Recommendations for the Novavax COVID-19 Vaccine Primary Series in Adults Ages 18 Years and Older

Clinician Outreach and Communication Activity (COCA) Call

Thursday, July 28, 2022

Free Continuing Education

- Free continuing education is offered for this webinar.
- Instructions on how to earn continuing education will be provided at the end of the call.

Continuing Education Disclaimer

- In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships, in any amount, with ineligible companies over the previous 24 months as well as any use of unlabeled product(s) or products under investigational use.

- CDC, our planners, and presenters wish to disclose they have no financial relationship(s) with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

- Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of Dr. Hall's and Dr. Twentyman's discussion of vaccine use under Emergency Use Authorization or Emergency Use Instruction.

- CDC did not accept financial or in-kind support from ineligible companies for this continuing education activity.

Objectives

At the conclusion of today's session, the participant will be able to accomplish the following:

1. Discuss current recommendations for COVID-19 vaccination with Novavax for adults ages 18 years and older, including those who are moderately or severely immunocompromised.
2. List key points for healthcare providers to use when discussing COVID-19 vaccination with Novavax.
3. Describe where to find online resources for clinicians about Novavax COVID-19 vaccination.

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov

Today's Presenters

Evelyn Twentyman, MD, MPH
Lead, Advisory Vaccine Policy Unit
COVID-19 Response
Centers for Disease Control and Prevention

Chris Duggar, MPH
Lead, COVID Vaccine Unit
COVID-19 Response
Centers for Disease Control and Prevention

Elisha Hall, PhD, RD
Lead, Clinical Guidelines Vaccine Policy Unit
COVID-19 Response
Centers for Disease Control and Prevention

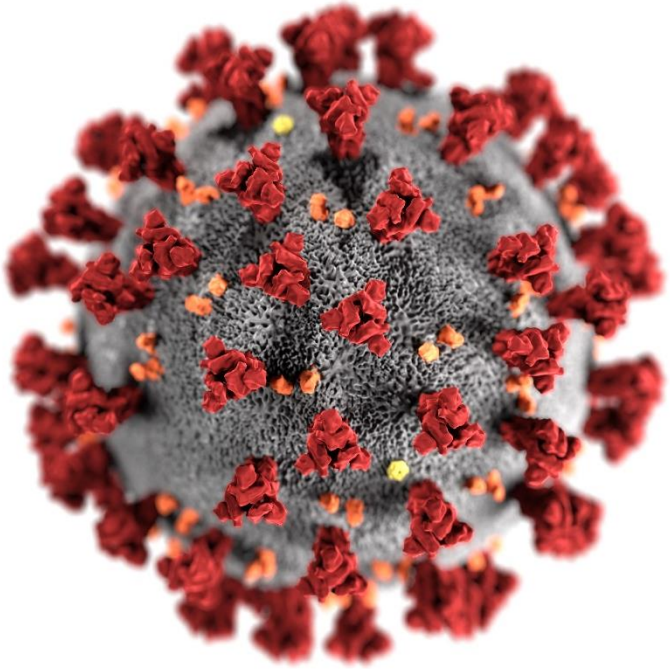
Tanya Myers, PhD, MSc
Co-lead, v-safe Team
COVID-19 Immunization Safety Unit
COVID-19 Response
Centers for Disease Control and Prevention

COVID 19
CORONAVIRUS DISEASE

Novavax COVID-19 Vaccine:

An adjuvanted protein subunit COVID-19 vaccine for use as a two-dose primary series in adults

Evelyn Twentyman, MD, MPH

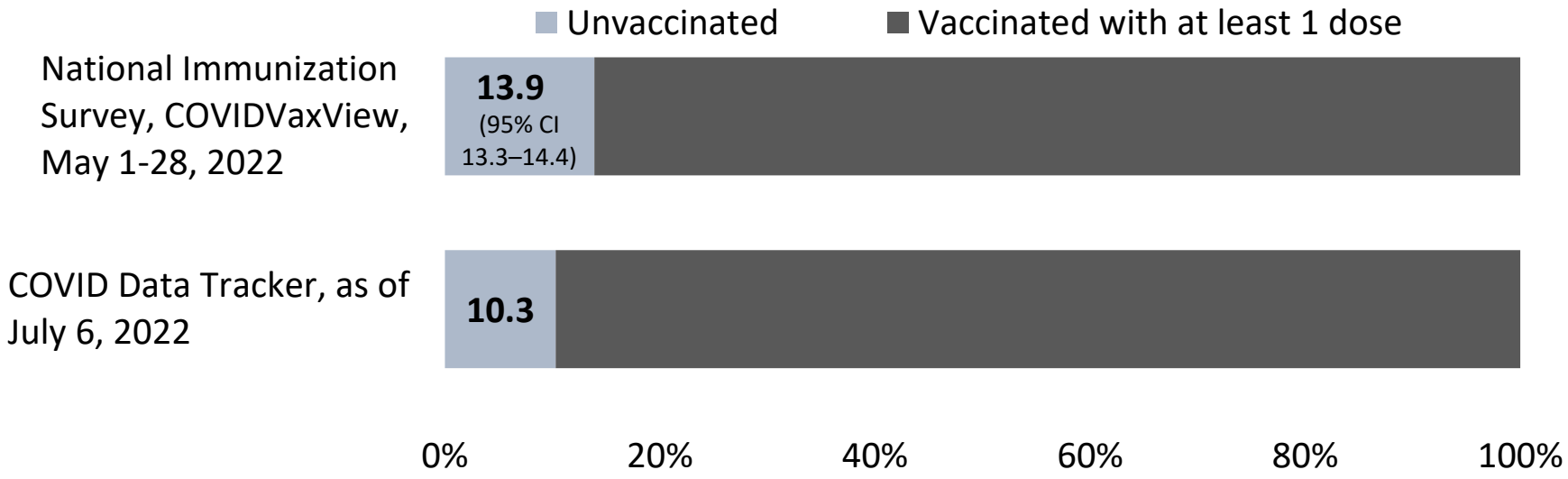


CDC

For more information: **www.cdc.gov/COVID19**

Need for Primary Series Vaccination Among U.S. Adults

Percent of U.S. Adults Ages ≥18 Years Not Yet Receiving a COVID-19 Vaccine

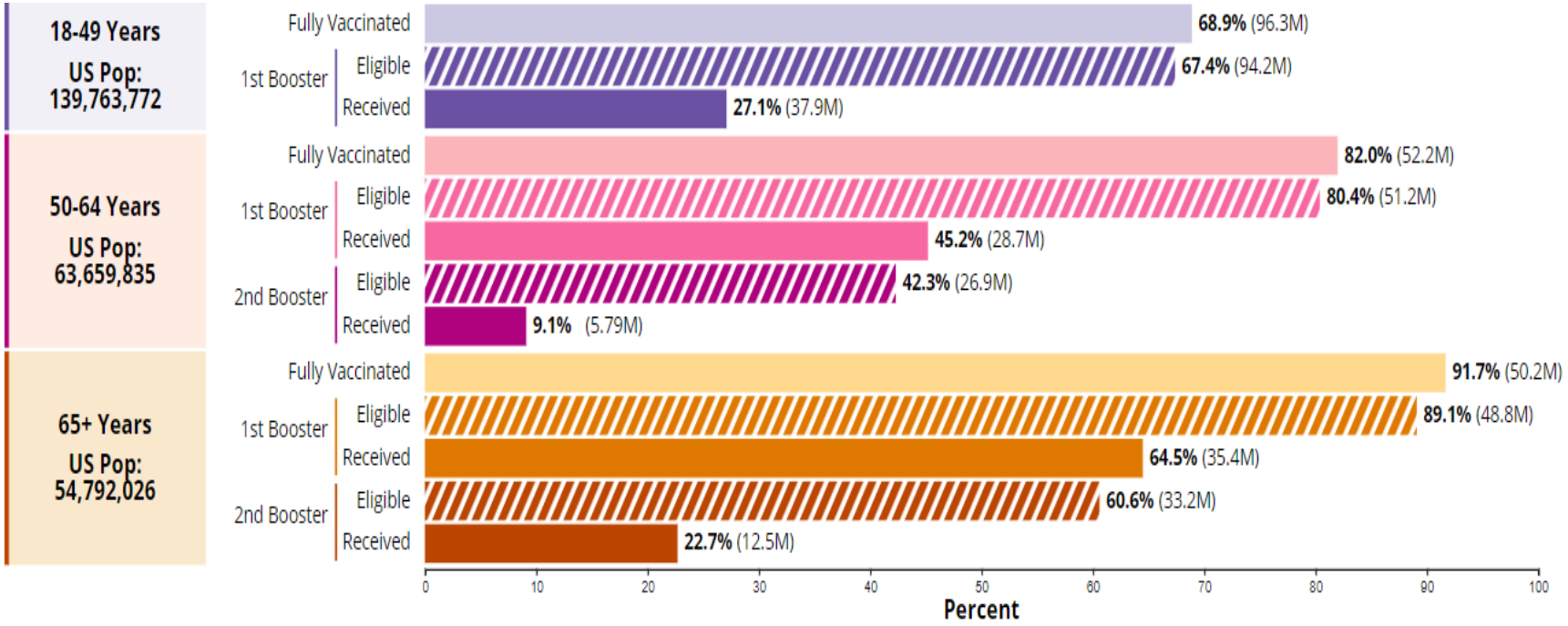


~26–37 million US adults have not yet received a COVID-19 vaccine

COVIDVaxView. Estimates produced by NORC at the University of Chicago using CDC's National Immunization Survey-Adult COVID-19 Module (NIS-ACM). https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html. Accessed July 14, 2022

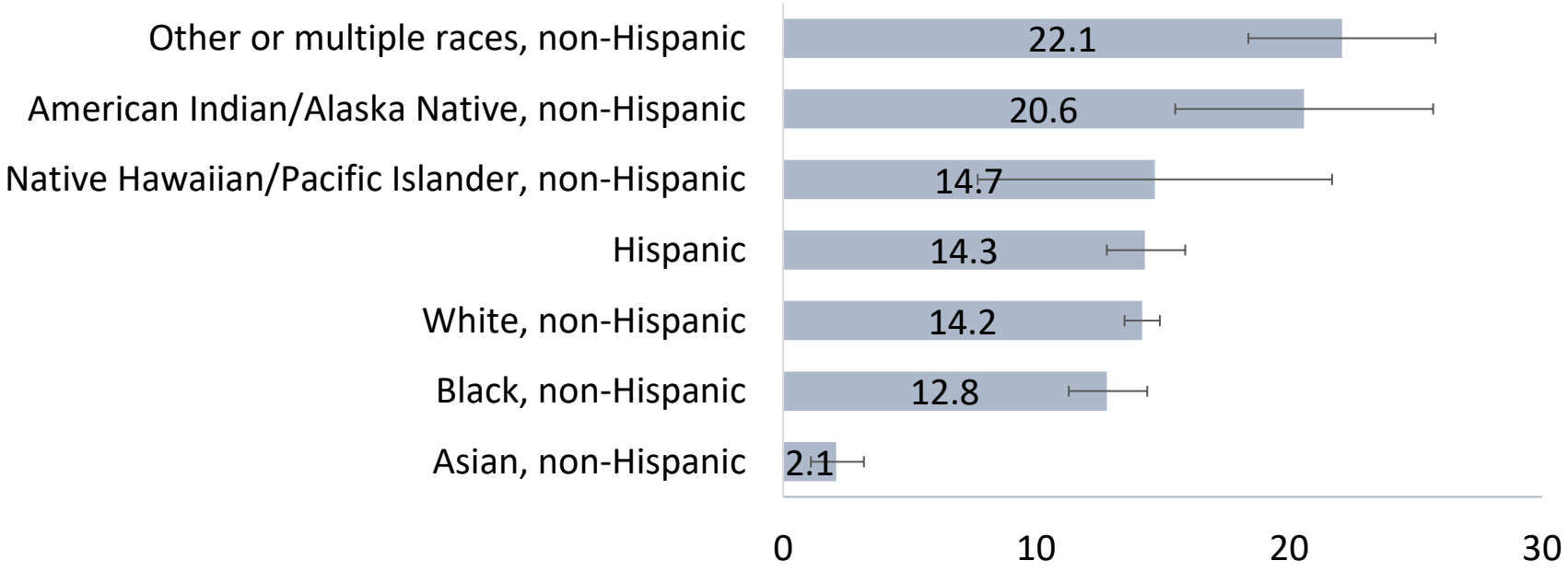
COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-additional-dose-totalpop. Accessed on July 13, 2022.

