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I-MOVE-COVID-19 Network

Multidisciplinary European network for research, prevention and control of the COVID-19 pandemic

COVID-19 European hospital surveillance: Draft generic protocol

JUNE 2020

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I-MOVE-COVID-19 Network

WP3 coordinated by Public Health Scotland

Based on: current literature, I-MOVE generic influenza protocol for hospitalised older adults 2019–2020, PERTINENT generic protocol 2018, v1.5

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Content

Abbreviations

COVID-19	Coronavirus disease 2019
EEA	European Economic Area
ECDC	European Centre for Disease Prevention and Control
EU	European Union
GP	General practitioner
HCW	Healthcare worker
ICD	International classification of diseases
ICU	Intensive care unit
ILI	Influenza-like illness
I-MOVE	Influenza – Monitoring Vaccine Effectiveness in Europe
MS	Member States
OR	Odds ratio
RT- PCR	Real-time polymerase chain reaction
SARI	Severe acute respiratory infection
SARS-CoV-2	Severe acute respiratory syndrome – coronavirus 2
VE	Vaccine effectiveness

- *Arrow marks with italicised text indicate the points that surveillance sites should adapt and provide details for in their study annexes*

1. Background

The end of 2019 saw the emergence of a novel severe acute respiratory syndrome – coronavirus 2 (SARS-CoV-2), which causes coronavirus disease 2019 (COVID-19). By the end of March 2020, there were over 400,000 cases of COVID-19 reported globally by over 150 countries, with an increasing proportion from countries in the European Union/European Economic Area (EU/EEA), as well as the United Kingdom (UK). As of 25 March, there were 204,930 cases and 11,810 deaths reported in the EU/EEA and the UK, from where the European Centre for Disease Prevention and Control (ECDC) reports that the number of reported COVID-19 cases is increasing rapidly, with an increase in notifications of a similar trajectory to Hubei province in late January/early February and in Italy in late February/early March.(1)

Data reported to ECDC show that clinical presentations of COVID-19 range from no significant symptoms (asymptomatic) to severe pneumonia, and that severe disease can lead to death. Thirty per cent of diagnosed COVID-19 cases in the EU/EEA with available data were hospitalised, while 4% had severe illness. Hospitalisation rates were higher for older adults (60 years+). Estimates showed that the risk as well as the absolute numbers of deaths rapidly increased with age for those 60 years and older in Germany, Italy and Spain. Among hospitalised patients, severe illness was reported in 15%, and death occurred in 12%, with higher case fatality in older adults.

ECDC recommends that all hospitalised severe acute respiratory illness (SARI) patients be tested for SARS-CoV-2 virus, so as to detect community transmission, nosocomial outbreaks, as well as for monitoring the intensity and impact of the pandemic.(1) There are also several questions to which urgent answers are needed to improve our understanding of SARS-CoV2, to inform us of the best interventions to prevent or delay the spread of COVID-19 and newly recommended treatment strategies.

Importantly, as we are now in a COVID-19 pandemic, having a pre-existing, well-established European platform to rapidly provide severe acute respiratory illness (SARI) surveillance already in place is allowing for immediate case identification and, once available, will allow for the rapid evaluation of any pandemic vaccine and adaptation of preventive and control strategies.

I-MOVE (Influenza – Monitoring Vaccine Effectiveness in Europe), first established in 2007,(2) was the first network to monitor influenza vaccine effectiveness (VE) within and across the seasons in the European Union (EU) and the European Economic Area (EEA). The network has two components, one for primary care practices, recruiting patients with influenza-like illness (ILI) and the other for hospitals, recruiting patients with severe acute respiratory illness (SARI).

In February 2020, many partners, already involved in studies within the I-MOVE network, came together as the I-MOVE-COVID-19 consortium, and were successful in a bid for the European Commission H2020 call on “Advancing knowledge for the clinical and public health response to the novel coronavirus epidemic”.

The I-MOVE-COVID-19 consortium aims to obtain epidemiological and clinical information on patients with COVID-19 as well as virological information on SARS-CoV-2, through different work packages (WPs): (a) provision of a flexible surveillance platform, adaptable to the epidemiological situation, through WP2 (primary care surveillance) and WP3 (hospital surveillance), (b) research studies, through WP4 and (c) evaluation of public health interventions (e.g. vaccination, antivirals) in WP2–4, in order to contribute to the knowledge base, guide patient management, and inform the public health response. This will be achieved through adaptation and expansion of the existing I-MOVE network to include COVID-19. The network includes primary care networks, hospitals, and national laboratory reference centres in 10 countries across the WHO European Region.[1]

The WP3 hospital surveillance for COVID-19 is coordinated by Public Health Scotland (PHS) with Epiconcept support. The hospital network comprises 11 surveillance sites involving 13 hospitals in five EU Member States (MS)[2] and Albania, the intensive care/high dependency unit (ICU/HDU) network from all hospitals in England and the hospital network in Scotland (where coverage is not yet at 100%, but the aim is to include all hospitals). The laboratory component of the network includes regional and national reference centres from the participating countries. While each of the surveillance sites can analyse their data separately, pooling the data for overall analysis will provide a sample size big enough to answer study questions with reasonable precision.

The surveillance sites will carry out hospital surveillance (including all wards), except for England, where surveillance will be limited to ICUs/HDUs in all hospitals.

This document presents the core European protocol for the hospital-based surveillance component of I-MOVE-COVID-19 for 2020, outlining the agreed methods for collecting COVID-19 and SARS-CoV2 data during this pandemic. The specificities of each site's COVID-19 data collection can be detailed in the individual site protocol annexes. Other generic protocols being developed are for the hospital-based risk factor study for severe COVID-19 and for COVID-19 in healthcare workers (HCWs). The severe COVID-19 risk factor study will be the first research study for the I-MOVE-COVID-19 hospital network, with a protocol largely based on this surveillance protocol. Some of the variables included for severe COVID-19 surveillance, therefore, will only be required for surveillance sites also participating in the risk factor study (see Annex 1).

This generic protocol will be updated according to the final surveillance strategy (target groups, treatments available etc.) in each of the participating countries, and depending on the identification of new groups at risk. In particular, it will be updated in the future to include estimation of COVID-19 VE, at the time when a vaccine becomes available.

[1]Albania, France, Ireland, Lithuania, the Netherlands, Portugal, Romania, Spain, Sweden, and the UK (England and Scotland).
[2]France, Lithuania, Portugal, Romania, and Spain.

This protocol is written in a generic manner and country-specific details of each study will be outlined in the study annexes (which will be added to Annex 6).

General principle

The I-MOVE hospital network comprises hospitals carrying out SARI surveillance for influenza and now COVID-19. Existing I-MOVE hospital sites are used to carrying out enhanced surveillance to collect data for influenza vaccine effectiveness (VE) studies.

This document is an adaptation of the current I-MOVE influenza generic surveillance protocol to permit

- Use of it for enhanced COVID-19 surveillance
- Collection of data for priority studies on COVID-19 risk factors at hospital level
- Use of the same protocol for influenza VE (as usual) from the 2020–21 season, **as well as** COVID-19 VE estimation once the vaccine becomes available (this will require further protocol adaptation in the late summer/early autumn of 2020)

This I-MOVE-COVID-19 protocol is for enhanced COVID-19 surveillance, but many elements within this protocol are the same for the risk factor and VE studies, for which there are separate protocols. Those protocols are similar to this one, but will collect more information. Where possible, we have indicated where further data for other studies will be collected. This protocol may be considered the baseline from which the others will be developed.

2. Objectives

2.1. Primary objectives

The primary objective will be to describe, for seven European countries, clinical and epidemiological characteristics of SARI patients hospitalised with COVID-19 and virological characteristics of SARS-CoV-2 in hospitalised patients, in order to contribute to the knowledge base, guide patient management, and inform the public health response.

2.2. Secondary objectives

Potential secondary objectives include:

- To strengthen preparedness to respond to COVID-19 through hospital surveillance

- To describe COVID-19 suspected, probable and confirmed cases with severe disease by sex, age-group, and other potential risk or protective factors
- To describe deaths from COVID-19 in hospital by country and pooled across the network
- To measure the incidence of hospitalised COVID-19 patients, by participating region/country (where appropriate)

in order to measure the impact of/inform decisions on mitigation measures, and to identify at-risk groups for severe disease.

➢ *Surveillance sites to define the secondary objectives of their study*

2.3. Future and additional objectives

Additional future objectives for the hospital surveillance network include to:

- Investigate risk factors for severe COVID-19 in hospitalised patients[3]
- Investigate risk factors for COVID-19 in HCWs[4] at hospital level
- Estimate the VE for hospitalised SARI patients of all ages (once a vaccine is available)[5]

3. Methods

3.1. Active hospital-based surveillance of COVID-19

3.1.1. Type of surveillance

- At surveillance site level: population-based surveillance (for sites where the catchment area of each participating hospital is known and well defined) or sentinel surveillance (for sites where the catchment area may not be known)
- At European level: multicentre population-based surveillance over several countries/regions

[3]This is part of WP4; see separate protocol by the I-MOVE-COVID-19 European Hospital Network: European study of risk factors for severe disease among hospitalised CVID-19 patients: Draft generic protocol.

[4]This is part of WP4; see separate protocol by the I-MOVE-COVID-19 European Hospital Network: European study of risk factors for COVID-19 among healthcare workers: Draft generic protocol.

[5]This protocol will be updated to include estimates of VE once vaccine(s) become available.

3.1.2. Population under surveillance

The surveillance population consists of the entire population living in the catchment areas of the participating hospitals.

- *Surveillance sites to define the population under surveillance (total population residing in catchment area) and the catchment area*
- *Surveillance sites to describe methods used to estimate catchment area*
- *Surveillance sites to describe the setting (number of hospitals included, number of beds, number and type of wards/specialties/services included)*

3.1.3. Surveillance and study period

The surveillance period starts in [*month*] 2020. Participating hospitals carry out surveillance throughout the year.

- *Surveillance sites to define the beginning of hospital-based surveillance (day/month/year)*

3.2. Outcomes

The two primary outcomes of interest will be laboratory-confirmed COVID-19 in patients hospitalised with SARI, and severe COVID-19 in patients hospitalised with SARI.

The secondary outcomes of interest will be:

- Suspected COVID-19 cases
- Probable COVID-19 cases
- Laboratory-confirmed SARS-CoV-2 by viral genetic clade (where possible).

3.2.1. Case definitions

Hospitalised patient

A hospitalised patient will be defined as a patient who has been admitted to one of the participating hospitals during the study period, and has not been discharged home or home-equivalent before 24h.

SARI patient (suspected COVID-19 patient)

A SARI patient will be defined as a hospitalised person with:

- at least one systemic symptom or sign: fever or feverishness, malaise, headache or myalgia or deterioration of general condition (asthenia or loss of weight or anorexia or confusion or dizziness)

AND

- at least one respiratory symptom or sign (cough, sore throat or shortness of breath; **or** tachypnoea **or** signs of low oxygen saturation)

at admission or within 48 hours after admission.

All SARI patients, until they are re-classified as COVID-19 negative, probable or confirmed (see below), will be considered as suspected COVID-19 patients.

SARI confirmed as COVID-19 (confirmed case(3))

A confirmed COVID-19 case will be defined as a patient hospitalised with SARI with a respiratory sample positive for SARS-CoV-2.

SARI probable COVID-19 (probable case(3))

A probable COVID-19 case will be defined as a patient hospitalised with SARI for whom

- testing for virus causing COVID-19 is inconclusive (according to the test results reported by the laboratory) (4)

OR

- testing was positive on a pan-coronavirus assay (4)

OR

- no laboratory tests are available but there is clinical confirmation with suggestive radiology

SARI negative for SARS-CoV-2

A COVID-19 negative patient will be defined as a patient hospitalised with SARI with a respiratory sample negative for SARS-CoV-2.

These SARI patients negative for SARS-CoV-2 will be used in I-MOVE-COVID-19 studies, including determining risk factors for COVID-19 and for VE (once a vaccine is available).

