



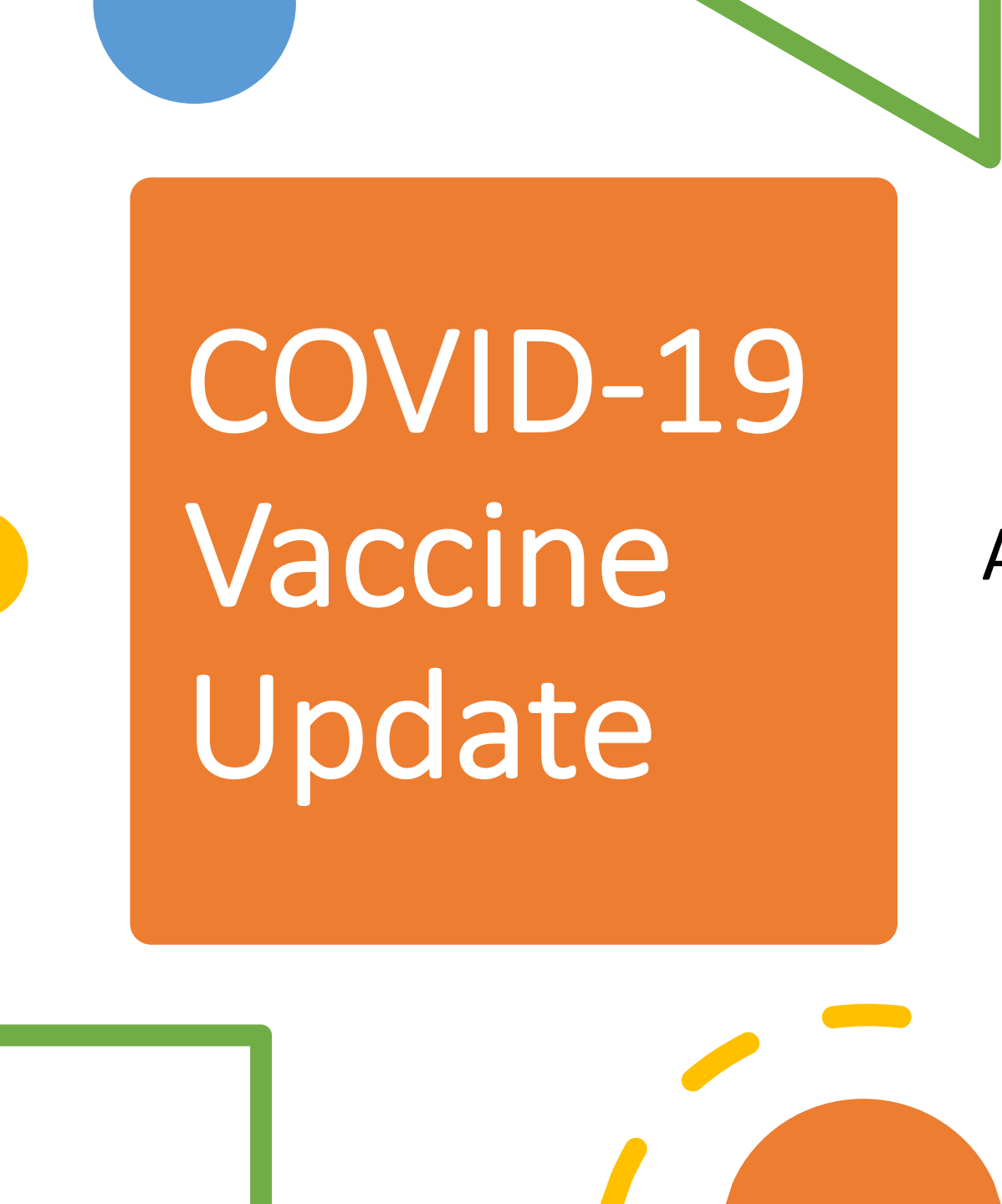
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COVID-19 Vaccine Update

