organization, Food and Agriculture Organization, World Organization for Animal Health. Joint statement on the prioritization of monitoring SARSCoV-2 infection in wildlife and preventing the formation of animal reservoirs. 2022; Retrieved from https://www.who.int/news/item/07-03-2022-joint-statement-on-theprioritization-of-monitoring-sars-cov-2-infection-in-wildlife-and-preventing-the-formation-ofanimal-reservoirs.
- 34. World Organization for Animal Health. World Animal Health Information System. Retrieved from https://wahis.woah.org/#/home.

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