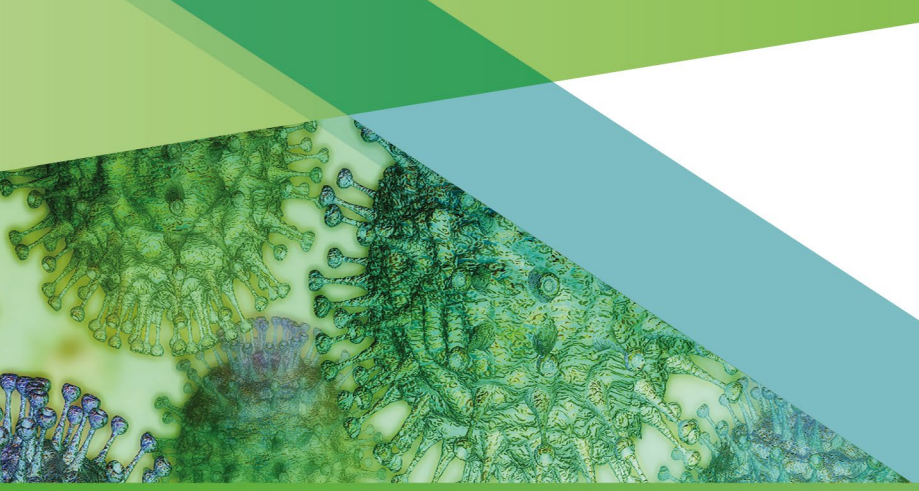

ECDC TECHNICAL REPORT

Data collection on COVID-19 outbreaks in closed settings: long-term care facilities

18 February 2022 Version 2.1

Purpose, aim and scope of this activity

The main aim of this activity is to collect information on the severity of breakthrough COVID-19 infections in outbreaks at long-term care facilities (LTCFs) and to obtain an estimate of relative risk of infection for vaccinated residents and staff members in these settings, by SARS-CoV-2 variant, vaccine product and number of vaccine doses. This activity is not intended to capture all outbreaks, generate comparative statistics, or obtain a national/sub-nationally representative sample.

Background

Most national COVID-19 vaccination programmes have prioritised LTCFs for COVID-19 vaccination because of the disproportionally high COVID-19 mortality among their elderly residents. By mid-March 2021, the impact of vaccination on COVID-19 was already noticeable in COVID-19 surveillance data, with decreasing case fatality overall and decreasing COVID-19 notification rates in people aged 85+ years. Meanwhile, COVID-19 notification rates were increasing in younger age groups [1].

However, with the emergence of SARS-CoV-2 variants of concern (VOCs) with reduced susceptibility to natural and vaccine-elicited antibodies [2], the protective effect of vaccination is likely to decrease as the circulation of immune escaping VOCs (e.g. the Delta and Omicron VOCs) increases. In addition, even when vaccines are effective, infections in vaccinated individuals ('breakthrough infections') are possible as vaccine efficacy is not 100% and immune response may wane over time, especially in the elderly population [3].

To date, in-depth information on COVID-19 outbreaks in LTCFs has not been captured in a standardised manner in TESSy (apart from some information in case-based COVID-19 surveillance using the TESSy record type 'NCOV'). However, ECDC epidemic intelligence is continuing to pick up media reports on outbreaks at LTCFs in EU/EEA countries. In addition, outbreaks in LTCFs have also been reported by national authorities in EWRS and/or ECDC's EpiPulse epidemic intelligence platform in free-text format. ECDC has followed up on these outbreaks and in July 2021 it published a summary of reported outbreaks in LTCFs with completed vaccination programmes as part of a corresponding risk assessment [4].

A first analysis of data collected using version 2.0 of the protocol showed that the protective effect of vaccines depended on the attack rate of the outbreak, with good protection in outbreaks where there was a low attack rate (AR<20%), but no protection when the attack rate was 20% or higher [5]. This observation, which is probably related to higher exposure to the virus in outbreaks with a high attack rate, highlighted the importance of early outbreak detection and rapid containment through effective infection prevention and control measures. The current version (2.1) of the protocol has been adapted slightly to take into account the administration of additional vaccine doses.

Suggested citation: European Centre for Disease Prevention and Control. Data collection on COVID-19 outbreaks with a completed vaccination programme: long-term care facilities. Version 2.1, 18 February 2022. Stockholm: ECDC; 2022.

Changes in version 2.0

The main changes in version 2.0 of this protocol, compared to version 1.0, are listed below.

- Removal of the first clinical assessment. Version 1 of the protocol (6 May 2021) foresaw two clinical assessments: one initial assessment at the beginning of an outbreak and one after the outbreak and clinical follow-up had ended. We now only foresee one single assessment, assuming that most data collected using this protocol will be sent after the end of the outbreak. If further clinical follow-up is needed, an updated report can follow.
- Reduction of the number of descriptive variables and addition of aggregate variables to allow estimation of vaccine effectiveness for infection, symptomatic disease, hospitalisation and death.
- Addition of two data collection forms (one for aggregate data and one for optional case-based data) for a quick understanding of the protocol and for use by data collectors.
- Addition of a section on the estimation of vaccine effectiveness based on data collected using the current protocol.
- Change of the COVID-19 severity definition to one agreed with the ECDC HAI-Net network on 8 June 2021, suitable for use in LTCFs (simplified) and for both community-associated and healthcare-associated COVID-19 (e.g. in hospitals).

Changes in version 2.1

The main changes in the current version of the protocol, compared to version 2.0[1], are listed below.

- In the title, the words 'with a completed vaccination programme' have been removed.
- In the section 'Background', the new fourth paragraph summarises a peer-reviewed article that used data collected according to protocol version 2.0. In addition, the methodology from the article is quoted in a new paragraph in the Methods section, under the sub-heading 'Considerations for estimation of relative risks and/or vaccine effectiveness'.
- In the section 'Objectives', the secondary objectives now include the text 'by number of vaccine doses'.
- The section 'National actions foreseen for this activity' has been re-organised under three new subheadings:
  - 'A. Choosing a (sub-)national sampling frame and representativeness'. This section now has more specific and explicit detail for the suggested national sampling frame, to promote collection of a representative sample of national outbreaks.
  - 'B. Outbreak-level data collection by (sub-)national teams'.
  - 'C. Data reporting by EU/EEA countries to ECDC'. This clarifies the process for reporting data that was unavailable at the time of the initial report (e.g. variant data).
- In Annex 2, the metadata for aggregate data has been updated.
- Annex 1 has been updated to reflect the updates in Annex 2.
- In Annex 4, the metadata for aggregate data has been updated.
- Annex 3 has been updated to reflect the updates in Annex 2.
- In Annex 5, a short section discusses variant-specific symptoms of non-severe cases of COVID-19.
- On ECDC's webpage for this protocol, there is an update of the ECDC data entry template (Excel spreadsheet). The update reflects all changes made to Annexes 1–4 in version 2.1.

Objectives

Primary objectives

- to assess the characteristics of COVID-19 outbreaks among vaccinated LTCF residents and staff;
- to monitor disease severity of infections in vaccinated LTCF residents and staff, by vaccine brand and VOC;
- to inform ECDC rapid risk assessments on COVID-19 and provide input on future ECDC guidance;
- to support investigations by authorities in EU/EEA countries.

Secondary objective

To obtain a timely estimate of vaccine effectiveness during COVID-19 outbreaks in LTCF residents, by vaccine brand, number of vaccine doses and VOC against:

- symptomatic and asymptomatic COVID-19;
- severe COVID-19, hospitalisation, and death.

