

Data collection on COVID-19 outbreaks in closed settings with a completed vaccination programme: long-term care facilities

Version 2.0, 3 September 2021

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 a timely estimate of vaccine effectiveness in these settings, by SARS-CoV-2 variant and vaccine product. This activity is not intended to capture all outbreaks, generate comparative statistics, or obtain a (sub-)nationally representative sample.

Background

Most national COVID-19 vaccination programmes have prioritised LTCFs for COVID-19 vaccination because of the disproportionately 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 variant) 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 with completed vaccination programmes 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 in 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]. The current protocol provides a structure for the collection of these data in accordance with the objectives.

Changes in version 2

Main changes in the current version of the protocol:

- 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).

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 and VOC against:

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

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.
- LTCFs are still eligible, even if their vaccination programme was conducted several months ago and additional residents have been admitted since (irrespective of whether the new residents are vaccinated).
- Vaccination of LTCF workers may have occurred on a different day and 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 vaccine effectiveness

- Vaccine effectiveness (VE) is calculated by pooling data from different outbreaks and comparing attack rates (ARs) in fully-vaccinated versus non-vaccinated individuals, as $VE = (AR_{\text{unvaccinated}} - AR_{\text{vaccinated}}) / AR_{\text{unvaccinated}}$, or the equivalent as $VE = 1 - \text{Relative Risk}$ [5].
- Estimations are made by variant and/or vaccine brand, if sample size allows.
- As vaccine coverage is usually very high in LTCFs, especially among residents, data should be pooled from different outbreaks to achieve 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.
- Risk of bias:
 - Reported outbreaks tend to be larger ones, meeting criteria for reporting in EWRS or having been detected by the media and followed-up by ECDC and country authorities. In these outbreaks, the VE may, for unknown reasons, be lower than in facilities with smaller outbreaks (e.g. 2–3 cases).
 - In order to counterbalance this bias, countries are invited to also apply the current protocol at LTCFs with smaller outbreaks.

National actions foreseen for this activity

Timeline of national investigations

The methodology foresees a single assessment of the clinical status of COVID-19 cases (note: in the first version of the protocol, two assessments were foreseen). A single assessment 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)). If a first assessment is submitted while the outbreak is still ongoing, please ensure that a second report is submitted with completed data (outcomes, variants) after the outbreak.

ECDC data collection forms

For each COVID-19 outbreak at an LTCF with a completed vaccination programme (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.

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 types of staff who should perform data collection.

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.

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 for all laboratory-confirmed COVID-19 samples. If sequencing is currently unavailable (sub-)nationally, then it is recommended that clinical samples be stored.
- ECDC is currently supporting the scale-up of sequencing and neutralisation assay capacity in EU/EEA countries. Please contact PHE.Support.Microbiology@ecdc.europa.eu for more information.

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.

Considerations for reporting

- Representativeness: representativeness/exhaustiveness is not an objective. We are seeking information on any outbreak of breakthrough infection at an LTCF with a completed vaccination programme that a country deems useful to share (e.g. hospitalised/fatal vaccinated cases). However, in order to assess potential bias of vaccine effectiveness estimates, it is recommended that both large and small outbreaks be investigated.
- Free text responses: the purpose of the forms is to offer a structure for the nationally-provided data. If it is impossible to provide structured information, countries can still report in EWRS or EpiPulse using free text, giving all the details available on the outbreak(s) – in particular severity, variant(s) and vaccine product(s).

Sequence data should ideally be reported to GISAID.

Timeline of data reporting to ECDC

- Either: one single report for each outbreak after the outbreak ended;
- Or: two reports for each outbreak - i.e. after the initial assessment and after the follow-up assessment.

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 [6] 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-19¹ without the need for oxygen therapy and having an oxygen saturation level $\geq 92\%$.
- 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.

¹ For a list of COVID-19 symptoms please see Annex 3.

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.
- 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.
- 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).

