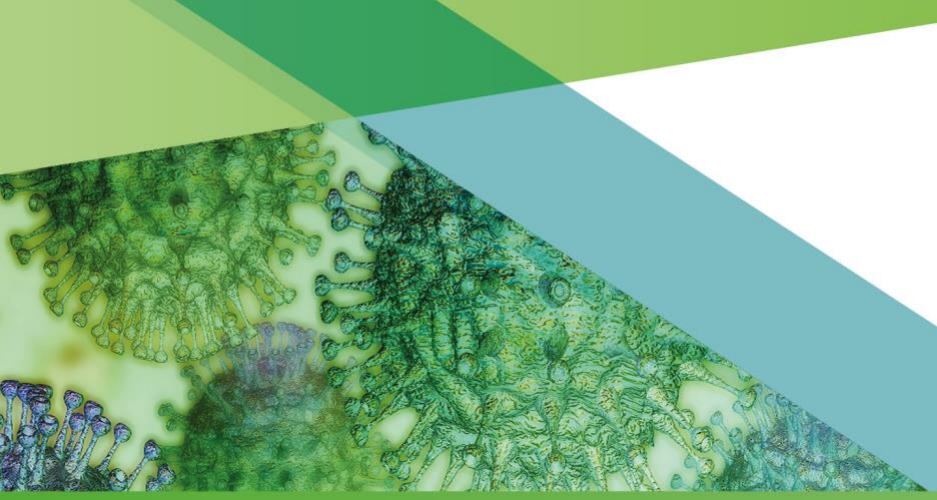

Novel coronavirus (SARS-CoV-2) Surveillance Strategy

Key messages

- Establish or strengthen surveillance systems for acute respiratory infection/influenza like illness, virological surveillance and severe acute respiratory infection (all hospitalised or in intensive care units)
- Increase the proportion of the population covered by sentinel surveillance for acute respiratory infection/influenza like illness in order to increase the sensitivity of the surveillance system
- Continue repurposed sentinel ARI/ILI and virological influenza surveillance systems for COVID-19 beyond week 20
- Increase the proportion of patients from primary care with acute respiratory infection/influenza like illness who are sampled, and test all specimens for COVID-19 in order to detect as early as possible community transmission of COVID-19
- Test all patients hospitalised with severe acute respiratory infection for COVID-19 in order to detect possible community transmission of COVID-19
- Plan for surveillance approaches in case of limited availability of laboratory and human resources

Background

This document outlines the proposed strategies for surveillance to be implemented in Member States during the various phases of the COVID-19 epidemic. Surveillance data are essential in order to inform specific public health actions. This document describes the surveillance objectives for each phase of the epidemic (based on scenarios explained in the Annex) together with relevant methods for achieving those objectives.

Surveillance strategy

Preparatory work

Countries need to ensure that regional and national data collection systems are established for rapid reporting of key epidemiological and clinical information on COVID-19 cases. This includes development or adaptation of data collection instruments such as electronic forms, data storage and reporting systems in clinical and laboratory settings, procedures for data collection and training of staff. When the number of reported cases are small, the priority is to implement a case-based reporting system in order to allow for collection of detailed data on cases

including exposure information, demographic data, clinical symptoms, pre-existing conditions, possible place of infection, hospitalisation, severity, links to other confirmed cases and clinical outcome. Mechanisms to allow the reporting of clinical outcome of cases should be established in advance. The data collection system should be able to collect variables required for TESSy reporting which are based on the WHO case reporting form [1, 2].

Considering the likelihood of eventual widespread transmission, countries should also plan for a reduced case-based dataset to facilitate reporting if healthcare systems become under pressure. While countries should plan for maintaining case based reporting for as long as possible, aggregated reporting forms and mechanisms should be developed if these can reduce the burden on healthcare personnel when under pressure.

Sentinel syndromic and virological surveillance of patients with acute respiratory infection (ARI) and/or influenza-like illness (ILI) visiting sentinel outpatient practices (primary care) will likely be a main source of data when transmission becomes widespread. Countries should therefore assess sentinel surveillance systems to ensure that they are resilient and able to function in case of widespread transmission of COVID-19 and pressure on healthcare services. The influenza sentinel surveillance system should be strengthened and expanded where possible to increase population coverage. Samples from sentinel sites should be tested for COVID-19 in order to allow for monitoring of spread and intensity of COVID-19 infection. The proportion of positives with COVID-19 among patients presenting with ILI or ARI (or in the population where population denominators are known) should be monitored.

