Title: RxSAPhE (**R**epeated **S**eroprevalence of COVID-19 **A**ntibodies in **Ph**armacy & Policy **E**mployees and Students) – Preliminary Findings

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Background

COVID-19 was first discovered in Wuhan, China and the World Health Organization warned of a novel coronavirus related pneumonia on January 9, 2020[1]. The first confirmed case of COVID-19 in the United States occurred on January 21, 2020[1] and since then, there have been almost 33 million cases of COVID-19 in the United States and over 168 million cases worldwide[2]. COVID-19 is responsible for more than 580 thousand deaths in the United States and over 3.49 million deaths around the world[2].

With the onset of a pandemic caused by a novel virus, assessing immunity in patients that have either had a natural infection has not been identified. Initial guidance suggested that there was a 3 month period of immunity after a natural infection to protect patients from re-infection. CDC recently released that the antibody response after a natural COVID-19 infection can be durable for 6 months or more[3]. It is unclear however, if an antibody response to COVID-19 is correlated to protection from an infection from SARS-CoV-2 virus. Antibodies only make up one part of the immune response, with virus specific memory T and B cells possibly playing a role in the immunity against SARS-CoV-2.

Methods

The objectives of the study were to Evaluate the prevalence and persistence of SARS-COV-2 antibodies in students, faculty and staff in a school of pharmacy. Secondary objectives were to look at reinfection rate throughout the study population.

This was a prospective, longitudinal study conducted at a school of pharmacy in Los Angeles. Inclusion criteria included any students, faculty and staff of the school over the age of 18. There were no exclusion criteria. Participants did not have to have a history of a COVID-19 diagnosis or vaccination to enroll in the study. The data was collected and stored in Redcap which is a HIPAA compliant software and is IRB approved. Enrollment began in February 2021.

Each study participant was screened at the initial appointment to ensure they met the inclusion criteria. Their baseline demographics and initial COVID-19 history of illness or vaccination was documented. At follow up appointments, any changes in vaccination history or document illness since the last visit was documented.

