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SARSCoV-2 serostatus amongst vaccinated employees at a pediatric hospital system

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ABSTRACT

To gain insights on the heterogeneity of immune responses to vaccination against SARS-CoV-2 and to identify factors that could make individuals vulnerable to infection due to lack of response to vaccination, our hospital started offering free voluntary post-antibody testing against the spike protein IgG for all fully vaccinated employees.

Post-vaccination response against SARS-CoV-2 was assessed using the FDA-EUA approved VITROS anti-SARS-CoV-2 IgG immunometric assay specific to the spike protein.

Out of a total of 3266 antibody tests performed in fully vaccinated Texas Children's, 99.4% had a positive antibody response to the spike protein. From the 21 employees (0.6%) that had a negative response, 66.7% reported taking immunosuppressive drugs and/or biologics.

Our data shows that most of the employees tested at our institution mounted an immune response to the immunogen in the vaccine. Post-vaccination antibody testing against SARS-CoV-2 can provide useful information to guide decisions about future vaccine doses.

1. Introduction

As part of the efforts to combat the SARS-CoV-2 pandemic, the United States Food and Drug Administration (FDA) has given emergency use authorization (EUA) to three vaccines against SARS-CoV-2: Pfizer/BioNTech (now with full approval), Moderna NIAID, and Johnson & Johnson/Janssen (J&J).Texas Children's Hospital initiated its employee vaccination campaign against SARS-CoV-2 on December 15, 2020, after the EUA for Pfizer/BioNTech on December 11, 2020. As of September 5, 2021, greater than 85% of the almost 15,000 workforce have been vaccinated (including medical staff and faculty). Beginning on February 21, 2021, the hospital also started offering free voluntary post-vaccination antibody testing against spike protein IgG for all fully vaccinated employees, at least 2 weeks post second dose. The main goals of post-vaccination antibody testing were to gain insights on the heterogeneity of immune responses to vaccination and to identify factors that could make individuals more vulnerable to infection with SARS-CoV-2 due to lack of response to vaccination. In addition, we wished to provide additional knowledge to frontline employees who were seeking assurance that their vaccination was effective. Notable, in September 2021, the hospital also made the vaccine mandatory for its employees.

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2. Methods

The study was approved by the Baylor College of Medicine Institutional Review Board. Using VITROS anti-SARS-CoV-2 IgG immunometric FDA-EUA approved test specific to the spike protein, post-vaccination response against SARS-CoV-2 was assessed.

3. Results

Table 1 summarizes the findings of our study. A total of 3266 antibody tests have been performed from February 21, 2021 to September 5, 2021 in fully vaccinated Texas Children's employees, with an overwhelming majority of employees, 3244 (99.4%) resulting in positive antibody response to the spike protein (IgG>1.0). Only 21 employees (0.6%) had a negative antibody response. The average days from the last vaccine dose to the first antibody test was 127 days (median: 117 days, range: 25–198 days). The 21 employees with negative antibody responses were subsequently interviewed to obtain more information on previous medical history and medications. Five out of these 21 employees (23.8%) who did not develop antibodies had been vaccinated with J&J vaccine, and the rest with Pfizer/BioNTech vaccine. Autoimmune diseases were reported by 10/21 (47.6%), including 2 rheumatoid arthritis, 2 psoriatic arthritis, 1 ankylosing spondylitis, 1 Crohn's disease and 4 non-specified (Table 2). Two of the non-responders were on immunosuppressive and biologic drugs, for organ transplantation and chronic lymphocytic leukemia, respectively. A total of 14/21 (66.7%) reported taking immunosuppressive drugs and/or biologics, including 4 (19%) of those with autoimmune disease. Lastly, two subjects did not have any obvious reasons for the low antibody titers after vaccination (a healthy pregnant female and a diabetic male).

4. Discussion

Our findings are consistent with recent studies that report lower spike protein antibody titers in some patients with chronic inflammatory diseases or organ transplant under immunosuppressive therapies [1,2]. The evidence of suboptimal immune response post vaccination against SARS-CoV-2 in immunocompromised individuals has prompted the approval of an additional dose for recipients of solid organ transplant and individuals with certain immunocompromising conditions [3]. The lack of response to vaccination extends to other scenarios, many of which can be explained by the use of drugs that dampen the immune response. Although antibody testing post-vaccination against SARS-CoV-2 is currently not recommended by the CDC/FDA [4,5], our study shows the value that the testing has in identifying individuals that could benefit from an additional intervention, e.g. an additional vaccine dose and/or modifying immunosuppressive medication regimens prior to vaccination. In addition, of note, following consultation with their specialists for existing conditions, 6 subjects took an additional dose after the negative antibody result and had a subsequent positive antibody result, 2 weeks post third dose.

