# Additional mRNA COVID-19 Vaccines for Moderately to Severely Immunocompromised People

Clinician Outreach and Communication Activity (COCA) Webinar

Tuesday, August 17, 2021

# Continuing Education

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# Today's Presenters

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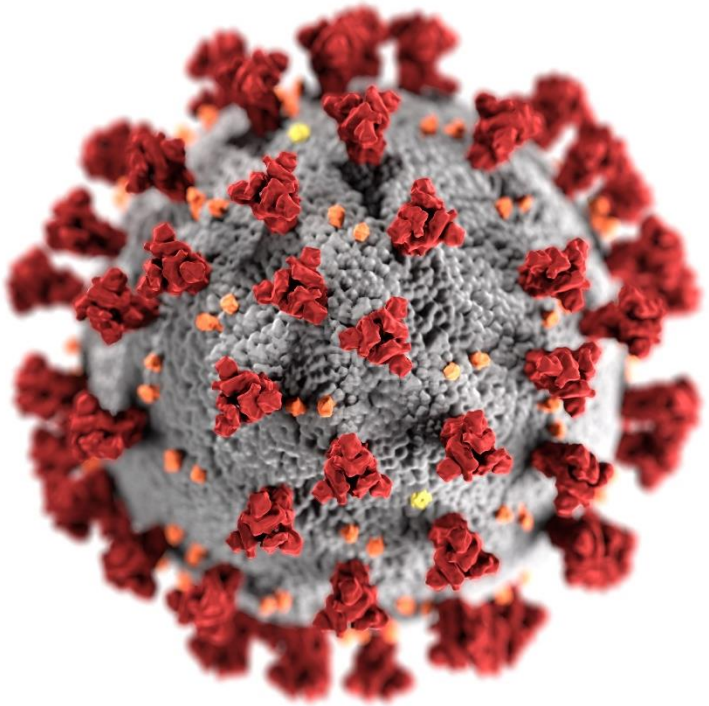
# Evidence to Recommendation Framework:

## An Additional Dose of mRNA COVID-19 Vaccine Following a Primary Series in Immunocompromised People

Dr. Kathleen Dooling, MD, MPH

COCA Call

August 17, 2021



cdc.gov/coronavirus

# FDA: Emergency Use Authorization (EUA) Amendment

- **August 12, 2021**: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals*
  - Other fully vaccinated individuals do not need an additional dose right now
  - Amendment applies to:
  - **Pfizer-BioNTech** COVID-19 vaccine (BNT162b2) (≥12 years old)
  - **Moderna** COVID-19 vaccine (mRNA-1273) (≥18 years old)

- Due to insufficient data, the EUA amendment for an additional dose does not apply to Janssen COVID-19 vaccine or to individuals who received Janssen COVID-19 as a primary series. CDC and FDA are actively engaged to ensure that immunocompromised recipients of Janssen COVID-19 vaccine have optimal vaccine protection

*https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised

# Evidence to Recommendations Framework

# Population: Immunocompromised People

People with medical conditions or people receiving treatments that are associated with moderate to severe immune compromise.[1]

- Active or recent treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ or recent hematopoietic stem cell transplants
- Severe primary immunodeficiency
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids, alkylating agents, antimetabolites, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

1. Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in general best practices for vaccination of people with altered immunocompetence, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host

# Intervention: An Additional Dose of mRNA COVID-19 Vaccine

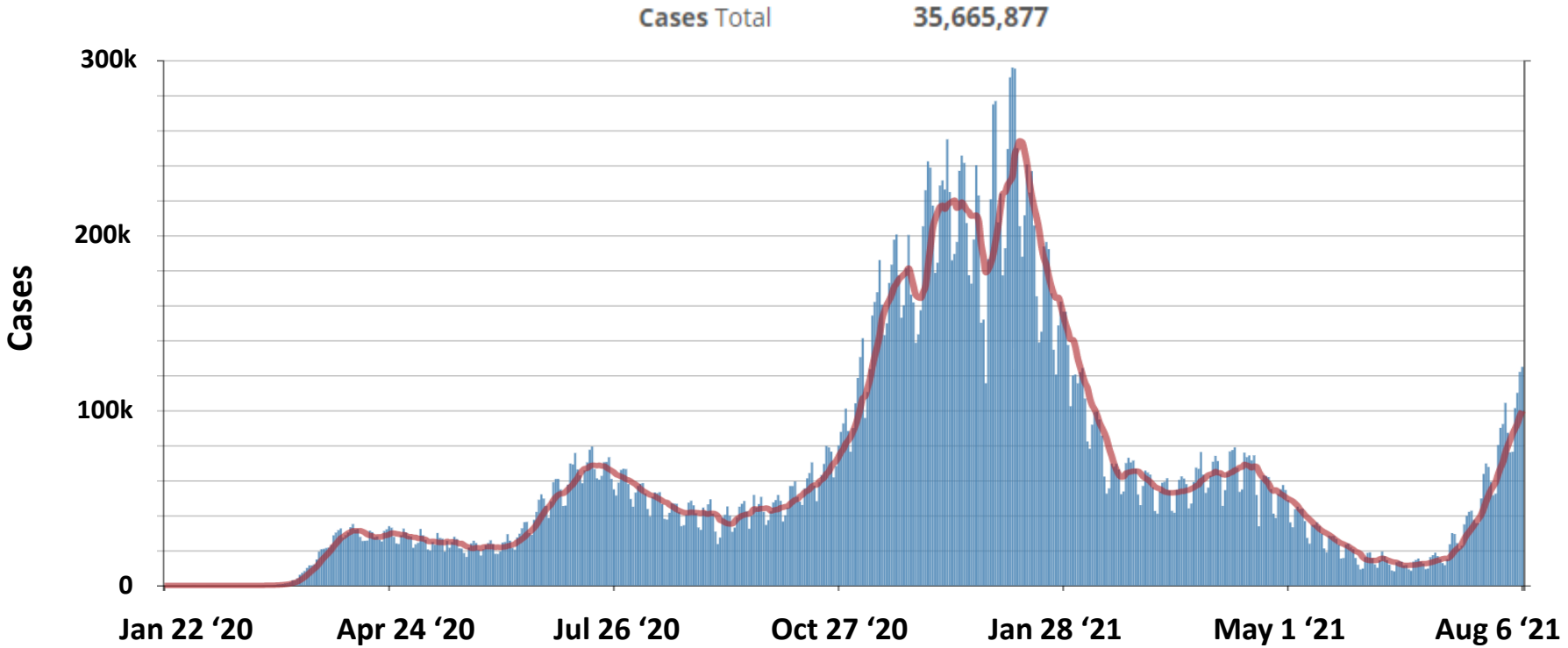
- An additional dose of
  - **Pfizer-BioNTech** COVID-19 vaccine (BNT162b2) (≥12 years old)
  - **Moderna** COVID-19 vaccine (mRNA-1273) (≥18 years old)

  after an initial 2-dose primary series of mRNA COVID-19 vaccine, in immunocompromised people
- Attempts should be made to match the additional dose type to the mRNA primary series, however if that is not feasible, a **heterologous additional dose is permitted**
- The additional dose of mRNA COVID-19 vaccine should be administered **at least 28 days** after completion of the primary mRNA COVID-19 vaccine series

