

# COVID-19 Vaccines

## Latest Facts and Fallacies

Deborah Levy, PhD, MPH  
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University of Nebraska  
Medical Center

COLLEGE OF PUBLIC HEALTH

# Disclaimers

- No conflicts of interests
- To the best of my knowledge, the information is current as of February 8, 2021



# Agenda

## Didactic

- Vaccine Types and Associated Facts
- Emerging SARS-CoV-2 Variants
- Vaccination Side Effects
- Clinical Considerations
- Vaccine Safety Monitoring
- Occupational Health Planning
- Vaccine Communication
- Vaccine Phase Allocation

## Discussion “All Teach All Learn”



# Learning Objectives

- Understand basic information about COVID-19 vaccines and their associated facts
- Provide appropriate responses to counter vaccine fallacies
- Identify effective communication strategies to address vaccine hesitancy

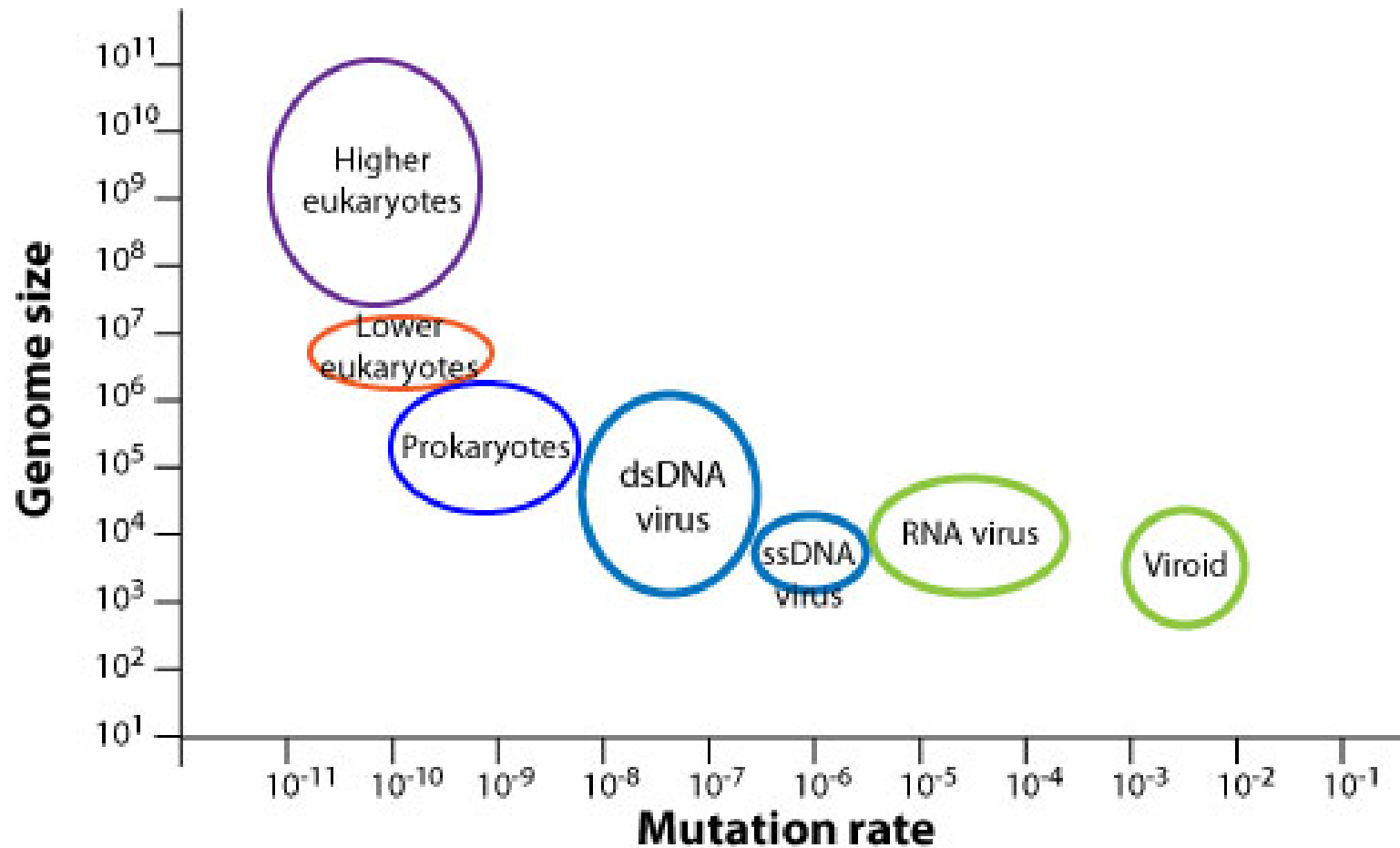


# COVID-19 Vaccine Types

- mRNA (Pfizer/BioNTech and Moderna)
- Viral vector (Janssen, AstraZeneca, and Merck)
- Protein subunit (Sanofi/GSK and Novavax)