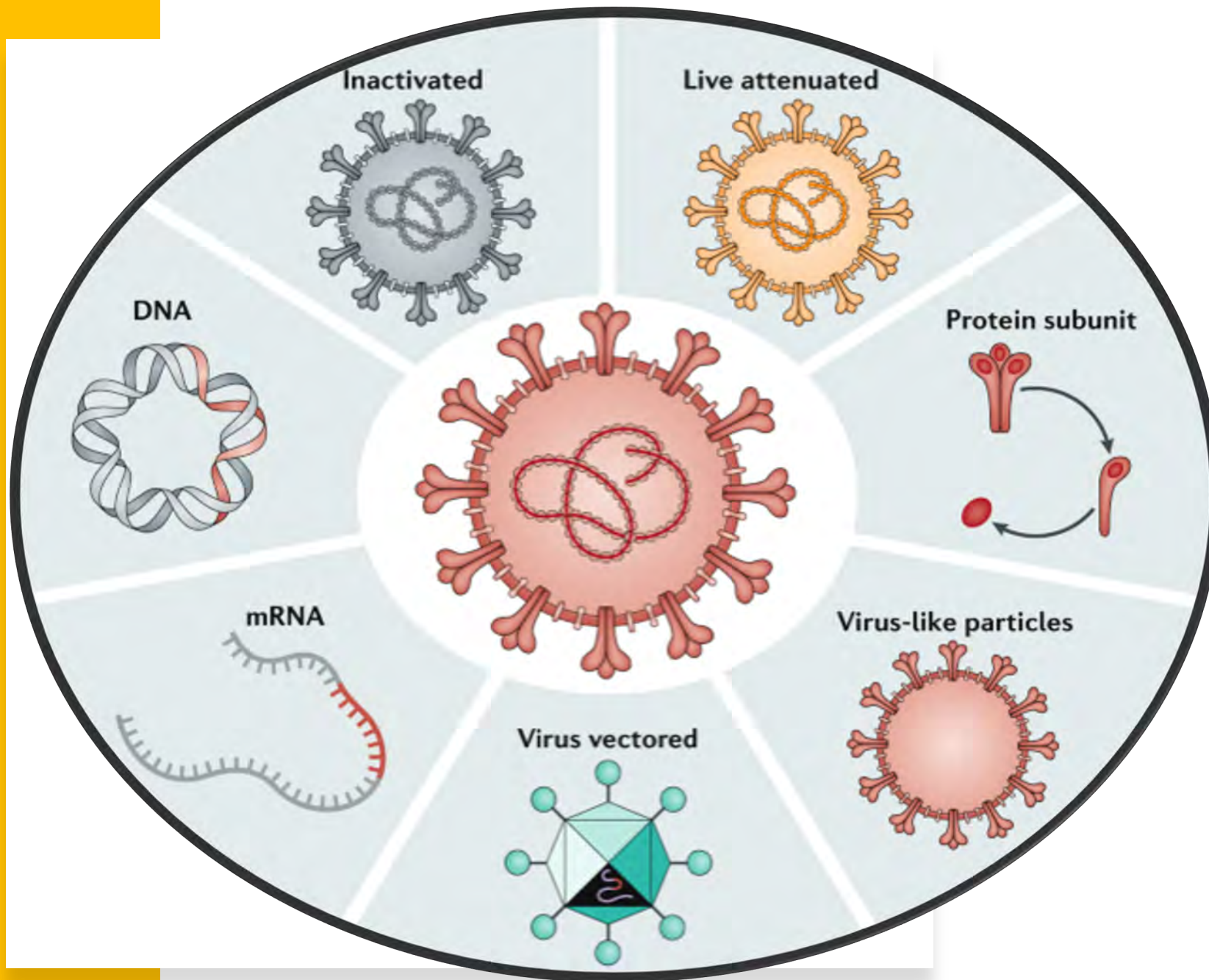
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Severe Acute Respiratory Syndrome Coronavirus-2 (SARS CoV-2)

- 85.6 million cases worldwide
- 1.85 million deaths worldwide
- 23 million cases in the US
- >390,000 deaths in the US
- Finding a safe and effective vaccine is critical

Why is this important in Minority Communities

Rate ratios compared to White, Non-Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases ¹	1.8x	0.6x	1.4x	1.7x
Hospitalization ²	4.0x	1.2x	3.7x	4.1x
Death ³	2.6x	1.1x	2.8x	2.8x



