Serologic Analysis of SARS-COV2 IgG Antibodies Found in UCLA Health Workers in Response to the Moderna, Pfizer-BioNTech, and Janssen COVID-19 Vaccines

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Background

- SARS-CoV-2 is positive-sense single-stranded RNA viruses that infects cells via the interaction between the receptor binding domain (RBD) located on the spike protein and angiotensin converting enzyme II[1]
- DiaSorin's LIASON SARS-CoV-2 S1/S2 IgG serologic assay measures IgG levels against the spike protein, indicating current or prior COVID-19 infection[2]
- No current test exists to measure vaccine efficacy
- Moderna, Pfizer-BioNTech, and Janssen vaccines introduce the spike protein, leading to an adaptive immune response and IgG production[3,4,5]
- Serologic analysis was conducted on UCLA healthcare workers who were vaccinated by the Moderna, Pfizer-BioNTech, and the Janssen COVID-19 vaccine
- The purpose of this study is to establish a range of IgG absorbance values seen in healthy population vaccinated by the Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccine that corresponds to immunity

Methods

- 978 Remnant plasma samples from QuantiFERON-TB Gold diagnostic tests were collected from UCLA Healthcare workers from March 1, 2021- May 31, 2021
- Date of birth, sex, and date of plasma collection was collected using lab database
- Vaccine status, type, dose, and date of administration was extracted from CareConnect
- Samples were analyzed with the DiaSorin's SARS-CoV-2 S1/S2 IgG serologic assay kit using LIAISON XL, a chemiluminescence analyzer
- Absorbance values (AU/ml) were collected and used for distribution analysis
- *For the Pfizer-BioNTech and Moderna vaccines, subjects were considered complete if they received the 1st and 2nd dose and if serum collection date is at least 2 weeks post 2nd dose. For the Janssen vaccine, subjects were considered complete if date of serum collection was at least 2 weeks post receiving the 1st dose.

References

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[5] Livingston EH, Malani PN, Creech CB. The Johnson & Johnson Vaccine for COVID-19. *JAMA*. 2021;325(15):1575. doi:10.1001/jama.2021.2927
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Results

Table 1: Pfizer-BioNTech, Moderna, Janssen Overview

Vaccine Overview	Total	Percentage (%)
Number of samples	978	-
Unvaccinated	202	20.65%
Received at least 1 dose (Moderna, Pfizer-BioNTech, and Janssen)	776	79.35%
Received Janssen COVID-19 Vaccine	8	1.03%
Received at least 1 dose of Pfizer-BioNTech	586	75.52%
Received at least 1 dose of Moderna	182	23.45%
Pfizer-BioNTech	**Total**	**Percentage (%)**
Received at least 1 dose of Pfizer-BioNTech	586	--
Received 2 doses of Pfizer-BioNTech	564	96.25%
Received single dose of Pfizer-BioNTech	22	3.75%
Moderna	**Total**	**Percentage (%)**
Received at least one dose of Moderna	182	--
Received 2 doses of Moderna	166	91.21%
Received single dose of Moderna	16	8.79%

Fig 1: Pfizer-BioNTech and Moderna Vaccine Absorbance Distributions

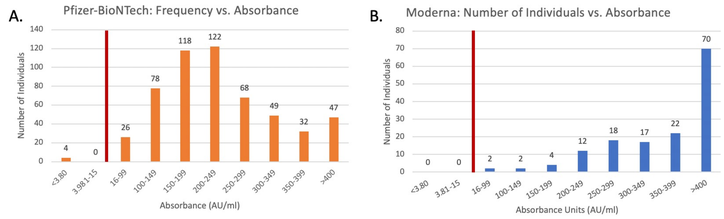

Figure 1: Pfizer-BioNTech and Moderna Vaccine Absorbance Distributions
A. Bar graph of absorbance values (AU/ml) to frequency of individuals who completed* the Pfizer-BioNTech vaccine (n=544).
B. Bar graph of absorbance values (AU/ml) to frequency of individuals who completed* the Moderna vaccine (n=147).

Fig. 2: Moderna and Pfizer-BioNTech Absorbance Distribution Stratified by Time Post Completion of Vaccine Series

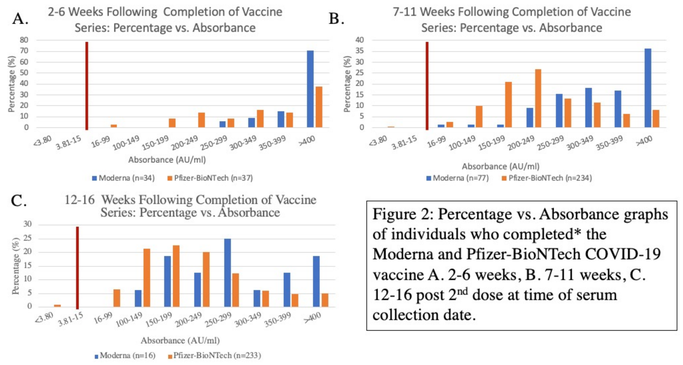

Figure 2: Percentage vs. Absorbance graphs of individuals who completed* the Moderna and Pfizer-BioNTech COVID-19 vaccine A. 2-6 weeks, B. 7-11 weeks, C. 12-16 post 2nd dose at time of serum collection date.

