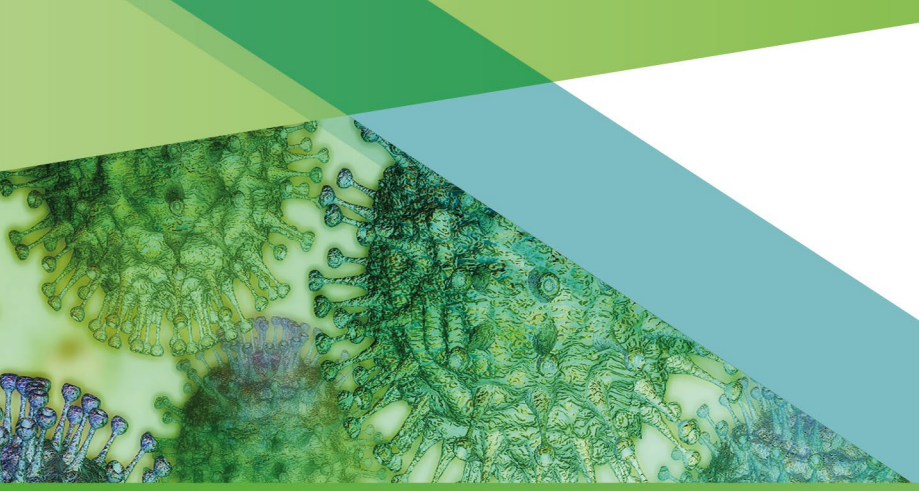

ECDC TECHNICAL REPORT

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

6 May 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, 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 long-term care facilities (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, while 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, such as the VOCs first detected in South-Africa (B.1.351, 20H/501Y.V2), in Brazil (P.1, 20J/501Y.V3) and other variants harbouring the E484K mutation (e.g. B.1.1.7+E484K) [2], the protective effect of vaccination is likely to decrease as the proportion of VOCs increases. In addition, the currently dominant variants (B.1.1.7 or 20I/501Y.V1 first detected in United Kingdom and the wild-type 'Wuhan' SARS-CoV-2), both of which both are neutralised by current vaccine-elicited antibodies, may cause infections in vaccinated individuals ('breakthrough infections') as vaccine efficacy is not 100% and immune response may wane over time, especially in the frail elderly population [3].

To date, in-depth information on COVID-19 outbreaks in LTCFs with completed vaccination programmes is not captured in a standardised manner in TESSy (apart from some information in case-based COVID-19 surveillance using the TESSy Record type 'NCOV'). Moreover, information from national COVID-19 reports is incomplete or not available. There have recently been media reports of outbreaks in LTCFs with a completed vaccination programme, involving VOCs B.1.351, B.1.1.7 and wild-type SARS-CoV-2 [2]. While anecdotal information suggests that these outbreaks have resulted in less severe disease, the severity of the infections in vaccinated individuals is largely unknown.

Suggested citation: European Centre for Disease Prevention and Control. Data collection on COVID-19 outbreaks with a completed vaccination programme: LTCFs. 6 May 2021. Stockholm: ECDC; 2021.

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

While awaiting the implementation of long-term studies on vaccine effectiveness and, depending on the sample size, to obtain a first 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 (commonly, such programmes consist of two one-day sessions during which vaccines are offered to all residents present in the LTCF);

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 various 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 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 existing vaccines).
- 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.

National actions foreseen for this activity

Timeline of national investigations

The methodology foresees two assessments of the clinical status of COVID-19 cases:

- An initial assessment at the time of the outbreak investigation.
- A follow-up assessment approximately three weeks after the start of the outbreak.

ECDC data collection forms

For each COVID-19 outbreak in an LTCF with a completed vaccination programme (see definitions below), the data specified in Annex 1 should be collected (for all variables where the data is available), and optionally also that indicated in Annex 2. Annex 2 specifies the case-based (line list) data that is reported as aggregate data in Annex 1.

- Annex 1: Aggregate data for the entire outbreak, including denominator data.
- Annex 2: Optional: case-based data (line list of cases).