[1] Available from: https://www.ecdc.europa.eu/en/publications-data/data-collection-covid-19-outbreaks-closed-settings-completed-vaccination

Methods

Inclusion criteria for long-term care facilities

An LTCF (see definitions) refers to a general nursing home, residential home, mixed facility or specialised LTCF that has:

- conducted a COVID-19 vaccination programme for LTCF residents;

AND

- currently has or has had a COVID-19 outbreak, with onset two weeks or more after completion of the COVID-19 vaccination programme. A COVID-19 outbreak is defined as the occurrence of more than one confirmed COVID-19 case among LTCF residents within a period of two weeks (14 days).

Considerations for the inclusion criteria

- All considerations are for guidance only.
- All LTCFs are eligible, even if their vaccination programme(s) were conducted several months previously and additional residents have been admitted since (irrespective of the vaccination status of the new residents).
- Vaccination of LTCF workers may have occurred on different day(s); this is not part of the inclusion criteria.
- If the residents were vaccinated outside the LTCF on different dates (e.g. at a doctor's practice), the date of completion of the vaccination programme will be the date when the last resident was vaccinated with the second dose of vaccine, provided that this resident had been admitted to the LTCF at the start of the first vaccination programme for residents.
- 'Completion' of a vaccination programme means that residents should have received the requisite number of doses to achieve 'full vaccination' (i.e. two doses for most of the COVID-19 vaccines in use).
- Irrespective of the criteria above, if the outbreak is considered to be of interest to other countries and to ECDC, then reporting should still be considered.

Considerations for the estimation of relative risks and/or vaccine effectiveness

- Vaccine effectiveness (VE) may be calculated by pooling data from different outbreaks and comparing attack rates (ARs) in fully-vaccinated versus non-vaccinated individuals, as $VE = (AR_{unvaccinated} - AR_{vaccinated})/AR_{unvaccinated}$, or the equivalent as VE = 1 – Relative Risk [6].
- As vaccine coverage is usually very high in LTCFs, especially among residents, data may be pooled from different outbreaks to obtain a sufficient number of unvaccinated individuals. Methods will be used to take into account the resulting data heterogeneity, such as correction of the VE 95% confidence intervals for the design effect resulting from the pooling of data.
- Estimations may be made by VOC and/or vaccine brand, if sample size allows.
- During analysis, pooled attack rates may be investigated using a mixed-effect generalised linear model with Poisson distribution, with country included as a random effect. In this analysis, adjusted relative risks (RRa) for vaccination against COVID-19 would be calculated with confounding and effect modification assessed in terms of the time since completion of vaccination, size and type of LTCF, country, and categories of outbreak attack rate (AR) in residents. Outbreaks are likely to be excluded from analysis if there are missing or discordant data for denominators and cases by vaccination status [5].

Potential risk of reporting bias

- In the absence of a systematic selection of outbreaks, the reported outbreaks for this activity may tend to be larger, meeting criteria for reporting in EWRS or having been detected by the media and followed-up by ECDC and/or national authorities. In these outbreaks, the VE may be lower than in facilities with smaller outbreaks (e.g. 2–3 cases) [5]. Therefore, the following section recommends a sampling frame to counterbalance this bias and to ensure that a variety of outbreak and LTCF sizes are included.

National actions foreseen for this activity

A. Choosing a (sub-)national sampling frame and representativeness

- Exhaustive data collection is not an objective of this activity.
- We are seeking information on any outbreak of breakthrough infection at an LTCF that a country deems useful to share (e.g. hospitalised/fatal vaccinated cases).
- The choice of the sampling frame for outbreaks should be balanced against available staff resources at national and sub-national level.

Example of sampling strategy: we recommend reporting the first X outbreaks of each calendar month, based on the reporting date (or any other available date), with the number of outbreaks determined by the assumed workload.

B. Outbreak-level data collection by (sub-)national teams

ECDC data collection forms

For each COVID-19 outbreak at an LTCF (see definitions below), the data specified in Annex 2 should be collected (for all variables where the data is available) using the form in Annex 1.

Optionally, data on cases can also be reported using the form in Annex 3, according to the definitions of case-based data specified in Annex 4. This is an alternative to reporting aggregate data on cases.

ECDC data entry template

A data entry template (Microsoft Excel spreadsheet) is available on ECDC's website and from HAI-Net@ecdc.europa.eu. It contains the variables specified in Annex 1 and 2, to facilitate reporting by EU/EEA Coordinating Competent Bodies to ECDC.

Timeline of national investigations

The methodology foresees a single assessment of the clinical status of COVID-19 cases. This assumes that the outbreak is over, or at an advanced stage by the time data are reported, so that data on the clinical course of COVID-19 cases are complete (possibly with the exception of severe cases still undergoing treatment – for example in an intensive care unit (ICU).

Note: if a first assessment is submitted while the outbreak is still ongoing, please ensure that a subsequent report is submitted with completed data (outcomes, variants)[2].

Considerations for data collection

- Denominators: when reporting, include all LTCF wards/units in the denominator that were included in the investigation of the outbreak.
- Data collectors: ECDC has no recommendation regarding the type of staff who should perform data collection.

C. Data reporting by EU/EEA countries to ECDC

Reporting available data to ECDC

Completed forms should be uploaded to the secure ECDC platform 'EpiPulse' (https://epipulse.ecdc.europa.eu/) that replaced the EPIS platform, under the item that has been created by ECDC for this activity. It is possible to add previously unavailable data, or to update data on a form which has already been uploaded (see footnote 2 below). In fact, this is recommended to ensure the accuracy of the analyses.

Timeline of data reporting to ECDC

Outbreak reports can be uploaded to EpiPulse at any time. ECDC communicates the timeline for intended analysis by ECDC (i.e. a 'data call') to Coordinating Competent Bodies in EU/EEA countries, via their National Focal Points for Healthcare-Associated Infections.

Considerations for reporting

- Reporting multiple outbreaks to EpiPulse: each ECDC data entry template (Excel spreadsheet) can be used to record aggregate data for up to four outbreaks, as it contains a set of four identical tabs (see tabs Outbreak 1 – Outbreak 4). For example, a country reporting aggregate data for 19 outbreaks could report these with a minimum of five spreadsheets. Conversely, if case-based data is reported, all outbreaks can be reported in one tab 'CaseBasedDataEntry', with one row per case, and each outbreak distinguishable by the variable OutbreakID (see Annexes 3 and 4).
- Free text responses: the purpose of this protocol is to provide data collection forms in order to offer a comparable data structure for nationally-provided data. If it is not possible to provide structured information using these forms, countries can still report details of outbreaks in EWRS or EpiPulse using free text.
- Sequence data should ideally be reported to GISAID.

[2] In the EpiPulse platform, to update a report, replace the original file by uploading an Excel spreadsheet with the same filename.

Recommendations for laboratory testing

When a COVID-19 outbreak, detected at an LTCF, meets the inclusion criteria set out above, ECDC recommends laboratory testing as follows:

- test all residents and staff at the LTCF for COVID-19. If there are multiple, physically-separated wards/buildings with dedicated staff, test all residents and staff in the affected ward/building as a minimum.
- to determine SARS-CoV-2 variant(s), ECDC recommends performing sequencing on laboratory-confirmed COVID-19 samples from LTCF residents, if typing capacity permits. If sequencing is currently unavailable (sub-)nationally, then it is recommended that clinical samples be stored, when this is feasible.
- ECDC supports the scale-up of sequencing and neutralisation assay capacity in EU/EEA countries. Please contact PHE.Support.Microbiology@ecdc.europa.eu for more information.

Definitions

COVID-19 outbreak

- A COVID-19 outbreak is defined as the occurrence of more than one confirmed COVID-19 case among LTCF residents within a period of two weeks (14 days).

COVID-19 case severity

The definition of COVID-19 case severity was modified in this version of the protocol. The previous definition based on the World Health Organization's clinical management guidance [7] was replaced on 8 June 2021 with a definition agreed by the ECDC HAI-Net network for the reporting of healthcare-associated COVID-19, suitable for use in LTCFs and hospitals. The definition should only be applied in the optional case-based data. For the aggregated data, only the distinction between asymptomatic and symptomatic cases is required.

