COVID-19 and Vaccine Q/A

Taison D. Bell, MD, MBA
About me

• Internal Medicine, Critical Care, and Infectious Disease certified physician at the University of Virginia

• Director of UVA Medical ICU

• Co-founder Owl Peal Labs

• Heavily involved in COVID-19 community education, patient care, vaccine rollout coordination

• Training background: Columbia Medical School, Mass General Hospital, Brigham and Women’s Hospital, National Institutes of Health
What Keeps Me Going
What I don’t do

• I’m not paid in any way by pharmaceutical companies

• I don’t speak for the State or Federal Government
My goal with you

• You should leave this session feeling like you understand COVID-19 and vaccination better than when you entered

• Present easily digestible information, avoid medical jargon

• Be honest. If I don’t know something I’ll freely admit it

• Give my personal take on the public health guidance

• I cannot give specific medical advice. But I will provide the same general advice that I have/would advise for my own friends and family
Questions
Background on the Vaccines

• What’s the difference between the Pfizer, Moderna, and J&J vaccines?
• Why do the vaccines have side effects?
• How in the world were we able to get these vaccines so quickly compared to other vaccines?
The Basics: The Coronavirus

• The coronavirus has RNA genes that allow it to copy itself and reproduce
  • Sometimes mistakes are made when the copying happens. These are called “variants”

• The spike protein is what allows the coronavirus to enter our cells and cause damage

• Spike protein sticks to our cells like a lock and key

Source: NY Times
The mRNA Vaccines

• The Pfizer/Moderna vaccines contain the messenger RNA to make just the spike protein

• Not live: they do not give you COVID-19

• Your body recognizes that the spike protein is a stranger and “presents” it to your immune system
Your immune response

- Your immune system creates special proteins called antibodies that recognize the spike protein.

- The antibodies allow your immune system to recognize the coronavirus much quicker if you are exposed.
Coronavirus is stopped!

- The antibodies block the coronavirus from entering the cells
- The antibodies can also recognize infected cells much sooner
- You do not become dangerously ill
J&J and AstraZeneca

• A harmless cold virus uses a DNA message to teach your body to make the spike protein

• Not live SARS-CoV-2: They do not give you COVID-19

• DNA is changed into mRNA → spike protein

• Different vehicle, same destination
Will the vaccine change my DNA?

- The vaccine mRNA or DNA does not mix with your own DNA

- The ingredients in the vaccine get broken down very quickly after entering the body

- Less concern for long term side effects
Are there any ______ in the vaccine?

The vaccines do not contain:
• Coronavirus, HIV, hepatitis
• Luciferase/bioluminescent material
• Microchips or tracking technology
• Material from aborted fetuses
Which is the “best” vaccine?

- **Moderna**: 94% efficacy
- **Pfizer**: 95% efficacy
- **AstraZeneca**: 76% efficacy
- **Johnson & Johnson**: 66% efficacy
A Closer Look at J&J

- Lower efficacy of the J&J vaccine compared to Pfizer/Moderna is very misleading
  - Pfizer/Moderna trial happened before variants were an issue
  - Pfizer and Moderna have booster shots (J&J is testing a 2-shot regimen)

<table>
<thead>
<tr>
<th></th>
<th>Moderate &amp; Severe (28 days)</th>
<th>Severe (28 days)</th>
<th>Severe (&gt;49 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US</strong></td>
<td>72%</td>
<td>85%</td>
<td></td>
</tr>
<tr>
<td><strong>Latin America</strong></td>
<td>66%</td>
<td>(100% death)</td>
<td>100%</td>
</tr>
<tr>
<td><strong>South Africa</strong></td>
<td>57%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(95% B.1.351 variant)</td>
<td></td>
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</tbody>
</table>
Hard to say which vaccine is “better”
Protection from death and hospitalization

- **moderna**: 100% protection
- **Pfizer**: 100% protection
- **AstraZeneca**: 100% protection
- **Johnson & Johnson**: 100% protection
# The Variants of Concern and Interest