Primary series completion among adults ages 18 years and older, United States, as of July 13, 2022



CDC COVID Data Tracker. COVID-19 Vaccinations in the United States. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-count-total Accessed July 18, 2022

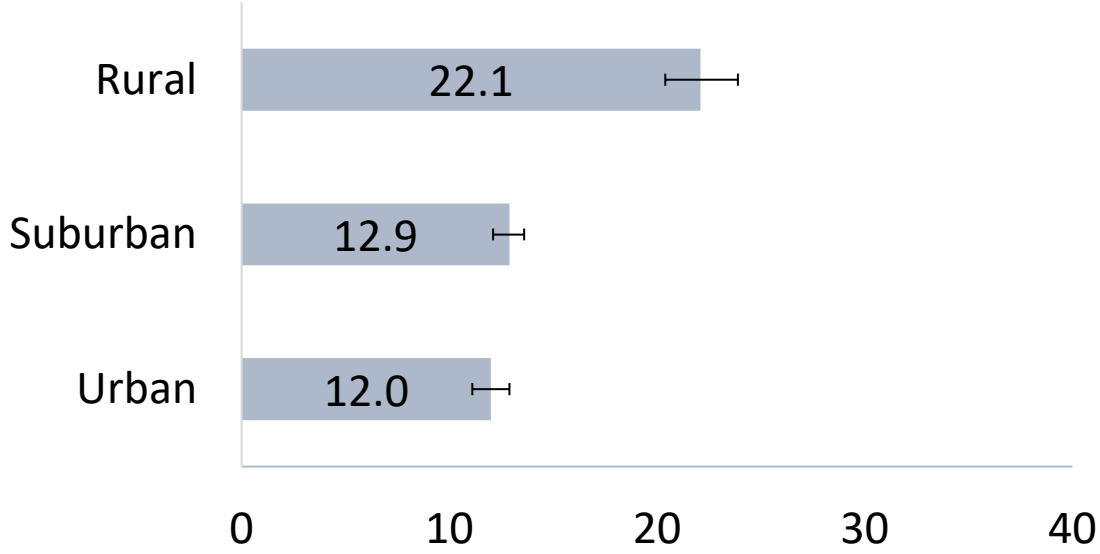
Percent of U.S. adults not yet receiving a COVID-19 vaccine by race/ethnicity — May 1–28, 2022



95% Confidence intervals shown by error bars

Source: COVIDVaxView. Estimates produced by NORC at the University of Chicago using CDC's National Immunization Survey-Adult COVID-19 Module (NIS-ACM). https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html. Accessed July 14, 2022

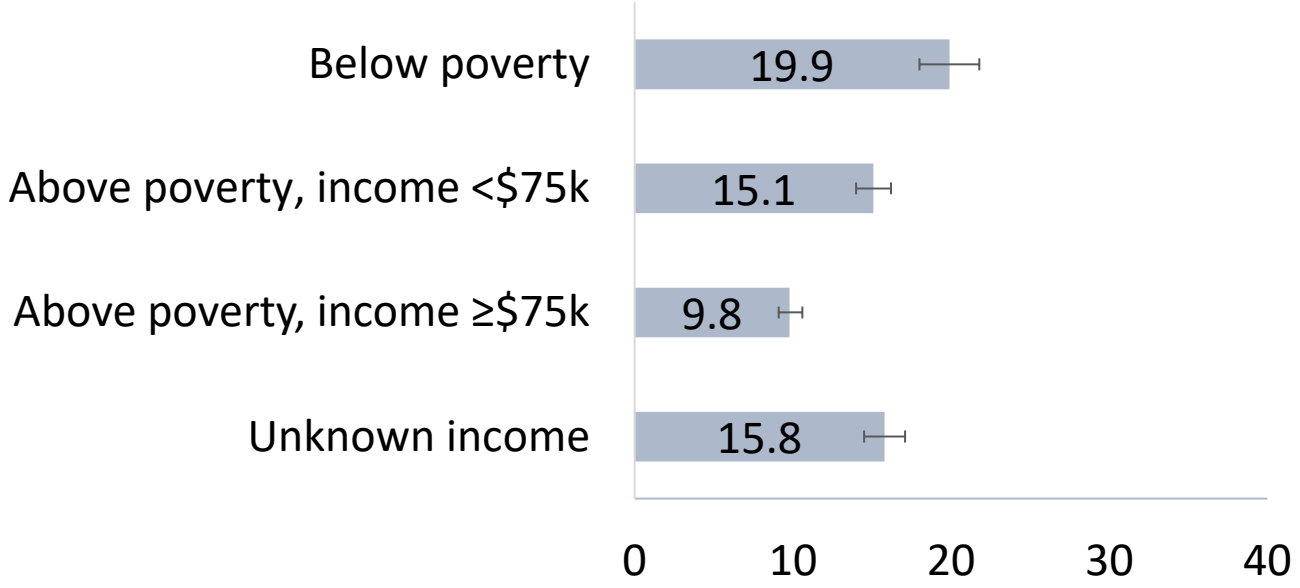
Percent of U.S. adults not yet receiving a COVID-19 vaccine by metropolitan statistical area — May 1–28, 2022



95% Confidence intervals shown by error bars

Source: COVIDVaxView. Estimates produced by NORC at the University of Chicago using CDC's National Immunization Survey-Adult COVID-19 Module (NIS-ACM). https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html. Accessed July 14, 2022

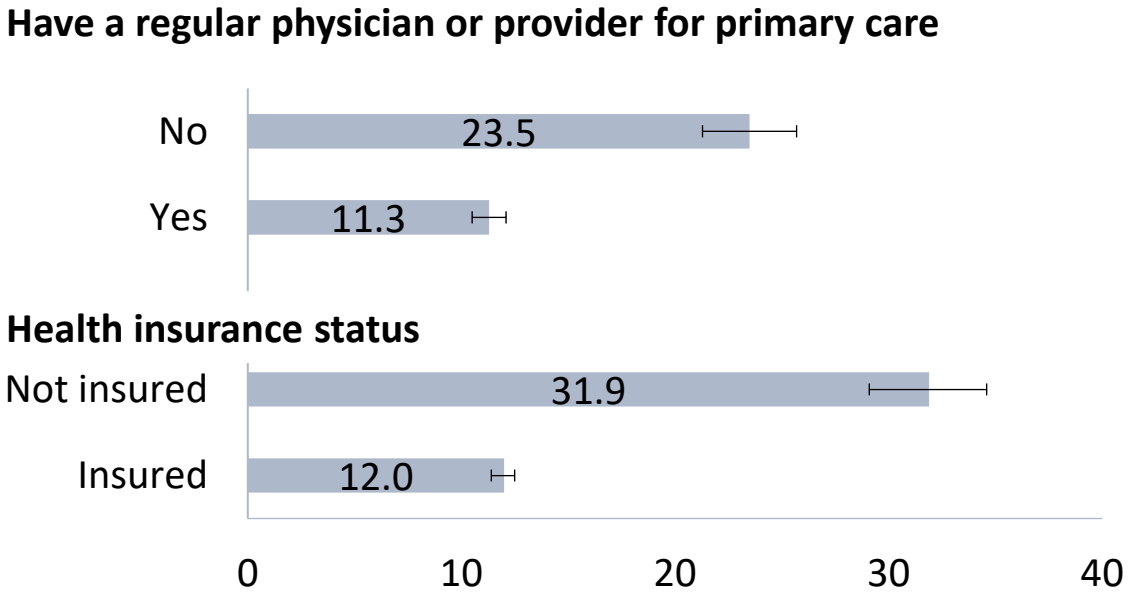
Percent of U.S. adults not yet receiving a COVID-19 vaccine by income and poverty status — May 1–28, 2022



95% Confidence intervals shown by error bars

Source: COVIDVaxView. Estimates produced by NORC at the University of Chicago using CDC's National Immunization Survey-Adult COVID-19 Module (NIS-ACM). https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html. Accessed July 14, 2022

Percent of U.S. adults not yet receiving a COVID-19 vaccine by markers of access to health care— May 1–28, 2022



95% Confidence intervals shown by error bars

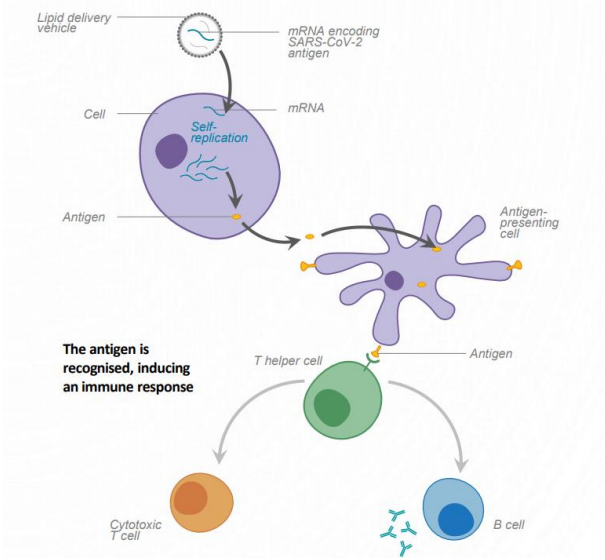
Source: COVIDVaxView. Estimates produced by NORC at the University of Chicago using CDC's National Immunization Survey-Adult COVID-19 Module (NIS-ACM). https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html. Accessed July 14, 2022

Vaccine Mechanism of Action

Mechanism of action of authorized COVID-19 vaccines

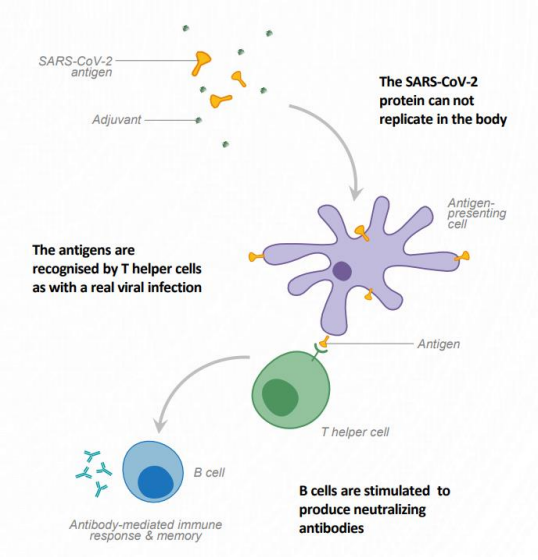
mRNA

Pfizer-BioNTech and Moderna COVID-19 vaccines



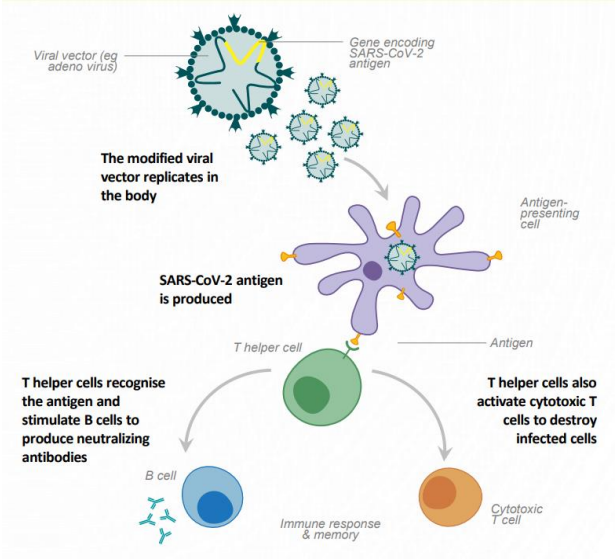
Protein subunit

Novavax COVID-19 vaccine



Viral vector

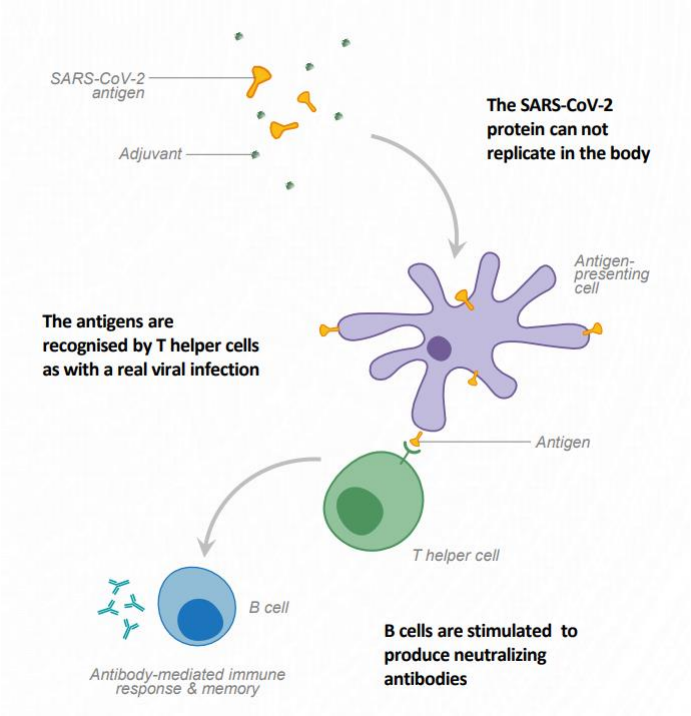
Janssen/J&J COVID-19 vaccine



Source: https://www.who.int/docs/default-source/coronaviruse/risk-comms-updates/update73_covid-19-vaccines-and-immune-response.pdf?sfvrsn=7902cc35_5