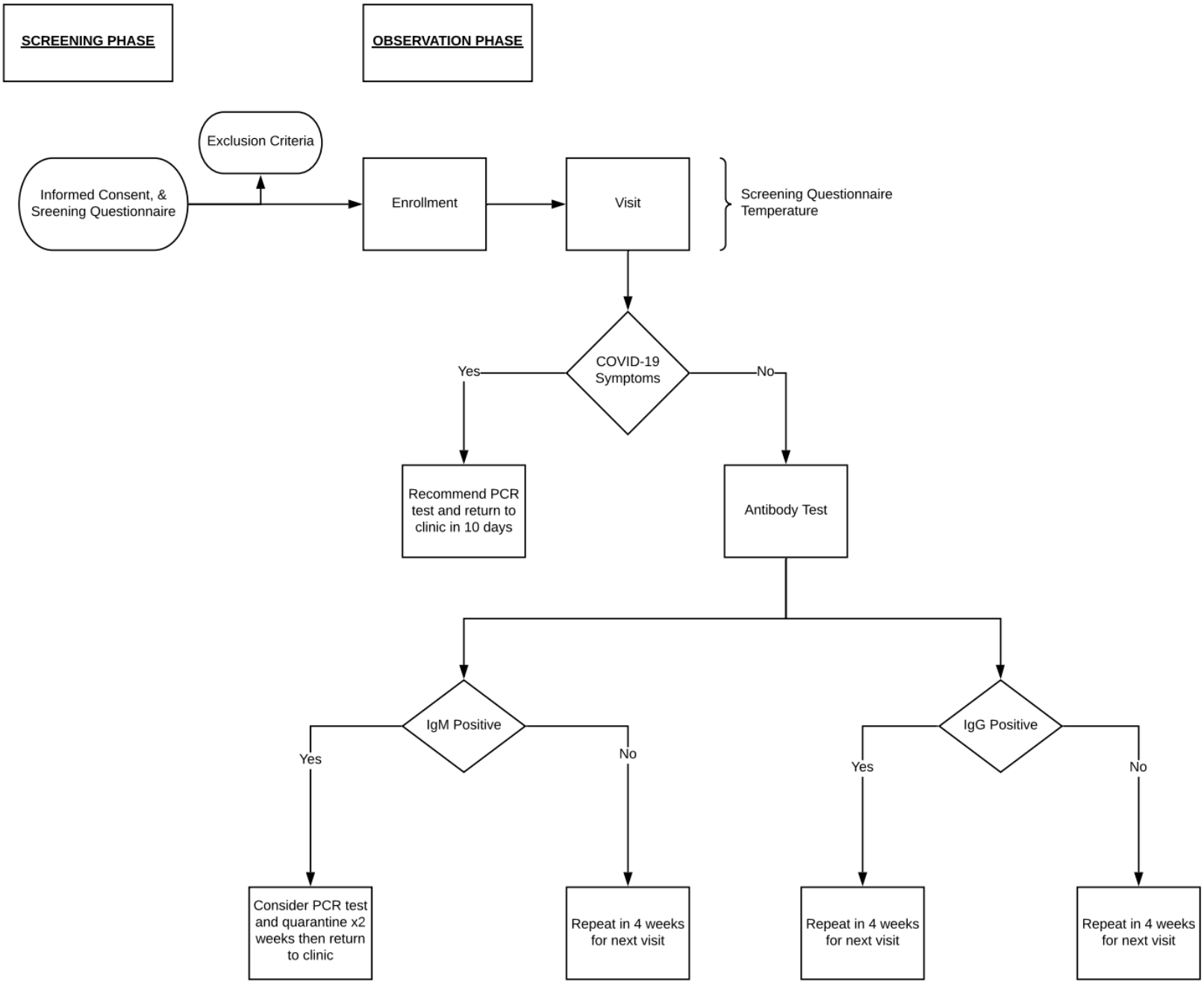

Figure 1: Workflow of each appointment.

After the baseline demographics or follow up questionnaire was asked, each participant then received a rapid COVID-19 IgG/IgM test (see Figure 2). Results were completed in 15 minutes and the test would signify either a positive or a negative for both IgG and IgM antibodies against COVID-19. The test was only qualitative, not quantitative, so the antibody levels could not be identified with this test.

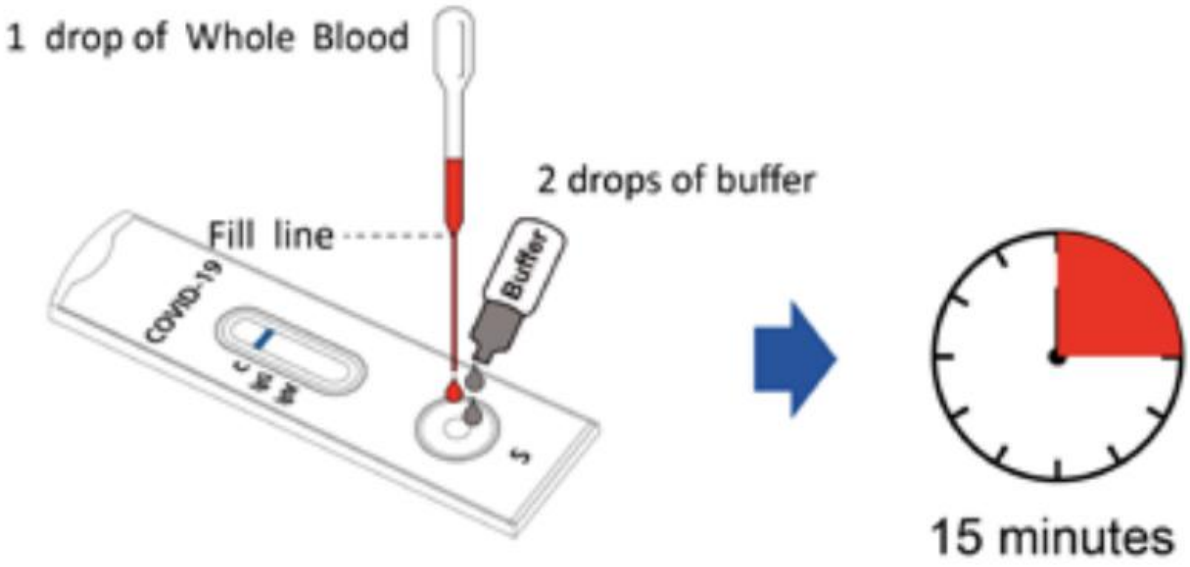

Figure 2: Example of rapid COVID-19 antibody test used

Follow up with each participant occurred once monthly. The duration of the study is expected to be once monthly for 12 months.