References

1. European Centre for Disease Prevention and Control (ECDC). COVID-19 country overviews. Section 3.2. EU/EEA Pooled notification rates and testing. Stockholm: ECDC; 2021. Available at: https://covid19-country-overviews.ecdc.europa.eu/#3_EUEEA
2. European Centre for Disease Prevention and Control (ECDC). Risk for SARS-CoV-2 transmission from newly infected individuals with documented previous infection or vaccination. Stockholm: ECDC; 2021. Available at: <https://www.ecdc.europa.eu/en/publications-data/sars-cov-2-transmission-newly-infected-individuals-previous-infection>
3. Moustsen-Helms IR, Emborg H-D, Nielsen J, Nielsen KF, Krause TG, Molbak K, et al. Vaccine effectiveness after 1st and 2nd dose of the BNT162b2 mRNA Covid-19 Vaccine in long-term care facility residents and healthcare workers—a Danish cohort study. MedRxiv [Preprint]. 2021. DOI: 10.1101/2021.03.08.21252200. Available at: <https://www.medrxiv.org/content/10.1101/2021.03.08.21252200v1>
4. European Centre for Disease Prevention and Control (ECDC). Rapid Risk Assessment: COVID-19 outbreaks in long-term care facilities in the EU/EEA in the context of current vaccination coverage. Stockholm: ECDC; 2021. Available at: <https://www.ecdc.europa.eu/en/publications-data/rapid-risk-assessment-covid-19-outbreaks-long-term-care-facilities-eueea>
5. US Centers for Disease Control and Prevention (CDC). Principles of Epidemiology in Public Health Practice, Third Edition. An Introduction to Applied Epidemiology and Biostatistics. Lesson 3, Section 6: Measures of Public Health Impact. Atlanta: CDC; 2012. Available at: <https://www.cdc.gov/csels/dsepd/ss1978/lesson3/section6.html>
6. World Health Organization (WHO). COVID-19 Clinical management. Living guidance. Available at: <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-1>

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	<input type="checkbox"/> General nursing home <input type="checkbox"/> Residential home <input type="checkbox"/> Mixed LTCF <input type="checkbox"/> LTCF for mentally disabled <input type="checkbox"/> LTCF for physically disabled <input type="checkbox"/> Palliative care facility <input type="checkbox"/> Psychiatric LTCF <input type="checkbox"/> Sanatorium <input type="checkbox"/> Other <input type="checkbox"/> Unknown
Outbreak location	
Date of report	__ / __ / ____
Date start outbreak	__ / __ / ____
Index case specification	<input type="checkbox"/> Staff/worker, vaccinated <input type="checkbox"/> Staff/worker, partially vaccinated <input type="checkbox"/> Staff/worker, unvaccinated <input type="checkbox"/> Resident, vaccinated <input type="checkbox"/> Resident, partially vaccinated <input type="checkbox"/> Resident, unvaccinated <input type="checkbox"/> Other <input type="checkbox"/> Unknown
Date end vaccination residents	__ / __ / ____
Vaccine brand residents (list)	
Date end vaccination staff/workers	__ / __ / ____
Vaccine brand staff/workers (list)	
Testing strategy for residents	<input type="checkbox"/> Only symptomatic <input type="checkbox"/> All in affected ward(s) <input type="checkbox"/> All in entire LTCF <input type="checkbox"/> Other
Testing strategy for staff/workers	<input type="checkbox"/> Only symptomatic <input type="checkbox"/> All in affected ward(s) <input type="checkbox"/> All in entire LTCF <input type="checkbox"/> 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						
<i>Asymptomatic</i>						
<i>Symptomatic</i>						
<i>Symptoms unknown</i>						
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						
<i>Asymptomatic</i>						
<i>Symptomatic</i>						
<i>Symptoms unknown</i>						
N of hospitalised cases						
N of deaths among cases						

= variables not to be collected if case-based data are reported

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 with completed vaccination programme

Var 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 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	HWWAC = 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 or 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 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 = OtherUNK = Unknown
10	R	DateEndVaccinationStaff	End date of the vaccination programme for LTCF staff. For definition of vaccination programme, see inclusion criteria. Specify exact date if available, otherwise provide week or month.	DATE	