Mechanism of action of the Novavax COVID-19 vaccine

- Components of Novavax COVID-19 vaccine, Adjuvanted, include:
  - SARS-CoV-2 recombinant spike (rS) protein is purified, full-length, and stabilized in its prefusion conformation
  - Matrix-M™ adjuvant facilitates activation of the cells of the innate immune system, which enhances the magnitude of the spike protein-specific immune response
- These two vaccine components elicit B- and T-cell immune responses to the spike protein, including neutralizing antibodies, which protect against COVID-19



Source: https://www.fda.gov/media/158914/download; https://www.who.int/docs/default-source/coronaviruse/risk-comms-updates/update73_covid-19-vaccines-and-immune-response.pdf?sfvrsn=7902cc35_5

Potential Benefits and Harms

Data Sources: Efficacy, Immunogenicity, and Safety

GRADE Evidence

- Formal standard evaluation of efficacy, immunogenicity, and safety to inform vaccine recommendations through this explicit, evidence-based approach
- Pre-crossover period of a single randomized clinical trial based in the US and Mexico
  - 2019nCoV-301
- Full analysis set: 19,963 vaccine; 9,982 placebo
- Per protocol set: 17,272 vaccine, 8,385 placebo

Additional Evidence to Inform EtR

- Efficacy: observations regarding circulating variants; VE in the context of variants
- Safety: broad capture of outcomes across all vaccine recipients
  - Pre- *and* post-crossover vaccine recipients of 2019-nCoV301, plus adolescent and booster *expansions* of 2019-nCoV301
  - All vaccine recipients across all Novavax clinical trials globally:
    - 2019nCoV-302
    - 2019nCoV-501
    - 2019nCoV-101
  - Total vaccine recipients aged ≥16 years: **41,546**
- Myocarditis and/or pericarditis:
  - Broader safety set, plus consideration of publicly available global post-authorization data

Outcome 1: Symptomatic lab-confirmed COVID-19
Studies with unvaccinated comparator (n=1)

Population	Events/Vaccine[a] (n/N)	Events/Placebo[a] (n/N)	Vaccine efficacy (95% CI)
Primary Outcome[b]			
Ages ≥18 years	17/17272	79/8385	89.6% (82.4%, 93.8%)
Ages 18–64 years	15/15228	75/7417	90.3% (83.1%, 94.4%)
Ages ≥65 years	2/2044	4/968	76.3% (-29.1%, 95.7%)
Any comorbidity[c] (18–64 years)	6/6957	38/3451	92.2% (81.5%, 96.7%)
Any comorbidity[c] (≥65 years)	1/1125	3/580	82.8% (-64.9%, 98.2%)

a. 19,963 and 9,982 persons were randomized to vaccine and placebo

b. Cases diagnosed ≥7 days post dose 2 among persons without evidence of prior SARS-CoV-2 infection

c. Comorbidities: obesity, chronic kidney disease, chronic lung disease, cardiovascular disease, diabetes mellitus type 2

CI: confidence interval

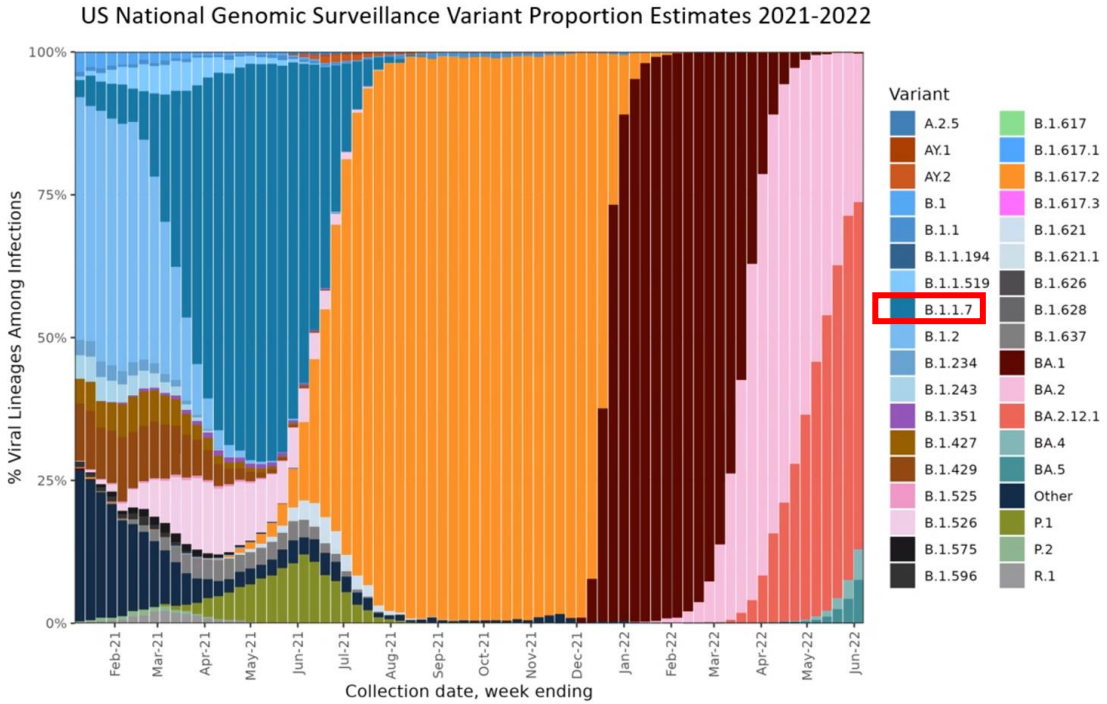
Summary of GRADE

Outcome	Importance	Design (# of studies)	Findings	Evidence Type
Benefits				
Symptomatic lab-confirmed COVID-19	Critical	RCT (1)	Novavax COVID-19 vaccine is effective in preventing symptomatic COVID-19 during a period of Alpha variant predominance	**1**
Hospitalization due to COVID-19	Critical	RCT (1)	Severe COVID-19 evaluated as a surrogate for this critical outcome. Novavax COVID-19 vaccine is effective in preventing severe COVID-19.	**3**
Death due to COVID-19	Important	RCT (1)	No events occurred in the study included in the review of evidence.	**No events**
Asymptomatic SARS-CoV-2 infection	Important	No studies	No systematically collected data on outcome not available in study included in the review of evidence.	**No data**
Harms				
Serious adverse events	Critical	RCT (1)	SAEs were balanced between vaccine and placebo arms.	**1**
Reactogenicity	Important	RCT (1)	Severe reactions were more common in vaccinated; any grade ≥3 reaction was reported by 16.3% of vaccinated vs. 4.0% of placebo group	**1**

Evidence type: 1=high; 2=moderate; 3=low; 4=very low

Novavax vaccine efficacy in study 301 was assessed during the period of Alpha predominance

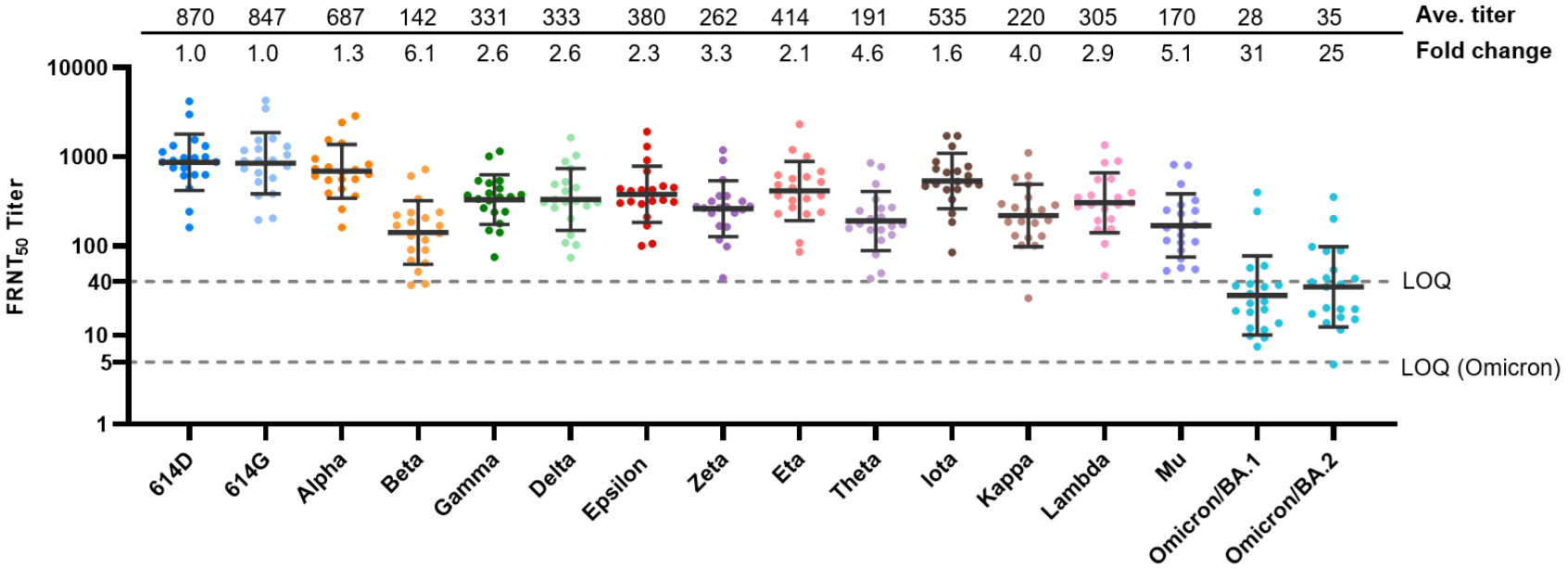
- Of 96 cases accrued in the primary efficacy analysis, pre-crossover, December 20, 2020—September 27, 2021, 75 had sequence data*:
  - 53% Alpha
  - 11% Iota
  - 7% Epsilon
  - 4% Gamma
  - 3% Beta
  - 1% Delta
  - 1% Kappa
  - 1% Zeta



*Novavax VRBPAC Briefing Document, June 7, 2022.

CDC COVID Data Tracker: Variant Proportions; Lambrou et al. Genomic Surveillance for SARS-CoV-2 Variants: Predominance of the Delta (B.1.617.2) and Omicron (B.1.1.529) Variants — United States, June 2021–January 2022 https://www.cdc.gov/mmwr/volumes/71/wr/mm7106a4.htm

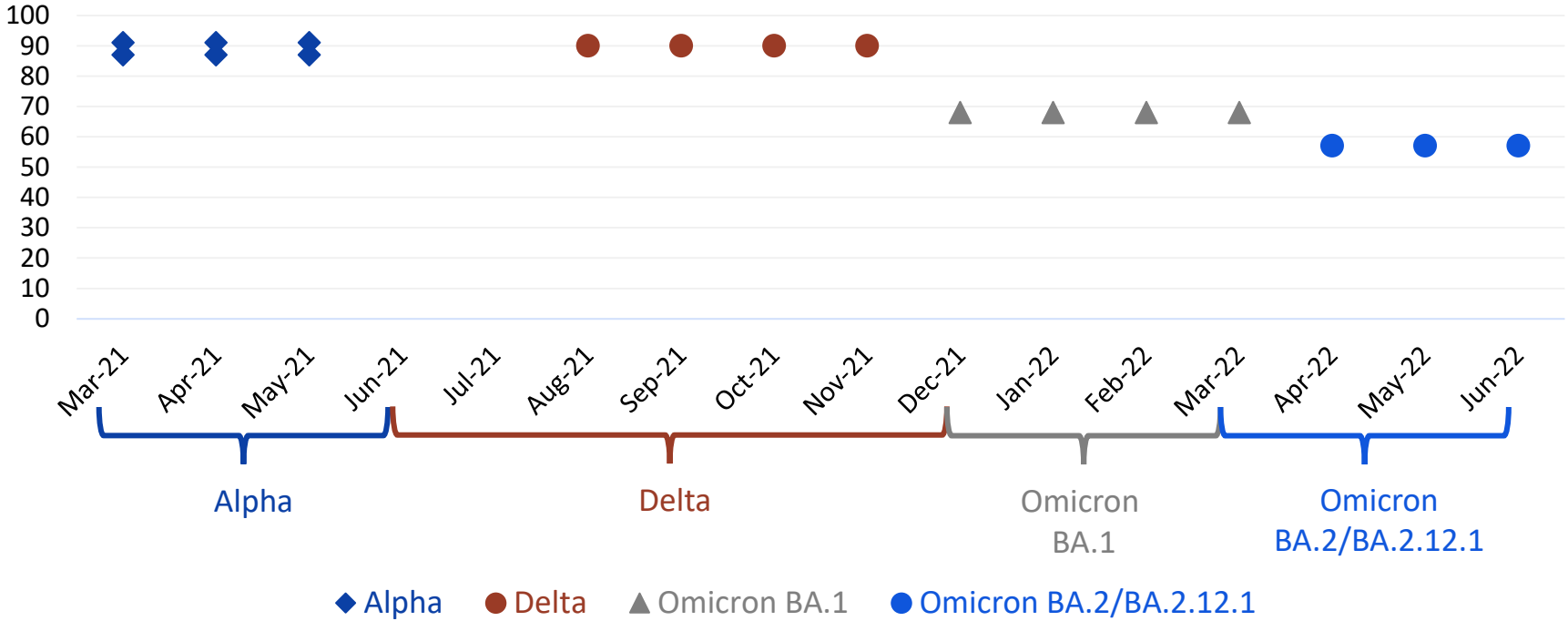
Neutralizing activity for 2 doses of mRNA vaccine sera against SARS-CoV-2 variants from Alpha to Omicron



