





DFW COVID-19 COMMUNITY PREVALENCE STUDY

Study Proposal June 12, 2020

THE REAL PREVALENCE OF THE VIRUS

COVID-19 has infected more than 2 million people in the United States and more than 7.5 million people worldwide. As of June 12, 2020, there have been more than 80,000 confirmed cases in Texas and almost 20,000 cases in Dallas and Tarrant Counties. Despite the high number of confirmed cases, the true prevalence of COVID-19 infections is believed to be underestimated, but to an unknown degree. There are many reasons for this, including insufficient testing capacity early in the pandemic that led to under-recognition of COVID-19 infections, as well as the fact that the CDC currently estimates that 35 percent of those infected with COVID-19 are asymptomatic.

As a result, there are few studies quantifying community-level exposure in the United States. Understanding the true prevalence of COVID-19 infection and the risk of exposure among vulnerable (e.g., racial/ethnic minorities, low socioeconomic status) and high-risk (e.g., health care workers, grocery store workers) populations is critical to inform policy decisions regarding testing, re-opening businesses, building infrastructure, and distributing resources for potential outbreaks in the future.

Exposure to COVID-19 and risk of infection may depend on several individual and community-level factors. For example, nationwide, non-Hispanic blacks account for approximately one-third of COVID-19-related hospitalizations despite only accounting for 13 percent of the population. Non-Hispanic whites account for 60 percent of the nationwide population, but only 45 percent of those hospitalized. The factors contributing to this disparity are likely multifactorial and may stem from differences in comorbidity (e.g., pulmonary disease, metabolic syndrome, and cancer predispose to worse outcomes), socioeconomic status, and ability to social distance (e.g., population density, housing).

While we have not yet seen evidence of similar disparities in Tarrant and Dallas Counties, we must carefully monitor for COVID-19 hot spots created by racial/ethnic and socioeconomic residential segregation, which would demand expanded interventions to mitigate COVID-19 spread and morbidity.

Additionally, a higher proportion of COVID-19 cases have occurred among persons with certain occupations, including healthcare workers, first responders, and day care and grocery store employees, and those who have not been able to engage in social distancing.

It is currently unknown how long COVID-19-specific antibodies remain in the body after infection and to what degree those antibodies confer long-term immunity. It is also unclear to what extent reinfection is possible. Some patients in South Korea and China tested negative after recovering, only to test positive again several weeks later. While recent reports indicate that these newly positive tests may represent "biological residue" rather than new active infections, recovered patients must be followed for a much longer period to truly understand reinfection risk. Such longitudinal studies are necessary to help us estimate how long immunity might last by measuring changes in blood antibody and virus levels over time. This information is central to making educated policy decisions over the long term based on our understanding of how herd immunity may develop in the population.

OUR SOLUTION

UT Southwestern and Texas Health Resources are joining forces to launch a large COVID-19 prevalence study in early July that encompasses Tarrant and Dallas Counties. We will test 44,000 individuals, including

14,000 high-risk workers and 30,000 community members—spanning the full breadth of socio-economic, racial, and geographic diversity throughout Tarrant and Dallas Counties—to understand the true prevalence of COVID-19 in DFW. To address these short-term and longer-term needs, we propose a multiphase project.

Phase 1A

Phase 1A is proposed as a cross-sectional study to characterize the prevalence of COVID-19 exposure and predisposing risk factors in Dallas and Tarrant Counties. We will include approximately 30,000 subjects for initial data collection.

Sampling strategy: We will take random samples from participants of different racial/ethnic, socioeconomic, and population compositions (max 1 person per household). This strategy will efficiently allow us to recruit equal numbers of patients across the three most common racial/ethnic groups in Dallas and Tarrant Counties (non-Hispanic white, non-Hispanic black, and Hispanic) and across socioeconomic status—representing the diversity of the area and spectrum of COVID-19 related risks.

Patients who are selected will be mailed an initial invitation letter describing the study, followed by a phone call to discuss the study with the selected household member, obtain informed consent, complete required survey questions, and schedule a visit to the testing site.

Data and sample collection: Information collected over the phone from patients who are selected will include demographics (age, sex, race/ethnicity), socioeconomic status, occupational status, household composition, underlying health conditions, any contact with suspected or known COVID-19-positive patients, potential COVID-19 symptoms, and self-reported social distancing. Patients will then travel to the nearest of our testing sites, which will be increased and strategically placed throughout Tarrant and Dallas Counties, to be tested for active and previous COVID-19 infections using PCR and antibody tests, respectively. All patients will be notified of their results, and public health authorities will be notified of positive results in order to follow-up with any necessary contact tracing.

Phase 1B

Phase 1B will be a cross-sectional study to characterize the prevalence of COVID-19 exposure among higher-risk groups who may serve as sources of disease spread. Higher-risk groups will be defined by occupation, including restaurant and grocery store workers, childcare providers, meat-packing employees, and those in the airline industry. Healthcare workers and first responders are not included because we are conducting a separate prevalence study for those groups, funded by Lyda Hill Philanthropies. We will include approximately 14,000 subjects from the various industries mentioned for data collection.

Strategy: Because these higher-risk groups may be under-represented in population-based sampling (Phase IA), we will partner with community organizations to facilitate random sampling of these individuals and then proceed as in Phase 1A. To make it easier for people to participate, on-site testing can be arranged with employers.

Phase 2

Beyond cross-sectional studies, longitudinal studies will help us understand immunity to COVID-19 after infection and the potential for reinfection, as well as monitor the development of new hot spots. As social distancing policies relax, such monitoring will be key to curbing future outbreaks.

Phase 2 will be a longitudinal study to estimate changes in the presence of antibodies and virus in blood tests over time. We will monitor for new hot spots by assessing the incidence of new COVID-19 exposures among patients who initially tested negative by both antibody and PCR. In order to better understand the development and duration of immunity to COVID-19, we will reassess antibody levels and look for new active infections by PCR among those who initially tested antibody-positive.

Sampling strategy: From phases 1A and 1B, a random sample of antibody-negative patients will be selected for repeat PCR and antibody tests, along with all antibody-positive patients.

Data and sample collection: At six months and one year after the initial test, PCR and antibody tests will be performed again. Patients also will be asked to report any influenza-like-illness symptoms in the past three months, new medical conditions, change in occupational status, and self-reported social distancing behavior.

COMMUNITY ENGAGEMENT AND REPORTING

To ensure success and educate the community, an engagement campaign will be launched along with the study. Outreach tactics will include a dedicated website, fliers, media placements, and engagement with places of worship in the community to encourage participation. Our current timeline is based on an assumption of 45 percent participation by those who are contacted. The higher our participation rate, the more quickly the study can be completed.

As the data will be analyzed by an internal team of data scientists at UT Southwestern, we will have the ability to provide frequent updates to community stakeholders and government officials to help lead the community through this challenging time.

MAKING IT HAPPEN

Philanthropy will be critical to helping UT Southwestern and Texas Health Resources identify the true spread of COVID-19 in our community. The sooner we can secure funding and start this important work, the sooner we can help business leaders and government officials make the best decisions in keeping North Texans safe and the economy open. We hope that you will join us in supporting this critical endeavor.