Similarly hospital-based surveillance systems monitoring hospitalized severe acute respiratory infections (SARI) or ICU admissions should be established or strengthened. All SARI cases presenting in hospital, especially ones admitted to ICUs, should be tested for COVID-19. Procedures for reporting of data on SARI cases including clinical management (such as ICU admission and ventilation), COVID-19 testing, and outcome should be established, ideally through a system covering all hospitals involved in management of COVID-19 patients. Furthermore, it is important to establish representative, population-based, hospital surveillance systems in order to estimate severity, mortality, and to measure the effectiveness and impact of public health measures on these indicators.

Surveillance systems for ARI/ILI and SARI should be extended throughout the year if the systems usually operate until week 20. Participating clinicians and hospitals should be appropriately trained and have adequate resources.

For all surveillance systems, countries need to ensure that systems are resilient in case of rapid increase in the number of cases and the eventual possibility of widespread transmission in the country and resulting pressures on healthcare workers and systems. This could be achieved by developing automated reporting systems from regional to national to international level to ensure data is transferred to all levels rapidly and within minimal input. Additional staff also need to be trained to be able to report data in case of significant absenteeism during the outbreak. Finally, datasets with reduced numbers of variables and/or aggregated reporting could reduce burden on staff and ensure that data continue to be reported even during the peak of the outbreak. The reduced dataset to be reported in TESSy is described in the reporting protocol.

Monitoring systems of all-cause excess mortality in the population should also be maintained, reviewed or developed in order to be able to detect any excess mortality linked to COVID-19 by age-group. Protocols and algorithms have been developed by EuroMOMO, which can support and provide rapid assessment of excess all cause mortality, by country in participating Member States. Member States not yet participating and reporting data on all-cause excess mortality are encouraged to initiate the collection of mortality data in their country and join the EuroMoMo network.

Templates for weekly reports analysing surveillance data should be developed considering the different scenarios.

Initial phase of the epidemic: scenario 1

Surveillance objectives:

- early detection of cases in order to limit onward transmission;
- early detection of community transmission in order to prevent further spread;
- rapid assessment of epidemiological, clinical and virological features of earliest cases, to estimate case-severity and transmissibility and to detect chains of transmission, especially in healthcare settings, in order to guide decision-making, preparedness and response activities;
- to identify and monitor changes in risk groups;
- provide data to inform real-time modelling, to predict and inform optimal interventions to mitigate impact and detect transmission in the general population, in order to guide decision-making, preparedness and response activities.

Surveillance methods/approach:

Surveillance of confirmed cases: the ECDC/WHO case definition for suspect cases aims to be sensitive (i.e, irrespective of severity) with testing based on geographical exposure criteria or exposure to known cases, in order to detect importation from risk areas and local clusters. Geographical risk areas are defined based on self-assessment by EU Member States reported in EWRS and published on the ECDC website for EU/EEA countries and on the WHO situation report for non-EU/EEA countries [3].

Probable and confirmed cases of COVID-19 infections using the case definition should be reported within 24 hours of identification through the Early Warning and Response System (EWRS) and IHR notification. Data on cases should be reported in TESSy ideally within 72 hours. Case-based data should be reported with the full set of variables, including the place of infection at NUTS3 level or equivalent GAUL. When the number of cases increases and reporting all variables on cases in TESSy is no longer feasible, a reduced dataset should be collected and reported at national level and in TESSy. The reduced dataset is described in the TESSy reporting protocol. Alternatively, countries may collect data on a limited set of variables initially and then update cases in national systems and TESSy with additional variables at a later stage.

Contact tracing: In the early phases of the epidemic, detailed data on contact tracing activities should be collected at regional and national level. Web-based tools such as Go.data can support such investigations. These data will allow for better delineation of clusters of cases and allow for assessment of transmission patterns as well as further scientific studies. Data from contact tracing investigations can provide evidence on when to change from a containment approach to mitigation.

Sentinel syndromic and virological surveillance: Syndromic-based surveillance collects data on number of patients with ARI or ILI symptoms visiting sentinel outpatient practices. Although the sentinel practices are considered to be representative in many countries, the system covers only 1-5% of the population. A subset of these patients are included in the virological testing and are swabbed for further testing in dedicated national influenza reference laboratories for influenza and other respiratory viruses. The syndromic and virological system is considered of limited sensitivity due to a low coverage of the population and limited sampling and is unlikely to be able to detect low-level local transmission. However, countries should integrate testing for COVID-19 into existing surveillance systems and test all samples from influenza outpatient sentinel sites for COVID-19 virus irrespectively of travel. This will allow countries to identify increasing levels of spread among the population and asses the level of outpatient visits with ILI/ARI, particularly during the spring and summer when influenza is circulation at low levels. Where possible, the number of sentinel sites collecting syndromic data and virological specimens should be expanded to increase population coverage and the number of collected samples.

