Antonio Grizzuti
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Stockholm, 21 August 2020
Our ref.: DPR-2020-OUT-2776-PiKrPaReGo

Dear Mr Grizzuti,

Re: Your application for access to documents – Ref 20-3291

We refer to your e-mail dated 3 August 2020 in which you make a request for access to documents, registered on the same day under the above mentioned reference number.

You requested documents containing
a detailed summary of all case definition issued by ECDC for Sars-CoV-2/Covid-19 suspect case, starting from January 1st, 2020 since today.

We regret to inform you that no documents were found that would correspond to the description given in your application. Case definitions were updated several times, but ECDC never produced any document containing a summary of all case definition issued.

Indeed, as specified in Article 2(3) of Regulation 1049/2001, the right of access as defined in that Regulation applies only to existing documents in the possession of the Institution. On this respect, we would like to point out that in accordance with the Judgment of the Court of 11 January 2017 in case C-491/15 P, *Typke v Commission* an application for access that would require an Institution to create a new document, even if that document were based on information already appearing in existing documents held by it, falls outside the framework of Regulation 1049/2001. Therefore, ECDC is not in a position to handle your request as an access to documents request in accordance to Regulation 1049/2001.

However, in line with the Code of Good Administrative Behaviour and with our strive to serve the European Citizens, we have requested one of our experts to make a list with the changes in case definitions. First of all, please note that the latest case definition is published in the following link to ECDC website:

https://www.ecdc.europa.eu/en/covid-19/surveillance/case-definition

Below you can find the list of previous changes prepared by our expert:

- 2 March 2020:

Case definition and European surveillance for COVID-19, as of 2 March 2020

Suspected case requiring diagnostic testing (not to be reported at the European level)

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Laboratory testing for COVID-19 should be performed for suspected cases according to the following criteria, based on the updated WHO case definition:

1) a patient with acute respiratory tract infection (sudden onset of at least one of the following: cough, fever, shortness of breath) AND with no other aetiology that fully explains the clinical presentation AND with a history of travel or residence in a country/area reporting local or community transmission* during the 14 days prior to symptom onset;

OR

2) a patient with any acute respiratory illness AND having been in close contact with a confirmed or probable COVID-19 case in the last 14 days prior to onset of symptoms;

OR

3) A patient with severe acute respiratory infection (fever and at least one sign/symptom of respiratory disease (e.g., cough, fever, shortness breath)) AND requiring hospitalisation (SARI) AND with no other aetiology that fully explains the clinical presentation.

* according to WHO classification, see respective daily updated Coronavirus disease (COVID-2019) situation reports at https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/

However, once local or community transmission has been reported in the country or area, all patients presenting with symptoms of acute respiratory infection in primary care or the accident and emergency department of a hospital (first contact with the healthcare system) will be considered as suspected cases.

Probable case
A suspected case for whom testing for virus causing COVID-19 is inconclusive (according to the test results reported by the laboratory) or for whom testing was positive on a pan-coronavirus assay.

Confirmed case
A person with laboratory confirmation of virus causing COVID-19 infection, irrespective of clinical signs and symptoms

Definition of close contact for the purpose of the case definition
Close contact of a probable or confirmed case is defined as:

A person living in the same household as a COVID-19 case;
A person having had direct physical contact with a COVID-19 case (e.g. shaking hands);
A person having unprotected direct contact with infectious secretions of a COVID-19 case (e.g. being coughed on, touching used paper tissues with a bare hand);
A person having had face-to-face contact with a COVID-19 case within 2 metres and > 15 minutes;

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A person who was in a closed environment (e.g. classroom, meeting room, hospital waiting room, etc.) with a COVID-19 case for 15 minutes or more and at a distance of less than 2 metres;
A healthcare worker (HCW) or other person providing direct care for a COVID-19 case, or laboratory workers handling specimens from a COVID-19 case without recommended personal protective equipment (PPE) or with a possible breach of PPE;
A contact in an aircraft sitting within two seats (in any direction) of the COVID-19 case, travel companions or persons providing care, and crew members serving in the section of the aircraft where the index case was seated (if severity of symptoms or movement of the case indicate more extensive exposure, passengers seated in the entire section or all passengers on the aircraft may be considered close contacts).
The epidemiological link to a probable or confirmed case may have occurred within a 14-day period before the onset of illness in the suspected case under consideration.

