COVID-19 Vaccines

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Clinical Trials Overview

- Vaccine clinical trials include at least 30,000 participants and are placebo controlled
  - A certain number of symptomatic COVID-19 cases are required to determine early efficacy
  - At least a median of 2 months of follow-up from the last dose of vaccine was required to determine safety
    • Evaluating side effects related to the vaccine
How did we get here so quickly?

- Rapid dissemination of information
- Increased funding
- Increased efforts
- Pre-existing design and data from earlier trials
  - Other coronaviruses SARS and MERS
  - Other mRNA vaccines - Ebola, Zika
- Novel vaccine technology
- Large population willing to participate and large number of cases
How do mRNA vaccines work?

1. Scientists generated an mRNA sequence that codes for the virus spike protein.

2. The RNA sequence, a blueprint for making the spike, is swathed in a lipid coating for delivery.

3. Once it arrives, cells read the information in the mRNA sequence to produce millions of copies of the spike protein.

4. The protein fragments spur the immune system to produce antibodies that can protect when a real virus enters the body.

Sources: Pfizer, Bloomberg research
## mRNA Vaccines – are they different?

<table>
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<tr>
<th></th>
<th>Moderna (mRNA-1273)</th>
<th>Pfizer (BNT162b2)</th>
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<tbody>
<tr>
<td>Participants and diversity</td>
<td>30,000 US participants including 37% of participants from communities of color</td>
<td>43,661 international participants including 42% of participants from communities of color (30% of US participants)</td>
</tr>
<tr>
<td>Reported cases of symptomatic COVID-19 after 7 days after second dose</td>
<td>196 cases with 185 in placebo group v. 11 in vaccine group</td>
<td>170 events with 162 in placebo group v. 8 in vaccine group</td>
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<tr>
<td>Severe COVID-19</td>
<td>30 cases of severe disease all in in the placebo group</td>
<td>10 cases of severe disease with 9 in the placebo group</td>
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<td>Efficacy</td>
<td>94.1%</td>
<td>95%</td>
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<td>Safety (median of 2 months after 2nd dose of half of the participants)</td>
<td>Localized injection site redness/pain, muscle and joint aches, headaches, fatigue often after second dose</td>
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<tr>
<td>EUA issued</td>
<td>12/11/20</td>
<td>12/18/20</td>
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What side effects should I anticipate?

- Occur within the first 1-3 days post-vaccination
- Resolve within 1-2 days of onset
- More common after 2\textsuperscript{nd} dose
- More common in younger patients
- Most frequent:
  - Pain at injection site ~ 75\% of participants (vs ~10\% placebo)
  - Fatigue ~ 50\% (vs ~30\% placebo)
  - Headache ~ 30\% (vs ~ 20\% placebo)
  - Fever ~ 15\% after 2\textsuperscript{nd} dose
  - Chills/myalgias ~ 35\% after 2\textsuperscript{nd} dose
What about people with allergies?

- Clinical trials excluded people with severe allergic reactions to vaccine
  - Hypersensitivity events in 137 (0.63%) vaccine recipients vs 111 (0.51%) placebo
  - No serious hypersensitivity events
- 29 cases of anaphylaxis have been reported to the FDA through VAERS
  - Most (80%) were in individuals with a history of allergic reactions including anaphylaxis
  - Median time to symptom onset was 13 minutes
- AAAAI recommend against vaccination of anyone with a history of hypersensitivity to polyethylene glycol, polysorbate or severe allergies to any vaccine

VAERS- Vaccine Adverse Event Reporting System
AAAAI- American Academy of Asthma, Allergy and Immunology
Who can get the vaccine?

- EUA Pfizer – adults 16 years of age or older
- EUA Moderna – adults 18 years of age or older
- Viral and/or serological testing not indicated prior to vaccination
- If acutely ill with COVID-19, defer vaccination until recovery from illness and no longer isolating
- If received convalescent plasma or monoclonal antibody must wait >90 days
- Must wait 14 days before or after receiving another vaccine (e.g. Shingrix, Flu)
Can a mRNA vaccine affect my DNA or give me COVID-19?

- mRNA vaccines have been studied for some time
- mRNA does not enter the nucleus of the cell so does not interact with our DNA
- mRNA breaks down quickly as does the spike protein it encodes
What if I am pregnant, thinking about pregnancy or breast feeding?

- Pregnant individuals and those who are breastfeeding were excluded from the trials

- Both ACOG and SMFM recommend vaccination in the appropriate circumstances
  - What is the likelihood of you being exposed to SARS-CoV-2?
Other populations?

- History of Guillan-Barre Syndrome (GBS)
  - No cases of GBS in either clinical trial
  - May receive vaccine

- History of Bells Palsy
  - Cases reported in both trials, however frequency not above that seen in general population
  - May receive vaccine

- Immunocompromised (IC)
  - At increased risk of severe disease
  - Not included in trials, no data on efficacy
  - Not a live virus, unlikely to pose risk but due to IC may not mount effective response
What about the UK variant (B.1.1.7)?

- Mutations in the spike protein
- More transmissible
- Not thought to be more pathogenic
- 12 cases reported in NYS
- No evidence that vaccine would not provide protection

https://www.biorxiv.org/content/10.1101/2021.01.07.425740v1 published 7Jan21
If I had COVID-19 should I get vaccinated?

Yes

▶ We don’t know how long natural immunity lasts and every person mounts a different antibody response to COVID-19

▶ Clinical trials did not exclude those who had baseline antibodies
Do I still need to wear a mask if I get vaccinated?

**Yes**

- The trials did not evaluate the incidence of asymptomatic infection
- It is going to take time to vaccinate a large number of the population
Thank you!