Virological detection should be performed by RT-PCR assay of at least one gene target and confirmation of positive result by a separate gene target. The assay could be an integrated multiplex RT-PCR assay with multiple gene targets. The virological surveillance should include also sequencing of subset of viruses. The subset for virological characterisation should include specimens representing different times in the epidemic, age groups, geographical areas of the country and different levels of clinical symptoms. The sequence results should be deposited in GISAID.

Laboratory data collected should include the number of COVID-19 tests performed from this sentinel system as well as the number of positive tests. ILI/ARI data should continue to be reported in TESSy following the influenza reporting protocol. Virological data should be reported in TESSy on a weekly basis within the COVID-19 aggregate reporting including zero reporting if no COVID-19 cases are identified. Any cases detected through sentinel surveillance should also be reported through case reporting at this stage as described in the previous paragraph and contact tracing performed according to national guidance.

Detection and assessment of community transmission: Detecting community transmission of COVID-19 is challenging as the suspect case definition is based on travel links, severe cases may present only when significant community transmission has already occurred and sentinel surveillance covers only a small proportion of the population and might not be sensitive enough to detect ongoing low level community transmission. Approaches to detect community transmission could include:

- Telephone helplines: data on calls to regional/national healthcare telephone helplines could be analysed to provide an indication of increases of ARI/ILI regionally and nationally. Statistical methods could be used to detect changes in trends. The helplines could also be used to sample a proportion of cases fitting the ARI/ILI case definition in order to provide indication of community transmission of COVID-19. In situations where community transmission is suspected to be occurring (eg SARI cases detected), the proportion of cases sampled could be increased temporarily to provide a more comprehensive assessment.
- Enhanced local syndromic ILI/ARI based surveillance: once cases are detected without links to known areas with community transmission, the level of community transmission of COVID-19 locally should be assessed. This assessment should include as many general practices in the defined geographical area (for example a municipality) as possible for a limited time period (such as two weeks). The general

practices should sample a proportion of ARI/ILI cases irrespectively of their travel history and these samples should be tested for COVID-19. Data on such investigations should be summarised and posted on EWRS to allow Member States to assess the risk of community transmission in the area. The results from these assessments can inform Member States on whether contact tracing is still a viable response in the area.

Hospital SARI surveillance: All patients admitted to hospitals (all wards or ICU) with SARI should be tested for COVID-19. Testing data on SARI cases and/or ICU SARI cases should be collected, either via comprehensive surveillance or sentinel hospitals. Data collected should include at a minimum the number of COVID-19 tests performed among patients with SARI and the number of positive tests. These data should be reported in TESSy on a weekly basis. In addition, countries could consider collecting data on the total number of SARI in all hospitals in the country and the bed occupancy as indicators of COVID-19 spread and burden on the healthcare system. Enhanced surveillance of SARI cases should be considered to identify risk groups for COVID-19, risk factors for severe illness and poor outcome. Such data are collected through the case-based reporting as described.

Additional investigations: Considering the lack of knowledge on key parameters which could inform the response, every possibility should be considered to investigate initial cases and clusters in a country to build on the evidence base and inform control measures. Important information include the proportion of asymptomatic cases, the role of children in transmission dynamics and risk factors for severe infection. These data could be obtained through household transmission studies and investigations in schools if cases among children are detected. Such studies could include a serological component to allow for validation of serological assays which could be of crucial importance in answering many epidemiological questions relevant for informing response measures.

Advanced phase of the epidemic: scenarios 2-4

Surveillance objectives:

- monitor the intensity and geographical spread of COVID-19 in the population;
- detect nosocomial outbreaks;
- identify and monitor changes in risk groups;
- measure the impact on population and the healthcare system and to measure the impact of any mitigation measures;
- monitor viral changes.

Surveillance methods/approach:

Surveillance of confirmed cases: although case finding based on the surveillance case definition might still be of benefit in areas with ongoing community transmission, limited resources for testing might mean that this cannot be comprehensive. Such surveillance is therefore unlikely to give a full picture of the epidemiology of COVID-19. Despite this, the data can be useful to assess risk groups and inform control measures. Surveillance systems should be able to capture information on affected healthcare workers. Surveillance of confirmed cases and national and international reporting of these data should therefore continue as long as possible. At this stage, it is likely that detailed reporting is not feasible and a reduced dataset should be used for case-based reporting at national level and in TESSy. Countries might also decide to collect aggregated data on confirmed cases at national level once the number of reported cases increases. These data can also be reported through TESSy. The number of samples tested for COVID-19 should also be collected.

