Project Baseline Health Study: Impact Analysis of the COVID-19 Pandemic on Clinical Operations and Participant Engagement in a Longitudinal Study

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BACKGROUND

Dr Ken Mahaffey (M.D.) and the late Dr. Sanjiv Sam Gambhir (M.D., Ph.D.), principle investigators, had the vision to map human health and offer a unique contribution to mankind through the Project Baseline Health Study (PBHS). After six years and over 9000 visits across three sites, we are now beginning the final year of the study.

It is doubtful that both principle investigators could have imagined that a once-in-a-century pandemic would come in the middle of this 5-year longitudinal study. While SARS-CoV-2 (COVID-19) shut down our site and resulted in approximately 700 missed clinic visits over two years, it is worthwhile to note that the PBHS research data set now includes human health data spanning from before the pandemic to a post-vaccinated era. During this turbulent period, our site also pivoted to a modified protocol offering a Virtual Visit Only (VVO) option to our participants to help them stay engaged with the study. Because of this, some of the onsite assessments can now be captured even when a participant is unable or prefers not to come onsite.

The impact of the statewide shelter-in-place (SIP), exercise limitations, restricted socialization and dietary changes can now be measured and analyzed using the PBHS research data acquired over the past few years. In addition, the other PBHS posters you see today will provide further insight into the challenges and benefits of running a longitudinal human health study during a pandemic.

RESULTS

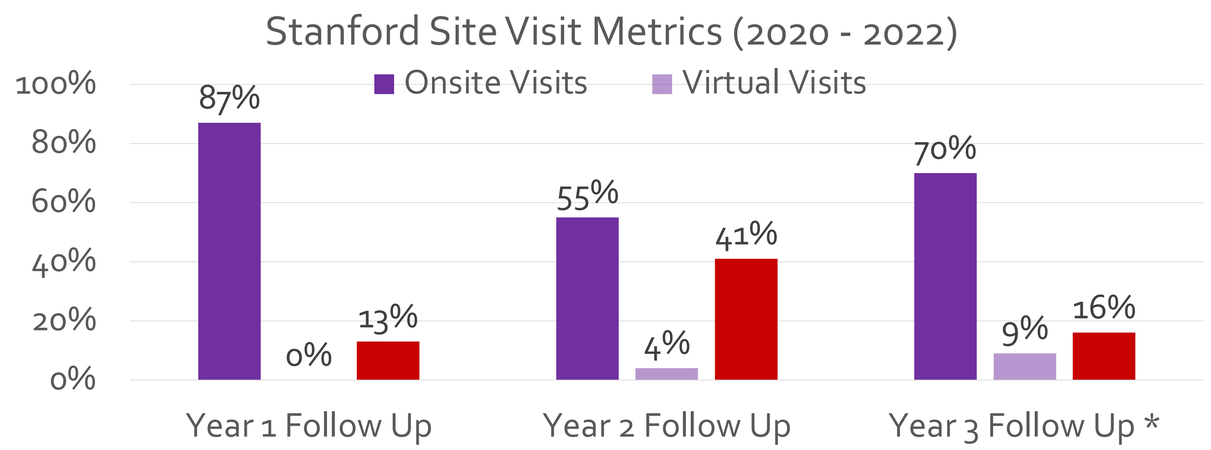

Figure 1 Stanford site visit metrics covering the period from before the start of the COVID-19 pandemic to its vaccine being widely available to the general public

* Ongoing visit, not all participants have completed this time point

Prior to the start of the COVID-19 pandemic in March 2020, Year 1 follow up onsite visits were robust with an 87% completion rate. However, with the COVID-19 related site shutdown from March to October 2020, Year 2 follow up onsite visits dropped significantly to just 55%. Post COVID-19 vaccination (October 2020), 70% of participants chose to complete their Year 3 follow up onsite and 9% of participants chose to complete just the virtual visit component. While missed visits were highest at 41% for the Year 2 follow up time point, this has improved significantly as the Stanford site re-opened and offered a VVO option to help participants stay engaged. Final year visit metrics – Year 4 follow up – will be captured and analyzed sometime in 2023.

RECENT PUBLICATIONS AND PRESENTATIONS

Project Baseline Health Study Articles and Poster Presentations:

Accelerated Aging is Associated with Cardiometabolic, Hematologic and Renal Abnormalities: a Project Baseline Health Substudy

Best Uchehara, Lydia Coulter Kwee, Jessica Regan, Ranee Chatterjee, Julie Eckstrand, Sue Swope, Garry Gold, Terry Schaack, Francois Haddad, Joy Wu, Scarlet Shore, Jessica Mega, Robert Califf, Adrian Hernandez, Kenneth W. Mahaffey, Neha Pagidipati, Svati H. Shah. Originally published - 8 Nov 2021 **Circulation.**

- Poster presentation at American Heart Association Annual Meeting; November 13-15, 2021, Boston, MA

General Anxiety Disorder-7 Questionnaire as a marker of low socioeconomic status and inequity

Julio C. Nunes, Megan K. Carroll, Kenneth W. Mahaffey, Robert M. Califf, P. Murali Doraiswamy, Sarah Short, Svati H. Shah, Susan Swope, Donna Williams, Adrian F. Hernandez, David S. Hong. **Accepted for publication**

- Poster presented at The American Psychiatric Association (APA) Annual Meeting; May 1-3, 2022, New Orleans, LA

Articles Associated with Project Baseline Health Study:

Multi-dimensional characterization of prediabetes in the Project Baseline Health Study Chatterjee, R., Kwee, L.C., Pagidipati, N. et al. Multi-dimensional characterization of prediabetes in the Project Baseline Health Study. 2022 **Cardiovasc Diabetol**.

Importance of Social Determinants in Screening for Depression

Robert M Califf, Celeste Wong, P Murali Doraiswamy, David S Hong, David P Miller, Jessica L Mega, Baseline Study Group. 17 Aug 2021, **Journal of General Internal Medicine**

Biological and clinical correlates of the patient health questionnaire-9: exploratory cross-sectional analyses of the baseline health study

Robert M Califf, Celeste Wong, P Murali Doraiswamy, David S Hong, David P Miller, Jessica L Mega, Baseline Study Group. 04 Jan 2022 **BMJ Open**

CONCLUSIONS

Next year we will have some interesting concrete research data and operational analysis to share with the SCCR. We will show relationships between COVID-19 and the PBHS data with determinants of longevity, mental health surveys, and other assessments from before and during the COVID-19 pandemic. It will also help us take into consideration how the pandemic has had an impact on health indirectly through influencing various social determinants of health, which will serve as a resourceful tool for improving public health.

The goal of Project Baseline Health Study was never meant for study investigators to write one article, but to create a robust and multi-modality data set for others to write and publish many articles. COVID-19 possibly created a once-in-a-century opportunity to examine the impact of pandemics on a large healthy population. We think that this is a fantastic contribution to mankind.

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