Severe COVID-19 case

For the purposes of surveillance, all hospitalised SARI patients with a COVID-19 diagnosis are severe COVID-19 cases. However, these hospitalised patients will be further classified as "severe hospitalised COVID-19 patients" if they have any of the following clinically, analytically or radiologically significant alterations/outcomes mentioned in the admission or discharge diagnosis:

- Bilateral pneumonia with ground-glass opacities
- Admitted to ICU/HDU
- On ventilation
    - Invasive (i.e. with intubation)
    - non-invasive (e.g. high-flow oxygen; or those needing >6L)
- Extracorporeal membrane oxygenation (ECMO)
- Death

A COVID-19 death is defined as a probable or confirmed COVID-19 case who died during his/her hospitalisation.

- *Surveillance sites to specify if there is any deviation from the case definitions above (e.g. minimum length of hospital stay, additional confirmation[6])*
- *Surveillance sites to specify if any adaptations to ventilation, ECMO use, etc. in their hospitals (e.g. limiting use of ECMO for specific age-groups/comorbid conditions/staff availability, etc.)*
- *Surveillance sites to list the complications included in their protocol and the definition of severity*
- *Surveillance sites to describe how death ascertainment is defined*
- *Surveillance sites to specify if there is any deviation from the proposed data collection for all hospitalised suspected, probable and confirmed COVID-19 cases, for all age-groups*

3.2.2. Exclusion criteria for surveillance

All SARI patients will be included in the surveillance unless the surveillance site/country requires consent and s/he:

[6]Note: some sites may have additional criteria. For example: a confirmed case may be defined as a SARI patient with symptoms and signs and radiological confirmation of COVID, in accordance with the Belgian Sciensano guidelines.

- is unwilling to participate or unable to communicate and give consent (the consent may also be given by her/his legal representative, or by specific consent procedures, acceptable according to the local ethical review process)

Note: in some countries, individual patient consent is not required for routine surveillance. In these countries, all SARI patients will be included.

- *Each surveillance site to specify the requirements for consent in their country and include as an Annex the patient information and consent forms*
- *Surveillance sites to document reasons for exclusion of any potentially eligible patients*

3.2.3. Case identification

To ensure a high sensitivity of the surveillance system, cases will be identified through screening of patients meeting the SARI clinical criteria described below or through the hospital laboratory records.

All SARI patients admitted to hospital and meeting the clinical eligibility criteria, or reported as real-time polymerase chain reaction (RT-PCR) or culture-positive by the laboratory, should be included in the surveillance system and, if required by the local ethical review process, invited to participate (through their legal tutor) and asked to provide informed consent. Once recruited, a surveillance nurse or doctor will take a specimen for COVID-19 testing and will interview the legal tutor (where applicable).

Clinical eligibility criteria include presenting with SARI symptoms (as described in case definitions earlier).

- *Surveillance sites to describe precisely all the steps of case identification:*
  - ✓ *source of case identification (e.g. emergency room, laboratory records)*
  - ✓ *person who identifies potential cases (e.g. study nurse, physician)*
  - ✓ *methods used to identify cases (e.g. use of International Classification of Disease [ICD] codes, screening of all potential cases by study staff)*
    - ❖ *If using ICD codes, list the diagnosis codes used to identify COVID-19 cases (see Table 1)*
  - ✓ *when are cases identified (e.g. specific time; once per day; changes during the weekends)*
  - ✓ *who collects the specimen and who interviews the patient (if applicable)*

3.2.4. SARI patient identification – algorithm for patient inclusion

A list of potential diagnosis codes for which patients could be screened for onset of SARI symptoms is provided in Table 1.

Table 1: Potential list of diagnosis codes for screening patients for onset of SARI symptoms, I-MOVE-COVID-19 hospital-based surveillance.

Category	Morbidity	ICD-9	ICD-10
Influenza-like illness	Cough	786.2	R05
	Difficulty breathing	786.05	R06
	Sore throat	784.1	R07.0
	Dysphagia	787.20	R13
	Fever	780.6	R50.9
	Headache	784.0	R51
	Myalgia	729.1	M79.1
	Fatigue/malaise	780.79	R53.1, R53.81, R53.83
Cardiovascular diagnosis	Acute myocardial infarction or acute coronary syndrome	410-411, 413-414	I20-23, I24-25
	Heart failure	428 to 429.0	I50, I51
Respiratory diagnosis	Emphysema	492	J43.9
	Chronic obstructive pulmonary disease	496	J44.9
	Asthma	493	J45
	Myalgia	729.1	M79.1
	Dyspnoea/respiratory abnormality	786.0	R06.0
	Respiratory abnormality	786.00	R06.9
	Shortness of breath	786.05	R06.02
	Tachypnoea	786.06	R06.82
	Other respiratory abnormalities	786.09	R06.00, R06.09, R06.3, R06.89
Infections	Pneumonia and influenza	480-488.1	J09-J18
	Other acute lower respiratory infections	466, 519.8	J20-J22
	Viral infection, unspecified	790.8	B34.9
	Bacterial infection, unspecified	041.9	A49.9
	Bronchitis	490, 491	J40, 41
	Myocarditis	429.0	I40.9
Inflammation	SIRS* non-infectious without acute organ dysfunction	995.93	R65.10
	SIRS* non-infectious with acute organ dysfunction	995.94	R65.11
Abdominal symptoms	Vomiting	787.0	R11
	Diarrhoea	009.3, 787.91	A07.9, K52.9
	Abdominal pain	789.0	R10

Diagnoses related to deterioration of general condition or functional status	General physical deterioration, lethargy, tiredness	780.79	R53.1, R53.81, R53.83
	Anorexia	783.0	R63.0
	Feeding difficulties	783.3	R63.3
	Abnormal weight loss	783.21	R63.4
	Other symptoms and signs concerning food and fluid intake	783.9	R63.8
	Disorientation/altered mental status	780.97	R41.0
	Dizziness and giddiness	780.4	R42
	Infective delirium	293.0, 293.1	F05
	Coma	780.01	R40.2
	Transient alteration of awareness	780.02	R40.4
	Other alteration of consciousness (somnolence, stupor)	780.09	R40.0, R40.1
	Febrile convulsions (simple), unspecified	780.31	R56.00
	Complex febrile convulsions	780.32	R56.01
Other	Anosmia, ageusia, myalgia	781.1, 729.1	R43.0, R43.2, M79.1

*SIRS: Systemic inflammatory response syndrome

SARI patients will be identified among patients hospitalised in one of the participating hospitals. For hospitals with electronic patient records and/or diagnosis codes commonly displayed, SARI-related ICD codes will be sought. Patients admitted with any of the ICD codes listed in Table 1 will be approached; those meeting the SARI case definition and the inclusion criteria will be invited to be part of the study and sign informed consent, where appropriate (Figure 1).

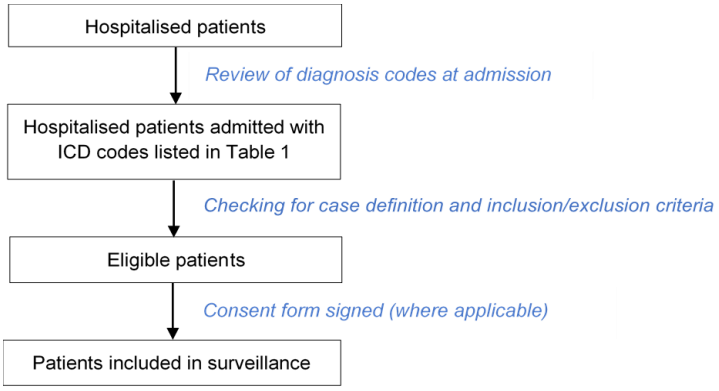

Figure 1: proposed inclusion algorithm for hospitals/services relying on common use of ICD codes, I-MOVE-COVID-19 hospital-based surveillance.

For hospitals where ICD codes at admission are not systematically collected or accessible, systematic screening of all patients admitted will be organised. This may be done by sensitisation of the medical staff before starting COVID-19 surveillance (Figure 2), and could include regular review by the surveillance site coordinator.

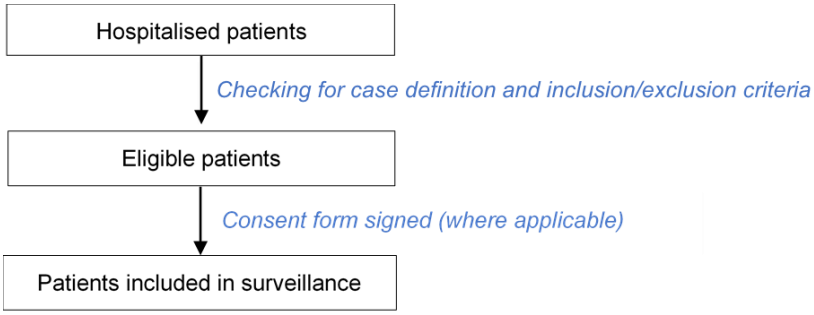

Figure 2: proposed inclusion algorithm for hospitals/services systematic screening of all admitted patients, I-MOVE-COVID-19 hospital-based surveillance.

Following the procedures outlined by each site (Figures 1 and 2), patients meeting the SARI case definition will be asked (directly or through their legal tutor) to provide consent (where required) and a nasal/throat respiratory specimen for SARS-CoV-2 testing and to respond to an interview.

For retrospective data collection, where swabs may have already been taken, for sites/countries where consent is required, patients will need to be contacted by telephone (if already discharged) and consent sought for collection of their data. For countries/sites where consent is not required, retrospective data collection may be performed from patient records.

- *Each surveillance site to describe procedures to identify study participants and to collect data (prospective or retrospective)*

In case of test scarcity, or budget limited to certain number of patients' inclusion, the surveillance sites may need to switch from exhaustive to systematic sampling (e.g. inclusion of patients every second day). Systematic sampling procedures should be planned ahead by the surveillance sites. During the period of systematic selection, the surveillance sites should make sure to document the sampling fraction.

- *Surveillance sites foreseeing budget limits to detail the systematic sampling procedure and provide total number of SARI patients and total number tested, by sex and age-group*

3.3. Laboratory methods

Surveillance nurses or physicians will collect respiratory specimens (see Section 4.4) from all eligible patients, respecting safety standards for COVID-19 and following WHO biosafety guidelines.[7]

- *Each surveillance site to describe the type and number of swabs taken for each patient*

Quality control tests should systematically be run using PCR to test for presence of cells in the respiratory specimens.

The ECDC-recommended SARS-CoV-2 laboratory confirmation is by viral RNA detection with nucleic acid amplification tests, such as RT-PCR.(1,4) Isolates will undergo molecular analysis for currently circulating SARS-CoV-2 virus. During influenza season, tests should also be performed for influenza viruses as long as there is circulation of influenza viruses.(1)

Following the procedures outlined by each study, a systematic sample of isolates (or all isolates) will undergo gene sequencing. The sampling procedure can include sequencing all isolates, or a systematic sample thereof. The systematic sample should be representative of cases and be large enough to provide reasonable precision when calculating proportions of virus change over time.

- *Each surveillance site to describe the laboratory procedures (samples taken, storage, transport)*
- *Each surveillance site to describe the tests and the kits used (and their sensitivity, specificity, PPV) for COVID-19 and, if needed, other respiratory virus detection*
- *Each surveillance site to describe if the laboratory participates in QA/QC (Quality Assurance/Quality Control) schemes*
- *Each surveillance site to describe the selection of specimens and the procedures for genetic and antigenic characterisation (see Annex 4 for an example of result presentation)*
- *Each surveillance site to describe genetic and antigenic analyses and specify sequencing methods*

[7]Any non-propagative diagnostics (e.g. sequencing, RT-PCR) should be conducted at a facility using procedures equivalent to biosafety level 2 (BSL-2), while propagative work (e.g. virus culture, isolation or neutralisation assays) should be conducted at a containment laboratory with inward directional airflow (BSL-3). Patient specimens from suspected or confirmed cases should be transported as UN3373, 'biological substance category B'. Viral cultures or isolates should be transported as category A, UN2814, 'infectious substance, affecting humans'.(5)

3.4. COVID-19 surveillance and severity risk factor study data to be collected

Collected information falls under the following seven main categories: study identifiers, hospital/ward information, patient characteristics, case/severity definitions, risk factors (including laboratory sequencing information), medications/interventions in hospital, and complications. These are listed in Table 2 below for rapid reference and are then described in more detail following the table (with information for risk factor studies only indicated in grey boxes). See also Annex 1 for a complete variable list including coding.

