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SPOTLIGHT ON CLINICAL RESEARCH
A Selection of COVID-19 Studies
at Penn Medicine Lancaster General Health

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Editor's note: *This is the seventh in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies. This report focuses on studies related to the SARS-CoV-2 virus (COVID-19).*

Physicians who wish to refer patients for any of the studies mentioned below, or who wish to learn about additional COVID-19 studies, are encouraged to contact the Penn Medicine Lancaster General Health Research Institute at 717-544-1777.

Other members of the Penn Medicine LGH staff who are conducting research and wish to have their studies described here are encouraged to contact the offices of JLGH at 717-544-8004.

SPONSORED STUDIES

An Open Label Trial of Transfusion of COVID-19 Convalescent Plasma (CCP) to Patients With Moderate to Severe COVID-19
Sponsor: Mayo Clinic
Principal Investigator: Joseph Kontra, M.D.

This study, developed by the Mayo Clinic, evaluates the safety and effectiveness of convalescent plasma for COVID-19. The research hypothesis is that transfusion of COVID-19 convalescent plasma (CCP) improves outcomes.

Patients 18 years or older with COVID-19 who have been admitted to an acute care facility with severe or life-threatening disease will receive transfusion of one unit of banked plasma from donors who have recovered from COVID-19. Eligible donors include patients who have recovered from COVID-19 with high titers of IgG antibody to this virus.

This treatment offers a potential rescue therapy for patients with severe and life-threatening COVID-19 disease, and explores its use in patients for whom progression to serious disease is likely.

More than 50 patients at LGH have received plasma as a part of this study.

Covid-19 Critical Care Consortium Observational Study: Incorporating ExtraCorporeal Membrane Oxygenation (ECMO) for 2019 Novel Coronavirus Acute Respiratory Disease
Sponsor: COVID-19 Critical Care Consortium & University of Pennsylvania Health System
Principal Investigator: Mark Epler, M.D.

The Covid-19 Critical Care Consortium is a research collaborative established to assist in pandemic planning on an international scale. Given the lack of COVID-19 therapies, this study aims to collect real-time observational data on COVID-19 patients in hospital and intensive care unit (ICU) settings, including those who require ECMO. The Consortium is then able to disseminate detailed data and insights across the globe with maximum efficiency.

This study began on January 1, 2020, and includes more than 350 sites in over 48 countries. The study enrolls patients at the time of ICU admission and follows them to the time of death, hospital discharge, or 28 days post-ICU admission, whichever occurs last. Any patient admitted to the ICU due to COVID-19 is included in this prospective, observational study. Patients are only excluded if they are on mechanical ventilators or ECMO for non-COVID-19 pulmonary reasons (e.g. trauma-related).

UPHS COVID-19 Critical Care Outcomes
Sponsor: University of Pennsylvania Health System
Principal Investigator: Maulik Patel, M.D.

With the prospect of a potential second wave of infections, physicians understand the need to identify risk factors associated with the COVID-19 virus. This retrospective study aims to determine the outcomes of hospitalized COVID-19 patients. It examines test-positive COVID-19 patients in the ICU and seeks to determine which risk factors are associated with 28-day mortality and 30-day all-cause hospital readmission. Study teams at six Penn Medicine hospitals plan to enroll approximately 1700 patients for retrospective analysis.

SARS CoV2 infection (COVID-19) Case Finding for Patients on Immunomodulatory Drugs

Sponsor: University of Iowa Hospitals and Clinics, Emerging Infections Network
Principal Investigator: David Abel, D.O.

This short-term study collects case findings on COVID-19 patients taking immunomodulatory drugs. The goal is to aggregate case finding results from COVID-19 patients from many geographical regions to study various treatments and outcomes. Using the Emerging Infections Network listserv, healthcare workers complete a survey for eligible patients, entering the data into a REDCap database.

INVESTIGATOR INITIATED STUDIES

COVID-19: Clinical and Objective Characteristics. Developing and Evaluating a Sequential Numerical Scoring Tool for Triage and Prognostication

Principal Investigator: Shakeel Amanullah, M.D.

The purpose of this retrospective, descriptive study is to develop a sequential scoring system. The study team hypothesizes the scoring system will be an invaluable tool when dealing not only with COVID-19 but future pandemics wherein specific antiviral treatments are unavailable. Researchers screen for and enroll patients who present at Penn Medicine Lancaster General Hospital with a positive COVID-19 test.

Data collection occurs in a REDCap database. Exploratory questions include but are not limited to:

- Is older age associated with lower inflammatory response and perhaps more susceptibility to virus activity?

- Is younger age associated with a more robust inflammatory response and perhaps more responsiveness to suppression of cytokine storm?

- Obesity and alcohol are independent markers of poor prognosis in the ICU. In China, the prevalence of obesity is 6%, versus 46% in the US. Do these markers have an exaggerated effect in COVID patients?

- Is early intubation associated with worse outcomes?

Surveillance of COVID-19 in a Single Institution

Principal Investigator: Adam Lake, M.D.

This is a prospective, observational follow-up study focused on determining the association between known health symptoms and a positive COVID-19 test. When individuals seek care from a primary care provider (PCP), urgent care facility, or a community testing site, they have the opportunity to complete the initial survey. Electronic consent is required before the patient is considered enrolled. The survey links to their electronic medical record, allowing the study team to collect demographic information in addition to the data the participants provide.

The study sends a second questionnaire via email to the participants at 90 days and 180 days post-enrollment. This second questionnaire targets patient outcomes and new or pre-existing conditions. Dr. Lake aims to enroll over 12,000 patients in this study.

Creation of a Research Repository within the COVID-19 Lancaster County Case Investigation and Contact Tracing Program

Principal Investigator: Barbara Martin, PhD
Author: Tawnya Vernon

This study seeks to create a data repository within a COVID-19 case investigation and contact tracing program for future research analyses. Following broad consent of participants in the contact tracing program, data are collected to allow investigators to explore many research questions. These include:
- The identification of geographic "hot spots" of cases,
- The association of length or type of exposure with a positive test,
- Health risk factors for testing positive for COVID-19,
- Trends over time,
- Changes in mitigation policies or testing guidelines,
- Social barriers to self-isolation and the effects of these barriers on the spread of the disease,
- Interventions that increase compliance with guidelines and/or decrease the spread of the disease,
- Factors influencing the spread of the disease in the non-institutionalized population.

At the time of this writing, nearly 500 patients have agreed to participate in this repository. Enrollment in this study is ongoing.