OPINION

Why, when, and how should recipients of the *COVID-19* vaccine be tested for anti-Sars-cov-2 antibodies?

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ABSTRACT

Coronavirus disease 2019 covid-19 hospitalizations and deaths can be prevented in large part by universal vaccination, although there is significant inter-individual variability in the effectiveness of the covid-19 vaccinations, mostly because of recipients' variable immunological responses. As a result, the objective of this opinion piece is to explore several elements of the possibility of monitoring anti-sars-cov-2 antibodies both before and after covid-19 vaccination, highlighting the benefits and drawbacks of this approach.

In conclusion, the benefits of testing anti-sars-cov-2 antibodies in people who have received the covid-19 vaccination include determining the baseline sero prevalence of sars-cov-2 infection in people who have not received the vaccine, early detection of low or non-responders to the covid-19 vaccination, and timely

Detection of faster anti-sars-cov-2 antibody level decay. Contrarily, potential drawbacks to date include an unproven equivalence between anti-sars-cov-2 antibody titer, neutralizing activity, and vaccine efficacy; the absence of cost-effective analyses of various testing strategies; and the enormous volume of blood draws and growth in laboratory workload that would be required to support universal anti-sars-cov-2 antibodies testing. Identification of cohorts to be tested first, such as those at higher risk of contracting variations of concern, those at higher risk of illness progression that is not favorable, and individuals in whom vaccination immunogenicity may be anticipated to be lower and/or shorter, is one potential option.

Key Words: *Immunoassays, Sars-Cov-2, Covid-19, Vaccination and Monitoring.*

INTRODUCTION

The severe infectious disease coronavirus disease 2019 covid-19, which was first identified as the unknown cause of pneumonia, in Wuhan City, China, on December 31, 2019, has now spread globally and is responsible for almost 3 million deaths. Reliable evidence now indicates that physical precautions including lockdowns, social isolation, extensive face mask use, and hand cleanliness are only partially successful in preventing or mitigating the catastrophic effects of covid-19on people's health, society, and the economy. Therefore, it appears that vaccination for all people will be the most effective means of preventing viral spread as well as the enormous number of hospital admissions and fatalities linked to Sars-cov-2 infections. The current covid-19vaccine arsenal includes a variety of possibilities, such as inactivated virus, viral proteins such as the Sars-cov-2 spike protein, DNA- and mRNA-based vaccines, and the most recent generation, lipid-based mRNA nanoparticle vaccines, According to data that has been released so far, the different vaccines have a significantly high clinical efficacy in preventing the risk of developing severe or critical forms of covid-19illness caused by the prototype Wuhan strain, while displaying a relatively lower clinical efficacy in patients with infections caused by new Sars-cov-2 variants and a similarly limited level of protection against any type of Sars-cov-2 infection.

Consequently, this would suggest that some types of monitoring vaccine efficacy would be prudent for estimating individual and community immunogenicity and the ensuing efficacy in all potential recipients. In order to discuss some aspects of the possibility of monitoring anti-Sars-cov-2 antibodies before and after *covid-19*vaccinations, the current opinion piece will do so.

Why?

The baseline serological monitoring now seems to be a viable option for guiding vaccine administration for at least three major reasons, namely assessing the baseline seroprevalence of *Sars-cov-2* infection in non-vaccinated individuals, evaluating the immune response in both

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anti-Sars-cov-2 seronegative or seropositive subjects at baseline, and eventually reducing the risk of experiencing negative events after a covid-19vaccination in patients with prior Sars-cov-2 infection. The first point is obvious, but how each person will react to the covid-19 vaccine remains entirely uncertain. For instance, individuals with a history of Sars-cov-2 infection appear to respond to the two-dose complete cycle of the mRNA covid-19vaccine less favorably than those who have not previously been exposed to the virus.

This appears to be primarily due to the fact that the majority of individuals who have experienced a prior Sars-cov-2 infection have already developed a straightforward humoral, cellular, and memory immune response. As a result, the modest increase in anti-Sars-cov-2 antibodies following the second vaccine dose in subjects who have strongly responded to the first seems to be primarily caused by this. This would also make it possible to administer the vaccine in the most effective way to those who might benefit from it helping to at least partially resolve the current vaccine manufacturing bottleneck that is perpetuating outbreaks and increasing the risk of the emergence of new mutant strains.