In Annex 1 and 2, the first three columns indicate whether each variable is recommended or optional, based on the primary and secondary objectives (see above). There are also four variables in Annex 1 and three variables in (optional) Annex 2 that are marked as mandatory.

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 from HAI-Net@ecdc.europa.eu and on ECDC's website. 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 is detected in an LTCF that 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 EPIS-AMR-HAI in the Urgent Inquiry (UI) area named 'Outbreaks of breakthrough COVID-19 infections in long-term care facilities'. In 2021, ECDC will launch a new secure platform, 'EpiPulse', that will replace EPIS-AMR-HAI. All UI data in EPIS-AMR-HAI will be transferred into this system to enable continuity.

Considerations for reporting

- Representativeness: representativeness/exhaustiveness is not an objective. This activity seeks information on any outbreak of breakthrough infection at an LTCF with a completed vaccination programme that the country deems useful to share (e.g. hospitalised/fatal vaccinated cases).
- 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 EPIS-AMR-HAI/'EpiPulse' using free text, giving all the details available on the outbreak(s), especially 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 - i.e. after the follow-up assessment.
- Or: two reports for each outbreak (preferred option) - i.e. after the initial assessment and also 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[1]

- Asymptomatic: an asymptomatic COVID-19 case is a person infected with SARS-CoV-2 who does not develop symptoms.
- Mild: a symptomatic case (see list of COVID-19 symptoms below) meeting the case definition for COVID-19 without evidence of viral pneumonia or hypoxia.
- Moderate:
  - clinical signs of pneumonia (fever, cough, dyspnoea, fast breathing) but no signs of severe pneumonia, including SpO2 ≥ 90% on room air;
  - while the diagnosis can be made on the basis of clinical evidence, chest imaging (radiograph, CT scan, ultrasound) may assist in diagnosis and identify or exclude pulmonary complications.
- Severe:
  - oxygen saturation < 90% on room air;
  - respiratory rate > 30 breaths/min;
  - signs of severe respiratory distress (accessory muscle use, inability to complete full sentences).

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

Long-term care facilities

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.

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, variant and by resident age (>85 vs <=85).
- Allows clinical severity to be described, including case fatality 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.
- Allows varying follow-up dates.
- 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 (29/53 variables of the aggregate data collection do not need to be collected).
- The case-based questionnaire can be used locally for outbreak investigation (and possibly to calculate the aggregate data).

[1] *Adapted from 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)*

References

1. European Centre for Disease Prevention and Control. COVID-19 country overviews. Section 3.2. EU/EEA Pooled notification rates and testing. Stockholm: ECDC; 2021. Available from: https://covid19-country-overviews.ecdc.europa.eu/#3_EUEEA
2. European Centre for Disease Prevention and Control. Risk for SARS-CoV-2 transmission from newly infected individuals with documented previous infection or vaccination. Stockholm: ECDC; 2021. Available from: 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

Annex 1 – Variables for collection of aggregate data

Table 1. Definition of variables for collection of aggregate data on COVID-19 outbreaks in LTCFs with completed vaccination programme

Variable no.	Requirement*				Variable	Description	Data type	Coded value list
	Overall	A. To permit minimal outbreak description	B. Outbreak severity by vaccine and strain	C. Vaccine effectiveness by vaccine and strain				
1	**M**	M	M	M	ReportingCountry	The country reporting the record.	CV	EU/EEA countries
2	**M**	M	M	M	OutbreakID	Unique identifier of the outbreak. ECDC does not collect the identity or the geographical location of LTCFs in this activity.	TEXT	
3	**R**	R	O	O	LTCFType	Type of long-term care facility (HALT coded value list)	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**	R	O	R	NumLTCFOccupiedBeds	Number of beds occupied by residents at the time of outbreak onset. Denominator (e.g. for vaccine coverage of residents). This figure also includes beds occupied by residents who were absent due to hospitalisation, on holiday or with family, etc. Beds shared by partners should be counted as two beds. When reporting, include all LTCF wards/units in the denominator that were included in the (sub-)national investigation of the LTCF.	NUM	
5	**O**	O	O	O	NumResidents85	Number of residents over 85 years at the time of outbreak onset. Only descriptor of LTCF population. When reporting, include all LTCF wards/units in the denominator that were included in the (sub-)national investigation of the LTCF.	NUM	
6	**R**	R	O	R	NumLTCFStaff	Number of staff (i.e. any LTCF worker, paid or unpaid, working in the LTCF at the time of outbreak onset). Denominator (e.g. for vaccine coverage of LTCF staff).	NUM	
7	**R**	O	O	R	NumVaccinatedResidentsFull	Number of fully-vaccinated residents (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	
8	**R**	O	O	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	