Var ¹	Req ²	Variable	Description	Data type	Coded value list
11	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 ⁵ above
12	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
13	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
14	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 aggregate data so only need to be collected if optional case-based data are not collected (see below).	NUM	
15	O	OutbreakDetails	Additional free text details concerning the outbreak.	TEXT	
Aggregate denominator data (also to be collected if optional case-based data are reported)					
16	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	
17	R	NumUnvaccinatedResidents	Number of unvaccinated LTCF residents.	NUM	
18	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	
19	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	
20	R	NumVaccinatedResidentsBooster	Number of fully-vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
21	R	NumVaccinatedResidentsUnk	Number of residents with unknown vaccination status.	NUM	
22	R	NumLTCFStaff	Total number of staff (i.e. any LTCF worker, paid or unpaid, working at the LTCF at the 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	
23	R	NumUnvaccinatedStaff	Number of unvaccinated LTCF staff/workers.	NUM	
24	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	

Var ¹	Req ²	Variable	Description	Data type	Coded value list
25	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	
26	R	NumVaccinatedStaffBooster	Number of fully-vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
27	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)					
28	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	
29	R	NumCasesResidentsUnvaccinated	Number of COVID-19 cases in unvaccinated residents.	NUM	
30	R	NumCasesResidentsPartialVaccin	Number of COVID-19 cases in partially-vaccinated residents.	NUM	
31	R	NumCasesResidentsFullVaccin	Number of COVID-19 cases in fully-vaccinated residents.	NUM	
32	R	NumCasesResidentsBooster	Number of COVID-19 cases in fully-vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
33	R	NumCasesResidentsUnkownVaccin	Number of COVID-19 cases in residents with unknown vaccination status.	NUM	
34	R	NumAsymptomaticCasesRes	Total number of asymptomatic cases among residents.	NUM	
35	R	NumAsyCasesUnvacRes	Number of asymptomatic cases among unvaccinated residents.	NUM	
36	R	NumAsyCasesPartialVacRes	Number of asymptomatic cases among partially vaccinated residents.	NUM	
37	R	NumAsyCasesFullyVacRes	Number of asymptomatic cases among fully vaccinated residents.	NUM	
38	R	NumAsyCasesBoosterVacRes	Number of asymptomatic cases among fully vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
39	R	NumAsyCasesUnkVacRes	Number of asymptomatic cases among residents with unknown vaccination status.	NUM	
40	R	NumSymptomaticCasesRes	Total number of symptomatic cases among residents.	NUM	
41	R	NumSymCasesUnvacRes	Number of symptomatic cases among unvaccinated residents.	NUM	
42	R	NumSymCasesPartialVacRes	Number of symptomatic cases among partially vaccinated residents.	NUM	
43	R	NumSymCasesFullyVacRes	Number of symptomatic cases among fully vaccinated residents.	NUM	
44	R	NumSymCasesBoosterVacRes	Number of symptomatic cases among fully vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
45	R	NumSymCasesUnkVacRes	Number of symptomatic cases among residents with unknown vaccination status.	NUM	
46	R	NumUnkSymCasesRes	Total number of cases among residents where it is unknown whether they had symptoms.	NUM	
47	R	NumUnkSymCasesUnvacRes	Number of cases among unvaccinated residents where it is unknown whether they had symptoms.	NUM	
48	R	NumUnkSymCasesPartialVacRes	Number of cases among partially vaccinated residents where it is unknown whether they had symptoms.	NUM	
49	R	NumUnkSymCasesFullyVacRes	Number of cases among fully vaccinated residents where it is unknown whether they had symptoms.	NUM	
50	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	

