BRIFFING

Requested by the ENVI committee



Assessment of COVID-19 surveillance case definitions and data reporting in the European Union

KEY FINDINGS

In a rapidly evolving pandemic, it is fundamental to **ensure consistency of definitions across Member States to provide the necessary comparability** to evaluate the public health response, the stress on the health system and the impact on the population's health.

All institutional bodies in the Member States follow, or base their approaches, on technical guidance by the European Centre for Diseases and Control (ECDC).

The approach to defining possible and probable cases shows considerable heterogeneity, while for confirmed cases, all Member States use the same definition requiring laboratory detection of SARS-CoV-2¹ with Reverse transcription polymerase chain reaction (RT-PCR). Comparability of the numbers of confirmed cases across the EU is still heavily dependent on the testing policies adopted. This heterogeneity seems rooted in rapidly evolving scientific advances and the different perceptions of risk in the technical institutions of Member States.

Many Member States still do not have an official definition of death due to COVID-19 available online and do not report on whether COVID-19 is the a primary or a secondary cause of death.

Recovery definition is broadly based on either clinical criteria or testing criteria (SARS-CoV-2 not detected anymore); only a few countries adopted a definition of recovery based solely on clinical criteria. While recovery based on clinical criteria has some advantages, it also carries some risks of early discharge / end of isolation when still infectious.

Harmonisation of COVID-19 case definitions is essential to mitigate disputes about data quality between Member States and coordinate, implement and evaluate EU policies.

Background

The COVID-19 pandemic is the most significant health crisis in the history of the European Union, with the unforeseen stress on the health system, an unprecedented impact on the health of the population, and economic consequences that are yet to be fully understood. The pandemic calls for a coordinated European Union approach to the challenge; this coordination has to be rooted in strong technical fundamentals that start with a standard case definition across the COVID-19 disease spectrum. The harmonisation of definitions



is critical to ensure comparability between Member States and to improve the quality of decision-making and the policy process.

Case definition for COVID-19

EU countries use clinical criteria, imaging (X-ray and CT Scan), laboratory, and epidemiological criteria to define what is a possible, a probable and a confirmed COVID-19 case. That is known as the 'case definition'.

In emerging diseases like COVID-19, the case definition can evolve. It usually reflects the evolution of the scientific and expert consensus on what is the best definition.

The European Centre for Disease Prevention and Control suggested a case definition according to three types of cases²: possible; probable and confirmed. The definitions have evolved, reflecting a better understanding of the disease over time. For example, radiological imaging was added later to the definitions.

1. How the Member States defined a case

a. Possible case criteria

The clinical criteria (signs and symptoms present in a patient) used to identify a possible case of COVID-19 vary considerably across Member States. The clinical criteria suggested by the ECDC consider only five symptoms (cough, fever, shortness of

Case classification

1. Possible case:

Any person meeting the clinical criteria

2. Probable case:

Any person meeting the clinical criteria with an epidemiological link

OR

Any person meeting the diagnostic criteria

3. **Confirmed case:**Any person meeting the laboratory criteria

breath and sudden onset of loss of smell and taste); however, Belgium and Bulgaria, for example, added certain minor symptoms to the clinical definition (e.g. fatigue, diarrhoea, loss of appetite).

b. Probable case criteria

Only a few countries use diagnostic imaging criteria in the case definition, as the scientific knowledge of what constitutes conventional imaging of COVID-19 only started to emerge in the course of the pandemic. That can explain why it is only seldom seen in the case definition.

c. Confirmed case criteria



The confirmed case definition is remarkably consistent across all Member States; this definition always requires laboratory confirmation of SARS-CoV-2 using Reverse transcription polymerase chain reaction (RT-PCR) methods, testing whether the genetic material of the virus is present. This definition is independent of the symptoms shown by the individual. This critical caveat makes it possible to capture the asymptomatic and pre-symptomatic dimension

of COVID-19, which has emerged in the scientific community as an important way of transmission.