Fig. 3: Pfizer-BioNTech Absorbance Distribution by Age

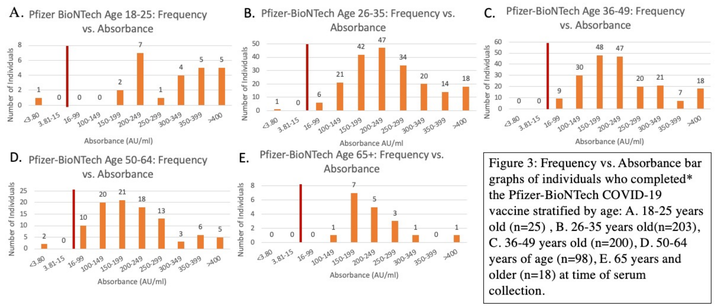

Figure 3: Frequency vs. Absorbance bar graphs of individuals who completed* the Pfizer-BioNTech COVID-19 vaccine stratified by age: A. 18-25 years old (n=25) , B. 26-35 years old(n=203), C. 36-49 years old (n=200), D. 50-64 years of age (n=98), E. 65 years and older (n=18) at time of serum collection.

Fig. 4: Moderna Absorbance Distribution by Age

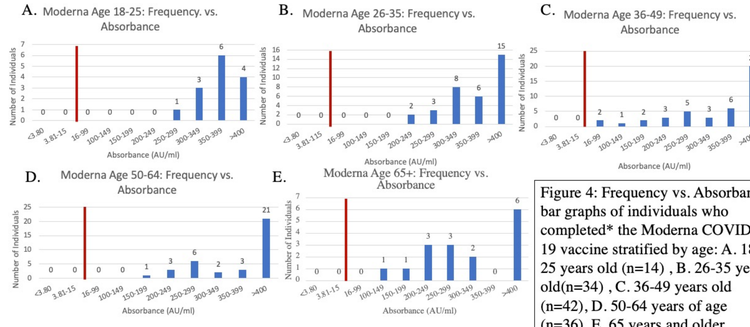

Figure 4: Frequency vs. Absorbance bar graphs of individuals who completed* the Moderna COVID-19 vaccine stratified by age: A. 18-25 years old (n=14) , B. 26-35 years old(n=34) , C. 36-49 years old (n=42), D. 50-64 years of age (n=36), E. 65 years and older (n=16) at time of serum collection.

Fig. 5: Absorbance Distribution of the Janssen Vaccine

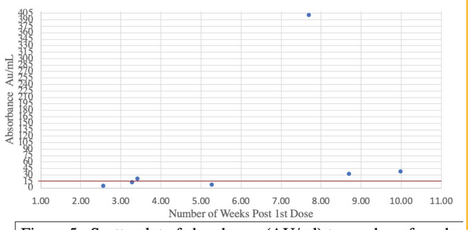

Figure 5 : Scatterplot of absorbance (AU/ml) to number of weeks post completion of the single dose Janssen COVID-19 Vaccine (n=7). Time period consists of 2-10 weeks post receiving the single dose.

**Results plotted at 400 AU/ml are equivalent to >400 AU/ml

Discussions and Conclusions

- There is a high variability in absorbance outputs in both Moderna and the Pfizer-BioNTech completed vaccinated group. (Fig. 1)
- The distribution of Pfizer-BioNTech looks like a bell shape curved, with most of the subjects measuring in the 200-249 AU/ml range (Fig. 1)
- The distribution of Moderna appears skewed to the right, with most of its subjects measuring >400 AU/ml (Fig. 1)
- Both Moderna and Pfizer-BioNTech exhibit a distribution skewed more to the right in the 2–6-week period post receiving the 2nd dose. In the 7–11-week period, Pfizer-BioNTech resembles a bell-shaped distribution, while Moderna remains slightly skewed to the right (Fig. 2). This suggests that as time passes, IgG levels fall to reach a stabilized level.
- When stratified by age, the Pfizer-BioNTech's absorbance distribution is higher in the younger population (18–25-year-old group) but resembles a bell-shaped distribution in the older population groups (Fig 3).
- In the studied Moderna population group, when stratifying by age it once against mirrors the general distribution seen in Fig. 1 where absorbance values are skewed to the right. However, it should be kept in mind of the small sample size in each age category. (Fig. 4)
- The absorbance distribution in the Janssen vaccine differs from the studied Pfizer-BioNTech and Moderna populations where 42.86% had a negative result on the IgG assay (Fig. 5)
- With preliminary data indicating that the Moderna and Pfizer-BioNTech is 94.1%[6] and 95%[7] effective respectively, data indicates that a positive result on DiaSorin's SARS CoV-2-S1/S2 serologic assay confers sufficient protection from COVID-19.

Limitations

- Serologic assay used has a limited absorbance output between <3.80->400 AU/ml
- Access to patient medical history was limited to CareConnect
  - •inaccurate categorization of immunization status due to lack of reconciliation from outside medical records
- Previous COVID-19 infection and other medical conditions were not considered during analysis, leading to confounding variables that effect IgG levels
  - •Previous infection
    - •40.63% of the unvaccinated population came out positive(>15 AU/ml) on the assay indicating previous infection, which highlights a confounding factor in measuring absorbance intensities.
  - •Immunocompromised status
- Uneven sample size between vaccine types, age, and time lapsed since vaccination

Future Directions

- Retest samples with additional serologic assays that expand the absorbance output range to allow for statistical analysis
- Expand sample size and collection duration to capture larger groups in each vaccine category, age group, and time period post completion of vaccine series
- Explore the impact of previous infection on IgG distribution levels
- I hope to provide an even larger picture on the duration of COVID-19 IgG production may look like 6-12 months post vaccination
- Establish a minimum absorbance level that indicates effectiveness of the Moderna, Pfizer-BioNTech, and Janssen vaccine