VarN ¹	Req ²	Variable	Description	Data type	Coded value list
51	R	NumUnkSymCasesUnkVacRes	Number of cases among residents with unknown vaccination status where it is unknown whether they had symptoms.	NUM	
52	R	NumHospitalisedCasesRes	Total number of hospitalised cases among residents.	NUM	
53	R	NumHospCasesUnvacRes	Number of hospitalised cases among unvaccinated residents.	NUM	
54	R	NumHospCasesPartialVacRes	Number of hospitalised cases among partially vaccinated residents.	NUM	
55	R	NumHospCasesFullyVacRes	Number of hospitalised cases among fully vaccinated residents.	NUM	
56	R	NumHospCasesBoosterVacRes	Number of hospitalised cases among fully vaccinated residents who received at least one additional dose of any vaccine brand.	NUM	
57	R	NumHospCasesUnkVacRes	Number of hospitalised cases among residents with unknown vaccination status.	NUM	
58	R	NumDeathsResidents	Total number of COVID-19 cases who died among residents.	NUM	
59	R	NumDeathsUnvacRes	Number of COVID-19 cases who died among unvaccinated residents.	NUM	
60	R	NumDeathsPartialVacRes	Number of COVID-19 cases who died among partially vaccinated residents.	NUM	
61	R	NumDeathsFullyVacRes	Number of COVID-19 cases who died among fully vaccinated residents.	NUM	
62	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	
63	R	NumDeathsUnkVacRes	Number of COVID-19 cases who died among residents with unknown vaccination status.	NUM	
64	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	
65	R	NumCasesStaffUnvaccinated	Number of COVID-19 cases in unvaccinated staff/workers.	NUM	
66	R	NumCasesStaffPartialVaccin	Number of COVID-19 cases in partially-vaccinated staff/workers.	NUM	
67	R	NumCasesStaffFullVaccin	Number of COVID-19 cases in fully-vaccinated staff/workers.	NUM	
68	R	NumCasesStaffBooster	Number of COVID-19 cases in fully-vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
69	R	NumCasesStaffUnkownVaccin	Number of COVID-19 cases in staff/workers with unknown vaccination status.	NUM	
70	R	NumAsymptomaticCasesStaff	Total number of asymptomatic cases among LTCF staff/workers.	NUM	
71	R	NumAsyCasesUnvacStaff	Number of asymptomatic cases among unvaccinated staff/workers.	NUM	
72	R	NumAsyCasesPartialVacStaff	Number of asymptomatic cases among partially vaccinated staff/workers.	NUM	
73	R	NumAsyCasesFullyVacStaff	Number of asymptomatic cases among fully vaccinated staff/workers.	NUM	
74	R	NumAsyCasesBoosterVacStaff	Number of asymptomatic cases among fully vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
75	R	NumAsyCasesUnkVacStaff	Number of asymptomatic cases among staff/workers with unknown vaccination status.	NUM	
76	R	NumSymptomaticCasesStaff	Total number of symptomatic cases among staff/workers.	NUM	
77	R	NumSymCasesUnvacStaff	Number of symptomatic cases among unvaccinated staff/workers.	NUM	
78	R	NumSymCasesPartialVacStaff	Number of symptomatic cases among partially vaccinated staff/workers.	NUM	
79	R	NumSymCasesFullyVacStaff	Number of symptomatic cases among fully vaccinated staff/workers.	NUM	
80	R	NumSymCasesBoosterVacStaff	Number of symptomatic cases among fully vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	

VarN ¹	Req ²	Variable	Description	Data type	Coded value list
81	R	NumSymCasesUnkVacStaff	Number of symptomatic cases among staff/workers with unknown vaccination status.	NUM	
82	R	NumUnkSymCasesStaff	Total number of cases among staff/workers where it is unknown whether they had symptoms.	NUM	
83	R	NumUnkSymCasesUnvacStaff	Number of cases among unvaccinated staff/workers where it is unknown whether they had symptoms.	NUM	
84	R	NumUnkSymCasesPartialVacStaff	Number of cases among partially vaccinated staff/workers where it is unknown whether they had symptoms.	NUM	
85	R	NumUnkSymCasesFullyVacStaff	Number of cases among fully vaccinated staff/workers where it is unknown whether they had symptoms.	NUM	
86	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	
87	R	NumUnkSymCasesUnkVacStaff	Number of cases among staff/workers with unknown vaccination status where it is unknown whether they had symptoms.	NUM	
88	R	NumHospitalisedCasesStaff	Total number of hospitalised cases among staff/workers.		
89	R	NumHospCasesUnvacStaff	Number of hospitalised cases among unvaccinated staff/workers.		
90	R	NumHospCasesPartialVacStaff	Number of hospitalised cases among partially vaccinated staff/workers.	NUM	
91	R	NumHospCasesFullyVacStaff	Number of hospitalised cases among fully vaccinated staff/workers.	NUM	
92	R	NumHospCasesBoosterVacStaff	Number of hospitalised cases among fully vaccinated staff/workers who received at least one additional dose of any vaccine brand.	NUM	
93	R	NumHospCasesUnkVacStaff	Number of hospitalised cases among staff/workers with unknown vaccination status.	NUM	
94	R	NumDeathsStaff	Total number of COVID-19 cases who died among staff/workers.		
95	R	NumDeathsUnvacStaff	Number of COVID-19 cases who died among unvaccinated staff/workers.		
96	R	NumDeathsPartialVacStaff	Number of COVID-19 cases who died among partially vaccinated staff/workers.	NUM	
97	R	NumDeathsFullyVacStaff	Number of COVID-19 cases who died among fully vaccinated staff/workers.	NUM	
98	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	
99	R	NumDeathsUnkVacStaff	Number of COVID-19 cases who died among staff/workers with unknown vaccination status.	NUM	
100	R	Variant1	Most frequently identified SARS-CoV-2 variant, including variants of concern (VOCs) and variants of interest (VOIs) listed on https://www.ecdc.europa.eu/en/covid-19/variants-concern . Specify values which are not included in the CV list in the field 'VariantOther1'. The label of the values in the current protocol is composed of 'Lineage+additional mutations' – 'WHO label (Greek letter)' – 'Country first detected'. For more information, please consult ECDC's website.	CV	VirusVariantNCOV ⁵ : 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.

