



COVID-19 Vaccines

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Pediatric Infectious Diseases

COVID-19's Impact

Data through April 13, 2021

	Total Cases	Total Deaths	CFR Rate
Global	137,066,492	2,951,768	2.1%
U.S.	31,335,197	563,375	1.8%
California	3,604,395	59,258	1.6%
Orange County	252,538	4,849	1.9%

Timeline Accelerated

Traditional Approach:



Accelerated Approach:



COVID-19 Vaccine Overview

mRNA

Directly provides cells with instruction to create SARS-CoV-2 spike protein. Doesn't enter cell nucleus or augment DNA.

- Pfizer
- Moderna

Viral Vector

Uses a safe virus to deliver the DNA of SARS-CoV-2 spike protein to human cells.

- Johnson & Johnson
- AstraZeneca/U of Oxford

Protein Subunit

Contains stabilized form of the SARS-CoV-2 spike protein. Delivers the protein directly.

- Novavax

mRNA COVID-19 Vaccines

- Discovered in the 1990's; studied for more than a decade (e.g. CMV, Zika).
- mRNA vaccines take advantage of the process that human cells use to make proteins to trigger an immune response.
 - mRNA enter cell cytoplasm giving instructions to make “spike” protein.
 - “Spike” protein displayed on cell surface generating an immune response.
 - Cell gets rid of the mRNA soon after it is finished using the instructions.
- mRNA vaccines do not contain live virus and cannot alter a person's DNA as they don't enter the cell nucleus.
- Fully synthetic thus fast production, low cost.

Johnson & Johnson Vaccine Overview

- EUA approval on 2/27/2021
- Single-dose vaccine
- 72% efficacy rate in the U.S.
- 93% efficacy against hospitalization
- Added gene for the COVID-19 spike protein to Adenovirus 26 – a common cold/flu virus
- Noted similar local and systemic side effects
- 4/13/21: Cerebral venous sinus thrombosis in six women age 18 – 48 years old



Image Source: CNBC

CDC Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the U.S.

Updated on Feb 10, 2021

- New recommendations for preventing, reporting and managing mRNA COVID-19 vaccine administration errors.
- Clarification on contraindications and precautions
- Updated information on delayed, local injection-site reactions after the 1st mRNA vaccine dose. These reactions are neither a contraindication or precaution to 2nd dose.
- Updated quarantine recommendations – Fully vaccinated persons who meet criteria will no longer be required to quarantine following exposure.
- Updated recommendations for TB testing. Can be done before or at the same time as mRNA vaccination, or otherwise delayed for >4 weeks after completion of vaccination.
- Table on Vaccine administration errors and deviations.

Co-administration with Other Vaccines

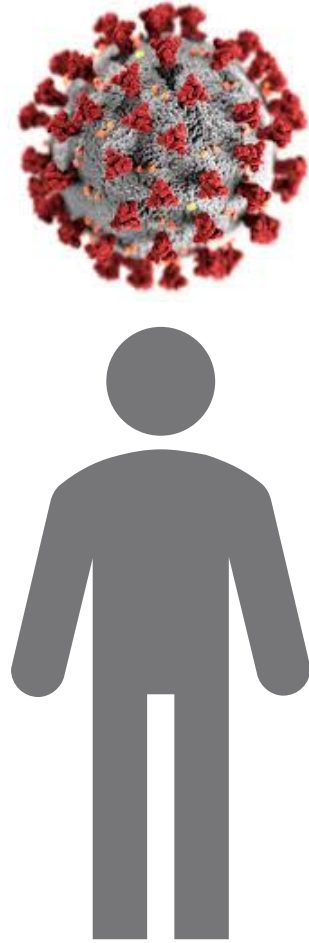
- Due to lack of data, there should be a minimum of 14 days before or after administration with any other vaccine.
- Can be given within shorter periods for certain situations (e.g., tetanus wound management).



Image Source: FiveThirtyEight

Vaccination of persons with a SARS-CoV-2 Infection or Exposure

- Vaccination should be administered regardless of history of prior infection.
- Serologic testing for the purposes of vaccine decision-making is not recommended.
- Vaccination should be deferred until isolation is discontinued.
- Persons with recent documentation of infection may choose to temporarily delay vaccination.
- Vaccination should be deferred 90 days for those who received monoclonal antibodies or convalescent sera.



Vaccination of persons with Underlying Medical Conditions

- Clinical trials demonstrated similar safety and efficacy with some underlying medical conditions.
- Individuals with these specific conditions can receive the vaccine though there is limited safety and efficacy data:
 - HIV or other immunocompromised individuals
 - Autoimmune conditions
 - Guillain-Barré syndrome
 - Bell's Palsy
 - History of dermal fillers



Image Source: USA Today

Contraindications

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of mRNA COVID-19 vaccine or any of its components.
- Immediate allergic reaction of any severity to a previous dose of mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG]).
- Immediate allergic reaction of any severity to polysorbate.

Precautions

- History of any immediate allergic reaction to any other vaccine or injectable therapy.
 - Consultation with an allergist may be considered.

Neither Contraindications or Precaution with Vaccination

- Allergic reactions (including severe) not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines (including PEG), or polysorbates such as allergic reactions to:
 - Food
 - Pets
 - Venom
 - Environmental allergies
 - Allergies to oral medications
- These vaccines do not contain eggs or gelatin.

Delayed-Onset Local Reactions

- Occur several days through the second week around the injection site after first dose.
- Erythema, induration, pruritus sometimes quite large
- No contraindication or precaution to receive second dose at the recommended interval, but preferably in the opposite arm.