# EtR Domain: Public Health Problem

# Daily Trends in Number of COVID-19 Cases in the US

January 22, 2020 – Aug 9, 2021




https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases

# Immunocompromised People and SARS-CoV-2 Infection

- Immunocompromised people comprise ~2.7% of U.S. adults (~7 million adults)[1]
- More likely to get severely ill from COVID-19[1,2]
- Higher risk for:
  - Prolonged SARS-CoV-2 infection and shedding[3-7, 14-16]
  - Viral evolution during infection and treatment (hospitalized patients)[3,6,8-10,14,17]
- Lower antibody/neutralization titers to SARS-CoV-2 variants compared to non-immunocompromised people [12]
- More likely to transmit SARS-CoV-2 to household contacts[11]

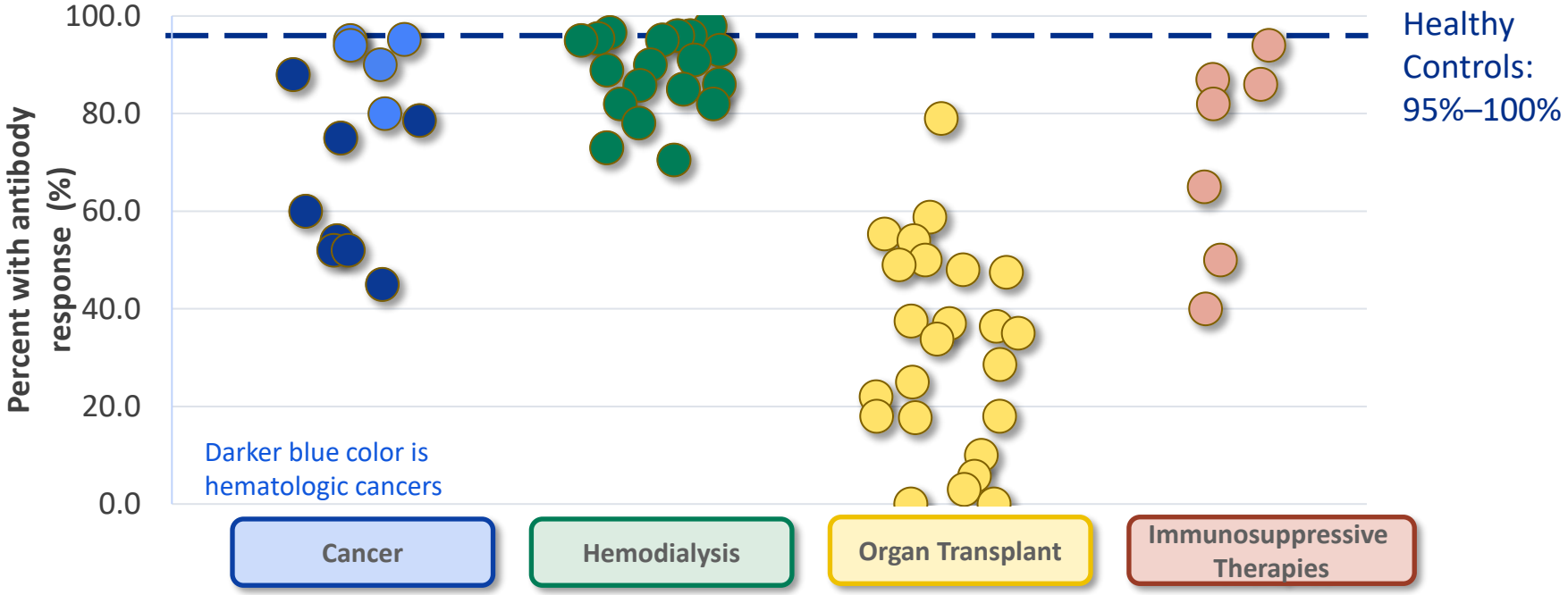
See reference slide at end

# Immunocompromised People and Vaccine Breakthrough Infection

- More likely to have breakthrough infection
  - 40-44% of hospitalized breakthrough cases are immunocompromised people in US study[1-2]
- Lower vaccine effectiveness
  - 59--72% VE among immunocompromised people vs. 90--94% among non-immunocompromised people after 2nd dose[1, 3-5]

See reference slide at end

# Percent of subjects with antibody response after two mRNA COVID-19 vaccine doses by immunocompromising condition and study (n=63)




- Studies that compared response after 1st and 2nd dose demonstrated less robust response after dose 1
- Antibody measurement and threshold levels vary by study protocol

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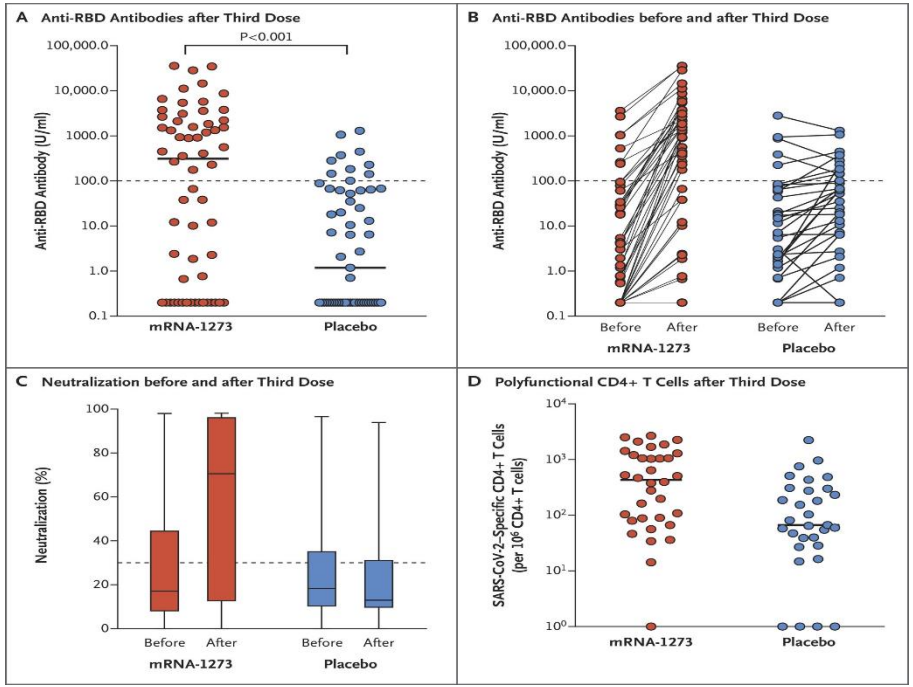
# EtR Domain: Benefits and Harms

# Benefits:

## Randomized Trial of a 3rd Dose of Moderna Vaccine in Transplant Recipients (n=120)




RBD antibody (≥100 U/ml) 1 month post dose 3:

33 of 60 patients
**(55%) vaccine group**
vs.
10 of 57 patients
**(18%) placebo group**

Hall et al. (2021) NEJM. Randomized Trial of a Third Dose of mRNA-1273 Vaccine in Transplant Recipients. DOI: 10.1056/NEJMc2111462

# Benefits:

| Study | Patient Population | 2nd Dose | | | 3rd Dose Seronegative after 2nd dose | | |
|---|---|---|---|---|---|---|---|
| | | Sample Size | Seronegative N (%) | Seropositive N (%) | Sample Size | Seronegative N (%) | Seropositive N (%) |
| Kamar et al. | Recipients of solid-organ transplant | 99 | 59 (60) | 40 (40) | 59 | 33 (56) | **26 (44)** |
| Werbel et al. | Recipients of solid-organ transplant | 30 | 24 (80) | 6 (20) | 24 | 16 (67) | **8 (33)** |
| Longlune et al. | Patients on hemodialysis | 82 | 13 (16) | 69 (84) | 12 | 7 (58) | **5 (42)** |
| Epsi et al. | Patients on hemodialysis | 106 | 66 (62) | 40 (38) | 12 | 6 (50) | **6 (50)** |
| Ducloux et al. | Patients on hemodialysis | 45 | 5 (11) | 40 (89) | 5 | 3 (60) | **2 (40)** |