Results

From February 2021 to April 2021, a total of 120 participants were enrolled in the study for the initial three month period. Each participant was able to completed the baseline characteristics (Table 1). A majority of the participants were already vaccinated with BNT162b2 or mRNA-1273 (84.2%) and only 14.2% had a diagnosed history of COVID-19.

Table 1: Baseline Characteristics

Baseline Characteristics	Total (n=120)
Race	
White	45 (37.5%)
Asian	40 (33.3%)
Black/African American	5 (4.2%)
Native American	2 (1.7%)
Multiracial	4 (3.3%)
Other	24 (20%)

Ethnicity	
Hispanic	28 (23.3%)
School of Pharmacy Affiliation	
Faculty	15 (12.5%)
Staff	54 (45%)
PharmD Student	40 (33.3%)
PhD Student	6 (5%)
Other	5 (4.2%)

Table 2: Baseline COVID-19 history

COVID-19 Vaccination History (n=120)	
BNT162b2	85 (70.8%)
mRNA-1273	16 (13.3%)
Neither	19 (15.8%)
History of COVID-19 Diagnosis	
Yes	17 (14.2%)
No	103 (85.8%)

For the first month appointment, the participants were separated into groups based off their vaccination history or natural infection. All participants that had a history of COVID-19, regardless of vaccination history, tested positive for IgG besides one participant. All participants that only had a history of COVID-19 vaccination all had IgG antibodies if they were 2 weeks post vaccination. There were 8 participants who were still less than 2 weeks from their vaccine and did not have any antibodies detected (Figure 4).

IgM antibodies were less predictable than IgG antibodies. A total of 22 participants tested positive for IgM. 15 of those only had a history of vaccination, and 7 had a documented history of COVID-19.

All participants who did not have a history of COVID-19 infection or vaccination tested negative for both IgG and IgM antibodies.