- Asymptomatic (COV-ASY): an asymptomatic COVID-19 case is a person infected with SARS-CoV-2 who does not develop symptoms.
- Mild/moderate (COV-MM): any sign or symptom compatible with COVID-19[3] without the need for oxygen therapy and having an oxygen saturation level ≥92%.
- Severe (COV-SEV): signs or symptoms compatible with COVID-19, with the need for oxygen therapy due to shortness of breath and/or an oxygen saturation level <92%.

Long-term care facilities

LTCFs include institutions such as nursing homes, skilled nursing facilities, retirement homes, assisted-living facilities, residential care homes or other facilities. These facilities take care of people requiring support who find it difficult to live independently in the community due to physical, mental, intellectual or sensory impairments, possibly resulting from old age, or chronic medical conditions. Long-term care facilities for all age groups are included.

LTCFs typically have residents who need constant supervision (24 hours a day) and skilled nursing care (i.e. more than 'basic' nursing care and assistance for daily living activities). Residents can also be medically stable and not in need of constant 'specialised medical care' (i.e. care administered by specialised physicians) or invasive medical procedures (e.g. ventilation).

National definitions

If a national definition is different from those provided above, use the national definition (e.g. the national definition of an outbreak). In such cases, please provide the national definition as free text.

Additional vaccine dose

For the purposes of this activity, an 'additional vaccine dose' also includes booster doses. Booster doses are given to vaccinated people (i.e. those who have completed a primary series of COVID-19 vaccination) to restore protection after immunity has waned. On the other hand, additional doses as part of a primary vaccination series may be given to people with severely weakened immune systems, as they may not achieve an adequate level of protection from the standard primary vaccination [8].

Added value of optional case-based data collection and reporting

The list below sets out the added value of the optional case-based data collection (Annex 2).

- Allows infections in LTCF residents and staff to be described and vaccine effectiveness to be estimated, not only by vaccination status (partial or full) and separately for residents and staff, but also by vaccine brand, and for mild/moderate versus severe cases.
- Allows clinical severity to be described by vaccination status (partial or full), vaccine brand, variant and separately for residents and staff.
- Allows more than two variants to be identified.

[3] For a list of COVID-19 symptoms please see Annex 3.

- Allows PCR CT-values to be captured in order to assess transmissibility.
- Allows the capture of varying vaccination dates and time intervals for cases within the same LTCF.
- Allows varying follow-up dates within the same LTCF
- Includes collection of data on pharmaceutical countermeasures (e.g. post-exposure prophylaxis).
- Allows age and gender description of cases.
- Data collection is less complicated than aggregate data collection and the data entry workload is only marginally higher if the number of cases is low, because there is no need to collect 77 aggregate variables with the number of asymptomatic and symptomatic cases, hospitalised cases and deaths by vaccination status since these are replaced with 24 case-based variables.
- The case-based questionnaire can be used locally for outbreak investigation (and possibly to calculate the aggregate data).

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Annex 1. Form for collection of aggregate data

COVID-19 breakthrough outbreaks in long-term care facilities - Data collection form (aggregate data)

Reporting country	
Outbreak ID	
LTCF type	☐ General nursing home ☐ Residential home ☐ Mixed LTCF ☐ LTCF for mentally disabled ☐ LTCF for physically disabled ☐ Palliative care facility ☐ Psychiatric LTCF ☐ Sanatorium ☐ Other ☐ Unknown
Outbreak location (free text)	
Date of report	__ / __ / ____
Date start outbreak	__ / __ / ____
Index case specification	☐ Staff/worker, vaccinated ☐ Staff/worker, partially vaccinated ☐ Staff/worker, unvaccinated ☐ Resident, vaccinated ☐ Resident, partially vaccinated ☐ Resident, unvaccinated ☐ Other
Date end full vaccination residents	__ / __ / ____
Vaccine brand residents (list)	
Date end additional dose 1 residents	__ / __ / ____
Vaccine brand additional dose 1 residents (list)	
Date end additional dose 2 residents	__ / __ / ____ ☐ Not applicable
Vaccine brand addional dose 2 residents (list)	
Date end vaccination staff/workers	__ / __ / ____
Vaccine brand staff/workers (list)	
Date end additional dose(s) staff/workers	__ / __ / ____
Vaccine brand additional dose(s)staff/workers (list)	
Testing strategy for residents	☐ Only symptomatic ☐ All in affected ward(s) ☐ All in entire LTCF ☐ Other
Testing strategy for staff/workers	☐ Only symptomatic ☐ All in affected ward(s) ☐ All in entire LTCF ☐ Other
Number of sequenced cases	
Variant1 (list)	
Variant1 other, please specify	
Number of variant1 cases	
Variant2 (list)	
Variant2 other, please specify	
Number of variant2 cases	
OutbreakDetails (free text)	

Residents	Vaccination Status					Total
	Un-vaccinated	Partial	Full	Additional dose(s)§	Unknown	
Total N of LTCF residents						
N of cases						
Asymptomatic						
Symptomatic						
Symptoms unknown						
N of hospitalised cases						
N of deaths among cases						

Staff/workers	Vaccination Status					Total
	Un-vaccinated	Partial	Full	Additional dose(s)§	Unknown	
Total N of staff/workers						
N of cases						
Asymptomatic						
Symptomatic						
Symptoms unknown						
N of hospitalised cases						
N of deaths among cases						

= variables not to be collected if case-based data are reported; § include all cases who received ≥1 additional or booster doses.

Annex 2. Definition of variables for collection of aggregate data

Table 1. Definition of variables for collection of aggregate data on COVID-19 outbreaks at LTCFs

VarN[1]	Req[2]	Variable	Description	Data type	Coded value list
1	M	ReportingCountry	The country reporting the record.	CV	EU/EEA countries
2	M	OutbreakID	National unique identifier of the outbreak.	TEXT	
3	R	LTCFType	Type of long-term care facility (HALT coded value list). Specify `other' in free text field 'DetailsOutbreak'	CV	LTCFTypeHALT: GNH = General nursing home RSH = Residential home MIX = Mixed LTCF MD = LTCF for mentally disabled PCF = Palliative care facility PH = LTCF for physically disabled PS = Psychiatric LTCF RH = Rehabilitation SAN = Sanatorium O = Other UNK = Unknown
4	R	OutbreakLocation	Community and/or larger subnational geographic area where the LTCF is located. Free text or NUTS code.	TEXT	
5	M	DateOfReport	Date on which the last clinical data for the current report were collected. Please provide a second report if the clinical follow-up was not completed at the time of the current report.	DATE	
6	R	DateStartOutbreak	Date of disease onset of the first COVID-19 case of the current outbreak among residents of the LTCF.	DATE	
7	O	IndexCaseSpec	Specify if the index case was an LTCF worker or a resident. If the infection of a resident was probably caused by a visitor, report the resident as index case. Specify 'other' in the free text field 'DetailsOutbreak'.	CV	HWVAC = LTCF worker, vaccinated HWPVAC = LTCF worker, partially vaccinated HWUVAC = LTCF worker, unvaccinated RESVAC = Resident, vaccinated RESPVAC = Resident, partially vaccinated RESUVAC = Resident, unvaccinated O = Other, please specify UNK = Unknown
8	R	DateEndVaccinationResidents	End date of the vaccination programme for residents of the LTCF – i.e. date on which the initial vaccination schedule was completed (usually two doses except for Janssen Ad26.COV 2.5). For definition of vaccination programme, see inclusion criteria. Specify exact date if available, otherwise provide week/month.	DATE	
9	R	VaccineBrandResidents	Vaccine brand administered to at least 80% of residents. If the brand used for the second dose differs from the brand used for the first dose, or if >20% of residents received a different vaccine, select MIX. Specify details for 'MIX' and 'Other' in the free text field 'DetailsOutbreak'.	CV	VaccineCOVID[5]: AZ = AstraZeneca - AZD1222 BECNBG = Beijing CNBG – Inactivated BHACOV = Bharat – Covaxin COM = Pfizer BioNTech - Comirnaty CVAC = Curevac – CVnCOV HAYATVAC = Hayat-VAC JANSS = Janssen - Ad26.COV 2.5 MOD = Moderna - mRNA-1273 QAZVAQ = QazCovid-In

