RAMP Project Abstract: New York Blood Center CRS, New York, NY, USA

Project Title: Examining the impact of the COVID-19 pandemic on participation in Phase I HIV vaccine clinical studies among diverse populations in New York City: A social networks perspective

Project Overview:

The goal of Project ACHIEVE/New York Blood Center Clinical Research Site based in New York City is to work on novel ways to prevent HIV and other infectious diseases, including the SARS-CoV-2 virus that causes COVID-19. As part of the research site, you will have the opportunity to work with a diverse team of clinical investigators, epidemiologists, social scientists, community engagement and recruitment staff, and more and be immersed in innovative clinical, socio-behavioral, and epidemiologic research.

As a RAMP scholar you will have the opportunity to work with Hong Van Tieu, MD, MS, Lab Head and Associate Member of the Laboratory of Infectious Disease Prevention/Project ACHIEVE at the New York Blood Center (NYBC), Jorge Soler, PhD, MPH and the Project Achieve research team consisting of co-investigators, clinicians, counselors, recruiters, and community educators who are experienced in recruitment, community engagement, study implementation and conduct, and retention in research studies among general and at-risk populations.

While participating in this 8 to 10-week program, you will work with the team to conduct a two-phase research project, (1) To examine the association between residing in a zip code impacted by COVID-19 and HIV and participating in a Phase I HIV vaccine clinical study, and (2) To identify individual and network-level influences associated with willingness to participate in a Phase I HIV vaccine clinical study. You will be integrally involved in all aspects of the study including developing the surveys and recruitment materials, programming the surveys, recruiting, analyzing the data, and preparing the manuscript. You will also be required to complete online human subject trainings.

Project Summary:

The COVID-19 pandemic and subsequent Phase III COVID-19 vaccine clinical studies have renewed the public’s awareness of clinical studies and vaccine research. This raises a critical question about how this awareness may be impacting people’s motivation to learn about and participate in HIV vaccine clinical research. COVID-19 has shed light again on barriers, that have existed for decades, related to vaccine uptake and clinical trial participation, thus potentially decreasing this motivation. However, experiencing the COVID-19 pandemic and the success of the COVID-19 vaccine clinical studies may also increase a person’s motivation to participate in vaccine studies not only for COVID-19 but also for other diseases. Empirical evidence on the potential impact of COVID-19 on HIV vaccine clinical study participation remains scarce.

Nationally, and in New York City (NYC), COVID-19 vaccine uptake is socially patterned by race and ethnicity, with vaccination rates lowest among Black/African American populations. This finding is consistent across other vaccines (influenza, pneumococcal, herpes zoster, Tdap) with rates among Latino/Hispanic and Asian populations also lagging that of white populations. A major limitation of this data is the grouping of people into broad racial and ethnic categories that erase within group differences and further obscure underlying disparities. Particularly in major metropolitan areas where these broad categories can comprise a range of racial and ethnic subpopulations, examining differences in vaccine uptake by national groups (ancestry/place of origin) can help identify gaps in vaccine uptake. Equitable implementation of vaccines across and within socio-demographic groups is critical for reducing health
disparities given the disproportionate rates of morbidity and mortality attributed to these diseases impacting racial and ethnic minority groups in the United States.

The HVTN’s community engagement model describes the role that community education, recruitment, and retention can play in reducing both hesitancy to vaccinate and hesitancy to participate in a vaccine clinical study. Specifically, community education is setting “the foundation for awareness, literacy, and support of HIV prevention and HIV clinical research locally.”. This definition acknowledges that people are embedded in communities that influence and are influenced by individual community members. A major effort of community education is establishing social norms that prepare communities to receive new ideas and innovations. From an implementation science perspective, a critical piece of this community preparedness is identifying key influential people and sources of information that can impact people’s acceptance of and participation in a new health intervention.

The proposed study aims to use a social networks approach to identify key people and relationships in a person’s network to characterize the network’s potential influence on awareness, knowledge, perceptions, and attitudes related to COVID-19 and HIV vaccine research. We will examine how these psychological antecedents shaped motivation to participate in an HIV vaccine clinical study by interviewing community members that were prescreened for participation in a Phase I HIV vaccine clinical study and completed their first in-person screening visit at the study site. Importantly, we will query how the impact of COVID-19 on people’s communities and networks may have influenced their decision to volunteer for a Phase I HIV vaccine clinical study.

We are proposing a two-phase study to:

1. Examine the association between residing in a zip code impacted by COVID-19 and HIV and participating in a Phase I HIV vaccine clinical study.
2. Identify individual and network-level influences associated with willingness to participate in a Phase I HIV vaccine clinical study.

Regulatory requirements for the project and plans for completing them:

IRB approval will be obtained from the New York Blood Center Institutional Review Board before the start of this study. The RAMP Scholar and all members of the research team will complete CITI and required IRB training before they are allowed to participate in the study. Online informed consent will be obtained from all research participants before they are directed to the main survey study. Electronic data will be stored on password protected computers at the NYBC; hard copies will be stored locked filing cabinets accessible to members of the research team only.

Expected Deliverables:

1. NYC HIV Prevention Community Advisory Board meeting – presentation
2. HVTN Full Group Meeting – presentation
3. Abstract submission to a scientific conference
4. Manuscript for submission to a scientific journal

Project Contact Person(s):

- Jorge Soler, PhD, MPH, jsoler@nybc.org
- Hong Van Tieu, MD, MS, htiue@nybc.org