The COVID-19 Critical Care Consortium observational study: Design and rationale of a prospective, international, multicenter, observational study

SUPPLEMENTAL FILES
SUPPLEMENT 1

STUDY PROTOCOL
Covid-19 Critical Care Consortium
Observational Study

Incorporating the
ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus
Acute Respiratory Disease

v. 1.2.8

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ACTRN12620000421932
Version 1.2.8
23 May 2020

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ACTRN12620000421932
Version 1.2.8
23 May 2020
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# Summary

**Scientific Title**
Covid-19 Critical Care Consortium
Incorporating the
ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (ECMOCARD)

**Study Design**
Prospective/Retrospective multi-centre short period incidence observational study of patients in participating hospitals and intensive care units (ICUs) with 2019 novel coronavirus (COVID-19).

**The Collaborative**
In response to the COVID-19 outbreak and to assist in pandemic planning both locally and globally, a research collaborative has been assembled. The collaborative consists of investigators from the Asia-Pacific extracorporeal life support organization (APELSO) in collaboration with centres within the SPRINT-SARI and ISARIC Network. In Australia, this study will be also complemented through collaboration with the “National registry on the treatment and outcomes of patients requiring ECMO” (EXCEL Registry).

**Study Aim and Objectives**
To describe clinical features; severity of pulmonary dysfunction; incidence of ICU admission and use of mechanical ventilation, coagulatory and thrombotic derangement, and ECMO technical characteristics; duration of ECMO; complications; and survival of patients with COVID-19.

**Inclusions/Exclusions**
All patients admitted to ICU with clinical suspicion or lab-confirmed COVID-19 infection by real-time PCR and/or next-generation sequencing will be included. Patients receiving mechanical ventilation or ECMO for other concomitant causes will be excluded.

**Consent**
Given the negligible risk associated with this study and the timely nature in which the data needs to be collected, a waiver of consent is sought.

**Study Setting**
International multi-centre study, conducted in all collaborating hospitals/ICU-based research networks in Asia, Australia and New Zealand, Europe.

**Sample Size**
All patients with confirmed COVID-19 infection admitted to ICUs at the collaborative centres.

**Study Start Date**
From the commencement of COVID-19 global epidemic

**Study Duration**
Until completion of COVID-19 global epidemic, as judged by the World Health Organization

ACTRN12620000421932
Version 1.2.8
23 May 2020
Patients will be studied from time of ICU admission until hospital discharge or up to 28 days post ICU admission, whichever occurs later. All clinical information will only be recorded if taken as part of routine clinical practice at each site. Only re-identifiable data will be submitted centrally (REDCap hosted at Oxford University for International centres and at Monash University for Australian centres). A specific ECMOCARD Case Report Form (CRF) will be used by participating sites to collect a minimum data set of ICU, mechanical ventilation and ECMO data. Data for ECMOCARD and SPRINT SARI observational study will be concomitantly collected. Data will be recorded into REDcap through standard data collection or interactive augmented human experience via digital interaction by voice or touch monitors or digital transcription of CRF hard copies. In Australia, patients concomitantly included into the EXCEL registry, EXCEL data will be requested to complement ECMOCARD data and reduce daily workload.
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Introduction

The ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (ECMOCARD Trial) will be carried out within the network and web-based case collection forms of the ISARIC consortium’s SPRINT-SARI study and in Australian and New Zealand centres, upon conclusion of the epidemics, potentially complemented through the study “A comprehensive national registry on the treatment and outcomes of patients requiring ECMO” (EXCEL Registry).

International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC)

The International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) was formed in 2011, in response to global recognition of the unmet need for timely and effective clinical research during outbreaks of emerging infectious disease with epidemic or pandemic potential. ISARIC represents a new paradigm for effective, coordinated, and timely collaborative clinical research during rapidly emerging threats to public health. It is collaboration among clinicians, clinical researchers, epidemiologists, ethicists, statisticians, laboratory-based clinicians, basic scientists, and public health experts. The mission of ISARIC is to develop operational readiness and to co-ordinate the conduct of essential clinical research to characterise and respond to new epidemic or pandemic infectious disease threats, thereby informing and guiding evidence-based optimal management. ISARIC is facilitating the coordination of SPRINT-SARI, which supports ISARIC’s goal of improving the effectiveness of clinical researching globally during a pandemic by:

1. Establishing protocols, with standardised definitions and study methods, for conducting time-critical research during outbreaks of emerging infectious diseases;
2. Coordinating a large number of globally diversified hospitals and/or ICU-based networks with pre-existing ethics, administrative, regulatory and logistics in place, sufficient to implement study protocols, especially including regions where this type of clinical research has traditionally not been performed;
3. Identifying and solving barriers to pandemic research, including those identified in SPRINT-SARI;
4. Studying SARI globally, providing evidence on SARI microbiology, treatment and outcome in both resource-rich and resource-poor settings;
5. Allowing ISARIC to evaluate its research capacity and capabilities; and
6. Assisting ISARIC to maintain network stakeholders during inter-pandemic periods.

**Short PeRiod IncideNce sTudy of Severe Acute Respiratory Infection (SPRINT-SARI)**

Severe acute respiratory infection (SARI) continues to be of major relevance to public health worldwide. In the last 10 years there have been multiple SARI outbreaks around the world. The 2009 H1N1 pandemic was estimated to result in more than 200,000 respiratory deaths globally. The World Health Organization (WHO) defines SARI as an acute respiratory infection of recent onset (within 10 days) requiring hospitalisation, manifested by fever (\(\geq 38^\circ\text{C}\)) or a history of fever and cough. There is international consensus that it is important to undertake observational studies of patients with SARI as an essential component of pandemic and epidemic research preparedness.

The primary aim of the SPRINT-SARI study was to establish a research response capability for future epidemics/pandemics through a global SARI observational study. The secondary aim of this study was to describe the clinical epidemiology and microbiology profiles of patients with SARI. The tertiary aim of this study was to assess the Ethics, Administrative, Regulatory and Logistic (EARL) barriers to conducting pandemic research on a global level. SPRINT-SARI was designed as a multi-centre, prospective, short period incidence observational study of patients in participating hospitals and intensive care units (ICUs) with SARI. The study period was planned to occur, in both Northern and Southern hemispheric winters. The study period comprised a 5 to 7-day cohort study in which patients meeting a SARI case-definition, who are newly admitted to the hospitals/ICUs at participating sites, will be included in the study. The study was planned to be conducted in 20 to 40-hospital/ICU-based research networks globally. All clinical information and sample data were planned to only be recorded if taken as part of the routine clinical practice at each site and only fully anonymised and re-identifiable data will be submitted centrally. The primary outcome of SPRINT-SARI was to test the feasibility of conducting a global study of SARI.

**Secondary Outcomes:**

1. Incidence of SARI
2. Disease severity and risk factors for severe disease due to SARI
3. Case Fatality Proportion of SARI
4. Duration of ICU/hospital stay due to SARI

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5. Microbiology of SARI, including variability in testing
6. Treatments received during hospitalization for SARI
7. Evaluate impact on incidence of alternative case-definitions of SARI
8. Evaluate the operational characteristics of this study, including CRF, Completion Guidelines, and entry criteria to provide information by which iterative improvement in study design can be achieved.
9. Explore the feasibility of extrapolation of results obtained at participating sites to population levels

**Coronaviruses**

Coronaviruses are a family of enveloped, single-stranded, positive-strand RNA viruses classified within the Nidovirales. Coronaviruses may infect mammals and birds, triggering respiratory, enteric, hepatic, and neurologic diseases. Six coronavirus species are known to cause human disease. The coronaviruses 229E, OC43, NL63, and HKU1 are prevalent worldwide and most commonly cause only marginal respiratory symptoms. Two other strains, the severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) have originated from animal to human transmission and have caused more serious, sometimes fatal, respiratory illnesses. In previous years, SARS-CoV\(^8,9\) and MERS-CoV\(^10,11\), have caused serious respiratory infections, with mortality rates of 10% for SARS-CoV\(^12\) and 37% for MERS-CoV\(^13\).

**2019 Novel Coronavirus (COVID-19)**

In late December, 2019, in Wuhan, Hubei, China, a new respiratory syndrome emerged with clinical signs resembling viral pneumonia and person-to-person transmission\(^14\). Prompt diagnostic methods, through deep sequencing analysis from lower respiratory tract samples, corroborated emergence of a novel coronavirus, namely the 2019 novel coronavirus (COVID-19). In particular, Na Zhu and collaborators\(^15\) were able to isolate the virus from bronchoalveolar lavage (BAL) from patients with pneumonia of unknown cause, who were in Wuhan on December 21, 2019 or later, and who had been present at the Huanan Seafood Market. RNA extracted from BAL fluid from the patients was used as a template to clone and sequence a genome using a combination of Illumina sequencing and nanopore sequencing. More than 20,000 viral reads from individual specimens were obtained, and most contigs

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matched to the genome from lineage B of the genus betacoronavirus — showing more than 85% identity with a bat SARS-like CoV (bat-SL-CoVZC45, MG772933.1) genome. Virus isolation from the clinical specimens was performed with human airway epithelial cells and Vero E6 and Huh-7 cell lines. 2019-nCoV–infected human airway epithelial cultures were examined with light microscopy and with transmission electron microscopy 6 days after inoculation. Cytopathic effects were observed 96 hours after inoculation on surface layers of human airway epithelial cells and lack of cillum beating was seen with light microscopy (Fig. 1).

**Figure 1**

![CPE](image)

Figure 1: Cytopathic effect of the novel coronavirus, as reported in previous publication. 

Through transmission electron microscopy, the authors were able to image the COVID-19 particles, that generally appeared spherical, of 60 to 140 nm, with some pleomorphism and distinctive spikes, about 9 to 12 nm (Fig. 3), and gave virions the appearance of a solar corona. This morphology corroborated the Coronaviridae family.

**Figure 2**

![TEM](image)

Figure 2: A: COVID-19 particles are depicted. B: COVID-19 in human airway epithelium, as reported in previous publication.
Finally, investigators carried out inclusive phylogenetic analysis that showed that COVID-19 falls into the genus betacoronavirus, which includes coronaviruses as SARS-CoV, bat SARS-like CoV, and others from humans, bats, and other wild animals.

Thus far, more than 111,000 confirmed cases, including health-care workers, have been identified worldwide, and several exported cases have been confirmed in other provinces in China, Thailand, Japan, South Korea, Germany, Italy, France, Iran, USA and many other countries. An early case report in 41 patients with laboratory-confirmed COVID-19 infection in Wuhan has been reported. The median age of the patients was 49 years and mostly men (73%). Among those, 32% were admitted to the ICU because they required high-flow nasal cannula or higher-level oxygen support measures to correct hypoxaemia. Less than half had underlying diseases, including diabetes (20%), hypertension (15%), and cardiovascular diseases (15%). On admission, 98% of the patients had bilateral multiple lobular and subsegmental areas of consolidation (Figure 3).

**Figure 3**

![Figure 3](image_url)

Figure 3 Caption: Transverse chest CT images from a 40-year-old man showing bilateral multiple lobular and subsegmental areas of consolidation on day 15 after symptom onset. Transverse chest CT images from a 53-year-old woman showing bilateral ground-glass opacity and subsegmental areas of consolidation on day 8 after symptom onset, adapted from.