VarN[1]	Req[2]	Variable	Description	Data type	Coded value list
					SGSK = Sanofi GSK – Subunit SIICOV = SII – Covishield SIN = Coronavac – Sinovac SPU = Gamaleya - Sputnik V SRCVB = SRCVB – EpiVacCorona UNK = Unknown WUCNBG = Wuhan CNBG – Inactivated ZFUZ = Sino-Uzbek - ZF-UZ-VAC O = Other UNK = Unknown
10	R	DateEndBooster1Residents	End date of the vaccination programme for administration of an additional vaccine dose to LTCF residents. Specify exact date if available, otherwise provide week or month. For this activity, 'additional doses' also include 'booster doses'. See the definition section of the protocol.	DATE	
11	R	Booster1BrandResidents	Vaccine brand administered to at least 80% of residents for their first additional (or booster) dose. If >20% of residents received a different vaccine, select MIX. Specify details for 'MIX' and 'Other' in the free text field 'DetailsOutbreak'.	CV	VaccineCOVID[§]: (see 'VaccineBrandResidents')
12	R	DateEndBooster2Residents	End date of the vaccination programme for administration of a second additional vaccine dose to LTCF residents. Specify exact date if available, otherwise provide week or month. For this activity, 'additional doses' also include 'booster doses'. See the definition section of the protocol.	DATE	
13	R	Booster2BrandResidents	Vaccine brand administered to at least 80% of residents for a second additional (or booster) dose. If >20% of residents received a different vaccine, select MIX. Specify details for 'MIX' and 'Other' in the free text field 'DetailsOutbreak'	CV	VaccineCOVID[§]: (see 'VaccineBrandResidents')
14	R	DateEndVaccinationStaff	End date of the vaccination programme for LTCF staff/workers. For definition of vaccination programme, see inclusion criteria. Specify exact date if available, otherwise provide week or month. Date where >=80% of currently vaccinated were vaccinated (if known)	DATE	
15	R	VaccineBrandStaff	Vaccine brand administered to at least 80% of LTCF staff/workers. If the brand used for the second dose differs from the brand used for the first dose, or if >20% of LTCF staff received a different vaccine, select MIX and specify in next variable. Specify details for 'MIX' and 'Other' in the free text field 'DetailsOutbreak'.	CV	See list VaccineCOVID[§] above
16	R	DateEndBooster1Staff	End date of the vaccination programme for administration of an additional vaccine dose to LTCF staff/workers. Specify exact date if available, otherwise provide week or month. For this activity, 'additional doses' also include 'booster doses'. See the definition section of the protocol.	DATE	
17	R	Booster1BrandStaff	Vaccine brand administered to at least 80% of LTCF staff/workers for their first additional (or booster) dose. If >20% of LTCF staff received a different vaccine, select MIX. Specify details for 'MIX' and 'Other' in the free text field 'DetailsOutbreak'	CV	VaccineCOVID[§]: (see 'VaccineBrandResidents')
18	R	TestingStrategyResidents	Testing strategy for LTCF residents during the current outbreak: testing of symptomatic residents only, testing of all residents in the affected ward(s), testing of all residents in the entire LTCF or other strategy. Specify other in free text field 'DetailsOutbreak'. Required to interpret the number of asymptomatic cases.	CV	TestStrategyLTCF: SYMONLY = Only symptomatic ALLWARD = All in affected ward(s) ALLLTCF = All in entire LTCF O = Other
19	R	TestingStrategyStaff	Testing strategy for LTCF staff/workers during the current outbreak: testing of symptomatic staff/workers only, testing of all staff/workers in the affected ward(s), testing of all staff/workers at the entire LTCF or other strategy. Specify other in free text field 'DetailsOutbreak'. Required to interpret the number of asymptomatic cases.	CV	TestStrategyLTCF: SYMONLY = Only symptomatic ALLWARD = All in affected ward(s) ALLLTCF = All in entire LTCF O = Other
20	R	NumSequencedCases	Number of cases for which SARS-CoV-2 sequencing was performed. Note: identified variants and number of cases by variant are part of the	NUM	

VarN[1]	Req[2]	Variable	Description	Data type	Coded value list
			aggregate data so only need to be collected if optional case-based data are not collected (see below).		
21	O	OutbreakDetails	Additional free text details concerning the outbreak.	TEXT	
		Aggregate denominator data (also to be collected if optional case-based data are reported)			
22	R	NumLTCFOccupiedBeds	Total number of residents = sum of unvaccinated, partially- vaccinated, fully-vaccinated residents, residents having received additional doses and residents with unknown vaccination status. Equals the number of beds occupied by residents at the time of outbreak onset. Denominator data also to be collected if optional case-based data are collected. When reporting, include all LTCF wards/units in the denominator that were included in the (sub-)national investigation of the LTCF.	NUM	
23	R	NumUnvaccinatedResidents	Number of unvaccinated LTCF residents.	NUM	
24	R	NumVaccinatedResidentsPartial	Number of partially-vaccinated residents (i.e. who were vaccinated, but had not received all required doses of the vaccine regimen or for whom the last dose was administered less than two weeks before the onset of the outbreak).	NUM	
25	R	NumVaccinatedResidentsFull	Number of fully-vaccinated residents (i.e. who had received all required doses of the vaccine, with the last dose at least two weeks before the onset of the outbreak).	NUM	
26	R	NumVaccinatedResidentsBooster	Number of fully-vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
27	R	NumVaccinatedResidentsUnk	Number of residents with unknown vaccination status.	NUM	
28	R	NumLTCFStaff	Total number of staff (i.e. any LTCF worker, paid or unpaid, working at the LTCF at time of outbreak onset) = sum of unvaccinated, partially vaccinated, fully vaccinated staff/workers, staff/workers having received additional doses and staff/workers with unknown vaccination status. Denominator data, also to be collected if optional case-based data are collected.	NUM	
29	R	NumUnvaccinatedStaff	Number of unvaccinated LTCF staff/workers.	NUM	
30	R	NumVaccinatedStaffPartial	Number of partially-vaccinated staff/workers (i.e. who were vaccinated, but had not received all required doses of the vaccine regimen, or for whom the last dose was administered less than two weeks before the onset of the outbreak).	NUM	
31	R	NumVaccinatedStaffFull	Number of fully-vaccinated staff/workers (i.e. who had received all required doses of the vaccine, with last dose at least two weeks before the onset of the outbreak).	NUM	
32	R	NumVaccinatedStaffBooster	Number of fully-vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
33	R	NumVaccinatedStaffUnk	Number of LTCF staff/workers with unknown vaccination status.	NUM	
		Aggregate data on COVID-19 cases. The following variables are only to be collected if no case-based data are reported (see Annex 3)			
34	M	TotCasesResidents	Total number of COVID-19 cases among residents. This is included as an internal consistency check and is mandatory if it is not possible to report cases by vaccination status.	NUM	
35	R	NumCasesResidentsUnvaccinated	Number of COVID-19 cases in unvaccinated residents.	NUM	
36	R	NumCasesResidentsPartialVaccin	Number of COVID-19 cases in partially-vaccinated residents.	NUM	
37	R	NumCasesResidentsFullVaccin	Number of COVID-19 cases in fully-vaccinated residents.	NUM	
38	R	NumCasesResidentsBooster	Number of COVID-19 cases in fully-vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
39	R	NumCasesResidentsUnkownVaccin	Number of COVID-19 cases in residents with unknown vaccination status.	NUM	
40	R	NumAsymptomaticCasesRes	Total number of asymptomatic cases among residents.	NUM	
41	R	NumAsyCasesUnvacRes	Number of asymptomatic cases among unvaccinated residents.	NUM	
42	R	NumAsyCasesPartialVacRes	Number of asymptomatic cases among partially vaccinated residents.	NUM	
43	R	NumAsyCasesFullyVacRes	Number of asymptomatic cases among fully vaccinated residents.	NUM	
44	R	NumAsyCasesBoosterVacRes	Number of asymptomatic cases among fully vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
45	R	NumAsyCasesUnkVacRes	Number of asymptomatic cases among residents with unknown vaccination status.	NUM	
46	R	NumSymptomaticCasesRes	Total number of symptomatic cases among residents.	NUM	
47	R	NumSymCasesUnvacRes	Number of symptomatic cases among unvaccinated residents.	NUM	