Confirmed cases are reported by Member States using different stratification approaches; most countries (except three) report confirmed cases by age and gender. However, it is less common to report on the symptoms at the point of diagnosis, as well as reporting on comorbidities (prior disease history). Whether this is a reporting strategy or reflects limitation in data collection is not clear.

While the shared standard definition for confirmed cases ensures a baseline degree of comparability between Member States, that comparability is dependent on assuming that all Member States have the same testing strategies, which is not the case. Some countries test only symptomatic individuals while other

PE 652.725

countries test the asymptomatic in certain conditions (i.e. being a high-risk contact of a positive case). These differences make comparisons between Member States challenging; a higher incidence per million inhabitants in some countries might reflect the testing strategy and not the true incidence of the disease.

2. How the case definition has evolved across the Member States



As is expected during an epidemic, the approach to case definition has evolved over the course of time. Denmark provides a good example of such evolution. In early January when the pandemic epicentre was in China the suspected case definition had a geographical location component: 'A stay in Wuhan, Hubei Province within the last 14 days before the symptom debut'. When the epicentre of the epidemic moved to Europe in early March, the suspected case definition changed and included the areas of active community transmission: 'A stay within the last 14 days before symptom onset in areas where there is a significant transmission of SARS-CoV-2'.

It is of note that the definition of confirmed cases has remained very stable since early January, when it became apparent that RT-PCR methods are the only reliable way to define a confirmed case.

3. Variations in reporting frequency across the Member-States

Most European countries report the new COVID-19 cases on a daily basis; only Cyprus does weekly reports. Romania and Slovakia do a daily and weekly report of cases. Austria updates the number of infections on an hourly basis.

4. Adherence to the guidance of the ECDC

The primary guidance on the case definition is either the ECDC (8 countries) or the World Health Organization (WHO)³ (12 countries). Other countries, like Belgium, have a definition that does not fully comply with the ECDC or WHO. In the case of Belgium, cases with a negative RT-PCR test but imaging suggestive of SARS-CoV-2 infection can be considered confirmed. Countries like Sweden do not report the definition of possible or probable cases, only confirmed cases.

5. Suspected and confirmed cases in reporting

On 29 May 2020, the ECDC recommended to no longer report suspected cases, defined as the cases eligible for laboratory testing. The change in testing strategy recommended by the ECDC was brought about by advances in scientific knowledge, specifically the contribution of asymptomatic and pre-symptomatic patients in the disease transmission dynamics. In the new testing strategy, asymptomatic individuals in specific settings are eligible for testing.

'In addition to testing of symptomatic persons and their contacts, testing of asymptomatic contacts may be considered depending on the availability of resources, especially in healthcare settings and long-term care facilities, to identify potential sources of infection and protect vulnerable individuals.'

ECDC Strategies for the surveillance of COVID-194

Many countries still use suspected COVID-19 cases in their reports. In Austria for example any person who fulfils the clinical criteria is considered suspected cased and tested. Croatia is an example of a Member State that stopped reporting suspected cases, following ECDC recommendations.

PE 652.725 3

'Death due to COVID-19' definition



Mortality data is paramount in epidemiology, and a powerful instrument to analyse the relative performance of European countries in response to the pandemic.

The WHO definition of 'death due to COVID-19' is broadly separated into two categories: deaths where the virus was identified using RT-PCR methods; and deaths that have a clinical diagnosis, probable or suspected COVID-19 deaths, but no virus was identified. This is reflected in the two codes defined for COVID-19 in the WHO International Classification of Diseases, 10th version: 'U07.1 COVID-19, virus identified' for confirmed deaths, where the

SARS-CoV-2 was identified by RT-PCR and 'U07.2 COVID-19, virus not identified'.

The ECDC followed with its definition:

'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 disease (e.g., trauma). There should be no period of complete recovery between illness and death. Death due to COVID-19 may not be attributed to another disease (e.g. cancer) and should be counted independently of pre-existing conditions that are suspected of triggering a severe course of COVID-19.'