Importantly, acute respiratory distress syndrome (ARDS) developed in 29% of the patients, while acute cardiac injury in 12%, and secondary infection in 10%. Invasive mechanical ventilation was required in 10% of those patients, and two of them (5%) had refractory hypoxaemia and received extracorporeal membrane oxygenation (ECMO).
In a later retrospective report by Wang and collaborators\textsuperscript{25}, clinical characteristics of 138 patients with COVID-19 infection were described. Those patients were admitted at Zhongnan Hospital of Wuhan University in Wuhan, China, from January 1 to January 28, 2020. The median age was 56 years and clinical signs of the infection comprised fever (98.6%), fatigue (69.6%), and dry cough (59.4%). Interestingly, lymphopenia occurred in 70.3% of the patients, prolonged prothrombin time 58%, and elevated lactate dehydrogenase 39.9%. ICU admission was required in 26.1% of the patients for acute respiratory distress syndrome (61.1%), arrhythmia (44.4%), and shock (30.6%). Among these patients, 11.1% received high-flow oxygen therapy, 41.7% noninvasive ventilation, and 47.2% invasive ventilation. ECMO support was needed in 11% of the patients admitted to the ICU. During the period of follow-up, overall mortality was 4.3%.
Objectives

Hypothesis

We hypothesize that a significant percentage of patients with COVID-19 infection will require admission to the intensive care unit, mechanical ventilation and ECMO for refractory hypoxemia, in addition a substantial proportion of patients will present coagulation disorders and thrombosis.

Aims

This is a multi-centre international study in patients with suspected or confirmed COVID-19 who require admission to the intensive care unit, mechanical ventilation and/or ECMO to characterize the following features:

1. Incidence of ICU admission, use of mechanical ventilation and ECMO
2. Risk factors
3. Clinical features
4. Coagulation disorders and thrombosis
5. Severity of respiratory failure
6. Need for non-invasive and invasive mechanical ventilation and ECMO
7. Settings of invasive mechanical ventilation
8. ECMO technical characteristics
9. Duration of ECMO
10. Complications
11. ICU survival
12. Hospital survival.
13. Requirements and the time frame for approvals in each participating network region

Materials and Methods

Study Design

This is an international multi-centre, prospective/retrospective observational study of patients in participating hospitals and ICUs with suspected or confirmed COVID-19 infection. The study will be conducted at 20 to 90 hospital networks globally and will aim to recruit as many patients as possible. The aim is to recruit all eligible patients at each study location and
there is no maximum number of patients that can be recruited from any one site. Patients will be studied from time of ICU admission up to 28 days or until hospital discharge, whichever occurs later. Information will be collected on demographics, co-existing illnesses, severity of illness, source and type of clinical specimens (upper versus lower respiratory tract and collection date), results of microbiological tests. ECMOCARD will specifically focus on collecting data of mechanical ventilation and ECMO and administration of other major therapies (including vasoactive therapies, hypoxaemia rescue therapies, and dialysis), administration of antibiotics and antivirals (and adjunctive therapies, e.g. immunomodulators, corticosteroids) and outcomes at ICU (if applicable), hospital discharge and 28 days.

Research centres

This is a collaborative effort among investigators of the Asia-Pacific extracorporeal life support organization (APELSO) in collaboration with centres within the SPRINT-SARI and ISARIC Network.

Study Population

We plan to recruit as many patients as possible of the patients with COVID-19 infection admitted to the ICU, in as many locations as possible, who meet the inclusion criteria with no-exclusion criteria at the participating sites. It is anticipated that each participating Institution could contribute between 5 and 50 patients. Each site’s recruitment will be determined by the incidence of the disease during the study period, and their ability to collect the required data.

Inclusion Criteria

1. Clinical suspicion or laboratory-confirmed COVID-19 infection by real-time PCR and/or next-generation sequencing
2. Admission to an intensive care unit

Exclusion Criteria

3. Patients treated with mechanical ventilation for other concomitant causes
4. Patients treated with ECMO for other concomitant causes

Co-enrolment

This is an observational study. Co-enrolment with other studies including interventional clinical trials is accepted.

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Ethics

Guiding Principles

The Chief Investigators and study management team are responsible for ensuring the study is performed in accordance with the protocol. This study is to be performed in accordance with the ethical principles of the Declaration of Helsinki (June 1964, most recently amended in October 2013), and the most recent, relevant ethical conduct of research guidelines published in the country of the participating site. The Principal Investigator at each site is responsible for maintenance of a securely held enrolment log linking the patient hospital record number and the study number as per their countries research guidelines.

Comply with all local requirements

National or regional Co-ordinators in their defined location will be responsible for clarifying the requirements for ethics approval. It is the responsibility of the site Chief Investigator and Research Co-ordinator to ensure ethics approval has been granted prior to commencing the study and all local requirements are addressed. Each participating site will require ethics approval for this protocol and data collection of the ECMOCARD and ISARIC SPRINT-SARI CRF (RAPID, CORE, SUPPLEMENTARY TO CORE, DAILY and EPIDEMIOLOGY) and any other study documents relevant to their region. When possible, each participating study site will be supported by the ECMOCARD, Project Officer with their application. The Principal Investigator will produce progress reports, and any other required documentation for the local independent Ethics Committee in accordance with their guidelines. It is the responsibility of the Chief Investigator at each participating hospital to keep an up to date record of all correspondence and applicable documentation with the local Independent Ethics Committee. We will be collecting data on the requirements and the time frame for approvals in each participating network region.

Confidentiality of patient data

No identifying data will be entered into the central database. Participants’ names will not be collected, and confidentiality of information in medical records will be preserved. The confidentiality of the participant will be maintained unless disclosure is to comply with the law. To adhere to international ethical review board requirements and facilitate global ECMOCARD and SPRINT-SARI ISARIC data polling/sharing the CliRes Data Management
System will convert all dates entered (DD/MM/YYYY) into the eCRF into a re-identifiable format (D1, D2) at a system level. The original entered data (DD/MM/YYYY) will only be accessible by the site Research Co-ordinator and the site Principal Investigator using their unique database account details. **In Australia, re-identifiable data will be entered into a central REDCap database hosted by Monash University and harmonised with the SPRINT-SARI study.**

**Rule of Transfer**

It is proposed that if a patient is transferred from a facility participating in ECMOCARD and SPRINT-SARI to another facility that is also participating, the patient’s previously allocated patient ID number will be documented in the CRF completed by the receiving hospital at time of admission. All sites participating in SPRINT-SARI will be asked to include a ECMOCARD and SPRINT-SARI study information sheet in the patients transferring documents, notifying the new hospital of the patient’s inclusion in ECMOCARD and SPRINT-SARI, the patients re-identifiable participation number, the contact details of the Principle Investigator of ECMOCARD and SPRINT-SARI in the country and the ECMOCARD and SPRINT-SARI coordinating centre. If you are unsure if a patient has previously been enrolled in ECMOCARD and SPRINT-SARI please check to see if the patients transferring hospital and ward/unit are included in the participating sites list on the ECMOCARD and SPRINT-SARI website (www.sprintsari.org). Please use the patients existing ECMOCARD and SPRINT-SARI participant number at the new hospital when entering data into the paper and/or eCRF. Sites will not have access to any data collected outside their hospital; it is the responsibility of each hospital to enter data pertaining to their component of the patient’s hospital admission. If a patient is transferred to a non-participating hospital, there will be no further data collection.

**International waiver of informed consent**

It is expected that this study will not require individual patient consent. This study is in effect a large-scale clinical audit, as all data is already recorded as part of routine clinical care, therefore justifying participant enrolment using a waiver of consent. Waiver of consent may be available for studies that submit only re-identifiable information and where involvement in the research carries no more than low risk. Any location that deems individual consent necessary can use potential forms reported in the Appendix A. In particular, only in

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patients who meet the inclusion/exclusion criteria, informed consent will be obtained directly from the patient, either before the study or retrospectively in case the patient is unconscious at the time of enrolment. If the patient is unable to provide a consent form upon admission, informed consent will be obtained by his/her next of kin.

Informed Consent in Australia

In Australia all patients admitted to the ICU and meeting all inclusion and no exclusion criteria will be included in ECMOCARD observational study. Their hospital data will be included under a waiver of consent, in line with the National Statement (chapter 2.3) and the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities, 2014.

Data for ECMOCARD and SPRINT SARI observational study will be concomitantly collected. In addition, to minimise workload for site staff, whenever possible, EXCEL data will be requested to complement ECMOCARD data. SPRINT-SARI and EXCEL have both been approved to recruit patients under a waiver of consent. Yet, it is important to emphasize that ethics approval certificate for Project 202/16 has the following special condition: “A waiver of the requirement for consent was granted for the collection and use of identifiable information during relevant epidemics and pandemics. An opt-out approach will be used at all other times.”

Data Collection

ISARIC Data Collection

As detailed in following paragraphs, we will collect data prospectively or retrospectively on patient demographics including age, sex, height, weight, and ethnicity, as well as the presence of predefined comorbidities. General data will be collected from each site using the SPRINT-SARI data tool, namely the WHO and ISARIC NOVEL CORONAVIRUS (nCoV) ACUTE RESPIRATORY INFECTION CLINICAL CHARACTERISATION (https://isaric.tghn.org/novel-coronavirus/). As shown in figure 4, SPRINT-SARI data collection will start upon admission to the Hospital. The CRF was assembled by ISARIC members on the basis of the WHO natural history protocol, INFINITE (ANZICS), MOSAIC and others5–26. The CRF was assembled to be a basic CRF with the aims of avoiding data duplication, and with the intention of being user friendly and applicable in all settings, regardless of the resources available27. The CRF has previously been used in Singapore, New
Zealand, Saudi Arabia, Vietnam, and North America and adapted by a working group for the purposes of this study with ISARIC approval to all changes made. In 2020, with the emergence of the COVID-19 epidemics, the ISARIC CRF eCRF were modified in order to characterize patients with this infection. In addition, Chief Investigators of the ECMOCARD trial further improved the ISARIC CRF eCRF to specifically describe COVID-19 patients admitted to the ICU and undergoing mechanical ventilation and ECMO.