With further large scale studies, due to the heterogeneity in response, the need and timing of an additional dose can also be monitored by antibody testing, providing a personalized vaccination approach. Nevertheless, there are challenges that cannot be overlooked in the use of antibody testing after vaccination, including test harmonization, selection of protein moieties to detect, reliable diagnostic performance, and cost [6].

Most of the employees that were tested at our institution generated antibodies against SARS-CoV-2 after being vaccinated (99.4%). These results provide reassurance that the vast majority of individuals successfully mounted an immune response to the immunogen in the vaccine (SARS-CoV-2 spike protein), likely resulting in protection against severe disease and hospitalization due to SARS-CoV-2 infection. Interestingly, the suboptimal response was not exclusive to mRNA vaccination, but was also seen after receiving an adenoviral vector vaccine, highlighting the importance to assess response for the variety of vaccines that are currently being administered against SARS-CoV-2. One limitation of the study that we acknowledge is that antibody testing may not reflect the entire spectrum of immune response and specifically T/B-cell function was not assessed.

5. Conclusions

Overall, we believe that post-vaccination antibody testing can provide useful information to guide decisions about future vaccine doses to protect against SARS-CoV-2 infections.

Table 1
Summary of SARS-CoV-2 antibody test post-vaccination in TCH employees.

	Number	Percentage
Total Antibody Tests	3266	100
Total Positive Response	3244	99.4
Total Negative Response	21	0.6
Subsequently had a positive Ab response after another vaccine dose	6	28.6[a]
On immunosuppressive therapy/biologics	14	66.7[a]
No obvious reason for negative response	2	10.5[a]

[a] Percentage within the 21 non-responders.

Table 2
Summary of non-responders to SARS-CoV-2 vaccination.

ID	Vaccine	Vaccine(s) date	Antibody test dates	Conditions	Medications	Additional dose, Antibodies
1	Pfizer	12/17/20, 01/07/21	03/07/21	Autoimmune condition	None	Yes (J&J), Yes
2	Pfizer	12/18/20, 01/08/21	03/07/21	None	Anti-inflammatory medications post trauma	Yes (Pfizer), Yes
3	Pfizer	12/17/20, 01/07/21	03/14/21	None	Biologic	Yes (Pfizer), Yes
4	Pfizer	12/17/20,01/07/21	03/28/21	Kidney transplant (10 years ago)	Immunosuppressants	No
5	J&J	03/10/21	04/04/21, 04/18/21	None	None	Yes(Pfizer), Yes
6	Pfizer	12/16/20, 01/06/21	6/25/21, 07/02/21	Type 2 Diabetes Mellitus	Anti-allergy injections	No
7	Pfizer	12/18/20, 01/08/21	07/01/21, 7/19/21	Rheumatoid Arthritis	Biologics; off during 1st dose, on during 2nd dose	No
8	Pfizer	12/16/20, 01/06/20	03/28/21, 04/18/21	Rheumatoid Arthritis	Biologics	No
9	Pfizer	12/23/20, 01/13/21	06/22/21, 7/14/21	Autoimmune condition (like lupus)	Immunosuppressants	No
10	J&J	03/01/21	06/19/21, 08/02/21	Diabetes, poor control	Anti-inflammatory medication	No
11	Pfizer	12/30/2020, 01/27/21	05/21,07/05/21	Chronic lymphocytic leukemia	Biologics	No
12	Pfizer	Dates not available	05/30/21	None	None	No
13	Pfizer	12/19/21, 01/09/21	07/09/21, 07/19/21	Psoriasis and arthritis	Biologics	No
14	J&J	03/11/21	07/09/21, 07/19/21	Pregnant at time of vaccination	Prenatal vitamins	Yes (Pfizer), Yes
15	Pfizer	12/18/20, 01/08/21	07/16/21, 07/30/21	Ankylosing spondylitis	Chemotherapeutic and biologic	No
16	Pfizer	12/18/20, 01/08/21	07/21/21, 07/29/21	Crohn's disease	Biologic	No
17	Pfizer	12/16/20, 01/06/21	7/23/21, 07/29/21	Diabetes	Biologic	Yes (Pfizer), Yes
18	J&J	03/10/21	07/23/21 08/02/21	Diabetes (insulin dependent), parathyroid tumor, autoimmune condition	Biologic	No
19	Pfizer	12/18/20, 01/08/21	04/22/21 06/22/21, 07/30, 08/06	Psoriatic arthritis	Biologic (held prior to vaccine)	Yes (Pfizer), Yes
20	J&J	03/08/2021	08/01/2021	Osteoarthritis	None identified	No
21	Pfizer	12/23/20, 01/13/21	06/30/21; 09/1/21	Diabetes	None identified	Yes

*Limit of detection for antibody test was 0.1 s/c, and results <1.0 s/c were negative.

Declaration of competing interest

Authors have no disclosures/competing interests.

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