

COVID-19 Vaccines

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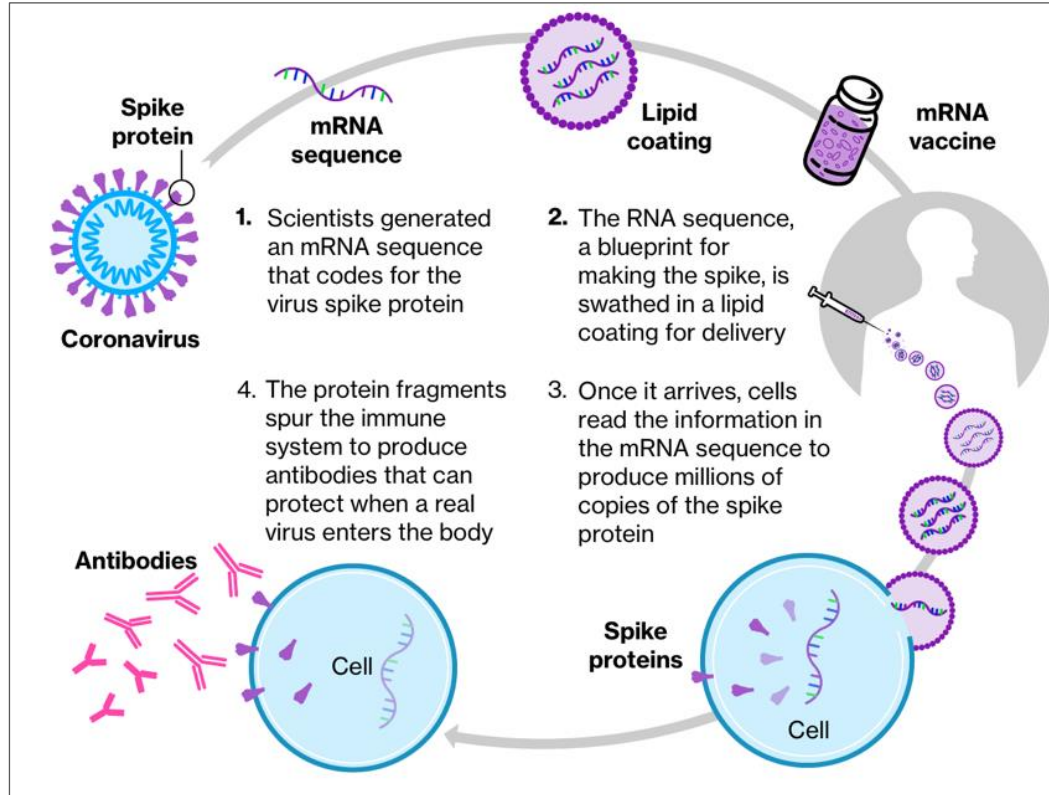
Clinical Trials Overview

- ▶ 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?



mRNA Vaccines – are they different?

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

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 2nd 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 2nd dose
 - Chills/myalgias ~ 35% after 2nd 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

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?

ACOG- American College of Obstetrics and Gynecology

SMFM- Society of Maternal and Fetal Medicine

ACIP- Advisory Committee on Immunization Practices

<https://www.acog.org/covid-19/covid-19-vaccines-and-pregnancy-conversation-guide-for-clinicians>

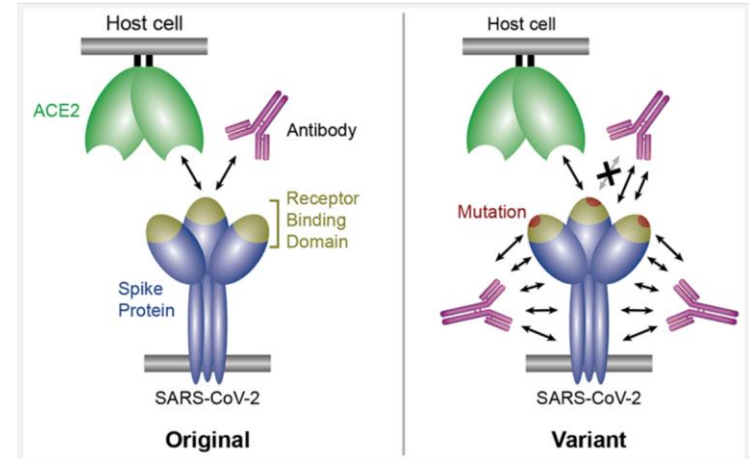
<https://www.smfm.org/covidclinical> updated 21Dec20

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**



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!