ECMOCARD Data Collection

Streamlined data-collection instruments and procedures will be used in an attempt to minimise the work in study centres. Specifically, we will collect data on the timing of ICU admission, endotracheal intubation, mechanical ventilation and ECMO commencement in relation to presumed onset of symptoms and hospital admission. We will investigate whether invasive mechanical ventilation and ECMO treatment was commenced in the participating hospital or whether the patient was retrieved and transferred while receiving invasive mechanical ventilation and/or ECMO from a referral centre. Severity of illness before endotracheal intubation and before ECMO will be investigated by respiratory rate, severity of hypoxemia, hypercapnia, non-pulmonary vital organ support, ventilator settings, and use of rescue ARDS therapies in the 12 hours before ECMO commencement. Dynamics of invasive mechanical ventilation and ECMO treatment will be recorded and characterized from commencement of invasive mechanical ventilation up to discontinuation (Figure 4). We will also collect administration of antiviral and antibiotic medications. Finally, duration of mechanical ventilation, ECMO, ICU and hospital stay, ICU and hospital mortality will be documented. In patients who died during hospital admission, we characterized the mode of death from a list of predefined options. Of note, in Australian centres, patients enrolled into the study “A comprehensive national registry on the treatment and outcomes of patients requiring ECMO (EXCEL Study) will be identified by the ECMOCARD eCRF. Likewise, in the EXCEL study eCRF, a specific question will be added to identify patients enrolled in the ECMOCARD. Thus, we will complement ECMOCARD CRF with data collected through the EXCEL study.
Coagulation Disorders and Thrombosis Sub-study Data Collection

In collaborative centres that routinely perform rotational thromboelastometry (ROTEM) or thromboelastography (TEG) in their clinical practice, we will carry out an additional observational sub-study to appraise coagulation disorders and/or pro-thrombotic risks in COVID-19 patients in the ICU. As detailed in following paragraphs, upon admission to ICU, and every 24 hours thereafter, we will collect data prospectively or retrospectively on coagulation disorders and pro-thrombotic risks until discontinuation of mechanical ventilation or in case of patients who are not mechanically ventilated, until 7 days post-ICU discharge. In addition, in centres that routinely use ROTEM, within 1h from a clinically relevant thrombosis/embolism or bleeding event, and 6h prior to commencement of ECMO, we will perform an additional ROTEM assessment to record TRAPTEM AUC, A6 and MS parameters. **Data for the Coagulation Disorders and Thrombosis Sub-study will be collected**
from each collaborating site using the dedicated REDcap CRF, hosted at the University of Queensland.

Data collection methods

Each site will have the option to collect data via Option 1 alone OR Option 1 +2. The method chosen will be a decision made at a site level. The options for data collection are as follows:

**OPTION 1: Standard Data Collection**

Both the SPRINT-SARI ISARIC and ECMOCARD CRF will be made available at all participating sites as a paper CRF. The SPRINT-SARI ISARIC and ECMOCARD CRFs will be available in a variety of languages and will be translated into languages appropriate for all participating sites. The translation of the paper and electronic CRFs from English into the required language will be the responsibility of the national lead investigators and collaborators of the Critical Care Research group and checked for consistency by an appropriate investigator in the relevant country. All data will be collected by trained staff at each study site and these individuals will enter all required data described in the protocol into the CRFs directly from the source data. Trained staff at sites with the IT capabilities can enter all required data directly into the protected online database, known as the eCRF; paper CRFs are the alternative option for direct data entry with subsequent transcription, upon completion, into the eCRF. Information recorded in the CRF should accurately reflect the participants’ medical/hospital notes. The Research Coordinator or Site Investigator will have the ability to choose the process they use to enter data into the eCRF, where data may be entered at one time or intermittently. If used, the original paper based CRF will be stored within a locked office in each study site. The intent of this process is to improve the quality of the clinical study by providing prompt feedback to the Investigators on the progress of the submitted data and to enhance the ability to collect early safety information in a more timely fashion to fully comply with the intent of GCP requirements. Data from International countries will be entered into an online eCRF database managed by the Oxford University Clinical Research Unit, Vietnam (OUCRU) for the SPRINT-SARI ISARIC and ECMOCARD tiers. Data from Australia will be entered into an online eCRF database managed by Monash University, and will be complemented with data from SPRINT SARI observational study (ALFRED HREC Reference 202/16) and EXCEL (ALFRED HREC Reference 534/18)). In Countries unable to upload data on a centralised database the right to retain a local database on a

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national server is available with aggregated completely anonymised data exported centrally for analysis. Each site will be identified via a 3-digit network code, a 3-digit site code, and each patient will be assigned a 4-digit sequential patient code making up the patient ID number at time of originally enrolment in SPRINT- SARI. The site-code will be specified as to whether it is an ICU, hospital ward, or other facility. The site code is obtained by registering on the eCRF, data management system. Patient numbers should be assigned sequentially for each site beginning with 0001. In the case of a single site recruiting patients on different wards, or where it is otherwise difficult to assign sequential numbers, it is acceptable to assign numbers in blocks. Alpha characters can also be used (e.g. Intensive Care Unit will assign A001 onwards, in-patient ward will assign B001 onwards). The full patient identification number will therefore be a 10-digit number, with the format of the following: network code - site code – individual patient code [...][...][...][...][...][...][...][...][...][...] (eg. 001-012-0001). The register of patient names and study numbers will not leave the participating hospital. Access to the data entry system will be protected by username and password. Username and password will be assigned during the registration process for individual Research Coordinators or Site Investigators. All electronic data transfer between study site and database will be username and password protected. Each centre will maintain a trial file including a protocol, ethics approval documentation, and paper CRFs. A participant list will be used in each study site to match identifier codes in the database to individual patients in order to record clinical outcomes and supply any missing data points. The Participant List is maintained locally and is not to be transferred to any other location. The Research Coordinator will compile an enrolment log including the patient’s name, age, hospital identification number and unique study number. Subsequent data will be identified by the unique study number only. The enrolment log and study data will be kept separately.

**OPTION 2: Interactive augmented data collection**

We will use platforms and solutions provided by Amazon to collect data and transfer data into the REDcap web application. Data will be collected through 1) voice commands; 2) digital video monitor interface and 3) through digital transcription of parameters collected via SPRINT-SARI/ECMOCARD paper CRFs. Similar to option 1, only de-identified information will be collected, encrypted and transferred directly to the REDCAP database. No data or
information of any kind will be directed elsewhere. Amazon Web Services will not have any direct interaction with the enhanced user-interface once it is implemented and will only act in an external consultancy capacity. Data will be fully encrypted from data ingestion into Amazon cloud, up to de-encryption into the REDcap web application. Thus Amazon platform will only channel, without being able to codify, data from hospitals into the REDCap system.

**Data collection methods (Coagulation Disorders and Thrombosis sub-study)**

As for the Coagulation Disorders and Thrombosis Sub-study, the CRF will be made available at all collaborating sites as a paper CRF. The Coagulation Disorders and Thrombosis Sub-study CRF will be only available in English. Data will be collected by trained staff at each study site and these individuals will enter all required data described in the protocol into the CRFs directly from laboratory results, ROTEM or TEG reports. Trained staff at sites with the IT capabilities can enter all required data directly into the protected online database hosted at UQ, known as the eCRF; paper CRFs are the alternative option for direct data entry with subsequent transcription, upon completion, into the eCRF. Information recorded in the CRF should accurately reflect the participants’ laboratory results, ROTEM or TEG reports. The Research Coordinator or Site Investigator will have the ability to choose the process they use to enter data into the eCRF, where data may be entered at one time or intermittently. If used, the original paper based CRF will be stored within a locked office in each study site. The intent of this process is to improve the quality of the clinical study by providing prompt feedback to the Investigators on the progress of the submitted data and to enhance the ability to collect early safety information in a more timely fashion to fully comply with the intent of GCP requirements. **Data will be entered into an online eCRF database managed by the University of Queensland.** In Countries unable to upload data on a centralised database the right to retain a local database on a national server is available with aggregated completely anonymised data exported centrally for analysis. **The full patient SPRINT-SARI/ECMOCARD identification number will be recorded to match results of the Coagulation Disorders and Thrombosis Sub-study with SPRINT-SARI/ECMOCARD records. The register of patient names and study numbers will not leave the participating hospital. Access to the data entry system will be protected by username and password.** Username and password will be assigned by the University of Queensland during the registration process for individual Research Coordinators or Site Investigators. All electronic data transfer between study site and

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database will be username and password protected. The Participant List of the Coagulation Disorders and Thrombosis Sub-study is maintained locally and is not to be transferred to any other location.

Screening log
No screening log will be maintained.

Data quality
Several procedures to ensure data quality and protocol standardisation will help to minimise bias. These include:

1. Online meetings for all research coordinators will be held to ensure consistency in procedures;
2. A detailed data dictionary will define the data to be collected on the case report form;
3. Quality checks will be built into the data management system and there will be quality checks of critical data points entered into the CRFs to ensure standardization and validity of the data collected;

An achievable data set will be fundamental to the success of the study. We have identified the key data points whilst not discouraging centres from participating through an excessive burden of data collection. Data queries may be generated, depending on resource availability. Any information that is not available for the investigator will not be considered as missing. No assumptions will be made for missing data.

Data management
Data entry and data management will be coordinated by ISARIC and ECMOCARD steering committee, including programming and data management support. On behalf of the management committee, ANZIC-RC and ISARIC will act as custodian of the data. The University of Queensland will receive data from the data custodians via data sharing agreements. The management committee of the trial will take responsibility for the content and integrity of any data. There will be periodic assessments of data burden to ensure that the infrastructure is organized to handle large amounts of incoming data in small time periods. SPRINT-SARI and ECMOCARD will adhere to the research and data sharing policies of ISARIC, Sample and Data Sharing Policy, Version 4, 21 July 2014. Clinical investigators contributing to the research efforts will be given full recognition for their efforts and will be

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given the opportunity to access data. Ownership of any data transferred to the eCRF will be retained by the site that contributed it. Networks will retain the right to request raw data for all sites included in their network for research purposes, provided that the research proposal has been reviewed and approved by the management committee, ISARIC and ECMOCARD following publication of the primary manuscript. All analysis of pooled data will be undertaken with the explicit agreement of each site who contributed. ISARIC and ECMOCARD will retain the right to use all pooled data for scientific and other purposes. All members of the study group will have the right to access the pooled data for research purposes provided the research proposal has been reviewed and deemed satisfactory by the management committee following publication of the primary manuscript. Only summary data will be presented publicly. Individual patient data provided by participating sites will remain the property of the respective institution. Of note, a data management plan will be developed to address researchers’ intentions related to generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information, the risks associated with these activities and any strategies for minimising those risks.

Monitoring

Data monitoring will be conducted on a randomly selected subset (up to 5%) of cases, through discussion with the local site investigator to discuss data collection techniques. Direct site visits will not be feasible, given the scope of the study.