- Among those who had **no detectable antibody** response to an initial mRNA vaccine series,

**33-50% developed an antibody response to an additional dose**

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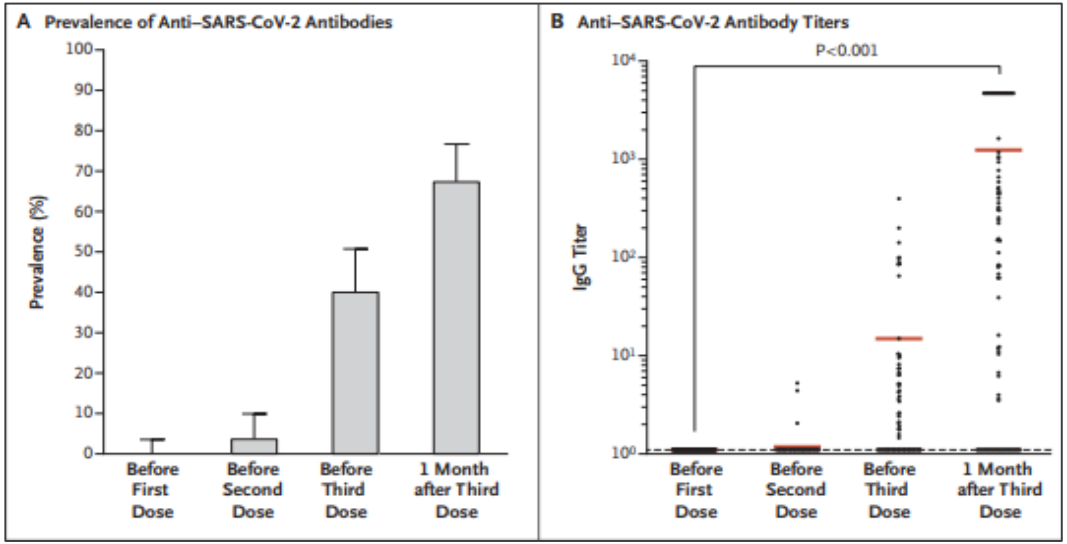
# Benefits and Harms:

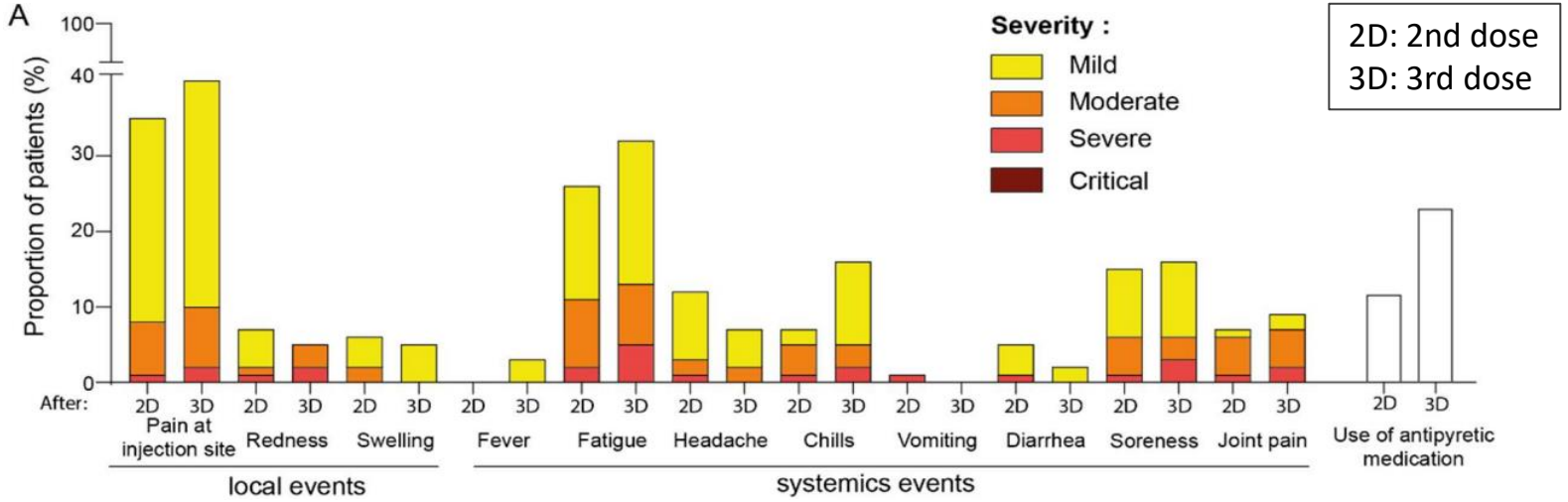



- The proportion of the group who are seropositive increase after each dose: **40%** post dose 2 and **68%** post dose 3
- Average antibody titers increased after each dose
- No serious adverse events were reported after administration of the 3rd dose, and no acute rejection episodes occurred (n=99 Solid Organ Transplant Patients)

Kamar et al. (2021) NEJM Three Doses of an mRNA Covid-19 Vaccine in Solid-Organ Transplant Recipients (nejm.org)

# Harms:

- No patients developed critical side effects which required hospitalization
- Symptoms reported were consistent with previous doses and the intensity of the symptoms was mostly mild or moderate




Epsi et al. (2021) medRxiv doi: https://doi.org/10.1101/2021.07.02.21259913

# Benefits and Harms:
## Summary of the Available Evidence

Benefits:

- Emerging experimental and observational data in adults suggest that an additional mRNA COVID-19 vaccine dose in immunocompromised people enhances antibody response and increases the proportion who respond to COVID-19 vaccine
- No efficacy or effectiveness studies of COVID-19 prevention following a 3rd dose

Harms:

- In small studies of an additional dose of mRNA vaccine
  - No serious adverse events were observed
  - Reactogenicity of the 3rd dose of mRNA vaccine was similar to prior doses
- mRNA COVID-19 vaccines are associated with rare but serious adverse events, including anaphylaxis as well as myocarditis and pericarditis in young adults. The impact of immunocompromising conditions on these rare events is unknown.
- There are no safety studies of an additional mRNA dose in immunocompromised adolescents

# Summary

| EtR Domain | Question | Work Group Judgments |
|---|---|---|
| **Public Health Problem** | Is COVID-19 disease among immunocompromised people of public health importance? | **Yes** |
| **Benefits and Harms** | How substantial are the desirable anticipated effects? | **Large** |
| | How substantial are the undesirable anticipated effects? | **Minimal** |
| | Do the desirable effects outweigh the undesirable effects? | **Favors additional dose of mRNA vaccine in immunocompromised people** |
| | What is the overall certainty of the evidence for the critical outcomes? | **Not GRADED** |
| **Values** | Does the target population feel the desirable effects are large relative to the undesirable effects? | **Large** |
| | Is there important variability in how patients value the outcomes? | **Probably not important variability** |
| **Acceptability** | Is an additional dose of mRNA COVID-19 vaccines acceptable to key stakeholders? | **Yes** |
| **Feasibility** | Is an additional dose of mRNA COVID-19 vaccine feasible to implement among immunocompromised people? | **Yes** |
| **Resource Use** | Is an additional dose of mRNA COVID-19 vaccine, given to immunocompromised people, a reasonable and efficient allocation of resources? | **Yes** |
| **Equity** | What would be the impact of an additional dose of mRNA COVID-19 vaccine, given to immunocompromised people, on health equity? | **Probably no impact** |