Variable no.	Requirement*				Variable	Description	Data type	Coded value list
	Overall	A. To permit minimal outbreak description	B. Outbreak severity by vaccine and strain	C. Vaccine effectiveness by vaccine and strain				
9	**O**	O	O	O	DateStartVaccinationResidents	Start date of the vaccination programme for residents of the LTCF. For definition of vaccination programme, see inclusion criteria.	DATE	
10	**R**	R	R	O	DateEndVaccinationResidents	End date of the vaccination programme for residents of the LTCF. For definition of vaccination programme, see inclusion criteria.	DATE	
11	**R**	R	R	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 and specify in next variable	CV	VaccineCOVID[§]: AZ = AstraZeneca - AZD1222 BECNBG = Beijing CNBG - inactivated BHACOV = Bharat - Covaxin COM = Pfizer BioNTech - Comirnaty 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 MIX = Different vaccine brands, please specify in *VaccineBrandResidentsDetail* O = Other, please specify in *VaccineBrandResidentsDetail* UNK = Unknown
12	**R**	R	R	R	VaccineBrandResidentsDetail	Specify other vaccine or different vaccines if MIX. Free text.	TEXT	
13	**R**	O	O	R	NumVaccinatedStaffFull	Number of fully-vaccinated staff (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	
14	**R**	O	O	R	NumVaccinatedStaffPartial	Number of partially-vaccinated staff (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	
15	**O**	O	O	O	DateStartVaccinationStaff	Start date of the vaccination programme for staff of the LTCF. For definition of vaccination programme, see inclusion criteria.	DATE	
16	**R**	R	R	O	DateEndVaccinationStaff	End date of the vaccination programme for staff of the LTCF. For definition of vaccination programme, see inclusion criteria.	DATE	
17	**R**	R	R	R	VaccineBrandStaff	Vaccine brand administered to at least 80% of LTCF staff. 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.	CV, TEXT	VaccineCOVID[§]: AZ = AstraZeneca - AZD1222 BECNBG = Beijing CNBG - Inactivated BHACOV = Bharat - Covaxin COM = Pfizer BioNTech - Comirnaty JANSS = Janssen - Ad26.COV 2.5 MOD = Moderna - mRNA-1273 SIICOV = SII - Covishield SIN = Coronavac – Sinovac

Variable no.	Requirement*				Variable	Description	Data type	Coded value list
	Overall	A. To permit minimal outbreak description	B. Outbreak severity by vaccine and strain	C. Vaccine effectiveness by vaccine and strain				
								SPU = Gamaleya - Sputnik V SRCVB = SRCVB - EpiVacCorona WUCNBG = Wuhan CNBG - Inactivated MIX = Different vaccine brands, please specify in *VaccineBrandStaffDetail* O = Other, please specify in *VaccineBrandStaffDetail* UNK = Unknown
18	**R**	R	R	R	VaccineBrandStaffDetail	Specify other vaccine or different vaccines if MIX. Free text.	TEXT	
19	**R**	R	O	O	DateIndexCase	Date of disease onset of the index case, if known (before the start of the outbreak).	DATE	
20	**O**	O	O	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.	CV, TEXT	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 Free text for 'O' not included in list.
21	**R**	R	O	O	DateStartOutbreak	Date of disease onset of the first secondary case among residents of the LTCF (followed by at least one other case among residents within two weeks).	DATE	
22	**R**	R	R	R	NumTestedResidents	Number of residents tested for COVID-19 since the start of this outbreak. This is required to understand whether the outbreak investigation included case finding for asymptomatic cases. When reporting, include all LTCF wards/units in the denominator that were included in the (sub-)national investigation of the LTCF.	NUM	
23	**R**	R	R	R	NumTestedStaff	Number of LTCF workers (staff) tested for COVID-19 since the start of this outbreak.	NUM	
24	**R**	R	R	R	NumSequencedCases	Number of cases for which SARS-CoV-2 sequencing was performed.	NUM	
25	**O**	O	O	O	OutbreakDetails	Additional free text details concerning the outbreak	TEXT	
					The following variables are only to be collected if no case-based data are reported (see Annex 2)			
26	**M**	M	M	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	
27	**R**	R	R	R	TotCasesStaff	Total number of COVID-19 cases in workers (staff).	NUM	