- 25 February 2020:

Case definition for EU surveillance of COVID-19, as of 25 February 2020

Suspected case requiring diagnostic testing (not to be reported at the European level)
Patients with acute respiratory infection (sudden onset of at least one of the following: cough, fever, shortness of breath) requiring hospitalisation or not,

AND

who in the 14 days prior to onset of symptoms have met at least one of the following epidemiological criteria:

close contact with a confirmed or probable case of COVID-19 infection
OR

having stayed in areas with presumed community transmission *
* People with a) acute respiratory infection requiring hospitalisation or not and b) returning from areas with presumed widespread community transmission fulfil the criteria for testing. The criteria for laboratory testing of people with a) acute respiratory infection requiring hospitalisation or not and b) returning from areas with presumed localised or low-level community transmission should include a case-by-case clinical judgement and be based on national recommendations.

Probable case
A suspected case for whom testing for virus causing COVID-19 is inconclusive (according to the test results reported by the laboratory) or for whom testing was positive on a pan-coronavirus assay.

Confirmed case
A person with laboratory confirmation of virus causing COVID-19 infection, irrespective of clinical signs and symptoms.

Close contact
Close contact of a probable or confirmed case is defined as:

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A person living in the same household as a COVID-19 case;
A person having had direct physical contact with a COVID-19 case (e.g. shaking hands);
A person having unprotected direct contact with infectious secretions of a COVID-19 case (e.g. being coughed on, touching used paper tissues with a bare hand)
A person having had face-to-face contact with a COVID-19 case within 2 metres and > 15 minutes;
A person who was in a closed environment (e.g. classroom, meeting room, hospital waiting room, etc.) with a COVID-19 case for 15 minutes or more and at a distance of less than 2 metres;
A healthcare worker (HCW) or other person providing direct care for a COVID-19 case, or laboratory workers handling specimens from a COVID-19 case without recommended PPE or with a possible breach of PPE;
A contact in an aircraft sitting within two seats (in any direction) of the COVID-19 case, travel companions or persons providing care, and crew members serving in the section of the aircraft where the index case was seated (if severity of symptoms or movement of the case indicate more extensive exposure, passengers seated in the entire section or all passengers on the aircraft may be considered close contacts).
The epidemiological link may have occurred within a 14-day period before the onset of illness in the case under consideration.

More about public health management of persons having had contact with novel coronavirus cases:

Contact tracing: Public health management of persons, including healthcare workers, having had contact with COVID-19 cases in the European Union
This document aims to provide guidance for EU/EEA public health authorities on the management of persons, including healthcare workers, who had contact with COVID-19 cases.

Criteria to initiate testing for COVID-19 virus for active epidemiological case finding
Prompt case confirmation is necessary to ensure rapid and effective contact tracing, implementation of infection prevention and control measures in accordance with national recommendations. Case confirmation is also needed for the collection of relevant epidemiological and clinical information.

Any person fulfilling the criteria of a suspected case should be tested for COVID-19 virus, as part of active case finding.

Based on clinical judgement, clinicians should also consider including COVID-19 testing as differential diagnosis for patients with viral pneumonia or severe acute respiratory infection admitted to hospitals. COVID-19 should also be considered in clusters of patients with viral pneumonia of unknown aetiology.

The laboratory method is provided below. The laboratory test should be initiated immediately.

Types of specimens
The rapid collection of the following specimens should be considered:

When possible, specimens from both lower and upper respiratory tracts should be collected:

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Lower respiratory tract:
bronchoalveolar lavage (BAL)
endotracheal aspirate (ETA)
expectorated sputum

Upper respiratory tract:
nasopharyngeal swab
oropharyngeal swab
nasopharyngeal aspirate or nasal wash

Additional specimens for later testing:
when serological testing becomes available: serum, acute and convalescent (possibly 2 to 4 weeks after acute phase) specimen,
other specimens to consider: blood, urine and faeces
Respiratory specimen collection from the upper and in particular lower respiratory tract should be performed under heightened infection prevention and control measures (airborne precautions) in accordance with WHO interim guidance on Infection prevention and control in healthcare settings when novel coronavirus (nCoV) infection is suspected.