Collected Parameters

The following parameters will be assessed and recorded based on the follow-up schedule and assessments reported in Figure 4. All the mandatory variables to be assessed are highlighted in red:

Demographics and Medical History

1. Personal Data

2. Medical History and comorbidities, including type of anti-hypertensive medications

3. Smoking habits

4. Chronic alcohol abuse

5. Intravenous drug abuse

6. Immuno-competency status
COVID-19 infection

1. Date of first signs of infection
2. Date of hospital admission
3. Date of ICU admission
4. Date of invasive mechanical ventilation
5. Blood gases before commencement of invasive mechanical ventilation
6. Use of continuous renal replacement therapy before commencement of invasive mechanical ventilation
7. Use of vasoactive drugs before commencement of invasive mechanical ventilation
8. Use of cardiac-assist devices before commencement of invasive mechanical ventilation
9. Acute physiology and chronic health evaluation (APACHE II) score upon ICU admission
10. Use of anti-viral treatment
11. Use of antibiotics
12. Cutaneous manifestations

Clinical parameters upon commencement of invasive mechanical ventilation

1. Date of invasive mechanical ventilation commencement
2. Use of prone position
3. Use of neuromuscular blockade
4. Use of recruitment manoeuvres
5. Use of inhaled nitric oxide
6. Use of bicarbonate
7. Blood gases
8. Ventilatory mode
9. Inspiratory fraction of oxygen
10. Respiratory rate
11. Tidal volume (ml/Kg of ideal body weight)
12. Positive end-expiratory pressure
13. Airway plateau pressure

Daily assessment of clinical parameters during invasive mechanical ventilation

1. Date of assessment

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2. Use of prone position
3. Use of neuromuscular blockade
4. Use of recruitment manoeuvres
5. Use of inhaled nitric oxide
6. Blood gases
7. Ventilatory mode
8. Inspiratory fraction of oxygen
9. Respiratory rate
10. Tidal volume (ml/Kg of ideal body weight)
11. Positive end-expiratory pressure
12. Airway plateau pressure
13. Haemoglobin
14. White blood cells
15. AST
16. ALT
17. Lactate
18. Creatinine
19. Ferritin
20. D-dimer
21. Troponins
22. BNP
23. Use of continuous renal replacement therapy
24. Use of vasoactive drugs
25. Use of anticoagulants
26. Transfused blood products
27. Infectious complications
28. Haemorrhagic complications

Clinical features before commencement of ECMO
1. Date of ECMO commencement
2. Use of prone position
3. Use of neuromuscular blockade

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4. Use of recruitment manoeuvres
5. Use of inhaled nitric oxide
6. Use of bicarbonate
7. Blood gases
8. Ventilatory mode
9. Inspiratory fraction of oxygen
10. Respiratory rate
11. Tidal volume (ml/Kg of ideal body weight)
12. Positive end-expiratory pressure
13. Airway plateau pressure

**ECMO characteristics**

1. Type and manufacturer of centrifugal blood pump driven circuit
2. Type and manufacturer of low-resistance oxygenator
3. Type of ECMO: venous-venous or venous-arterial
4. Peripheral access: femoral, jugular, both
5. ECMO blood flow rate day 0, and every 24 hours thereafter
6. ECMO gas flow rate day 0, and every 24 hours thereafter
7. Anticoagulation during ECMO
8. Frequency of ECMO circuit change
9. Ventilatory settings on ECMO
10. Vasoactive support on ECMO
11. Organ dysfunctions on ECMO

**ECMO adverse effects**

1. Transfused blood during ECMO
2. Transfused plasma during ECMO
3. Transfused platelets during ECMO
4. Transfused cryoprecipitates during ECMO
5. Type and source of infectious complications
6. Type and source of haemorrhagic complications
7. Other complications
**ECMO adverse effects**

1. Transfused blood during ECMO
2. Transfused plasma during ECMO
3. Transfused platelets during ECMO
4. Transfused cryoprecipitates during ECMO
5. Type and source of infectious complications
6. Type and source of haemorrhagic complications
7. Other complications

**Daily assessments for Coagulation Disorders and Thrombosis Sub-study**

1. SPRINT-SARI/ECMOCARD patient number
2. Date of assessment
3. Lactate dehydrogenase
4. Ferritin
5. D-dimer
6. Fibrinogen
7. Activated clotting time
8. Activated partial thromboplastin time
9. International normalised ration
10. Plasma free haemoglobin
11. ROTEM parameters (EXTEM, FIBTEM, INTEM, HEPTEM, TRAPTEM, NATTEM if patients undergoing treatment with low molecular weight heparin and ECATEM if patients undergoing treatment with direct thrombin inhibitors)
12. TEG parameters

**Main outcomes**

1. Date of ECMO discontinuation
2. Date of invasive mechanical ventilation discontinuation
3. Date of ICU Discharge
4. Date of Hospital Discharge
5. Mortality at 28 days
6. Main cause of death
Data Analysis

The global analysis of SPRINT-SARI/ECMOCARD and Coagulation Disorders and Thrombosis Sub-study categorical variables will be described as proportions and will be compared using chi-square or Fisher’s exact test. Continuous variables will be described as mean and standard deviation if normally distributed or median and inter-quartile range if not normally distributed. Comparisons of continuous variables will be performed using one-way ANOVA or Mann-Whitney test, as appropriate. A logistic regression model will be performed to assess independent association between prognostic factors and outcomes, taking into account the hierarchical nature of the data. Significance will be set at p<0.05.
Reference List


doi:10.1016/S1473-3099(20)30086-4


Regulation, Ethics and Governance

Protocol and any following amendment to the original protocol will be translated to the main language of the collaborative institution and submitted for the approval of each institutional review board (IRB). All protocols of the study will require approval by each institutional review board, before enrolment of patients. Sites should apply for a waiver of consent to be granted given the negligible risk nature of the study and the need for rapid data collection to inform pandemic responses globally.

Conflict of interest

The investigators of the APELSO network DO NOT have any significant financial or personal interest that would reasonably appear to be affected by the proposed research activities.

Data collection and Site Monitoring plan

Data Collection

Data will be collected in dedicated electronic forms and/or hard copies as provided by the SPRINT-SARI and ISARIC Organisations (APPENDIX B) and the ECMOCARD Steering Committee (APPENDIX C). Data for Coagulation Disorders and Thrombosis Sub-study can be found in the APPENDIX D. A custom-designed electronic case report form has been developed in REDcap, which is hosted at the University of Oxford and for all Australian centres will be hosted at Monash University, Melbourne, Australia. A custom-designed electronic case report form has been developed in REDCap for the Coagulation Disorders and Thrombosis Sub-study, which is hosted at the University of Queensland. Hard copies and electronic data will be kept for at least 7 years following the conclusion of the study. Each investigator will be responsible to collect and preserve data obtained at his/her collaborative institution.

Site Monitoring

Periodic conference calls will be organized with all investigators or investigators of specific collaborative centres to monitor the quality of the data collected, address specific issues in data collection and prepare future publications

Compensations

No compensation will be offered to collaborating institutions.
Data Access

All essential documentation of the SPRINT-SARI/ECMOCARD and the Coagulation Disorders and Thrombosis Sub-study will be stored in an Investigator Study File (ISF), which will be held by the Critical Care Research Group (CCRG), University of Queensland. On completion of the study, this information will be archived by the CCRG. Following the publication of the primary and secondary outcomes, additional analyses could be undergone on the data collected. In the event of publications arising from these analyses, those responsible will need to provide the Chief Investigator with a copy of the manuscript for approval prior to submission.

Feasibility

This is a multi-centre study performed within the COVID-19 Critical Care Consortium, which comprises the SPRINT-SARI, ISARIC, ELSO and APELSO networks of clinical research institutions, during an emergent new respiratory infection caused by the new COVID-19 virus. The study will be conducted in intensive care units with broad experience in mechanical ventilation, ECMO and coagulation disorders and thrombosis. Further intra-mural and extra-mural collaborations beyond the COVID-19 Critical Care Consortium and SPRINT-SARI, ISARIC and APELSO networks will be potentially pursued to promptly achieve goals. In summary, the COVID-19 Critical Care Consortium multidisciplinary and international research team of collaborators provides ideal conditions to perform reported study.

Dissemination and Publication

Publication policy

Ownership of the data arising from the study resides with the study teams. Data requested from SPRINT-SARI and EXCEL investigators will resides with their own study teams. After the study, results will be analysed and tabulated, and a study report will be prepared. This report will be made available to the study collaborators and the relevant IRBs. The study findings will be presented at national and international meetings. We plan to publish our study findings in a high-quality peer reviewed journal. SPRINT-SARI and EXCEL studies will be fully acknowledged in all publications and presentations.
Authorship policy

Authorship will be determined according to the internationally agreed criteria for authorship (www.icmje.org). Authorship of parallel studies conducted outside of the main trial will be according to the individuals involved in the study but must acknowledge the contribution of the involved investigators.
SUPPLEMENT 2

COLLABORATING SITES
### COLLABORATING SITES

<table>
<thead>
<tr>
<th>Country</th>
<th>City</th>
<th>Site Name</th>
<th>Principal Investigator</th>
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<td>Brisbane</td>
<td>The Prince Charles Hospital</td>
<td>Kiran Shekar</td>
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<td>Carol Hodgson</td>
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| West Java | Hasan Sadikin Hospital | | Gezy Giwangkancana (Adult)  
Dadang H Somasetia (Paeds) |
| Surabaya | Airlanna University | | Dr Neurinda Permata Kusumastuti  
Bastian Lubis |
| Medan | Adam Malik Hospital | | Moh Supriatna |
| Semarang | Dr Kariadi Hospital Semarang | | Desy Rusmawatiningtyas (Paeds)  
Dr. Bhirowo (Adult) |
| Yogyakarta | Sardjito Hospital | |  |
| Sapporo | Teine Keijinkai Hospital | | Takako Akimoto  
Singo Ichiba |
| Tokyo | Nippon Medical School Hospital | |  |
| Kawasaki | St Marianna Medical University Hospital | | Shigeki Fujitani (Adults)  
Shimizu Naoki (Paeds) |
| Utsunomiya | Saiseikai Utsunomiya Hospital | | Keibun Liu |
| Hokkaido | Hokkaido University | | Dr Koji Hoshino  
Dr Yuk Uchinami |
| Kyoto | Kyoto Medical Centre | | Hiro Tanaka  
Dr Yokoyama |
| Yokohama | Yokohama City University Medical Center | | Hayato Taniguci  
Dr Yokoyama |
<p>| Aichi | Tosei Hospital | |  |
| Maebashi | Japan Red Cross Maebashi Hospital | | Hiroyuki Suzuki |
| Gunma | Gunma University Graduate School of Medicine | | Kanamoto Masafumi |
| Chiba | Chiba University Graduate School of Medicine | | Ryuozo Abe |
| Hiroshima | Hiroshima University | | Shinichiro Ohshimo |
| Tokyo | Tokyo Metropolitan Medical Center | | Keiki Shimizu |
| Hakodate | Hakodate City hospital | | Yoshihiro Takeyama |
| Ryukyu | Ryukyu University | | Ichiro Kukita |</p>
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<th>Hospital/Institution</th>
<th>Authors</th>
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<td>Brazil</td>
<td>Belo Horizonte</td>
<td>Hospital Mater Dei</td>
<td>Ana Luiza Valle Martins</td>
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<td>Hospital das Clínicas da Faculdade de Medicina da USP (HCFMUSP)</td>
<td>Suely Pereira Zeferino</td>
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<td>Sunimol Joseph</td>
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<td>Konstanty S. Szuldrzynski</td>
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<td>Jana Assy</td>
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<td>Jackie Stone</td>
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<td>Brahim Housni</td>
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<td>Younes Oujidi</td>
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<td>Jawad Tadili</td>
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SUPPLEMENT 3