Vaccine Strategies for SARS CoV-2



Company	Platform	Dosing	Phase 3	Sample size
Moderna	mRNA	2 doses (0,28)	Published	30,000
Pfizer/ Biontech		2 doses (0,21)	Published	44,000
Astra Zeneca	Adeno- virus vector	2 doses (0,28)	Published	30,000
Janssen		1 dose	Enrolled	45,000
Novavax	Recombinant protein	2 doses (0,21)	Started enrollment	30,000
Sanofi/GSK		2 doses (0,21)	Starting soon	30,000

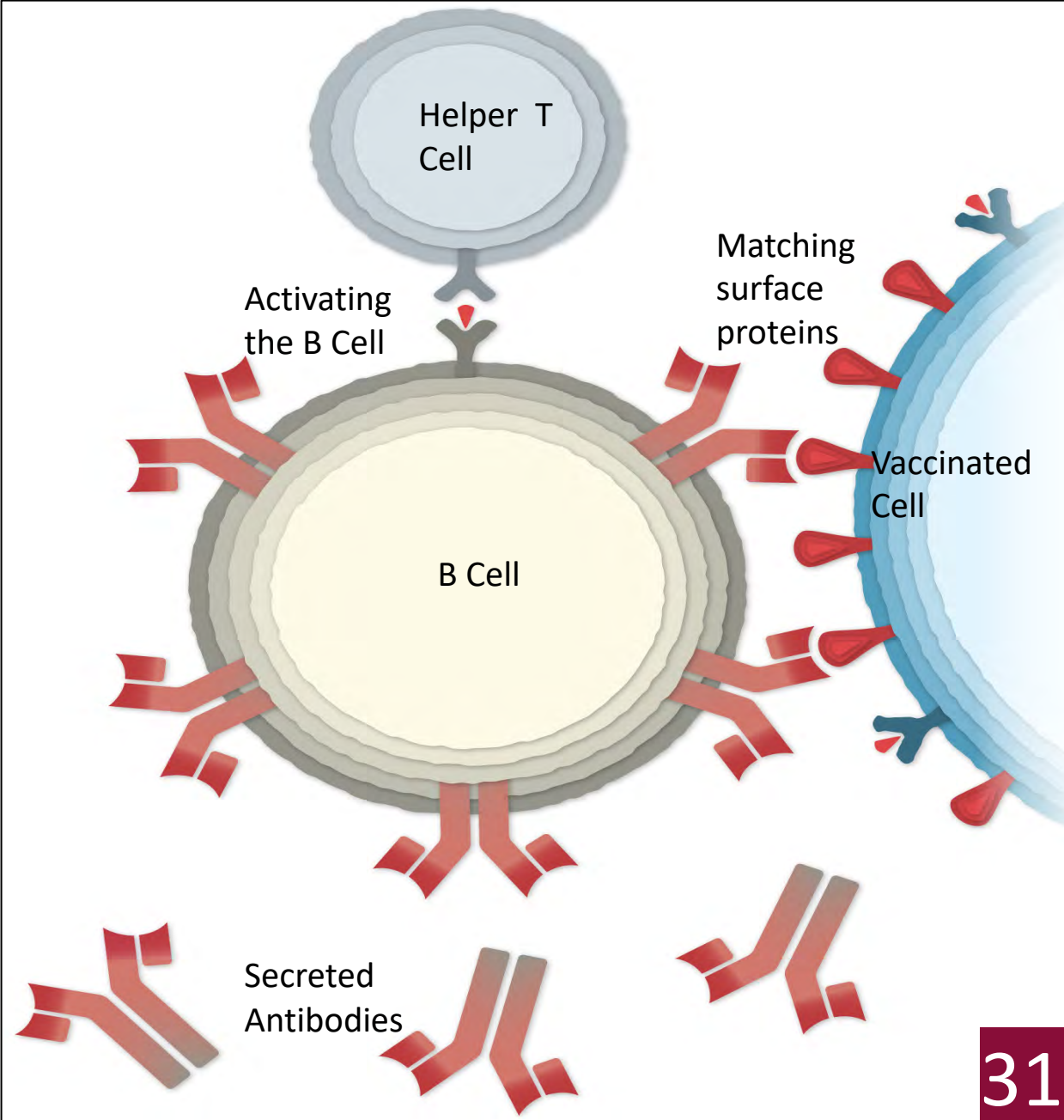
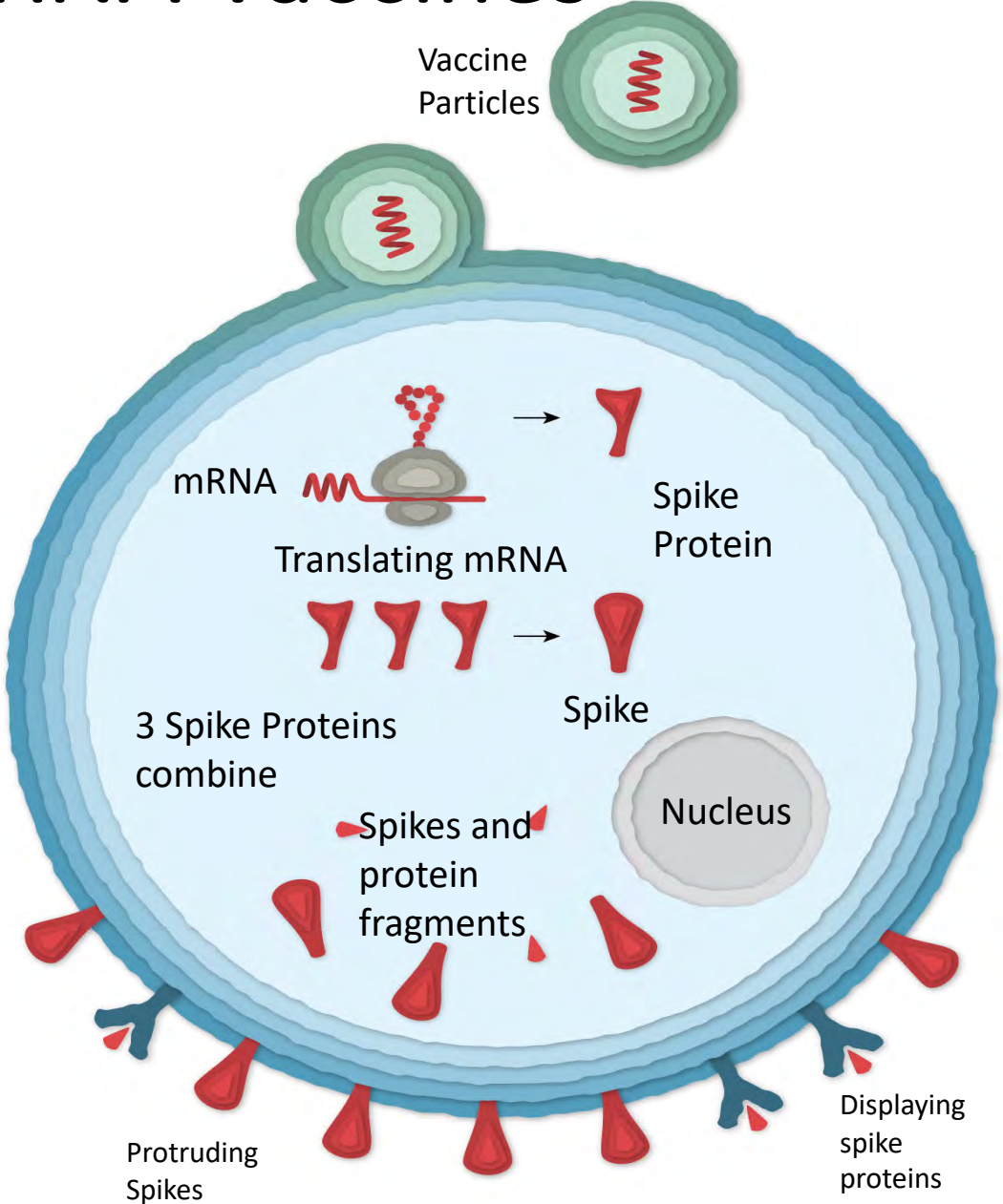
Current Phase 3 Vaccine Studies in US



mRNA Approaches

- Eliminates need to work with the virus directly
- Facilitated early vaccine development
- mRNA with lipid nanoparticle
- **Does not integrate with host genome**
- Disintegrates after a short time in the body

mRNA Vaccines



Moderna mRNA-1273 Vaccine

- Established safety and effectiveness in animal models
- Phase 1 and 2 studies showed that it was safe and possibly effective
- Second dose showed better neutralizing antibody titers
- Safety and efficacy supporting Phase 3 study
- 100 mcg, 2 doses 28 days apart