Recent population investigations on baseline anti-*Sars-cov-2* seronegative individuals showed that immunogenicity following mRNA vaccination varied significantly amongst recipients, with differences in the amount of neutralizing antibodies spanning between 1 and 2 orders of magnitude. Salvagno specifically mentioned that following a full cycle of the Pfizer Bnt162b2 vaccination, women and participants younger than 60 years old had overall anti-Sars-cov-2 *RBD* antibody values that were 20% and 30% higher than those of men and the elderly, respectively. In comparison to young women, older males had a total antibody response to the anti-Sars-cov-2 *RBD* that was about 50% lower. Similar data was gathered in other research, where it was noted that older individuals and or males had decreased vaccine immunogenicity.

These groups may be more vulnerable in the presence of a weakened immune response due to the higher risk for poor *covid-19*development and outcomes associated with advanced age and male sex. Notably, there has lately been concern stated that those who are obese or overweight may experience decreased immunogenicity from the *covid-19*immunization. The levels of anti-Sars-cov-2 spike IgG antibodies induced by vaccination were between 50 and 60% lower in pre-obese and obese people, according to preliminary results published by Pellini in recipients of the Pfizer Bnt162b2 vaccine. Additionally, a significant risk factor for severe covid-19and one that is linked to greater mortality is obesity. The third crucial factor supporting the significance of monitoring the anti-*Sars-cov-2* response in recipients of covid-19vaccinations is the potential appearance of adverse effects. Evidence is mounting that suggests *Sars-cov-2* seropositive patients may have adverse outcomes with mRNA immunization more frequently than Sars-cov-2 naive people. After receiving the first dose of the vaccine, baseline seropositive subjects experienced higher rates of fatigue, headache muscle discomfort, and fever compared to baseline seronegative subjects.

Manni also demonstrated that after receiving the first and second doses of the mRNA bnt162b2 vaccine, Sars-cov-2 seropositive patients experienced more self-reported systemic adverse events than seronegative individuals. Therefore, the risk of developing adverse events as a result of unwarranted vaccine administration may be avoided by the timely detection of baseline *Sars-cov-2* seropositive subjects displaying an effective antibody level.

There have been worries that the introduction of so-called variations of concern could considerably reduce vaccine efficacy. All of these VOCs, which appear to have independently emerged from convergent selection pressure at various latitudes, tend to share some significant mutations that either increase their binding affinity to host receptors or may vary their immunogenicity, making them less effectively counteracted by humoral and cellular immune responses that are developed following natural infection with another *Sars-cov-2* strain or following administration of vaccines based on that strain. It was recently discovered that the neutralizing power of antibodies generated following *Sars-cov-2* infection or *covid-19* immunization would be diminished, according to a foundational article written by Hoffmann. Others who studied the receivers of other vaccine formulations, such as Pfizer *Bnt162b2* or Oxford-AstraZeneca, Pfizer *Bnt162b2* or Moderna *mRNA-1273*, or Sputnik *Gam-Covid-Vac*, produced comparable data. According to several recent exploratory prospective investigations, this biological evidence may then translate into a real clinical risk. For instance, Shinde. monitored nearly 4000 participants who were randomized to receive the Novavax *NVX-CoV2373* vaccination or a placebo for at least one dosage.

When

The timing of blood collection and testing is the second crucial component of the serological evaluation of *covid-19*vaccine recipients. While extensive information on the persistence of immune responses has not yet been able to be gathered due to the relatively recent introduction of *covid-19*vaccinations, some significant evidence has recently been available. Doria, Rose found a constant degradation rate over time, with a half-life between 109 and 119 days for anti-*Sars-cov-2 RBD* antibodies and between 69 and 173 days for anti-*Sars-cov-2* neutralizing antibodies, respectively, in 33 healthy people who received the Moderna *mRNA1273* vaccination. These findings coincide with those made public about individuals who had spontaneous *SARS-CoV-2*, where it was discovered that the half-life of anti-*Sars-cov-2 Rbd Igg* antibodies was 110 days. In a different study Ketas observed the immunogenicity of the *COVID-19*vaccination over time in 45 healthy recipients. Three months after receiving the full course of vaccinations with either the Pfizer *Bnt162b2* or Moderna mRNA-1273 mRNA vaccines, a sustained response of all anti-*Sars-cov-2 RBD* antibodies classes was still noticeable in these recipients. The current evidence would therefore suggest that the initial time points may involve a baseline assessment followed by serial measurements at 1 and 6 months after the last vaccine dose, even though more information is required to establish medium- and long-term plans for anti-*Sars-cov-2* antibodies' titration after *covid-19*vaccinations.

