New Research Finds that at-Home Antibody Tests could Drive higher COVID-19 Booster Rates

A group of researchers evaluated the feasibility and benefits of lateral flow assay (LFA)-based antibody tests for detecting inadequate <u>coronavirus disease 2019</u> (COVID-19) immunity and informing booster vaccination decisions in a healthcare provider (HCP) cohort.



Introduction

By the end of 2022, over 96% of United States (US) individuals aged 16 or older had severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibodies from <u>infection</u> or vaccination.

However, immunity wanes over time and is less effective against new variants. Major variants like Delta and Omicron have spike protein mutations affecting <u>vaccine</u>-induced antibody binding and neutralization.

With the emergence of <u>Omicron subvariants</u>, waning immunity raised concerns, yet booster uptake remains low. Factors such as vaccine hesitancy and side effects contribute to this. Further research is needed to validate the effectiveness of point-of-care (POC) tests in diverse populations and to optimize strategies for enhancing booster vaccine uptake.

<u>Study</u>

The present study enrolled 237 HCPs from George Washington University Hospital's (GWUH)s <u>emergency department</u>, recruited via emails, notifications, and fliers. Samples were collected at five time points: May/June 2020 (baseline, T0), January 2021 (post-first dose, T1), March 2021 (post-second dose, T2a), July/August 2021 (pre-booster, T2b), and November/December 2021 (post-booster, T3).

Venous blood samples were refrigerated for serum separation and stored at -80°C, while saliva samples were collected using the Oracol S14 device and stored similarly. Past SARS-CoV-2 infection history was determined using <u>polymerase chain reaction</u> (PCR) and nucleocapsid antibody tests.

Neutralization assays with live virus constructs measured the neutralizing activity of serum samples. Oral fluid antibody responses were assessed with a multiplex immunoassay, and T cell receptor β chain sequencing was performed using the Immunosequencing (immunoSEQ) Assay.

Recombinant protein antigens were used in Enzyme-Linked Immunosorbent Assay (ELISA) assays to measure antibody responses. Multiplex surrogate neutralization assays evaluated Angiotensin-Converting Enzyme 2 (ACE2) blocking antibodies to <u>SARS-CoV-2 variants</u>.

LFAs with blood and oral fluid samples detected SARS-CoV-2 Immunoglobulin G/Immunoglobulin M (IgG/IgM) <u>antibodies</u>.

Findings

To evaluate the dynamics of binding and functional antibodies after a two-dose messenger Ribonucleic Acid (mRNA) vaccine based on the Wuhan strain of SARS-CoV-2, samples were analyzed from 35 <u>naïve-vaccinated</u> (NV) and nine infected-vaccinated (IV) subjects in the HCP cohort at two post-second dose time points: T2a (4 to 9 weeks) and T2b (19 to 36 weeks).

Spike and receptor binding domain (RBD) binding <u>antibody levels</u> declined by 43 to 77% between T2a and T2b in both NV and IV subjects, with a more significant reduction in RBD-directed antibodies.

NV subjects showed a 62% decrease in ACE2-blocking antibodies and a 56% decrease in neutralizing activities, while IV subjects experienced a 33% reduction in ACE2-blocking antibodies and an insignificant change in <u>neutralizing antibodies</u>.

To support informed decisions about COVID-19 booster vaccinations, the study investigated whether simple laboratory binding assays could predict low functional neutralizing antibodies in <u>blood samples</u>. Initial evaluations using RBD ELISA binding results accurately predicted weak neutralizing activity.

The Cellex quantitative (q)SARS-CoV-2 IgG/IgM Rapid test, a low-cost POC test, was also evaluated. Negative results from the Rapid test highly correlated with low RBD binding activity and weak live-<u>virus</u> neutralization for Wuhan and Delta strains, though correlation with the Omicron strain was lower.

Next, due to their noninvasive nature, the study assessed oral fluid samples as an alternative to blood testing. The Emergency Use Authorization (EUA) CovAb SARS-CoV-2 IgG test for oral fluid showed strong correlations between negative test results and low RBD binding activity and weak neutralizing activities for Wuhan, Delta, and <u>Omicron strains</u>.

The oral fluid <u>LFA test</u> demonstrated good positive and negative agreement with live-virus neutralization assays, supporting its use in informing individuals about weak SARS-CoV-2 functional antibody responses.

The study then evaluated vaccine-induced antibody responses in LFA-positive and LFA-negative groups, tracking dynamics of Spike RBD binding, live-virus neutralization activity, and <u>ACE2</u> <u>inhibition</u> activity against various variants.

Both groups showed declines between T2a and T2b but significant increases after the booster dose, with the LFA-negative group showing higher fold increases. However, both groups benefited from the <u>booster vaccine</u> in developing neutralizing antibodies, especially against the Omicron strain.

To assess antibody avidity, the study measured the strength of RBD-directed antibodies before and after the third booster dose. The booster improved avidity for Wuhan and <u>Delta strains</u> in both groups, with Omicron binding showing notable increases post-booster.

Additionally, the study found that mRNA vaccine-induced antibodies had broad neutralizing activity against phylogenetically distant <u>sarbecoviruses</u>.

T-cell responses were also analyzed, showing similar contraction and expansion patterns postvaccination and post-booster in both LFA-positive and LFA-negative groups. However, no significant differences in <u>T-cell breadth</u> and depth were observed between the two groups before or after the booster dose.

Conclusion

To summarize, as new SARS-CoV-2 strains emerge, tailored vaccines may be optimal. By May 2023, <u>bivalent booster</u> uptake in the US was under 20% and 41% for those 65 and older, indicating the need for new strategies.

This study used EUA blood- and oral fluid-based lateral flow POC antibody tests to detect inadequate SARS-CoV-2 <u>immunity</u> in healthy adults post-two-dose mRNA vaccination. Negative POC test results correlated with low neutralizing antibodies for various strains, guiding booster vaccination needs.

Boosters significantly improved antibody levels, especially in those with initially <u>weak responses</u>, highlighting the importance of repeated doses for enhanced protection.

Source:

https://www.news-medical.net/news/20240617/At-home-antibody-tests-could-drive-higher-COVID-19-booster-rates-new-research-finds.aspx