Currently, there is limited information about the best point in time for specimen collection. Similar to other viral respiratory infections, it is likely that respiratory specimens collected early after symptom onset would yield higher virus concentrations. According to WHO interim guidance for clinical management of SARI, when nCoV infection is suspected, the frequency of specimen collection for hospitalised patients should be at least every 2 to 4 days until there are two consecutive negative results at least 24 hours apart.

See WHO resources:

WHO interim guidance on Infection prevention and control in healthcare settings when novel coronavirus (nCoV) infection is suspected
WHO interim guidance for clinical management of SARI, when nCoV infection is suspected
Testing methodology
The specific tests currently recommended by WHO for the diagnosis and confirmation of SARS-CoV-2 are described in a dedicated WHO webpage and an ECDC webpage on laboratory support (for primary/and or confirmatory testing) by coronavirus-specialised laboratories in the EU.

It is recommended that the specimens of the first five positive cases and the first 10 negative cases that meet the COVID-19 case definition for testing should be shipped for confirmation to the national reference laboratory for SARS-CoV-2; if there is no national capacity, these specimens should be shipped to one of the specialised laboratories that offered international support (see list of laboratories below). After that, the laboratories can test for SARS-CoV-2 independently but should collaborate with specialised laboratories to resolve confounding results.

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A single positive test should be confirmed by a second RT-PCR assay targeting a different SARS-CoV-2 gene. A single negative SARS-CoV-2 test (especially if from an upper respiratory tract specimen) or a positive test result for another respiratory pathogen result does not exclude COVID-19 infection. If there is a strong suspicion for COVID-19 infection, another specimen should be tested with the primary and secondary RT-PCR assays.

If possible, sequence information should be generated from positive specimens. ECDC encourages the timely sharing of sequence data. The publically available sequence database GISAID accepts the upload of COVID-19 sequences.

- 26 January 2020:

Case definition and European surveillance for human infection with novel coronavirus (SARS-CoV-2)

For surveillance at the European level, ECDC and the WHO Regional Office for Europe request countries to report probable and confirmed cases of SARS-CoV-2 infections using the global case definition within 24 hours after identification. EU/EEA countries must notify probable and confirmed cases of SARS-CoV-2 through the Early Warning and Response System (EWRS).

ECDC and the WHO Regional Office for Europe are coordinating the rapid reporting of data as requested in the WHO case reporting form in collaboration with their surveillance networks in Member States.

Case reporting forms will be collected using The European Surveillance System - TESSy.

The World Health Organization published an interim guidance for global surveillance of novel coronavirus infection (2019-nCoV). The guidance includes a case definition for suspect, probable and confirmed cases, and an interim case reporting form. The case definition for suspect cases was based on the information available on the outbreak at that time. Following the confirmation of community transmission in Wuhan and reports of a wider disease spectrum, ECDC updated the criteria for laboratory testing of suspect cases. The ECDC definition of suspect cases includes patients with acute respiratory infection (ARI) regardless of severity, that in the 14 days prior the onset of illness, had a close contact with a confirmed SARS-CoV-2 visited a healthcare facility where SARS-CoV-2 cases were being treated, or travelled to areas with presumed ongoing community transmission.

Case definition for surveillance

Suspected case requiring diagnostic testing (not to be reported at European level)

Patients with acute respiratory infection (sudden onset of at least one of the following: cough, sore throat, shortness of breath) requiring hospitalisation or not

AND

In the 14 days prior to onset of symptoms, met at least one of the following epidemiological criteria:

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- Were in close contact with a confirmed or probable case of SARS-CoV-2 infection;

OR

- Had a history of travel to areas with presumed ongoing community transmission;

OR

- Worked in or attended a health care facility where patients with SARS-CoV-2 infections were being treated.

Close contact

Close contact of a probable or confirmed case is defined as:

a person living in the same household as a SARS-CoV-2;
a person having had face-to-face contact or was in a closed environment with a SARS-CoV-2 case;
a healthcare worker or other person providing direct care for a SARS-CoV-2 case, or laboratory workers handling SARS-CoV-2 specimens;
a contact in an aircraft sitting within two seats (in any direction) of the SARS-CoV-2 case, travel companions or persons providing care, and crew members serving in the section of the aircraft where the index case was seated (if severity of symptoms or movement of the case indicate more extensive exposure, passengers seated in the entire section or all passengers on the aircraft may be considered close contacts). Click here to read the guidelines.
The epidemiological link may have occurred within a 14-day period before or after the onset of illness in the case under consideration.