## Variants of concern

<table>
<thead>
<tr>
<th>Lineage</th>
<th>Variant name</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.1.7</td>
<td>Variant of Concern 202012/01, or 501Y.V1</td>
<td>Emerged in Britain in December and thought to be roughly 50 percent more infectious. Now dominant in the U.S.</td>
</tr>
<tr>
<td>B.1.351</td>
<td>501Y.V2</td>
<td>Emerged in South Africa in December. Reduces the effectiveness of some vaccines.</td>
</tr>
<tr>
<td>P.1</td>
<td>501Y.V3</td>
<td>Emerged in Brazil in late 2020. Has mutations similar to B.1.351.</td>
</tr>
<tr>
<td>B.1.427, B.1.429</td>
<td>CAL.20C</td>
<td>Common in California and thought to be about 20 percent more infectious. Carries the L452R mutation.</td>
</tr>
</tbody>
</table>

## Variants of interest

<table>
<thead>
<tr>
<th>Lineage</th>
<th>Variant name</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.525</td>
<td>—</td>
<td>Spreading in New York. Carries some of the same mutations as B.1.1.7.</td>
</tr>
<tr>
<td>B.1.526</td>
<td>—</td>
<td>Spreading in New York. One version carries the E484K mutation, another carries S477N.</td>
</tr>
<tr>
<td>B.1.617</td>
<td>—</td>
<td>Prevalent in India. Carries the L452R spike mutation, among others.</td>
</tr>
</tbody>
</table>

Source: NY Times
So Far So Good

- Vaccines all show protection against hospitalization and death from the known variants

- B.1351 has shown potential to cause vaccines to be less effective (but still protective)
  - Israel pre-print showing potential “breakthrough.” I’m not convinced yet
  - 6 month Pfizer phase 3 follow up shows good protection

- NEJM Study of 417 vaccinated students and employees of Rockefeller University: only two breakthrough infections (72% isolates = variants)

- Possibility that we may need a booster or an update

Source: Seminars in Immunology Vol 50, August 2020, 101422
How do we have these vaccines so quickly?

When producing something, you get to have two of the following three things:

- Good
- Cheap
- Fast

So if you make something that is:

- Fast
- Cheap
- Good

If you make something that is:

- Cheap
- Good
- Fast

If you make something that is:

- Good
- Fast
- Cheap

Most Vaccines

COVID-19 Vaccines
How do we have these vaccines so quickly?

Nature volume 586, pages516–527(2020)

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Comparison of side effects

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Pfizer</th>
<th>Moderna</th>
<th>J&amp;J</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site pain</td>
<td>84%</td>
<td>92%</td>
<td>49%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>63%</td>
<td>69%</td>
<td>38%</td>
</tr>
<tr>
<td>Headache</td>
<td>55%</td>
<td>63%</td>
<td>39%</td>
</tr>
<tr>
<td>Muscle pain</td>
<td>38%</td>
<td>60%</td>
<td>33%</td>
</tr>
<tr>
<td>Joint pain</td>
<td>24%</td>
<td>45%</td>
<td>1%</td>
</tr>
<tr>
<td>Fever</td>
<td>14%</td>
<td>15%</td>
<td>9%</td>
</tr>
<tr>
<td>Chills</td>
<td>32%</td>
<td>43%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Takeaways:
- All reactions were self limiting, resolved in 24-48h
- Reactions are a sign that the immune system is working
- J&J looks like a better tolerated vaccine. Maybe because 1 dose???
- Among my friends colleagues, their experience is similar
Side effects/special populations

• Any issues with women who want to get pregnant or pregnant mothers and the vaccine?

• What’s going on with these blood clots in AZ and J&J?