# Evidence to Recommendations Framework

## Summary: Work Group Interpretations

| | | | | | | |
|---|---|---|---|---|---|---|
| **Balance of consequences** | Undesirable consequences *clearly outweigh* desirable consequences in most settings | Undesirable consequences *probably outweigh* desirable consequences in most settings | The balance between desirable and undesirable consequences is *closely balanced* or *uncertain* | Desirable consequences *probably outweigh* undesirable consequences in most settings | Desirable consequences *clearly outweigh* undesirable consequences in most settings | There is insufficient evidence to determine the balance of consequences |

# Evidence to Recommendations Framework

## Summary: Work Group Interpretations

| **Type of recommendation** | We do not recommend the intervention | We recommend the intervention for individuals based on shared clinical decision-making | We recommend the intervention |
|---|---|---|---|

# ACIP Vote – Interim Recommendation

An additional dose of Pfizer-BioNTech COVID-19 vaccine (≥12 years) or Moderna COVID-19 vaccine (≥18 years) is recommended following a primary series in immunocompromised people*

*under the FDA's Emergency Use Authorization

# Acknowledgements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  - COVID-NET
  - DVD Enhanced Surveillance
  - Community Surveillance
  - Seroprevalance
- Data, Analytics and Visualization Task Force
- Respiratory Viruses Branch

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# References: Immunocompromised people and SARS-CoV-2 infection (Slide 19)


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# References: Percent of subjects with antibody response after two mRNA vaccine doses (Slide 20 - 4)


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- Patients show a highly diminished antibody response after COVID-19 mRNA vaccination compared to healthy controls." MedRxiv (2021).
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# References: Percent of subjects with antibody response after 3 mRNA vaccine doses (Slide 29)


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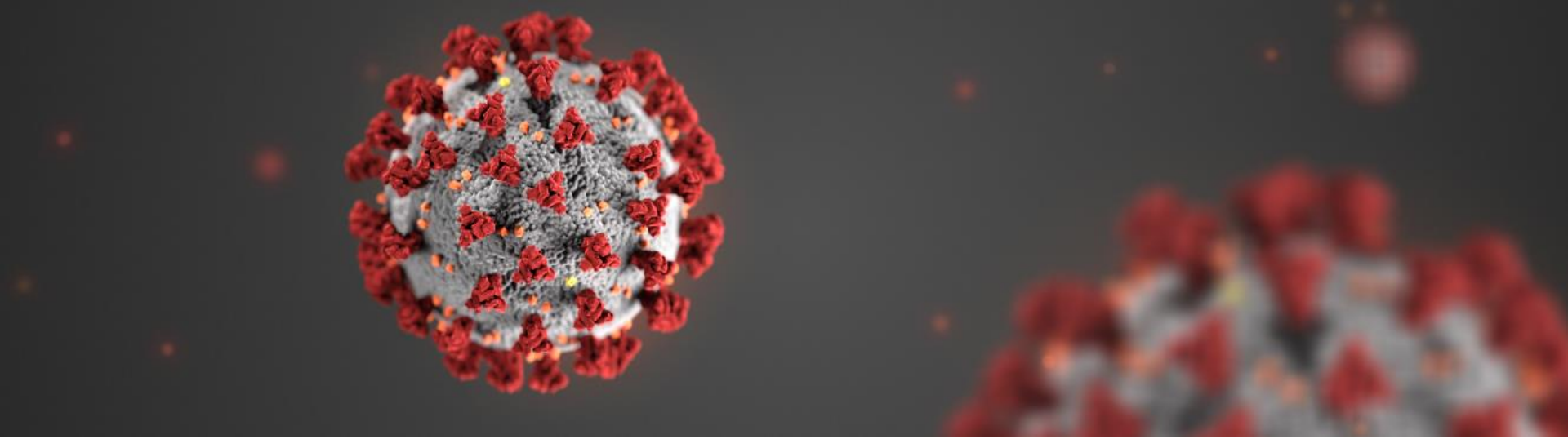

For more information, contact CDC
1-800-CDC-INFO (232-4636)
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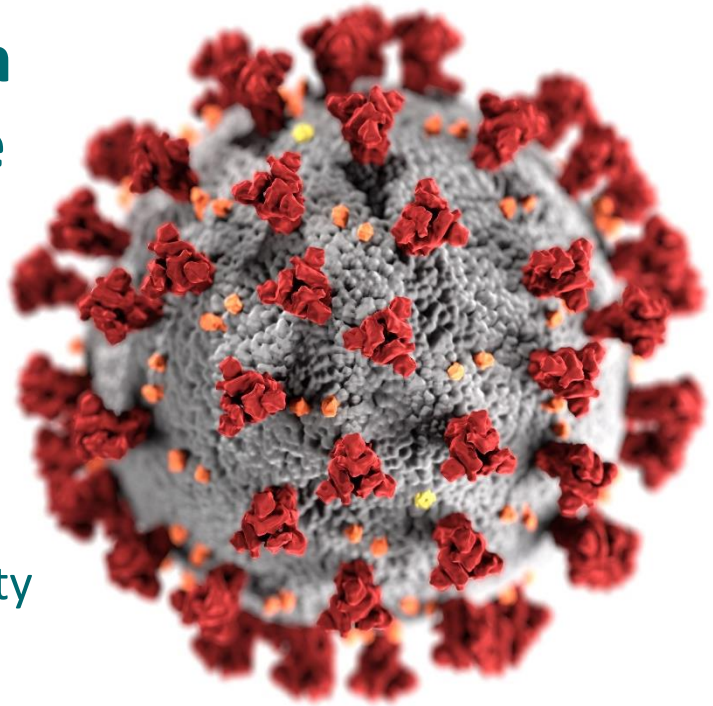
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

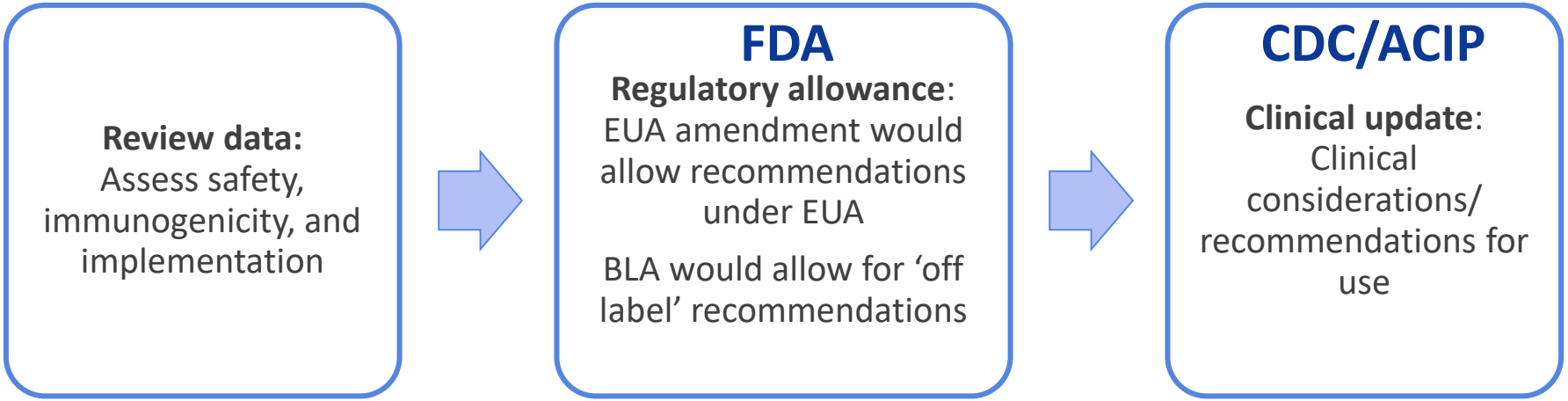
# Clinical Considerations for Use of an Additional mRNA COVID-19 Vaccine Dose Following a Primary mRNA COVID-19 Vaccine Series for Immunocompromised People



Neela D. Goswami, MD, MPH
CDC Clinician Outreach and Communication Activity
August 17, 2021

cdc.gov/coronavirus

# Additional doses in immunocompromised people




EUA= Emergency Use Authorization; BLA= Biologics License Application

# Roles of an Additional Dose

There are two distinct potential uses for an additional vaccine dose:

- **Additional dose after an initial primary vaccine series**: administration of an additional vaccine dose associated with the primary vaccine series when the initial immune response to that primary vaccine series is likely to be insufficient.