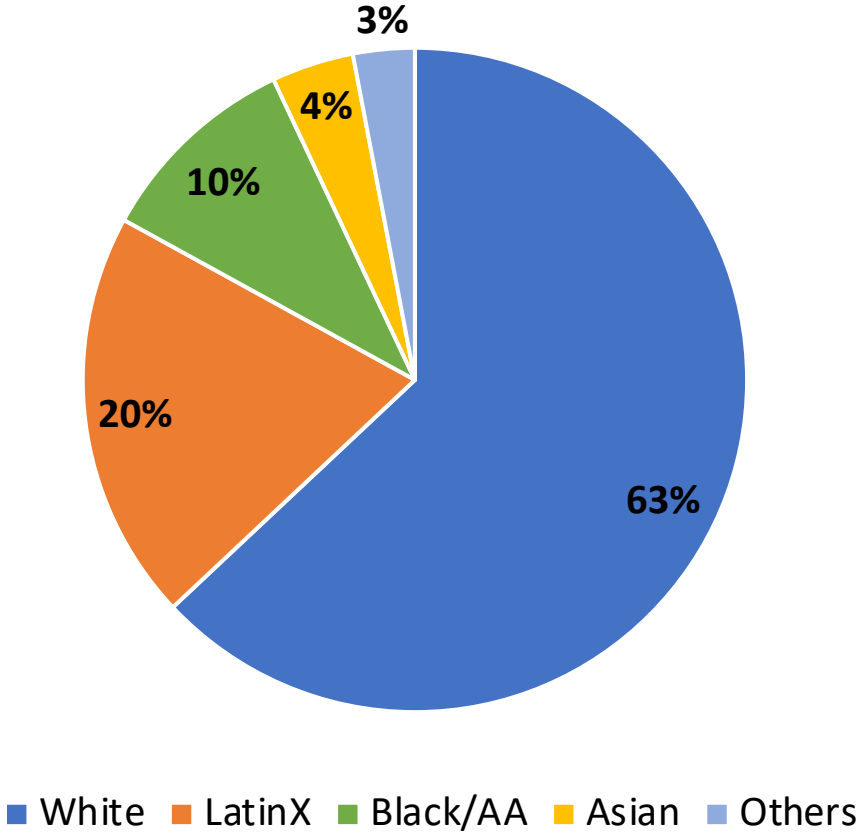
Moderna mRNA-1273 Vaccine

Phase 3 COVE Study

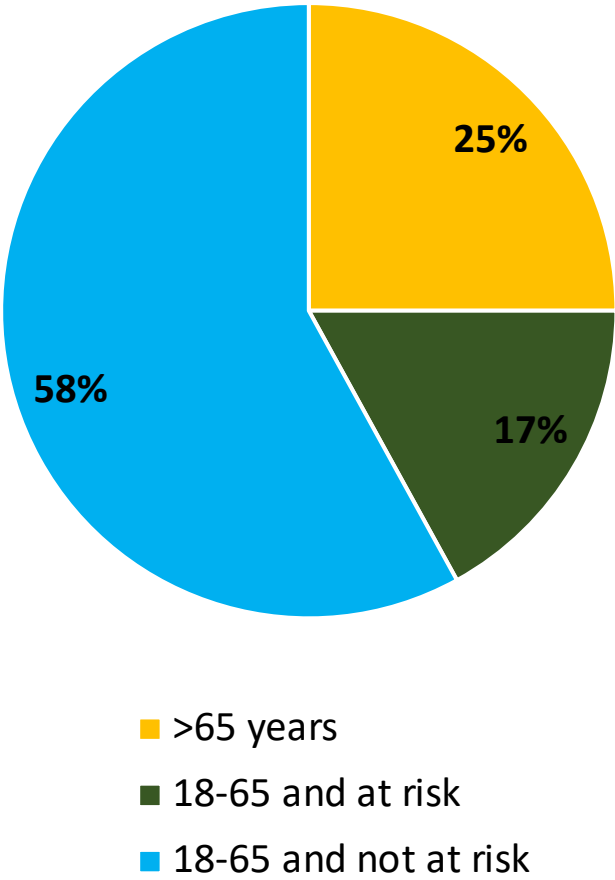
- 30,420 enrolled
- 1:1 Phase 3 randomized, stratified, observer-blinded, placebo-controlled trial
- Symptomatic COVID-19 14 days after second dose of vaccine among seronegative participants
 - Two designated symptoms AND one sample PCR positive for SARS-CoV-2