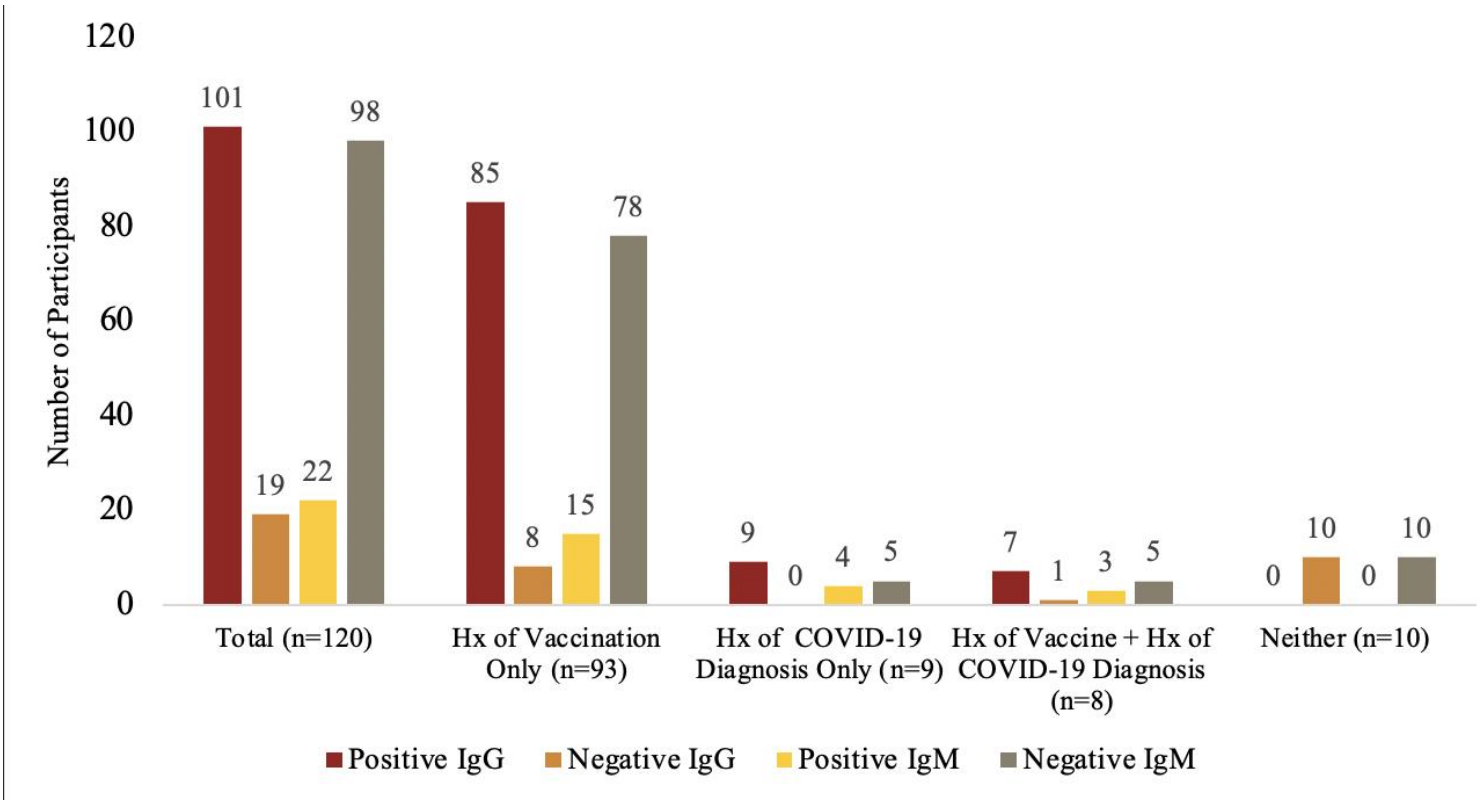

Figure 3: Month 1 IgG and IgM antibody test results

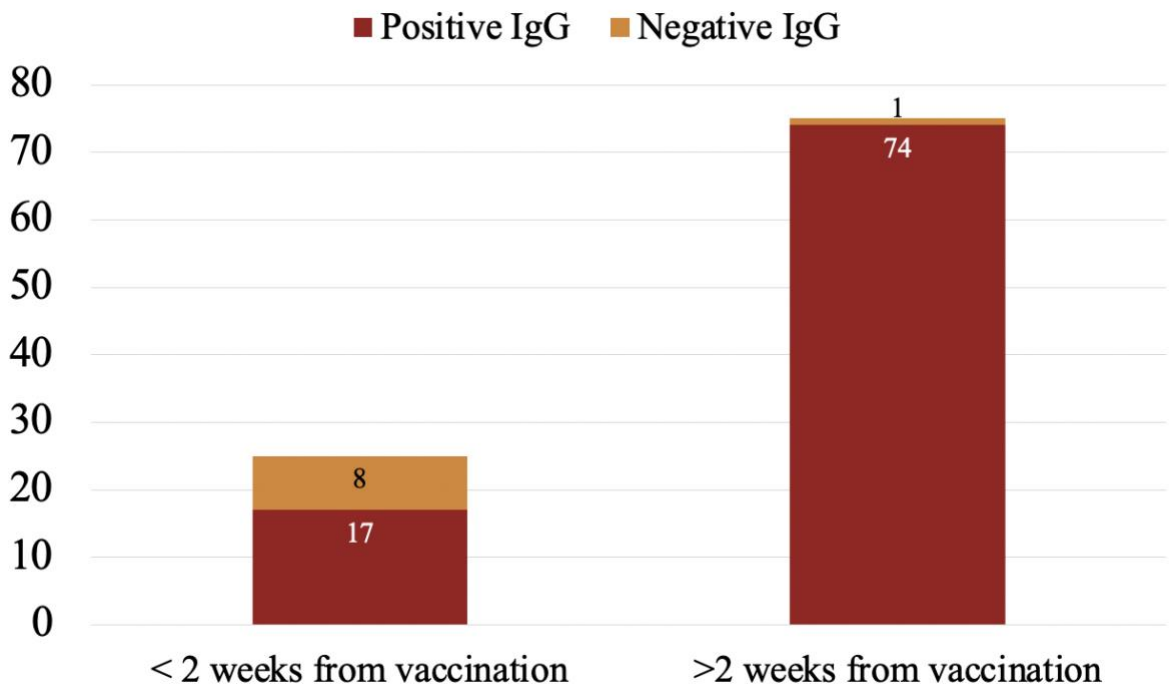

Figure 4: First month appointment

Month 2

Of the 120 participants the completed the first month appointments, 97 enrollees completed their second month appointment. Of those participants who tested positive for COVID-19 antibodies with history of vaccination and/or documented diagnosis of COVID-19 history, all continued to test positive for IgG antibodies. 6 participants who had a history of vaccination only continued to have both IgG and IgM antibodies with an average of 30 days post vaccination.

Month 3

Of the 120 participants enrolled in the study, 77 were able to complete their third month appointment. Of those participants who tested positive for COVID-19 antibodies with history of vaccination and/or documented diagnosis of COVID-19 history, all continued to test positive for IgG antibodies. Only 2 of the participants continued to have both IgG and IgM with only a history of COVID-19 vaccination (30 and 98 post second dose). As of the third month appointment, there have not been any participants that have been infected with COVID-19 since the start of the study.

Discussion

While we cannot say that the presence of IgG and IgM antibodies leads to protection for COVID-19, it is an interesting and easily testable lab value to follow how long those antibodies can be detected for and if that is associated with any cases of reinfection. With a majority of the participants already vaccinated due to being frontline health care workers, we weren't able to have a large sample of non-vaccinated and without

Current recommendations from the CDC state that a person counts as fully vaccinated if they are 2 weeks past their second dose. The data shown in Figure 4 supports that recommendation with several people still 2 weeks post vaccination having no antibodies formed. There was one participant who was exactly 2 weeks from vaccination that still was negative for antibodies, which turned positive at the next appointment. Although there was a slight delay in the one person's seroconversion, a very high majority had already completed seroconversion by that 2 week mark.