Sera from 2-6 weeks after completing second dose of Moderna (10 sera) and Pfizer-BioNTech (10 sera) vaccines, tested with recombinant SARS-CoV-2 reporter viruses

LOQ=Limit of quantitation. Zhou B, Davis T, Thornburg N, Wentworth D (CDC), *in publication*

Vaccine effectiveness for 2 doses of mRNA vaccines against COVID-19-associated hospitalization, by variant



Alpha estimates for Pfizer-BioNTech and Moderna separately from: Thompson et al. NEJM https://www.nejm.org/doi/full/10.1056/nejmoa2110362

Delta estimates for mRNA vaccines combined from: Thompson et al. MMWR https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e3.htm

Omicron estimates for mRNA vaccines combined from: Link-Gelles et al. MMWR https://www.cdc.gov/mmwr/volumes/71/wr/mm7129e1.htm

Novavax COVID-19 vaccine efficacy against the Beta (B.1.351) variant of SARS-CoV-2, South Africa, 2020—2021

- Among 2684 participants seronegative at baseline, vaccine efficacy against symptomatic COVID-19 disease was **49.4% (6.1%, 72.8%)**
- Among **HIV negative** participants who were seronegative at baseline, vaccine efficacy was 60.1% (19.9%, 80.1%)
- Of 41 sequenced isolates, 38 (92.7%) were Beta variant
- Post hoc vaccine efficacy against the Beta variant was **51.0% (-0.6%, 76.2%)**

Shinde et al. Efficacy of NVX-CoV2372 COVID-19 vaccine against the B.1.351 variant. NEJM 2021; 384:1899-1909.

Myocarditis/Pericarditis

- Intensive post-authorization COVID-19 vaccine surveillance has identified a small risk of myocarditis associated with mRNA vaccination, particularly after a second dose in adolescent males and young men[1]

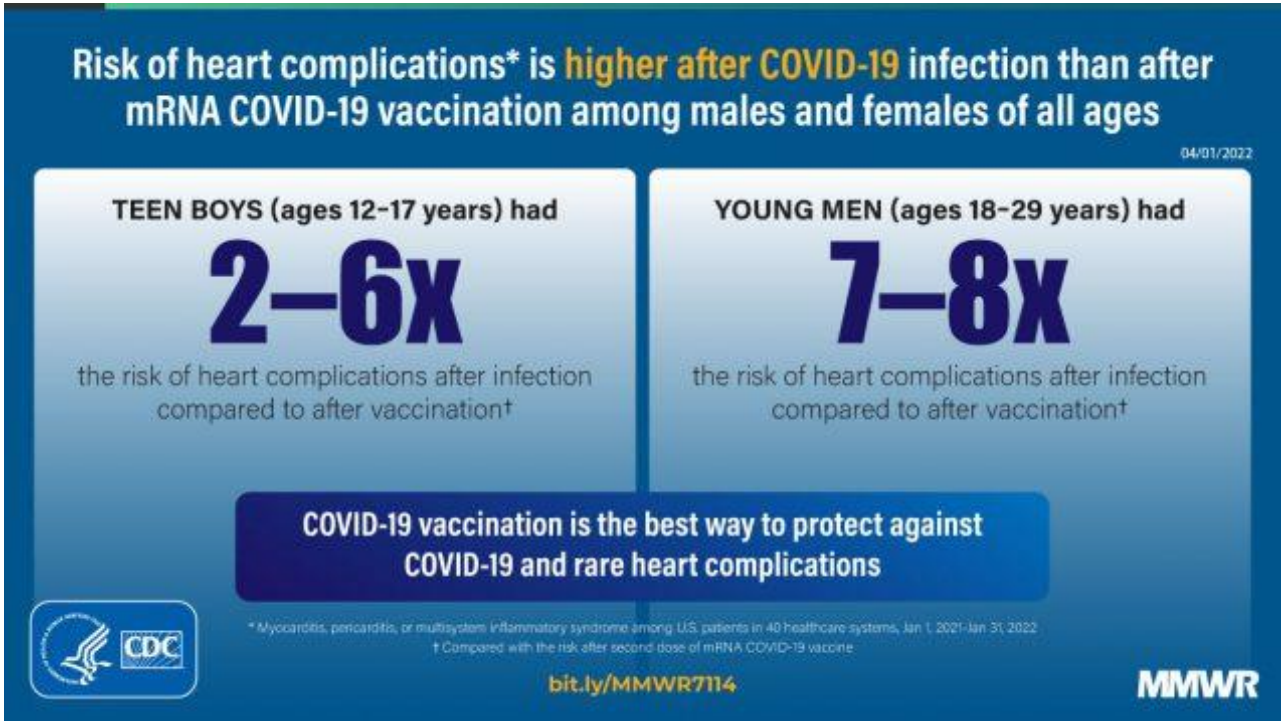
- COVID-19 **disease** is associated with risk of myocarditis, pericarditis, stroke, acute coronary syndrome, myocardial infarction, heart failure, arrhythmia, and cardiac death[2]

[1] Oster et al. *JAMA.* 2022;327(4):331-340. doi:10.1001/jama.2021.24110;

[2] Basu-Ray I, Almaddah Nk, Adeboye A, et al. Cardiac Manifestations Of Coronavirus (COVID-19) StatPearls Publishing; 2022 Jan. https://www.ncbi.nlm.nih.gov/books/NBK556152/

Myocarditis and pericarditis: Benefits of COVID-19 vaccination outweigh risks

- COVID-19 vaccination is the best way to protect against COVID-19 and rare cardiac complications[1]



[1] Block JP, Boehmer TK, Forrest CB, et al. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination — PCORnet, United States, January 2021–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:517-523. DOI: http://dx.doi.org/10.15585/mmwr.mm7114e1.

Myocarditis and pericarditis cases identified across Novavax clinical trials

- Total **clinical safety** database included a total of **41,546** vaccine recipients
- **Four** cases of myocarditis and/or pericarditis were identified as having a temporal relationship and lack of alternative etiology concerning for a causal relationship with vaccine:
  - Male, age 16, myocarditis, with onset 2 days post dose 2. Peak troponin ~32,000 and treated with IVIG.
  - Male, age 19, myocarditis, with onset 2 days post dose 2. Peak troponin ~7,800.
  - Male, age 28, myocarditis vs. non-ST-elevation MI, with onset 3 days post dose 3. Peak troponin ~300.
  - Female, age 60, pericarditis, with onset 8 days post dose 2. Troponin normal.
- All four hospitalized with serious events; all experienced complete clinical **resolution**
- Also identified across clinical trials:
  - Male, age 20, pericarditis and myocarditis, 10 days post dose 1, with alternative explanation of streptococcal myocarditis. Normal troponin. No hospitalization.
  - Male, age 67, myocarditis, 28 days post dose 1 with concomitant COVID-19 disease, considered unrelated to vaccine. Hospitalized. Peak troponin 5,329 + AKI.
  - Female, age 31, myocarditis, 72 days post placebo dose 2 with alternative explanation, considered unrelated to placebo. Hospitalized. Peak troponin 330.

FDA VRBPAC Briefing Document. June 7, 2022. https://www.fda.gov/media/158912/download

Myocarditis and pericarditis cases identified in post marketing safety data: Context

- As of April 30, 2022, a total of **744,235** doses[1] of NVX vaccine had been administered post-authorization and/or approval in:
  - Australia
  - Canada
  - European Union
  - New Zealand
  - South Korea

[1] Lee L. FDA review of effectiveness and safety of Novavax COVID-19 vaccine in adults ≥18 years of age. June 7, 2022. https://www.fda.gov/media/159004/download

World map courtesy of the Nations Online Project: https://www.nationsonline.org/oneworld/map/world_map.htm

Myocarditis and pericarditis cases identified in post marketing safety data: Cases

- **35** unique reports including a total of 36 adverse events:
  - **29** cases of **pericarditis**
    - *Including **5** reports in **individuals with a history of pericarditis after mRNA vaccine***
  - 4 cases of **myocarditis**
  - 2 cases of **myopericarditis**
  - 1 case of **carditis** not otherwise specified

- Limited additional data available:
  - Median known age was 34 years (range 23–62)
  - Males n=20, females n=15

Lee L. FDA review of effectiveness and safety of Novavax COVID-19 vaccine in adults ≥18 years of age. June 7 2022. https://www.fda.gov/media/159004/download; VRBPAC June 7, 2022 Briefing Document https://www.fda.gov/media/158912/download

Summary of cases of myocarditis and/or pericarditis following Novavax vaccination, doses administered & reporting rates

Setting	Cases	Doses administered	Reporting rate** (cases/million doses administered)
Novavax COVID-19 Vaccine clinical trials[1]	4–6*	41,546	**96–144**
Sponsor submission of post-marketing reports in Australia, Canada, EU, New Zealand & South Korea[2]	36	744,235	**48**
Australia post-marketing reports[3]	15	160,000	**94**

[1] Total expanded safety population approximated from FDA EUA Novavax Letter of Authorization July 13, 2022: Study 1 = 26,151; Study 2 ≈ 10,800; Study 3 + 4 ≈ 5500. Precise denominators requested of the sponsor.
[2] Lee L. FDA review of effectiveness and safety of Novavax COVID-19 vaccine in adults ≥18 years of age. June 7, 2022. https://www.fda.gov/media/159004/download.
[3] https://www.tga.gov.au/periodic/covid-19-vaccine-safety-report-30-06-2022#section-1865. Of these 15 cases reported in Australia, 3 were likely to represent myocarditis; 12 were likely to represent pericarditis.

*Includes a 16-year-old vaccine recipient from the adolescent safety data set; 4 = cases in temporal relationship without alternative etiology, 5 = cases in temporal relationship, with or without alternative etiology, 6 = all cases in vaccine recipients in clinical trials, regardless of temporal relationship or alternative etiology
**Reporting rate calculated as: (# cases)/(# doses administered*1,000,000)

Potential Benefits and Harms

Summary

- Novavax COVID-19 vaccine had **high efficacy** in setting of **Alpha** (B.1.1.7) variant
  - Consistent with other authorized COVID-19 vaccines at that time
  - Efficacy with recent SARS-CoV-2 variants **unknown**
  - **Reactogenicity** reported after Novavax COVID-19 vaccine **similar** to what has been reported for other COVID-19 vaccine primary series
- Reports of myocarditis after Novavax COVID-19 vaccine during clinical trials and early post-authorization data
- Based on available data, **cannot directly compare** VE or myocarditis rates for Novavax and mRNA COVID-19 vaccines
  - Post-authorization monitoring for both vaccine effectiveness and safety will be important

Considerations for Implementation

Survey of vaccination intent for a protein-based COVID vaccine among unvaccinated adults

- Survey designed to assess vaccination intentions for protein-based COVID vaccine with/without adjuvant among unvaccinated Americans
- Data collection period: January 27 – February 2, 2022
- Current unvaccinated sample (N = 541)

	GENDER	AGE	ETHNICITY
Partial or Unvaccinated	59% Female 41% Male or Other Gender Identity	43% 18-39 Years 39% 40-59 Years 18% 60+ Years	38% Non-Hispanic White 34% Non-Hispanic Black 28% Hispanic

NOTE: Weights based on population gender, age, and race/ethnicity will be created once data collection is complete

CDC and University of Iowa/RAND survey, unpublished

16% of unvaccinated respondents “probably” or “definitely” would get an adjuvanted protein-based COVID-19 vaccine

CDC and University of Iowa/RAND survey, unpublished

Adjuvanted protein subunit vaccine intentions by demographic characteristics among unvaccinated adults, United States, January—February 2022

- Vaccination intentions were significantly higher among men (21.9%) than among women (11.9%)
- Vaccination intentions were significantly lower among non-Hispanic White adults (9.6%) than among non-Hispanic Black adults (20.1%) or among Hispanic adults (19.5%)
- Vaccine intentions did not vary by US region, metropolitan status, age, or education

CDC and University of Iowa/RAND survey, unpublished

Morning Consult Survey: Perceptions of Vaccine Safety

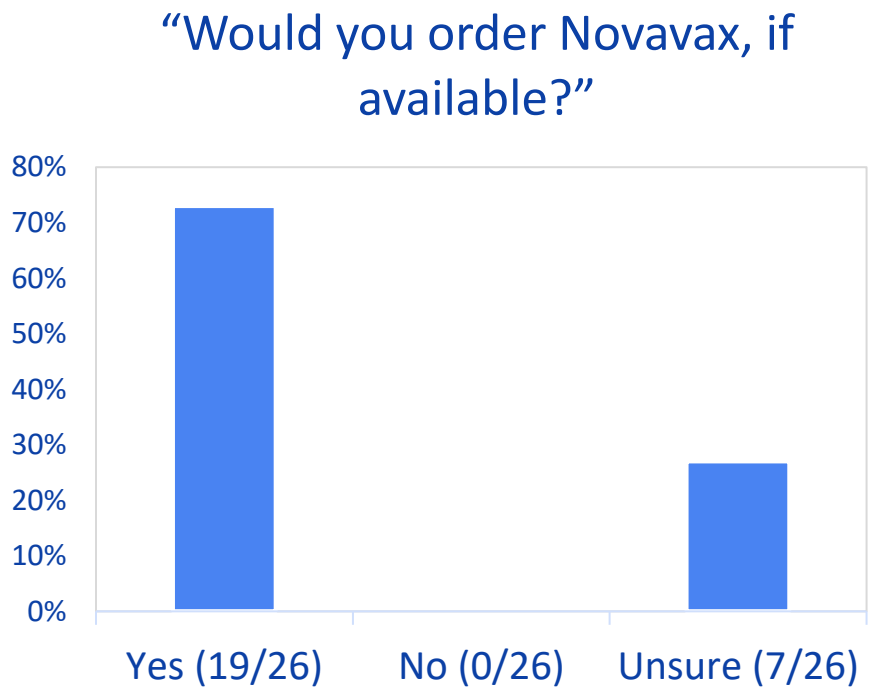
- U.S. adults were asked to what extent they view traditional protein-based and mRNA vaccines as safe:

Survey conducted June 18-23, 2022, among a representative sample of 1,788 unvaccinated U.S. adults, with an unweighted margin of error of +/-2 percentage points.