COVE Study Demographics

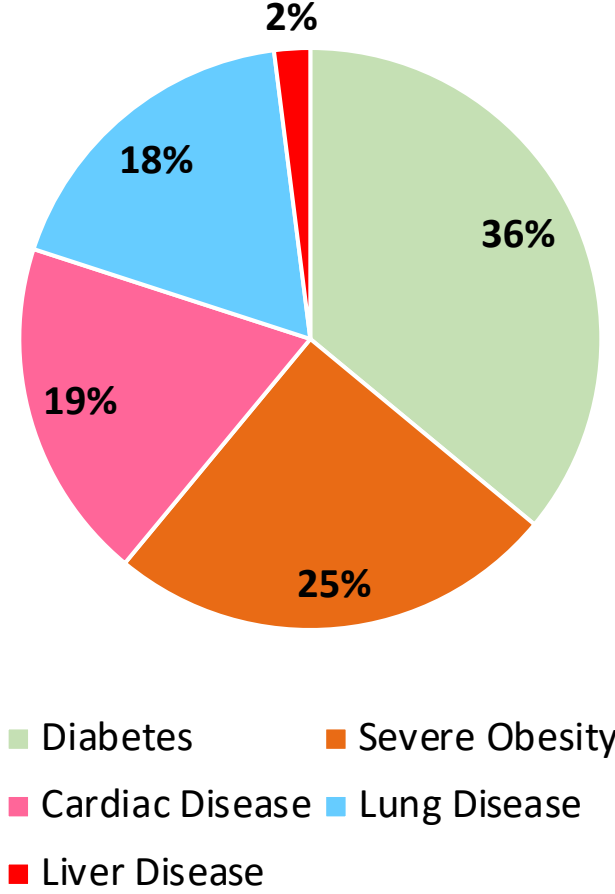
Race and Ethnicity



Risk Stratification



Comorbidities



Solicited Local and Systemic Adverse Events

- Slightly worse after second dose but generally got better within 48 hours
- Local
 - Pain, redness or swelling
- Systemic
 - Headache and fatigue commonest
 - Muscle and joint pains
- Older people tolerated it better

Vaccine Efficacy

- 94 % effective in preventing symptomatic COVID-19
- Effective in all age groups, sex, racial groups and underlying risk factors
- 93.2% effective in Whites and 97.5% effective in communities of color

