COVID-19 vaccine efficacy studies: challenges and successes

HANA EL SAHLY, MD
BAYLOR COLLEGE OF MEDICINE
I received funding from the NIH for the design and implementation of the Phase 3 clinical trial evaluating mRNA-1273 COVID-19 vaccine and the implementation of the SARS-CoV-2 rS with Matrix-M1™ COVID-19 vaccine.
 Wuhan unexplained pneumonia has been isolated test results will be announced [as soon as available]

On the evening of [30 Dec 2019], an "urgent notice on the treatment of pneumonia of unknown cause" was issued, which was widely distributed on the internet by the red-headed document of the Medical Administration and Medical Administration of Wuhan Municipal Health Committee.

On the morning of [31 Dec 2019], China Business News reporter called the official hotline of Wuhan Municipal Health and Health Committee 12320 and learned that the content of the document is true.

12320 hotline staff said that what type of pneumonia of unknown cause appeared in Wuhan this time remains to be determined.

According to the above documents, according to the urgent notice from the superior, some medical institutions in Wuhan have successively appeared patients with pneumonia of unknown cause. All medical institutions should strengthens the management of outpatient and emergency departments, strictly implement the first-in-patient responsibility system, and find that patients with unknown cause of pneumonia actively adjust the power to treat them on the spot, and there should be no refusal to be pushed or pushed.
A vaccine is/was needed
SARS-CoV-2 Vaccine Development

Any lessons from seasonal coronaviruses?

Bradburne et al. BMJ 1967
SARS-CoV-2 Vaccine Development

Any lessons from seasonal coronaviruses?

- Previous infections partially protective against disease
- Previous infections not protective against re-infection
- Neutralizing Abs wane over time
COVID-19 vaccine development
Which Antigen? Which Platform?

- First generation COVID-19 vaccine: most are S-based, some are whole inactivated virus
- WHO: 105 vaccines in clinical testing and 184 vaccines are in pre-clinical testing
- In the US: Six constructs reached Phase 3 clinical testing.

**m-RNA based**
- Pfizer
- Moderna

**Adenovirus vector**
- Janssen
- AstraZeneca

**S-Protein+adjuvant**
- Novavax
- Sanofi
- Pasteur/GSK
COVID-19 vaccine development

Why the S protein?

- SARS-CoV: S protein is primary target of neutralizing Ab
- Passive transfer and vaccines against S: Protect mice from SARS-CoV challenge
- Passive transfer and vaccine against N protein: not protective and possibly enhancing disease
- Similar findings with MERS CoV
- SARS-CoV-2 Pandemic: Humans develop robust Neut Ab against S and specifically its Receptor Binding Domain (RBD)
Covid-19 vaccine development Funding Source

Using the resources of the federal government and the U.S. private sector, Operation Warp Speed (OWS) will accelerate the testing, supply, development, and distribution of safe and effective vaccines, therapeutics, and diagnostics to counter COVID-19 by January 2021.

DEVELOPING A VACCINE

VACCINE DISTRIBUTION PROCESS

Information on DOD’s deliberate and phased plan to distribute and administer the COVID-19 vaccine to DOD personnel.
Accelerated research and development

**Time**

- **January 13, 2020**
  Sequence for mRNA-1273 against the novel coronavirus finalized

- **March 16, 2020**
  First participant in NIH-led Phase 1 study was dosed

- **April 16, 2020**
  Award from U.S. government agency BARDA for up to $483 million to accelerate development

- **April 27, 2020**
  IND submitted to US FDA for Phase 2 study

- **May 1, 2020**
  Collaboration announced with Lonza Ltd to manufacture mRNA-1273

- **May 18, 2020**
  Positive interim Phase 1 data announced

- **May 29, 2020**
  First participants dosed in Phase 2 study

- **July 2020**
  Phase 3 start

Total of 63 days from sequence selection to first human dosing
Vaccine Clinical Trial Phases

Traditional development
- Design and exploratory preclinical studies (years)
- Process development preclinical, toxicology studies (2–4 years)
- IND submitted
- Clinical trials (5–7 years total)
- BLA submitted
- Regulatory review by FDA, EMA etc. (1–2 years)
- Large-scale production and distribution
- 15 years or longer

SARS-CoV-2 vaccine development
- Design and exploratory preclinical studies
- Process development preclinical, toxicology studies
- IND submitted
- Overlapping clinical phases
- Production (at risk)
- BLA submitted
- Regulatory review by FDA, EMA etc. (1–2 months)
- 10 months to 1.5 years total

Krammer F, Nature 2020
Phase 3 clinical Trial Study Design: What are the options?