Morning Consult. July 5, 2022. Novavax Protein-Based COVID Vaccine Survey. https://morningconsult.com/2022/07/05/novavax-protein-based-covid-vaccine-survey/ Accessed July 18, 2022

Impressions from a jurisdictional partner listening session, 26 jurisdictions present: July 7, 2022

- Most participants would order Novavax COVID-19 vaccine, if it were available
- Participants expressed high interest in support related to Novavax, including:
  - Storage and handling information
  - Estimated ordering quantities ahead of time
  - Talking points/communications packages
- Intent of use varied substantially, including:
  - Private provider offices
  - Pharmacies
  - Local health departments
  - All of the above



Novavax COVID-19 vaccine: qualitative logistical comparisons with current COVID-19 vaccines

- Relative logistical **advantages** of Novavax COVID-19 vaccine
  - Easy storage: standard refrigerator; 36–46°F
  - Familiar schedule: 2 primary doses, 3–8 weeks apart
  - Easy preparation: no diluent

- Relative logistical **disadvantages** of Novavax COVID-19 vaccine
  - Short seal beyond use date (BUD) time: Vial to be discarded if the vaccine is not used with 6 hours after first puncture
    - Additionally, no recommendations for any unrefrigerated storage prior to puncture
  - 10 dose packaging
    - As it is currently only authorized for use as primary series, possibility for increased wastage
  - Product less familiar for providers

Summary

ACIP COVID-19 Work Group interpretation

- Novavax COVID-19 vaccine had **high efficacy** against symptomatic COVID-19 disease in setting of **Alpha** predominance
- Reports of myocarditis after Novavax COVID-19 vaccine during clinical trial and early post-authorization data
- Based on available data, **cannot directly compare** VE or myocarditis rates for Novavax and mRNA COVID-19 vaccines
  - Post-authorization monitoring for both vaccine effectiveness and safety will be important
- **Vaccination** remains the best way to protect against SARS-CoV-2 and rare cardiac risks of COVID-19 disease

ACIP COVID-19 Work Group interpretation

- As always, the **top priority** remains **vaccination** of **unvaccinated individuals**
- An additional COVID-19 vaccine, utilizing traditional vaccine technology, will provide an **additional option** for unvaccinated individuals
- Overall, **benefits** of Novavax COVID-19 vaccine **outweigh risks**

ACIP Vote

Interim Recommendation

A two-dose **Novavax COVID-19 vaccine, adjuvanted** is recommended as a COVID-19 vaccine **primary series** for persons **ages 18 years and older** under the EUA issued by FDA

Self-knowledge Check: Current data for the Novavax COVID-19 vaccine for adults 18 and older are for a ___-dose primary series:

A. 4
B. 3
C. 2
D. 1
E. 0

Answer: Current data for the Novavax COVID-19 vaccine for adults 18 and older are for a ___-dose primary series:

A. 4
B. 3
C. 2
D. 1
E. 0

Rationale: A **2-dose** Novavax COVID-19 vaccine series is recommended for adults ages 18 years and older.

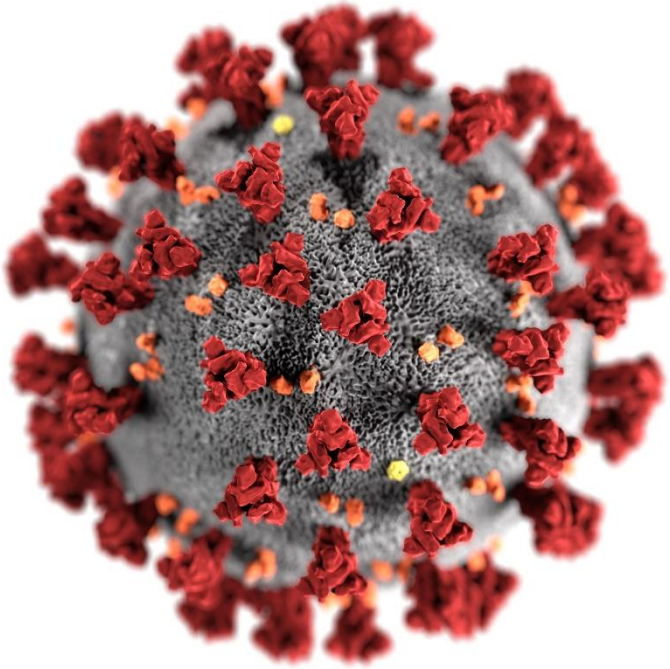
Acknowledgments

- Sara Oliver
- Megan Wallace
- Hannah Rosenblum
- Katherine Fleming-Dutra
- Lauren Roper
- Joy Hsu
- Danielle Moulia
- Sarah Meyer
- Tara Anderson
- Amy Rubis
- Monica Godfrey
- Roodly Archer
- Susan Goldstein
- Mary Chamberland
- Elisha Hall
- Valerie Morelli
- JoEllen Wolicki
- Meg Freedman
- Heather Scobie
- Ruth Link-Gelles
- Sierra Scarbrough
- Jefferson Jones
- Stephen Hadler
- Eddie Shanley
- Epi Task Force
- Data Analytics and Visualization Task Force
- Respiratory Viruses Branch
- National Center for Immunization and Respiratory Diseases

COVID 19
CORONAVIRUS DISEASE

Interim Clinical Considerations for Novavax COVID-19 Vaccine

Elisha Hall, PhD

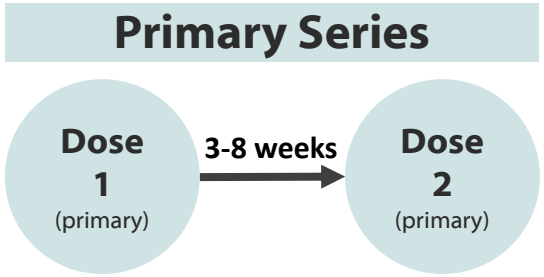


For more information: **www.cdc.gov/COVID19**

Novavax COVID-19 Vaccination Schedule

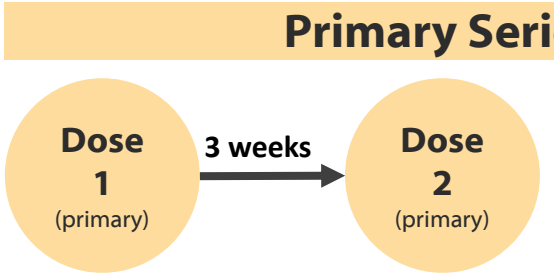
People who are **NOT** moderately or severely immunocompromised

Novavax
(18 years and older)



People who **ARE** moderately or severely immunocompromised

Novavax
(18 years and older)



Doses NOT Currently Authorized

- For people receiving a Novavax COVID-19 Vaccine primary series, the following are **NOT** currently authorized:
  - Third primary dose for people who are moderately or severely immunocompromised
  - Booster dose using ANY COVID-19 vaccine after a Novavax primary series
- CDC provides clinical guidance for what FDA authorizes; **once authorized**, these doses can be added to the COVID-19 vaccination schedule

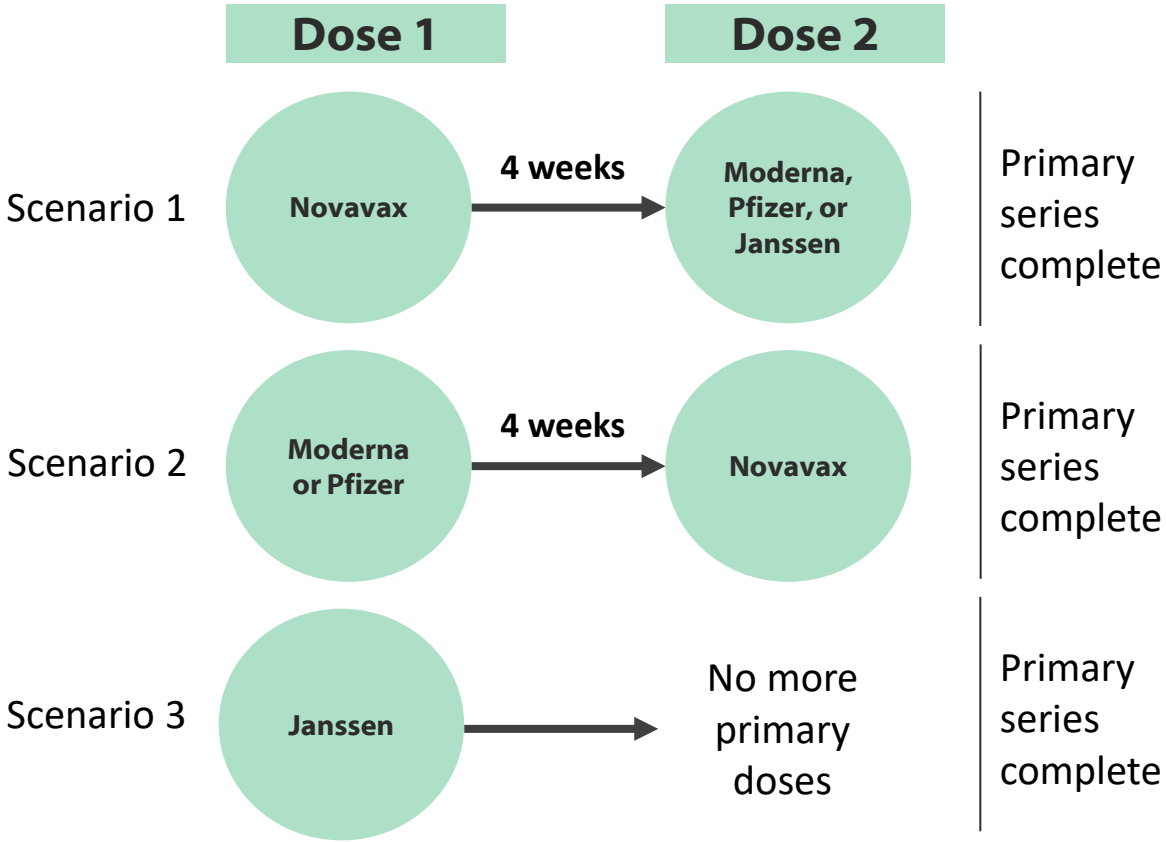
Mixed Primary Series

- The **same** vaccine product should be used for all doses in the primary series.
- There are limited data on the safety and efficacy of a mixed primary series composed of any combination of Moderna, Novavax, and Pfizer-BioNTechCOVID-19 vaccines.
- If a mixed primary series is inadvertently administered
  - The series is complete, and doses do not need to be repeated
  - This is considered an error; report to the Vaccine Adverse Event Reporting System (VAERS)