REGIONAL LEADS/ASSISTANTS

OPERATIONAL TEAM
## REGIONAL LEADS/ASSISTANTS

<table>
<thead>
<tr>
<th>Country</th>
<th>Regional Lead</th>
<th>Regional Lead Affiliation</th>
<th>Regional Coordinator/Assistant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Hergen Buscher</td>
<td>St Vincent’s Hospital, Sydney</td>
<td>India Lye</td>
</tr>
<tr>
<td>Australia</td>
<td>Carol Hodgson</td>
<td>The Alfred Hospital, Melbourne</td>
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<tr>
<td>New Zealand</td>
<td>Shay McGuinness</td>
<td>Auckland City Hospital</td>
<td>Rachael Parke</td>
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<tr>
<td>Hong Kong</td>
<td>Simon Wai Ching Sin</td>
<td>Queen Mary Hospital, Hong Kong</td>
<td>Pauline Yeung</td>
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<tr>
<td>Indonesia</td>
<td>Eva Marwali</td>
<td>National Cardiovascular Center Harapan Kita, Jakarta</td>
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<td>Indonesia</td>
<td>Erlina Burhan</td>
<td>Persahabatan Hospital, Jakarta</td>
<td>Keibun Liu, Takako Akimoto</td>
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<tr>
<td>Japan</td>
<td>Shingo Ichiba</td>
<td>Nippon Medical School Hospital, Tokyo</td>
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<td>Kollengode Ramanathan</td>
<td>National University Hospital, Singapore</td>
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<td>Young-Jae Cho</td>
<td>Seoul National University Bundang Hospital</td>
<td>Hwa Jin Cho, Jae-Seung Jung</td>
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<td>Yih-Sharng Chen, Jung-Yien Chien, Chih-Hsien Wang</td>
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<td>Vinh Chau</td>
<td>Hospital for Tropical Diseases, Ho Chi Minh City</td>
<td>Trieu Huynh, Sophie Yacoub, Angela McBride</td>
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<td>Italy</td>
<td>Antonio Pesenti, Mauro Panigada</td>
<td>Fondazione IRCCS Policlinico of Milan</td>
<td>Michela Leone and Sebastiano Colombo</td>
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<td>USA</td>
<td>Robert Bartlett</td>
<td>University of Michigan Medical School</td>
<td>Leticia Helms</td>
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<td>Daniel Brodie</td>
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<td>Phillip Mason</td>
<td>Brooke Army Medical Center, San Antonio</td>
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<td>USA</td>
<td>Archit Sharma</td>
<td>University of Iowa Hospitals &amp; Clinics</td>
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<td>Vadim Gudzenko</td>
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<td>Bishop Zakhary</td>
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<td>Brij Patel</td>
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<td>University of Glasgow</td>
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</tbody>
</table>
COORDINATING CENTRE OPERATIONAL TEAM

1. Cooper Ansicar
2. Chris Chan
3. William Crawford
4. Gaenor Cross
5. Courtney Dwyer
6. Alessandro Ferrioli
7. Halah Hassan
8. Samuel Huth
9. Lacey Irvine
10. Christine Jackman
11. Varun Karnik
12. Katrina Ki
13. Niki McGuinness
14. Hollier O’Neill
15. Janice Reid
16. Kei Sato
17. Declan Sela
18. Yvgeniy Shek
19. Emily Wood
20. Stephanie Yerkovich
21. Taylor Zhang
SUPPLEMENT 4

CASE REPORT FORM
Data Collection Form

CORE CASE RECORD FORM (EOT ICU Admis)

1. UPON ICU ADMISSION – Please complete the below data as of the date and time of the patient’s admission to the ICU

| DATE OF ICU ADMISSION: _____ / _____ / _____ (ONLY DATE, FROM 14/12/2019) |
| 1.1 HEIGHT (cm): __________ |

If this data has already been entered into the ‘Signs and Symptoms’ section of the ISARIC CRF, please DO NOT re-enter the data here. Leave this ‘1.1 Height’ box blank.

| 1.2 BODY WEIGHT (Kg): __________ |

If this data has already been entered into the ‘Signs and Symptoms’ section of the ISARIC CRF, please DO NOT re-enter the data here. Leave this ‘1.2 Body Weight’ box blank.

| 1.3 Arterial Hypertension |
| Yes |
| No |

If this data has already been entered into the ‘Co-Morbidities & Risk Factors’ section of the ISARIC CRF, please DO NOT re-enter the data here. Leave this ‘1.3 Hypertension’ box blank.

| 1.3a Chronic anti-hypertensive therapy (if ‘Yes’ to 1.3. Please select up to three) |
| Diuretics |
| Calcium channel blockers |
| ACE inhibitors |

If this data has already been entered in the ‘Pre-Admission Medication’ section of the ISARIC CRF, please DO NOT re-enter the data here. Leave this ‘ACE inhibitors’ box blank.

| Angiotensin II receptor antagonists |
| Renin inhibitors |
| Beta blockers |
| Alpha blockers |
| Vasodilators |
| Aldosterone receptor antagonist |
| Alpha-2 adrenergic receptor agonists |
| Not applicable |

| 1.4 GASTROINTESTINAL AND PANCREATIC COMORBIDITIES |
| Yes |
| No |

Version 1.2.7
8 May 2020
1.5 HEPATIC AND BILIARY COMORBIDITIES
   Yes
   No

1.6 HAEMATOLOGIC AND SPLEEN COMORBIDITIES
   Yes
   No

1.7 IMMUNOLOGICAL AND TRANSPLANT COMORBIDITIES
   Yes
   No

1.8 ENDOCRINOLOGICAL COMORBIDITIES
   Yes
   No

1.9 GENITO-URINARY COMORBIDITIES
   Yes
   No

1.10 CHRONIC ALCOHOL ABUSE
   Yes
   No

1.11 INTRAVENOUS DRUGS ABUSE
   Yes
   No

1.12 IMMUNO-COMPETENT
   Yes
   No

1.13 APACHE II SCORE: ________ (ONLY NUMBERS FROM 0 to 71)
   APACHE II score can be calculated at the following link: https://www.mdcalc.com/apache-ii-score
   □ Not available

1.14 SOFA SCORE: ________ (ONLY NUMBERS FROM 0 to 24)
   SOFA score can be calculated at the following link: https://www.mdcalc.com/sequential-organ-failure-assessment-sofa-score
   □ Not available

   BLOOD GAS ANALYSIS (Qs 1.15 – 1.20) – Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to ICU admission. ‘Worst’ blood gas is defined as the blood gas with the lowest PaO2/FiO2 ratio.

1.15 ARTERIAL pH IN THE LAST 6h: ________ (ONLY NUMBERS FROM 6.500 TO 7.600)

Version 1.2.7
8 May 2020
Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to ICU admission. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. Not available

1.16 ARTERIAL PARTIAL PRESSURE OF OXYGEN IN THE LAST 6h (mmHg): ____ (ONLY NUMBERS FROM 20 TO 500)

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to ICU admission. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. Not available

1.17 ARTERIAL PARTIAL PRESSURE OF CARBON DIOXIDE IN THE LAST 6h (mmHg): ____ (ONLY NUMBERS FROM 10 TO 100)

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to ICU admission. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. Not available

1.18 ARTERIAL BICARBONATE (HCO3) IN THE LAST 6h ____________ mEq/L

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to ICU admission. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. Not available

1.19 ARTERIAL Base excess IN THE LAST 6h ____________ mmol/L

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to ICU admission. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. Not available

1.20 Lactate IN THE LAST 6h ____________ mmol/L

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to ICU admission. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. Not available

1.21 Ferritin in the last 12 hours: ____________ (ng/mL)

Only numbers from 0-1000

Not available

1.22 D-dimer in the last 12 hours:

____________ (ng/mL or mcg/mL)

Only numbers from 0-15000

Not available

1.23 Troponin in the last 12 hours:

- Troponin T: __________ (ng/mL or ng/L)
- Troponin I: _________ (ng/mL or ng/L)
- High sensitivity troponin T: __________ (ng/mL or ng/L)
- High sensitivity troponin I: _________ (ng/mL or ng/L)

Not available

1.24 Cardiac BNP in the last 12 hours:

____________ (picograms/mL)

Only numbers between 0-1000

Not available

Version 1.2.7
8 May 2020
1.25 Upon ICU admission, did the patient present with cutaneous manifestations?

☐ Yes
☐ No
☐ Not available

If yes to 1.25, type of cutaneous manifestations (please select up to three (3) options)

☐ Bullae
☐ Macules
☐ Nodules
☐ Papules
☐ Plaques
☐ Purpura
☐ Pustules
☐ Rash
☐ Scale
☐ Urticaria
☐ Vesicles
☐ Other: __________

If yes to 1.25, specify the involved regions (please select up to three (3) options):

☐ Face
☐ Truck
☐ Upper limbs
☐ Hands
☐ Lower limbs
☐ Feet
CORE CASE RECORD FORM (EOT Mech Vent)

2. UPON COMMENCEMENT OF MECHANICAL VENTILATION - ‘Mechanical ventilation’ includes invasive mechanical ventilation via an endotracheal tube or tracheostomy only. Importantly, this module will be active only when you click ‘YES’ in the field ‘1.17 Invasive ventilation?’ of the SPRINT-SARI form.

2.1 DATE OF START OF MECHANICAL VENTILATION: _____ / _____ / _____ (ONLY DATE, FROM 14/12/2019)

2.2 SITE OF INTUBATION

- Outside hospital
- Intensive Care Unit
- Emergency Department
- Hospital Ward
- Different hospital, then patient was transferred
- Other

2.3 TYPE OF INTUBATION

- Elective
- Emergent

2.4 CARDIAC ARREST

- Yes
- No

2.5 VENTILATORY SUPPORT BEFORE INTUBATION

- High-Flow Oxygen Ventilation
- Mask non-invasive ventilation
- Full Face-mask non-invasive ventilation
- Helmet non-invasive ventilation
- Simple face mask oxygen therapy
- Venturi mask oxygen therapy
- Non-re-breather face mask oxygen therapy
- Nasal prongs oxygen therapy
- Other
- Not available

BLOOD GAS ANALYSIS (Qs 2.6 – 2.11) – Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. ‘Worst’ blood gas is defined as the blood gas with the lowest PaO2/FiO2 ratio.

2.6 ARTERIAL pH IN THE 6 HOURS BEFORE START OF MV: _________ (ONLY NUMBERS FROM 6.500 TO 7.600)

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

2.7 ARTERIAL PARTIAL PRESSURE OF OXYGEN (mmHg) IN THE 6 HOURS BEFORE START OF MV: _________ (ONLY NUMBERS FROM 20 TO 500)
Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. ‘Worst’ is defined as the blood gas with the lowest PaO2/FIO2 ratio.

☐ Not available

2.8 ARTERIAL PARTIAL PRESSURE OF CARBON DIOXIDE (mmHg) IN THE 6 HOURS BEFORE START OF MV: ___________ (ONLY NUMBERS FROM 10 TO 100)

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. ‘Worst’ is defined as the blood gas with the lowest PaO2/FIO2 ratio.

☐ Not available

2.9 ARTERIAL HCO3 in the 6 HOURS BEFORE START OF MV ___________ mEq/L

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. ‘Worst’ is defined as the blood gas with the lowest PaO2/FIO2 ratio.

☐ Not available

2.10 ARTERIAL Base excess IN THE 6 HOURS BEFORE START OF MV ___________ mmol/L

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. ‘Worst’ is defined as the blood gas with the lowest PaO2/FIO2 ratio.

☐ Not available

2.11 Lactate IN THE 6 HOURS BEFORE START OF MV ___________ mmol/L

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of mechanical ventilation. ‘Worst’ is defined as the blood gas with the lowest PaO2/FIO2 ratio.