Detection and assessment of community transmission: Detecting community transmission of COVID-19 is challenging as the suspect case definition is based on travel links. Severe cases may present only when significant community transmission has already occurred and sentinel surveillance covers only a small proportion of the population and might not be sensitive enough to detect ongoing low-level community transmission. Approaches to detecting community transmission could include:

- **Telephone helplines:** data on calls to regional/national healthcare telephone helplines could be analysed to provide an indication of increases of ARI/ILI regionally and nationally. Statistical methods could be used to detect changes in trends. The helplines could also be used to sample a proportion of cases fitting the ARI/ILI case definition in order to provide indication of community transmission of COVID-19. In situations where community transmission is suspected to be occurring (e.g. SARI cases detected), the proportion of cases sampled could be increased temporarily to provide a more comprehensive assessment.
- **Enhanced local syndromic ILI/ARI-based surveillance:** once cases are detected without links to known areas with community transmission, the local level of community transmission of COVID-19 should be assessed. This assessment should include as many general practices in the defined geographical area (for example a municipality) as possible for a limited time period (such as two weeks). The general

practices should sample a proportion of ARI/ILI cases irrespective of their travel history and these samples should be tested for COVID-19. Data on such investigations should be summarised and posted on EWRS to allow Member States to assess the risk of community transmission in the area. The results from these assessments can inform Member States on whether contact tracing is still a viable response in the area.

Sentinel syndromic and virological surveillance: with increasing transmission, it is likely that sentinel syndromic and virological surveillance will become increasingly more important in order to assess intensity and spread of infection. The number of outpatient sentinel sites should be increased to improve coverage of the population under syndromic surveillance. Data on the number of patients visiting with ILI/ARI symptoms will provide information on spread and intensity as well as the most affected age groups in primary care. These data should continue to be reported in TESSy according to the influenza protocol. Data on the number of COVID-19 tests performed and number of positive tests from sentinel surveillance should continue to be collected and reported in TESSy on a weekly basis within the COVID-19 reporting.

If healthcare authorities recommend that patients with ARI/ILI do not visit general practitioners, there could be a significant impact on ARI/ILI surveillance systems, and sentinel surveillance might not be suitable to monitor COVID-19 intensity and spread. In these circumstances, sentinel general practices consulted through telephone could report at least the number and proportion of telephone consultations due to ARI/ILI. In addition, sites where ARI/ILI patients are directed and tested (e.g. dedicated testing centres) should be included in the surveillance, although historical data will not be available for comparison. Monitoring of healthcare telephone helplines as described above, ideally with linked systematic sampling could be an alternative or complementary approach.

Depending on the resources, virological detection by RT-PCR assay could be reduced to single-gene target testing. For the specimens where the first gene test is technically not interpretable or the cycle threshold value is above 35, confirmation of positive results should be performed by a separate gene target or repeated sampling should be performed. The subset for virological characterisation including sequencing should include specimens representing different times, age groups, geographical areas of countries and different levels of clinical symptoms in order to monitor viral changes. If sequencing is not feasible in the short term during the epidemic, the specimens should be kept for later sequencing of a subset of viruses.

Hospital SARI surveillance: all hospitalised patients with SARI should be tested for SARS-CoV-2 virus irrespective of travel history in order to detect community transmission, detect nosocomial outbreaks and to monitor intensity and impact. Testing data on SARI cases and/or ICU SARI cases should be collected, either via comprehensive surveillance or sentinel hospitals. Data collected should include at a minimum the number of COVID-19 tests performed among patients with SARI and the number of positive tests. These data should be reported in TESSy on a weekly basis. Enhanced surveillance of SARI cases can be used to identify risk groups for COVID-19, risk factors for severe illness and poor outcome.

Indicators for monitoring: Countries should collect basic indicators from each region on transmissibility, seriousness and impact of the disease [4]. Transmissibility can be based on ILI/ARI rates, seriousness on hospitalisation or ICU admission rates and impact on how hospitals are coping with the burden of COVID-19 infections. The assessment of the impact on hospitals should be based on bed occupancy levels in hospitals and intensive care units, and the capacity for ventilation, and could use simple indicators such as 'capacity sufficient' or 'overwhelmed'. These indicators would inform decisions on social distancing and quarantine measures which would need to be taken in the context of large pressures on public health services. The indicators should be collated at national level and reported at EU level.