ECDC Surveillance definitions for COVID-195

All EU Member States report COVID-19 deaths, but the definition they use varies considerably. The reason for this heterogeneity is not easy to explain, but might stem from delays in advice from relevant international bodies. The first COVID-19 death in the EU occurred on 15 February 2020 in France, while the first WHO document with a death definition is dated 16 April 2020⁶, and the ECDC only published a definition on its website on 29 May 2020. In the absence of European and international standards early in the pandemic, each country adopted a national definition of death due to COVID-19.

In the EU, only six out of 27 countries followed the ECDC definition of death due to COVID-19. One such example is Italy, which reports on deaths by age, gender, and comorbidities. Denmark, on the other hand, has adopted a more comprehensive definition and initially included deaths within 60 days after a COVID-19 diagnosis; after 29 March 2020, this 60-day period was shortened to 30 days. When compared with other countries, Denmark might thus be over-reporting deaths due to COVID-19.

Even some of the countries with more detailed information about deaths due to COVID-19 do not provide information on whether COVID-19 is the primary or a secondary cause of death. With a new disease, it might be difficult for clinicians to assess and distinguish primary and secondary causes of death, and hence, examples of what might be considered a primary or secondary cause of death in such cases could contribute to further standardisation. Overall, only six out of 27 EU countries do report whether COVID-19 is the primary or a secondary cause of death.

Some countries, despite reporting COVID-19 deaths, have not published online an official definition of death due to COVID-19. These countries tend not to stratify deaths by age, sex, symptoms, comorbidities and whether COVID-19 was confirmed or suspected. The reason for not making an explicit 'death due to COVID-19' definition is unclear, while the reasons for not stratifying might be due to lack of structured data in the death certificate. Also, the time needed to produce official cause-specific information on mortality, such as 'death due to COVID-19' in the Member States is an issue; the latest Eurostat data available for cause-specific

PE 652.725

mortality is from 2016. The COVID-19 pandemic is an opportunity to improve the process of classification and reporting of cause-specific mortality in the European Union.

Small changes in the definition might have a significant impact on the mortality data. Those countries that exclude from the 'death due to COVID-19' those cured patients where SARS-CoV-2 is no longer detected by RT-PCR while the patient remains ill and in life-threatening condition, might be underestimating the impact of COVID-19 on mortality. Standardisation is paramount to ensure proper comparability between countries, even if no definition is perfect and some might underestimate and others over-estimate COVID-19 cause-specific mortality.

The heterogeneity in the definition of 'death due to COVID-19' makes it extremely difficult to compare case fatality rates between countries. Countries that have adopted the ECDC definition might be more comparable. Countries which adopted a definition based on testing might be under-reporting COVID-19 mortality, and mortality data is more susceptible to changes in the testing policies. Likewise, death in long-term care facilities in countries where testing policies do not include mass testing in these facilities can underestimate the impact of COVID-19 mortality.

Given the limitations in defining COVID-19-specific mortality, excess all-cause mortality is the most reliable indicator for country comparisons⁷. The EU-funded EuroMOMO⁸ project has made considerable progress in harmonization of reporting, analysis and dissemination of all-cause mortality and excess mortality (above the average for that time of the year). This project should be institutionalised by the European institutions and expanded to all European Member States⁹.

Recovery definition for COVID-19 and guidelines for ending patient isolation



The importance of recovery definitions should not be understated. As the pandemic progresses, a clear definition of recovered patients provides a framework to calculate the active cases (i.e. confirmed cases that are not recovered but still alive). This metric provides a better estimate of the risk of infection in a Member State.

Thirteen Member States still do not provide a clear definition of the recovered patient, and definitions differ across those Member States that do provide such a definition. In the same way as with mortality,

there are recovered patient definitions also based on either RT-PCR testing or on the presence of clinical symptoms. On 8 April 2020, the ECDC published a technical report for guidance on ending isolation ^{10,11}. That document favours the end of isolation based on RT-PCR testing and recommends it for hospitalised individuals. For individuals in the community, it states that RT-PCR testing should be done if the testing capacity is sufficient.

