

Novel study design could improve research on future pandemics

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A special report published in *The Journal of Applied Laboratory Medicine* describes the design, operations, and methodology of the COVID Immunity Study, a large-scale scientific study by ADLM that took place in September 2021. By detailing the design of this novel study, the special report aims to facilitate similar studies by other



scientific societies. These could fill in gaps in infectious disease research and potentially improve the global response to future pandemics.

The COVID Immunity Study is the first scientific study performed by a professional association that combines an online health survey, on-site blood collection, off-site testing and analysis, provision of SARS-CoV-2 testing results to participants, and sample banking to address questions of SARS-CoV-2 immunity. Large-scale epidemiological studies such as this are crucial for understanding how viruses evolve and for making informed public health decisions.

Because these types of studies demand tremendous resources, they are typically conducted by <u>government agencies</u> or as <u>collaborative efforts</u> by academic research groups. As the COVID Immunity Study shows, though, scientific societies also have the resources and expertise to perform large-scale <u>epidemiological studies</u>.

These organizations are also in a position to investigate potentially important lines of inquiry that traditionally funded research can't look into. While several papers that were either recently published or in preparation focus on the results of the COVID Immunity Study, this special report discusses the methodology of the study and unique challenges it encountered with the goal of providing a model for other scientific societies to follow.

The COVID Immunity Study was mainly conducted at the 2021 AACC Annual Scientific Meeting in Atlanta. Blood was drawn on-site from 698 participants, who provided consent and completed general health and COVID-19 questionnaires beforehand.

A portion of each sample was sent to Quest Diagnostics for T-cell function analysis, while serum and plasma were obtained from the remaining samples, which were stored at Centers for Disease Control



and Prevention (CDC) facilities in Atlanta and made available to medical and research communities. Partnerships between ADLM staff and subject-matter experts such as clinical laboratory scientists and immunologists, as well as state and local health departments, were crucial to the success of the study.

The study group encountered several logistical and practical challenges during the execution of the COVID Immunity Study, including staffing shortages due to the pandemic, the lack of prior on-site facilities for a scientific study, unavailable and back-ordered supplies, and the large number of participants required to donate blood. Though the COVID Immunity Study was successfully planned and executed in 6 months, the paper's authors recommend a 12-month or longer period for such a study, especially if conducted in pandemic conditions.

"ADLM believes that the unique makeup of <u>scientific societies</u> positions them well to ask and answer pressing questions in their fields that might otherwise not fall into a clear area of interest by traditional research funding sources," the report authors said. "We hope that this paper will serve as a reference—and set a precedent—for member-based organizations to contribute to future such scientific studies."

More information: Caitlin Ondracek et al, Large-Scale Scientific Study Led by a Professional Organization during the COVID-19 Pandemic: Operations, Best Practices, and Lessons Learned, *The Journal of Applied Laboratory Medicine* (2023). DOI: 10.1093/jalm/jfad089

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