Variable no.	Requirement*				Variable	Description	Data type	Coded value list
	Overall	A. To permit minimal outbreak description	B. Outbreak severity by vaccine and strain	C. Vaccine effectiveness by vaccine and strain				
						This is included as an internal consistency check and is mandatory if it is not possible to report cases by vaccination status.		
28	**R**	O	O	R	NumCasesResidentsFullVaccin	Number of COVID-19 cases in fully-vaccinated residents.	NUM	
29	**R**	O	O	R	NumCasesResidents PartialVaccin	Number of COVID-19 cases in partially-vaccinated residents.	NUM	
30	**R**	O	O	R	NumCasesResidents NotVaccinated	Number of COVID-19 cases in unvaccinated residents.	NUM	
31	**R**	O	O	R	NumCasesResidents UnkownVaccin	Number of COVID-19 cases in residents with unknown vaccination status.	NUM	
32	**R**	O	O	R	NumCasesStaffFullVaccin	Number of COVID-19 cases in fully-vaccinated staff.	NUM	
33	**R**	O	O	R	NumCasesStaffPartialVaccin	Number of COVID-19 cases in partially-vaccinated staff.	NUM	
34	**R**	O	O	R	NumCasesStaffNotVaccinated	Number of COVID-19 cases in unvaccinated staff.	NUM	
35	**R**	O	O	R	NumCasesStaffUnkownVaccin	Number of COVID-19 cases in staff with unknown vaccination status.	NUM	
36	**R**	R	R	R	Variant1	Most frequently identified SARS-CoV-2 variant. Specify values which are not included in the CV list in the field 'VariantOther1'.	CV	VirusVariantNCOV[§]: VOC_202012_01 = B.1.1.7/ 20I/ 501Y.V1 variant; mutations: del 69-70, del 144, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H 501_V2 = B.1.351/20H/501Y.V2 variant (defined by mutations: D80A, D215G, E484K, N501Y, A701V) P1 = P1/20J/501Y.V3 variants (L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, H655Y, T1027I, V1176F) B.1.1.7+E484K = mutations: del 69-70, del 144, E484K, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H 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 sublineage of B.1.617 (common mutations:D614G,L452R,P681R) CLUSTER_5 = Denmark cluster 5 associated with mink (defined by mutations: del 69-70, Y453F, I692V, M1229I)