Some countries, such as Bulgaria, Cyprus, Italy, Latvia, Lithuania, Portugal and Slovakia require either one or two negative tests after a certain period of time in order for infected individuals to end the isolation period. This approach tends to minimise the risk of early lifting of isolation and premature social integration of sick individuals; however, it can prolong the isolation of some individuals for long periods if tests remain positive even with complete clinical recovery.

Other countries, such as Denmark and the Netherlands, base the recovery criteria on the absence of symptoms for a period of time, i.e. 24 to 48 hours. These approaches prioritise early integration and shorten the isolation period. However, the extent to which clinically recovered COVID-19 patients remain infectious is still not clear in the scientific community. For asymptomatic individuals, the Netherlands declares recovery 72 hours after the diagnosis. One advantage of the clinical recovery approach is that is reduces the need for testing, which can be useful where there are problems in the supply of RT-PCR testing.

PE 652.725 5

Despite these differences, 17 Member States have broadly adopted the ECDC guidelines on ending isolation and hospital discharge. Member States usually do not report details on age at recovery, gender, and prior disease for recovered patients.

Guidance and responsibilities

Governance of technical guidance is fundamental during a pandemic to ensure consistency of procedures within each Member State. Most Member States rely on a specialised agency for defining and implementing the case definition and reporting. Most countries rely on a single national agency, but in some countries the chain of command is not evident, like in Italy, where several agencies provide information.

Institutions responsible for COVID-19 technical guidance in the EU

Country	Institution responsible for technical guidance	
	English name	Local name
Austria	Federal Ministry of Social Affairs, Health, Care and Consumer Protection of Austria	Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz
Belgium	National Health Agency of Belgium	<u>Sciensano</u>
Bulgaria	Ministry of Health of Bulgaria	Министерството на здравеопазването
Croatia	Institute of Public Health of Croatia	<u>Hrvatski zavod za javno zdravstvo</u>
Cyprus	Ministry of Health of Cyprus	Υπουργείο Υγείας
Czechia	Ministry of Health of the Czech Republic	Ministerstvo zdravotnictví ČR
Denmark	Health Authority of Denmark	<u>Sundhedsstyrelsen</u>
Estonia	Estonia Health Board	<u>Terviseamet</u>
Finland	Institute for Health and Welfare of Finland	<u>Terveyden ja hyvinvoinnin laitos</u>
France	Public Health Agency of France	<u>Santé Publique France</u>
Germany	Public Health Agency of Germany	Robert Koch-Institut
Greece	Public Health Organization of Greece	Εθνικός Οργανισμός Δημόσιας Υγείας
Hungary	Center for Public Health of Hungary	Nemzeti Népegészségügyi Közpon
Ireland	Health Service Executive of Ireland	<u>Health Service Executive</u>
Italy	Institute of Public Health of Italy Civil Protection of Italy	<u>Istituto Superiore di Sanità</u> <u>Dipartimento della Protezione Civile</u>
Latvia	Center for Disease Prevention and Control of Latvia	Slimību profilakses un kontroles centra
Lithuania	Ministry of Health of the Lithuania Republic	<u>Lietuvos Respublikos sveikatos apsaugos</u> <u>ministerija</u>
Luxembourg	Ministry of Health of Luxembourg	<u>Ministère de la Santé</u>

PE 652.725

Country	In stitution responsible for technical guidance	
	English name	Local name
Malta	Ministry for Health of Malta	Ministry for Health
Netherlands	National Institute for Public Health and the Environment of the Netherlands	Rijksinstituut voor Volksgezondheid en Milieu
Poland	Chief Sanitary Inspectorate of Poland	<u>Główny Inspektorat Sanitarny</u>
Portugal	Directorate-General of Health of Portugal	<u>Direção-Geral da Saúde</u>
Romania	Centre for the Surveillance and Control of Communicable Diseases of Romania	<u>Centrul National de Supraveghere si</u> <u>Control al Bolilor Transmisibile</u>
Slovakia	Public Health Authority of Slovakia	<u>Úrad verejného zdravotníctva Slovenskej</u> <u>republiky</u>
Slovenia	Ministry of Health of Slovenia National Institute of Public Health of Slovenia	<u>Ministrstvo za zdravje</u> <u>Nacionalni inštitut za javno zdravje</u>
Spain	National Health Agency of Spain	<u>Instituto de Salud Carlos III</u>
Sweden	Public Health Agency of Sweden	<u>Folkhälsomyndigheten</u>