VarN[1]	Req[2]	Variable	Description	Data type	Coded value list
48	R	NumSymCasesPartialVacRes	Number of symptomatic cases among partially vaccinated residents.	NUM	
49	R	NumSymCasesFullyVacRes	Number of symptomatic cases among fully vaccinated residents.	NUM	
50	R	NumSymCasesBoosterVacRes	Number of symptomatic cases among fully vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
51	R	NumSymCasesUnkVacRes	Number of symptomatic cases among residents with unknown vaccination status.	NUM	
52	R	NumUnkSymCasesRes	Total number of cases among residents where it is unknown whether they had symptoms.	NUM	
53	R	NumUnkSymCasesUnvacRes	Number of cases among unvaccinated residents where it is unknown whether they had symptoms.	NUM	
54	R	NumUnkSymCasesPartialVacRes	Number of cases among partially vaccinated residents where it is unknown whether they had symptoms.	NUM	
55	R	NumUnkSymCasesFullyVacRes	Number of cases among fully vaccinated residents where it is unknown whether they had symptoms.	NUM	
56	R	NumUnkSymCasesBoosterVacRes	Number of cases among fully vaccinated residents who received at least one additional dose of any vaccine brand, where it is unknown whether they had symptoms.	NUM	
57	R	NumUnkSymCasesUnkVacRes	Number of cases among residents with unknown vaccination status where it is unknown whether they had symptoms.	NUM	
58	R	NumHospitalisedCasesRes	Total number of hospitalised cases among residents.	NUM	
59	R	NumHospCasesUnvacRes	Number of hospitalised cases among unvaccinated residents.	NUM	
60	R	NumHospCasesPartialVacRes	Number of hospitalised cases among partially vaccinated residents.	NUM	
61	R	NumHospCasesFullyVacRes	Number of hospitalised cases among fully vaccinated residents.	NUM	
62	R	NumHospCasesBoosterVacRes	Number of hospitalised cases among fully vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
63	R	NumHospCasesUnkVacRes	Number of hospitalised cases among residents with unknown vaccination status.	NUM	
64	R	NumDeathsResidents	Total number of COVID-19 cases who died among residents.	NUM	
65	R	NumDeathsUnvacRes	Number of COVID-19 cases who died among unvaccinated residents.	NUM	
66	R	NumDeathsPartialVacRes	Number of COVID-19 cases who died among partially vaccinated residents.	NUM	
67	R	NumDeathsFullyVacRes	Number of COVID-19 cases who died among fully vaccinated residents.	NUM	
68	R	NumDeathsBoosterVacRes	Number of COVID-19 cases who died among fully vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
69	R	NumDeathsUnkVacRes	Number of COVID-19 cases who died among residents with unknown vaccination status.	NUM	
70	M	TotCasesStaff	Total number of COVID-19 cases in LTCF staff/workers. This is included as an internal consistency check and is mandatory if it is not possible to report cases by vaccination status.	NUM	
71	R	NumCasesStaffUnaccinated	Number of COVID-19 cases in unvaccinated staff/workers.	NUM	
72	R	NumCasesStaffPartialVaccin	Number of COVID-19 cases in partially-vaccinated staff/workers.	NUM	
73	R	NumCasesStaffFullVaccin	Number of COVID-19 cases in fully-vaccinated staff/workers.	NUM	
74	R	NumCasesStaffBooster	Number of COVID-19 cases in fully-vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
75	R	NumCasesStaffUnkownVaccin	Number of COVID-19 cases in staff/workers with unknown vaccination status.	NUM	
76	R	NumAsymptomaticCasesStaff	Total number of asymptomatic cases among LTCF staff/workers.	NUM	
77	R	NumAsyCasesUnvacStaff	Number of asymptomatic cases among unvaccinated staff/workers.	NUM	
78	R	NumAsyCasesPartialVacStaff	Number of asymptomatic cases among partially vaccinated staff/workers.	NUM	
79	R	NumAsyCasesFullyVacStaff	Number of asymptomatic cases among fully vaccinated staff/workers.	NUM	
80	R	NumAsyCasesBoosterVacStaff	Number of asymptomatic cases among fully vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
81	R	NumAsyCasesUnkVacStaff	Number of asymptomatic cases among staff/workers with unknown vaccination status.	NUM	
82	R	NumSymptomaticCasesStaff	Total number of symptomatic cases among staff/workers.	NUM	
83	R	NumSymCasesUnvacStaff	Number of symptomatic cases among unvaccinated staff/workers.	NUM	
84	R	NumSymCasesPartialVacStaff	Number of symptomatic cases among partially vaccinated staff/workers.	NUM	
85	R	NumSymCasesFullyVacStaff	Number of symptomatic cases among fully vaccinated staff/workers.	NUM	

