

COVID-19 HIV Registry Protocol

Objective:

This internet-based survey will capture information about COVID-19 cases among people living with HIV (PLWH) in the United States. Data will be used in quality improvement/surveillance efforts aiming to improve treatment of these patients, including:

- Management of HIV in light of the COVID-19 pandemic
- Prevention and treatment of COVID-19 in PLWH

Background and Significance:

Coronavirus disease 2019 (COVID-19) is a respiratory tract infection caused by a newly emergent coronavirus, SARS-coV-2. As of March 2020, WHO characterized COVID-19 as a pandemic. There is no data to advise PLWH as to their risk of COVID-19, and published data is limited to case studies of individuals or very small groups. People with HIV are currently advised that HIV specific immunosuppression may lead to worsened outcomes for those with low CD4 counts or those not on antiretroviral treatment, but again this is not currently known.

With more than 1.1 million PLWH living in the United States (Owens et al., 2019), and 122,653 cases of COVID-19 in the United States as of March 29, 2020 ((CDC), 2020) it is assumed that multiple hundred cases of COVID-19 currently exist within PLWH. The opportunity to gather data specifically about those persons with HIV who are infected with COVID-19 could help to better inform the population of their risks as future waves of this infection are expected.

Research Design and Methods:

People living with HIV who have confirmed or suspected COVID-19 infection will be identified by treating clinicians. De-identified patient data will be entered into a web-based survey developed by the University of Maryland, Baltimore Institute of Human Virology (UMB) and Dr. Anita Kohli and hosted by UMB using the secure REDCap tool. Data will be hosted on a UMB server with state-of-the-art data and privacy protection procedures in place. A computer-generated study identifier will be assigned to each patient at the time of data entry. Data to be collected includes information about HIV treatment, labs and status, COVID-19 treatments and outcomes. PHI such as names, or date of birth will not be collected. Providers entering data in the registry may retain the unique study identifier if they would like to later enter updated information.

Data will be analyzed for relationships between disease state, medication exposure and outcomes such as hospital admission, ICU admission, intubation and death. Care will be taken to account for confounding and to interpret data correctly with respect to correlation and causation.

Human Subjects:

This study will be submitted to the Integreview IRB for determination of human subjects research. It is expected that this study will not require consent or HIPAA.

Potential Risks:

This study poses minimal risk. There is a very small risk of a breach of confidentiality of medical record information and associated privacy, which is mitigated by a) not collecting PHI in the survey, b) assigning a study identifier to each patient.

Potential Benefits:

We are collecting data with the aim of rapidly improving prevention and treatment of COVID-19 in PLWH. If patients whose data is captured have ongoing COVID-19 related treatment needs when changes to care are implemented, they may receive direct benefit from this study. Otherwise, there will be no direct benefits to patients whose data is captured.

Secondary and Future Data Uses:

The de-identified data collected as part of this study will be maintained at UMB on a secure server and shared in aggregated form with the HIV provider community and with the public. It may be used in other studies to evaluate the relationship between HIV and health outcomes.

Dissemination and publication of outcomes

We anticipate that results will be used to inform national and international practice regarding management of HIV, and may ultimately be published in peer-reviewed journals. We would expect to release weekly summaries of collected data during the pandemic.

References:

Centers for Disease Control and Prevention (2020). Coronavirus Disease: Cases in the United States. Retrieved March 29, 2020, from <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>

Owens, D. K., Davidson, K. W., Krist, A. H., Barry, M. J., Cabana, M., Caughey, A. B., ... Wong, J. B. (2019). Screening for HIV Infection: US Preventive Services Task Force Recommendation Statement. *JAMA - Journal of the American Medical Association*, 321(23), 2326–2336. <https://doi.org/10.1001/jama.2019.6587>