Public health surveillance for COVID-19

Interim guidance 14 February 2022



Key points

The objectives of COVID-19 surveillance are to:

- monitor SARS-COV-2 incidence and COVID-19 morbidity and mortality among different age groups and population groups at higher risk for developing severe disease and death
- track potential epidemiological changes over time
- detect and contain outbreaks of new SARS-CoV-2 variants and continue monitoring the trends of existing variants
- guide the **implementation and adjustment of COVID-19 control measures including isolation of cases, contact tracing and quarantine of contacts**, while enabling safe resumption of economic and social activities
- evaluate the impact of the pandemic on health care systems and society
- contribute to the understanding of the co-circulation of SARS-CoV-2, influenza, other respiratory viruses and other pathogens.

Key actions for comprehensive COVID-19 surveillance are to:

- use, adapt and strengthen **existing surveillance systems** (including influenza-like illness/severe acute respiratory infection systems and sentinel sites)
- strengthen laboratory and testing capacities, particularly at sub-national levels
- mobilize the public health workforce to carry out case finding, contact tracing, as per WHO guidance, and testing.

Testing

- Nucleic acid amplification test (NAAT) testing is the reference standard method to identify SARS-CoV-2 infection. If other diagnostic methods are used, the number of tests conducted and infections confirmed by each diagnostic method used should be recorded and reported.
- Antigen-detecting rapid diagnostic tests (Ag-RDTs) rely on direct detection of SARS-CoV-2 viral proteins, are much faster and simpler to perform, and offer rapid, inexpensive, and early detection of the most infectious SARS-CoV-2 infections in places where NAAT testing is not available. The case definitions include Ag-RDT as a confirmation method.
- It is also important to **collect information on testing criteria and document changes in the testing strategy** and the denominators for SARS-CoV-2 testing to provide context for analyses

COVID-19 surveillance reporting recommendations from Member States to WHO-HQ

- daily cases and deaths, as per IHR regulations
- required weekly reporting to WHO of detailed surveillance variables:
 - age and gender of cases and deaths, (probable and confirmed)
 - cases and deaths among health and care workers,
 - o number of cases hospitalized, and discharged,
 - o number of persons tested with NAAT and other testing methods.
- vaccination: doses administered, number of persons fully vaccinated.

What is new in this version

This version has been developed through a structured process of which the inception pre-dates the emergence of the variant of concern Omicron. Consequently, several recommendations retained from the prior version of this guidance may be challenging to implement in the current context. However, because several important amendments are introduced here, this guidance is being issued while the process has already begun to adapt the next version to the evolving epidemiological and societal context of the COVID-19 pandemic. New elements include:

- update of contact definitions, in line with latest contact tracing guidance
- definitions of Variant of Concern and Variant of Interest, in line with latest statements from the Technical Advisory Group for Virus Evolution
- surveillance of variants: referencing to Interim Guidance for surveillance of SARS-CoV-2 variants published on 9 August 2021

- update of detection strategies in line with updated version of WHO SARS-CoV-2 testing guidance
- reinfection evidence standardization and surveillance: molecular, genomic and immunological evidence of reinfection
- inclusion of clinical case definition of Post COVID-19 condition as defined by WHO
- vaccination surveillance, in line with latest vaccination deployment guidance
- new definition of breakthrough infection
- update of the Case Report Form: insertion of vaccine status, reinfection, variant screening
- update of serological surveillance, in line with latest protocols
- new approaches and toolkits for mortality surveillance.
- links to WHO COVID-19 surveillance dashboards

Background

This interim guidance describes the functions and considerations to implement public health surveillance of coronavirus disease 2019 (COVID-19) in humans caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (hereafter referred to as COVID-19 surveillance). This guidance provides an update to the document of the same name issued on 16 December 2020.

This document should be read in conjunction with the WHO guidance on <u>preparedness</u>, <u>readiness</u> and <u>response activities</u>¹, and <u>contact tracing</u>² for COVID-19. Updated information and other guidance on COVID-19 can be found on the <u>COVID-19 website</u>.

Purpose of this document

This document provides guidance to Member States on the implementation of surveillance for COVID-19 disease and the SARS-CoV-2 virus that causes it, and the reporting requirements for WHO.

Methodology

The recommendations in this document are primarily based on existing WHO guidance as referenced throughout the sections, and this updated interim guidance aims to align recommendations with latest published tools.

A literature review was conducted on SARS-CoV-2 reinfection, encompassing both published and unpublished articles, from January 2021 through to June 2021. Search terms included SARS-CoV-2 reinfections, surveillance, evidence, and encompassed a wide range of different methodologies, from case studies to systematic reinfection assessments in public health databases. The WHO Reinfection Technical Working Group contributed on the listing of evidence for reinfection investigations.

Additional references were provided by technical advisors from various WHO departments including, but not limited to, Serosurveillance, Laboratory and Diagnostics, Clinical Management, Immunization. Existing guidance documents from WHO and other partners (European Center for Disease Control, US Centers for Disease Control) were also used.

This interim guidance was reviewed by Regional Offices surveillance technical teams, who particularly assessed the feasibility and acceptability of the latest recommendations.

1. Definitions for surveillance

1.1. Case definition

The case definitions for suspected, probable and confirmed cases below have not been changed since the 16 December 2020 update.

Countries may need to adapt these case definitions depending on their local epidemiological situation and other factors. All countries are encouraged to publish adapted definitions online and in regular situation reports and to document periodic updates to definitions that may affect the interpretation of surveillance data.

Suspected case of SARS-CoV-2 infection (three options, A through C)

A. A person who meets the clinical AND epidemiological criteria:

Clinical criteria:

1. Acute onset of fever AND cough;

OR

2. Acute onset of ANY THREE OR MORE of the following signs or symptoms: fever, cough, general weakness/fatigue,¹ headache, myalgia, sore throat, coryza, dyspnoea, anorexia/nausea/vomiting, diarrhoea, altered mental status.

AND

Epidemiological criteria:

1. Residing or working in a setting with high risk of transmission of the virus: for example, closed residential settings and humanitarian settings, such as camp and camp-like settings for displaced persons, any time within the 14 days before symptom onset;

OR

- 2. Residing in or travel to an area with community transmission anytime within the 14 days before symptom onset; **OR**
- 3. Working in a health setting, including within health facilities and within households, anytime within the 14 days before symptom onset.

B. A patient with severe acute respiratory illness (SARI: acute respiratory infection with history of fever or measured fever of \geq 38 C°; and cough; with onset within the last 10 days; and who requires hospitalization).

C. An asymptomatic person not meeting epidemiologic criteria with a positive SARS-CoV-2 antigen-detecting rapid diagnostic test (Ag-RDT).²

Probable case of SARS-CoV-2 infection (four options, A through D)

A. A patient who meets clinical criteria above **AND** is a contact of a probable or confirmed case or is linked to a COVID-19 cluster.³

B. A suspected case (described above) with chest imaging showing findings suggestive of COVID-19 disease.⁴

C. A person with recent onset of anosmia (loss of smell) or ageusia (loss of taste) in the absence of any other identified cause.

D. Death, not otherwise explained, in an adult with respiratory distress preceding death **AND** who was a contact of a probable or confirmed case or linked to a COVID-19 cluster.³

Confirmed case of SARS-CoV-2 infection (three options, A through C)

A. A person with a positive Nucleic Acid Amplification Test (NAAT)

B. A person with a positive SARS-CoV-2 Ag-RDT AND meeting either the probable case definition or suspected criteria A OR B

C. An asymptomatic person with a positive SARS-CoV-2 Ag-RDT AND who is a contact of a probable or confirmed case.

Note: Clinical and public health judgment should be used to determine the need for further investigation in patients who do not strictly meet the clinical or epidemiological criteria. Surveillance case definitions should not be used as the sole basis for guiding clinical management.

¹ Signs separated with slash (/) are to be counted as one sign.

² In instances of lower pretest probability, such as low incidence of SARS-CoV-2 infection in the community, clinical discretion should determine if positive Ag-RDT results need confirmation by NAAT, see <u>Diagnostic testing for SARS-CoV-2</u>²⁵

³ A group of symptomatic individuals linked by time, geographic location and common exposures, containing at least **one NAAT**-confirmed case or at least **two** epidemiologically linked, symptomatic (meeting clinical criteria of Suspect case definition A or B) persons with **positive Ag-RDTs** (based on \geq 97% specificity of test and desired >99.9% probability of at least one positive result being a true positive)

⁴ Typical chest imaging findings suggestive of COVID-19 include the following⁵⁷:

⁻ chest radiography: hazy opacities, often rounded in morphology, with peripheral and lower lung distribution

⁻ chest CT: multiple bilateral ground glass opacities, often rounded in morphology, with peripheral and lower lung distribution

⁻ lung ultrasound: thickened pleural lines, B lines (multifocal, discrete, or confluent), consolidative patterns with or without air bronchograms.

