CORONA

COre ultRasound of cOvid in iNtensive care & Acute medicine

National service evaluation of lung and heart ultrasound in patients with suspected or proven COVID-19

Protocol for Participating Units
**Background**

Coronavirus disease 2019 (COVID-19) is a respiratory tract infection caused by a newly emergent coronavirus, SARS-CoV-2. Knowledge on how best to manage this new condition is incomplete but rapidly evolving. The use of point of care ultrasound (POCUS) has potentially significant advantages over conventional radiology in the assessment of patients with confirmed or suspected COVID-19 across the spectrum of disease severity. The diagnostic performance of POCUS is not currently well established in clinical studies and work is needed to evaluate and subsequently optimise its use. The practical benefits of POCUS are particularly prominent during anticipated surges in demand which may limit timely access to X-ray imaging.

**What is CORONA?**

CORONA is a collaborative service evaluation designed and implemented by the Intensive Care Society (ICS) and Society for Acute Medicine (SAM). By drawing on the collective experience of practitioners involved at different points within the care pathway, a comprehensive picture of the role of POCUS in the assessment and management of COVID-19 can be developed.

**Setting**

Hospitals in the UK providing acute care to patients with suspected or confirmed COVID infection which currently perform POCUS as part of routine clinical assessment are invited to participate. POCUS may be employed at different points within the acute care pathway and data may be collected at any point during the illness. It is expected that POCUS will be employed during initial assessment, during inpatient admission, and to guide assessment and treatment on the intensive care unit.
**Actions required to register**

We have taken every effort to make your participation in CORONA as easy as possible. However, we do need you to do three simple things before taking part:

1. Inform the central administrative team that you wish to take part in CORONA by emailing:
   - ICS: chloe@ics.ac.uk
   - SAM: famus@acutemedicine.org.uk

2. We recommend registering your participation with your Trust audit office as a service evaluation

3. Inform your Trust / Hospital Caldicott Guardian that you are participating in CORONA, and obtain their permission for you to upload fully anonymized data to the secure REDCap database (an electronically signed Caldicott Form should be kept locally with your CORONA Master List forms). This for is available via the SAM and ICS websites and should also have been sent to you directly

It is expected that units registering to participate will be familiar with the service evaluation aims, objectives and outline available on the same websites.
**REDCap and Master list**

Data will be collected using an online database called REDCap using any either directly or via a paper dataset (again, available via the SAM and ICS websites). All data uploaded to the REDCap database must be anonymised.

You will be given access to the database through a unit-specific username and password shortly after registering with your lead Society - this will limit users to see only data entered from their unit. Detailed information regarding how to use REDCap will be included in the registration email.

Each patient will be recorded on REDCap with a case number / unique identifier, and subsequent records for that patient should be recorded with the same case number – this will allow the sonographic changes to be documented over the duration of the illness. For every patient, you will need to keep a secure log of each patient’s REDCap case number, linked with an appropriate patient identifier such as hospital number. The linked case number and patient identifier form the Master list, and allow multiple images from each patient to be entered onto the database using the same case number. A Master list is available from the SAM and ICS websites. Hospitals collecting data within both Acute Medicine and Intensive Care Medicine will need to work together to harmonise case numbers for each patient. The Master list must be stored securely to allow cross-referencing during the period of the project.

**Data collection**

There is core and optional data to be recorded for each patient evaluation, though none is mandated at the point of upload to the database. There is the possibility to add routine information (such as swab results) to a record after initial data upload. For details of the data to be collected, please see the project proposal.
An individual patient may have more than one scan conducted at different time points during their illness, and in relation to different clinical decisions. These should be linked on the database through the anonymized case number.

**Information governance**

CORONA involves the recording of routinely collected healthcare data to evaluate outcomes associated with service delivery within participant units. The CORONA study design complies with Caldicott Principles, since only anonymised data will be uploaded to REDCap. Data collection is limited to routine healthcare data i.e. there are no additional questions or tests requested. Only units where POCUS is a routine part of clinical practice are invited to contribute. Collection of routine healthcare data by clinical teams does not require ethical review, and Research Ethic Committee approval is not required (please see project proposal for more details).

We recommend registering the project as a service evaluation with your local audit team. Participating sites may freely use locally collected data for internal analysis and evaluation (site data should be available for download at any point from REDCap). We will not ask you for any additional information about the patients you include in CORONA, and we will never ask for any information which could identify your patients.

A designated person or group of people at each site will be provided with REDCap project server login details, allowing secure access to submit the data. The Master list containing patient identifiable information and associated case numbers is to be stored and maintained locally and must not leave the participating Trust.

Anonymised data submitted via REDCap will be stored and analysed on a secure server based at the Institute of Applied Health Research in the University of Birmingham. Identifiable data will not be released to any third party, unless required to do so by law (Public bodies may be obliged to release certain data under the Freedom of Information Act). An individual patient can ask for access to their data - for example if they were making
a complaint or legal challenge regarding their care – although they will not be identifiable on the central database. The Master list must be stored securely and in a separate place to data collected on paper forms (if paper forms are used). The Master list and data collected on paper should be kept for one year.

The pooled database will be the intellectual property of the Society for Acute Medicine and Intensive Care Society. Participating units are free to share their own data with other organisations, and can and should be used to evaluate and guide local service development. It is intended that important findings from CORONA will be written-up for submission to peer reviewed journals - individual units will not be identified within this output. Data and aggregated findings may also be published through approved social media channels.

Approval to Participate

The lead investigator at each participating site is responsible for obtaining necessary local approvals in line with their hospitals’ regulations (this can be any clinician). A Caldicott approval form will be available to be customized for each participating unit. The project should be registered as a service evaluation.
Steering committee
Society for Acute Medicine

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Chair FAMUS working group
Surrey and Sussex Healthcare NHS Trust

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Institute of Applied Health Research
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