Regardless of which vaccine a participant received, BNT162b2 or mRNA-1273, all participants continued to test positive for IgG antibodies. Pfizer and BioNTech have released data that their vaccine protects recipients for 6 months post vaccination. Several of the recipients were 4 months post second dose and continuing to test for positive for antibodies. This will be interested to continue to follow to see if there are any recipients that fall below detectable levels in the next couple months of the study.

IgM antibodies were detected less frequently in both participants with a history of vaccination and a history of a natural infection. IgM antibodies are expected to be detected if a person has a natural infection, as it is the immediate and short term antibodies. These antibodies eventually

convert into IgG which is the longer lasting antibody. A participant was 6 months post diagnosis of COVID-19 and still continuing to test positive for both IgG and IgM. Typically, with vaccines, only IgG antibodies are formed. There were some participants who had tested positive for IgM post vaccination, with a majority of them converting to negative within the next two appointments. There are still two participants who have tested positive for IgM, with one of them being almost 100 days post second dose which is significantly longer than IgM typical lasts for.

Throughout the duration of the study, several limitations were experienced. Due to the pandemic, access to campus was limited with most faculty, staff and students working from home. A study size of 500-1000 was initially planned, there just weren't that many people working and studying on campus to have that sample size. Due to this, it was also difficult to have participants follow up at each month's appointment, as seen with the decrease in numbers at the second and third month times. Another limitation is that the test that we are using is only qualitative and not quantitative.

Future directions will lead to another period of enrollment when everyone comes back to campus to further increase the sample size and lead to better results. The study will continue on for 12 months to help assess persistence of antibodies formed.

References:

1. https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020
2. "Cases in U.S. | CDC." https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html. Accessed 25 May 2021.
3. https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html