1.2. Definition of a contact

Identifying contacts

The following definition of a contact has not been changed since the 16 December 2020 update, with the exception of the periods of exposure to a symptomatic or asymptomatic case.

A contact is a person who has had any one of the following exposures to a probable or confirmed case:

- face-to-face contact with a probable or confirmed case within 1 meter and for at least 15 minutes;
- direct physical contact with a probable or confirmed case;
- direct care for a patient with probable or confirmed COVID-19 disease without the use of <u>recommended personal</u> <u>protective equipment</u>³; or
- other situations as indicated by local risk assessments.

Exposure must have occurred during the infectious period of the case, and defined as follows:

- <u>Exposure to a symptomatic case:</u> 2 days before and 10 days after symptom onset of the case, plus at least 3 additional days without symptoms (including without fever and without respiratory symptoms), for a minimum of 13 days total after symptom onset.
- Exposure to an asymptomatic case: 2 days before and 10 days after the date on which the sample that led to confirmation was taken. Contacts should be managed in the same way as for a symptomatic case.

In some situations, contacts who have infection-induced or vaccine-derived immunity may not need to be quarantined; please see <u>Considerations for implementing and adjusting public health and social measures in the context of COVID-19</u>⁴.

WHO recommends supported quarantine for a duration of 14 days from the last contact with a probable or confirmed case to minimize risk of onward transmission, as per <u>the considerations for quarantine of contacts of cases</u>⁵. As the evidence base grows, confidence in the duration of the incubation period has also grown. Multiple observations indicate that nearly all cases develop symptoms within 14 days of exposure, with a median incubation rate of approximately five to six days. Testing using accurate and rapid tests throughout and/or at the end of a shortened quarantine period can improve confidence that a contact leaving quarantine is not infected.

Occurrence of any signs or symptoms of COVID-19 should be closely monitored during quarantine either directly or through selfreporting to the contact tracing team. If contacts develop symptoms, they should follow the established referral pathway for testing and treatment in their area, and their contacts should be traced and asked to quarantine.

The monitoring phase ends once the quarantine period has been completed or if the contact develops COVID-19 symptoms and is confirmed as a positive case. In that case, isolation is recommended for at least 10 days after symptom onset, adding an additional three days without symptoms.

If contacts are in close proximity to each other, such as being in the same household, and one of them becomes a COVID-19 probable or confirmed case, the follow-up period of other contacts is reset to 14 days (or locally established quarantine duration) after the last exposure to the new case.

In situations where contact tracing capacity is overstretched, the aim of contact tracing may need to shift to reducing morbidity and mortality rather than attempting to break all chains of transmission. In these situations, prioritization for contact tracing should be given to:

- **contacts at highest risk of getting infected** and those such as health and care workers who are at highest risk of spreading the virus to vulnerable people, particularly those working in nursing homes, long-term care facilities and hospitals and other frontline essential workers
- contacts at highest risk for development of severe disease, such as people who have comorbidities or are immunosuppressed, elderly individuals and unvaccinated or under-vaccinated adults with no known prior SARS-CoV-2 infection.

As per WHO guidance, if a contact develops symptoms, that individual should be considered as being suspected of having COVID-19, and a referral pathway to testing should be available and recommended.⁴ In resource-constrained settings and/or when testing capacity is limited and thus testing of all symptomatic contacts is not possible, highest-risk contacts should be prioritized²⁰, as noted above. Further information can be found in forthcoming updated contact tracing guidance.

More information on contact ascertainment is available in <u>latest PHSM guidance</u>⁴, <u>considerations for quarantine of contacts of cases</u>⁵, and <u>Contact tracing in the context of COVID-19</u>².

1.3. Definition of COVID-19 death for surveillance purposes

The definition of COVID-19 death below has not been changed since the 16 December 2020 update.

A COVID-19 death is defined for surveillance purposes as a death resulting from a clinically compatible illness in a probable or confirmed COVID-19 case, unless there is a clear alternative cause of death that cannot be related to COVID-19 disease (e.g. trauma). There should be no period of complete recovery between the illness and death.

It is recognized that in extremely high transmission contexts, some decedents will test positive for SARS-CoV-2 infection incidentally. This points to the importance of accurately assessing whether the clinical features of the death are compatible with COVID-19.

Stillbirths that were tested positive for SARS-CoV-2 should not be recorded either in the cases or deaths, consistently following stillbirth recording standards for other pathogens.

For further guidance on COVID-19 as cause of death, <u>see International guidelines for certification and classification (coding) of</u> <u>COVID-19 as a cause of death</u>⁶.

1.4. Vulnerable and "high-risk" populations

Risk factors for severe disease

- Age more than 60 years (increasing with age).
- Underlying noncommunicable diseases (NCDs): diabetes, hypertension, cardiac disease, chronic lung disease, cerebrovascular disease, dementia, mental disorders, chronic kidney disease, immunosuppression, HIV [98], obesity and cancer have been associated with higher mortality.
- Other risk factors associated with higher risk include: smoking and higher sequential organ failure assessment (SOFA) score and D-dimer >1 µg/L on admission were associated with higher mortality
- In pregnancy, increasing maternal age, high BMI, non-white ethnicity (in specific settings), chronic conditions and pregnancy specific conditions such as gestational diabetes and pre-eclampsia

Further guidance can be found in COVID-19 Clinical management: living guidance7.

"High-risk" or vulnerable populations

These populations include:

- People aged ≥ 60 years and/or with comorbidities that increase the risk of severe disease;
- Disadvantaged groups such as refugees, internally displaced people, migrants, and vulnerable communities; those in high density/low resource settings (e.g., camps, informal settlements, slums, places of detention) and lower income groups;
- Health workers, defined by WHO as all people engaged in actions with the primary intent of enhancing health, including social care workers who often have roles in the provision of care in long-term care facilities and in community settings.

See <u>IASC guidance</u>⁸ and <u>Public health and social measures for COVID-19 preparedness and response in low capacity and <u>humanitarian settings</u>⁹ for further details.</u>

1.5. Variant definitions

WHO definitions of Variants of Interest and Variants of Concern can be found <u>here¹⁰.</u> These are working definitions and may be updated regularly:

Variants of Interest (VOI) Working definition

A SARS-CoV-2 variant:

- With genetic changes that are predicted or known to affect virus characteristics such as transmissibility, disease severity, immune escape, diagnostic or therapeutic escape; AND
- Identified to cause significant community transmission or multiple COVID-19 clusters, in multiple countries with increasing relative prevalence alongside increasing number of cases over time, or other apparent epidemiological impacts to suggest an emerging risk to global public health.

Variants of Concern (VOC) Working definition:

A SARS-CoV-2 variant that meets the definition of a VOI (see below) and, through a comparative assessment, has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance:

- Increase in transmissibility or detrimental change in COVID-19 epidemiology; OR
- Increase in virulence or change in clinical disease presentation; OR
- Decrease in effectiveness of public health and social measures or available diagnostics, vaccines, therapeutics.

The <u>Guidance for surveillance of SARS-CoV-2 variants: Interim guidance, 9 August 2021¹¹</u> provides guidance on timely detection and reporting of SARS-CoV-2 variants.

1.6. Reinfection: standard evidence for investigation

Background

Seasonal coronaviruses, commonly associated with the common cold, can re-infect humans ¹². For SARS-CoV-2, sporadic cases of reinfection have been widely documented ^{13–15}. though most individuals develop strong protective immune responses following infection with SARS-CoV-2. More information can be assessed in the WHO Scientific Briefing on immunity <u>here¹⁶</u>. In a published systematic review, reinfection was an uncommon event (absolute rate 0%–1.1%)¹⁷. If SARS-CoV-2 reinfection rates become high, this may indicate immune escape, particularly in the context of circulation of variants with unknown phenotypical characteristics in regard to immune functions, which may have direct implications on adjustment of public health measures.

Clusters of cases of reinfections should trigger an investigation for potential emerging variants that may escape immunity; see <u>variant surveillance guidance¹¹</u>.

Suspected reinfection case

Confirmed or probable COVID-19 case (following WHO case definition), with **a history of a primary** confirmed, or probable **COVID-19 infection**, with at least 90 days between the episodes.