- Statistically efficient
- Randomization at the subject level within site
- Of value when there is heterogeneity in disease incidence
- If the vaccine has indirect effect then there maybe reduction in disease incidence in comparator arm: *impact efficacy assessment*
Phase 3 clinical Trial Study Design: What are the options?

- Efficient when more than one candidate is to be tested simultaneously
- Resource-saving approach
- Potential to diversify the vaccine candidates reaching the market
- Minimizes the effects of temporal trends in disease epidemiology on vaccine efficacy estimates.
Phase 3 clinical Trial Study Design: What are the options?

- All subjects in a cluster receive the same intervention.
- Randomization occurs at the unit level: household, high-risk communities, town, transmission network (ring)
- Allows measurement of total (direct and indirect) effect.
- Less efficient than iRCT
Phase 3 clinical Trial Study Design: What are the options?

- The vaccine is given to all subjects in a randomized order.
- Complex planning and analysis
- All subjects and units are to be enrolled/randomized before vaccination.
- Slow to perform

Dean et al. Sci Transl Med 2019
Phase 3 clinical Trial Study Design: What are the options?

- Six constructs were moving to Phase 3 clinical testing in Apr-May.
- A multi-arm RCT is most efficient at testing the VE.
- It would require collaboration and planning between various pharmaceuticals.
- There was variability in the readiness of some of the constructs to launch within a similar timeframe.
Phase 3 clinical Trial Primary Endpoint: What are the options?

- Infection
- Disease
- Severe Disease

A study with a primary endpoint that captures all the endpoints of public health importance is likely not feasible.
Phase 3 clinical Trial
Infection as endpoint

- Detecting infection with and without symptoms requires frequent sampling and surveillance.
- Seroconversion as an endpoint: can be a proxy for infection. Requires validated tests.
- Many vaccines of public health importance do not prevent infection but prevent disease: setting up the vaccine for failure and not helping public health
Phase 3 clinical Trial
Severe disease as endpoint

- Severe disease is the most clinically meaningful outcome to prevent
- Lower frequency indicates the need for even larger sample sizes
- For most vaccines, preventing mild disease also prevents severe disease
- Inactivated measles, Formalin inactivated RSV vaccine resulted in worsening/severe disease

At a minimum severe disease should be assessed.
Phase 3 clinical Trial
Symptomatic COVID-19 as endpoint

- Virologically confirmed symptomatic disease: represents a disease outcome of interest
- Precedent with other viruses.
- Improved feasibility: sample size consideration.

- Another good compromise: Burden of disease as endpoint (weighing severe cases more than mild-moderate cases)
Phase 3 clinical Trial
Symptomatic COVID-19 as endpoint

- Vaccine efficacy of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the second dose of study product.

COVID-19

TWO of: Fever ($\geq 38^\circ$C), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s)

OR

ONE of: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia;

AND

Respiratory Sample positive for SARS-CoV-2 by RT-PCR
Phase 3 COVID-19 vaccine efficacy study mRNA-1273-P301

- Clinical trial principle: the study population should represent the vaccine target population.
- Problem: clinical trial participation is traditionally predominantly Caucasians.
- COVID-19 disproportionately affects minorities: higher incidence and higher mortality.
COVID-19: Mortality by key demographics

Williamson EJ, et al. Nature 2020
COVID-19: Race/Ethnicity differences in mortality

**Unadjusted for age**
- Distribution of COVID-19 deaths (%)
- Unweighted distribution of population (%)

- Non-Hispanic White: 50%
- Hispanic: 20%
- Non-Hispanic Black: 10%
- Non-Hispanic Asian: 5%
- Other: 5%
- Non-Hispanic American Indian or Alaska Native: 3%
- Non-Hispanic Hawaiian or Other Pacific Islander: 2%

**Age-standardized**
- Non-Hispanic White: 50%
- Hispanic: 20%
- Non-Hispanic Black: 10%
- Non-Hispanic Asian: 5%
- Other: 5%
- Non-Hispanic American Indian or Alaska Native: 3%
- Non-Hispanic Hawaiian or Other Pacific Islander: 2%
Mortality by COVID-19 by underlying co-morbidity

Williamson EJ, et al. Nature 2020
Phase 3 clinical Trial
Symptomatic COVID-19 as endpoint

- Stratification: usually pre-specified to account for variables that affect the outcome in a predictable fashion

- AGE < 65

- AGE of 65 and older

- Presence of severe disease risk criteria
mRNA1273 Efficacy in older persons and persons with co-morbidities


