

The use of antibody tests to determine level of immunity against coronavirus disease 2019 (COVID-19) after vaccination: A recent trend in India

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To The Editor—India, the second worst-hit country due to the coronavirus disease 2019 (COVID-19) pandemic, has registered a total of 30 million cases, and 392,000 deaths.¹ To combat the huge loss of life in the second wave of the pandemic due to the delta variant of the coronavirus, the Government of India announced its third phase of vaccination. Eligibility was extended to all adults aged ≥ 18 from May 1, 2021, onward, with 3 vaccines being provided: Covishield/Oxford AstraZeneca (adenovirus viral vector), Covaxin (inactivated SARS-CoV-2), and Sputnik-V (adenovirus viral vector).²

As of June 23, 2021, 261 million doses of the Oxford AstraZeneca vaccine, 35.3 million doses of Covaxin, and 50,000 doses of Sputnik-V have been distributed.³ As the number of vaccinated individuals has increased, concern has also increased among beneficiaries due to a proportion of vaccinated individuals continuing to contract the virus. Although the numbers of vaccinated individuals testing positive remains low (0.03% of individuals after the second dose of Covishield and 0.04% after the second dose of Covaxin⁴), the public has continued to use tests that detect antibodies against SARS-CoV-2 spike proteins, which have been advertised by private laboratories to “detect levels of immunity” after vaccination.

The popularity of these tests rose dramatically during the second pandemic wave, especially among recent beneficiaries of the vaccine, due to the worry that they were not sufficiently protected even post vaccination and also due to increased advertisement of these antibody tests by private laboratories. A private laboratory in the city of Pune, India, reported a 25% increase in the sale of these tests in June 2021 compared to April and May.⁵ Another news article reported that private laboratories had observed a 3-fold increase in patients opting for these antibody tests compared to February 2021.⁶

In June 2021, a resident of the city of Lucknow, India, registered a legal complaint after a negative rapid antibody test, 28 days after taking the first dose of Covishield (Oxford-AstraZeneca) vaccine.⁷ Such incidents are inciting individuals to go as far as revaccination with a different type of vaccine after negative antibody test results.

The COVID-19 virus comprises nearly 30 proteins, of which special attention has been given to M (membrane), E (envelope), N (nucleocapsid), and S (spike) proteins.⁸ The M, E, and N proteins are surface proteins that are critical for viral assembly, whereas the S protein is responsible for entering and infecting host cells and fusion with the host cell membrane. The S protein has 2 further

subunits: S1 (the globular head) and S2 (the stalk embedded within the viral envelope). S1 binds to receptors on the host cell surface, whereas S2 is responsible for conformational changes that lead to fusion with the host cell membrane.⁸ Because the S protein is responsible for viral propagation, vaccines tend to target it by producing antibodies against the S protein. The S protein is also responsible for induction of neutralizing antibodies (NAbs),⁸ which makes it a good target for vaccines. Four types of tests are available to check for antibodies against these spike proteins: rapid diagnostic tests, which are growing in popularity, enzyme-linked immunosorbent assay (ELISA), neutralisation assays, and chemiluminescent assays.

The FDA, USA, however, has advised against the use of such antibody tests for quantitative/qualitative analysis of immunity achieved after vaccination, advising that such tests are only to be used to indicate a history of COVID-19. The FDA cites many reasons for its position, including false-negative results due to incorrect proteins being tested. It is possible for a person who has been vaccinated to receive a negative result if the antibody test in question is only testing for antibodies against nucleocapsid (N) protein, which are achieved via natural infection and not vaccination, whereas antibodies against the S protein are produced in response to vaccination. Concern is also growing that a positive antibody test may result in individuals taking fewer precautions, leaving them vulnerable to infection.⁹ The CDC also warns against the use of antibody tests to assess immunity after vaccination because these antibody tests can identify a humoral response. However, these tests do not identify the role played by cell-mediated immunity through B and T cells, which is increased by vaccination.¹⁰

Dr Carl Fichtenbaum, infectious disease specialist at the University of Cincinnati College of Medicine, argues against the use of these tests, stating that these tests are in an early and unestablished phase of development. He argues that while such antibody tests are beneficial for diseases such as measles and mumps, they have been developed over decades. Dr Peter Hotez, dean of the National School of Tropical Medicine at the Baylor College of Medicine, has a similar stance that sufficient published evidence to confirm the threshold of antibodies against spike proteins, which deems a patient safe from subsequent infection, is still lacking. However, Dr Hotez states that there may be benefit in such tests, especially in immunocompromised individuals who require increased surveillance because they are at increased risk.¹¹

In conclusion, these tests should be used only when necessary and not as measures of detection of immunity after vaccination until sufficient studies have established the threshold of antibodies at which a person is considered immune. As healthcare workers, it is imperative that we guide the public to understand the way these tests work so that they are used in the correct circumstances rather than causing confusion among the masses.

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