# Virus Mutation Rate



# Genomic Language

- **Mutation:** change in the DNA sequence in a living organism
- **Variant (strain):** gene variation seen in an individual of any species, groups or population
  - A variant can emerge with multiple mutations
- **Lineage:** single line of descent or linear chain within the tree
- **Clade:** a (usually branched) monophyletic group, containing a single common ancestor and all its descendants



# Emerging SARS-CoV-2 Variants

- *B.1.1.7 lineage (a.k.a. 20I/501Y.V1)*
  - First identified in UK in September 2020
  - Mutation N501Y, Deletion69/70, Mutation P681H (S1/S2 furin cleavage site)
  - Number of spike protein changes = 8
  - Increased transmissibility, may increase risk of death
- *B.1.351 lineage (a.k.a. 20H/501Y.V2)*
  - Mutations K417N, E484K, N501Y
  - First identified in South Africa
  - Number of spike protein changes = 10
  - No impact on disease severity thus far
- *P.1 lineage (a.k.a. 20J/501Y.V3)*
  - Variant branch off of B.1.1.28 lineage
  - First reported in Japan in four travelers from Brazil
  - Mutations K417T, E484K, and N501Y
  - Number of spike protein changes = 12
  - May affect transmissibility and antigenic profile, with propensity for re-infection





# mRNA Vaccines

- DNA and RNA are molecular and composed of nucleic acids
  - DNA stores our genetic code
  - Messenger RNA translates DNA information and codes for proteins
  - Some viruses carry their genetic information in RNA, not DNA
  - RNA cannot change DNA
- Components of the mRNA vaccines
  - Contain the nucleoside-modified mRNA encoding the viral spike glycoprotein, 4 lipid nanoparticles, and salts, sugars, and buffers
  - Are absorbed into the cytoplasm of the cell
  - Do not enter the nucleus of the cell
  - Stem cell lines used but approved by religious authorities



# Pfizer-BioNTech vs Moderna Vaccines

## Pfizer-BioNTech

- Age **16** and older
- 95.0% efficacy, measured starting from **7** days after second dose
- Appears to be equally protective across age groups, and racial and ethnic groups
- Reduces the risk of severe COVID-19 disease
- Unknown if vaccinated persons can transmit the virus\*
- Intramuscular two doses, **21** days apart
- Dose contains **30** mcg of vaccine
- Side effects more common after second dose
- Safety not tested in pregnant or lactating women
- Ship at **-94F** (ultra-cold freezer)
- Use within **5 days of thawing**

## Moderna

- Age **18** and older (currently testing in 12-17yrs)
- 94.1% efficacy, measured starting **14** days after second dose
- Appears to have slightly lower efficacy in those 65 and older (but too few cases in this age group to determine), and equally effective across racial and ethnic groups
- Reduces the risk of severe COVID-19 disease
- Unknown if vaccinated persons can transmit the virus\*
- Intramuscular two doses, **28** days apart
- Dose contains **100** mcg of vaccine
- Side effects more common after second dose
- Safety not tested in pregnant or lactating women
- Ship at **-4F** (regular refrigerator freezer)
- Stable at **freezer** temperature for **30 days** and at **room** temperature for **12 hours**



# Viral Vector Vaccines – Janssen

- Vaccine candidate is 72% effective in the US and 66% effective overall at preventing moderate to severe COVID-19, 28 days after vaccination
- Vaccine candidate is 85% effective overall in preventing severe disease and demonstrated complete protection against COVID-19 related hospitalization and death as of day 28
- Protection against severe disease across geographies, ages, and multiple virus variants, including the SARS-CoV-2 variant from the *B.1.351 Lineage* observed in South Africa
- Single-shot compatible with standard vaccine distribution channels
- Estimated to remain stable for two years at -20°C (-4°F), at least three months of which can be at temperatures of 2-8°C (36°F–46°F)
- Request for EUA submitted to FDA on February 4, 2021



# Viral Vector Vaccines – AstraZeneca

- Phase III clinical trials from the UK, Brazil, and South Africa, published as a preprint in The Lancet confirmed COVID-19 Vaccine AstraZeneca is safe and effective at preventing COVID-19, with no severe cases and no hospitalizations, more than 22 days after the first dose
- Results demonstrated vaccine efficacy of 76% (CI: 59% to 86%) after a first dose, with protection maintained to the second dose
- With an inter-dose interval of 12 weeks or more, vaccine efficacy increased to 82% (CI: 63%, 92%)
- The analysis also showed the potential for the vaccine to reduce asymptomatic transmission of the virus, based on weekly swabs obtained from volunteers in the UK trial
  - The data showed that PCR positive readings were reduced by 67% (CI: 49%, 78%) after a single dose, and 50% (CI: 38% to 59%) after the two-dose regimen