- **Booster dose:** a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose have not been established

# Roles of an Additional Dose

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# Focus of Clinical Considerations

For people with moderate to severe immune compromise due to a medical condition or immunosuppressive treatment, the potential to increase immune response coupled with an acceptable safety profile support consideration for an additional dose of mRNA COVID-19 vaccine following an initial 2-dose primary mRNA COVID-19 vaccine series in this population

# Moderately and severely immunocompromised people*

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

*ACIP General Best Practice Guidelines for Immunization; CDC Yellow Book; 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host

# Additional considerations

- Whenever possible, mRNA COVID-19 vaccination primary series and additional dose should be given at least two weeks before initiation or resumption of immunosuppressive therapies, but timing of COVID-19 vaccination should take into consideration immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine
- Patient's clinical team is best situated to determine the degree of immune compromise and appropriate timing of vaccination
- Factors to consider in assessing the general level of immune competence of patients include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment
- Utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., need for an additional dose) has not been established and is not recommended at this time

# Implementation Considerations

- The additional dose should be the same mRNA vaccine as the primary series
- Alternate mRNA product can be used if primary series product not available
- Until more data are available, the additional dose should be administered at least 28 days after completion of the initial primary series
- Currently there are not data to support the use of an additional mRNA COVID-19 vaccine dose after a primary Janssen COVID-19 vaccine in immunocompromised people.  FDA and CDC are actively working to provide guidance on this issue.
- These clinical considerations for use of an additional dose of an mRNA COVID-19 vaccine apply only to people who are moderately or severely immunocompromised

# Importance of infection prevention measures

- Immunocompromised people (including those who receive an additional mRNA dose) should be counseled about the potential for reduced immune response to COVID-19 vaccination and need to follow prevention measures*
  - Wear a mask
  - Stay 6 feet apart from others they don't live with
  - Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider

- Close contacts of immunocompromised people should be strongly encouraged to be vaccinated against COVID-19

* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

# Updates to additional clinical resources

## Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 12 Years of Age and Older

**Purpose**

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

**Policy**

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who
- "Procedure" section below without examination or direct order from t time of the interaction.

**Procedure**

- Assess persons 12 years of age and Pfizer-BioNTech COVID-19 Vaccine
  - History of myocarditis or pericar dose of an mRNA COVID-19 vacc
    - Defer the second dose of an r Administration of the second vaccine series can be consider after the episode of myocardit completely resolved. Consider www.cdc.gov/vaccines/covid-covid-19-vaccines-us.html#un
  - History of myocarditis or pericar vaccination
    - May receive any FDA-authorize episode of myocarditis or perica
  - Has not completed a COVID-19 brand. If 2 doses of an mRNA va or a single dose of Janssen vacci additional doses are recommen
  - If the recipient has received 1 pr COVID-19 Vaccine, administer th least 21 days (but preferably bef
  - If the vaccine product given as t determined or is no longer availa vaccine product may be adminis first dose.
- Inform recipients, especially males and their parents/legal representat possibility of myocarditis or perica COVID-19 vaccines and the need t myocarditis or pericarditis develop
- For people who received a COVID-
- Defer vaccination with Pfizer-BioNTech COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
    - Immediate allergic reaction[5] of any severity to a previous dose or

## Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

**Purpose**

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

**Policy**

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

**Procedure**

- Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:
  - History of myocarditis or pericarditis after receiving the first dose of an mRNA COVID-19 vaccine
    - Defer the second dose of an mRNA COVID-19 vaccine. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions
  - History of myocarditis or pericarditis prior to COVID-19 vaccination
    - May receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
  - Has not completed a COVID-19 vaccination series, regardless of brand. If 2 doses of an mRNA vaccine have been administered or a single dose of Janssen vaccine has been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, administer the second dose at an interval of least 28 days (but preferably before 42 days).[1]
  - If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
- Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination.[2]
- For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
- Moderna COVID-19 vaccine may be coadministered with other vaccines - on the same day, as well as within 14 days of each other.[3]
- Defer vaccination with Moderna COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
    - Immediate allergic reaction[5] of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine (see Table 1 in this document for a list of vaccine components)

**Note:** Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote).[4] Prior to administration of Janssen COVID-19 Vaccine, inform women 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group.[6] Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.

  - Precautions:
    - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
    - History of an immediate allergic reaction[5] of any severity to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
      - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polyethylene glycol (PEG) or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
      - People with a contraindication to Janssen COVID-19 Vaccine have a precaution to both mRNA vaccines (see footnote).[4]
    - Moderate to severe acute illness

[1] Administer the second dose as close as possible to the recommended interval (28 days). If the second dose is not administered within 42 days of the first dose, the series does not need to be restarted. Doses inadvertently administered less than 28 days apart do not need to be repeated.

[2] Educational materials are available at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

[3] When deciding whether to coadminister COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

[4] An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

[5] Consider consultation with an allergist-immunologist to help determine if a patient with a contraindication to an mRNA vaccine can safely receive the Janssen COVID-19 vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

[6] Educational materials are available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/J-Jupdate.html

## Prevaccination Checklist for COVID-19 Vaccines

vaccine recipients:

lowing questions will help us determine if there is any reason ould not get the COVID-19 vaccine today. **If you answer "yes" question, it does not necessarily mean you should not be ated.** It just means additional questions may be asked. If a on is not clear, please ask your healthcare provider to explain it.