Probable reinfection case:

- Positive RT-qPCR testing results for both episodes or equivalent positive antigen tests fitting the WHO Case Definition with episodes occurring at least 90 days apart, based on the sampling date.

OR

- Genomic evidence for the second episode is available and includes lineage that was not submitted to SARS-CoV-2 genomic databases at the time of first infection.

Molecular evidence of confirmed reinfection:

Samples available for both primary and secondary episodes allowing for full genomic sequencing, whereby samples must be shown to be phylogenetically distinct from one another. Evidence should be generated at clade/lineage, as defined by genomic classification of SARS-CoV-2 between the first and second infection.

If evidence of different clades is demonstrated in episodes less than 90 days apart, this also constitutes evidence of confirmed reinfection.

If there are more than two nucleotide differences for every month separating the samples between the sequences for first and second infections, i.e., exceeding the expected Single Nucleotide Variation, these would be considered as different linages/clades.

The 90-day cut off should ideally be determined between onset dates (for probable cases), or sampling dates (for confirmed cases) of primary and secondary episodes.

For further guidance on genomic information classification and lineage, please see guidance on genomic sequencing¹⁸.

Investigation process and items for case definition

The following items for a standardized and harmonized investigation for SARS-CoV-2 reinfection should be considered:

• Suspect case definition for screening purposes

The definition provided above is designed to accommodate a common screening algorithm for clinical and public health purposes, either by retrospectively reviewing health records to identify potential reinfections, or prospectively to provide data to clinicians and healthcare authorities on the incidence of reinfection cases.

A follow-up investigation is warranted to confirm reinfection status for suspected or probable cases of reinfection.

• Infection episodes

Infection and reinfection episodes should be investigated and confirmed as per the <u>WHO case definition¹⁹</u>. Cases can be confirmed through NAAT or Ag-RDT. The current reinfection definition is intended for all patients, including immunocompromised patients who may be transmitting the virus over a longer period of time.

<u>Clinical evidence of disease</u>

The clinical phenotype of reinfections is not characterized, and it is unknown whether there is an impact on clinical severity when compared with an initial infection with SARS-CoV-2. Molecular detection should follow the <u>standard WHO Covid-19 case</u> <u>definition criteria</u>¹⁹. Clinical management should not be different given the number of infections suspected or reported by the patient and should follow the <u>clinical management guidance</u>⁷.

• Interval between episodes

Prolonged duration of virus shedding up to 90 days has been reported to be associated with persistent infections and may be misinterpreted as reinfection. Such cases should be further assessed through RT-qPCR, sequencing, serological testing, and clinical evaluation. A time interval of less than 45 days makes reinfection considerably less likely although not impossible.

Conversely, persistent primary infections of up to 100 days have also been documented in immunocompromised hosts but are not considered common among immunocompetent individuals.

WHO advises the adoption of a minimum interval of 90 days between primary and secondary infection.

• <u>Clinical specimen collection for laboratory diagnosis</u>

Ideally, paired upper respiratory swab and serum specimens of both primary and secondary episodes with RT-qPCR Ct values and genomic sequences as well as antibody data, respectively, would allow for comparison.

However, since it is highly unlikely that samples from primary episodes would still be available at the time of secondary onset, the standard nasopharyngeal swab for secondary episode would still allow for reinfection investigation. Assessment of the serological profile could aid in analysis.

• <u>Molecular laboratory tests</u>

Molecular test positivity, as in the WHO case definition, is necessary to determine evidence of infection. Owing to the variability across molecular platforms, Ct values should be considered with care and may not have clinical relevance (see Genomic sequencing of SARS-CoV-2: a guide to implementation for maximum impact on public health¹⁸).

Whole genome sequence analysis of the virus from both episodes could provide insight on the evolution between clades from both episodes; the expected single nucleotide variation (SNV) rate is two nucleotides per month ²⁰.

Additional studies

Where resources allow it, large population-based observational study designs have proven to be good tools to estimate reinfection rates ²¹.

A more definitive approach to establish actual reinfection rates must be conducted through longitudinal studies involving large cohorts, where sample size will depend upon evidence generated from prior epidemiological data as reinfection rates prove to be rare (<1%). The SIREN study 22 is an example of a prospective cohort study on reinfections, allowing for estimation of the protective effect of previous infection.

Prospectively monitoring confirmed cases of SARS-CoV-2 infection, coupled with genomic and immunological surveillance, provides the opportunity of paired samples and the use of comparable molecular testing for both episodes. It also provides valuable real-time information to healthcare authorities to assist in effectively establishing reinfection rates and enhancing epidemiological surveillance, including contact tracing, and vaccination monitoring. Serial sampling and testing of convalescent cases will enhance the understanding of SARS-CoV-2 reinfections and better define host immunity dynamics in relation to SARS-CoV-2 genomic diversity at population levels, in different age cohorts and among those with different immunological profiles.

Immunological assessments

Virus neutralization titres are expected to increase between the first and second infections, and <u>serological investigations</u>²³ could be a useful strategy to be incorporated into confirmatory investigations once the markers and titres are better understood. However, the following proposed molecular assessments for reinfection do not include recommendation of specific serological studies, as there is wide variation among immunoassays, and the kinetics of immunological markers are not yet widely understood.

It is advised to perform immunological assessments in suspected reinfection cases, if possible, with paired samples at the early stages of both episodes (before day 7).

Trends in detection and persistence of antibodies, with a focus on neutralizing antibodies, as well as other immunological markers, including markers for cellular immunity, could lead to better understanding of immunological dynamics in case of reinfection.

Accounting for vaccination

Antibody testing against SARS-CoV-2 will need to account for vaccination status of the subjects. Following the worldwide deployment of vaccination, the development of immunological and molecular technology will allow for differentiation between serological evidence of previous infection and vaccine-induced immunity. At the time of publication, such tests exist but are not widely available, and it is not recommended to differentiate infection-derived immunity from vaccine-derived immunity for surveillance purposes. Nevertheless, it is advised to collect the vaccination status of reinfection cases, as displayed below in the recommended data set.

Reporting

Although WHO does not require reporting of reinfection cases, Member States are advised to keep a line list of suspected reinfection cases, in close linkage with clinical, epidemiological, and sequencing data for surveillance of new variants, as well as vaccine coverage monitoring. Table 1 lists the recommended data elements for such a line list.

Sections		Variables
Patient ID		Age
		Gender
		Location (following locally relevant geographic disaggregation)
First episode	Vaccination status	Vaccination status on first onset (one dose/ two doses)
		Date of vaccination for each dose
		Vaccine product(s) received
		Date of first onset
		Date of sampling for first positive RT-qPCR or ag-RDT
		Clinical characteristics of first episode
	Sampling and	Severity (hospitalization, ICU, mechanical ventilation)
	Jah anatam	Date of first sample antibody testing
	laboratory	First antibody titre assay used (brand, batch)
		Date of sampling for first episode for sequencing
		First sequence phylogenetic reference
		Date of negative RT-qPCR following first onset (if applicable, if not leave blank)
Interval		Interval in days between two positive PCR or ag-RDT samples (using dates of sampling)
	Vaccination	Vaccination status on second onset (one dose/ two doses)
	status	Date of vaccination for each dose
		Vaccine product(s) received
	Sampling and laboratory	Date of second episode onset
		Date of sampling for positive RT-qPCR testing or ag-RDT for second episode
Second enisode		Clinical characteristics of second episode
Second episode		Severity (hospitalization, intensive care, mechanical ventilation)
		Date of sampling for second antibody testing
		Second antibody titre assay used (brand, batch)
		Date of sampling for second episode for sequencing
		Second sequence phylogenetic reference
		Patient outcome
Remarks		

Table 1: recommended items for recording of suspected reinfection cases

1.7. Breakthrough Infections in vaccinated persons

Vaccines should be approved by a Stringent Regulatory Authority or listed under WHO Emergency Use Listing.

Cases and infections are expected in vaccinated persons, albeit in a predictable proportion, in relation to vaccine efficacy values. The following definitions should be used to characterize infections and cases in vaccinated persons:

- Asymptomatic breakthrough infection: detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person without COVID-19-like symptoms \geq 14 days after they have completed all recommended doses of the vaccine series.
- Symptomatic breakthrough case: detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from . a person with COVID-19-like symptoms \geq 14 days after they have completed all recommended doses of the vaccine series.

NB: COVID-19-like symptoms should fit those listed in the COVID-19 case definition.