VarN ¹	Req ²	Variable	Description	Data type	Coded value list
101	R	VariantOther1	Specify Variant1 values which are not included in the CV list 'VirusVariantNCOV'. If applicable, please use lineage as specified on https://www.ecdc.europa.eu/en/covid-19/variants-concern - e.g. for variants being monitored.	TEXT	
102	R	NumCasesVariant1	Number of cases confirmed with Variant 1.	NUM	
103	R	Variant2	Second (frequently) identified SARS-CoV-2 variant, if any.	CV	see list VirusVariantNCOV above [§]
104	R	VariantOther2	Specify Variant 2 values which are not included in the CV list 'VirusVariantNCOV'. If applicable, please use lineage as specified on https://www.ecdc.europa.eu/en/covid-19/variants-concern - e.g. for variants being monitored.	TEXT	
105	R	NumCasesVariant2	Number of cases confirmed with Variant 2.	NUM	

¹VarN: variable number; ²Requirement: 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 48. 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 optional case-based data (line list)																								
Outbreak ID	Case Number	Case Type	Age	Gender	Vaccinated	Date Vacc Dose1	Date Vacc Dose2	Date Vacc Dose3	Brand Dose1	Brand Dose2	Brand Dose3	Date of Diagnosis	Ct Value	Virus Variant	Virus Variant Other	Report Date	Severity	Hospitalisation	ICU	Date Onset Symptoms	Outcome	Date of Death	Case Details	

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.1.1.7 = 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; **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 with completed vaccination programme

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 (e.g. booster dose). Leave empty if not received.	DATE	Allows UNK.
10	O	BrandDose1	Vaccine brand used for first dose. Leave empty if not received.	CV	VaccineCOVID ⁵ : 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.
11	R	BrandDose2	Vaccine brand used for second dose. Leave empty if not received.	CV	See list above.
12	O	BrandDose3	Vaccine brand used for third dose. Leave empty if not received.	CV	See list above.
13	R	DateDiagnosis	Date on which the case was diagnosed as confirmed COVID-19 case.	DATE	
14	O	CTValue	PCR CT value at DateDiagnosis	NUM	Allows UNK
15	R	VirusVariant	Was sequencing performed? If yes, which variant was identified?	CV	VirusVariantNCOV ⁵ 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

Var ¹	Req ²	Variable	Description	Data type	Coded value list
					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.
16	R	VirusVariantOther	Specify variant if not included in the coded value list. If applicable, please use lineage as specified on https://www.ecdc.europa.eu/en/covid-19/variants-concern - e.g. for variants being monitored.	TEXT	
17	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	
18	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 $\geq 92\%$, 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
19	R	Hospitalisation	Hospitalised for treatment of COVID-19 during this outbreak, before or on report date .	CV	YesNoUnk: N = No Unk = Unknown Y = Yes
20	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
21	O	DateOnsetSymptoms	Date of onset symptoms (leave empty for asymptomatic cases).	DATE	
22	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
23	O	DateOfDeath	Date of death, if applicable.	DATE	
24	O	CaseComments	Free text comments on the current case.	TEXT	

¹VarN: variable number²Requirement: 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 48. 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 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: 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>.