Variable no.	Requirement*				Variable	Description	Data type	Coded value list
	Overall	A. To permit minimal outbreak description	B. Outbreak severity by vaccine and strain	C. Vaccine effectiveness by vaccine and strain				
								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) 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 VARIANT_OTHER = Novel variant of potential concern. Provide details in VirusVariantOther WILD_TYPE = None of the variants described for this variable UNK = Sequence information unknown or not available.
37	**R**	R	R	R	VariantOther1	Specify Variant1 values which are not included in the CV list 'VirusVariantNCOV'.	TEXT	
38	**R**	R	R	R	NumCasesVariant1	Number of cases confirmed with Variant 1.	NUM	
39	**R**	R	R	R	Variant2	Second (frequently) identified SARS-CoV-2 variant, if any.	CV	see list VirusVariantNCOV above[§]
40	**R**	R	R	R	VariantOther2	Specify Variant 2 values which are not included in the CV list 'VirusVariantNCOV'.	TEXT	
41	**R**	R	R	R	NumCasesVariant2	Number of cases confirmed with Variant 2.	NUM	
42	**R**	O	R	O	DateCaseSeverity1	Date of initial outbreak report when the first assessment of the clinical severity of COVID-19 cases was made.	DATE	
43	**R**	R	R	O	NumAsymptomaticCases1	Number of asymptomatic cases in residents or staff at first assessment.	NUM	
44	**R**	O	R	O	NumMildCases1	Number of mild cases in residents or staff at first assessment.	NUM	WHO definitions (case management guidance)
45	**R**	O	R	O	NumModerateCases1	Number of moderate cases in residents or staff at first assessment.	NUM	
46	**R**	O	R	O	NumSevereCases1	Number of severe cases in residents or staff at first assessment.	NUM	
47	**R**	R	R	O	NumHospitalisedCases1	Number of hospitalised cases in residents or staff at first assessment.	NUM	
48	**R**	O	R	O	NumICUCases1	Number of cases in residents or staff that were admitted to an intensive care or high dependency unit at first assessment.	NUM	
49	**M**	M	M	M	NumDeaths1	Number of deaths in residents or staff at first assessment.	NUM	
50	**R**	R	R	O	DateCaseSeverity2	Date of follow-up assessment of disease severity, ≥3 weeks after outbreak onset.	Date	

Variable no.	Requirement*				Variable	Description	Data type	Coded value list
	Overall	A. To permit minimal outbreak description	B. Outbreak severity by vaccine and strain	C. Vaccine effectiveness by vaccine and strain				
51	**R**	R	R	O	NumAsymptomaticCases2	Number of asymptomatic cases in residents or staff at second assessment.	NUM	
52	**R**	O	R	O	NumMildCases2	Number of mild cases in residents or staff at second assessment.	NUM	WHO definitions (case management guidance)
53	**R**	O	R	O	NumModerateCases2	Number of moderate cases in residents or staff at second assessment.	NUM	
54	**R**	O	R	O	NumSevereCases2	Number of severe cases in residents or staff at second assessment.	NUM	
55	**M**	M	M	O	NumHospitalisedCases2	Number of hospitalised cases in residents or staff at second assessment.	NUM	
56	**R**	R	R	O	NumICUCases2	Number of cases in residents or staff that were admitted to an intensive care or high dependency unit at second assessment.	NUM	
57	**M**	M	M	M	NumDeaths2	Number of deaths in residents or staff at second assessment.	NUM	

**Requirement: M - mandatory; R - recommended; O - optional.*

§ This coded value list is aligned with the coded value lists in TESSy MetaDataSet 48 (2021-04-30). 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 2 – 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

Variable no.	Requirement*				Variable	Description	Data type	Coded value list
	Overall	A. To permit minimal outbreak description	B. Outbreak severity by vaccine and strain	C. Vaccine effectiveness, by vaccine and strain				
1	**M**	M	M	M	OutbreakID	Unique identifier of the outbreak	TEXT	
2	**M**	M	M	M	CaseNumber	Anonymised case number. Linked to case ID at facility level for validation purposes.	NUM	
3	**M**	M	M	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**	O	O	O	Age	Age of the reported case at diagnosis, in years.	NUM	
5	**O**	O	O	O	Gender	Gender of the reported case.	CV	F = Female M = Male O = Other (e.g. transsexual) Unk = Unknown
6	**R**	R	O	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.	CV	NO = Not vaccinated PART = Partially vaccinated FULL = Fully vaccinated UNK = Unknown
7	**O**	O	O	O	VacStatusSpec	Reason for non- or partial vaccination	CV	REFUSE = refusal, no-show NEW = new admission to LTCF or new LTCF worker. COVID = had confirmed COVID-19 before or at time of vaccination. CONTRA = contraindication (too frail, other contraindication). O = other UNK = Unknown
8	**O**	O	O	O	DateVaccDose1	Date of first COVID-19 vaccine dose. Leave empty if not received.	DATE	Allows UNK
9	**R**	O	R	R	DateVaccDose2	Date of second COVID-19 vaccine dose. Leave empty if not received.	DATE	Allows UNK
10	**O**	O	O	O	DateVaccDose3	Date of third COVID-19 vaccine dose (e.g. VOC booster). Leave empty if not received.	DATE	Allows UNK
11	**O**	O	O	O	BrandDose1	Vaccine brand used for first dose.	CV	see list above
12	**R**	O	R	R	BrandDose2	Vaccine brand used for second dose.	CV	see list above
13	**O**	O	O	O	BrandDose3	Vaccine brand used for third dose.	CV	see list above
14	**R**	R	R	R	DateDiagnosis	Date the case was diagnosed as confirmed COVID-19 case.	DATE	
15	**O**	O	O	O	CTValue	PCR CT value at DateDiagnosis	NUM	Allows UNK
16	**R**	R	R	R	VirusVariant	Was sequencing performed? If yes, which variant was identified?	CV	See list VirusVariantNCOV[§]
17	**R**	R	R	R	VirusVariantOther	Specify variant if not included in the coded value list.	TEXT	