Vaccine Efficacy of mRNA-1273 to Prevent Covid-19 in Subgroups

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Placebo (N=14,073)</th>
<th>mRNA-1273 (N=14,134)</th>
<th>Vaccine Efficacy (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>185/14,073</td>
<td>11/14,134</td>
<td>94.1 (89.3–96.8)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥18 to &lt;65 yr</td>
<td>156/10,521</td>
<td>7/10,551</td>
<td>95.6 (90.6–97.9)</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>29/3552</td>
<td>4/3583</td>
<td>86.4 (61.4–95.2)</td>
</tr>
<tr>
<td>Age, risk for severe Covid-19</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 to &lt;65 yr, not at risk</td>
<td>121/8403</td>
<td>5/8396</td>
<td>95.9 (90.0–98.3)</td>
</tr>
<tr>
<td>18 to &lt;65 yr, at risk</td>
<td>35/2118</td>
<td>2/2155</td>
<td>94.4 (76.9–98.7)</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>29/3552</td>
<td>4/3583</td>
<td>86.4 (61.4–95.2)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>87/7462</td>
<td>4/7366</td>
<td>95.4 (87.4–98.3)</td>
</tr>
<tr>
<td>Female</td>
<td>98/6611</td>
<td>7/6768</td>
<td>93.1 (85.2–96.8)</td>
</tr>
<tr>
<td>At risk for severe Covid-19</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>43/3167</td>
<td>4/3206</td>
<td>90.9 (74.7–96.7)</td>
</tr>
<tr>
<td>No</td>
<td>142/10,906</td>
<td>7/10,928</td>
<td>95.1 (89.6–97.7)</td>
</tr>
<tr>
<td>Race and ethnic group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>144/8916</td>
<td>10/9023</td>
<td>93.2 (87.1–96.4)</td>
</tr>
<tr>
<td>Communities of color</td>
<td>41/5132</td>
<td>1/5088</td>
<td>97.5 (82.2–99.7)</td>
</tr>
</tbody>
</table>
### Janssen Vaccine Efficacy by age and comorbidity

<table>
<thead>
<tr>
<th>Age group and comorbidity presence</th>
<th>Onset at Least 14 Days</th>
<th></th>
<th>Onset at Least 28 Days</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ad26.COV2.S</td>
<td>Placebo</td>
<td>VE%* (95% CI)</td>
<td>Ad26.COV2.S</td>
</tr>
<tr>
<td>Person-yrs</td>
<td>Cases (N)</td>
<td>Person-yrs</td>
<td></td>
<td>Person-yrs</td>
</tr>
<tr>
<td>18-59, no</td>
<td>89 (8346)</td>
<td>258 (8411)</td>
<td>65.6% (56.1, 73.3)</td>
<td>58 (8267)</td>
</tr>
<tr>
<td></td>
<td>1433.5</td>
<td>1428.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-59, yes</td>
<td>48 (4404)</td>
<td>131 (4371)</td>
<td>63.9% (49.4, 74.7)</td>
<td>29 (4350)</td>
</tr>
<tr>
<td></td>
<td>671.5</td>
<td>661.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥60, no</td>
<td>14 (3391)</td>
<td>57 (3335)</td>
<td>76.0% (56.3, 87.6)</td>
<td>11 (3355)</td>
</tr>
<tr>
<td></td>
<td>541.6</td>
<td>530.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥60, yes</td>
<td>22 (3373)</td>
<td>63 (3427)</td>
<td>64.9% (42.2, 79.4)</td>
<td>15 (3334)</td>
</tr>
<tr>
<td></td>
<td>467.4</td>
<td>469.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

VRBPAC FDA briefing book, 26FEB2021
Enrollment Diversity Over Time
How Did we turn the tide?

- Commitment from Operation Warp Speed leadership and beyond
- DSMB: Diversity as a primordial study metric
- Mobilization of the CoVPN Operations:
  1. CoVPN Registry: rollout to CoVPN and non-COVPN sites
  2. Educational and Promotional Material Production
- CoVPN leadership: frequent communications to the sites “keep the eye on the goal”
- Sponsor buy-in: send directive to slow (or stop) enrollment at sites with high % Caucasian participants
How Did we turn the tide?