• Will there be long-term side effects?
COVID-19 vaccine response in pregnant and lactating women: a cohort study

Kathryn J Gray, Evan A Bordt, Caroline Atyeo, Elizabeth Deriso, Babatunde Akinwunmi, Nicola Young, Aranxta Medina Baez, Lydia L Shook, Dana Cvrk, Kaitlyn James, Rose M De Guzman, Sara Brigida, Khady Diouf, Ilona Goldfarb, Lisa M Bebell, Lael M Yonker, Alessio Fasano, Sayed A Rabi, Michal A Elovitz, Galit Alter, Andrea G Edlow

PMID: 33758889  PMCID: PMC7987048  DOI: 10.1101/2021.03.07.21253094

• 131 women who received mRNA vaccines studied
  • 84 pregnant, 31 lactating, and 16 non-pregnant

• Vaccine-induced immune responses were the same in pregnant and lactating vs non-pregnant women
  • Titers higher than that seen in pregnant women who contracted COVID-19

• Antibody titers present in umbilical cord blood and breastmilk

• No concerning side effects seen
Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons

- 35,691 pregnant women studied who received mRNA vaccine
  - 84 pregnant, 31 lactating, and 16 non-pregnant

- Very reassuring safety data
  - Arm pain more frequent in pregnant women
  - Headache, fevers, chills and body aches less frequent in pregnant women
  - No neonatal deaths
  - No difference seen in rates of pre-term labor, miscarriage/pregnancy loss, or other adverse outcomes
What if I’m pregnant, considering pregnancy, or breastfeeding?

COVID-19 Vaccination leads to:
- Protection for mothers
- Protection for babies (antibody transfer)
- Peace of mind

COVID-19 leads to:
- Higher rates of miscarriage
- Higher rates of preterm labor
- Higher risk of serious illness and death for pregnant women
Quotes from the field

Stats from the CDC Program
- Over 94,335 pregnant women have been vaccinated
- Over 700 live births now among vaccinated mothers
- No difference seen in rates of miscarriage, stillbirth, pregnancy complications, and neonatal outcomes

“As a first-time mom it was scary to think about bringing a baby into the world in the middle of a pandemic. I couldn’t think of a better way to protect my baby than vaccinating myself so I could pass antibodies to him.”
-NP

“I was initially worried about the vaccines and fertility. But honestly, after I got vaccinated, I felt so great that my husband and I wanted to celebrate! Well, there’s nowhere to go and nothing really to do so…now I’m pregnant!”
-Pharmacy tech
Cerebral Venous Sinus Thrombosis

• Reported with both AZ and J&J
  • AZ: 62 cases out of 25m vaxed
  • J&J: initial 6 cases out of 6.8m vaxed

• Mechanism is different from usual blood clots
  • CVST combined with low platelets
  • Treatment is different

• Reported more in women of child-bearing age
Results from ACIP Analysis

<table>
<thead>
<tr>
<th>Age Group</th>
<th>TTS Cases</th>
<th>Doses given</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-29 years</td>
<td>3</td>
<td>579,709</td>
<td>5.2/mil</td>
</tr>
<tr>
<td>30-39</td>
<td>7</td>
<td>594,215</td>
<td>11.8/mil</td>
</tr>
<tr>
<td>40-49</td>
<td>3</td>
<td>692,370</td>
<td>4.3/mil</td>
</tr>
<tr>
<td>50-64</td>
<td>2</td>
<td>1.36m</td>
<td>1.5/mil</td>
</tr>
<tr>
<td>65+</td>
<td>0</td>
<td>757,710</td>
<td>0/mil</td>
</tr>
</tbody>
</table>

- 15 cases seen in 4m doses administered to women
  - Most seen in women aged 18-49 years
  - Median time to symptoms onset: 8 days
  - Not strongly associated with OCPs, hypothyroid, or coagulation disorders

- ACIP recommendation: reaffirm indication for all adults.
  - Warning label added for TTS
Why pause J&J if risk was so low?

Three reasons to pause:

1. Get critical information to physicians on signs and treatment

2. Collect information in a focused way

3. Prioritize safety over everything else

Risk of death from CVST/TTS in women 1 per 1.3 million

Young adult risk of death from COVID-19 1,800 per 1 million

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Vaccines and long-term side effects

• Extremely rare to see side effects that appear after 2-4 weeks

• Vaccine products are broken down by the body rapidly

• Nothing seen so far in the medium-term follow up

• Protection from COVID-19 side effects favors vaccination
  • “Long COVID”
The COVID-19 Vaccines are Like UPS

Like UPS, the vaccines:
• Go to the address (cells)
• Delivers a package (mRNA)
• Goes away (broken down)
Life After Vaccination

• Does vaccination protect from transmission or just from becoming ill?