# Protein Subunit Vaccines

- Sanofi is collaborating with GSK on a COVID-19 vaccine candidate using the same recombinant protein-based manufacturing technology as one of Sanofi's seasonal influenza vaccines, combined with GSK's established pandemic adjuvant platform
- Phase I and II study results of the vaccine candidate showed an immune response comparable to patients who recovered from COVID-19 in adults aged 18 to 49 years, but a low immune response in older adults likely due to an insufficient concentration of the antigen
- Sanofi will provide BioNTech access to its state-of-the-art production infrastructure
- From summer 2021, Sanofi will perform late-stage manufacturing to supply over 125 million doses of COVID-19 vaccine for the European Union



# Vaccination Side Effects

- Reactogenicity usually occurs within a few days (3-7 days) of vaccination
  - Immunological responses due to cytokines
  - Demonstrates that the vaccine is working
  - Excessive reaction (e.g., anaphylaxis) has occurred in a small number of individuals
- Potential cause of the reaction could be one of the lipid nanoparticles
  - NIH has launched a study to determine the ingredient
  - Possibly polyethylene glycol (PEG), which is used in other vaccines
- Symptoms should resolve within 1-2 days
- Symptoms to watch for, especially after second dose
  - NORMAL: fever, fatigue, headache, chills, muscle aches, joint pain
  - **NOT CAUSED BY VACCINE:** cough, shortness of breath, rhinorrhea, sore throat, loss of taste and/or smell
    - Assess individual for another cause such as COVID-19 or other respiratory virus
- Positive PCR and/or antigen diagnostic test is **NOT** caused by the vaccine



# Clinical Considerations for Vaccination

## Insufficient trial data for firm conclusions

- Persons with known SARS-CoV-2 exposure: likely ineffective
- Persons who previously received passive antibody therapy for COVID-19: can defer for up to 90 days to avoid interference with vaccine-induced immune response
- Pregnant or lactating women: unlikely to pose a risk, recommend in US
- Immunocompromised persons: no contraindications, recommend but counsel about effectiveness and potential for reduced immune response
- Persons with autoimmune conditions: no imbalances in occurrence of symptoms noted, recommend
- Persons with a history of Guillain-Barre syndrome: no cases reported, no contraindications, recommend
- New genomic variants of emergent lineages: even if only partially effective, recommend



# Vaccine Safety Monitoring

- Safety process for the clinical trials (phase I, II, and III) was the same as for other vaccines
- Shortened timeline due to not waiting to determine
  - Prevention of infection vs. disease as outcome
  - Length of protective immunity
- Pfizer/BioNTech and Moderna trials and the other vaccine trials will continue
- Post EUA safety monitoring includes
  - V-Safe – new, active surveillance, smartphone-based texting for survey completion
  - VAERS – passive surveillance, rapidly detects potential safety problems and rare events
  - VSD – vaccine safety datalink, 9 integrated healthcare organizations, 12 million people
  - CISA – individual case consults, 7 medical research centers
- V-Safe includes
  - Daily text for 1 week, weekly for 6 weeks thereafter, then at 3, 6, and 12 months post vaccination; timeline is reset at the 2nd vaccine dose
  - Week 1 for reactogenicity, then health impact determining if unable to do normal activities, missed work, or sought medical care
- Reporting side effects doesn't violate HIPAA compliance





# Occupational Health Planning

- Occupational health considerations
  - Vaccinate preceding 1-2 days off
  - Stagger vaccination by single department, service, or unit
  - Plan for timely assessment of symptoms and options for diagnostic testing
  - Non-punitive sick leave
  - No data on pregnant or lactating women – case by case discussion (e.g., personal risk, family considerations, community transmission)
- Approaches to evaluation if staff exhibits symptoms
  - Received vaccination in prior 3 days?
  - Any known exposures?
  - Symptoms not typical of the vaccination?
- Exclude from work if have a fever, symptoms persist more than 2 days
- Can vaccinate if previously had confirmed COVID-19 and/or had monoclonal antibody therapy, but could defer for up to 90 days