1.8. Post Covid Condition

A clinical case definition of post COVID-19 condition has been published by WHO and is available here²⁴, in which Post COVID-19 condition has been described as :

"Post COVID-19 condition occurs in individuals with a history of probable or confirmed SARS-CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms that last for at least 2 months and cannot be explained by an alternative diagnosis.

Common symptoms include fatigue, shortness of breath, cognitive dysfunction but also others as described in the document, which generally have an impact on everyday functioning. Symptoms may be new onset, following initial recovery from an acute COVID-19 episode, or persist from the initial illness. Symptoms may also fluctuate or relapse over time. A separate definition may be applicable for children"

2. Recommended COVID-19 surveillance for Member States

This section provides an overview of surveillance approaches that Member States should consider for comprehensive national surveillance for COVID-19. The section emphasizes the need to adapt and reinforce existing national systems where appropriate and to scale up surveillance capacities as needed.

When considering national capacities for surveillance, Member States should include regular reporting to WHO according to the requirements below.

2.1. Aims and objectives

The aim of national surveillance for COVID-19 is to enable public health authorities to optimize intervention strategies to reduce transmission of SARS-CoV-2, thereby limiting associated morbidity and mortality.

- The objectives of COVID-19 surveillance are to:
 - monitor SARS-COV-2 incidence and COVID-19 morbidity and mortality among different age groups and population groups at higher risk for developing severe disease and death
 - track potential epidemiological changes over time
 - detect and contain outbreaks of new SARS-CoV-2 variants and continue monitoring the trends of existing variants
 - guide the **implementation and adjustment of COVID-19 control measures including isolation of cases, contact tracing and quarantine of contacts**, while enabling safe resumption of economic and social activities
 - evaluate the impact of the pandemic on health care systems and society
 - contribute to the understanding of the co-circulation of SARS-CoV-2, influenza, other respiratory viruses and other pathogens.

Regarding SARS-CoV-2 variant surveillance and associated public health risks, specific guidance can be found <u>here¹¹</u>.

2.2. Diagnostic tools

Data on the number of individuals tested for SARS-CoV-2 should be collected from all relevant laboratories. NAAT testing is the reference standard method to identify SARS-CoV-2 infection. If other diagnostic methods are used, the number of tests conducted and infections confirmed by each diagnostic method used should be recorded and reported. Although surveillance systems will typically capture the number of cases of SARS-CoV-2 infection, it is also important to collect information on the testing criteria and to document changes in the testing strategy, and the total number of individuals tested for SARS-CoV-2 (this is distinct from the number of tests conducted, which may not be an accurate denominator owing to the possibility of repeat testing of a single individual). Knowing the testing denominator can indicate the level of surveillance activity, and the proportion of positive tests can indicate the intensity of transmission among individuals.

• <u>Nucleic acid amplification tests</u>

In the initial stages of the epidemic, nucleic acid amplification test or NAAT (e.g. RT-qPCR) was the only WHO-recommended assay for confirmation of a case. RT-qPCR and other NAAT assays can be manual or have varying degrees of automation that simplify use. For the purposes of surveillance, however, all NAAT tests are considered equal. More information can be found in Diagnostic testing for SARS-CoV-2²⁵.

<u>Antigen-detecting rapid diagnostic tests (Ag-RDTs)</u>

In addition to NAAT tests, which remain the reference standard, Ag-RDTs can serve as a complementary method for diagnostic confirmation given certain circumstances as detailed in the case definition. The minimum performance requirements for Ag-RDTs is $\geq 80\%$ sensitivity and $\geq 97\%$ specificity, as established through a formal process of target product profile (TPPs) development for priority SARS-CoV-2 diagnostics.

This technology for SARS-CoV-2 detection is much simpler and faster to perform than nucleic acid amplification tests like RTqPCR and can be conducted outside of clinical and laboratory settings, by <u>trained individuals</u>²⁶. Although these Ag-RDTs are less sensitive than NAAT, they offer rapid, inexpensive, and early detection of the most infectious SARS-CoV-2 infections in places where NAAT testing is not available or results are not timely. However, when there is no transmission or low transmission, the positive predictive value of Ag-RDTs will be low, and NAATs are preferable as first-line testing or for confirmation of Ag-RDT positive results.

Further information is available in <u>Antigen detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays</u>²⁷ and <u>use of antigen detection rapid diagnostic testing</u>²⁸.

• Antibody detection (serology)

Serological assays that detect antibodies produced by the human body in response to infection with the SARS-CoV-2 can be useful in various settings. WHO has developed standardized seroepidemiology protocols to support national public health and social measures, promote the international comparability of research and address gaps in current knowledge of COVID-19. More information can be found <u>here</u>²³.

Sero-surveillance studies can be used to support the investigation of an ongoing outbreak and to support the retrospective assessment of the attack rate or the size of an outbreak. As SARS-CoV-2 is a novel pathogen, understanding of the antibody responses it engenders is still emerging; therefore, antibody detection tests should be used with caution and not to determine acute infections.

Non-quantitative assays for antibody detection are currently not recommended for acute diagnosis and clinical management, and their role in epidemiologic surveys is being studied. For more information on the utility of rapid immunodiagnostic tests, refer to the WHO scientific brief with advice on <u>SARS-CoV-2 point-of-care immunodiagnostic tests</u>²⁹.

Immune seroconversion is determined by testing for the presence (and concentration) of antibodies directed against various SARS-CoV-2 proteins early in the course of disease (acute phase – first few days after onset of symptoms) and again weeks later, after symptoms have resolved (convalescent phase). A significant rise in antibody from baseline to the convalescent phase allows retrospective case confirmation. More information can be found in <u>Diagnostic testing for SARS-CoV-2</u>²⁵.

• Broadened use of diagnostics in widespread asymptomatic population screening and self-testing for SARS-CoV-2

The measurable impact and cost-effectiveness of widespread asymptomatic population screening for SARS-CoV-2 infection, including through self-testing, are under review by WHO. Considerations include the considerable financial cost of such programs, and potential negative implications for outbreak management, such as reduced centralized capacity to monitor disease trends and diminished PPV (the likelihood that a positive test result is a true positive).

Further applications of self-testing are being explored. Review of the evidence of the potential benefits and harms, including the behaviour of individuals and adherence to public health measures following self-testing, is underway, in order to make future recommendations and guide priority needs for evidence generation.

• Genomic sequencing

This topic is addressed in <u>Genomic sequencing of SARS-CoV-2</u>: a guide to implementation for maximum impact on public <u>health³⁰</u> and in the <u>Variant Surveillance guidance¹¹</u>.

2.3. Surveillance approaches

Most countries need significantly strengthened surveillance capacities to rapidly identify and care for cases of COVID-19, trace and quarantine their contacts (as per WHO guidance), and monitor disease trends over time. Comprehensive national surveillance for COVID-19 will require the adaptation and reinforcement of existing national systems, where appropriate, and the scale-up of additional surveillance capacities, as needed. Digital technologies for rapid reporting, contact tracing, and data management and analysis may support these capacities.

Robust surveillance, once in place, should be maintained even in areas where transmission has been controlled and even if there are few or no cases, using, at minimum, a sentinel approach. Ongoing surveillance for COVID-19 is also important to understand longer-term epidemiological trends, such as incidence and mortality among different age groups, which population groups are at higher risk for severe disease and death, and potential epidemiological changes over time.

Key actions for COVID-19 surveillance by national public health authorities are to:

- use, adapt and strengthen existing surveillance systems
- strengthen laboratory and testing capacities
- mobilize the public health workforce to carry out case finding, contact tracing and testing, where indicated.

It is important to maintain routine syndromic surveillance for other infectious diseases, especially those caused by respiratory pathogens, such as influenza and respiratory syncytial virus, through surveillance for influenza-like-illness (ILI), severe acute respiratory infection (SARI) and acute respiratory infections (ARI), with sampling and laboratory testing of all or a subset of cases through sentinel surveillance sites, as well as universal/national reporting of clusters of unusual or unexplained respiratory syndromes. This is critical for understanding trends in other diseases with similar presentations to guide appropriate public health preparedness and clinical management.

As vaccination is deployed, surveillance helps us to better understand the impact on transmission dynamics and monitor vaccine effectiveness at population level; see <u>Vaccine guidance</u>¹¹.

2.4. Essential surveillance for COVID-19

Surveillance systems should be geographically comprehensive, and surveillance for vulnerable or high-risk populations (see definitions) should be enhanced. This will require a combination of surveillance systems, including contact tracing, where applicable, at all levels of the health care system, the community level, closed residential settings and in other vulnerable groups. See latest interim guidance on <u>Considerations for implementing and adjusting public health and social measures in the context of COVID-19⁴.</u>

2.5. Surveillance strategies

Detection and testing strategies should be prioritized and diversified across existing settings, for the best yield of early case and contact detection.