The study sites understood the importance of diversity and got busy and creative:

1. Increasing utilization of CoVPN registry
2. Sorting existing registries and prioritizing minorities
3. Outreach to local communities’ leaders: churches, community centers
4. Outreach to fire department, police department, retail, post office
5. Establish satellite sites in areas with high prevalence of minorities
6. Establish flexible clinic hours to accommodate participants’ needs
7. Interviews in local media outlets catering to minorities
8. Community trust/engagement based on previous experiences
Ethnic/Racial Representation
Janssen Phase 3

Race
- American Indian: 5%
- Asian: 9%
- Black, African American: 47%
- Native Hawaiian/Pacific Islander: 18%
- White: 0%
- Multiple: 64%
- Unknown: 5%

Ethnicity
- LatinX: 52%
- Non-LatinX: 45%
- Unknown: 3%

VRBPAC FDA briefing book, 26FEB2021
Ethnic/Racial Representation
EUA Receipt

- Hispanic/Latino
- American Indian/Alaska Native, Non-Hispanic
- Asian, Non-Hispanic
- Black, Non-Hispanic
- Native Hawaiian/Other Pacific Islander, Non-Hispanic
- Multiple/Others, Non-Hispanic

- Percent among Persons who completed all recommended doses in last 14 days
- Percent among Persons who are Fully Vaccinated
- Percentage of the US Population in this Demographic Category
CONCLUSIONS

- Representation of populations in whom the vaccine will be used is key:
  1. Predict responses and efficacy
  2. Facilitate uptake
  3. Inform policies

- Representation and progress are two different metrics
After EUA: Questions that remain to be answered

- Need to detect less common or delayed safety events: Will there be enhanced disease severity as antibody levels wane?
- Study Management: ethics of maintaining the blind
- Durability of vaccine efficacy, over 2 years
- Correlate of protection
- Efficacy against emerging strains
- Is there need for a boost? If so, when?
Modernata Vaccine Study
Placebo Cross Over/unblinded

Follman et al. Ann Intern Med 2021
**Randomized Trial of Immediate vs Delayed Vaccination**

Placebos Crossover to Vaccine

<table>
<thead>
<tr>
<th>Randomized to</th>
<th># cases August-November</th>
<th># cases December-March</th>
<th>Randomized to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine</td>
<td>25</td>
<td>60</td>
<td>Immediate Vaccine</td>
</tr>
<tr>
<td>Placebo</td>
<td>125</td>
<td>30</td>
<td>Delayed Vaccine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>150</td>
<td>Inferred Placebo</td>
</tr>
</tbody>
</table>

**Placebos Crossover to Vaccine**

Vaccine Efficacy 80%

**Estimated Vaccine Efficacy in Period 2**

\[
\text{Estimated Vaccine Efficacy in Period 2} = \frac{60}{150} = 60\%
\]

Based on estimated VE for newly vaccinated of 80%

Adapted from Follman D 2021
In come the variants...

<table>
<thead>
<tr>
<th>Variants of Concern</th>
<th>Lineage</th>
<th>Location of emergence/prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha</td>
<td>B.1.1.7</td>
<td>Britain</td>
</tr>
<tr>
<td>Beta</td>
<td>B.1.351</td>
<td>South Africa</td>
</tr>
<tr>
<td>Gamma</td>
<td>P.1</td>
<td>Brazil</td>
</tr>
<tr>
<td>Delta</td>
<td>B.1.617.2</td>
<td>India</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variants of Interest</th>
<th>Lineage</th>
<th>Location of emergence/prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epsilon</td>
<td>B.1.427, B.1.429</td>
<td>California</td>
</tr>
<tr>
<td>Zeta</td>
<td>P.2</td>
<td>Brazil</td>
</tr>
<tr>
<td>Eta</td>
<td>B.1.525</td>
<td>New York</td>
</tr>
<tr>
<td>Theta</td>
<td>P.3</td>
<td>Phillippines</td>
</tr>
<tr>
<td>Iota</td>
<td>B.1.526</td>
<td>New York</td>
</tr>
<tr>
<td>Kappa</td>
<td>B.1.617.1</td>
<td>India</td>
</tr>
</tbody>
</table>
Reduced Neutralization Activity of Vaccine Sera Relative to Wildtype/Dominant Strain, by Study (n=31)
<table>
<thead>
<tr>
<th>Type of Infection or Disease</th>
<th>PCR-Positive Persons</th>
<th>PCR-Negative Persons</th>
<th>Effectiveness (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vaccinated</td>
<td>Unvaccinated</td>
<td>Vaccinated</td>
</tr>
<tr>
<td><strong>Infection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCR-confirmed infection with the B.1.1.7 variant†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After one dose</td>
<td>892</td>
<td>18,075</td>
<td>1241</td>
</tr>
<tr>
<td>≥14 days after second dose</td>
<td>50</td>
<td>16,354</td>
<td>465</td>
</tr>
<tr>
<td>PCR-confirmed infection with the B.1.351 variant‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After one dose</td>
<td>1329</td>
<td>20,177</td>
<td>1580</td>
</tr>
<tr>
<td>≥14 days after second dose</td>
<td>179</td>
<td>19,396</td>
<td>698</td>
</tr>
<tr>
<td><strong>Disease</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe, critical, or fatal disease caused by the B.1.1.7 variant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After one dose</td>
<td>30</td>
<td>468</td>
<td>61</td>
</tr>
<tr>
<td>≥14 days after second dose</td>
<td>0</td>
<td>401</td>
<td>20</td>
</tr>
<tr>
<td>Severe, critical, or fatal disease caused by the B.1.351 variant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After one dose</td>
<td>45</td>
<td>348</td>
<td>35</td>
</tr>
<tr>
<td>≥14 days after second dose</td>
<td>0</td>
<td>300</td>
<td>14</td>
</tr>
<tr>
<td>Severe, critical, or fatal disease caused by any SARS-CoV-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After one dose</td>
<td>139</td>
<td>1,966</td>
<td>220</td>
</tr>
<tr>
<td>≥14 days after second dose</td>
<td>3</td>
<td>1,692</td>
<td>109</td>
</tr>
</tbody>
</table>