Name _____

Age _____

| | Yes | No | Don't know |
|---|---|---|---|
| e you feeling sick today? | ☐ | ☐ | ☐ |
| ve you ever received a dose of COVID-19 vaccine? | ☐ | ☐ | ☐ |
| f yes, which vaccine product did you receive? ☐ Pfizer ☐ Moderna ☐ Janssen (Johnson & Johnson) ☐ Another Product _____ | | | |
| cination record card or other documentation? *(yes/no)* | ☐ | ☐ | |
| rgic reaction to: *ic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)* | | | |
| ID-19 vaccine, including either of the following: | | | |
| *PEG)*, which is found in some medications, such as laxatives and noscopy procedures | ☐ | ☐ | ☐ |
| found in some vaccines, film coated tablets, and intravenous steroids | ☐ | ☐ | ☐ |
| ID-19 vaccine | ☐ | ☐ | ☐ |
| rgic reaction to another vaccine *(other than COVID-19 vaccine)* on? *gic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that It would also include an allergic reaction that caused hives, swelling, or respiratory distress,* | ☐ | ☐ | ☐ |
| u: | | | |
| ages 18 and 49 years old | | | |
| ges 12 and 29 years old | | | |
| carditis or pericarditis | | | |
| eaction to something other than a vaccine or injectable therapy such as food, pet, venom, medication allergies | | | |
| s treated with monoclonal antibodies or convalescent serum | | | |
| ystem Inflammatory Syndrome (MIS-C or MIS-A) after a COVID-19 infection | | | |
| nune system (i.e., HIV infection, cancer) | | | |
| sive drugs or therapies | | | |
| der | | | |
| arin-induced thrombocytopenia (HIT) | | | |
| t or breastfeeding | | | |
| fillers | | | |

Date _____

Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists

1

Updates will be posted at: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

# Acknowledgements


- Kristine Schmit
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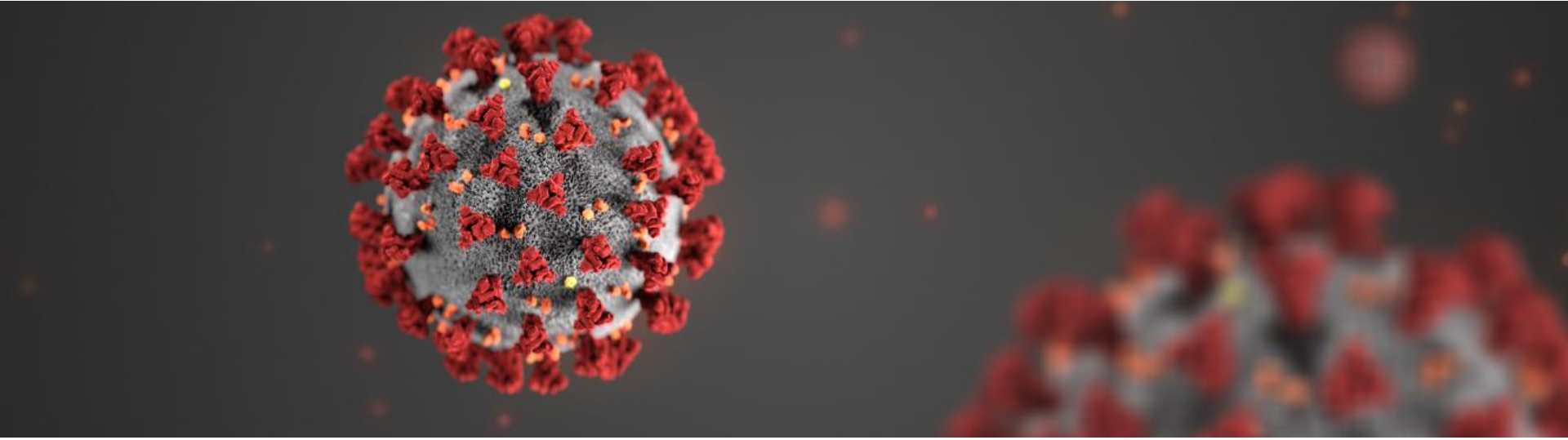

For more information, contact CDC
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TTY: 1-888-232-6348 www.cdc.gov

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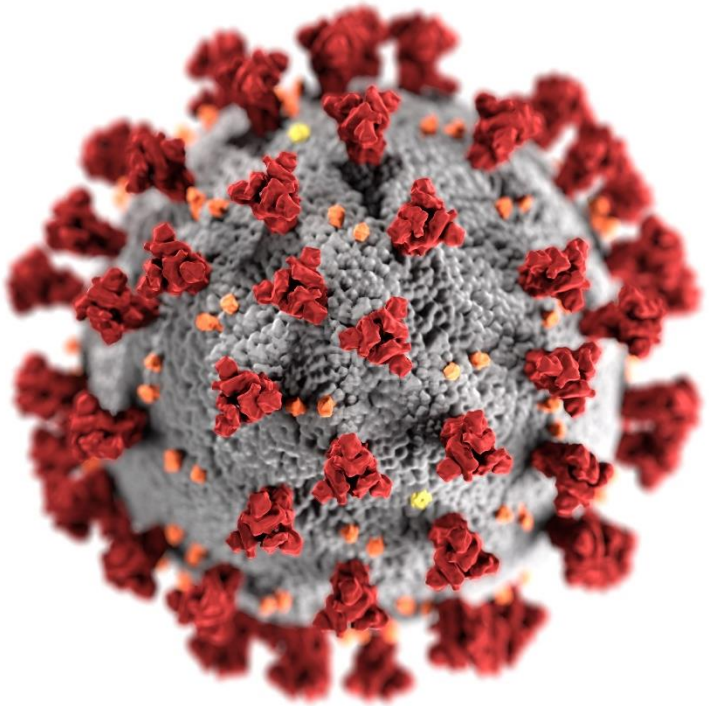
# CDC Vaccine Safety Monitoring Systems

**August 17, 2021**



**Tom Shimabukuro, MD, MPH, MBA**
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CDC COVID-19 Vaccine Task Force

**cdc.gov/coronavirus**

# Disclaimer

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC) or the U.S. Food and Drug Administration (FDA)
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC or FDA

Morbidity and Mortality Weekly Report (*MMWR*)

CDC

# The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021

*Weekly* / May 21, 2021 / 70(20);749–752

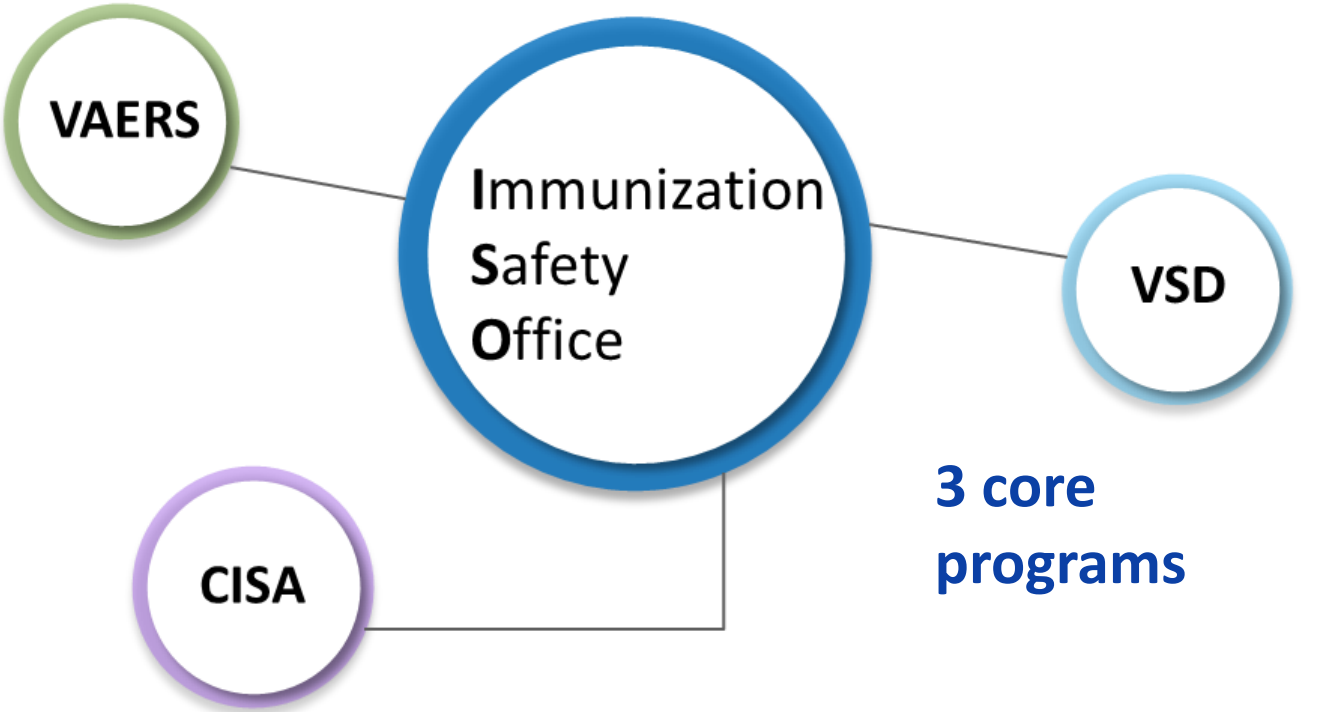
*On May 14, 2021, this report was posted online as an* MMWR *Early Release.*