Probable case

A suspected case for whom testing for SARS-CoV-2 is inconclusive (the result of the test reported by the laboratory) or for whom testing was positive on a pan-coronavirus assay.

Confirmed case

A person with laboratory confirmation of SARS-CoV-2 infection, irrespective of clinical signs and symptoms

Criteria to initiate testing for SARS-CoV-2

Prompt case confirmation is necessary to ensure rapid and effective contact tracing, implementation of infection prevention and control measures according to national recommendations, and collection of relevant epidemiological and clinical information.

Any person fulfilling the criteria for a suspected case should be tested for SARS-CoV-2. The laboratory method is provided below. The laboratory test should be initiated immediately.

Types of specimens

Rapid collection of the following specimens should be considered:

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When possible, specimens from both lower and upper respiratory tracts should be collected:

Lower respiratory tract:

bronchoalveolar lavage (BAL)
endotracheal aspirate (ETA)
expectorated sputum

Upper respiratory tract:
nasopharyngeal swab
oropharyngeal swab
nasopharyngeal aspirate or nasal wash

Additional specimens for later testing:
when serological testing becomes available: serum, acute and convalescent (possibly 2-4 weeks after acute phase) specimen,
other specimens to consider: blood, urine and faeces

Practical guide for appropriate sampling, can be found in the WHO guide for field operations: Collecting, preserving and shipping specimens for the diagnosis of avian influenza A(H5N1) virus infection.

Respiratory specimen collection from the upper and in particular lower respiratory tract, should be performed under heightened infection prevention and control measures (airborne precautions) according to WHO interim guidance on Infection prevention and control in healthcare settings when novel coronavirus (nCoV) infection is suspected.

Currently there is limited information about the best point in time for specimen collection. Similar to other viral respiratory infections, it is likely that respiratory specimens collected early after symptom' onset would yield higher virus concentrations. According to WHO interim guidance for clinical management of SARI, when nCoV infection is suspected, for hospitalised patients the frequency of specimen should be at least every 2 to 4 days until there are two consecutive negative results at least 24 hours apart.

Testing methodology
The specific tests currently recommended by WHO for the diagnosis and confirmation of SARS-CoV-2 are described in a dedicated WHO webpage, where the laboratory diagnostic protocol for real-time RT-PCR developed by Charité, Berlin Germany can also be found .

It is recommended that the specimens of the first five positive cases and first 10 negative cases meeting the SARS-CoV-2 case definition for testing should be shipped for confirmation to the national specialised laboratory for SARS-CoV-2 or in lack of national capacity to one of the specialised laboratories that offered international support (see list of laboratories below). After that time, the laboratories can test for SARS-CoV-2 independently but use the specialised laboratories to resolve confounding results.

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A single positive test should be confirmed by a second RT-PCR assay targeting a different SARS-CoV-2 gene. A single negative SARS-CoV-2 test (especially if from upper respiratory tract specimen) or a positive test result for another respiratory pathogen result does not exclude SARS-CoV-2 infection. If there is a strong suspicion for SARS-CoV-2 infection, another specimen should be tested with the primary and secondary RT-PCR assays.

When possible, sequence information should be generated from positive specimens. ECDC encourages the timely sharing of sequence data. Publically available sequence database GISAID is accepting the upload of SARS-CoV-2 sequences.

- 25 January 2020:

European surveillance for human infection with novel coronavirus (2019-nCoV)

On January 22 the World Health Organization published an interim guidance for global surveillance of novel coronavirus infection (2019-nCoV). The guidance includes a case definition for suspect, probable and confirmed cases, and an interim case reporting form. The case definition for suspect cases is based on the current information available on the outbreak and may be subject to revision depending on new data becoming available.

For surveillance at the European level, ECDC and the WHO Regional Office for Europe request countries to report probable and confirmed cases of 2019-nCoV infections using the global case definition within 24 hours after identification. EU/EEA countries must notify probable and confirmed cases of 2019-nCoV through the Early Warning and Response System (EWRS).

ECDC and the WHO Regional Office for Europe are coordinating the rapid reporting of data as requested in the WHO case reporting form in collaboration with their surveillance networks in Member States.

Case reporting forms will be collected using TESSy (The European Surveillance System).