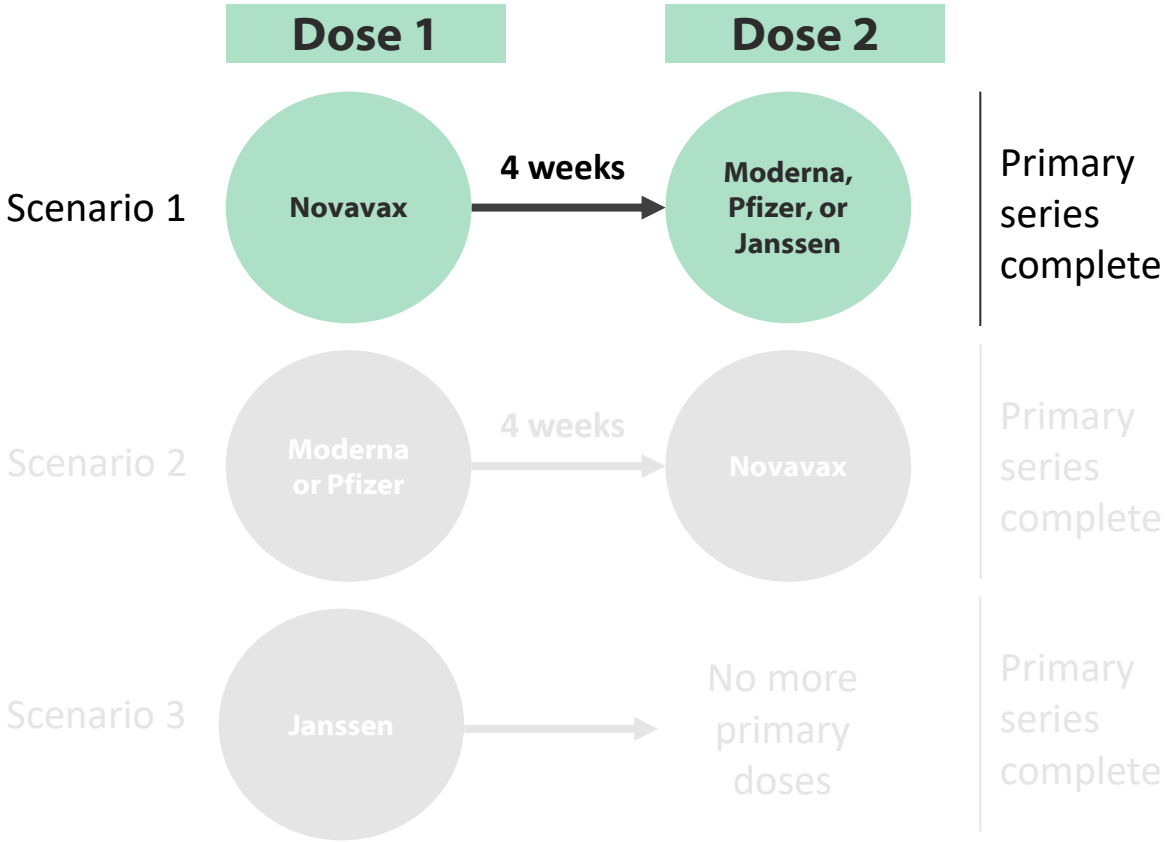
Mixed Primary Series, Continued

- In the following exceptional situations, a different, age-appropriate COVID-19 vaccine may be administered to complete a primary series at a minimum interval of 28 days from the last COVID-19 vaccine dose:
  - The same vaccine is not available
  - The first dose is unknown
  - A person starts but is unable to complete a primary series with the same COVID-19 vaccine due to a contraindication.
- This would not need to be reported to VAERS.

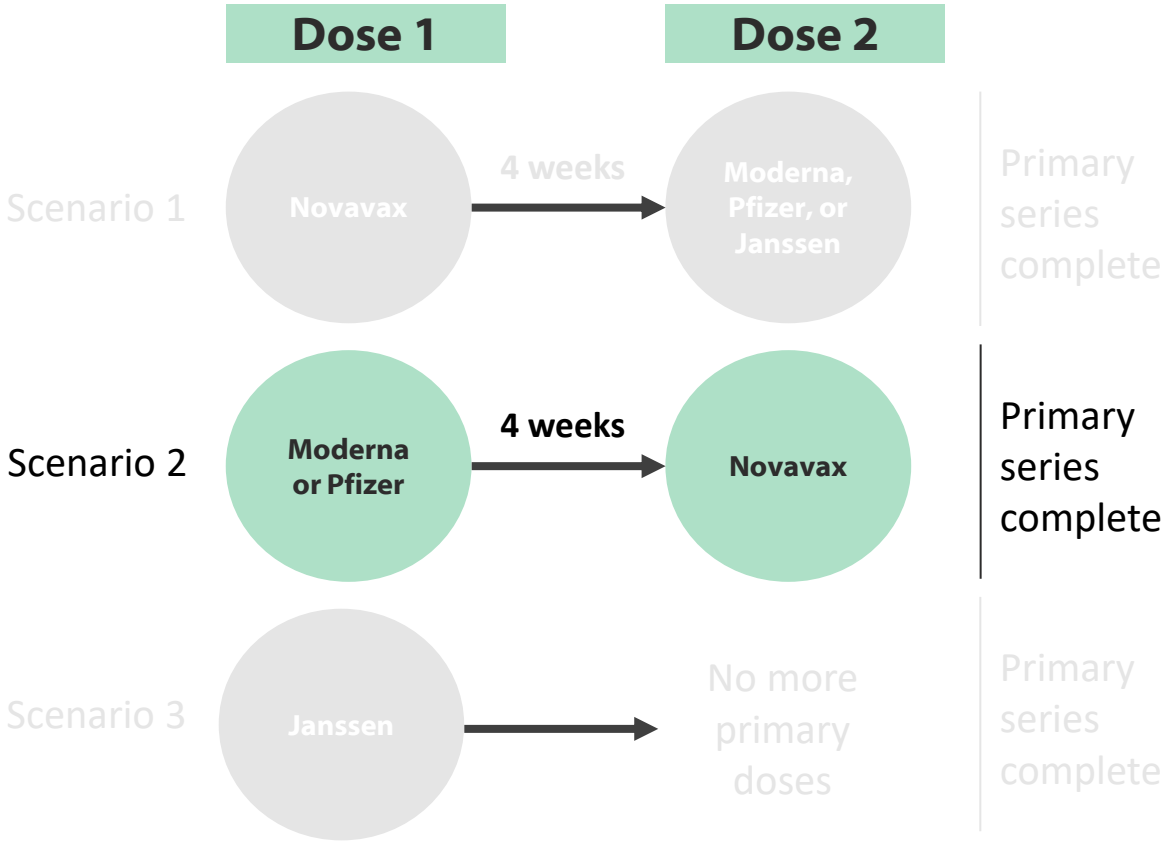
Mixed Primary Series, Continued



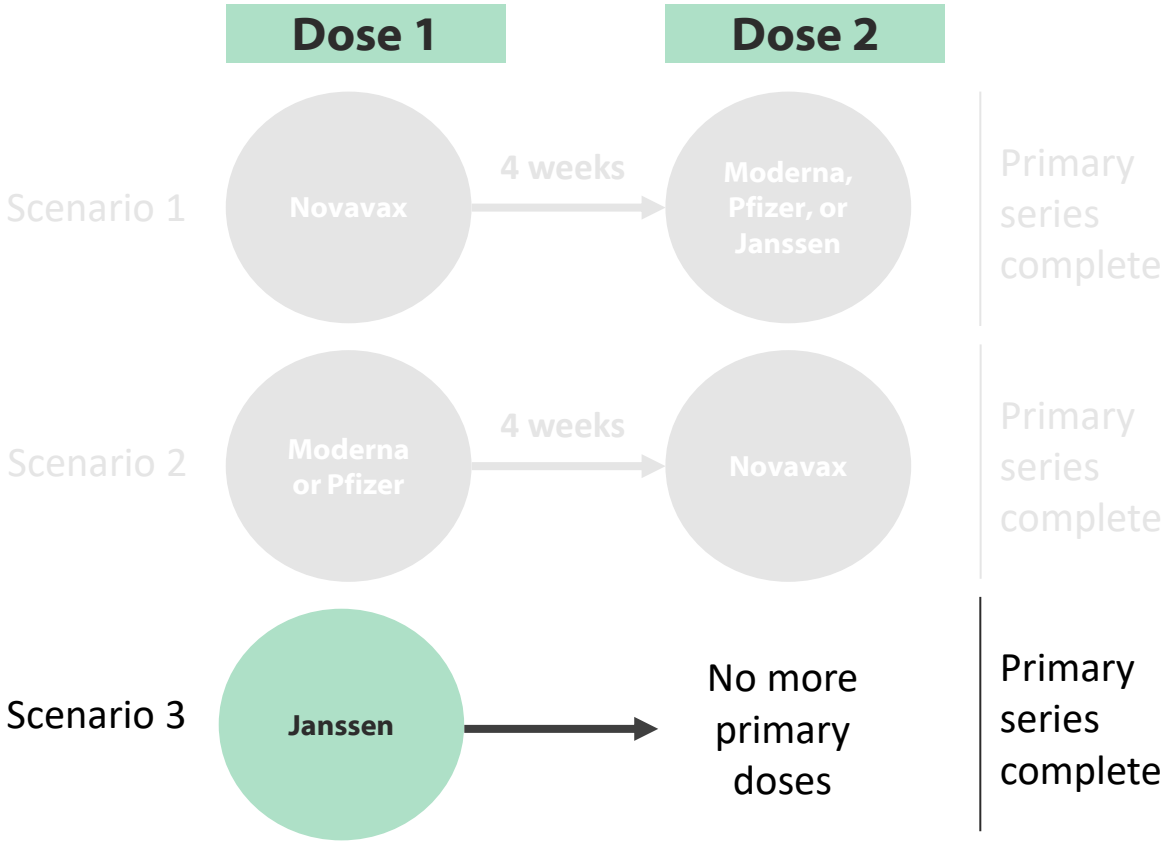
Mixed Primary Series, Continued



Mixed Primary Series, Continued

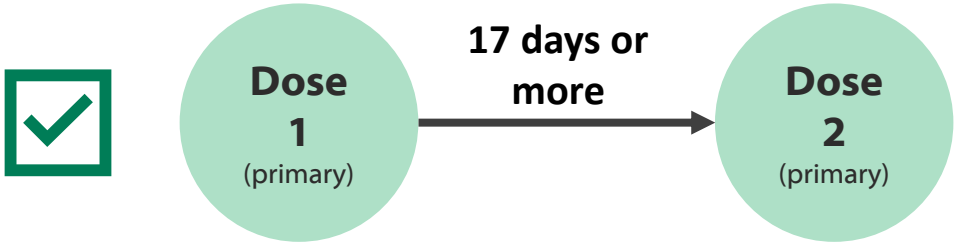


Mixed Primary Series, Continued



4-Day Grace Period

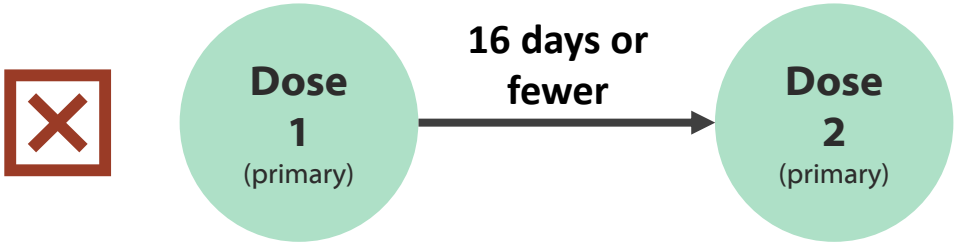
- Primary doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid.



- **DO**: Use the grace period to determine if doses are valid when retrospectively reviewing records.
- Do **NOT**: Use the grace period to schedule appointments earlier than the recommended interval.

4-Day Grace Period

- Primary doses administered **prior to the grace period** are invalid.



- Doses administered prior to this time should be repeated.
  - Space the repeat dose after the dose given in error by at least the recommended interval. Some experts recommend an 8-week interval.

Coadministration

- In general, COVID-19 vaccines may be administered without regard to timing of other vaccines.
  - ☑ Same day
  - ☑ Any time before
  - ☑ Any time after
- Routine administration of all age-appropriate doses of vaccines simultaneously is recommended for people for whom no specific contraindications exist at the time of the healthcare visit
- There are additional considerations for orthopoxvirus vaccines.

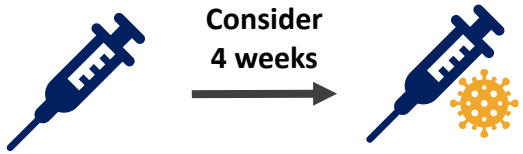
Coadministration

- When deciding whether to coadminister another vaccine(s) with COVID-19 vaccine, providers may consider:
  - ☑ Whether a person is behind or at risk of becoming behind on recommended vaccines
  - ☑ Likelihood of the person returning for another vaccination
  - ☑ Person's risk of becoming infected with a vaccine-preventable disease
  - ☑ Person's risk for severe disease if infected
  - ☑ Reactogenicity profile of the vaccines

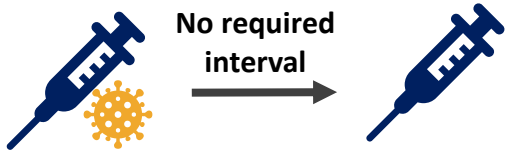
Coadministration

- Additional consideration for orthopoxvirus vaccination:

<u>If orthopoxvirus vaccine administered first:</u>
Might consider waiting 4 weeks before receiving a Moderna, Novavax, or Pfizer-BioNTech vaccine

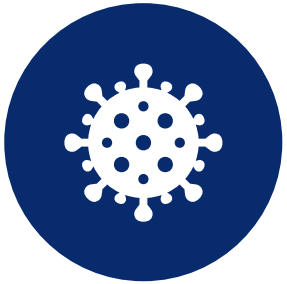


<u>If Moderna, Novavax, or Pfizer-BioNTech administered first</u>:
No minimum interval necessary before receiving orthopoxvirus vaccination for prophylaxis in the setting of an outbreak



Novavax COVID-19 Vaccine: Preparation and Administration

Age indication:
18 years and older



Dose: 5 mcg SARS-CoV-2rS
50 mcg Matrix-M™ adjuvant

Injection volume:
0.5 mL

Preparation:
Do not dilute

Doses per vial:
10 doses

Injection route/site:
Intramuscular/deltoid

Novavax COVID-19 Vaccine: Storage

Storage:
Refrigerator 2° to 8°C (36°to 46°F).