• What can I/Can’t I do after vaccination?

• Is mass vaccination having an impact on the global pandemic?
Is vaccination having an effect so far?

- In US, rates of cases, deaths, hospitalizations are overall down! This likely reflects:
  - Seasonal nature of coronaviruses
  - Vaccination + natural immunity
  - Ongoing public health measures
  - Plateau now at ~50k, variants? Re-opening?
The UTSW Experience

- Infections among employees at UTSW dropped by 90% after vaccination

- At the same time infections among the community were increasing
Vaccination can prevent transmission

mRNA COVID-19 vaccines are highly effective in preventing infections in real-world conditions

Nearly 4,000* health care personnel, first responders, and essential workers were tested weekly for the virus that causes COVID-19.

Those who were fully vaccinated¹ were 90% less likely to get infected.

* Effectiveness of Pfizer-BioNTech and Moderna mRNA vaccines among 3,950 study participants in eight U.S. locations from December 14, 2020, to March 13, 2021. Participants self-collected specimens weekly regardless of symptoms and collected additional specimens if they became sick.

¹ Fully vaccinated = 2 weeks after 2nd dose.
What Can I do After Vaccination? (CDC)

Fully vaccinated people can:

- Visit with other fully vaccinated people indoors without wearing masks or physical distancing
- Visit with unvaccinated people from a single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing
- Refrain from quarantine and testing following a known exposure if asymptomatic

For now, fully vaccinated people should continue to:

- Take precautions in public like wearing a well-fitted mask and physical distancing
- Wear masks, practice physical distancing, and adhere to other prevention measures when visiting with unvaccinated people who are at increased risk for severe COVID-19 disease or who have an unvaccinated household member who is at increased risk for severe COVID-19 disease
- Wear masks, maintain physical distance, and practice other prevention measures when visiting with unvaccinated people from multiple households
- Avoid medium- and large-sized in-person gatherings
- Get tested if experiencing COVID-19 symptoms
- Follow guidance issued by individual employers
- Follow CDC and health department travel requirements and recommendations
Scenarios
If you are fully vaccinated:

- Friends or family from another household that are fully vaccinated
- Friends or family from another household not vaccinated and low risk
- Friends or family not vaccinated and high risk
- Or multiple households regardless of vaccination
Recommendations for Work

• Wear a mask still in most settings
  • Protects from infection (vaccines are very good but not 100%)
  • There are other viral infections circulating

• Encourage family members to get vaccinated

• Get tested if you have symptoms of COVID-19
CDC Travel Recommendations

<table>
<thead>
<tr>
<th></th>
<th>Departure</th>
<th>Return</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic</td>
<td>- No test requirement</td>
<td>- No test requirement unless required by local regulation</td>
</tr>
<tr>
<td></td>
<td>- No quarantine requirement</td>
<td>- No quarantine requirement unless required by local regulation</td>
</tr>
<tr>
<td>International</td>
<td>- Test and quarantine requirement per destination country</td>
<td>- Negative test before boarding return flight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Test 3-5 days after return</td>
</tr>
</tbody>
</table>
General COVID-19 questions

• Children and COVID-19

• Should I get the vaccine if I have had COVID-19?

• How safe is spending time outside without masks?
Children and COVID-19

• In general, children tend to do well if they contract COVID-19

• More likely to be infected by an adult in close contact

• Less likely to spread, especially younger children

• Older children (teenagers) tend to spread like adults, but still tend to do well if infected

• Pzifer vaccine results in children 12-15 are very promising
Vaccination after COVID-19?

Yes! I had my mom and dad get vaxed after having COVID-19
The Great Outdoors

- Outdoor activities are much safer than indoor activities
- Still want to maintain distance if possible
- Mask if that isn’t possible
Thank you for your time