Image Source: Psychology Today

Public Health Recommendation for Vaccinated Persons

- Vaccinated persons should continue to follow current guidance including wearing a mask, physical distancing, avoiding crowds, and hand hygiene.
- However, vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are not required to quarantine if they meet all the following criteria:
 - 2 weeks after vaccine series completion
 - Within three months following the receipt of the last dose in the series
 - Have remained asymptomatic
 - Continue to monitor for symptoms



Wear a mask. Save lives.

Wear a face cover

Wash your hands

Keep a safe distance

Image Source: CDC

Additional Information

- Table on vaccine errors and deviations available
- Table on potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following mRNA vaccination available
- New guidelines will become available for the Johnson & Johnson vaccine.



**CENTERS FOR DISEASE
CONTROL AND PREVENTION**

First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021

Julianne Gee¹; Paige Marquez¹; John Su¹; Geoffrey M. Calvert¹; Ruiling Liu¹; Tanya Myers¹; Narayan Nair²; Stacey Martin¹; Thomas Clark¹;
Lauri Markowitz¹; Nicole Lindsey¹; Bicheno Zhano¹; Charles Licata¹; Amelia Iazwa¹; Mark Sotir¹; Tom Shimabukuro¹

Summary

What is already known about this topic?

Two COVID-19 vaccines have received Emergency Use Authorization for administration in the United States. In preauthorization clinical trials, local and systemic reactions were reported; no serious safety problems were detected.

What is added by this report?

Monitoring, conducted as part of the U.S. vaccination program, indicates reassuring safety profiles for COVID-19 vaccines. Local and systemic reactions were common; rare reports of anaphylaxis were received. No unusual or unexpected reporting patterns were detected.

What are the implications for public health practice?

Health care providers and vaccine recipients can be reassured about the safety of Pfizer BioNTech and Moderna COVID-19 vaccines. Counseling vaccine recipients to expect transient local and systemic reactions might ease concerns and encourage completion of the 2-dose vaccination series.

Variants Bottom Line

- We need to get people vaccinated to stop the virus from replicating. It can't mutate if it's not replicating!
- We need to 70-85% population immunity to achieve herd immunity.



Image Source: Beaumont Health

COVID Vaccinations in Pregnant Women

- Pregnant women who get COVID-19 are more likely than non-pregnant women to require intensive care and greater risk of death.
- Risk of COVID-19 complications due to other underlying medical conditions is higher in pregnant women.
- Risk of COVID-19 to fetus: intrauterine transmission is rare and may include fetal growth restriction and pre-term birth.
- mRNA vaccines are known to work locally at the site of inoculation, then rapidly degraded and removed by lymphatic system, thereby making the likelihood of the vaccine reaching and crossing the placenta low.



Image Source: MGH Center for Women's Mental Health

COVID Vaccinations and Fertility

- The short answer: COVID-19 vaccine **should not cause infertility** in women.
- The long answer:
 - The claim regarding syncytin-1 protein
 - Biochemically shared protein sequences
 - Natural infection is not causing infertility

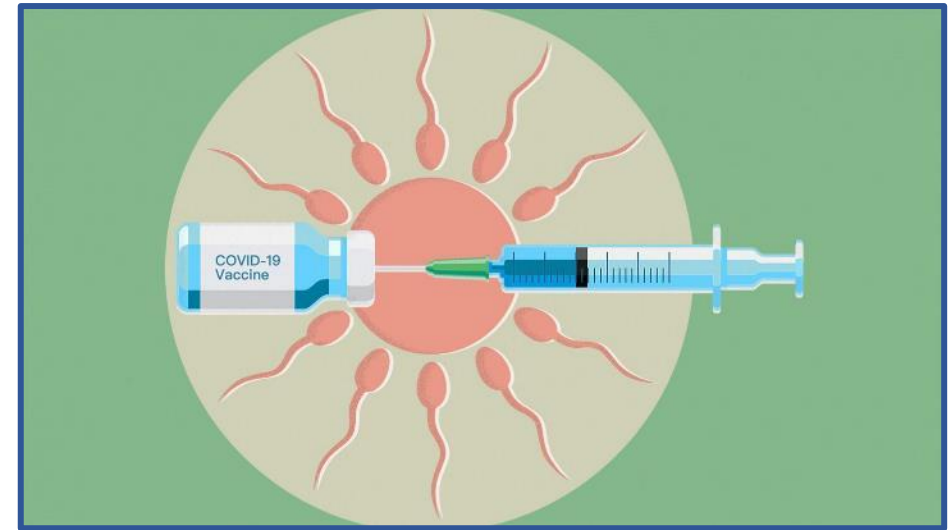


Image Source: Everyday Health

COVID Vaccination and Mammography

- Swollen lymph nodes are a known reaction to vaccinations, including the COVID-19 vaccine.
- Society of Breast Imaging (SBI) recommends:

“If possible, and when it does not unduly delay care, consider scheduling screening exams prior to the first dose of a COVID-19 vaccination or 4-6 weeks following the second dose of a COVID-19 vaccination.”



Image Source: MD Anderson

Pediatric Vaccines – Why?

- Children get severe disease less often, but it still happens, particularly in those with underlying medical problems.
- Children have experienced MIS-C.
- Children constitute 22% of the population, so including them will help us achieve herd immunity.
- Protecting children will facilitate return to school, opening the economy and getting back to normal.

Pediatric Vaccines

- Pfizer vaccine may soon be granted approval for 12-15 yr olds
- Experts hope that vaccine for children <12 yrs might be available by late 2021 – early 2022.
- Both Pfizer and Moderna are conducting trials in children down to age 6 months; other companies are also conducting pediatric trials.

Summary

- COVID-19 vaccines are safe and effective.
- New vaccine platforms offer promise.
- Side effects are common, but short lived.
- Vaccinating pregnant women can help keep themselves and their babies safe.
- Pediatric vaccines will offer children protection, and help allow a return to normal.

Questions?