Excess mortality surveillance: Monitoring of all-cause or specific excess mortality is essential at this stage in order to assess the impact of the epidemic in addition to monitoring deaths among confirmed cases.

Dissemination of surveillance data: Results from surveillance activities should be reported regularly to stakeholders and policy makers in order to inform control strategies. During the initial phase, extremely high demand for information from the public, stakeholders and policy makers will mean that daily reports or regularly updated dashboards are required. Weekly surveillance reports should also be developed collating data from multiple surveillance sources, including ARI/ILI sentinel surveillance, SARI surveillance, virological surveillance, case-based surveillance (as long as this is implemented), mortality data and qualitative indicators on the burden in hospitals and intensive care units. At the EU level, similar reports will be produced only a weekly basis and published on the ECDC website.

Limited resources: in general, surveillance data should continue to be collected at the most detailed level possible as long as capacity allows, in order to provide the best evidence for control interventions. When resources are limited, countries should move to more limited datasets as described above and eventually to aggregate reporting where this reduces burden.

A number of countries have reported shortages of laboratory reagents and resources for COVID-19 testing. Such shortages could become more acute in the context of large increases in cases. In circumstances with shortages, testing capacity should be reserved for more severe cases and hospital use and SARI cases.

If there is no capacity for testing of samples from sentinel clinics, sentinel syndromic surveillance for ARI/ILI through sentinel general practices and/or telephone helplines should be used to assess the intensity and spread of infection. This might be challenging if influenza and/or other respiratory pathogens are co-circulating. If testing capacity remains in hospitals or intensive care units, then SARI/ICU surveillance should be used for surveillance purposes. In the event that no testing capacity remains at all in hospitals, the qualitative indicators described above could be used.

Annex: Description of scenarios 0-4

Scenario 0 describes a situation with no reported cases in the country and multiple introductions and/or community transmission elsewhere in Europe. At this stage, the main objective for public health measures should be to enable rapid detection and isolation of individual cases to prevent domestic transmission chains, and to prepare for the response once cases are detected in the country. As of 2 March 2020, several EU/EEA countries had not reported cases and are therefore presumed to be in this scenario.

Scenario 1 describes a situation with multiple introductions and limited local transmission in the country. Despite the introductions there is no apparent sustained transmission (only second generation cases observed or transmission within sporadic contained clusters with known epidemiological links). In this situation, the objective is containment of the outbreak by blocking transmission opportunities, through early detection of imported and locally-transmitted COVID-19 cases in order to try to avoid or at least delay the spread of infection and the associated burden on healthcare systems. Delaying the start of local transmission will allow the current influenza season to end, freeing up some healthcare capacity. As of 2 March 2020, several EU/EEA countries had reported limited local transmission and were considered to be in this scenario.

Scenario 2 describes a situation with increasing number of introductions and of more widespread reports of localised human-to-human transmission in the country (more than two generations of cases outside of sporadic clusters with known epidemiological links). In this situation, the objective remains to contain where practicable and otherwise slow down the transmission of the infection and to monitor viral changes. This will increase the time available for development, production and distribution of PPE and effective therapeutic options, and would play a crucial role in reducing the burden on the healthcare system and other sectors, particularly if wider transmission of COVID-19 is delayed beyond the ongoing influenza season. A reduced burden would also allow for more time to increase laboratory capacity, and increase surge capacity in healthcare services. All these measures will facilitate effective treatment of infected patients [5]. Rapid collection and analysis of epidemiological and virological data will enable targeting of measures in this scenario and later. Within EU/EEA countries, Italy is currently in this scenario. Other countries in the EU/EEA might also be in this scenario, which may have undetected transmission ongoing due to lower level of case detection.

Scenario 3 describes a situation with localised outbreaks, which start to merge becoming indistinct. In this scenario, there is sustained human-to-human transmission in the country (more than two generations of cases outside of sporadic clusters with known epidemiological links) and an increasing pressure on healthcare systems. The objective at this stage is to mitigate the impact of the outbreak by decreasing the burden on healthcare systems, protect populations at risk of severe disease and to monitor viral changes. At the same time, operational research should guide developing better and more efficient diagnostic and treatment options.

Scenario 4 describes a situation with widespread sustained transmission where healthcare systems are over-burdened due to a large demand for emergency healthcare services, a strained ICU capacity, overworked healthcare workers and reduced staff availability due to illness, lack of PPE and lack of diagnostic testing capacity. The objective at this stage is still to mitigate the impact of the outbreak, decrease the burden on healthcare services, protect populations at risk of severe disease and reduce excess mortality.

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