How

There is now substantial proof that antibodies directed against the Sars-cov-2 spike protein and/or its *RBD* are primarily responsible for the post-infection or post-vaccination serum's ability to neutralize pathogens. Voss and colleagues' excellent study, which was just published, showed that the N-terminal domain of the S1 subunit of the Sars-cov-2 spike protein is highly protective in a model of lethal viral infection and that up to 84% of all neutralizing antibodies target regions outside the RBD. Since these will reflect the greatest burden of neutralizing potential, the chosen immunoassay

should preferably be based on the detection of antibodies targeting the Sars-cov-2 trimetric spike glycoprotein conformation, its S1/S2 subunit, and it's RBD. Given that only antibodies against these protein moieties will be elicited in baseline seronegative recipients, it goes without saying that the use of these immunoassays would be required in patients receiving mRNA- or DNA-based vaccines encoding for the Sars-cov-2 spike protein, as well as in patients receiving vaccines based on the direct administration of a recombinant form of the Sars-cov-2 spike protein. The Task Force on Covid-19of the International Federation of Clinical Chemistry and Laboratory Medicine also noted that there is insufficient information on which anti-Sars-cov-2 antibodies assessment would be preferable for the purpose of anti-Sars-cov-2 antibodies testing in recipients of covid-19vaccinations, so that conclusive indications on this matter cannot be made. Despite this, measuring anti-Sars-cov-2 IgM antibodies in this situation was disregarded due to their ambiguous protective role, slow increase, and rapid decay. Instead, anti-Sars-cov-2 IgA assessment should be taken into account, as this antibody class may reflect the effectiveness of mucosal protection against Sars-cov-2 infection. The decision between qualitative, semi-quantitative, or quantitative serological anti-Sars-cov-2 immunoassays is another crucial factor. Since this would enable defining the pre-vaccination baseline especially in baseline seropositive individuals, as well as allowing for simple and accurate monitoring of anti-Sars-cov-2 antibodies' decay over time, it is obvious that automated techniques for supporting larger volumes of testing that provide an accurate quantitative measure of the antibody titer should be preferred. If different anti-Sars-cov-2 immunoassays each detect different immunoglobulin's that target different viral epitopes and are characterized by heterogeneous detection limits, different cut-offs, and dissimilar ranges of antibody concentrations, the issue of using different methodological approaches could further contribute to challenging standardization and/or harmonization initiatives. Therefore, this will be viewed as a real obstacle to developing a global strategy for tailored vaccination. Despite the fact that a global standard was just introduced. Therefore, achieving satisfactory harmonization of the numerous commercially available immunoassays is still anticipated to be quite difficult. Therefore, it would be highly recommended to apply an identical immunoassay to track the kinetics of anti-Sars-cov-2 antibodies in vaccine recipients over time. Assessing IgG2a and IgG1 for identifying type 1 T helper and type 2 T helper immune responses, respectively, could also be taken into consideration.

CONCLUSIONS

Testing for anti-Sars-cov-2 antibodies in people who have received the covid-19vaccine has unquestionable clinical benefits, but it may also present significant biological, financial, and logistical difficulties. We hope that our analysis will persuade policymakers, healthcare administrators, clinicians, and even laboratory professionals to form multidisciplinary teams with the aim of defining the local cost-effectiveness of post-covid-19 vaccination sero-surveillance campaigns despite the fact that the evidence gathered so far does not permit drawing firm conclusions on this matter. The selection of cohorts to be given testing priority is one potential sensible solution. Older men, subjects with a high body mass index or receiving immunosuppressive treatments, patients with cancer or severe impairment of renal function, are all at higher risk of contracting more severe forms of covid-19illness. These individuals are also at higher risk of contracting VOCs and or those in whom vaccine immunogenicity appears lower and or shorter. In particular, the WHO's recent assertion that international covid-19trials should be launched with a greater emphasis on immunological response gives substantial support for targeted anti-Sars-cov-2 antibody testing for evaluating the efficacy of current treatments, including vaccinations.