☐ Not available

2.12 USE OF CONTINUOUS RENAL REPLACEMENT THERAPY BEFORE START OF MV

Yes
No

2.13 USE OF VASOACTIVE DRUGS BEFORE START OF MV

Yes
No

2.14 USE OF CARDIAC ASSIST DEVICES BEFORE START OF MV

Yes
No

2.15 ANTIMICROBIALs BEFORE START OF MV

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<td>Nalidixic Acid</td>
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CORE CASE RECORD FORM (EOT Start ECMO)

3. UPON COMMENCEMENT OF ECMO. Importantly, this module will be active only when you click 'YES' in the field '1.18 ECLS?' of the SPRINT-SARI form.

3.1 DATE OF START OF ECMO: ___/___/___ (ONLY DATE FROM 14/12/2019)

3.2 Is this patient enrolled in the EXCEL study?
Yes
No

3.3 If Yes, what is the patient's EXCEL study number ______________________

3.4 LOCATION OF ECMO CANNULATION:
Same Hospital
Other Hospital, then patient was retrieved and transferred

3.5 Type and Manufacturer of centrifugal blood pump driven circuit: __________ (TEXT)

3.6 Type and Manufacturer of low-resistance oxygenator: ________ (TEXT)

3.7 TYPE OF ECMO:
Venous-venous
Venous-arterial

3.8 DRAINAGE CANNULA INSERTION SITE:
Left femoral vein
Left internal jugular vein
Right femoral vein
Right internal jugular vein

3.9 RETURN CANNULA INSERTION SITE:
Left femoral vein
Left internal jugular vein
Right femoral vein
Right internal jugular vein
Left femoral artery
Right femoral artery

3.10 CARDIAC ARREST BEFORE START OF ECMO
Yes
No

3.11 USE OF PRONE POSITION BEFORE START OF ECMO:
Yes
No

3.12 USE OF NEUROMUSCULAR BLOCKADE BEFORE START OF ECMO:
Yes
No

3.13 USE OF RECRUITMENT MANOEUVRES BEFORE START OF ECMO:

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3.14 USE OF INHALED NITRIC OXIDE BEFORE START OF ECMO:

Yes
No

3.15 USE OF BICARBONATE BEFORE START OF ECMO

Yes
No

3.16 VENTILATORY MODE BEFORE START OF ECMO:

Synchronized Intermittent Mandatory Ventilation – Volume-Controlled (SIMV-V)
Synchronized Intermittent Mandatory Ventilation – Pressure-Controlled (SIMV-P)
Volume Controlled Ventilation
Pressure Controlled Ventilation
Pressure Regulated Volume Control (PRVC)
Airway Pressure Release Ventilation (APRV)
Pressure Support Ventilation (PSV)
Volume Support Ventilation (VSV)
High Frequency Oscillatory (HFO)
Bilevel Positive Airway Pressure (BiPAP)
Continuous Positive Airway Pressure (CPAP)
Proportional Assist Ventilation (PAV)
Neurally Adjusted Ventilatory Assist (NAVA)
Other: __________ (TEXT)

MECHANICAL VENTILATION & BLOOD GAS ANALYSIS (Qs 3.17- 3.28) – Please document the ‘worst’ value in the 6 hours before the commencement of ECMO. ‘Worst’ means the values associated with the arterial blood gas with the lowest PaO2/FiO2 ratio. Please report ventilatory settings associated with the worst arterial blood gas.

3.17 INSPIRATORY FRACTION OF OXYGEN IN THE 6 HOURS BEFORE START OF ECMO: __________
(ONLY NUMBERS, BETWEEN 21 and 100)

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.18 RESPIRATORY RATE IN THE 6 HOURS BEFORE START OF ECMO (breaths/min): __________
(ONLY NUMBERS, BETWEEN 2 and 60)

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.19 TIDAL VOLUME (ml/Kg of Ideal Body Weight): __________ (ONLY NUMBERS, BETWEEN 1 and 14)

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

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Ideal Body Weight formula:
Male patients: 50 + (0.91 x [height in cm – 152.4])
Female patients: 45.5 + (0.91 x [height in cm – 152.4])

☐ Not available

3.20 POSITIVE END EXPIRATORY PRESSURE IN THE 6 HOURS BEFORE START OF ECMO (cmH2O): ____________ (ONLY NUMBERS, BETWEEN 0 and 25)
Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.21 PEAK AIRWAY PRESSURE IN THE 6 HOURS BEFORE START OF ECMO (cmH2O): ____________ (ONLY NUMBERS, BETWEEN 0 and 85)
Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.22 AIRWAY PLATEAU PRESSURE IN THE 6 HOURS BEFORE START OF ECMO (cmH2O): ____________ (ONLY NUMBERS, BETWEEN 0 and 50)
Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.23 ARTERIAL pH IN THE 6 HOURS BEFORE START OF ECMO: ____________ (ONLY NUMBERS FROM 6.500 TO 7.600)
Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.24 ARTERIAL PARTIAL PRESSURE OF OXYGEN IN THE 6 HOURS BEFORE START OF ECMO (mmHg): ____________ (ONLY NUMBERS FROM 20 TO 500)
Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.25 ARTERIAL PARTIAL PRESSURE OF CARBON DIOXIDE IN THE 6 HOURS BEFORE START OF ECMO (mmHg): ____________ (ONLY NUMBERS FROM 10 TO 150)
Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.26 ARTERIAL HCO3 IN THE 6 HOURS BEFORE START OF ECMO ____________ mEq/L

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Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.27 ARTERIAL Base excess IN THE 6 HOURS BEFORE START OF ECMO ___________ mmol/L

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.28 Lactate IN THE 6 HOURS BEFORE START OF ECMO ___________ mmol/L

Please document the values associated with the ‘worst’ blood gas analysis in the 6 hours prior to commencement of ECMO. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

☐ Not available

3.29 USE OF CONTINUOUS RENAL REPLACEMENT THERAPY BEFORE START OF ECMO:

Yes
No

3.30 USE OF VASOACTIVE DRUGS BEFORE START OF ECMO:

Yes
No

3.31 USE OF CARDIAC ASSIST DEVICE BEFORE START OF ECMO:

Yes
No

3.32 USE OF ANTIBIOTICS BEFORE START OF ECMO:

Yes
No

3.33 ANTIBIOTICs BEFORE START OF ECMO:

Yes
No

Amikacin
Amoxicillin
Amoxicillin +
Clavulanate
Ampicillin
Ampicillin + Sulbactam
Atovaquone
Azithromycin
Aztreonam
Bacampicillin
Bacitracin

Capreomycin
Carbenicillin indanyl
sodium
Cefaclor
Cefadroxil
Cefamandole
Cefazolin
Cefdinir
Cefditoren
Cefepime
Cefixime

Cefmetazole
Cefonicid
Cefoperazone
Cefotaxime
Cefotetan
Cefoxitin
Cefpodoxime Proxetil
Cefprozil
Ceftaroline
Ceftazidime
Ceftributen

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4. DAILY CASE RECORD FORM
Complete one form 24 hours after commencement of mechanical ventilation, and daily up to discontinuation of mechanical ventilation or death, whichever occurs first. Importantly, parameters related to mechanical ventilation or ECMO will be active only when you click ‘YES’ in the field ‘1.17 Invasive ventilation?’ or when you click ‘YES’ in the field ‘1.18 ECLS?’, respectively, of the SPRINT-SARI form.

4.1 DATE: ___________________________ (ONLY DATE, FROM 14/12/2019)

4.2 PATIENT POSITION IN THE LAST 24h:
Please report the position applied predominantly during the 24 hours.

  - Supine
  - Prone

4.3 HIGHEST ECMO FLOW RATE IN THE LAST 24h (L/min): __________

4.4 HIGHEST ECMO GAS FLOW RATE IN THE LAST 24h (L/min): __________

4.5 ECMO CIRCUIT CHANGE IN THE LAST 24h:
  - Yes
  - No

4.6 USE OF NEUROMUSCULAR BLOCKADE IN THE LAST 24h:
  - Yes
  - No

4.7 USE OF RECRUITMENT MANOEUVRES IN THE LAST 24h:
  - Yes
  - No

4.8 USE OF INHALED NITRIC OXIDE IN THE LAST 24h:
  - Yes
  - No

4.9 MOST FREQUENT VENTILATORY MODE IN THE LAST 24h:
  - Synchronized Intermittent Mandatory Ventilation – Volume-Controlled (SIMV-V)
  - Synchronized Intermittent Mandatory Ventilation – Pressure-Controlled (SIMV-P)
  - Volume Controlled Ventilation
  - Pressure Controlled Ventilation
  - Pressure Regulated Volume Control (PRVC)
  - Airway Pressure Release Ventilation (APRV)
  - Pressure Support Ventilation (PSV)
  - Volume Support Ventilation (VSV)
  - High Frequency Oscillatory (HFO)
  - Bilevel Positive Airway Pressure (BiPAP)
  - Continuous Positive Airway Pressure (CPAP)

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Proportional Assist Ventilation (PAV)
Neurally Adjusted Ventilatory Assist (NAVA)
Other: ________ (TEXT)

**MECHANICAL VENTILATION & BLOOD GAS ANALYSIS (Qs 4.10 – 4.21)** – Please document the ‘worst’ value in the last 24 hours. ‘Worst’ means the values associated with the arterial blood gas with the lowest PaO2/FiO2 ratio. Please report ventilatory settings associated with the worst arterial blood gas.

### 4.10 INSPIRATORY FRACTION OF OXYGEN IN THE LAST 24h: ________ (ONLY NUMBERS, BETWEEN 21 and 100)

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio.

- □ Not available

### 4.11 RESPIRATORY RATE IN THE LAST 24h (breaths/min): ________ (ONLY NUMBERS, BETWEEN 2 and 60)

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. □ Not available

### 4.12 TIDAL VOLUME IN THE LAST 24h (ml/Kg of Ideal Body Weight): ________ (ONLY NUMBERS, BETWEEN 1 and 14)

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. Ideal Body Weight formula:

- Male patients: $50 + (0.91 \times \text{height in cm} - 152.4)$
- Female patients: $45.5 + (0.91 \times \text{height in cm} - 152.4)$

- □ Not available

### 4.13 POSITIVE END EXPIRATORY PRESSURE IN THE LAST 24h (cmH2O): ________ (ONLY NUMBERS, BETWEEN 0 and 25)

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. □ Not available

### 4.14 AIRWAY PLATEAU PRESSURE IN THE LAST 24h (cmH2O): ________ (ONLY NUMBERS, BETWEEN 0 and 50)

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. □ Not available

### 4.15 ARTERIAL pH IN THE LAST 24h: ________ (ONLY NUMBERS FROM 6.500 TO 7.600)

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. □ Not available

### 4.16 ARTERIAL PARTIAL PRESSURE OF OXYGEN IN THE LAST 24h: (mmHg): ________ (ONLY NUMBERS FROM 20 TO 500)

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/FiO2 ratio. □ Not available

### 4.17 ARTERIAL PARTIAL PRESSURE OF CARBON DIOXIDE IN THE LAST 24h: (mmHg): ________ (ONLY NUMBERS FROM 10 TO 100)
Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/ FiO2 ratio.

4.18 ARTERIAL HCO3 IN THE LAST 24h: _______________ mEq/L

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/ FiO2 ratio.