Variable no.	Requirement*				Variable	Description	Data type	Coded value list
	Overall	A. To permit minimal outbreak description	B. Outbreak severity by vaccine and strain	C. Vaccine effectiveness, by vaccine and strain				
18	**O**	O	O	O	ReportDate1	Date when the first assessment of the clinical severity of this COVID-19 case was made.	DATE	
19	**O**	O	O	O	Severity1	Worst severity recorded for this case during the outbreak, before or on report date 1	CV	ASYMP = Asymptomatic MILD = Mild MOD = Moderate SEV = Severe DEATH = Death Unk = Unknown
20	**R**	O	R	R	Hospitalisation1	Hospitalised for treatment of COVID-19 during this outbreak, before or on report date 1.	CV	YesNoUnk: N = No Unk = Unknown Y = Yes
21	**O**	O	O	O	ICU1	Admitted to the ICU for treatment of COVID-19 during this outbreak, before or on report date 1.	CV	YesNoUnk: N = No Unk = Unknown Y = Yes
22	**R**	R	R	O	ReportDate2	Date when the follow-up assessment of the clinical severity of this COVID-19 case was made. It is recommended to perform the follow-up assessment at least three weeks after the start of the outbreak.	DATE	
23	**R**	R	R	R	Severity2	Worst severity recorded for this case during this outbreak, before or on report date 2.	CV	ASYMP = Asymptomatic MILD = Mild MOD = Moderate SEV = Severe DEATH = Death
24	**R**	R	R	R	Hospitalisation2	Hospitalised for treatment of COVID-19 during this outbreak, before or on report date 2.	CV	YesNoUnk: N = No Unk = Unknown Y = Yes
25	**O**	O	O	O	ICU2	Admitted to the ICU for treatment of COVID-19 during this outbreak, before or on report date 2.	CV	YesNoUnk: N = No Unk = Unknown Y = Yes
26	**O**	O	O	O	Date symptom onset	Date of onset symptoms (leave empty for asymptomatic cases).	DATE	

Variable no.	Requirement*				Variable	Description	Data type	Coded value list
	Overall	A. To permit minimal outbreak description	B. Outbreak severity by vaccine and strain	C. Vaccine effectiveness, by vaccine and strain				
27	**R**	R	R	R	Outcome	Outcome at assessment date 2.	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
28	**O**	O	O	O	DateOfDeath	Date of death, if applicable.	DATE	

**Requirement: M - mandatory; R - recommended; O - optional.*

§ This coded value list is aligned with the coded value lists in TESSy MetaDataSet 48 (2021-04-30). 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. List of COVID-19 symptoms

Most people experience fever (83–99%), cough (59–82%), fatigue (44–70%), loss of appetite (40–84%), shortness of breath (31–40%) and myalgias (11–35%).

Other non-specific symptoms have also been reported such as sore throat, nasal congestion, headache, diarrhoea, nausea and vomiting. Loss of smell (anosmia) or loss of taste (ageusia) preceding the onset of respiratory symptoms has 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 and confusion.

Symptoms such as dyspnoea, fever, gastrointestinal symptoms or fatigue due to other diseases may overlap with COVID-19 symptoms.