All core variables are to be collected for surveillance (see second column below) but variables in the third column are for the risk factor study only (the risk factor studies will also collect core surveillance variables).

Table 2: Variable list by category and type (core: surveillance and additional: risk factor study only)

Category	**Variable list**	
	Core (surveillance) variables	**Additional variables: risk factor study only**
1. Study identifiers	Country/site, hospital, patient unique id, consent (where relevant)	Reasons for refusal
2. Hospital/ward information	Previous hospital stay, first ward of referral, date admission/ discharge (hospital, ICU/HDU), date sample, prior hospital stay (last 12 months)	
3. Patient characteristics	Sex, age, smoking, pregnant, healthcare worker, residence	Clinical frailty score at admission
4. Case/severity definitions	SARI signs/symptoms, date onset, COVID tests/results, severity indicators (bilateral pneumonia, ventilation, ECMO, admit ICU/ HDU, death)	
5. Risk factors	5.1. Patient characteristics	
		5.2. Pre-symptomatic treatment/intervention • ACE inhibitors, ARBs, NSAIDs, statins, metformin, steroids, corticosteroids, DMARDs, chemotherapy, gliclazides, psychotropics, antivirals • influenza and pneumococcal vaccination, BCG vaccination
	5.3. Close contact setting	
		5.4. Early clinical symptoms/signs • fever, cough, shortness of breath • anosmia, ageusia, etc. as in (3)
	5.5. Time onset to admission	
	5.6. Exam/lab results on admission or during hospitalisation • CT scan (or CXR if no CT), ECG • Oxygen saturation (%) before support	• Exam /lab results on admission or during hospitalisation • Blood group • Confusion **or** GCS **or** AVPU score

	• Lab sequencing ○ lab results (genetic group and antigenic group/clade) 5.7. Pre-existing chronic conditions • anaemia/chronic haematologic disease, asplenia, asthma • cancer, chronic liver disease/cirrhosis • dementia, diabetes mellitus • heart disease (excluding hypertension), hypertension • Immunodeficiency/organ transplant • lung disease, liver disease, neuromuscular disorders • obesity, renal disease (exclude acute renal failure), rheumatologic diseases • stroke, tuberculosis	• Blood urea, BUN, respiratory and heart rates • Systolic/diastolic BP (mmHg) • Lymphocyte, platelet counts • Neutrophil/lymphocyte ratio • LFT (ALP, AST, ALT) • Ferritin, LDH, D-Dimer • Eosinophil count, CRP • Creatine phosphokinase • Troponin-I • Triglycerides, cholesterol • Fibrinogen • NT-proBNP • BNP • HbA1c 5.8. Other respiratory viruses
6. In-hospital medications/ interventions	Prone position, ventilation	Hydroxychloroquine, corticosteroids, monoclonal antibody/IL6 blockers, antibiotics, oxygen (nasal, high-flow), antivirals, sepsis fluid resuscitation, study drugs, nebuliser, etc.
7. Complications		ARDS, bronchiolitis, encephalitis, myocarditis, Pneumonia (secondary bacterial), other secondary bacterial infection, sepsis, acute renal injury, heart failure, multiorgan failure, diarrhoea/colitis, dermatological manifestations of COVID-19, ICU-related polyneuromyopathy, Guillain-Barré syndrome, death

Note: variables in grey already listed in another category.

3.4.1. Study identifiers

We will document the following study characteristics.

- Country, site
- Hospital
- Patient unique ID (note: this is not a patient identifiable ID such as date-of-birth or national ID number, but a unique identifier for the pooled database)

3.4.2. Hospital/ward information

We will document following dates and other hospital information to monitor severity.

- First ward of referral
- Hospital stay in previous 12 months
- Date of admission (hospital, ICU/HDU)
- Date of discharge (hospital, ICU/HDU)
    - Whether multiple admissions to ICU/HDU (total # times)
    - Length of time in hospital and in ICU (total), where known
- Date of swab/sample
- Whether the current admission is the first or a subsequent admission (>7 days from first admission), and if subsequent, which re-admission number this is

3.4.3. Patient characteristics

We will document following patient characteristics to describe the study population.

- Age (in years; in months if <2 years)
- Sex
- Smoking history
- Pregnancy
- Healthcare worker
- Place of residence
    - home/institutionalised
    - postcode where possible
    - pre-hospitalisation dependence on home support/care

*For the risk factor study, we will collect the following **additional** information on patient characteristics:*

- Clinical frailty score at admission (where possible)
    - ➢ *Each surveillance site to describe type of clinical frailty score in use, where available*

Smoking history will be collected and coded as follows: never-smoker, former smoker (stopped smoking at least 1 year before inclusion in the study), current smoker.

Information on pregnancy will be collected and coded as follows: pregnant now or gave birth within the past 6 weeks: yes/no/unknown; if Yes: unknown trimester, trimester 1–3; <6 weeks post partum.

3.4.4. Case definition and severity information

We will document the following information to better understand the clinical spectrum of disease as well as to classify patients as suspected, probable and confirmed cases, and further as severe cases:

- Case definitions (all)
    - SARI symptoms and signs
        - fever or feverishness
        - cough
        - sore throat
        - shortness of breath
        - sudden onset
    - Other symptoms
        - tachypnoea or other signs of low oxygen saturation (restlessness)
        - rapid heartbeat
        - chest pain
        - coryza
        - malaise
        - headache
        - myalgia
        - deterioration of general condition (asthenia, weight loss, anorexia)
        - confusion
        - dizziness
        - diarrhoea
        - abdominal pain
        - nausea
        - vomiting
        - ageusia
        - anosmia
        - conjunctivitis
        - rash or other dermatological manifestations
    - Date of onset of first symptom
    - COVID-19 test(s) and laboratory results
        - on admission
        - including information on antigenic and genetic analysis, when available
- Case definitions (severe): as above plus any of the following

    - Bilateral pneumonia with ground-glass opacities (from radiological imaging results)
    - Invasive/non-invasive mechanical ventilation
    - ECMO
    - ICU/HDU admission
    - Death
        - Date of death, cause of death

- Additional signs at admission, collected for the RF study
    - Glasgow Coma Scale (GCS) score
    - AVPU score

3.4.5. Potential risk or preventive factors for severe COVID-19

The following will be included in surveillance data to be collected, as exposures which are potential risk or protective factors. Those included for surveillance are listed first and will only be *described*, while others (in grey box) will be key for the hospital risk factor studies.

Close contact setting

Information on any close contact setting with a person with a probable or confirmed case in the 14 days prior to symptom onset will be collected, using the following settings:

- Family setting
- Healthcare setting
- Workplace
- Long-term care facility
- Prison setting
- Other setting
- Unknown

Time from onset to admission

It is possible that delayed admission could lead to more severe COVID-19 as the disease will have progressed prior to hospitalisation. We will collect information on date of onset and date of admission to describe mean time to admission for surveillance, and for WP4 to investigate delayed admission as a risk factor for severity.

Laboratory or examination results on admission or during hospitalisation

Some laboratory or examination results will help with the classification of cases into severe or non-severe COVID-19, so these will be required for surveillance.

- Computed tomography (CT) scan
- Chest X-ray findings, when CT scan is unavailable or not included in routine testing
- Oxygen saturation on admission to hospital (on air), %
- Laboratory results (type of test and result); second PCR and result (if first was negative)
- Laboratory sequencing results (genetic group, antigenic group/clade, as appropriate and where possible)

Other laboratory results (e.g. low lymphocyte count and high C-reactive protein or CRP) and examination findings (e.g. abnormal CT) have been suggestive of more severe COVID-19.

We will collect information on the following additional examinations for WP4 (risk factor studies) to investigate predictive capacity, where possible, both (a) at admission and (b) the ***most pathologic*** *result during hospital stay:*

- Blood urea nitrogen (BUN)
- Urea
- Respiratory rate
- Heart rate
- SBP, DBP
- ABO blood group (only at admission)
- Platelet count
- Lymphocyte count (range: <500, 500–800, >800)
- Neutrophil/lymphocyte ratio
- Eosinophil count
- Liver function test (LFT) including
    - Serum albumin
    - Serum total bilirubin
    - Serum conjugated bilirubin
    - GGT
    - Serum total protein
    - Alkaline phosphatase (ALP)
    - Aspartate aminotransferase (AST)
    - Alanine transaminase (ALT)
    - Prothrombin time
- Lactic acid dehydrogenase (LDH)
- Ferritin
- D-Dimer
- Fibrinogen
- C-reactive protein (CRP)

- Creatinine phosphokinase
- Cardiac troponin-I
- Triglycerides
- Cholesterol
    - Low density lipoprotein (LDL)
    - High density lipoprotein (HDL)
    - Total cholesterol
- N-terminal-prohormone B-type natriuretic peptide (NT-proBNP)
- B-type natriuretic peptide (proBNP)
- Single glycated haemoglobin (HbA1c)

Information on previous positive COVID-19 tests

Among the hospitalised SARI patients, some may have already had a positive COVID-19 test. We will collect information on those who have had more than one infection to help with the control selection for the risk factor study. If possible, we will collect whether

- Patient had previous positive COVID-19 test
    - type of test: PCR, point-of-care test
    - date of test

Pre-existing chronic conditions

The following underlying conditions will be collected and described as potential factors impacting COVID-19 severity (for ICD codes see Table 3). Note that most of these are already collected for influenza VE, so all will be left here and included for surveillance.

- anaemia / chronic haematologic disease
- asplenia
- asthma
- cancer (solid organ and haematological)
- chronic liver disease/cirrhosis (excluding cancer)
- dementia
- diabetes mellitus
- heart disease (excluding hypertension)
- hypertension
- immunodeficiency and organ transplant
- lung disease

For the risk factor studies we will also include information on lung disease and

- use of non-invasive ventilation / oxygen therapy
- chronic obstructive pulmonary disease (COPD)

- neuromuscular disorder
- obesity
    - height
    - weight
    - or: BMI (sites to include whichever is feasible/available)
- renal disease (exclude cancer and acute renal failure)
- rheumatologic diseases
- stroke
- tuberculosis

Data will also be collected on whether the patient had been admitted to hospital at least once in the 12 months prior to admission, as an indicator of the severity of the condition.

- *Each surveillance site to define the list of chronic conditions to be included and describe what the source of information will be*

Data will also be collected on whether the patient had visited a GP or other primary care service in the 14 days prior to admission.

Table 3: ICD-9 and ICD-10 codes for chronic conditions.