Surveillance System Site/ Context	Immediate case notification	Cluster investigations	Mortality surveillance	Serologic surveillance	Genomic surveillance	Environmental surveillance
Community		Х	Х	Х	Х	Х
Primary Care sites		Х		Х	Х	
Hospitals		Х	Х	Х	Х	
Sentinel ILI/ARI/ SARI sites					Х	
Closed settings*	Х	Х	Х	Х	Х	Х
Health care-associated SARS-CoV-2 infection	X	X	X	X	X	
Travelers at Points of Entry		Х			Х	Х

Table 2: Surveillance systems across different sites/contexts

*Including but not limited to long-term living facilities, prisons and dormitories.

Genomic surveillance strategies are described in the <u>Variant guidance¹¹</u> and recommend the following for sequencing:

- randomized sampling for a subset of cases, for routine monitoring
- targeted sampling for specific populations (vaccinated, immunocompromised, travelers, etc.)
- investigation of alerts.

2.5.1. Transmission scenarios and detection strategies

Guidance on testing strategies haves been published <u>here³¹</u>, see below for key points relevant to surveillance.

- Individuals meeting the suspected case definition for SARS-CoV-2 infection should be tested, regardless of vaccination status or disease history (1).
- If resources are constrained and it is not possible to test all individuals meeting the case definition, the following cases should be prioritized for testing:
 - o individuals who are at risk of developing severe disease (see definitions above)
 - \circ health and care workers
 - o inpatients in health facilities
 - the first symptomatic individual or subset of symptomatic individuals in a closed setting (e.g. long-term care facilities) in the setting of a suspected outbreak.
- Nucleic acid amplification tests (NAAT) are the reference standard for diagnosis of acute SARS-CoV-2 infection.
- Countries can use high quality antigen-detection lateral flow or rapid diagnostic tests (Ag-RDTs), which are simple to use and offer rapid results, to achieve high coverage of testing, ideally testing all symptomatic individuals meeting the suspected case definition as soon as possible from disease onset (within the first week of illness). Interim guidance on the use of Ag-RDTs can be found here²⁷.
- Testing of asymptomatic individuals with NAAT or Ag-RDTs is currently recommended only for specific groups, including contacts of confirmed or probable cases of SARS-CoV-2 infection, and frequently exposed groups, such as health and care workers and long-term care facility workers.
- Widespread screening of asymptomatic individuals is not currently recommended, owing to the significant costs associated with it and the lack of data on its operational effectiveness.
- Mutation-detecting NAAT assays may be used as a screening tool for SARS-CoV-2 variants, but the presence of a specific variant should be confirmed through sequencing. Such tests should be appropriately validated for this purpose.
- The network of SARS-CoV-2 testing facilities should leverage and build on existing capacities and capabilities and be able to integrate new diagnostic technologies and adapt capacity according to the epidemiological situation, available resources, and country-specific context.

Table 3: Prioritization for testing strategy

Situation where testing and response capacity is outstretched	Alternative measures
Individual meeting case definition for suspected SARS-CoV-2 infection, mild, with no risk factors	Test when possible. If Ag-RDT or NAAT is not available, register as a suspected case and home isolate, as per WHO guidance. Prioritize testing of persons from vulnerable populations (e.g. health and care workers) as per definitions above.
Individual meeting case definition for COVID-19, requiring admission to health care facility	Strongly recommended to test using Ag-RDT or NAAT, where available. If testing is not possible, implement isolation measures to prevent nosocomial transmission.
Symptomatic health care worker with no known COVID-19 contact	Strongly recommended to test using Ag-RDT or NAAT.
Increased number of suspected cases in a specific group (potential cluster)	Test a subset of the cases using Ag-RDT or NAAT. Consider all other symptomatic individuals as probable cases and isolate, as per WHO guidance (1).
Symptomatic individuals in closed settings, including schools, hospitals, long-term living facilities	Test a subset of the cases using Ag-RDT or NAAT. Consider all other symptomatic individuals as probable cases and isolate, as per WHO guidance (1).
Recovering patient	Not necessary to test.
Asymptomatic contacts of confirmed or probable cases, including health and care workers	Quarantine as per WHO guidance with testing, where possible, to shorten quarantine. If contacts become symptomatic, assume COVID-19 and isolate, as per WHO guidance (19).

Testing individuals with immunity for SARS-CoV-2

Any individuals meeting the suspected case definition, regardless of vaccination status or previous infection with SARS-CoV-2, should be tested, if testing is indicated. Further details can be found <u>here³¹</u>.

2.5.2. Case detection and testing in the community

Individuals in the community can play an important role in the surveillance of COVID-19. Community-based surveillance (CBS) – the systematic detection and reporting of events of public health significance within a community, by community members – may serve to bridge the gap between the community and the health system. In CBS, alerts generated by trained volunteers are reported to health authorities for verification and response through established surveillance and referral mechanisms. More guidance on establishing CBS, including simplified alert case definitions, is available from the International Federation of Red Cross and Red Crescent Societies, here.

Table 5: Community case definitions

Health risk	Suggested community definition	Related diseases
Cough and difficulty breathing	Fever with dry cough or difficulty breathing	COVID-19 ARIs Tuberculosis
Cluster of unusual illnesses or deaths	Cluster of people (3+) suddenly sick or died with the same signs of illnesses	Any COVID-19

Where possible, individuals who have signs and symptoms of COVID-19 and all suspected cases should be able to access evaluation and testing, ideally at the primary care level. When testing at the primary level is not accessible, a complementary option is to establish outreach SARS-CoV-2 testing facilities with sampling for NAAT or ag-RDTs, such as drive-through sites or fixed sites in community buildings. Self-tests using saliva are not included for these testing strategies, as evidence on performance is still needed. If testing capacity is scarce, the probable case definition described above can be used without testing to initiate response activities. Cases identified through travel-related testing should be included in the data reported. In low-resource settings, these samples may represent a large proportion of tests performed, which may bias the representativeness of reported cases.

2.5.3. Surveillance at the primary care level

Surveillance in primary care settings is needed to detect cases and clusters in the community. Where possible, testing should be available at primary care clinics. Rapid data reporting and analysis are critical to detect new cases and clusters and to initiate appropriate control measures. Therefore, a minimum number of data variables should be collected for each case: age, sex, location of residence, date of illness onset, date of sample taken and test result. Data reporting to local or national public health authorities can be facilitated using online systems, through mobile phone applications, via SMS text message or over the telephone. Zero

reporting – the reporting of zero cases when none are detected – by all sites at the primary care level – is crucial to verifying that the surveillance system is continuously functioning and for monitoring virus circulation.

At the primary care level, private facilities and laboratories provide a large proportion of the tests performed and should be included in the detection strategies and reporting systems.

2.5.4. Hospital-based surveillance

Patients with probable or confirmed COVID-19 admitted to hospitals should be notified to national public health authorities in a timely manner. Some essential data (e.g., outcome) may not be immediately available but should not delay notification to public health authorities.

The minimum essential data from hospital settings should include:

- Age, sex/gender and place of residence
- Date of illness onset, date of sample collection, date of admission
- Type of laboratory test and laboratory test result
- Whether the case is a health and care worker or not
- Vaccination status (number of doses and date(s) of vaccination, vaccine product(s))
- Severity of the patient's illness at the time of reporting (admitted and treated with ventilation or admitted to intensive care unit)
- Outcome of the patient after illness (date of discharge or death).

Zero reporting from hospitals is crucial to verify that the surveillance system is continuously functioning.

2.5.5. Sentinel site (ILI/ARI/SARI) surveillance

Sentinel syndromic surveillance is a complementary approach to the other forms of surveillance listed in this document. The advantage of using a sentinel surveillance system is that a systematic, standardized approach to testing is used based on syndromic case definitions and not affected by changes in testing strategies affecting the other COVID-19 surveillance approaches.

Countries that conduct primary care or hospital-based sentinel surveillance for influenza-like-illness (ILI), acute respiratory infection (ARI), severe acute respiratory infection (SARI) or pneumonia should continue this syndromic surveillance and continue to collect respiratory specimens using existing case definitions through sentinel networks. Laboratories should continue virologic testing of routine sentinel site samples for influenza, with the addition of testing samples for SARS-CoV-2. Multiplex assays have been developed to ensure joint testing of influenza and SARS-CoV-2. Countries are encouraged to conduct year-round sentinel surveillance for acute respiratory syndromes with testing of samples for SARS-CoV-2.