BnT1262b2 effectiveness against VARIANTS OF INTEREST

Abu Raddad et al. NEJM 2021
<table>
<thead>
<tr>
<th>Vaccination status</th>
<th>Test negative controls</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>B.1.1.7 or S-gene target negative</td>
<td>B.1.617.2 or S-gene target positive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>cases</td>
<td>cases:controls</td>
<td>aVE(%)</td>
<td>cases</td>
<td>cases:controls</td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>58253</td>
<td>4891</td>
<td>0.084</td>
<td>base</td>
<td>695</td>
<td>0.012</td>
</tr>
<tr>
<td>Any vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose 1</td>
<td>32703</td>
<td>1481</td>
<td>0.045</td>
<td>51.1 (47.3 to 54.7)</td>
<td>279</td>
<td>0.009</td>
</tr>
<tr>
<td>Dose 2</td>
<td>8483</td>
<td>74</td>
<td>0.009</td>
<td>86.8 (83.1 to 89.6)</td>
<td>27</td>
<td>0.003</td>
</tr>
<tr>
<td>BNT162b2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose 1</td>
<td>7036</td>
<td>344</td>
<td>0.049</td>
<td>49.2 (42.6 to 55.0)</td>
<td>49</td>
<td>0.007</td>
</tr>
<tr>
<td>Dose 2</td>
<td>6412</td>
<td>28</td>
<td>0.004</td>
<td>93.4 (90.4 to 95.5)</td>
<td>13</td>
<td>0.002</td>
</tr>
<tr>
<td>ChAdOx1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose 1</td>
<td>25667</td>
<td>1137</td>
<td>0.044</td>
<td>51.4 (47.3 to 55.2)</td>
<td>230</td>
<td>0.009</td>
</tr>
<tr>
<td>Dose 2</td>
<td>2071</td>
<td>46</td>
<td>0.022</td>
<td>66.1 (54.0 to 75.0)</td>
<td>14</td>
<td>0.007</td>
</tr>
</tbody>
</table>

**Effectiveness of BNT1262b2 and ChAdOx1 vaccine against Delta Variant**
<table>
<thead>
<tr>
<th>Vaccination status</th>
<th>Number of cases</th>
<th>Ratio B.1.617.2 to B.1.1.7</th>
<th>aOR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B.1.1.7</td>
<td>B.1.617.2</td>
<td></td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>8268</td>
<td>691</td>
<td>0.084</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any vaccine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose 1</td>
<td>2237</td>
<td>272</td>
<td>0.122</td>
</tr>
<tr>
<td>Dose 2</td>
<td>81</td>
<td>25</td>
<td>0.309</td>
</tr>
<tr>
<td>Dose 1 or 2</td>
<td>2511</td>
<td>322</td>
<td>0.128</td>
</tr>
<tr>
<td>Vaccine type (dose 1 or 2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BNT162b2</td>
<td>720</td>
<td>68</td>
<td>0.094</td>
</tr>
<tr>
<td>ChAdOx1</td>
<td>1791</td>
<td>254</td>
<td>0.142</td>
</tr>
</tbody>
</table>

Odds ratios for detection of B.1.617.2 relative to B.1.1.7 in vaccinated compared to unvaccinated individuals
Questions?

Email: Hana.ElSahly@bcm.edu