Category	ICD-9	ICD-10	Underlying conditions included
Anaemia	280–285	D50-64	Nutritional anaemias, Haemolytic anaemias, Aplastic and other anaemias and other bone marrow failure syndromes
Asplenia	746.87, 759.0	Q89.01, Q20.6, Z90.81	Malposition of heart, Anomalies of spleen, Isomerism of atrial appendages, Acquired and Congenital absence of spleen
Asthma	493.0, 493.1, 493.9	J45	Extrinsic asthma, Intrinsic asthma, Predominantly allergic asthma, Non-allergic asthma, Mixed asthma, Asthma unspecified
Chronic liver disease	571	K70, K72-74, K754, K769	Alcoholic liver disease, Hepatic failure, Chronic hepatitis, Fibrosis and cirrhosis of liver, Other inflammatory liver diseases
Cardiovascular diseases	093, 112.81, 130.3, 391, 393–398, 402, 404, 410–429, 745, 746, 747.1, 747.49, 759.82, 785.2-3	A52.01, B37.6, B58.81, I05-9, I11, I13, I20-25, I26.09, I26.9, I27, I30-51, I97.0-1, R00.1, T81.718A, T81.72XA, T82.817A, T82.818A, Q20-24, Q25.1-2, Q26.0-1, Q26.8, Q87.4, R01.1-2	Syphilitic aneurysm of aorta, Candidal endocarditis, Toxoplasma myocarditis, Chronic rheumatic heart diseases, Ischemic heart diseases, Hypertensive heart and chronic kidney disease, pulmonary embolism with acute cor pulmonale, pulmonary heart diseases, diseases of pulmonary vessels, Other forms of heart disease (including Nonrheumatic valve disorders, pericarditis, endocarditis,

			myocarditis, cardiomyophathy, heart failure, block, cardiac arrhythmias, heart failure), Complication of other artery / vein following a procedure, Embolism of cardiac/vascular prosthetic devices, implants and grafts, congenital malformations of cardiac chambers and connections or heart, Coarctation or atresia of aorta, Congenital malformations of great veins, Marfan's syndrome, Cardiac murmur
Diabetes	250	E10-11	Type 1 and Type 2 diabetes mellitus
Hypertension	401, 401.0, 401.9, 405, 405.91, 405.99,	I10, I15.8, I15, I15.1, I15.2, I97.3, I27.0	Hypertension (essential and secondary), Secondary to other [renal or endocrine] disorders, Malignant hypertension
Obesity	27800, 278.01, 278.03	E66.01, E66.2, E66.9	Obesity
Immunodeficiency* or organ transplant	042, 279, V08, V42	B20, D80-84, D89.8-9, Z21, Z94	HIV, immune deficiency, organ or tissue replaced by transplant
Neuromuscular disorders	358.00-358.1, 358.8, 358.9, 378.73, 775.2	G70-G70.01, G70.2, G70.80, G70.81, G70.9, G70.89, G73.7,	Myasthenia gravis, Myoneural disorders NEC/NOS, Neuromuscular disease strabism, Congenital and developmental myasthenia, Lambert-Eaton syndrome, Myoneural disorder NOS
Renal disease	274.1, 408, 580–591, 593.71–593.73, 593.9	M10.30, N00-19, N20.0, N28.9	Gout due to renal impairment, Glomerular diseases, Renal tubulo-interstitial diseases, Acute kidney failure and chronic kidney disease, Calculus of kidney, Disorder of kidney and ureter, unspecified
Dementia	290, 294, 331	F01, F03, F05, G30, G31, G91, G94	Vascular dementia, other dementia, Delirium due to known physiological condition, Alzheimer's disease, Other degenerative diseases of nervous system
Stroke	348, 438	G93, I67.83, I69	Brain disorders, Posterior reversible encephalopathy syndrome, Sequelae of cerebrovascular disease
Rheumatologic diseases	446, 710, 714	M30-34, M35.0, M35.5, M35.8-9, M05-06, M08, M12.00	Polyarteritis nodosa and related conditions, Other necrotizing vasculopathies, Systemic lupus erythematosus (SLE), Dermatopolymyositis, Systemic sclerosis, Sicca syndrome, Multifocal fibrosclerosis, other systemic involvement of connective tissue, Rheumatoid arthritis with rheumatoid factor, Other rheumatoid arthritis, Juvenile arthritis, Chronic post-rheumatic arthropathy

Cancer	140–208	C00-96	Malignant neoplasms and neuroendocrine tumours
Lung disease	011, 490–511, 512.8, 513–517, 518.3, 518.8, 519.9, 714.81	A15, J40–47, J60–94, J96, J99, J182, **M34.81, M05.10**	Respiratory tuberculosis, Bronchitis, not specified as acute or chronic, Chronic bronchitis, Emphysema, Other chronic obstructive pulmonary disease, Asthma, Bronchiectasis, Hypersensitivity pneumonitis due to organic dust, Pneumoconiosis, Airway disease due to specific organic dust, Hypersensitivity pneumonitis due to organic dust, Respiratory conditions due to inhalation of chemicals, gases, fumes and vapor, Pneumonitis due to solids and liquids, Respiratory conditions due to other external agents, Acute respiratory distress syndrome, Pulmonary edema, Pulmonary eosinophilia, not elsewhere classified, Other interstitial pulmonary diseases, Abscess of lung and mediastinum, Pyothorax, Pleural effusion, Pneumothorax and air leak, Other pleural conditions, Intraoperative and postprocedural complications and disorders of respiratory system, not elsewhere classified, Other diseases of the respiratory system, Hypostatic pneumonia, unspecified organism, **Systemic sclerosis with lung involvement, Rheumatoid lung disease with rheumatoid arthritis**
Tuberculosis		A15–A19	Primary respiratory tuberculosis, Respiratory tuberculosis unspecified, Tuberculosis of nervous system, Tuberculosis of other organs, Miliary tuberculosis

*Note: Patients who are only treated with glucocorticoids and have no other immune deficiency, are considered immune suppressed when treated with high-dose corticosteroids (≥ 20 mg/day of prednisone or equivalent for ≥2 weeks) in the last 3 months.

3.4.6. Administration of medications and interventions in hospital

Administering medications and/or interventions in may have a protective or deleterious effect towards the development of severe COVID-19. We will document whether the patients received any of the following while in hospital:

- Nasal oxygen
- Prone position

- Nebuliser treatment
- Ventilation
    - positive end-expiratory pressure (PEEP)
    - bilevel positive airway pressure (BiPAP)
    - continuous positive airway pressure (CPAP)
- High-flow oxygen

    For the risk factor studies we will also include information on oxygen flow rate as follows:
    - 6L/min or higher
    - using OptiFlow technique
    - date of increase in oxygen concentration

In addition, for the risk factor study, we will collect the following information on other medications/ interventions received in hospital:

- Antivirals (remdesivir, ritonavir, lopinavir, favipiravir, umifenovir)
    - with doses, where/if possible
- Monoclonal antibodies/IL-6 blockers (e.g. tocilizumab)
- Hydroxychloroquine/chloroquine
- Corticosteroids
    - with doses, where/if possible
- Antibiotics (e.g. azithromycin)
- Sepsis fluid resuscitation
- Other drugs like azithromycin, ribavirin
- Use of study drugs
    - convalescent plasma
    - GM-CSF
- Other (specify)

➢ *Each study site to list any medications and interventions administered in hospital*

*The following **additional** information will be collected for the risk factor study.*

Pre-symptomatic treatment or intervention (including vaccination)

We will document whether the patients received any of the listed medications in the 2 weeks preceding symptom onset.

Pre-symptomatic medication status:

The three main medications to be included are angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs) and non-steroidal anti-inflammatory drugs (NSAIDs). Additional medications include antivirals, statins and other anti-hypertensive medication. For each of these:

- An individual will be considered as “on” the medication if s/he has received at least one dose on or before onset of symptoms
- An individual will be considered as “not on” the drug if s/he did not receive it on or before symptom onset.

Current list of pre-symptomatic medications:

- Antivirals
- Statins
- ACE inhibitors
- ARBs
- NSAIDs
- Chloroquine/hydroxychloroquine
- Metformin
- Steroids
- Corticosteroids
- Monoclonal antibodies/IL-6 blockers
- Other biological disease-modifying anti-rheumatic drugs (DMARDs)
    - rituximab, tocilizumab, etc.
- Current/recent cancer chemotherapy (within previous 6 months)
- Gliclazide (for diabetes or heart failure)
- Psychotropic drugs (including benzodiazepine, etc.)

Pre-symptomatic medication use status ascertainment

Medication history includes date the patient started on the medication, where known, or just the year, if the patient was known to have been on one of the medication types before epidemic started or if the precise date is unknown. If both of these are unknown, then a simple yes/no response for each medication as to whether the patient was on the drug on 01 January 2020 will be used.

The sources of information for pre-symptomatic medication status may include:

- consultation of the patient’s hospital record
- (telephone) interview with the patient’s GP
- (telephone) interview with the patient’s pharmacist
- data from the patient’s insurance company showing evidence of pharmacy delivery or reimbursement for these medications since 01 January 2020
- interview of the patient and/or his/her relatives (by telephone)

- *Each surveillance site to describe how pre-symptomatic medication use is collected and ascertained*

Current list of pre-symptomatic vaccinations:

- Bacille Calmette Guérin (BCG) vaccination (ever; with approximate year, if possible)
- Recent seasonal influenza vaccination (with date)
- Latest pneumococcal vaccination (with date)

Any prior BCG vaccination, as well as 2019/20 vaccination against influenza and vaccination against pneumococcal diseases will be collected. This may not be possible for BCG vaccination in some sites, but instead these could indicate if there was no BCG vaccination policy at all, or if e.g. "assume that those born after 1956 would be vaccinated", etc.

The sources of information for vaccination may include:

- vaccination registry
- consultation of the patient's vaccination card
- (telephone) interview with the patient's GP
- (telephone) interview with the patient's pharmacist
- data from the patient's insurance company showing evidence of pharmacy delivery or reimbursement of influenza vaccine during the current influenza season.
- interview of the patient and/or his/her relatives (by telephone)

- *Each surveillance site to describe how influenza and pneumococcal vaccination status are documented*

- *Each surveillance site to describe BCG vaccination status determination or national-level assumption*

In addition, once available, information will be collected on COVID-19 pandemic vaccination including number of doses, date, and product.

Presence of early clinical symptoms/signs

There are some early clinical symptoms or signs which are hypothesised as being predictive for COVID-19. We will collect information on them to investigate whether they are potential factors impacting COVID-19 severity (note: these are all signs already included in the general symptoms/signs on admission, but will be collected also as pre-admission symptoms/signs).

Other respiratory viruses

Patients admitted with underlying lung diseases may be included due to an exacerbation of underlying conditions unrelated to SARI. Due to their underlying conditions, these patients may be more likely to be infected with COVID-19, or to develop more severe disease than the source population. *We will collect information on the presence of respiratory infection among all COVID-19 patients for the risk factor study.*

- *Each surveillance site to list the other respiratory infection viruses tested for (including influenza)*

Complications

Information on the following in-hospital complications will be collected as potential risk factors for severe disease:

- ARDS (acute respiratory distress syndrome)
- Bronchiolitis
- Encephalitis
- Myocarditis
- Pneumonia (secondary bacterial pneumonia)
- Other secondary bacterial infection
- Sepsis
- Acute renal injury (AKI)
- Heart failure
- Multiorgan failure
- Diarrhoea/colitis
- Dermatological manifestations of COVID-19
- ICU-related polyneuromyopathy
- Guillain-Barré syndrome
- Death
- Other (specify)

3.5. Data

3.5.1. Sample size

For COVID-19 hospital-based surveillance, there is no minimum sample size. Surveillance sites will conduct active surveillance to identify all potential COVID-19 cases occurring in participating hospitals' catchment areas.

3.5.2. Denominators

Denominators for the population at risk (the entire population of the catchment area) are needed to calculate COVID-19 incidence.

- *Surveillance sites to provide the estimated population size in the hospitals' catchment area, by age group and gender, together with the description of the estimation method used and its potential limitation, and the frequency of denominator updates*
- *In addition, if possible, surveillance sites to provide the number and proportion of COVID-19 cases seen in the community (outside of the hospital setting). If not available, sites to provide number of hospitalisations per week (SARI and/or all)*

3.5.3. Data collection instruments

Data will be collected using a standardised questionnaire/data collection form. The source(s) of data may include:

- hospital medical records
- interview with patient or his/her family
- interview with patient's GP
- interview with patient's pharmacist
- vaccination register
- laboratory

- *Each surveillance site to define the sources of information used for each variable collected*

Pandemic vaccine data will be collected once vaccine(s) is available, and will be revised as more information on the vaccine and the target groups becomes available.

3.5.4. Data entry validation

For hospitals using electronic medical records, if paper questionnaires are used, a sample of them will be checked against the medical records and against the study database. The agreement between patient vaccine records/vaccination status reported by study participant/vaccine registries will be measured when vaccination registries are available.