# Vaccine Communication

- It is normal to be skeptical and have hesitancy
- How to affect behavior
  - What people think or feel – little impact
  - Social processes – promising and builds on a person's network contagion
  - Direct behavior change – most impact
    - Presumptive healthcare provider recommendations
    - Onsite vaccination
    - Default appointment
    - Incentives
    - Vaccine requirements (cannot mandate while under EUA)
- Build on favorable intentions and reduce barriers (e.g., non-punitive sick leave)
- Ask what is your main concern, listen actively, and repeat back
- Show leadership, be visible, and be transparent about what is known and not known
- Be comfortable, and have your own concerns and questions addressed
- Vaccination has not been shown to increase risky behavior, and this vaccine is very effective
- Continue to wear masks, social distance, and perform hand hygiene



# “Original” Vaccine Phase Allocation by ACIP

## Prevention of morbidity and mortality, and preservation of societal functioning

- **Phase 1a:** healthcare personnel and long-term care residents
- **Phase 1b:** persons 75 years and older, and frontline essential workers (first responders, education, food and agriculture, manufacturing, corrections, US postal service, public transit, grocery store)
- **Phase 1c:** persons 65-74 years old, persons 16-64 with high-risk medical conditions, and other essential workers (transportation and logistics, food service, shelter and housing [construction], finance, IT and communication, energy, media, legal, public safety [engineers], water and wastewater)
- **Phase 2:** all persons 16 years and older not already covered in the previous phases



# Discussion About Common Myths

1. My family could get COVID-19 from me after I get vaccinated
2. The vaccination will make me sick with COVID-19
3. I already had COVID-19 and recovered so I don't need the vaccine
4. I won't need to wear a mask after I'm vaccinated
5. The vaccine is not safe because it was rapidly developed and tested
6. The vaccine will permanently change my DNA
7. The vaccine is used to microchip people
8. The vaccine will cause sterility



# Resources – 1

ACIP's COVID-19 Vaccine Recommendations

<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>

Moderna EUA – Fact Sheet for Healthcare Providers

<https://www.fda.gov/media/144637/download>

Moderna EUA – Fact Sheet for Recipients and Caregivers

<https://www.fda.gov/media/144638/download>

Pfizer-BioNTech COVID-19 Vaccine Information

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

Moderna COVID-19 Vaccine Information

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>

COVID-19 Vaccines: Update on Allergic Reactions, Contraindications, and Precautions – Video and Slide Set from December 30, 2020

[https://emergency.cdc.gov/coca/calls/2020/callinfo\\_123020.asp](https://emergency.cdc.gov/coca/calls/2020/callinfo_123020.asp)



# Resources – 2

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020

[https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7002e1-H.pdf?ACSTrackingID=USCDC\\_921-DM45827&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2070%2C%20January%206%2C%202021&deliveryName=USCDC\\_921-DM45827](https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7002e1-H.pdf?ACSTrackingID=USCDC_921-DM45827&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2070%2C%20January%206%2C%202021&deliveryName=USCDC_921-DM45827)

What to Expect after Getting a COVID-19 Vaccine

[https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html?ACSTrackingID=USCDC\\_2067-DM46142&ACSTrackingLabel=What%20to%20Expect%20After%20Getting%20](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html?ACSTrackingID=USCDC_2067-DM46142&ACSTrackingLabel=What%20to%20Expect%20After%20Getting%20)

Poll: The Language of Vaccine Acceptance by de Beaumont Foundation

<https://www.debeaumont.org/news/2020/new-poll-reveals-effective-language-to-improve-covid-19-vaccine-acceptance/>

Guide to COVID-19 vaccine communications - A practitioner's guide to the principles of COVID-19 vaccine communications

<https://covid19vaccinescommunicationprinciples.org/downloads/>

“Protects Me, Protects You” campaign is to build confidence in getting vaccinated in order to reduce transmission of the coronavirus

<https://www.protectsmeprotectsyou.org/>



# Resources – 3

CDC – Emerging SARS CoV-2 Variants

<https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html>

Genomic epidemiology identifies emergence and rapid transmission of SARS-CoV-2 B.1.1.7 in the United States

<https://www.medrxiv.org/content/10.1101/2021.02.06.21251159v1>

Johnson & Johnson Announcement

<https://www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-endpoints-in-interim-analysis-of-its-phase-3-ensemble-trial>

AstraZeneca Announcement

<https://www.astrazeneca.com/media-centre/press-releases/2021/covid-19-vaccine-astrazeneca-confirms-protection-against-severe-disease-hospitalisation-and-death-in-the-primary-analysis-of-phase-iii-trials.html#!>

Sanofi to provide support to BioNTech in manufacturing their COVID-19 vaccine

<https://www.sanofi.com/en/media-room/press-releases/2021/2021-01-27-07-30-00>

What Does a Multi-Dose Series Mean for the COVID-19 Vaccination Effort?

<https://www.kff.org/coronavirus-covid-19/issue-brief/what-does-a-multi-dose-series-mean-for-the-covid-19-vaccination-effort/>



# “All Teach All Learn” Discussion



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