Within the existing surveillance systems, the patients selected for additional testing for SARS-CoV-2 should preferably be representative of the population and include all ages and genders. If possible, continue to collect samples from both ILI and SARI sentinel sites to represent both mild and severe illness. It is recognized that, based on the local situation, resources, and epidemiology, countries may wish to prioritize sampling among inpatients (SARI or pneumonia cases) to understand SARS-CoV-2 circulation in patients with more severe disease. Further guidance on sampling for testing in sentinel sites can be found in <u>Global</u> Epidemiological Surveillance Standards for Influenza³².

SARS-CoV-2 infections identified through sentinel surveillance should be reported in overall national SARS-CoV-2/COVID-19 case counts, as well as through relevant sentinel-site channels.

Additional guidance on sentinel site surveillance for COVID-19 is found in the interim guidance for maintaining surveillance of influenza and monitoring of COVID-19³³.

2.5.6. Closed settings

Dedicated enhanced surveillance for some high-risk groups residing or working in closed settings is necessary to ensure the prompt detection of cases and clusters faster than through primary-care or hospital-based surveillance. People who live in closed environments, such as prisons, residential facilities, retirement communities and care homes for persons with disabilities, can be especially vulnerable to COVID-19. The reasons include living in settings where the probability of transmission may be higher than in the general population or having health conditions or predisposing factors that increase the risk of developing severe illness and death. Enhanced surveillance in closed settings includes the use of active case finding through frequent screening for signs and symptoms for COVID-19; and zero reporting for all individuals in high-risk groups under surveillance.

2.6. Health care-associated SARS-CoV-2 infections

In countries with mandatory reporting systems for health care-associated infections, SARS-CoV-2 infection should be included as a priority condition for reporting within these systems, in addition to being counted within general COVID-19 surveillance. All cases and clusters in health care settings should be investigated and documented for their source and transmission patterns to allow rapid control. Specific reporting of the number of COVID-19 cases and deaths (including asymptomatic SARS-CoV-2 infections) in health and care workers should be implemented and reported to the national surveillance system, in line with the latest reporting format. Additional resources on COVID-19 among health and care workers in a health care setting can be accessed here³⁴, here³⁵ and here³⁶.

2.7. Mortality surveillance

There are three main approaches to estimate both COVID-19-attributable mortality and excess mortality due to indirect effects on health systems:

- Civil registration and vital statistics: legal requirements of death certification, including cause of death attributable to COVID-19, should be done as routinely required by civil registration systems. Countries should also monitor deaths resulting from non-specific respiratory causes (e.g., unspecified pneumonia), which may represent undiagnosed COVID-19. In addition, vital statistics should monitor excess all-cause mortality over time, as changes may be related to the COVID-19 pandemic effects on health systems.
- Ad hoc surveys: Where civil registration and vital statistics systems are limited or non-existent, rapid mortality surveillance may be considered. Further guidance can be found in the document <u>Revealing the toll of COVID-19</u>³⁷, and on the webpage <u>The true death toll of COVID³⁸</u>.
- Using COVID-19 surveillance data: the number of COVID-19 deaths occurring in hospitals should be reported at least weekly. The number of COVID-19 deaths occurring in the community, including in long-term-care facilities, should also be reported at least weekly. For both hospital and community COVID-19 deaths, the age, sex, and location of death should be recorded. Surveillance data can be used to model excess mortality.

To ascertain cause of death for COVID-19 for deaths occurring outside of health care settings, the <u>WHO Verbal Autopsy tool</u>³⁹ has included COVID-19 in the updated toolkit.

2.8. SARS-CoV-2 variant surveillance

See variant surveillance guidance¹¹.

2.9. Vaccination effectiveness and impact

As COVID-19 vaccination is relatively new, there are different objectives of disease surveillance as it relates to vaccination, which apply in the short, medium and long term. Globally, given the many vaccines used by different countries, in addition to the surveillance being conducted to guide the outbreak response to COVID-19, countries should conduct basic surveillance to help understand vaccine impact in their context. Data needed to support monitoring of vaccine impact should, as much as possible, leverage existing systems already in place for COVID-19 surveillance.

Objectives include:

-Characterizing the epidemiologic context to guide vaccine rollout. Based on surveillance data, countries should determine where (geographically and/or by sub-population) COVID-19 burden remains high, and use this information to guide phased vaccine introduction.

- Understanding vaccine effectiveness (VE) and impact of vaccination. An option to monitor VE over time, is to nest vaccine effectiveness studies in existing surveillance systems. Surveillance systems would need to be reinforced to ensure that there is no selection bias in the population included in the VE study, that vaccination, outcome and confounding factors/effect modifiers are well documented.

Ideally, this is best done through sentinel site surveillance, and can be efficiently added to influenza sentinel site surveillance (e.g., influenza-like illness, <u>acute respiratory infection and SARI sites</u>⁴⁰) by adding questions related to vaccination and SARS-CoV-2 testing. Other potential sentinel surveillance sites include acute febrile illness sentinel sites or COVID-19 diagnostic centers. In all settings, case definitions must be adhered to strictly and reliable high-quality data must be collected. It is valuable to consider collecting data from a variety of sentinel sites that cover both outpatient and inpatient services to help understand the impact of the vaccine on the severity of disease.

- Understand long-term immunity, duration of immunity, and potential need for booster doses due to waning immunity: This is a medium- to longer term objective that can be achieved via a combination of sentinel site surveillance and research studies.

Further guidance can be found here: <u>Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines</u>, here: <u>Monitoring COVID-19 vaccination</u>: <u>Considerations for the collection and use of vaccination data</u>, and here <u>Guidance on</u> <u>conducting vaccine effectiveness evaluations in the setting of new SARS-CoV-2 variants</u>: <u>Interim guidance</u>, 22 July 2021. <u>Addendum to Evaluation of COVID-19 vaccine effectiveness</u>

3. Additional surveillance methods and approaches for COVID-19

Additional surveillance approaches can be used along with the essential elements of comprehensive surveillance for COVID-19. New approaches, such as environmental surveillance of non-infective viral fragments of the SARS-CoV-2 virus in wastewater, are being developed.

3.1. Event-based surveillance

The capacity to rapidly detect any changes in the overall COVID-19 situation can be further strengthened through robust eventbased surveillance (EBS) mechanisms. EBS captures unstructured information from formal and informal channels, such as online content, radio broadcasts and print media across all sectors to complement conventional public health surveillance efforts. Successful EBS implementation requires dedicated human resources and clear processes to sift through large volumes of information to filter, triage, verify, compare, assess, and communicate relevant content. Many web-based systems have been developed over the years to support EBS activities, many of which converge through the WHO-led <u>Epidemic Intelligence from</u> <u>Open Sources⁴¹</u> (EIOS) initiative. It is equally important to monitor for other potential events that may emerge in parallel, having further effects on lives and compromising COVID-19 response efforts. Further guidance on EBS is available from the Africa Centres for Disease Control and Prevention, <u>here⁴²</u>.

3.2. Telephone hotlines

Telephone hotlines made available to the public for advice and referral to health-care services may provide an early indication of disease spread in a community. Effectively running a telephone hotline service requires dedicated resources and trained staff to triage calls and appropriately refer callers to health care or other services.

3.3. Participatory surveillance

Participatory disease surveillance enables members of the public to self-report signs or symptoms, without laboratory testing or assessment by a health care provider Participatory disease surveillance relies on voluntary reporting, usually through dedicated smartphone applications. Although this type of surveillance may not be very specific for identifying cases of COVID-19, the analysis of trends of self-reported illness by members of the public can indicate communities where early disease spread may be occurring. Data collected from participatory surveillance can also give indications of changes in health care-seeking behavior, which are important to understand when interpreting facility-based surveillance data ⁴³.

3.4. Serological surveys

Population-based serological surveys and the use of serology in specific settings/populations can help provide estimates of the proportion of a population that has been infected by SARS-CoV-2 virus as measured by antibodies. Enhanced surveillance, surveys, and outbreak investigations can assess the extent of infection in the general population or subpopulations, in specific age groups and, potentially, the proportion of unrecognized infections (e.g. asymptomatic or subclinical infections).