- *Each surveillance site to specify how data are validated*

3.5.5. Data management

Data collection and entry

Web-based data collection methods or paper-based methods can be used. Data entry will include checks to minimise data entry errors. Double data entry is recommended unless electronic medical records are used.

Laboratory information will be reported to the surveillance site coordinator using the reporting procedures existing in each surveillance site for COVID-19 surveillance.

Epiconcept provides the option of web-based data collection methods, if so desired by the countries. These methods can also be combined with paper-based methods.

If the Epiconcept web-based data collection methods are not used, data can be coded as outlined in Annex 1, but it is not required.

There are three methods for data collection of COVID-19 in the I-MOVE-COVID-19 surveillance system:

(1) As for I-MOVE influenza for most countries, data collection through your usual method with transfer of your electronic database to the coordinating hub through the secure data transfer platform, EPIFiles

(2) As for I-MOVE influenza for some countries, data entry directly into the Epiconcept software Voozanoo, which Epiconcept will adapt to include the additional COVID-19 variables

(3) ISARIC (the International Severe Acute Respiratory and Emerging Infection Consortium) provides a modular electronic case report form (e-CRF) which some countries/sites may already be using. Some of the modules and the Rapid CRF are co-created with the WHO. The e-CRF uses the REDCap platform, and sites may either download the application and use the CRF in electronic format (on laptop, tablet, mobile telephone) or can also print the e-CRF and collect the data on paper and then enter onto the electronic system. For COVID-19, ISARIC has developed a rapid data collection e-CRF comprising three modules, from which many variables in module 1 and a few from module 3 are the same as those to be collected by the I-MOVE-COVID-19 surveillance network. Epiconcept and PHS are working with ISARIC to develop the best solution for sites to include any additional items required. If your site choses the ISARIC e-CRF:

- Sites not already using ISARIC may register to use the full rapid COVID-19 e-CRF with modules 1–3
    - together with those sites already registered for ISARIC use, only the additional variables not covered by ISARIC would need to be completed for each patient (remaining variables will be automatically populated from the already completed modules 1–3)

- note that for these sites there will be more data to be filled in, but only the data relevant for the I-MOVE-COVID-19 surveillance network will be used for this surveillance system

- *Surveillance sites to specify procedures of data management and procedures to comply with the GDPR requirements*
- *Surveillance sites to indicate which of the three data collection options they will use*
- *Surveillance sites to provide a codebook that includes the variable names, variable descriptions, and the coding of variable values.*

Data storage and transfer to ECDC

For the multi-centre pooled analysis, surveillance sites will send an anonymised database to the coordinating team through the secure data transfer system EpiFiles.

It is important for surveillance sites to understand how, by whom and when data are stored locally, prior to transfer to the coordination hub.

- *Surveillance sites to describe who analyses the data locally, and where/how (software) it is stored*
- *Surveillance sites to describe how and who performs the database anonymisation prior to local data analysis*

It is important during a pandemic to have complete regional as well as global information so that countries may all learn from each other and come together to combat the disease. For the EU/EEA Member States, ECDC will require data to be collected for The European Surveillance System (TESSy). The coordination hub has worked with ECDC to ensure that the variables requested for the I-MOVE-COVID-19 surveillance system are aligned with those required for TESSy. Sites selecting options (1) or (2) above will have a dataset from which the TESSy extract will not be problematic. For option (3), ISARIC will ensure access to their own dataset for each individual site. Similarly, an extract from this to submit to TESSy should not raise issues.

- S*urveillance sites to indicate whether they may require assistance with extraction of data for submission to TESSy*

Data cleaning

Summary and frequency tables as well as visual representations of appropriate variables will be used to find illegal, implausible or missing values within the dataset. Checks for inconsistencies will be carried out (e.g. date of discharge from hospital before date of onset of symptoms). Ideally, these checks will be included as warnings in the electronic questionnaire in order to avoid inconsistencies in the data entry. These values will be checked against the questionnaires or queried with the hospitals. Any changes to the data will be

documented and stored separately from the crude database. Any recoding of data (e.g. age) will be documented. A guide and/or an example Stata do-file for data cleaning will be provided if so desired.

- *Surveillance sites to specify the data checking and cleaning process*

Data storage and management database for pooled analysis

The minimum dataset will be transmitted to the coordination hub where individual data will be pooled. Data will be stored in the EU data repository, as required by the European Commission (EC).

The coordinating team will conduct the pooled analysis. Data validation, cleaning and verification will be carried out at study level with additional data checks by the coordinating team (and feedback to surveillance sites). Each individual study database will be sent to the coordinating team study database using a secure protocol (see Annex 2: Dataflow for pooled database). All personal identifier information such as names, addresses, and medical registration codes will be deleted before data transmission to the coordinating team, where all individual data will be pooled. Study databases can be sent to the coordination hub in any format (e.g. Stata, CSV, EpiData, etc.).

A country (or study) identifier will be included in each record (e.g. ES for Spain, UK for the United Kingdom), a hospital code will be included (e.g. a unique number), and each record will be given a unique number. This number will also be included in the study team's database and will be used by the coordinating team and the surveillance sites during pooling, so that records can be traced back whilst maintaining anonymity, if there should be any further queries. Tracing back will be performed by the surveillance sites, not by the coordinating team.

Summary and frequency tables and graphic displays of appropriate variables will be performed by the coordination team at pooled level, and used to indicate any illegal, implausible or missing values within the dataset. Checks for inconsistencies will be carried out (e.g. date of respiratory specimen collection before date of onset of symptoms). Any improbable, illegal or missing values will be reported to the surveillance site in question.

Any subsequent changes to the data will be fully documented and stored separately from the crude database, to ensure reproducibility and transparency of data management.

A study site-specific flowchart of exclusions and restrictions will be shared with each of the surveillance sites. Variables will be recoded and new variables generated. The recoded data will be stored separately from the crude data and recoding will be documented.

Missing data

Any missing data will be described.

3.5.6. Plan of analysis

The analysis will be carried out first for each individual surveillance site and shared with the site surveillance team for validation. In a second step, a pooled analysis will be conducted. The methods used for surveillance site analysis and pooled analysis are the same. Specificities related to the pooled analysis are specified in the "Pooled analysis" section below.

The weekly incidence rate of COVID-19 will be calculated, using as denominator the population of the participating hospitals' catchment areas (see list of indicators in Annex 7). If denominators by age-group are available, the incidence will be calculated by age-group.

Data checking

As mentioned above, the following data checks will be completed:

- Identification of inconsistencies, outliers
- Checking for missing information

Descriptive analysis

The proportion of eligible hospitalised cases included in the surveillance of COVID-19 will be calculated. Reasons for non-participation will be documented. Surveillance participants will be described by baseline characteristics.

Patients will be described according to (depending on sample size):

- COVID-19 confirmed, probable, suspected
- sex
- age groups
- time: new cases by day, week, month?
- absence, presence of at least one, presence of more than one high-risk condition
- specific chronic conditions (e.g. respiratory, cardiovascular diseases)
- use of pre-symptomatic medications (including statins)
- BCG, influenza and pneumococcal vaccination status
- respiratory co-infections

Pooled analysis

The coordinating team will conduct the pooled analysis and will perform all necessary data checking (going back to study sites to obtain information where necessary) and cleaning. The coordination team will

document and share any further data cleaning and analysis with all surveillance site coordinators to ensure it can be reproduced.

The timing to conduct each interim analysis will depend on the time needed to reach the appropriate sample size. This will depend mainly on the incidence of hospitalisation, COVID-19 incidence, the recruitment strategy within hospitals and the number of participating hospitals/services per hospital.

We will report:

- number of participating hospitals and catchment population
- length of the surveillance period overall
- the number of patients recruited: total, eligible, enrolled overall, by age-group and by participating hospital
- percentage of eligible cases among SARI patients, by hospital
- reasons for non-inclusion

The description of cases (and deaths) will include the distribution by age, sex, hospital, week/month of symptom onset, chronic conditions, co-morbid respiratory infections, pregnancy, smoking status, vaccination status (BCG, influenza and pneumococcal vaccines), pre-symptomatic medications, complications, ICU admission, and death. These variables will also be used in WP4 for the study identifying risk factors for severe COVID-19.

For sites testing for other pathogens (multiplex RT-PCR), we will describe cases (co-infections) by pathogen identified.

3.5.7. Ethical considerations

Each surveillance site will comply with national ethics committee requirements. Where required, informed consent will be sought from all participants or legal tutors. The national ethics committees will specify whether oral, written, or no consent will be required. Specific consent procedures may be needed for unconscious patients and patients with deterioration of general condition or functional status, unable to sign the consent (e.g. oral witnessed consent, consent by the next of kin, etc). A copy of the ethical approvals should be sent to the coordinating centre.

- *Each surveillance site to describe the procedures to comply with the national ethics committee requirements and the type of informed consent needed as well as whether consent can be obtained for a legal tutor*
- *Each surveillance site to send a copy of the ethical approval to the coordinating centre*

3.5.8. Dissemination of results

The enrolment of patients to the surveillance system will be regularly updated by each site coordinator on a website developed for the multicentre study. Initial results will be disseminated as soon as feasible after the surveillance starts; further estimates will follow monthly (to be reviewed for feasibility) and at the end of the pandemic (final estimates).

The coordinating hub will only analyse and disseminate I-MOVE-COVID-19 results at site level (as opposed to a pooled analysis), if the site believes that this will provide an added value (e.g. to have all I-MOVE-COVID-19 country-specific data reported in the same place, or additional analyses carried out). Otherwise the coordinating hub will not disseminate the site level I-MOVE-COVID-19 data, but provide a link to a site-specific report or a website link. In some cases, the I-MOVE-COVID-19 coordination team will do both (analyse the data and provide a site-specific report/website link).

The results will be placed on the I-MOVE-COVID-19 website (https://www.imoveflu.org/i-move-covid-19/) with unrestricted access.

This report (in PDF) will also be uploaded onto the Zenodo platform as open access. Zenodo is a research repository launched in 2013 and hosted by CERN. It is GDPR-compliant and different access levels exist (https://about.zenodo.org/). Additionally, pooled (fully anonymised) surveillance data underpinning the reports will be made publicly available on the Zenodo platform, along with a data codebook and scripts where possible. This will enable validation of the reports and ensure transparency and reproducibility. It will also enable other researchers to access and use the data for COVID-19 research. Site-specific data will only be shared openly with the site's consent.

3.5.9. Publications, scientific communication

Results of the individual studies should only be published in open-source journals (this is a requirement of the European Commission's H2020 funding received for this surveillance project). Surveillance site coordinators can decide which scientific conferences will be attended in order to present the results. An article presenting the results of the pooled analysis and will be submitted to an open-source, peer-reviewed journal.

The list of authors will respect the recommendations of authorship stated by the International Committee of Medical Journal Editors (http://www.icmje.org/ethical_1author.html). The actual authorship for the pooled article will be discussed and agreed with the surveillance sites at the beginning of the study.

I-MOVE-COVID-19 results will be shared widely with other H2020 project teams and the public, as required by the European Commission's H2020 "open data" policy.

3.6. Training

Investigators and data collectors will be trained on the study protocol before the start of the surveillance. They will receive the protocol and questionnaires.

- *Each surveillance site to describe the training to be organised*

4. Logistical aspects

4.1. Surveillance site leader

In each surveillance site, a principal investigator will coordinate the surveillance at the country level and act as focal point for the European study. The coordinating team is in charge of the pooled analysis.

The National Centre for Microbiology, Instituto de Salud Carlos III, Madrid, Spain is in charge of compiling and summarising the genetic data from the study sites.

4.2. Human resources

In each hospital/hospital network, an investigator will be in charge of monitoring data collection at the hospital level. Surveillance investigators at the hospital will collect information from positive and negative patients. The specific human resources needed in each country are detailed in the study annexes. Public Health Scotland ensures the overall coordination of the various surveillance sites.