VarN[1]	Req[2]	Variable	Description	Data type	Coded value list
86	R	NumSymCasesBoosterVacStaff	Number of symptomatic cases among fully vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
87	R	NumSymCasesUnkVacStaff	Number of symptomatic cases among staff/workers with unknown vaccination status.	NUM	
88	R	NumUnkSymCasesStaff	Total number of cases among staff/workers where it is unknown whether they had symptoms.	NUM	
89	R	NumUnkSymCasesUnvacStaff	Number of cases among unvaccinated staff/workers where it is unknown whether they had symptoms.	NUM	
90	R	NumUnkSymCasesPartialVacStaff	Number of cases among partially vaccinated staff/workers where it is unknown whether they had symptoms.	NUM	
91	R	NumUnkSymCasesFullyVacStaff	Number of cases among fully vaccinated staff/workers where it is unknown whether they had symptoms.	NUM	
92	R	NumUnkSymCasesBoosterVacStaff	Number of cases among fully vaccinated staff/workers who received at least one additional dose of any vaccine brand where it is unknown whether they had symptoms.	NUM	
93	R	NumUnkSymCasesUnkVacStaff	Number of cases among staff/workers with unknown vaccination status where it is unknown whether they had symptoms.	NUM	
94	R	NumHospitalisedCasesStaff	Total number of hospitalised cases among staff/workers.		
95	R	NumHospCasesUnvacStaff	Number of hospitalised cases among unvaccinated staff/workers.		
96	R	NumHospCasesPartialVacStaff	Number of hospitalised cases among partially vaccinated staff/workers.	NUM	
97	R	NumHospCasesFullyVacStaff	Number of hospitalised cases among fully vaccinated staff/workers.	NUM	
98	R	NumHospCasesBoosterVacStaff	Number of hospitalised cases among fully vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
99	R	NumHospCasesUnkVacStaff	Number of hospitalised cases among staff/workers with unknown vaccination status.	NUM	
100	R	NumDeathsStaff	Total number of COVID-19 cases who died among staff/workers.	NUM	
101	R	NumDeathsUnvacStaff	Number of COVID-19 cases who died among unvaccinated staff/workers.	NUM	
102	R	NumDeathsPartialVacStaff	Number of COVID-19 cases who died among partially vaccinated staff/workers.	NUM	
103	R	NumDeathsFullyVacStaff	Number of COVID-19 cases who died among fully vaccinated staff/workers.	NUM	
104	R	NumDeathsBoosterVacStaff	Number of COVID-19 cases who died among fully vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
105	R	NumDeathsUnkVacStaff	Number of COVID-19 cases who died among staff/workers with unknown vaccination status.	NUM	
106	R	Variant1	If sequencing data is available, provide the variant, according to the list of codes in Annex 6. Annex 6 Table 3A lists all variants currently specified on ECDC variant-listing webpage[§§]. Annex 6 Table 3B lists all other variants that are included in the current TESSy metadata[§] (Table 3B). Given the current predominance of the Omicron and Delta variants in the EU/EEA, common codes are likely to be 'B.1.1.529' (i.e. Omicron) and 'B.1.617.2' (i.e. Delta). If the variant is not included in Annex 6, use the code 'VARIANT_OTHER', and specify the variant in the variable 'VirusVariantOther'	CV	See Annex 6 (Tables 3A and 3B).
107	R	VariantOther1	Specify variant if not included in the list of codes in Annex 6 - e.g. 'Omicron (BA.2)'.	TEXT	
108	R	NumCasesVariant1	Number of cases confirmed with Variant 1.	NUM	
109	R	Variant2	Second (frequently) identified SARS-CoV-2 variant, if any.	CV	see list VirusVariantNCOV above[§]
110	R	VariantOther2	Specify variant if not included in the list of codes in Annex 6 - e.g. 'Omicron (BA.2)'.	TEXT	
111	R	NumCasesVariant2	Number of cases confirmed with Variant 2.	NUM	

[1]VarN: variable number; [2]Requirement: M – mandatory, R – recommended (= required to fulfil the objectives of the protocol), O - optional.

§ This coded value list is aligned with the coded value lists in TESSy MetaDataSet 49. Whenever possible, align with current TESSy metadata. Updates to TESSy metadata are published at the URL: https://tessy.ecdc.europa.eu/TessyHelp/index.aspx?navigation=TechnicalGuidelines

Annex 3. Form for the collection of optional case-based data (line list)

COVID-19 breakthrough outbreaks in long-term care facilities - Data collection form for optional case-based data (line list)																										
Outbreak ID	Case Number	Case Type	Age	Gender	Vaccinated	Date Vacc Dose1	Date Vacc Dose2	Date Vacc Dose3	Date Vacc Dose4	Brand Dose1	Brand Dose2	Brand Dose3	Brand Dose4	Date of Diagnosis	Ct Value	Virus Variant	Virus Variant Other	Medication In LTCF	Medication In LTCF Other	Report Date	Severity	Hospital-isation	ICU	Date Onset Symptoms	Outcome	Date of Death	Case Comments

Case type: RES = resident, STAFF = staff, LTCF worker, UNK = unknown; **Gender**: F = Female, M = Male, O = Other, UNK = Unknown; **Vaccinated**: NO = Not vaccinated, PART = Partially vaccinated, FULL = Fully vaccinated, BOOST = Additional dose(s), UNK = Unknown; **Brand Dose** 1-2-3: AZ = AstraZeneca - AZD1222, BECNBG = Beijing CNBG - inactivated, BHACOV = Bharat - Covaxin, COM = Pfizer BioNTech – Comirnaty, HAYATVAX = Hayat-VAX, JANSS = Janssen - Ad26.COV 2.5, MOD = Moderna - mRNA-1273, SIICOV = SII - Covishield, SIN = Coronavac – Sinovac, SPU = Gamaleya - Sputnik V, SRCVB = SRCVB - EpiVacCorona, WUCNBG = Wuhan CNBG – inactivated, ZFUZ = Sino-Uzbek - ZF-UZ-VAC, MIX = Different vaccine brands, O = Other, UNK = Unknown; **Virus Variant**: B.1.1.529 = B.1.1.529-Omicron-South Africa, B.1.1.7 = B.1.1.7-Alpha-UK, B.1.1.7+E484K = B.1.1.7+E484K-n/a-UK, B.1.351 = B.1.351-Beta-South Africa, B.1.525 = B.1.525-Eta-Nigeria, B.1.617.1 = B.1.617.1-Kappa-India, B.1.617.2 = B.1.617.2-Delta-India, B.1.620 = B.1.620-n/a-Unclear, B.1.621 = B.1.621-Mu-Colombia, C.37 = C.37-Lambda-Peru, P.1 = P.1-Gamma-Brazil, P.3 = P.3-Theta-The Philippines, VARIANT_OTHER = Novel variant of potential concern. Provide details in VariantOther, WILD_TYPE = None of the variants described for this variable, UNK = Sequence information unknown or not available; **Medication in LTCF**: PAX = Paxlovid (PF-07321332 / ritonavir), REG = Regkirona (regdanvimab), RON = Ronapreve (casirivimab / imdevimab), VEK = Veklury (remdesivir), XEV = Xevudy (sotrovimab), LAG = Lagevrio (molnupiravir), EVU = Evusheld (tixagevimab / cilgavimab), O = other, NONE = none, UNK = Unknown; **Severity**: ASYMP = Asymptomatic, MM = Mild/Moderate, SEV = Severe, UNK = Unknown; **Hospitalisation, ICU**: N = no, Y = yes, UNK = unknown; **Outcome**: ALIVE = Alive, recovered, cured, DIEDNCOV = COVID-19 was main or contributing cause of death, DIEDOTHER = Death not related to COVID-19 infection, DIEDUNK = Cause of death unknown, STILLTREATMENT = Still on medical treatment (not recovered), UNK = Unknown outcome.

Annex 4. Definition of variables for optional collection of case-based data at LTCF level

Table 2. Definition of variables for collection of case-based data on COVID-19 outbreaks in LTCFs