DO NOT FREEZE

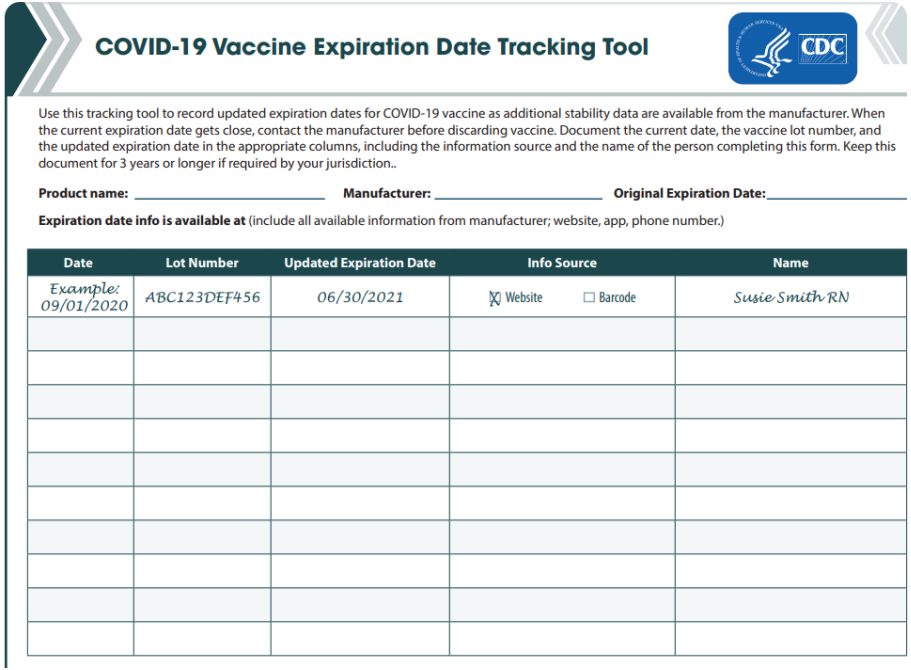
Beyond use time:
6 hours after first puncture

Expiration:
No expiration date is printed on the vial or carton

https://us.novavaxcovidvaccine.com/hcp

Novavax COVID-19 Vaccine: Storage

- Before preparing and administering vaccine, always check the expiration date.
- COVID-19 Vaccine Expiration Date Tracking Tool:
- https://www.cdc.gov/vaccines/covid-19/downloads/expiration-tracker.pdf



COVID-19 Vaccine Expiration Date Tracking Tool

Use this tracking tool to record updated expiration dates for COVID-19 vaccine as additional stability data are available from the manufacturer. When the current expiration date gets close, contact the manufacturer before discarding vaccine. Document the current date, the vaccine lot number, and the updated expiration date in the appropriate columns, including the information source and the name of the person completing this form. Keep this document for 3 years or longer if required by your jurisdiction..

Product name: _____ **Manufacturer:** _____ **Original Expiration Date:** _____

Expiration date info is available at (include all available information from manufacturer; website, app, phone number.)

Date	Lot Number	Updated Expiration Date	Info Source	Name
Example: 09/01/2020	*ABC123DEF456*	*06/30/2021*	☒ Website ☐ Barcode	*Susie Smith RN*

Types of COVID-19 Vaccines

mRNA
- Moderna
- Pfizer-BioNTech

Adenovirus vector
- Janssen

Protein subunit
- Novavax

Contraindications & Precautions

- Contraindications
  - History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component Novavax COVID-19 Vaccine
  - History of a known diagnosed allergy to a component of Novavax COVID-19 Vaccine

Contraindications & Precautions

- People with an allergy-related contraindication to one type of COVID-19 vaccine have a contraindication or precaution to the other type of COVID-19 vaccines
  - Contraindication: People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen
  - In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types

Contraindications & Precautions

- Precautions
  - History of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy
  - History of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose Novavax COVID-19 Vaccine
  - Moderate or severe acute illness, with or without fever
  - History of MIS-C or MIS-A
  - History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

Myocarditis and Pericarditis

- Myocarditis or pericarditis after a dose of an mRNA or Novavax:
  - Precaution to a subsequent dose of any COVID-19 vaccine
  - Considerations for subsequent vaccination include:
    - Whether myocarditis or pericarditis was considered unrelated to mRNA or Novavax vaccination
    - Personal risk of severe acute COVID-19
    - Timing of immunomodulatory therapies
  - For people ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, some experts advise using Janssen
    - People choosing Janssen should be informed of the risk of thrombosis with thrombocytopenia syndrome; the highest risk is in females ages 30–49 years

Myocarditis and Pericarditis

- History of myocarditis or pericarditis prior to COVID-19 vaccination
  - Not a precaution
  - May receive any currently authorized or approved vaccine after the episode of myocarditis or pericarditis has resolved

Extended Interval Between Dose 1 & 2

- No specific data on extended interval between dose 1 & 2 of Novavax
- Evidence of benefits of an extended interval in mRNA recipients
  - The small risk of myocarditis and/or pericarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses
  - Vaccine effectiveness may be increased
- Therefore an 8-week interval may be used between dose 1 & 2 to potentially reduce the risk of myocarditis and/or pericarditis

Considerations for Extended Interval Between Dose 1 & 2

3-week interval

- People who are moderately or severely immunocompromised
- People ages 65 years and older
- When protection needs to be achieved soonest
  - High risk for severe disease
  - Living, working, or traveling to an area with high COVID-19 community levels

8-week interval

- Reduced myocarditis risk
  - Young adult males
- Optimize vaccine effectiveness

Considerations for Extended Interval Between Dose 1 & 2

3-week interval	8-week interval

• People who are moderately or severely immunocompromised
• People ages 65 years and older
• When protection needs to be achieved soonest
  • High risk for severe disease
  • Living, working, or traveling to an area with high COVID-19 community levels
	• Reduced myocarditis risk
	  • Young adult males
	• Optimize vaccine effectiveness

Knowledge Check: Which of the following are authorized for Novavax?

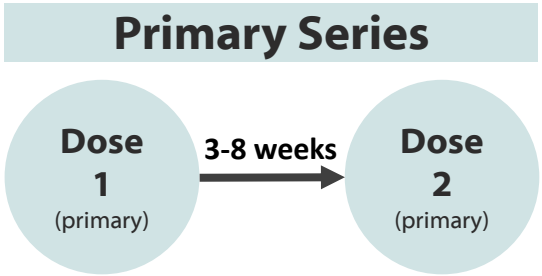
A) 2-dose primary series
B) A third (additional) dose
C) A booster dose
D) All of the above

Knowledge Check: Which of the following are authorized for Novavax?

A) 2-dose primary series

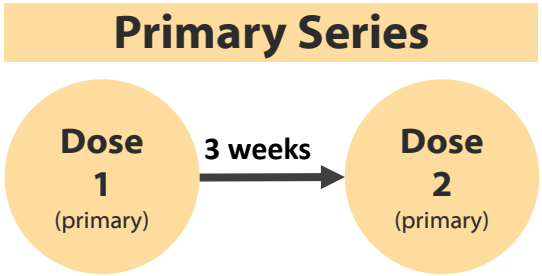
People who are **NOT** moderately or severely immunocompromised

Novavax (18 years and older)



People who **ARE** moderately or severely immunocompromised

Novavax (18 years and older)

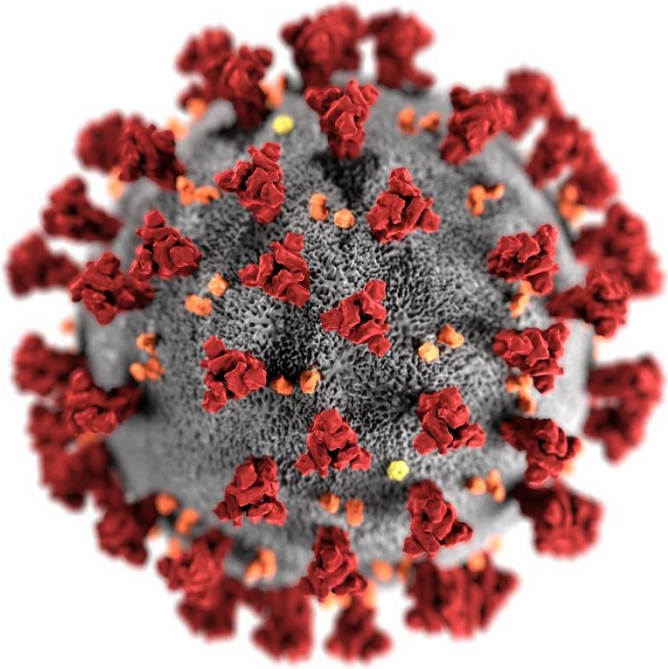


Acknowledgements

- Karen Broder
- Mary Chamberland
- Margaret Cortese
- Laura Daniel
- Megan Freedman
- Sue Goldstein
- Lauren Hughes
- Joy Hsu
- Sarah Meyer
- Sarah Morales
- Valerie Morelli
- Sara Oliver
- Evelyn Twentyman
- JoEllen Wolicki

Distribution and Allocation for Novavax COVID-19 Vaccine

Chris Duggar, MPH



For more information: **www.cdc.gov/COVID19**

Novavax COVID-19 Vaccine

- Allocated across all channels:
  - One-time pro rata (unvaccinated adults) threshold
- Ordering began July 25
  - First deliveries arrived July 27
- **Novavax COVID-19 vaccine specifications:**
  - Shipped and stored at standard vaccine refrigeration temperatures (2°C to 8°C).
  - Packaging: 10-dose vials in cartons of 10 vials each (100 doses total).
    - Minimum order quantity of 100 doses (1 carton of 10 vials).
  - Ancillary supplies provided: 1-inch and 1.5-inch needles and syringes as well as other materials

Novavax COVID-19 Vaccine

- One of three USG COVID-19 vaccines utilizing CDC's Central Distribution:
  - **Novavax COVID-19 vaccine** like Moderna and Janssen is processed by McKesson Specialty
  - Orders are cut off at 12 NOON (EST) daily
  - Deliveries normally arrive within 48-72 hours, Monday through Friday
- Novavax Customer Service
  - 1-855-239-9174
  - novavax.com/contact
  - https://www.novavaxcovidvaccine.com/
- Novavax Expiry Lookup
  - https://us.novavaxcovidvaccine.com/hcp

Self-knowledge Check: Ordering has begun for the Novavax COVID-19 vaccine for adults 18 and older.

A. True
B. False

Answer: Ordering has begun for the Novavax COVID-19 vaccine for adults 18 and older.

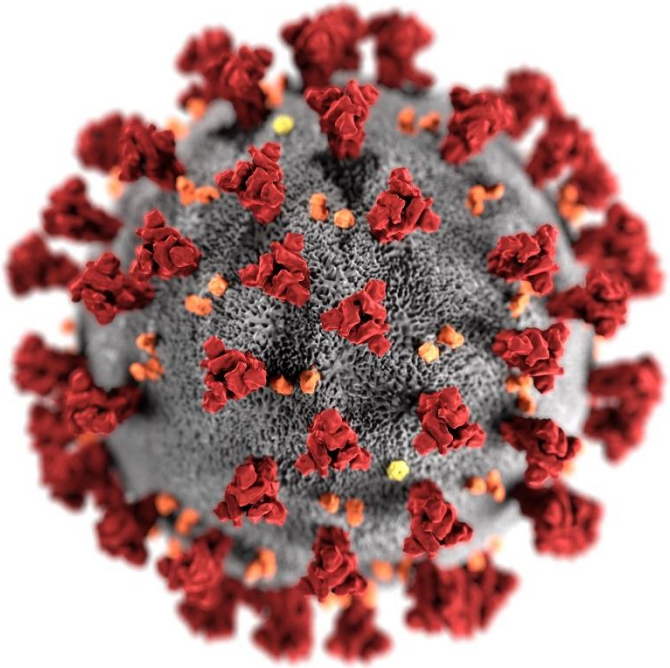
A. **True**

B. False

Rationale: Ordering for the Novavax COVID-19 vaccine began Monday, July 25, 2022.