4.3. Supervision

Site visits and joint workshops (remote if required) will be organised by the coordinating team/surveillance sites in order to carry out an appraisal of the ongoing studies in the various countries involved. The appraisal team will be composed of two persons from the various project partners.

4.4. Respiratory specimen collection

By default, the respiratory specimen will be collected through nasopharyngeal swabbing or concurrent nasal and oropharyngeal swabbing (or endotracheal aspirates in ICU).

- *Each surveillance site to describe specimen collection procedures.*

4.5. Standard operating procedures

Standard operating procedures (SOPs) should be used by investigators during all the steps of the surveillance for identification of patients, recruitment, data collection, laboratory methods, data entry, monitoring, etc.

- *Each surveillance site to develop (or adapt pre-existing) surveillance SOPs to be used by the study team*

4.6. Site reports

Each surveillance site will write a report at the end of the pandemic and submit it to the study coordination team. Public Health Scotland will write a final report, presenting the results of the pooled analysis.

5. Limitations

5.1. Representativeness of subjects included in the study

The study includes only cases that are hospitalised for SARI. Containment and mitigation strategies for the COVID-19 pandemic may differ by country depending on the case management strategy (e.g. recommendation of contacting a GP or health centre by telephone first, vs staying at home until symptoms worsen then contacting emergency services). In some cases, the management strategy will have an impact on the delay between onset of symptoms and hospitalisation. This, in turn, may have an impact on the time lag between onset and respiratory specimen collection, and currently we do not know if this may affect positivity rates between surveillance sites. Beside the collection of dates of onset/admission/respiratory specimen collection, case-containment/ mitigation strategies should be described for each country.

- *Each surveillance site to describe the potential limitations in terms of representativeness of the subjects included*

5.2. Ascertainment of protective and risk factors

This surveillance protocol is the baseline for the severe COVID-19 risk factor study (WP4). It is not a requirement for participating sites in the I-MOVE-COVID-19 surveillance to participate in the risk factor study.

For sites choosing/able to participate in the risk factor study, all potential risk factors collected in the surveillance will be exposures of interest for the hospital-based risk factor study, and should therefore be checked carefully for e.g. information bias (for any items reported by a patient proxy and not recorded in notes, for example). When possible, characteristics such as vaccination status should be validated using an independent source (i.e. vaccination register, GPs). As not every surveillance site will participate in the risk factor study, this is only a requirement for those who will be part of the study.

- *Each surveillance site intending to participate in the risk factor study to describe the validation of each source of exposure and its potential limitations*

6. References

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8. Annexes

8.1. Annex 1: List of variables, definitions and coding; I-MOVE-COVID-19 hospital-based **surveillance** minimum dataset

Individual data (to be adapted to TESSy format)

- *Surveillance sites to list all the variables collected and their coding*
- *Surveillance sites to indicate all modifications in the variables collected compared to variables below*

Existing partners: in yellow highlight are new variables not collected for I-MOVE influenza (or coding changes)

	Variable	Type	Values and coding	Definition
Study identifiers	idcountry	Numeric (categorical)	Coded according to international country codes	Identifier uniquely identifying the country
	id	Numeric	Unique integer	Unique number for each patient
	hospitalcode	Numeric	Unique integer	Unique number for each hospital
	consent	Numeric	0 = No 1 = Yes 8 = Do not know	Agreement of patient to participate (where appropriate, i.e. in countries/sites where consent required for surveillance)
Hospital/ward information (see new vars added at end of this table)	prevhosp	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Prior admission to hospital (at least once in previous 12 months)
	admitdate	Date	dd/mm/yyyy	Date of hospital admission
	hospitalward	Text	THIS VAR HAS CHANGED	First ward of referral SEE END OF TABLE
	dischargedate	Date	dd/mm/yyyy	Date of hospital discharge
	icu	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Admission to intensive care unit (ICU) or high-dependency unit (HDU)
	icuadmitdate	Date	dd/mm/yyyy	Date first admitted ICU/HDU
	icudisdate	Date	dd/mm/yyyy	Date last discharged from ICU/HDU
	los_icu	Numeric (integer)		Length of stay in ICU/HDU (if no dates for ICU/HDU admission/discharge)
	swabdate	Date	dd/mm/yyyy	Respiratory specimen collection date
Patient characteristics	sex	Numeric	0 = female 1 = male 3 = other 8 = do not know	Sex of patient
	dob	Date	dd/mm/yyyy	Date of birth (only if no age; once age calculated from dob this will be dropped)
	age_y	Numeric		Age of patient (if unable to provide dob) in years for those aged 2 years and older
	age_m	Numeric		Age of patient (if unable to provide dob in months for those aged <2 years
	residence	Numeric	0 = at home, not dependent on home support/care 1 = at home, but dependent on home support/care 2 = institutionalised 3 = Do not know	Patient residence at time of SARI onset. Whether patient was living at home or was institutionalised, or had pre-hospital dependence on home support/care

	Variable	Type	Values and coding	Definition
Patient characteristics	postcode	Text		Postcode of residence (where possible)
	smoking	Numeric (categorical)	0 = Never 1 = Former 2 = Current 8 = Do not know	Never, former (stopped smoking at least 1 year before inclusion in the study), current smoker
	pregnant	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient is pregnant
	trimester	Numeric (categorical)	1 = Trimester 1 2 = Trimester 2 3 = Trimester 3 8 = Unknown trimester	Trimester of pregnancy
	postpartum	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient is within the first 6 weeks post partum
	hcw	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether the patient is a healthcare worker
Case/severity definitions (COVID or not)	lab_covtest	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Tested for SARS-CoV-2
	lab_covtesttype	Numeric (categorical)	1 = RT-PCR 2 = Serology 3 = Rapid test 4 = Other 8 = Do not know	Type of lab test used
	lab_covtesttype_sp	Text		Specify other type of lab test
	lab_covid	Numeric (categorical)	0 = Negative 1 = Positive 8 = Do not know	Laboratory result: virus type SARS-CoV-2
	covid	Numeric	0 = Not COVID-19 1 = Confirmed 2 = Probable 3 = Other coronavirus 4 = Suspected 8 = Do not know	Whether patient is a case of COVID-19 or not (this classification will be done by re-coding after data collection)
Case/severity definitions (SARI signs/ symptoms at admission)	feverishness	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Sub-febrility (37–38°C) (to construct SARI case definition)
	fever	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	History of fever (to construct SARI case definition)
	malaise	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Malaise (to construct SARI case definition)
	headache	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Headache (to construct SARI case definition)
	myalgia	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Myalgia (to construct SARI case definition)

	Variable	Type	Values and coding	Definition
Case/severity definitions (SARI signs/ symptoms at admission continued; onset date)	sorethroat	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Sore throat (to construct SARI case definition)
	cough	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Cough (to construct SARI case definition)
	suddenonset	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Sudden onset
	sob	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Shortness of breath (to construct SARI case definition)
	general_deter	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Deterioration of general condition (asthenia or loss of weight or anorexia or confusion or dizziness) (to construct SARI case definition)
	vomit	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Vomiting
	diarr	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Diarrhoea
	abdopain	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Abdominal pain
	ageusia	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Loss of sense of taste
	anosmia	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Loss of sense of smell
	onsetdate	Date	dd/mm/yyyy	Date of onset of symptoms
Case/severity definitions (severity indicators)	outcome	Numeric (categorical)	1 = Died in hospital 2 = Discharged from hospital 3 = Still on treatment 8 = Unknown outcome	Indicate the outcome of the patient known at the time of data collection (note: this may be updated later)
	deathdate	Date	dd/mm/yyyy	Date of death
	deathcause	Numeric (categorical)	1 = died from COVID-19 2 = died other cause 8 = died unknown cause	Cause of death
	vent	Numeric (categorical)	0 = No 1 = ECMO 2 = Oxygen (high-flow) 3 = Ventilator (non-invasive) 4 = Ventilator (invasive) 5 = Other 8 = Do not know	Patient's level of mechanical ventilation. Note that option 1 is for respiratory support level ECMO, option 2 includes any high-flow (6L/min or higher, including OptiFlow), and option 3 includes any non-invasive, positive pressure ventilator.
	vent_sp	Text		Specify other mechanical ventilation

	Variable	Type	Values and coding	Definition
Case/severity definitions (severity indicators continued)	vent_type		1 = PEEP 2 = BiPAP 3 = CPAP 4 = Other invasive ventilation	Type of invasive ventilation: positive end-expiratory pressure (PEEP), bilevel positive airway pressure (BiPAP), continuous positive airway pressure (CPAP) or other
	venttype_sp	Text		Specify other invasive ventilation type
	bilat_pneu	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Presence of bilateral pneumonia with ground-glass opacities (this classification will be done by re-coding after data collection)
Risk factors (close contact setting)	closecont	Numeric (categorical)	1 = Family setting 2 = Health care setting 3 = Workplace setting 4 = Long-term care facility 5 = Prison 6 = Other 8 = Do not know	Close contact setting with a person who is a probable or confirmed case in the 14 days prior to symptom onset
	closecont_sp	Text		Specify other close contact setting
Risk factors (exam/labs results on admission or during hospital stay)	ct_us_ecg	Numeric (categorical)	0 = No CT, u/s scan, CXR, ECG 1 = CT scan 2 = Ultrasound 3 = ECG 4 = Other 8 = Do not know 9 = Chest X-ray	Indicate whether patient had CT, ultrasound, Chest X-ray, ECG, or none of these (note: several selections may be made, e.g. if patient had CT and u/sound)
	ct_res	Numeric (categorical)	0 = Normal 1 = Bilateral lung involvement 2 = Peripheral lung distribution 3 = Ground-glass opacities 4 = Consolidation 5 = Other 6 = Infiltrates 8 = Do not know	CT, u/sound and CXR results. Ground-glass opacification defined as hazy increased lung attenuation with preservation of bronchial and vascular margins. Consolidation defined as opacification with obscuration of margins of vessels and airway walls
	ct_res_sp	Text		Specify other significant finding on CT/ultrasound/CXR
	cxr	Numeric (categorical)	0 = Not done 1 = No findings 2 = Infiltrates 3 = Other 8 = Unknown	Chest X-ray findings NOTE: This field is only for TESSy data so does **not** need to be completed if the combined (ct_res) results are completed (from which it can be populated later)
	cxr_sp	Text		
	examoth_sp	Text		List any other in-hospital examinations and their most significant findings
	ecg_qt	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Specify presence/absence of long QTc on ECG findings
	oxsat	Numeric (integer)		Patient's oxygen saturation on admission to hospital (on air), %
	seq	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient sample was sequenced/sent for sequencing
	genetic_group	Text		Laboratory result: genetic group

	Variable	Type	Values and coding	Definition
Underlying chronic conditions	anaemia	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Anaemia/chronic haematologic disease
	asplenia	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Asplenia (absence of/damage to spleen)
	asthma	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Asthma
	cancer	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Cancer (any)
	hypert	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Hypertension
	dement	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Dementia
	diabetes	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Diabetes
	heartdis	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Heart / cardiac disease (excluding hypertension)
	hypert	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Hypertension
	immuno	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	HIV (including other immunodeficiency, organ transplantation)
	liverdis	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Chronic liver disease (excluding cancer)
	lungdis	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Lung disease (excluding asthma)
	neuromusc	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Neuromuscular disorder
	height	Numeric (integer)		Height of patient in metres
	weight	Numeric (integer)		Weight of patient in kg
	bmi	Numeric (1 d.p)		BMI of patient (only if available in place of missing wt/ht)
	obese	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Obesity (only if height, weight and BMI not collected; can be calculated)
	rendis	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Renal disease (excluding cancer and acute renal failure)

	Variable	Type	Values and coding	Definition
Underlying chronic conditions (continued)	rheumat	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Rheumatologic disease
	Stroke	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Stroke
	tuberc	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Tuberculosis
Risk factors (in-hospital medications/ interventions)	ox_nasal	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Nasal oxygen (not high-flow)
	prone	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient was placed in prone position for ventilation
	nebu	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Nebuliser treatment