VarN[1]	Req[2]	Variable	Description	Data type	Coded value list
1	**M**	OutbreakID	Unique identifier of the outbreak	TEXT	
2	**M**	CaseNumber	Anonymised case number. Linked to case ID at facility level for validation purposes.	NUM	
3	**M**	CaseType	Whether case is resident or LTCF staff. LTCF staff includes all LTCF workers, paid or unpaid.	CV	RES = Resident STAFF = Staff, LTCF worker UNK = Unknown.
4	**O**	Age	Age of the reported case at diagnosis, in years.	NUM	
5	**O**	Gender	Gender of the reported case.	CV	F = Female M = Male O = Other (e.g. transsexual) UNK = Unknown.
6	**R**	Vaccinated	Vaccination status at diagnosis. FULL = received all required doses of the vaccine, with last dose at least two weeks before the onset of the outbreak. PARTIAL = did not receive all required doses of the vaccine regimen, or last dose was administered less than two weeks before the onset of the outbreak. BOOST = received at least one additional dose of any vaccine brand after full vaccination	CV	NO = Not vaccinated PART = Partially vaccinated FULL = Fully vaccinated BOOST = Additional dose(s) UNK = Unknown.
7	**O**	DateVaccDose1	Date of first COVID-19 vaccine dose. Leave empty if not received.	DATE	Allows UNK
8	**R**	DateVaccDose2	Date of second COVID-19 vaccine dose. Leave empty if not received.	DATE	Allows UNK
9	**O**	DateVaccDose3	Date of third COVID-19 vaccine dose (additional/booster dose). Leave empty if not received.	DATE	Allows UNK.
10	**O**	DateVaccDose4	Date of fourth COVID-19 vaccine dose (additional/booster dose). Leave empty if not received.	DATE	Allows UNK.
11	**O**	BrandDose1	Vaccine brand used for first dose. Leave empty if not received.	CV	VaccineCOVID[§]: AZ = AstraZeneca - AZD1222 BECNBG = Beijing CNBG - Inactivated BHACOV = Bharat - Covaxin COM = Pfizer BioNTech - Comirnaty CVAC = Curevac - CVnCOV HAYATVAC = Hayat-VAC JANSS = Janssen - Ad26.COV 2.5 MOD = Moderna - mRNA-1273 QAZVAQ = QazCovid-In SGSK = Sanofi GSK - Subunit SIICOV = SII - Covishield SIN = Coronavac – Sinovac SPU = Gamaleya - Sputnik V SRCVB = SRCVB - EpiVacCorona UNK = Unknown WUCNBG = Wuhan CNBG - Inactivated ZFUZ = Sino-Uzbek - ZF-UZ-VAC O = Other UNK = Unknown
12	**R**	BrandDose2	Vaccine brand used for second dose. Leave empty if not received.	CV	See list above.
13	**O**	BrandDose3	Vaccine brand used for third dose. Leave empty if not received.	CV	See list above.
14	**O**	BrandDose4	Vaccine brand used for fourth dose. Leave empty if not received.	CV	See list above.
15	**R**	DateDiagnosis	Date on which the case was diagnosed as confirmed COVID-19 case.	DATE	
16	**O**	CTValue	PCR CT value at DateDiagnosis	NUM	Allows UNK
17	**R**	VirusVariant	If sequencing data is available, provide the variant, according to the list of codes in Annex 6. Annex 6 Table 3A lists all variants currently specified on ECDC's variant-listing webpage[§§]. Annex 6 Table 3B lists all other variants included in the current TESSy metadata[§] (Table 3B). Given the current predominance of Omicron and Delta variants in the EU/EEA, common codes are likely to be 'B.1.1.529' (i.e. Omicron) and 'B.1.617.2' (i.e. Delta). If the variant is not included in Annex 6, use the code 'VARIANT_OTHER', and specify the variant in the variable 'VirusVariantOther'	CV	See Annex 6 (Tables 3A and 3B).

VarN[1]	Req[2]	Variable	Description	Data type	Coded value list
18	**R**	VirusVariantOther	Specify variant if not included in the list of codes in Annex 6 - e.g. 'Omicron (BA.2)'.	TEXT	
19	**O**	MedicationInLTCF	Anti-COVID medication given to the COVID-19 case, if applicable. This variable records the first three letters of all antiviral COVID-19 treatments listed by the European Medicines Agency (EMA), including those that are currently authorised or under review and listed on EMA's webpage https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-treatments, except for medications likely to be exclusive to hospital settings (i.e. Kineret (anakinra), RoActemra (tocilizumab), Olumiant (baricitinib)). If the medication is 'other', specify this in the free text field 'MedicationInLTCFOther'	CV	Antiviral-COVID: PAX = Paxlovid (PF-07321332 / ritonavir) REG = Regkirona (regdanvimab) RON = Ronapreve (casirivimab / imdevimab) VEK = Veklury (remdesivir) XEV = Xevudy (sotrovimab) LAG = Lagevrio (molnupiravir) EVU = Evusheld (tixagevimab / cilgavimab) O = other NONE = none UNK = Unknown
20	**O**	MedicationInLTCFOther	Specify the full name of any other anti-COVID medication given to the COVID-19 case, if applicable.	TEXT	
21	**R**	ReportDate	Date when the clinical status of the current COVID-19 case was assessed. Please provide a second report if the clinical follow-up was not completed at the time of the current report.	DATE	
22	**R**	Severity	Worst severity recorded for this case during the outbreak, before or on report date. Asymptomatic: no COVID-19 symptoms, Mild/Moderate: any COVID-19 symptoms without need of oxygen therapy or oxygen saturation ≥92%, Severe: COVID-19 symptoms with need for oxygen therapy due to shortness of breath due to COVID-19 and/or oxygen saturation level <92%.	CV	ASYMP = Asymptomatic MM = Mild/Moderate SEV = Severe UNK = Unknown
23	**R**	Hospitalisation	Hospitalised for treatment of COVID-19 during this outbreak, before or on report date .	CV	YesNoUnk: N = No Unk = Unknown Y = Yes
24	**O**	ICU	Admitted to the ICU for treatment of COVID-19 during this outbreak, before or on report date .	CV	YesNoUnk: N = No Unk = Unknown Y = Yes
25	**O**	DateOnsetSymptoms	Date of onset symptoms (leave empty for asymptomatic cases).	DATE	
26	**R**	Outcome	Outcome at report date.	CV	OutcomeNCOV: ALIVE = Alive, recovered, cured DIEDNCOV = COVID-19 was main or contributing cause of death DIEDOTHER = Death not related to COVID-19 infection DIEDUNK = Cause of death unknown STILLTREATMENT = Still on medical treatment (not recovered) UNK = Unknown outcome
27	**O**	DateOfDeath	Date of death, if applicable.	DATE	
28	**O**	CaseComments	Free text comments on the current case.	TEXT	

[1]VarN: variable number

[2]Requirement: M – mandatory, R – recommended (=required to fulfil the objectives of the protocol), O - optional.

§ This coded value list is aligned with the coded value lists in TESSy MetaDataSet 49. Whenever possible, align with current TESSy metadata. Updates to TESSy metadata are published at the URL: https://tessy.ecdc.europa.eu/TessyHelp/index.aspx?navigation=TechnicalGuidelines

§§ For the list of variants available on ECDC's website: https://www.ecdc.europa.eu/en/covid-19/variants-concern

Annex 5. List of COVID-19 symptoms

The most frequent symptoms are fever, cough, fatigue, shortness of breath, anorexia, myalgias, loss of smell (anosmia) and loss of taste (ageusia). Other non-specific symptoms, such as sore throat, nasal congestion, headache, diarrhoea, nausea and vomiting, have also been reported.

Additional neurological manifestations reported include dizziness, agitation, weakness, seizures, or findings suggestive of stroke including trouble with speech or vision, sensory loss, or problems with balance in standing or walking.

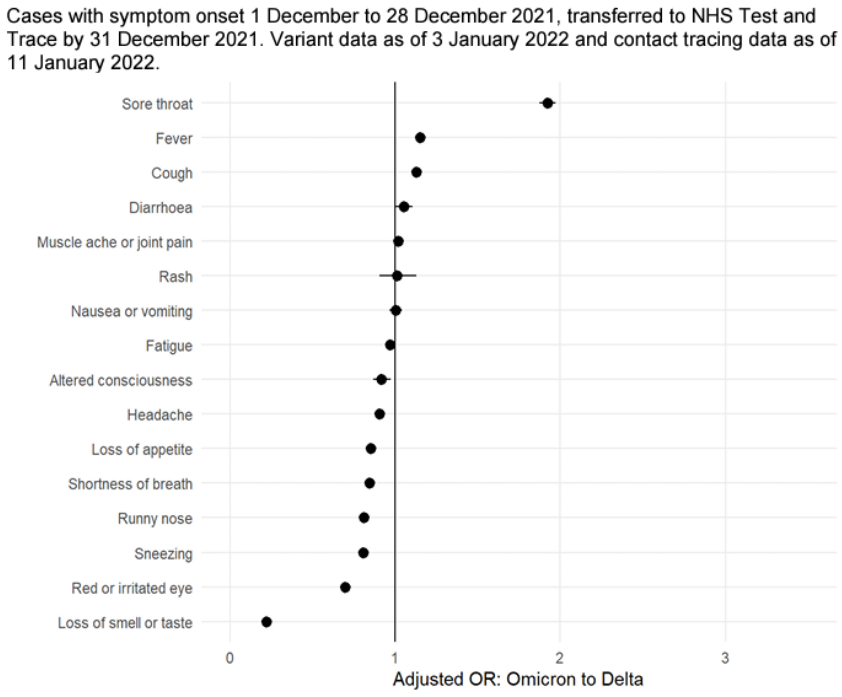
Older people, and immunosuppressed patients in particular, may present with atypical symptoms such as fatigue, reduced alertness, reduced mobility, diarrhoea, loss of appetite, confusion, and an absence of fever.