4.19 ARTERIAL Base excess IN THE LAST 24h: _______________ mmol/L

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/ FiO2 ratio.

4.20 Lactate IN THE LAST 24h: _______________ mmol/L

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/ FiO2 ratio.

☐ Not available

If this data has already been entered in the ‘Daily Case Report Form – Laboratory Results’ section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave ‘4.20 Lactate’ blank.

4.21 CREATININE IN THE LAST 24h (mg/dL): __________

Please document the values associated with the ‘worst’ blood gas analysis in the last 24 hours. ‘Worst’ is defined as the blood gas with the lowest PaO2/ FiO2 ratio.

☐ Not available

If this data has already been entered in the ‘Daily Case Report Form – Laboratory Results’ section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave ‘4.21 Creatinine’ blank.

4.22 USE OF CONTINUOUS RENAL REPLACEMENT THERAPY:

Yes
No

4.23 USE OF VASOACTIVE DRUGS IN THE LAST 24h:

Yes
No

4.24 TYPE OF VASOACTIVE DRUG 1:

☐ Dobutamine
☐ Dopamine
☐ Enoximone
☐ Epinephrine: YES ☐ NO ☐
☐ Esmolol
☐ Levosimendan
☐ Metaraminol
☐ Metoprolol
☐ Milrinone
☐ Nicardipine
☐ Nitroglycerin
☐ Nitroprusside
☐ Norepinephrine: YES ☐ NO ☐
☐ Phentylephrine
☐ Tolazoline
☐ Vasopressin
4.25 HIGHEST DOSE OF VASOACTIVE DRUG 1 IN THE LAST 24h (mcg/Kg/min): _________

4.26 TYPE OF VASOACTIVE DRUG 2:
- Dobutamine □
- Dopamine □
- Enoximone □
- Epinephrine: YES □ NO □
- Esmolol □
- Levosimendan □
- Metaraminol □
- Metoprolol □
- Milrinone □
- Nicardipine □
- Nitroglycerin □
- Nitroprusside □
- Norepinephrine: YES □ NO □
- Phenylephrine □
- Tolazoline □
- Vasopressin □

4.27 HIGHEST DOSE OF VASOACTIVE DRUG 2 IN THE LAST 24h (mcg/Kg/min): _______

4.28 TYPE OF VASOACTIVE DRUG 3:
- Dobutamine □
- Dopamine □
- Enoximone □
- Epinephrine: YES □ NO □
- Esmolol □
- Levosimendan □
- Metaraminol □
- Metoprolol □
- Milrinone □
- Nicardipine □
- Nitroglycerin □
- Nitroprusside □
- Norepinephrine: YES □ NO □
- Phenylephrine □
- Tolazoline □
- Vasopressin □

4.29 HIGHEST DOSE OF VASOACTIVE DRUG 3 IN THE LAST 24h (mcg/Kg/min): _______

4.30 USE OF CARDIAC ASSIST DEVICES IN THE LAST 24h:
- Yes
- No

4.31 USE OF ANTIBIOTICS IN THE LAST 24h:
**ANTIBIOTICS:**

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Antibiotic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin</td>
<td>Ciprofloxacin</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>Clarithromycin</td>
</tr>
<tr>
<td>Amoxicillin + Clavulanate</td>
<td>Clindamycin</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Cloxacillin</td>
</tr>
<tr>
<td>Ampicillin + Sulbactam</td>
<td>Colistimethate</td>
</tr>
<tr>
<td>Atovaquone</td>
<td>Cyclodolcycline</td>
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<td>Bacampicillin</td>
<td>Dicloxacillin</td>
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<tr>
<td>Bacitracin</td>
<td>Dirithromycin</td>
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<tr>
<td>Capreomycin</td>
<td>Dofloxycycline</td>
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<tr>
<td>Carbenicillin + indanyl</td>
<td>Enoxacin</td>
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<tr>
<td>Sodium</td>
<td>Ertapenem</td>
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<tr>
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<td>Gentamicin</td>
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<td>Cefditoren</td>
<td>Grepafloxacin</td>
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<td>Cefepime</td>
<td>Imipenem/ cilastatin</td>
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<td>Nalidixic Acid</td>
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<td>Netilmicin</td>
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<td>Nitrofurantoin</td>
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<td>Prazopressin</td>
<td>Retapamulin</td>
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<tr>
<td>Pseudoephedrine</td>
<td>Rifapentine</td>
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<td>Pyrazine</td>
<td>Rifaximin</td>
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<td>Saturated Solution of Potassium Iodide (SSKI)</td>
<td>Sparfloxacin</td>
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<td>Tazobactam</td>
<td>Spectinomycin</td>
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<td>Teicoplanin</td>
<td>Streptomyacin</td>
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<td>Telavancin</td>
<td>Suladiazine</td>
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<tr>
<td>Terbinafine</td>
<td>Sulafenoxazole</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>Sulfisoxazole</td>
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<td>Ticarcillin</td>
<td>Sulphur, precipitated in petrolatum</td>
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<tr>
<td>Ticarcillin + Clavulanic</td>
<td>TCA (trichloroacetic acid), BCA (bichloroacetic acid), Acid</td>
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<tr>
<td>Tigecycline</td>
<td>Telithromycin</td>
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<td>Tobramycin</td>
<td>Terbinaine</td>
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<tr>
<td>Sulfamethoxazole</td>
<td>Ticarcillin</td>
</tr>
<tr>
<td>Trovafloxacin</td>
<td>Vancomycin</td>
</tr>
</tbody>
</table>

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4.32 Haemoglobin IN THE LAST 24h  g/dL ____________

☐ Not available

If this data has already been entered in the ‘Daily Case Report Form – Laboratory Results’ section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave ‘4.32 Haemoglobin’ blank.

4.33 White Blood Cells IN THE LAST 24h

☐ Not available

If this data has already been entered in the ‘Daily Case Report Form – Laboratory Results’ section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave ‘4.33 White Blood Cells’ blank.

4.34 White Blood Cells Unit

X 10^9/L
X 10^3/microL

4.35 AST/SGOT IN THE LAST 24h  U/L ____________

☐ Not available

If this data has already been entered in the ‘Daily Case Report Form – Laboratory Results’ section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave ‘4.34 AST’ blank.

4.36 ALT/SGPT IN THE LAST 24h  U/L ____________

☐ Not available

If this data has already been entered in the ‘Daily Case Report Form – Laboratory Results’ section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave ‘4.36 ALT’ blank.

4.37 ANTICOAGULANTS IN THE LAST 24h

Yes
No

4.38 TYPE OF ANTICOAGULANTS IN THE LAST 24h

Continuous infusion of unfractionated heparin
Subcutaneous unfractionated heparin only
Low molecular heparin
Danaparoid Lepirudin
Argatroban
Hirulog and bivalirudin
Desirudin
Nafamostat Mesilate
Other

4.39 TRANSFUSED PACKED RED BLOOD CELL CONCENTRATE IN THE LAST 24 HOURS

Yes
No

4.40 TRANSFUSED PLATELETS CONCENTRATE IN THE LAST 24 HOURS

Yes
No
4.41 TRANSFUSED FRESH FROZEN PLASMA IN THE LAST 24 HOURS
   Yes
   No

4.42 TRANSFUSED CRYOPRECIPITATES IN THE LAST 24 HOURS
   Yes
   No

4.43 INFECTION COMPLICATION 1:
   Yes
   No

4.44 SOURCE OF INFECTIOUS COMPLICATION 1
   Lungs
   Gastro-intestinal
   Genito-urinary
   Skin and soft tissue
   Central nervous system
   Osteoarticular and bone
   Cardiac
   Bloodstream
   Not known

4.45 CAUSATIVE PATHOGEN 1:
   Acinetobacter baumannii
   Actinomyces
   Aeromonas
   Bacillus anthracis
   Bacillus species
   Bacteroides fragilis
   Bacteroides species
   Bartonella species
   Borrelia burgdorferi
   Borrelia species
   Brucella Species
   Burkholderia cepacia
   Burkholderia mallei
   Burkholderia pseudomallei
   Campylobacter and related species
   Campylobacter jejuni
   Capnocytophaga
canimorsus
   Chlamydia trachomatis
   Chlamydophila
   pneumoniae
   Chlamydophila psittaci
   Citrobacter species
   Clostridium botulinum
   Clostridium difficile
   Clostridium species
   Clostridium tetani
   Corynebacterium diphtheriae
   Coxiella burnetii
   Ehrlichia species
   Eikenella corrodens
   Enterobacter species
   Enterococcus
   Erysipelothrix rhusiopathiae
   Escherichia coli
   Francisella tularensis
   Haemophilus ducreyi
   (Chancroid)
   Haemophilus influenzae
   Helicobacter cinaedi and related species
   Helicobacter pylori
   Klebsiella granulomatis
   (Antibiotic Guide)
   Klebsiella species
   ESBL Klebsiella pneumoniae
   Lactobacillus
   Legionella pneumophila
   Legionella species
   Leptospira interrogans
   Listeria monocytogenes
   Lymphogranuloma venereum (LGV)
   Methicillin Resistant Staphylococcus aureus
   Moraxella catarrhalis
   Morganella
   Mycobacterium abscessus
   Mycobacterium avium-complex (MAC, MAI, non-HIV)
   Mycobacterium cheloneae
   Mycobacterium fortuitum
   Mycobacterium gordonae
   Mycobacterium kansasii
   Mycobacterium leprae
   Mycobacterium marinum
   Mycobacterium scrofulaceum
   Mycobacterium tuberculosis
   Mycobacterium ulcerans
   Mycobacterium xenopi
Mycoplasma
pneumoniae (Antibiotic Guide)
Neisseria gonorrhoeae
Neisseria meningitidis
Nocardia
Other atypical mycobacteria
Pasteurella multocida
Peptostreptococcus/Pep tooccus
Plesiomonas
Propionibacterium species
Proteus species
Providencia
Pseudomonas aeruginosa
Rhodococcus equi
Rickettsia rickettsii
Rickettsia species
Salmonella species
Serratia species
Shigella dysenteriae
Shigella species
Staphylococci, coagulase negative
Staphylococcus aureus
Stenotrophomonas maltophilia
Streptobacillus moniliformis
Streptococcus pneumoniae
Streptococcus pyogenes (Group A)
Streptococcus species
Treponema pallidum (syphilis)
Tropheryma whipplei
Vancomycin Resistant Enterococcus species
Vancomycin Resistant Staphylococcus aureus
Vibrio cholerae
Vibrio species (noncholera)
Yersinia pestis
Yersinia species (non-plague)
Absidia
Aspergillus
Basidiolebolomyces
Blastomyces dermatitidis
Candida albicans
Candida glabrata
Candida guilliermondii
Candida krusei
Candida lusitaniae
Candida parapsilosis
Candida species
Candida tropicalis
Chromomyces
Coccidioides immitis
Cryptococcus neoformans
Cunninghamella
Dermatophytes
Fusarium
Histoplasma capsulatum
Mucor
Mycetoma
Pneumocystis carinii
Pneumocystis jirovecii
Pseudallescheria boydii
Rhizomucor
Rhizopus
Saksanea
Sporothrix schenckii
Zygomycetes