New variables added in v08:

	Variable	Type	Values and coding	Definition
Hospital/ward information	multiple_hosp	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient had >1 hospital admission for SARI or suspected COVID-19 as part of this current episode (> 14 days from onset)
	multiple_hosp	Numeric (categorical)	1 = Re-admission 1 2 = Re-admission 2 3 = Re-admission 3 4 = Re-admission 4 5 = Re-admission 5 6 = Re-admission 6 7 = Unknown re-admission number	Number of re-admissions (where known)
	hospitalward	Numeric (categorical)	0 = Special COVID-19 ward 1 = Lung, pulmonary or respiratory 2 = Internal medicine 3 = Infectious diseases 4 = Emergency or A&E 5 = Cardiology 6 = Geriatric 7 = Intensive care or high-dependency unit 8 = Do not know 9 = Other	First ward of referral
	hospitalward_sp	Text		Specify other first ward of referral

	Variable	Type	Values and coding	Definition
Prior healthcare contact	healthcare_contact	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient had any contact with their GP or other healthcare setting in the 14 days prior to admission
Symptoms at admission	chills	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	"Chills", shivering
	tach	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Tachypnoea or signs of low oxygen saturation
	coryza	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Coryza
	confusion	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Confusion
	dizzy	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Dizziness
	chest	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Chest pain
	palp	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Palpitations
	nausea	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Nausea
	conjunct	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Conjunctivitis
	dermato	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Rash or other dermatological manifestations of COVID-19
Laboratory results	pcr2	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether a second PCR was done (if first PCR was negative)
	lab_covidpcr2	Numeric (categorical)	0 = Negative 1 = Positive 8 = Do not know	Second PCR result for virus type SARS-COV-2

When a vaccine(s) become(s) available, these additional variables will be required:

	Variable	Type	Values and coding	Definition
Pandemic COVID-19 vaccination	panvaccany	Numeric (categorical)	0 = No	Received pandemic COVID-19 vaccination
			1 = Yes	
			8 = Do not know	
	panvaccdate1	Date	dd/mm/yyyy	Vaccination date first dose
	panvaccdate2	Date	dd/mm/yyyy	Vaccination date second dose
	panvacctype	Text		Type of vaccine (product name)
	panvaccdose	Numeric	0, 1, 2	Number of doses received

8.2. Annex 2: List of **additional** variables, definitions and coding to those provided in Annex 1, for the I-MOVE-COVID-19 hospital-based **severity risk factor** minimum dataset

Individual data (to be adapted to TESSy format)

- *Study sites to list all the variables collected and their coding*
- *Study sites to indicate all modifications in the variables collected compared to variables below*

Existing partners: in yellow highlight are new variables not collected for I-MOVE influenza (or coding changes)

	Variable	Type	Values and coding	Definition
Study identifiers	consent_sp	Text		Reason provided for non-participation
Patient characteristics	VAR CHANGED: SEE END OF THIS TABLE	Numeric (categorical)	To be updated with coding depending on score used	Clinical frailty score at admission (where possible)
Case/severity definitions (SARI signs/ symptoms **pre**-admission)	feverish_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Sub-febrility (37–38°C) (to construct SARI case definition)
	fever_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	History of fever
	malaise_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Malaise
	headache_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Headache
	myalgia_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Myalgia
	sorethroat_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Sore throat
	cough_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Cough
	suddenonset_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Sudden onset
	sob_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Shortness of breath
	general_deter_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Deterioration of general condition (asthenia or loss of weight or anorexia)
	vomit_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Vomiting

	Variable	Type	Values and coding	Definition
Case/severity definitions (SARI signs/ symptoms **pre**-admission continued)	diarr_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Diarrhoea
	abdopain_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Abdominal pain
	ageusia_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Loss of sense of taste
	anosmia_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Loss of sense of smell
	onsetdate_pre	Date	dd/mm/yyyy	Date of onset of symptoms
Risk factors (Pre-symptomatic treatment/intervention: medication)	statin_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Patient was on statins since or from 01 January 2020
	ace_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	ACE inhibitor (angiotensin converting enzyme inhibitors)
	arb_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	ARB (angiotensin II receptor blockers)
	nsaid_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	NSAID (non-steroidal anti-inflammatory drugs)
	metform_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Metformin
	steroids_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Steroids
	corticost_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Corticosteroids
	dmards_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Other biological disease-modifying anti-rheumatic drugs (DMARDs) e.g. rituximab
	chemo_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Chemotherapy (within 6 months or currently) for cancer
	gliclaz_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Gliclazides (for diabetes or heart failure)
	psychotrop_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Psychotropic drugs (including benzodiazepine, etc.)

	Variable	Type	Values and coding	Definition
Risk factors (Pre-symptomatic treatment/ intervention: medication continued)	other1_pre_sp	Text		Other pre-symptomatic medication #1
	other2_pre_sp	Text		Other pre-symptomatic medication #2
	other3_pre_sp	Text		Other pre-symptomatic medication #3
Risk factors (Pre-symptomatic treatment/intervention: vaccination)	flu_vacc	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Received current seasonal influenza vaccination
	flu_vaccdate	Date	dd/mm/yyyy	Date of last influenza vaccination
	ppv_vacc	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Received PPV23 vaccination
	ppv_vaccdate	Date	dd/mm/yyyy	Date of last PPV23 vaccination
	pcv_vacc	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Received PCV7/10 or 13 vaccination
	pcv_vaccdate	Date	dd/mm/yyyy	Date of last PCV7/10 or 13 vaccination
	bcg_vacc	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Received BCG vaccination
	bcg_vaccyear	Numeric	yyyy	Year of BCG vaccination
	bcg_scar	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Presence of BCG scar (if known, and if BCG unknown)
Risk factors (exam/labs results on admission)	confus	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient was confused at admission
	gcs_motor	Numeric (integer)		Glasgow Coma Scale (GCS) motor score on admission (range 0–6)
	gcs_verbal	Numeric (integer)		GCS verbal score (0–5) on admission
	gcs_visual	Numeric (integer)		GCS eye-opening score on admission (0–4)
	gcs	Numeric (integer)		GCS total score on admission (0–15). Can be calculated from M, V, E scores (provide either M, V, E **or** this total)
	avpu	Numeric (categorical)	0 = AVPU not done 1 = Alert 2 = Verbal 3 = Pain 4 = Unresponsive	AVPU score (Alert, Verbal, Pain or Unresponsive) on admission
	bloodurea	Numeric (integer)		Blood urea nitrogen (mmol/L)
	resprate	Numeric (integer)		Respiratory rate (breaths/min)
	bpsys	Numeric (integer)		Systolic blood pressure (mmHg)
	bpdia	Numeric (integer)		Diastolic blood pressure (mmHg)
	abo	Numeric (categorical)	0 = O 1 = A 2 = B 3 = Rh + 4 = Rh -	ABO blood grouping (Note: for AB, select both A and B)

	Variable	Type	Values and coding	Definition
Risk factors (exam/labs results on admission continued)	lymphoc	Numeric (integer)	OR: <500, 501-800, 801+	Lymphocyte count per µL
	plat	Numeric (integer)		Platelet count per µL
	neutro	Numeric (integer)		Neutrophil count per µL
	lft	Numeric (integer)	THIS VAR HAS CHANGED	Liver function test SEE END OF TABLE
	alp	Numeric (integer)		Alkaline phosphatase (ALP)
	ast	Numeric (integer)		Aspartate aminotransferase (AST)
	alt	Numeric (integer)		Alanine transaminase (ALT)
	ferritin	Numeric (integer)		Ferritin
	ldh	Numeric (integer)		Lactic acid dehydrogenase (LDH)
	dimer	Numeric (integer)		D-Dimer
	fibrin	Numeric (integer)		Fibrinogen
	eosin	Numeric (integer)		Eosinophil count per µL
	crp	Numeric (integer)		C-reactive protein
	cpk	Numeric (integer)		Creatine phosphokinase
	trop	Numeric (integer)		Troponin-I
	trigly	Numeric (integer)		Triglycerides
	ldl	Numeric (integer)		Cholesterol – high-density lipoprotein
	hdl	Numeric (integer)		Cholesterol – low-density lipoprotein
	nt_probnp	Numeric (integer)		N-terminal-prohormone B-type natriuretic peptide (NT-proBNP)
	hba1c	Numeric (integer)		Single glycated haemoglobin (HbA1c)
Risk factors (chronic conditions)	lungdis_sp	Numeric (categorical)	0 = No 1 = non-invasive ventilation/ oxygen therapy 2 = COPD 8 = Do not know	If lung disease: specify if use of non-invasive ventilation / oxygen therapy or chronic obstructive pulmonary disease (COPD)
Risk factors (other respiratory virses)	lab_fluany	Numeric (categorical)	0 = Negative 1 = Positive 2 = Not done 8 = Do not know	Laboratory result: any influenza virus type
	lab_mers	Numeric (categorical)	0 = Negative 1 = Positive 2 = Not done 8 = Do not know	Laboratory result: virus type MERS-CoV
	lab_othcov	Numeric (categorical)	0 = Negative 1 = Positive 2 = Not done 8 = Do not know	Laboratory result: virus type other coronavirus
	resp_virus	Numeric (categorical)	0 = None 1 = RSV 2 = Metapneumovirus 3 = Other respiratory infection 8 = Do not know	Which other non-influenza, non-coronavirus patient tests positive for

	Variable	Type	Values and coding	Definition
Risk factors (pre-symptomatic antivirals)	antivir_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Has the patient received an antiviral treatment within the 2 weeks before swabbing?
	antivirtype	Text		Type of antivirals (list brand names)
Risk factors (in-hospital medications/ interventions)	hydroxychl	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Hydroxychloroquine
	chlor	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Chloroquine
	cortico	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Corticosteroids
	il6	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Monoclonal antibodies/IL-6 blockers (e.g. tocilizumab)
	il6_type	Text		Specify brand names of IL-6 blockers and dose if possible
	antibiot	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Antibiotics (e.g. azithromycin)
	antibiot_type	Text		Specify brand names of key antibiotics and dose if possible
	antivir_med	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Antivirals e.g. remdesivir, ritonavir, lopinavir, favipiravir, umifenovir
	antivir_type	Text		Specify brand names of key antivirals with doses if possible
	sep_resus	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Sepsis fluid resuscitation
	study_convpl	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Use of study/trial drugs: convalescent plasma
	study_gm_csf	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Use of study/trial drugs: GM-CSF
	meds_oth1	Text		Specify any other important medications #1
	meds_oth2	Text		Specify any other important medications #2
	meds_oth3	Text		Specify any other important medications #3

	Variable	Type	Values and coding	Definition
Complications	complic	Numeric (categorical)	0 = None 1 = ARDS (acute resp distress syndr) 2 = Bronchiolotis 3 = Encephalitis 4 = Myocarditis 5 = Pneumonia (sec bacterial) 6 = Other sec bac infection 7 = Sepsis 8 = Acute renal injury 9 = Heart failure 10 = Multi-organ failure 11 = Dermatological 12 = ICU-relayed myopathy 13 = Other (specify)	Complications which the patient may have experienced at any time; note that option 11 refers to any dermatological manifestations of COVID-19
	complic_sp	Text		Specify other complication