Source [7]: WHO. COVID-19 Clinical Management. Living Guidance. 25 January 2021. Available from https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-1.

Differences in symptom spectrum by variant type

The list of symptoms above should not necessarily be considered exhaustive or definitive. Data from the UK (December 2021) suggest that non-severe COVID-19 cases (i.e. those with mild/moderate symptoms) experienced a different set of symptoms, depending on whether they were infected by the circulating Omicron or Delta . For example, cases with the Omicron were more likely to report a sore throat, and less likely to report a loss of sense of smell, as has been reported elsewhere [9,10][9, 10].

Figure 1. Forest plot of adjusted* odds ratios of symptoms reported among cases with Omicron versus Delta variant



* Odds ratios adjusted for age group, sex, ethnicity, self-reported vaccination status (2 or more doses, one or no dose, or missing data), geographical region of residence, and the week in which symptoms began

Note: Trends from crude analysis may differ from those in adjusted analysis due to differences in demographic and other characteristics between cases with each of the variants.

Source [9]: UK Health Security Agency: 'SARS-CoV-2 variants of concern and variants under investigation in England; Technical briefing 34' (14 January 2022). Available from: https://www.gov.uk/government/publications/investigation-of-sars-cov-2-variants-technical-briefings

Annex 6. List of codes to report variants

Tables 3A and 3B contain a list of all codes that can currently be reported to TESSy. Table 3A presents all variants of concern, variants of interest and variants under monitoring listed on ECDC's webpage, as of 9 February 2022. Note that the webpage is updated periodically. Table 3B lists all variants that can be reported to TESSy using its current metadata. Note that this list is not intended to be exhaustive. If the identified strain is not included in Table 3A or 3B, then report **VARIANT_OTHER** and specify the variant in the variable **VirusVariantOther**.

Table 3A. Variants listed on ECDC's webpage 'SARS-CoV-2 variants of concern as of 2 February 2022'

Code to report [1]	WHO label [2]	Category [3]	Country first detected (community) [4]	Spike mutations of interest [5]
B.1.351	Beta	VOC	South Africa	K417N, E484K, N501Y, D614G, A701V
P.1	Gamma	VOC	Brazil	K417T, E484K, N501Y, D614G, H655Y
B.1.617.2	Delta	VOC	India	L452R, T478K, D614G, P681R
B.1.1.529	Omicron	VOC	South Africa and Botswana	See [5]
B.1.621	Mu	VOI	Colombia	R346K, E484K, N501Y, D614G, P681H
C.37	Lambda	VOI	Peru	L452Q, F490S, D614G
AY.4.2	n/a	VOI	United Kingdom	L452R, T478K, D614G, P681R, A222V, Y145H
B.1.1.318	n/a	VUM	Unclear	E484K, D614G, P681H
B.1.617.2 + K417N	n/a	VUM	United Kingdom	L452R, T478K, D614G, P681R, K417N
C.1.2	n/a	VUM	South Africa	D614G, E484K, H655Y, N501Y, N679K, Y449H
B.1.617.2 + E484X (d)	n/a	VUM	India	L452R, T478K, D614G, P681R, E484X (d)
B.1.617.2 + Q613H	n/a	VUM	India	L452R, T478K, D614G, P681R, Q613H
B.1.617.2 + Q677H	n/a	VUM	India	L452R, T478K, D614G, P681R, Q677H
B.1.640	n/a	VUM	The Republic of Congo	D614G, F490R, N394S, N501Y, P681H, R346S, Y449N, 137–145del

Table 3B. Additional variant codes in the coded value list VirusVariantNCOV in TESSy MetaDataSet 49 (2022-01-14)

Code to report [1]	Description [6]
B.1.1.7	B.1.1.7 (Alpha; mutations: del69-70,del144,N501Y,A570D,D614G,P681H,T716I,S982A,D1118H)
B.1.1.7+E484K	B.1.1.7+E484K (mutations as B.1.1.7 and additionally E484K)
B.1.427/B.1.429	B.1.427/B.1.429 (mutations: L452R, D614G)
B.1.525	B.1.525 (mutations: E484K, D614G, Q677H)
B.1.616	B.1.616 (mutations: D215G,D614G,142del,G669S,H66D,H655Y,N1187D,Q949R,V483A,Y144V)
B.1.617	B.1.617 lineage or any sub-lineage of B.1.617(common mutations: D614G,L452R,P681R)
B.1.617.1	B.1.617.1 (mutations: L452R, E484Q, D614G, P681R)
B.1.617.3	B.1.617.3 (mutations: L452R, E484Q, D614G, P681R)
B.1.620	B.1.620 (mutations: S477N, E484K, D614G, P681H)
BA.1	BA.1 or B.1.1.529 with mutations del69-70, ins214EPE, S371L, G496S, T547K
BA.2	BA.2 or B.1.1.529 with mutations V213G, T376A, R408S
BA.3	BA.3 or B.1.1.529 with mutations del69-70, ORF1a:A3657V, ORF3a:T22V
CLUSTER_5	Denmark cluster 5 associated with mink (defined by mutations: del 69-70, Y453F, I692V, M1229I)
E484K	Detected via an SNP assay specific for E484K
N501Y	Detected via an SNP assay specific for N501Y
ORF1a(del3675-3677)	Variants carrying ORF1a deletion (del 3675-3677)
P.3	P.3 (mutations: E484K, N501Y, D614G, P681H)
S_GENE_DELETION	Variant virus with deletion in S-gene (defined by mutation: del 69-70 or by negative S-gene RT-PCR)
Y453F	Y453F associated with farmed minks; defined by mutation: Y453F
WILD_TYPE	None of the variants described for this variable
VARIANT_OTHER	Novel variant of potential concern. Provide details in VirusVariantOther
UNK	Sequence information unknown or not available.

[1] Enter the code from this column into the data reporting form (Annex 1), as relevant.

[2] From 31 May 2021 onwards, WHO proposed labels for global SARS-CoV-2 variants of concern and variants of interest to be used alongside the scientific nomenclature in communications about variants to the public. This list includes variants on WHO's global list of VOC and VOI, and is updated as WHO's list changes.

[3] VOC – variant of concern; VOI – variant of interest; VUM – variant under monitoring. For definitions, see ECDC webpage 'SARS-CoV-2 variants of concern as of 3 February 2022 (www.ecdc.europa.eu/en/covid-19/variants-concern). Note that it is possible for a VOC, VOI or VUM to also be a part of a broader VOC, VOI, or VUM definition (e.g. B.1.617.2+E484X is also a part of B.1.617.2). This means that there is enough evidence to fulfil the VOC, VOI or VUM criteria for this variant using the broader variant as a reference.

[4] Additional characteristic spike protein changes. An alternate description may be used if the variant is not easy to describe using this nomenclature. For updated information on Pango lineages and definition of lineages and for instructions on how to suggest new lineages, visit the Pango lineages website (https://cov-lineages.org/). Each lineage in the table is linked to the respective lineage page on the Pango lineages website.

[5] Only present if there is moderate confidence in the evidence relating to the first country of detection.

[6] This is the description that appears in MetaDataSet 49 (2022-01-14)