Other Key Points

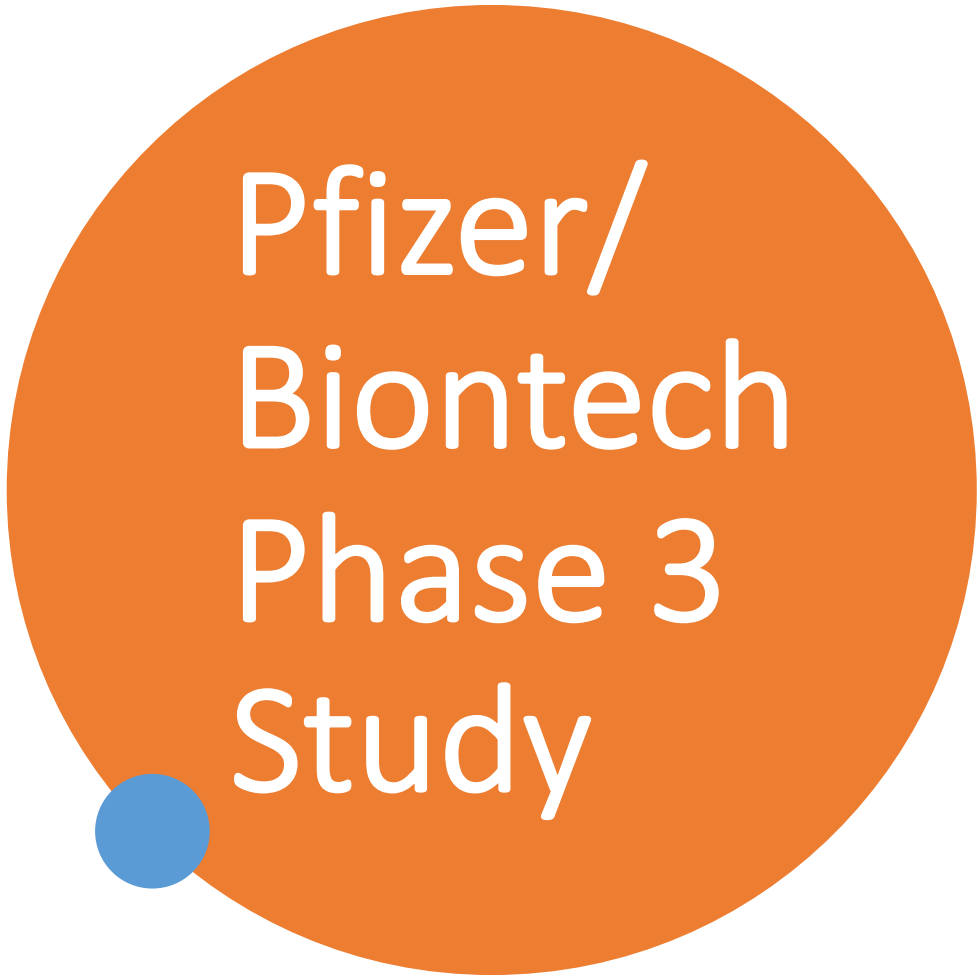
- 100% effective in preventing severe COVID-19
- Received EUA approval Dec 18, 2020
- Approved for ALL ADULTS >18 years
- Pediatric study to start soon