Initial seroprevalence of a novel coronavirus in the population is assumed to be negligible. Therefore, surveillance of antibody seropositivity in a population, when analysed in combination with vaccination data, can allow inferences to be made about the cumulative incidence of infection in the population. Serological surveillance can be used to assess population-level exposure to SARS-CoV-2 and help estimate the burden of infections and deaths that could be under-reported by weak surveillance systems, as well as identifying the contribution of asymptomatic infections. Gender and age disaggregation of serosurveillance data should be compared with that of the disease surveillance system, to determine the ascertainment potential and quality of the surveillance system.

At this stage, for countries undertaking serological surveillance for SARS-CoV-2, the following primary objectives are recommended:

- to measure the seroprevalence of antibodies to SARS-CoV-2 in the general population by sex and age group, and vaccination status to ascertain the cumulative population immunity; and
- to estimate the fraction of asymptomatic, pre-symptomatic or subclinical infections in the population and by sex and age group.

Serological surveillance can also provide the opportunity to inform or evaluate secondary objectives, such as:

- to determine risk factors for infection by comparing the exposures of infected and non-infected individuals;
- to contribute to an improved estimation of the infection fatality rate
- to contribute to an improved understanding of **antibody kinetics at the level of populations** following sars-cov-2 infection.
- to contribute to a greater understanding of the immunity due to vaccination alongside that from infection
- to estimate uptake of vaccination against SARS-CoV-2 in the population by sex, age and priority target groups; and
- assess Knowledge Attitudes and Practices (KAP) to COVID-19 vaccination and Public Health Social Measures (PHSM) in the population by sex and age.

The three study designs listed below are recommended for countries considering serological surveillance for SARS-CoV-2 infection, with participants recruited preferentially through random (e.g. random selection of participants from a sampling list such as through population-based household surveys) or convenience (e.g. residual sera of attendees at healthcare facilities, or blood donors) samples of population:

- 1) One-time cross-sectional seroprevalence survey
- 2) Repeated cross-sectional seroprevalence survey in the same geographic area (but not sampling the same individuals)
- 3) Longitudinal investigation with serial sampling of the same individuals each time

WHO has developed standardized seroepidemiology protocols to support national public health and social measures, promote the international comparability of research and address gaps in current knowledge of COVID-19. More information can be found <u>here</u>²³. A WHO generic protocol "Population-based age-stratified sero-epidemiological investigation protocol for coronavirus 2019 (COVID-19) infection" is available <u>here</u>⁴⁴. In light of vaccine roll-out, this protocol is being adapted to include estimation of vaccine uptake and other indicators (e.g. case fatality ratio and proportion of asymptomatic infections) stratified by vaccination status.

3.5. Surveillance in humanitarian and other low-resource settings

In refugee camps and among displaced populations and in other humanitarian or low-resource settings, there are additional considerations for implementation.

Detection of SARS-CoV-2 infection in these settings can include several strategies. Event-based surveillance can help pick up early warnings and alerts. Where Early Warning, Alert and Response (EWAR) or Community Based Surveillance (CBS) systems are in place, COVID-19 disease should be integrated into them, and active case finding can be conducted where feasible. In health care facilities, syndromic surveillance may be put in place. Vulnerable groups, including health and care workers, persons with risk factors for developing severe disease and persons with insufficient access to health care should be prioritized for surveillance and response, as should those in closed settings with high risk of disease transmission.

Testing strategies should target suspect cases following WHO case definitions. Further prioritization can depend on the transmission classification, "high-risk" groups and resources available.

Further information can be found in the Interagency Guidance on <u>scaling-up COVID-19 outbreak readiness and response</u> operations in humanitarian situations⁸. Additional guidance for humanitarian operations, camps and other fragile settings can be found <u>here⁴⁵</u>.

3.6. Environmental surveillance

Routine clinical SARS-CoV-2 surveillance programs have been augmented with community-scale environmental surveillance (ES) in an increasing number of settings globally. The most experience has been gained with the sampling of sewage to capture SARS-CoV-2 genetic material shed in faces and respiratory discharges.

A number of scenarios have emerged in which ES has been used to detect unrecognized transmission and provide an additional source of information to support decision-making about whether to adjust public health and social measures. These include:

- early warning (3-7 days) of increasing trends in cases (moderate to high prevalence settings).
- overcoming complacency for clinical testing by publicizing presence or increase of ES signal in wastewater in an area (low to moderate prevalence settings)
- cost effective targeting of clinical testing resources to areas with higher ES signals (spatially differentiated low to moderate prevalence settings)
- informing early and targeted restrictions in pockets of re-emergence to help reduce the extent and economic impact or restrictions (spatially differentiated, low prevalence settings)
- targeted surveillance for early warning of circulation in; vulnerable or high-risk contexts such as managed isolation facilities, aged care facilities, prisons, informal settlements, refugees and displaced persons; transport vessels such as planes and ships at boarders; events and gatherings; and isolated communities
- identification of known variants (where presence of variants is uncertain), identification and tracking emergence of novel variants using whole genome sequencing (moderate to high prevalence settings).

Wherever ES has been used its application has been adjunct to, and not in place of, clinical surveillance. Clarity on coordination, data sharing and interpretation of results between entities responsible for ES and PH surveillance is critical to make effective use of ES data with COVID response strategies. Methods for sampling, analysis and interpretation of data are evolving. Several protocols exist but as yet there is no internationally agreed protocol for ES of SARS-COV-2.

Applications to date have been most successful in settings with high sewerage coverage. Pilot testing in settings with low sewerage coverage and predominantly on-site sanitation systems have deployed sampling strategies and capacities from the polio ES programs.

See scientific brief <u>here⁴⁶.</u> Additional guidance is in development.

4. Reporting COVID-19 surveillance data to WHO

4.1. International Health Regulations

WHO requests that Member States report daily counts of cases and deaths and weekly aggregate counts of cases and deaths at different levels of aggregation, as per IHR requirements⁴⁷.

4.2.Case-based reporting

Reporting of individual case report forms is no longer required by WHO at the global level.

On a voluntary basis, Member States may wish to continue to submit case report forms in consultation with their WHO Regional Offices. Data-sharing policies regarding case-based data and analysis strategy and output sharing will be managed by the relevant Regional Office.

An updated version of the Case Report Form template, including vaccination status, can be found here.

Although WHO recommends ceasing case-based reporting for surveillance, the Organization encourages countries to participate in the reporting of clinical data on COVID-19 patients using the dedicated tools available <u>here</u>⁴⁸. To note, this is not related to surveillance reporting as described in the present guidance.

4.3. Daily aggregated data collection

Daily counts of SARS-CoV-2 infections/COVID-19 cases and deaths are compiled by WHO Regional Offices, which in turn receive data either directly from Member States or through extraction from official government public sources (e.g. Ministry of Health websites). Member States are thus encouraged to continue providing these daily counts, where collected. WHO tallies and reports the number of confirmed infections and deaths regularly in its situation reports, global dashboard (covid19.who.int) and elsewhere.

Counts are based on <u>WHO case definitions</u>⁴⁹ unless otherwise stated (see <u>Country, territory, or area-specific updates and errata</u>⁵⁰). All data represent date of reporting rather than date of symptom onset. All data are subject to continuous verification and may change based upon retrospective updates to accurately reflect trends, changes in country case definitions or reporting practices.

Counts of new infections and deaths are calculated by subtracting previous cumulative total counts from the current count. Owing to differences in reporting methods, cut-off times, retrospective data consolidation and reporting delays, the number of new infections may not always reflect daily totals published by individual countries, territories or areas. Further information on the data collected and displayed can be found in the global dashboard (covid19.who.int).

4.4.Weekly aggregated reporting

The aim of ongoing weekly aggregate reporting is to obtain further information on global COVID-19 trends for enhanced analysis, and the following data set should be considered as the core list of surveillance indicators to be included in routine weekly reporting to WHO.

- number of confirmed cases
- number of probable cases
- number of confirmed deaths
- number of probable deaths
- number of individuals hospitalized (confirmed and probable)
- number discharged (confirmed and probable)
- number of health and care workers infected (confirmed + probable) as a subset of total case count
- number of health and care workers who died from covid-19 (confirmed + probable) as a subset of total death count
- number of persons tested
- number of persons tested by NAAT
- confirmed + probable cases by age group and sex (see below)
- confirmed + probable deaths by age group and sex (see below).

The following age categories (in years) are requested: 0-4, 5-9, 10-14, 15-19, 20-29, 30-39, 40-49, 50-59, 60-64, 65-69, 70-74, 75-79, 80 and over.

The deadline for Member State submission of weekly data for each epidemiologic week is Thursday of the following week. Member States are requested to submit weekly data even when no new cases were reported during the week (zero reporting).

