Public health surveillance for COVID-19

Interim guidance

14 February 2022

World Health Organization

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 sex of cases and deaths, (probable and confirmed)
  - cases and deaths among health and care workers,
  - number of cases hospitalized, and discharged,
  - 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 preparedness, readiness and response activities[1], and contact tracing[2] for COVID-19. Updated information and other guidance on COVID-19 can be found on the COVID-19 website.

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 ≥ 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.

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[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 Diagnostic testing for SARS-CoV-2 [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 ≥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 following[57]:
- 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 recommended personal protective equipment[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:

- Exposure to a symptomatic case: 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 Considerations for implementing and adjusting public health and social measures in the context of COVID-19[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 the considerations for quarantine of contacts of cases[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 self-reporting 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 prioritized[20], as noted above. Further information can be found in forthcoming updated contact tracing guidance.

More information on contact ascertainment is available in latest PHSM guidance[4], considerations for quarantine of contacts of cases[5], and Contact tracing in the context of COVID-19[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, see International guidelines for certification and classification (coding) of COVID-19 as a cause of death[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, 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 guidance[7].

"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 IASC guidance[8] and Public health and social measures for COVID-19 preparedness and response in low capacity and humanitarian settings[9] for further details.

1.5. Variant definitions

WHO definitions of Variants of Interest and Variants of Concern can be found here[10]. 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 above) 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 Guidance for surveillance of SARS-CoV-2 variants: Interim guidance, 9 August 2021[11] 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 here[16]. 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 variant surveillance guidance[11].

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 sequencing[18].

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 WHO case definition[19]. 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.

- Clinical evidence of disease

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 standard WHO Covid-19 case definition criteria[19]. Clinical management should not be different given the number of infections suspected or reported by the patient and should follow the clinical management guidance[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.

- Clinical specimen collection for laboratory diagnosis

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.

- Molecular laboratory tests

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 health[18]).

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 serological investigations[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.

Table 1: recommended items for recording of suspected reinfection cases

Sections		Variables
Patient ID		Age
		Sex
		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
	Sampling and laboratory	Date of first onset
		Date of sampling for first positive RT-qPCR or ag-RDT
		Clinical characteristics of first episode
		Severity (hospitalization, ICU, mechanical ventilation)
		Date of first sample antibody testing
		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)
Second episode	Vaccination status	Vaccination status on second onset (one dose/ two doses)
		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
		Clinical characteristics of 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		

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 ≥ 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 ≥ 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.