Source: Author's own elaboration

Note: When it was not entirely clear the agency responsible for technical guidance the Ministry of Health was considered the institution responsible

The International Committee on Taxonomy of Viruses classified the new virus as severe acute respiratory syndrome coronavirus 2, SARS-CoV-2.

Disclaimer and copyright. The opinions expressed in this document are the sole responsibility of the authors and do not necessarily represent the official position of the European Parliament. Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the European Parliament is given prior notice and sent a copy. © European Union, 2020. © Images used under licence from Adobe Stock

IP/A/ENVI/2020-14; Manuscript completed: July 2020; Date of publication: July 2020 Administrators responsible: Zsuzsanna LAKY, Christian KURRER; Editorial assistant: Catherine NAAS Contact: Poldep-Economy-Science@ep.europa.eu
This document is available on the internet at: www.europarl.europa.eu/supporting-analyses

Print ISBN 978-92-846-6566-2 | doi:10.2861/02941 | QA-02-20-517-EN-C PDF ISBN 978-92-846-6565-5 | doi:10.2861/822698 | QA-02-20-517-EN-N

² European Centre for Disease Prevention and Control. Case definition for coronavirus disease 2019 (COVID-19). Stockholm: ECDC; 2020. Available at: https://www.ecdc.europa.eu/enecovid-19/surveillance/case-definition.

World Health Organization. Global surveillance for COVID-19 caused by human infection with COVID-19 virus. Geneva, WHO. Available at: https://www.who.int/publications/i/item/qlobal-surveillance-for-covid-19-caused-by-human-infection-with-covid-19-virus-interim-quidance.

⁴ European Centre for Disease Prevention and Control. Strategies for the surveillance of COVID-19. Stockholm: ECDC; 2020. Available at: https://www.ecdc.europa.eu/en/covid-19/surveillance/testing-strategies.

⁵ European Centre for Disease Prevention and Control. Surveillance definitions for COVID-19, Stockholm: ECDC; 29th May 2020. Available at: https://www.ecdc.europa.eu/en/covid-19/surveillance/surveillance-definitions.

World Health Organization. Guidelines Cause of Death COVID-19. Geneva, 16th April, 2020, WHO. Available at: https://www.who.int/classifications/icd/Guidelines Cause of Death COVID-19.pdf?ua=1.

Marina Karanikolos, Martin McKee. How comparable is covid-19 mortality across countries? European Observatory on Health Systems and Policies. WHO. Brussels 2020. Available at: https://analysis.covid19healthsystem.org/index.php/2020/06/04/how-comparable-is-covid-19-mortality-across-countries/.

⁸ Euromomo. Graphs and maps of all-cause mortality. Available at: https://www.euromomo.eu/graphs-and-maps/.

⁹ At the time of publication, 20 countries participate in EuroMOMO: Austria, Belgium, Denmark, Estonia, Finland, France, Germany (Berlin, Hesse), Greece, Hungary, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK. These EU countries do not participate yet: Poland, Slovenia, Croatia, Bulgaria, Romania, Slovakia, Czech Republic, Lithuania, Germany (other states) and Latvia.

European Centre for Disease Prevention and Control. Guidance for discharge and ending isolation in the context of widespread community transmission of COVID-19, 8 April 2020. Stockholm: ECDC; 2020. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-quidance-discharge-and-ending-isolation-first%20update.pdf.

European Centre for Disease Prevention and Control. Discharge criteria for confirmed COVID-19 cases – When is it safe to discharge COVID-19 cases from the hospital or end home isolation? Stockholm: ECDC; 2020. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-Discharge-criteria.pdf.