**SECURE-Cirrhosis - COVID-19 in patients with chronic liver disease or post liver transplantation; an international registry of non-identifiable patient data**

**Aims**

SECURE-Cirrhosis aims to create a prospective international registry of baseline characteristics and clinical outcomes of patients with laboratory confirmed COVID-19 and chronic liver disease or liver transplantation for completion by health care professionals.

**Purpose**

The SECURE-Cirrhosis project will allow assessment of disease outcomes in patients with liver disease and COVID-19 (the disease caused by the novel virus SARS-CoV-2). We intend to identify factors associated with respiratory outcome from COVID-19 and also factors associated with liver-specific outcomes.

The hepatology community is urgently asking for information on outcome from COVID-19, particularly as many of our patient population are either functionally or formally immunosuppressed. The relationship of factors to the disease course and outcomes of COVID-19 remain unknown.

**Lead study team**

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**Design and methodology**

A short online Case Report Form (CRF) has been created and can be viewed at covidcirrhosis.org. It has been designed to balance collecting a useful dataset with speed and ease of data input. It contains no Personal Health Identifiers (PHI). Once completed, the CRF will be automatically uploaded to REDCap platform ([www.project-redcap.org](http://www.project-redcap.org)) to collect and collate the data. REDCap is a widely used secure web application hosted through thousands of academic and healthcare institutions across the world. We will be using a REDCap installation hosted at the University of North Carolina. A specific advantage of the platform is that our major collaborators in the UK (http://covid-hep.net) are using the same platform. We have agreed to combine data for a registry with worldwide coverage.

**Outcomes**

We will capture the etiology of the underlying liver disease and pre-existing drug therapy, the effects of COVID-19 on liver parameters, and clinical outcomes of liver patients infected with COVID-19. Clinical outcomes will include both requirements for hospitalization, respiratory support, intensive care support and death from COVID-19, and also evidence of decompensation of chronic liver disease. The responses will be evaluated by the team above and basic individual (non-identifiable) data will be reported on our website (<https://covidcirrhosis.web.unc.edu/updates-and-data/>) in near real time.

As the dataset grows, we intend to formalise and publish our analysis (as Open Access) for wider dissemination.

**Dissemination plans**

The collaborative project between SECURE-Cirrhosis and Covid-Hep has already been met with huge enthusiasm by the hepatology community and has been formally endorsed by the European Association for Study of the Liver (EASL), International Liver Cancer Association (ILCA), British Society of Gastroenterology (BSG), and the British Association for Study of the Liver (BASL). Additionally, we have received promotion from the American Association for the Study of Liver Diseases (AASLD) and American College of Gastroenterology (ACG). These organisations have committed to updating stakeholders on the projects progress via their websites, email correspondence and social media platforms. With regards to acknowledgements and authorship in any future publication(s), we intend to acknowledge every individual and centre that submits one or more cases to the registry. It is anticipated that first and senior authorship of any publications is shared between the Universities of North Carolina and Oxford. Senior members of major contributing centres will also be invited to form part of the authorship of future publication(s).

In addition to the above, we will update the hepatology community via Twitter (@SecureCirrhosis) with summary data in real time on covidcirrhosis.org.

**Ethical and regulatory approval**

We have created a registry that contains only de-identified data, in accordance with [HIPAA Safe Harbor De-Identification standards](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html). The UNC-Chapel Hill Office for Human Research Ethics has determined that storage and analysis of de-identified data does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 and 21 CFR 56.102] and does not require IRB approval.

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