A North American registry of the digestive manifestations of COVID-19

Significance: As of 17 March 2020, in excess of 5000 cases of COVID-19 have been diagnosed in North America with many more unconfirmed due to inadequate testing. Emerging evidence suggests that the novel coronavirus (SARS-CoV-2) infects the gastrointestinal tract in addition to the respiratory system and may be spread by fecal-oral transmission, particularly at the time of endoscopy. Little is known about the digestive manifestations of COVID-19 or the contribution of these manifestations to the spread and virulence of disease, especially in North America. A comprehensive understanding of the GI manifestations of this disease as it emerges may have important implications in the care of affected patients and in informing public health initiatives to extinguish the pandemic.

Objective: To characterize the digestive manifestations of COVID-19 by developing a registry of affected patients at medical centers across North America.

Specific Aim: To collect and compile data on gastrointestinal and hepatologic signs and symptoms in hospitalized patients with a confirmed diagnosis of COVID-19.

Study sample: Patients at participating institutions with a confirmed diagnosis of COVID-19 based on any testing modality available at that institution. Eligible patients will be identified by site investigators using various methods, including but not limited to, institutional laboratory records, data warehouse queries, electronic health record research subject identification tools, and discussions with the infectious disease or critical care services.

Data collection: Data will be collected by study personnel via review of the electronic health record at the time of patient identification and every 3-5 days subsequently throughout the duration of hospitalization. Deidentified data will be input into the database will include information about patient demographics, institution, medical history (including respiratory, cardiac, gastrointestinal (extensive symptoms such as N/V, early satiety, abdominal pain or discomfort, diarrhea, bleeding, jaundice), and other symptoms and signs), medications, physical examination findings, laboratory data, treatment interventions (pharmacological and mechanical) and outcomes (hospitalization, length of hospital stay, death, etc.).

Data management and quality assurance: Data management will be handled by the Data Management Team at the Medical University of South Carolina (MUSC). All study activities will be conducted in coordination with the registry PIs and the clinical sites, and will use an electronic data acquisition method wherein all clinical data on included subjects will be entered directly by the site personnel. The latest version of each CRF will be available as a PDF file on the study website for use as worksheets and source documents by study personnel.

The study data will be managed (including data queries) using the RedCap system. This system will be used for secure data entry and transfer, data validation, project progress monitoring,

and subject tracking if necessary. Continual central data monitoring will be conducted by the Data Management Team at MUSC to ensure accuracy and absence of duplication.

Data security and confidentiality: Throughout the study period, user access to the data housed within the study database will be restricted to core study staff at MUSC. In addition to use of passwords and other security measures, all documents containing identifying information on individuals or physicians are considered confidential materials and will be safeguarded to the greatest possible extent. No information, which identifies a specific person, hospital, or physician, will be released to, or discussed with anyone other than study staff members. The study database only identifies study subjects by unique study identification codes. All data will be stored in a manner that is HIPAA compliant, without the ability to track the information back to a specific subject except through a password protected system. All study personnel at the primary institution are certified by the NIH Office of Human Subjects Research in the Protection of Human Research Subjects course.

Data dissemination: A primary goal of this registry is to provide results on its study website as often as possible, in case this information is important and actionable in certain settings. Aggregate database results will be updated every 24-48 hours, allowing a reasonable period of time for quality and accuracy assessment and for data corrections/clarifications as needed.

Publications policy: Presenting registry data at national and international meetings and peer-reviewed publications are important priorities to this coalition. All publication proposals will be reviewed by the North American Coalition for the study of Digestive Manifestations of COVID-19 Steering Committee. Authorship will be agreed upon unanimously or an authorless masthead will be used.