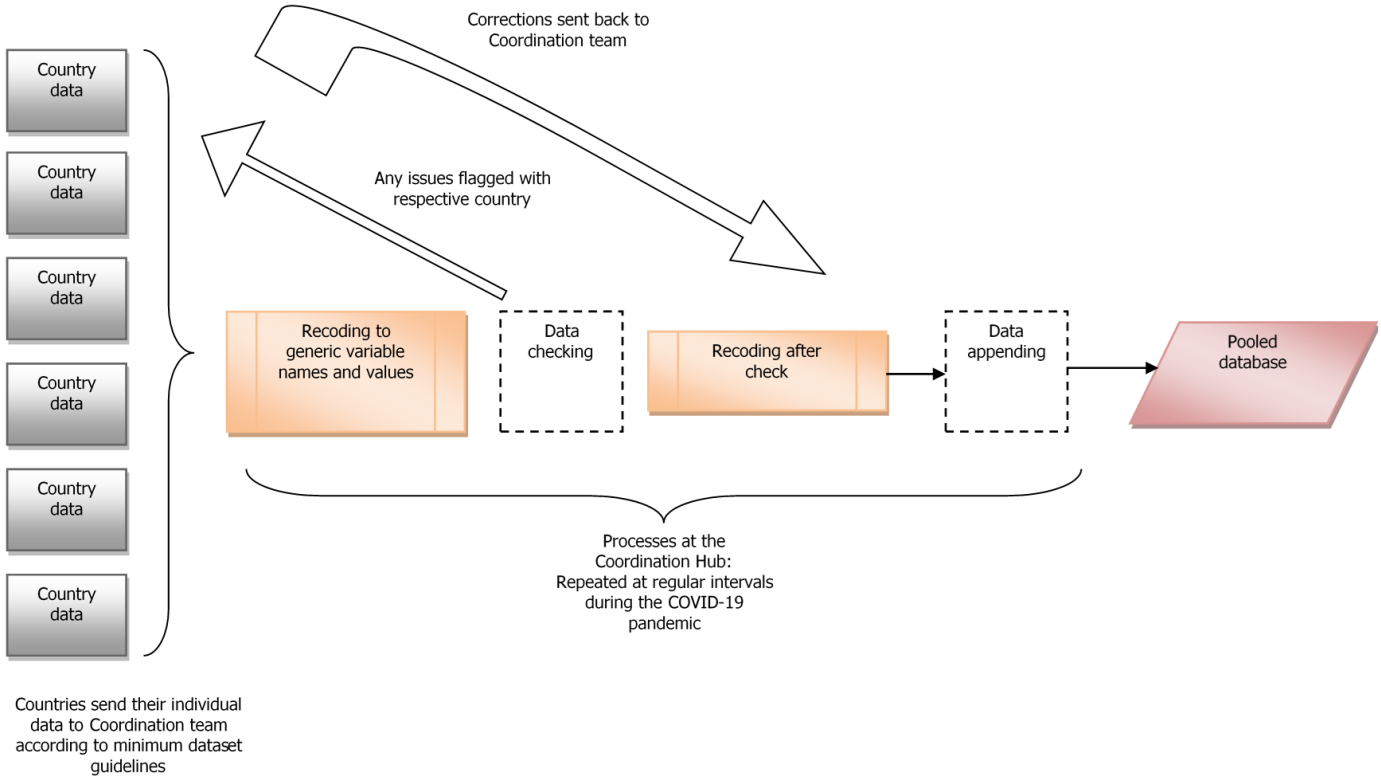
Variables added in v08:

	Variable	Type	Values and coding	Definition
Pre-symptomatic medication	chloroq_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient had chloroquine pre-symptoms
	hydroxychloroq_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient had hydroxychloroquine pre-symptoms
	il6_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether patient had monoclonal antibodies or IL-6 blockers (e.g. tocilizumab) pre-symptoms
	il6_pre_type	Text		Specify type of monoclonal antibody taken pre-symptoms
	corticost_pre_type	Numeric (categorical)	1 = Inhaled 2 = Systemic 3 = Other 8 = Do not know	Specify type of corticosteroids taken pre-symptoms
Frailty assessments	frailty_any	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether any type of clinical frailty score was used at admission to assess patient
	frailty_type	Numeric (categorical)	1 = Barthel Index 2 = Clinical Frailty Score (CFS) 3 = Other 8 = Do not know	Indicate which type of clinical frailty score was used
	frailty_sp	Text		Specify which other clinical frailty score was used
	frailty_barthel	Text		Barthel score at admission
	frailty_cfs	Text		CFS score at admission

	Variable	Type	Values and coding	Definition
Frailty assessments (continued)	gcs	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether GCS score was measured at admission
Case/severity definitions (SARI signs/ symptoms **pre**-admission)	confusion_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Confusion
	dizzy_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Dizziness
	chest_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Chest pain
	palp_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Palpitations
	nausea_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Nausea
	conjunct_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Conjunctivitis
	dermato_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Rash or other dermatological manifestations of COVID-19
	chills_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	"Chills", shivering
	tach_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Tachypnoea or signs of low oxygen saturation
	coryza_pre	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Coryza
Risk factors (exam/lab results on admission)	urea	Numeric (integer)		Urea (mmol/L)
	heartrate	Numeric (integer)		Heart rate (beats/min)
	lft_any	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether any liver function test (LFT) was performed
	lft_alb	Numeric (decimal)		Serum albumin g/dL
	lft_bili	Numeric (decimal)		Serum total bilirubin mg/dL
	lft_bili_conj	Numeric (decimal)		Serum conjugated bilirubin mg/dL
	lft_ggt	Numeric (integer)		GGT (gamma glutamyltransferase) IU/L
	lft_totprot	Numeric (integer)		Serum total protein g/L
	lft_prothromb	Numeric (decimal)		Prothrombin time
	bnp	Numeric (decimal)		B-type natriuretic peptide (BNP) pg/mL

	Variable	Type	Values and coding	Definition
Risk factors (**most pathologic** exam/labs results) Risk factors (**most pathologic** exam/labs results continued)	bloodurea_mp	Numeric (integer)		Blood urea nitrogen (mmol/L)
	urea_mp	Numeric (integer)		Urea (mmol/L)
	resprate_mp	Numeric (integer)		Respiratory rate (breaths/min)
	heartrate_mp	Numeric (integer)		Heart rate (beats/min)
	bpsys_mp	Numeric (integer)		Systolic blood pressure (mmHg)
	bpdia_mp	Numeric (integer)		Diastolic blood pressure (mmHg)
	plat_mp	Numeric (integer)		Platelet count per µL
	lymphoc_mp	Numeric (integer)	0 = <500 1 = 501-800 2 = 801+	Lymphocyte count per µL
	neutron_mp	Numeric (integer)		Neutrophil count per µL
	eosin_mp	Numeric (integer)		Eosinophil count per µL
	lft_any_mp	Numeric (categorical)	0 = No 1 = Yes 8 = Do not know	Whether any liver function test (LFT) was performed
	lft_alb_mp_mp	Numeric (decimal)		Serum albumin g/dL
	lft_bili_mp	Numeric (decimal)		Serum total bilirubin mg/dL
	lft_bili_conj_mp	Numeric (decimal)		Serum conjugated bilirubin mg/dL
	lft_ggt_mp	Numeric (integer)		GGT (gamma glutamyltransferase) IU/L
	lft_totprot_mp	Numeric (integer)		Serum total protein g/L
	alp_mp	Numeric (integer)		Alkaline phosphatase (ALP)
	ast_mp	Numeric (integer)		Aspartate aminotransferase (AST)
	alt_mp	Numeric (integer)		Alanine transaminase (ALT)
	lft_prothromb_mp	Numeric (integer)		Prothrombin time
	ldh_mp	Numeric (integer)		Lactic acid dehydrogenase (LDH)
	ferritin_mp	Numeric (integer)		Ferritin
	dimer_mp	Numeric (integer)		D-Dimer
	fibrin_mp	Numeric (integer)		Fibrinogen
	crp_mp	Numeric (integer)		C-reactive protein
	cpk_mp	Numeric (integer)		Creatine phosphokinase
	trop_mp	Numeric (integer)		Troponin-I
	hba1c_mp	Numeric (integer)		Single glycated haemoglobin (HbA1c)
	trigly_mp	Numeric (integer)		Triglycerides
	ldl_mp	Numeric (integer)		Cholesterol – high-density lipoprotein
	hdl_mp	Numeric (integer)		Cholesterol – low-density lipoprotein
	nt_probnp_mp	Numeric (integer)		N-terminal-prohormone B-type natriuretic peptide (NT-proBNP)
	bnp_mp	Numeric (decimal)		B-type natriuretic peptide (BNP) pg/mL

8.3. Annex 3. Data flow for pooled dataset



8.4. Annex 4: Genetic and antigenic analysis data (example)

COVID-19	Country	Region/ City	GISAID EpiCoV number	ID number I-MOVE-COVID-19 surveillance	Date sample	Strain	CT value
Row for 2020 vaccine reference strain							
Row for strain with substitutions compared with vaccine reference strain							

8.5. Annex 5: Surveillance indicators

- Description of participating hospitals/sites
    - Number and % of participating hospitals/sites
    - Mean and total size of catchment population for participating hospitals, by country/site and pooled overall
    - Total and mean number of suspected, probable and confirmed cases reported by hospital/site
        - overall and by month

- Description of cases by week/month (and by sex and age-group) overall and by hospital/site for suspected COVID-19 patients
    - Number and % tested for SARS-COV-2

- Description of cases by week/month (and by sex and age-group) overall and by hospital/site for probable and confirmed COVID-19 patients
    - Number and % overall for each type of patient
    - Number and % by ward type (non-ICU, ICU/HDU)
    - Number and % by type of residence at SARI onset (if possible)
    - Median length of stay in hospital (overall) and in ICU/HDU
    - Incidence for each main outcome (discharge/death) by week/month by surveillance site

- Description of cases by clinical characteristics for probable and confirmed COVID-19 patients
    - Number and % overall, by hospital and by surveillance site
        - by symptoms/groups of symptoms at admission
        - by ultrasound result, lung CT scan on admission
        - by severe outcome (bilateral pneumonia with ground-glass opacities, ICU/HDU, ventilation, ECMO, death)

- Description of cases (for all outcomes) by preventive and risk factors for confirmed and probable
    - Number and % of COVID-19 patients by
        - age-group, sex
        - chronic conditions (none/one, >one; individual; grouped immunocompromised vs immunocompetent)
            - by treatment for chronic conditions, if available
        - pregnant women
        - smoking status
        - healthcare worker
        - close contact setting
        - PCR, serology results on admission

        - respiratory support (oxygen, high-flow, (non-)invasive ventilation, prone position, nebuliser, ECMO)

- Laboratory indicators
    - Number of cases by test performed? (if several tests are used?)
    - Other respiratory viruses (co-infections)
    - Number of cases by sequence type (if/when available)

8.6. Annex 6: Study-specific annexes

Study specifications for each country are summarised in the annexes. Each surveillance site annex should include:

- description of the hospitals participating in the study (wards involved, bed capacity, catchment population, detailed mode of recruitment including the use of computerised system to identify SARI patients)
- definition of beginning of pandemic
- pandemic (when applicable) vaccines used
- vaccine status ascertainment method
- details on methods for data collection, data entry and data transmission
- data validation procedures
- laboratory issues (laboratory performing tests; tests used: PCR, culture, strain characterisation; methods for specimen collection, storage, transport; selection procedures for strain characterisation)
- consent, ethical procedures (oral/written consent; submission to ethics committee)
- human resources needed
- provisions to train hospitals.

8.7. Annex 7: Summary of study on risk factors for severe COVID-19 among hospitalised COVID-19 patients

The objective of the risk factor study is to identify key risk and protective factors against **severe** outcomes in order to guide patient management though improved understanding of which target groups are at risk for severe disease.

This study is complementary to the I-MOVE-COVID-19 study on risk factors for hospitalisation and death among primary care patients.

The study of risk factors for severe disease among hospitalised COVID-19 patients is a cohort study. Among the cohort of probable and laboratory-confirmed COVID-19 patients in participating hospitals, the severe outcomes of hospitalisation will be sought: ICU/HDU admission, ventilation, ECMO and/or death.

Among this cohort of severe COVID-19 patients, early risk and protective factors for each outcome will be measured using multivariable regression models. For full details, please see the draft generic protocol for the European study of risk factors for severe disease among hospitalised COVID-19 patients.

8.8. Annex 7: History of changes to the generic surveillance protocol

The broad adaptation and use of this generic protocol led to identifying potential points of improvement. This paragraph aims at listing the changes brought to the protocol throughout its use. Changes are displayed in red text.