Case definition for surveillance

Suspect case (not to be reported at European level)

A. Patients with severe acute respiratory infection (fever, cough, and requiring admission to hospital), AND with no other aetiology that fully explains the clinical presentation AND at least one of the following:

- a history of travel to or residence in the city of Wuhan, Hubei Province, China in the 14 days prior to symptom onset, or
- patient is a health care worker who has been working in an environment where severe acute respiratory infections of unknown aetiology are being cared for.

B. Patients with any acute respiratory illness AND at least one of the following:

- close contact with a confirmed or probable case of 2019-nCoV in the 14 days prior to illness onset, or
- visiting or working in a live animal market in Wuhan, Hubei Province, China in the 14 days prior to symptom onset, or

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- worked or attended a health care facility in the 14 days prior to onset of symptoms where patients with hospital-associated 2019-nCov infections have been reported.

Probable case

A suspect case for whom testing for 2019- nCoV is inconclusive or for whom testing was positive on a pan-coronavirus assay.

Confirmed case

A person with laboratory confirmation of 2019-nCoV infection, irrespective of clinical signs and symptoms

Criteria to initiate testing for 2019-nCoV

Prompt case confirmation is necessary to ensure rapid and effective contact tracing, implementation of infection prevention and control measures according to national recommendations, and collection of relevant epidemiological and clinical information.

Any person fulfilling the criteria for a suspect case should be tested for 2019-nCoV. The laboratory method is provided below. The laboratory test should be initiated immediately.

Types of specimens

According to WHO interim guidance on laboratory testing of human suspected cases of nCoV infection, rapid collection of the following specimens should be considered:

- respiratory material (from upper respiratory tract (URT) nasopharyngeal and oropharyngeal swab in ambulatory patients and expectorated sputum (if produced) and/or endotracheal aspirate or bronchoalveolar lavage from lower respiratory tract (LRT) in patients with more severe respiratory disease);
- serum for serological testing, acute sample and convalescent sample (this is additional to respiratory materials and can support the identification of the true agent, once serologic assay is available)
- other specimens to consider in unresolved cases: blood for culture, urine for Legionella and pneumococcal antigen detection.

LRT (vs. URT) specimens are more likely to be positive and for a longer period and are therefore preferable. Respiratory specimen collection from upper and in particular lower respiratory tract, should be performed under heightened infection prevention and control measures (airborne precautions) according to WHO interim guidance. As per WHO interim laboratory guidance, repeat sampling and testing of LRT specimens is strongly recommended in severe or progressive disease. According to the WHO interim guidance for Clinical management of SARI when nCoV infection is suspected, for hospitalised patients, the frequency of specimen should be at least every 2 to 4 days until there are two consecutive negative results at least 24 hours apart.

Currently there is limited information about the best point in time for specimen collection. In analogy to other viral respiratory infections, it is likely that respiratory specimens collected early after symptoms' onset would yield higher virus concentrations.

Testing methodology

The specific tests currently recommended by WHO for the diagnosis and confirmation of 2019-nCoV are described in a dedicated WHO webpage, where the laboratory diagnostic protocol for real-time RT-PCR developed by Charité, Berlin Germany can also be found . Additional confirmation of positive results

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should be performed in specialised laboratories for coronavirus e.g. as indicated below. When possible, sequence information should be generated from positive specimens and shared, to allow comparison with available sequence data. Sequencing of viral isolates should be performed by national reference laboratories or specialised laboratories experienced in handling coronavirus analysis.

Laboratory support (for primary/and or confirmatory testing) by Coronavirus specialised laboratories in the EU

Any positive test can be sent for confirmation to one of the two European expert laboratories for coronaviruses:

- Charité – Universitätsmedizin Berlin Institute of Virology, Berlin, Germany
- Erasmus Medical Center, Department of Viroscience, Rotterdam, the Netherlands.

Means of redress

With regards to our reply to your request for access to documents, and in accordance with Article 7(2) of Regulation 1049/2001, you are entitled to make a confirmatory application requesting ECDC's Director to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the following address:

ECDC
Legal Services
Gustav III:s Boulevard 40
16973 Solna
Sweden

or by email to: confirmatory.requests@ecdc.europa.eu.

Yours faithfully,

Piotr Kramarz
Deputy Head of Unit Disease Programmes

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