Pfizer/
BionTech
BNT162b2

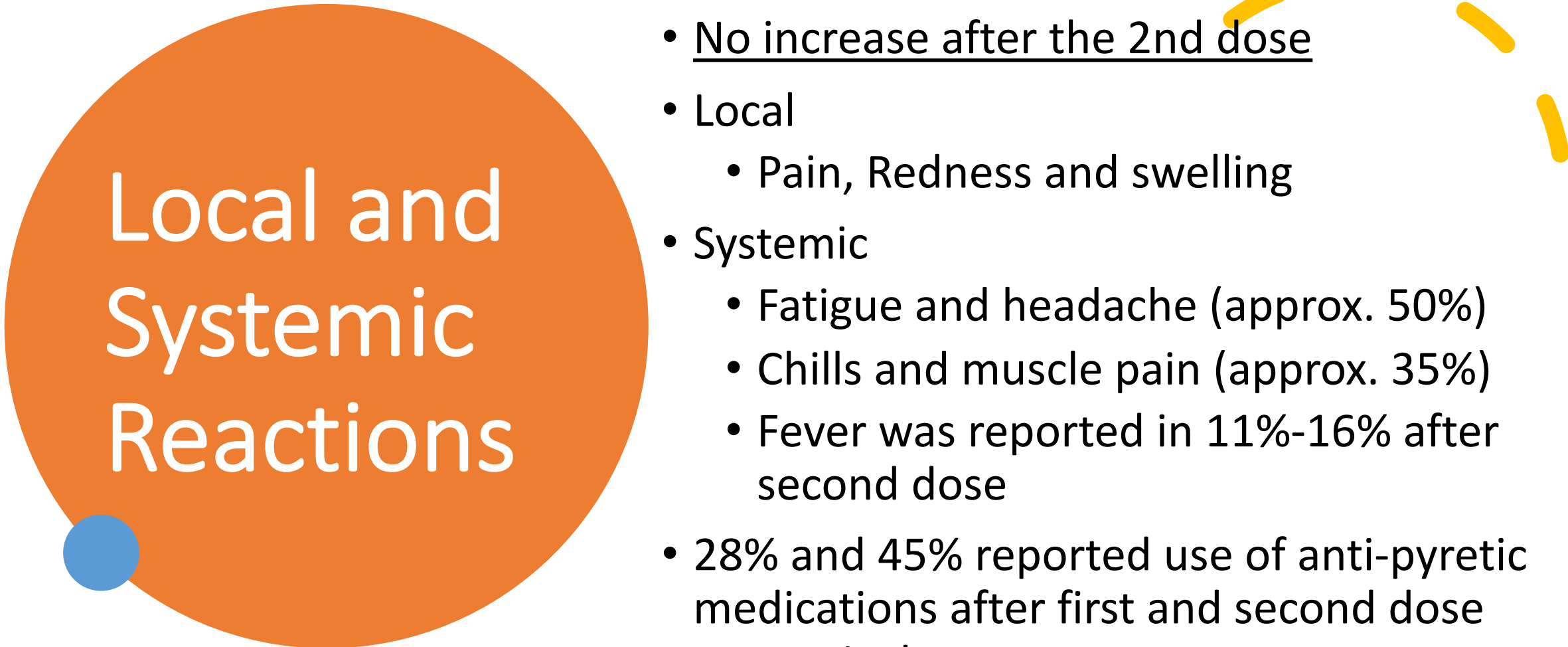


- Animal models and Phase I/II studies showed that vaccine safe and likely effective
- 30 mcg, 21 days apart used for phase 3

A large orange circle containing the text 'Pfizer/Biontech Phase 3 Study' in white. A smaller blue circle is positioned at the bottom left of the orange circle. In the top right corner of the slide, there are several yellow curved lines of varying lengths, resembling a stylized sun or a decorative element.

Pfizer/ Biontech Phase 3 Study

- N=44,820 screened
- 49% female
- 83% White, 9% Black, 28% were Latinx
- 21% had at least one coexisting condition
- Median age was 52 years, and 42% of participants were >55 years old



Local and Systemic Reactions

- Participants >55 years had fewer adverse events
- No increase after the 2nd dose
- Local
 - Pain, Redness and swelling
- Systemic
 - Fatigue and headache (approx. 50%)
 - Chills and muscle pain (approx. 35%)
 - Fever was reported in 11%-16% after second dose
- 28% and 45% reported use of anti-pyretic medications after first and second dose respectively



Vaccine Efficacy

- Vaccine was 95% effective in preventing COVID-19
- Of the 10 cases of severe Covid-19 that were observed after the first dose, only 1 occurred in the vaccine group
- No difference in effectiveness by age, sex, race or underlying health conditions
- Received EUA Dec 11, 2020
- Approved for >16 years of age

Allergic Reactions

- Likely related to lipid nano-particle
- No anaphylaxis reported in either study
- Few cases of allergic reactions to mRNA vaccines have been reported
- **EXTREMELY RARE and ALL PERSONS RECOVERED**

Allergic Reactions

- Persons who have experienced mild or moderate allergic reaction (hives, swelling) to first dose should not receive second dose
- Allergies to food and medications is not a contraindication to mRNA vaccines
- Persons allergic to PEG or polysorbate should not receive mRNA COVID-19 vaccine



Other Key Points

Pregnant and Breast Feeding Women

- 13 pregnancies occurred in the mRNA-1273 study
- 23 pregnancies in the BNT162b2
- mRNA are not live vaccines
- Consider vaccination based on risk group
- Pregnancy test prior to vaccination is not recommended

Myths about COVID Vaccines

- Vaccines were developed too quickly so they are not safe
- Vaccines will cause long term side effects
- The vaccine will give you COVID-19
- If you had COVID-19, you don't need to get vaccinated
- If you have underlying health problems or suppressed immune system, you should not take the vaccine
- Vaccines will alter your DNA
- You can stop wearing masks etc. after vaccination

Ongoing Monitoring

- Study participants followed for 12-25 months
- <http://vsafe.cdc.gov>
- Vaccine Adverse Event Reporting System or VAERS
- Almost 38 million vaccinated worldwide
- 13 M people vaccinated in the US

Vaccines are coming but.....

- Wear a mask
- Watch your distance
- Wash your hands

- As of January 21, 2021
- Over 16 million vaccinations in the US
- 54 million worldwide

Vaccines don't
prevent disease
VACCINATIONS
prevent disease



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