4.46 INFECTION COMPLICATION 2:
Yes
No

4.47 SOURCE OF INFECTIOUS COMPLICATION 2:
Lungs
Gastro-intestinal
Genito-urinary
Skin and soft tissue
Central nervous system
Osteoarticular and bone
Cardiac
Bloodstream
Not known

4.48 CAUSATIVE PATHOGEN 2:
Acinetobacter baumannii
Actinomyces
Aeromonas
Bacillus anthracis
Bacillus species
Bacteroides fragilis
Bacteroides species
Bartonella species
Bordetella species
Borrelia burgdorferi
Borrelia species
Brucella Species
Burkholderia cepacia
Burkholderia mallei
Burkholderia pseudomallei
Campylobacter and related species
Campylobacter jejuni
Capnocytophaga canimorsus
Chlamydia trachomatis
Chlamydia pneumoniae
Chlamydia psittaci
Citrobacter species
Clostridium botulinum
Clostridium difficile
Clostridium species
Clostridium tetani (Tetanus)
Corynebacterium diphtheriae
Coxiella burnetii
Ehrlichia species
Eikenella corrodens
Enterobacter species
Enterococcus
Erysipelothrix
Rhusiopathiae
Escherichia coli

Francisella tularensis
Haemophilus ducreyi (Chancroid)
Haemophilus influenzae
Helicobacter cinaedi and related species
Helicobacter pylori
Klebsiella granulomatis (Antibiotic Guide)
Klebsiella species
ESBL Klebsiella pneumoniae
Lactobacillus
Legionella pneumophila
Legionella species
Leptospira interrogans
Listeria monocytogenes
Lymphogranuloma venereum (LGV)
Methicillin Resistant Staphylococcus aureus
Moraxella catarrhalis
Morganella
Mycobacterium abscessus
Mycobacterium avium-complex (MAC, MAI, non-HIV)
Mycobacterium chelonae
Mycobacterium fortuitum
Mycobacterium gordonae
Mycobacterium kansasii
Mycobacterium leprae
Mycobacterium marinum
Mycobacterium scrofulaceum
Mycobacterium tuberculosis
Mycobacterium ulcerans
Mycobacterium xenopi
Mycoplasma pneumoniae (Antibiotic Guide)
Neisseria gonorrhoeae
Neisseria meningitidis
Nocardia
Other atypical mycobacteria
Pasteurella multocida
Peptostreptococcus/Peptococcus
tococcus
Plesiomonas
Propionibacterium
cpecies
Proteus species
Providencia Pseudomonas
aeruginosa
Rhodococcus equi
Rickettsia rickettsii
Rickettsia species
Salmonella species
Serratia species
Shigella dysenteriae
Shigella species
Staphylococci, coagulase negative
Staphylococcus aureus
Stenotrophomonas
malophilia
Streptobacillus
moniliformis
Streptococcus pneumoniae
Streptococcus pyogenes (Group A)
Streptococcus species
Treponema pallidum (syphilis)
Tropheryma whippelii
Vancomycin Resistant Enterococcus species
Vancomycin Resistant Staphylococcus aureus
Vibrio cholerae
Vibrio species (non-cholera)
Yersinia pestis
Yersinia species (non-plague)
Absidia
Aspergillus
Basidiobolomyces
Blastomyces dermatitidis
Candida albicans
Candida glabrata
Candida guilliermondii
Candida krusei
Candida lusitaniae
Candida parapsilosis
Candida species
Candida tropicalis
Chromomycosis
Coccidioides immitis
Cryptococcus
neoforans
Cunninghamella
Dermatophytes
Fusarium
Histoplasma capsulatum
Mucor
Mycetoma
Pneumocystis carinii
Pneumocystis jirovecii
Pseudallescheria boydii
Rhizomucor
Rhizopus
Saksanaea
Sporothrix schenckii
Zygomycetes

4.49 INFECTION COMPLICATION 3:
Yes
No

4.50 SOURCE OF INFECTIOUS COMPLICATION 3:
Lungs
Gastro-intestinal
Genito-urinary
Skin and soft tissue
Central nervous system
Osteoarticular and bone
Cardiac
Bloodstream
Not known

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4.51 CAUSATIVE PATHOGEN 3:
Acinetobacter baumannii
Actinomyces
Aeromonas
Bacillus anthracis
Bacillus species
Bacteroides fragilis
Bacteroides species
Bartonella species
Bordetella species
Borreliia burgdorferi
Borrelia species
Brucella Species
Burkholderia cepacia
Burkholderia mallei
Burkholderia pseudomallei
campylobacter and related species
Campylobacter jejuni
Capnocytophaga
caninorum
Chlamydia trachomatis
Chlamydia pneumoniae
Chlamydia psittaci
Citrobacter species
Clostridium botulinum
Clostridium difficile
Clostridium species
Clostridium tetani (Tetanus)
Corynebacterium
diphtheriae
Coxiella burnetii
Ehrlichia species
Eikenella corrodens
Enterobacter species
Enterococcus
Erysipelothrix rhusiopathiae
Escherichia coli
Francisella tularensis
Haemophilus ducreyi
(Chancroid)
Haemophilus influenzae
Helicobacter cinaedi and related species
Helicobacter pylori
Klebsiella granulomatis
(Antibiotic Guide)
Klebsiella species
ESBL Klebsiella pneumoniae
Lactobacillus
Legionella pneumophila

Legionella species
Leptospira interrogans
Listeria monocytogenes
Lymphogranuloma venereum (LGV)
Methicillin Resistant
Staphylococcus aureus
Moraxella catarrhalis
Morganella
Mycobacterium abscessus
Mycobacterium avium-complex (MAC, MAI, non-HIV)
Mycobacterium cheloneae
Mycobacterium fortuitum
Mycobacterium gordonae
Mycobacterium kansasii
Mycobacterium leprae
Mycobacterium marium
Mycobacterium
sorfulaceum
Mycobacterium
tuberculosis
Mycobacterium ulcerans
Mycobacterium xenopi
Mycoplasma pneumoniae
(Antibiotic Guide)
Neisseria gonorrhoeae
Neisseria meningitidis
Nocardia
Other atypical
mycobacteria
Pasteurella multocida
Pectostreptococcus/Peptococcus
Plesiomonas
Propionibacterium species
Proteus species
Providencia
Pseudomonas aeruginosa
Rhodococcus equi
Rickettsia rickettsii
Rickettsia species
Salmonella species
Serratia species
Shigella dysenteriae
Shigella species
Staphylococci, coagulase negative
Staphylococcus aureus
Stenotrophomonas maltophilia
Streptococcus pneumoniae
Streptococcus pyogenes
(Group A)
Streptococcus species
Treponema pallidum
(syphilis)
Trichophyta
Vaginomyces Resistens
Enterococcus species
Vancomycin Resistant
Staphylococcus aureus
Vibrio cholerae
Vibrio species (noncholera)
Yersinia pestis
Yersinia species (plague)
Absidia
Aspergillus
Basidiobolomycosis
Blastomyces dermatitidis
Candida albicans
Candida glabrata
Candida guilliermondii
Candida krusei
Candida lusitaniae
Candida parapsilosis
Candida species
Candida tropicalis
Chromomycosis
Coccidioides immitis
Cryptococcosis neoformans
Cunninghamella
Dermatophytes
Fusarium
Histoplasma capsulatum
Mucor
Mycetoma
Pneumocystis carinii
Pneumocystis jirovecii
Pseudallescheria boydii
Rhizomucor
Rhizopus
Saksanea
Sporothrix schenckii
Zygomycetes
4.52 HAEMORRHAGIC COMPLICATION 1:
Yes
No

4.53 SOURCE OF HAEMORRHAGIC COMPLICATION 1:
- Lungs: Central nervous system
- Gastro-intestinal: Osteoarticular and bone
- Genito-urinary: Cardiac
- Skin and soft tissue: Bloodstream
- Not known

4.54 HAEMORRHAGIC COMPLICATION 2:
Yes
No

4.55 SOURCE OF HAEMORRHAGIC COMPLICATION 2:
- Lungs: Skin and soft tissue
- Gastro-intestinal: Central nervous system
- Genito-urinary: Osteoarticular and bone
- Cardiac
- Bloodstream
- Not known

4.56 OTHER NON-HAEMORRHAGIC COMPLICATION (Please describe):

4.57 Ferritin in the last 24 hours: ___________ (ng/mL)
Only numbers from 0-1000

☐ Not available

If this data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave ‘4.57 Ferritin’ blank.

4.58 D-dimer in the last 24 hours:
__________ (ng/mL or mcg/mL)
Only numbers from 0-15000

☐ Not available

If this data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave ‘4.58 D-dimer’ blank.

4.59 Troponin in the last 24 hours:

☐ Troponin T: __________ (ng/mL or ng/L)
☐ Troponin I: __________ (ng/mL or ng/L)

If this data has already been entered in the 'Daily Case Report Form – Laboratory Results' section of the ISARIC CRF, please DO NOT re-enter the data here. Please leave ‘4.59 Troponin I’ blank.

☐ High sensitivity troponin T: __________ (ng/mL or ng/L)
☐ High sensitivity troponin I: __________ (ng/mL or ng/L)

☐ Not available

4.60 Cardiac BNP in the last 24 hours:
__________ (picograms/mL)
Only numbers between 0-1000

☐ Not available

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CORE CASE RECORD FORM (EOT Final)

5 OUTCOMES

5.1 DATE OF ECMO DISCONTINUATION: _____ / _____ / _____ (ONLY DATE, FROM 14/12/2019)
5.2 DATE OF INVASIVE MECHANICAL VENTILATION DISCONTINUATION: _____ / _____ / _____ (ONLY DATE, FROM 14/12/2019)

5.3 DATE OF ICU DISCHARGE: _____ / _____ / _____ (ONLY DATE, FROM 01/01/2019)
5.4 DATE OF HOSPITAL DISCHARGE: _____ / _____ / _____ (ONLY DATE, FROM 01/01/2019)

5.5 DATE OF DEATH: _____ / _____ / _____ (ONLY DATE, FROM 01/01/2019)
- Not applicable

5.6 SITE OF DEATH
- ICU
- HOSPITAL
- OUTSIDE HOSPITAL
- Not applicable

5.7 MAIN CAUSE OF ICU DEATH
- Respiratory Failure
- Cardiac Failure
- Liver Failure
- Cardio-vascular accident
- Septic shock
- Haemorrhagic shock
- Other
- Not applicable

5.8 ALIVE AT 28 DAYS POST ICU ADMISSION?
- Yes
- No

5.9 FINAL ASSESSMENT NOTES

(TEXT)

5.10 At any time post ICU admission and until ICU discharge, did the patient present new cutaneous manifestations?
- Yes
- No
- Not available

If yes to 5.10, type of cutaneous manifestations (please select up to three (3) options)
- Bullae
☐ Macules
☐ Nodules
☐ Papules
☐ Plaques
☐ Purpura
☐ Pustules
☐ Rash
☐ Scale
☐ Urticaria
☐ Vesicles
☐ Other: ________

If yes to 5.10, specify the involved regions (please select up to three (3) options):

☐ Face
☐ Truck
☐ Upper limbs
☐ Hands
☐ Lower limbs
☐ Feet