WHO no longer requests Member States to report transmission classifications to WHO.

Weekly aggregated reporting data can be reported via Excel using the form <u>"Global Surveillance of COVID-19: WHO process for</u> reporting aggregated data- V2⁵¹" A data dictionary is included. Members States can also report via regional existing platforms or the dedicated submission weekly surveillance platform. The weekly surveillance platform for the collection of the minimum variables at the national level is available for Member States to self-report their weekly data directly to WHO (for further information or to obtain login credentials please email <u>covidsurveillance@who.int</u>).

Country metadata

Member States are requested to provide additional surveillance metadata to WHO to facilitate interpretation of submitted surveillance data:

- definition of epidemiologic period/week in use in country (e.g. "Monday to Sunday")
- case definitions used by the country, and the date these definitions came into effect
- surveillance/detection strategy or strategies in place in the country, and the date these strategies came into effect noting that articulating the surveillance strategy is particularly important where surveillance does not seek to capture all cases, e.g. is limited to sentinel sites
- testing strategy or strategies in place in the country and the date these strategies came into effect
- situation reports whenever they are issued.

Changes in definitions or criteria have an impact on case ascertainment and, consequently, multiple epidemiologic parameters, such as the epidemic curve and calculation of the case fatality ratio. Metadata should be submitted using the dedicated mailbox for COVID-19 surveillance (covidsurveillance@who.int) or through respective WHO Regional Offices.

Countries are also encouraged to monitor the quality of COVID-19 surveillance by monitoring such performance indicators as timeliness, completeness, and representativeness of surveillance data.

4.5.DHIS2 packages

The COVID-19 DHIS2 digital data package includes standard metadata aligned with this guidance and implementation guidance to enable rapid deployment in countries.

Features include case-based surveillance, contact tracing, aggregate surveillance, and vaccination surveillance.

Guidance for these packages may be found <u>here⁵².</u>

4.6.Reporting of COVID-19 through the Global Influenza Surveillance and Response System (GISRS)

WHO has a long history of monitoring influenza trends and virology through the Global Influenza Surveillance and Response System (GISRS), which gathers information on ILI, ARI, SARI and pneumonia cases and mortality, mainly through sentinel surveillance. Countries are encouraged to maintain and strengthen existing sentinel syndromic surveillance and to test samples collected for influenza surveillance for SARS-CoV-2. Data from sentinel syndromic surveillance and from laboratory testing for influenza and SARS-CoV-2 (numbers tested and numbers positive) identified at GISRS sites should be reported to WHO via existing reporting platforms and existing formats and frequencies, both through the GISRS system and the aggregate reporting for COVID-19 (as outlined above). Further information about reporting to GISRS can be found at <u>Operational considerations for COVID-19 surveillance using GISRS⁵³</u>.

4.7. Data analysis, display and outputs

WHO utilizes reported data to elaborate a number of internal and public goods, to provide information for evidence-based operational decision-making. Major uses are outlined in the table below.





4.8. Monitoring and evaluation framework

The COVID-19 <u>Strategic Response and Preparedness Plan for 2021</u>⁵⁴ includes surveillance as a strategic element of preparedness and response. As part of the Monitoring and Evaluation framework, two indicators for surveillance are based on the surveillance data reported to WHO:

	Indicator: Proportion of Member States with COVID-19 detailed surveillance reporting to WHO	Indicator: Proportion of Member states reporting COVID-19 health and care worker infections to WHO
Definition of	A Member State is considered to have reported COVID-	A Member State is considered to have reported
key terms	either:	in the past month if it has provided either:
	1) at least one weekly aggregate surveillance reporting	1) at least one weekly aggregate surveillance reporting
	submission providing at least age and sex data of cases	submission providing cases or deaths of health worker
	OR;	cases
	2) for countries maintaining case-based surveillance, has	OR;
	provided Case Reporting Forms (CRFs) for at least 50%	2) for countries maintaining case-based surveillance,
	of incident cases reported for any week of past month,	has provided Case Reporting Forms (CRFs) for at least
	providing at least age and sex of cases	50% of incident cases reported for any week of past month providing health and care worker status for the
		recorded cases.
Measurement		
Measurement Numerator	Number of Member States reporting detailed COVID-19	Number of Member States reporting COVID-19 health
Measurement Numerator	Number of Member States reporting detailed COVID-19 surveillance data to WHO	Number of Member States reporting COVID-19 health and care worker infections
Measurement Numerator Denominator	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194)	Number of Member States reporting COVID-19 health and care worker infections All Member States (n=194)
MeasurementNumeratorDenominatorDisaggregation	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194) There is no disaggregation for this indicator	Number of Member States reporting COVID-19 health and care worker infectionsAll Member States (n=194)COVID-19 health and care worker death reporting may
Measurement Numerator Denominator Disaggregation	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194) There is no disaggregation for this indicator	Number of Member States reporting COVID-19 health and care worker infectionsAll Member States (n=194)COVID-19 health and care worker death reporting may be shown as a disaggregation to provide more detailed
Measurement Numerator Denominator Disaggregation	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194) There is no disaggregation for this indicator	Number of Member States reporting COVID-19 health and care worker infections All Member States (n=194) COVID-19 health and care worker death reporting may be shown as a disaggregation to provide more detailed analysis of available data reporting
Measurement Numerator Denominator Disaggregation Scope Transit	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194) There is no disaggregation for this indicator All Member States	Number of Member States reporting COVID-19 health and care worker infectionsAll Member States (n=194)COVID-19 health and care worker death reporting may be shown as a disaggregation to provide more detailed analysis of available data reportingAll Member States1009/
Measurement Numerator Denominator Disaggregation Scope Target Data collection	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194) There is no disaggregation for this indicator All Member States 100%	Number of Member States reporting COVID-19 health and care worker infectionsAll Member States (n=194)COVID-19 health and care worker death reporting may be shown as a disaggregation to provide more detailed analysis of available data reporting All Member StatesAll Member States100%
Measurement Numerator Denominator Disaggregation Scope Target Data collection	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194) There is no disaggregation for this indicator All Member States 100% and reporting	Number of Member States reporting COVID-19 health and care worker infections All Member States (n=194) COVID-19 health and care worker death reporting may be shown as a disaggregation to provide more detailed analysis of available data reporting All Member States 100%
Measurement Numerator Denominator Disaggregation Scope Target Data collection Data source Remarking start	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194) There is no disaggregation for this indicator All Member States 100% and reporting WHO global surveillance system January 2021	Number of Member States reporting COVID-19 health and care worker infections All Member States (n=194) COVID-19 health and care worker death reporting may be shown as a disaggregation to provide more detailed analysis of available data reporting All Member States 100% WHO global surveillance system Immuner: 2021
Measurement Numerator Denominator Disaggregation Scope Target Data collection Data source Reporting start date	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194) There is no disaggregation for this indicator All Member States 100% and reporting WHO global surveillance system January 2021	Number of Member States reporting COVID-19 health and care worker infections All Member States (n=194) COVID-19 health and care worker death reporting may be shown as a disaggregation to provide more detailed analysis of available data reporting All Member States 100% WHO global surveillance system January 2021
Measurement Numerator Denominator Disaggregation Scope Target Data collection Data source Reporting start date Reporting	Number of Member States reporting detailed COVID-19 surveillance data to WHO All Member States (n=194) There is no disaggregation for this indicator All Member States 100% and reporting WHO global surveillance system January 2021 Monthly	Number of Member States reporting COVID-19 health and care worker infections All Member States (n=194) COVID-19 health and care worker death reporting may be shown as a disaggregation to provide more detailed analysis of available data reporting All Member States 100% WHO global surveillance system January 2021 Monthly

For further guidance, see <u>SPRP M&E framework</u>⁵⁵.

4.9. Vaccination

• Monitoring of vaccine deployment

WHO is monitoring vaccine deployment at national level through vaccination data published online and provided officially through WHO Regional Offices. See. S table 6 for variables collected and displayed through the WHO global COVID-19 dashboard.

Table 2: Variables for aggregate reporting of vaccination deployment

Variable	Frequency
Start date of vaccination (for each vaccine)	Once
Authorizations for vaccine products, deployment of authorized products	Ad hoc
Target groups	Ad hoc
Total number of vaccine doses administered	Weekly
People vaccinated with at least one dose	Weekly
Daily doses administered	Weekly
People fully vaccinated	Weekly

WHO is also monitoring vaccine deployment monthly via the eJRF (Electronic Joint Reporting Forms) available in the vaccination monitoring guidance⁵⁶.

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