Early Safety Monitoring for COVID-19 Vaccine Doses:
Reports to VAERS and v-safe

Tanya Myers, PhD, MSc

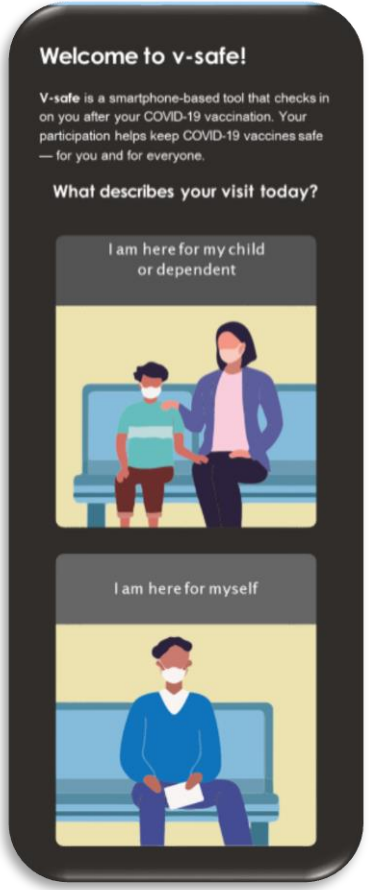


For more information: **www.cdc.gov/COVID19**

V-safe: Smartphone-based safety monitoring for COVID-19 vaccines

V-safe conducts active safety monitoring for all COVID-19 vaccines in the United States

- Self registration on smartphone – open to anyone who has received a COVID-19 vaccine, starting after any dose
- Children ages 15 years and younger are added to a registered parent's account
- Text message reminders prompt survey completion
- To register or access your account go to https://vsafe.cdc.gov/en/



V-safe uses text messages and web surveys to check in

- Surveys are brief – can be completed in less than a minute
- Questions solicit adverse events and health impacts after COVID-19 vaccination
  - Local and systemic reactions (e.g., pain, redness, fatigue, headache, joint pain)
  - Health impacts (e.g., unable to perform normal daily activities, missed school or work, or received care)
- Surveys include questions to identify participants who may be interested in and eligible for a pregnancy registry
- **V-safe** languages: English, Spanish, Chinese, Korean, and Vietnamese

Promoting v-safe in practice – we need your help!

How:

- Direct patients to https://vsafe.cdc.gov/en/
- Provide **v-safe** information sheet to patients
- Display posters about **v-safe**

https://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/vsafe/printresources.html

Get vaccinated.
Get your smartphone.
Get started with v-safe.

What is v-safe?

V-safe provides personalized and confidential health check-ins via text messages and web surveys so you can quickly and easily share with CDC how you or your dependent feel after getting a COVID-19 vaccine. It takes just a few minutes to enroll and your participation in **v-safe** helps us monitor the safety of COVID-19 vaccines for everyone.

V-safe features:

- **Enroll your dependents** and complete check-ins on their behalf
- **Enter** and report how you feel after **first, second, additional, and booster doses**

How can I enroll and how does it work?

You can enroll in **v-safe** after any dose of COVID-19 vaccine by using your smartphone and going to vsafe.cdc.gov.

During the first week after each vaccination, **v-safe** will send you a text message each day to ask how you are feeling. After that, you will receive occasional check-ins, which you can opt out of at any time. Depending on your answers, someone from CDC may call to get more information. Your personal information in **v-safe** is protected so it's safe and private*.

How can I enroll my child or dependent?

You can enroll any family member (or friend) who is eligible to be vaccinated in **v-safe.** Children under 16 years old must be enrolled using a parent or guardian's **v-safe** account. You can add a dependent to your existing account or create a new account if you don't have one yet. Creating an account to enroll a dependent does not require that you enter your own vaccination information or complete health check-ins for yourself.

Need step-by-step instructions? Go to: www.cdc.gov/vsafe

*v-safe uses existing information systems managed by CDC, FDA, and other federal agencies. These systems use strict security measures to keep information confidential. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

v-safe
after vaccination health checker

Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe

CS324195-L 06/10/2022

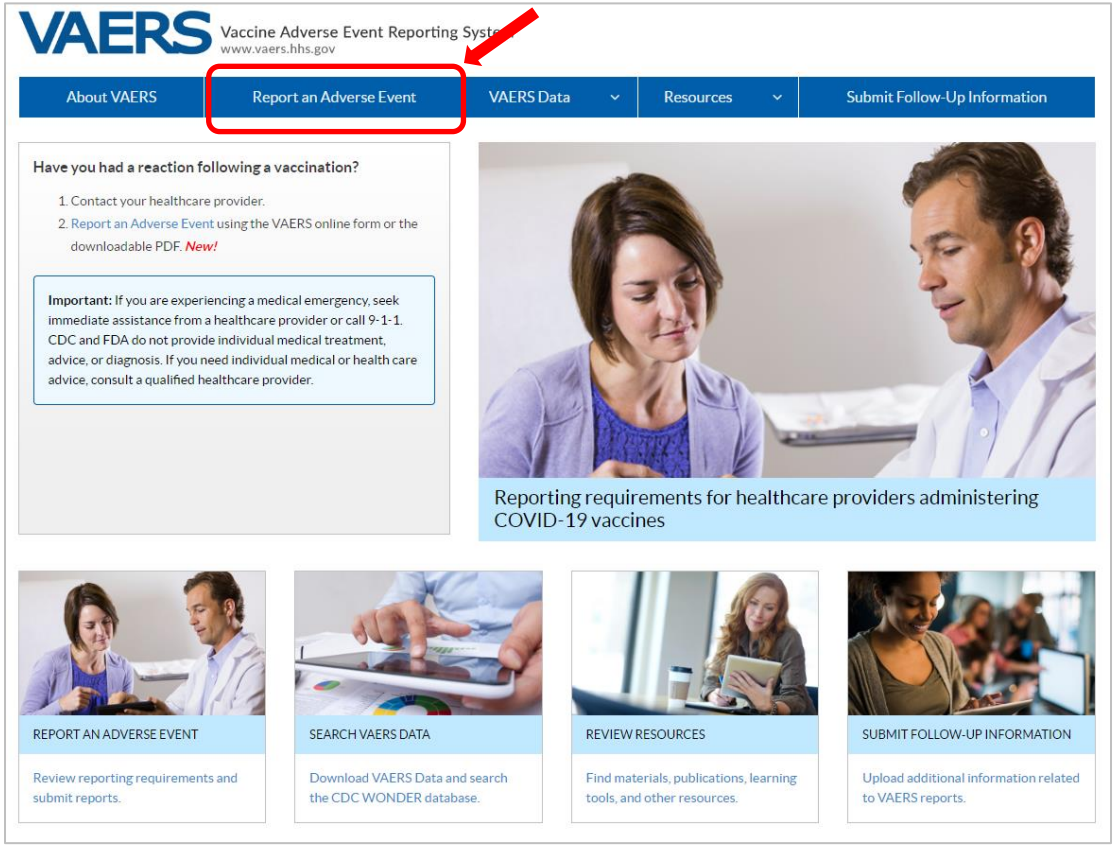
VAERS is the nation's early warning system for vaccine safety

Vaccine Adverse Event Reporting System

- National, passive surveillance system
- Covers entire US population
- Accepts reports of possible side effects from anyone
- Early signal detection

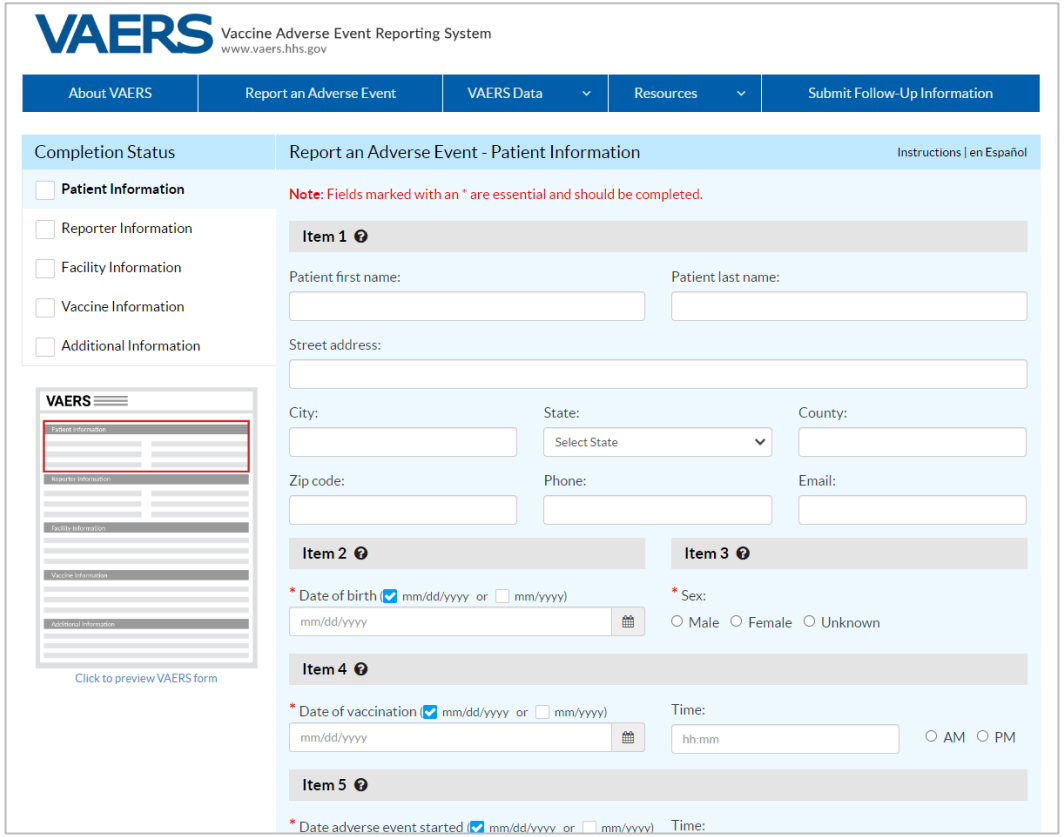
http://vaers.hhs.gov

VAERS resources available online



http://vaers.hhs.gov

VAERS Data Entry Form



https://vaers.hhs.gov/esub/index.jsp

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov

Continuing Education

- All continuing education for COCA Calls is issued online through the CDC Training & Continuing Education Online system at https://tceols.cdc.gov/.

- Those who participate in today's COCA Call and wish to receive continuing education please complete the online evaluation by **August 29, 2022,** with the course code **WC4520-072822**. The access code is **COCA072822.**

- Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation between **August 30, 2022,** and **August 30, 2024,** and use course code **WD4520-072822**. The access code is **COCA072822.**

- Continuing education certificates can be printed immediately upon completion of your online evaluation. A cumulative transcript of all CDC/ATSDR CEs obtained through the CDC Training & Continuing Education Online System will be maintained for each user.

Today's COCA Call Will Be Available to View On-Demand

- **When:** A few hours after the live call ends*
- **What:** Video recording
- **Where:** On the COCA Call webpage https://emergency.cdc.gov/coca/calls/2022/callinfo_072822.asp

**A transcript and closed-captioned video will be available shortly after the original video recording posts at the above link.*

Upcoming COCA Calls & Additional COVID-19 Resources

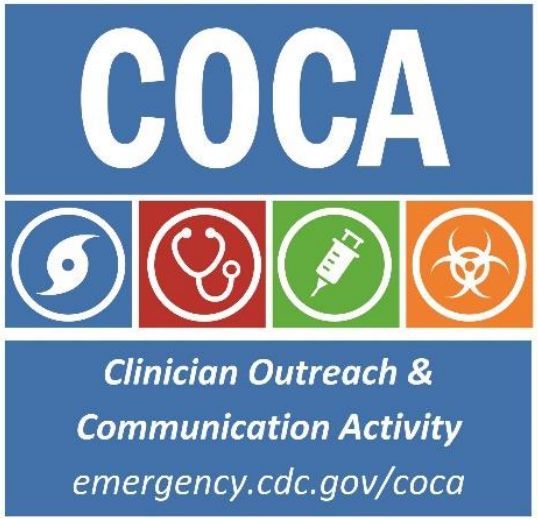
- Continue to visit https://emergency.cdc.gov/coca/ to get more details about upcoming COCA Calls, as COCA intends to host more COCA Calls to keep you informed of the latest guidance and updates on COVID-19.

- Subscribe to receive notifications about upcoming COCA calls and other COCA products and services at emergency.cdc.gov/coca/subscribe.asp.

- Share call announcements with colleagues.

Your COCA Subscription…

- **Includes information about:**
  - Upcoming COCA Calls
  - Health Alert Network (HAN) messages
  - CDC emergency response activations
  - Emerging public health threats
  - Emergency preparedness and response conferences
  - CDC and other Federal Agency Training opportunities



emergency.cdc.gov/coca/subscribe.asp

Join Us on Facebook

https://www.facebook.com/CDCClinicianOutreachAndCommunicationActivity

Thank you for joining us today!

https://emergency.cdc.gov/coca/