Megan Wallace, DrPH[1,2]; Kate R. Woodworth, MD[1]; Julia W. Gargano, PhD[1]; Heather M. Scobie, PhD[1]; Amy E. Blain, MPH[1]; Danielle Moulia, MPH[1]; Mary Chamberland, MD[1]; Nicole Reisman, MPH[1]; Stephen C. Hadler, MD[1]; Jessica R. MacNeil, MPH[1]; Doug Campos-Outcalt, MD[3]; Rebecca L. Morgan, PhD[4]; Matthew F. Daley, MD[5]; José R. Romero, MD[6]; H. Keipp Talbot, MD[7]; Grace M. Lee, MD[8]; Beth P. Bell, MD[9]; Sara E. Oliver, MD[1] (View author affiliations)

## Considerations for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people

On August 12, 2021 FDA modified the Emergency Use Authorizations (EUAs) for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to allow for administration of an additional dose (i.e., a third dose) of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for certain immunocompromised people (i.e., people who have undergone solid organ transplantation or have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise). The age groups authorized to receive the additional dose are unchanged from those authorized to receive the primary vaccination series:

# Vaccine safety systems




+

v-safe℠
after vaccination health checker

**3 core programs**

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

CDC + FDA

VAERS

**Vaccine Adverse Event Reporting System**


http://vaers.hhs.gov

# VAERS

VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

## key strengths

- Rapidly detects potential safety problems
- Can detect rare adverse events

## key limitations

- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

# How to report an adverse event to VAERS

- go to [vaers.hhs.gov](vaers.hhs.gov)
- submit a report online

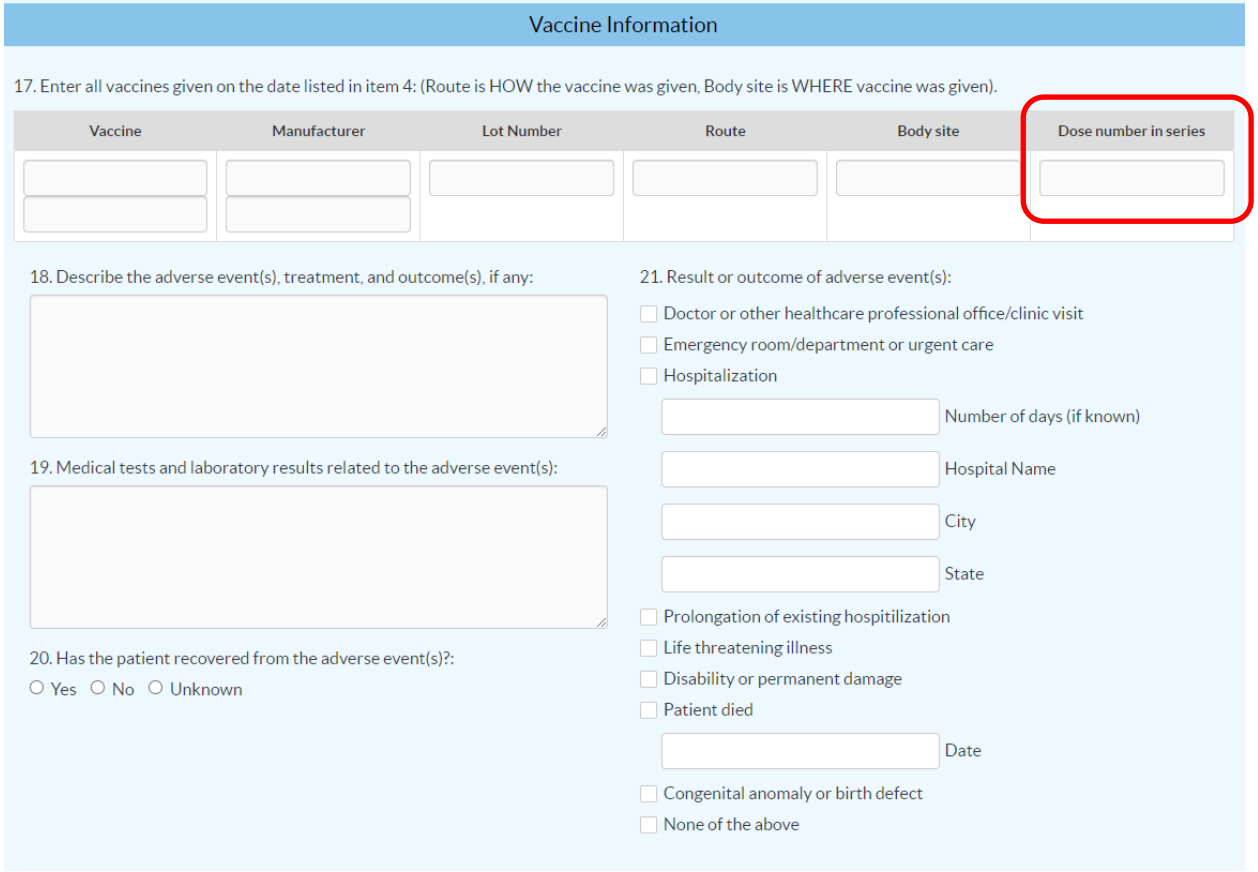
for help:

call
1-800-822-7967

email
info@VAERS.org

video instructions
https://youtu.be/sbCWhcQADFE

# How to report an adverse event to VAERS



Vaccine Information

17. Enter all vaccines given on the date listed in item 4: (Route is HOW the vaccine was given, Body site is WHERE vaccine was given).

| Vaccine | Manufacturer | Lot Number | Route | Body site | Dose number in series |
|---|---|---|---|---|---|
| | | | | | |

18. Describe the adverse event(s), treatment, and outcome(s), if any:

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?:

○ Yes ○ No ○ Unknown

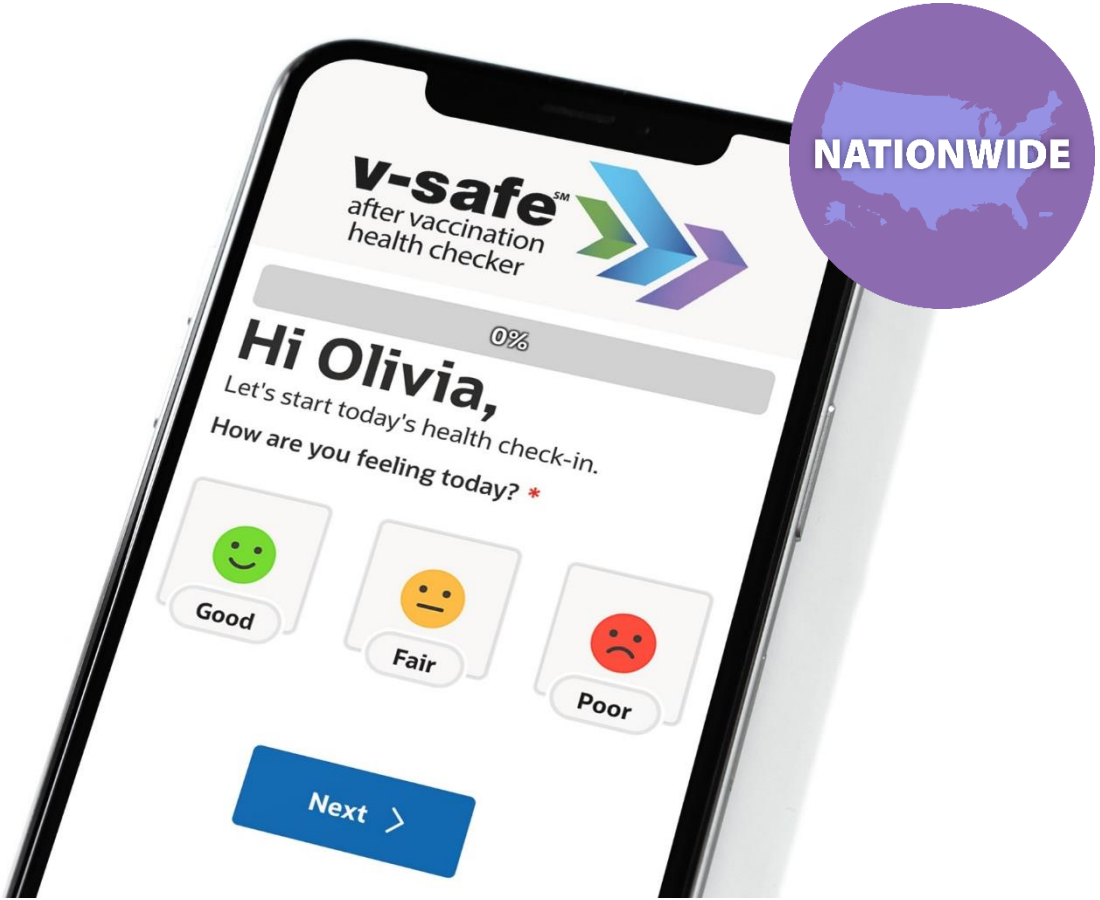
21. Result or outcome of adverse event(s):

- ☐ Doctor or other healthcare professional office/clinic visit
- ☐ Emergency room/department or urgent care
- ☐ Hospitalization
  - Number of days (if known)
  - Hospital Name
  - City
  - State
- ☐ Prolongation of existing hospitilization
- ☐ Life threatening illness
- ☐ Disability or permanent damage
- ☐ Patient died
  - Date
- ☐ Congenital anomaly or birth defect
- ☐ None of the above

# Smartphone-based active safety monitoring

v-safe[SM]
after vaccination
health checker

http://cdc.gov/vsafe

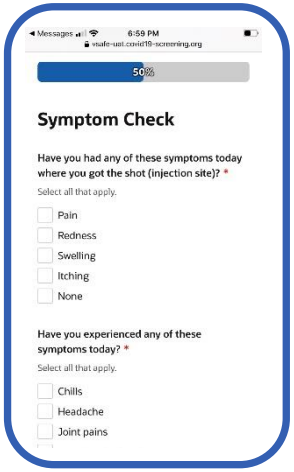


# Active safety monitoring for COVID-19 vaccines

- **V-safe** is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety
  - uses text messaging and web surveys to check-in with vaccine recipients after vaccination
  - participants can report side effects or health problems after COVID-19 vaccination
  - reports are accepted after dose 1, 2, and 3
  - includes active telephone follow-up by CDC for reports of a medically-attended health impact event
  - identifies women who are pregnant when vaccinated or become pregnant shortly after vaccination

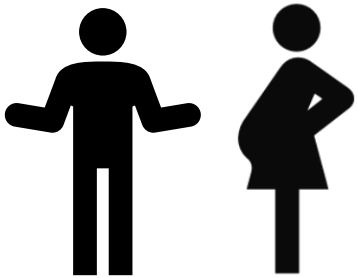
# Timing of health check-ins

- **V-safe** conducts electronic health check-ins with vaccine recipients
  - daily for first week post-vaccination; weekly thereafter until 6 weeks post-vaccination
  - additional health checks at 3, 6, and 12 months post-vaccination
- Enrollment in the **v-safe** pregnancy registry occurs through a separate pregnancy follow-up process




1. text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

vaccine recipient completes web survey*



**Vaccine recipients**

v-safe℠ after vaccination health checker

2. clinically important health impact reported

✓ **received medical care**

**Call center**

3. **V-safe** call center conducts active telephone follow-up on a clinically important event and takes a VAERS report if appropriate

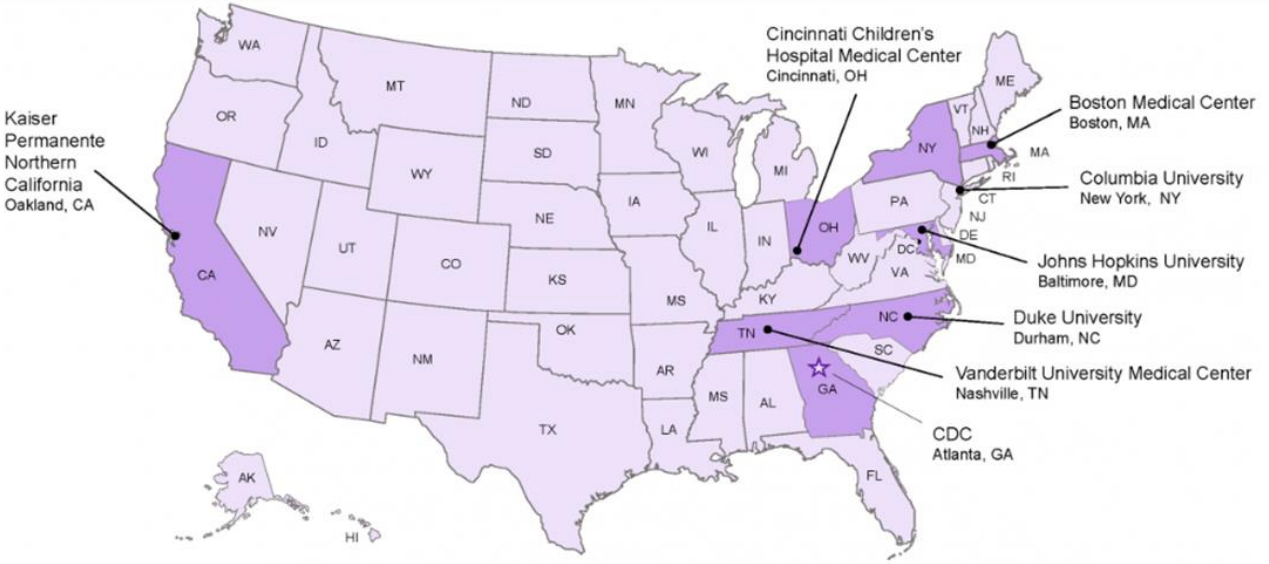
4. pregnancy registry team conducts outreach to assess eligibility for registry and obtain consent for enrollment and follow-up

**Call center**

* Selected web surveys capture information on pregnancy status

# CISA

## Clinical Immunization Safety Assessment (CISA) Project



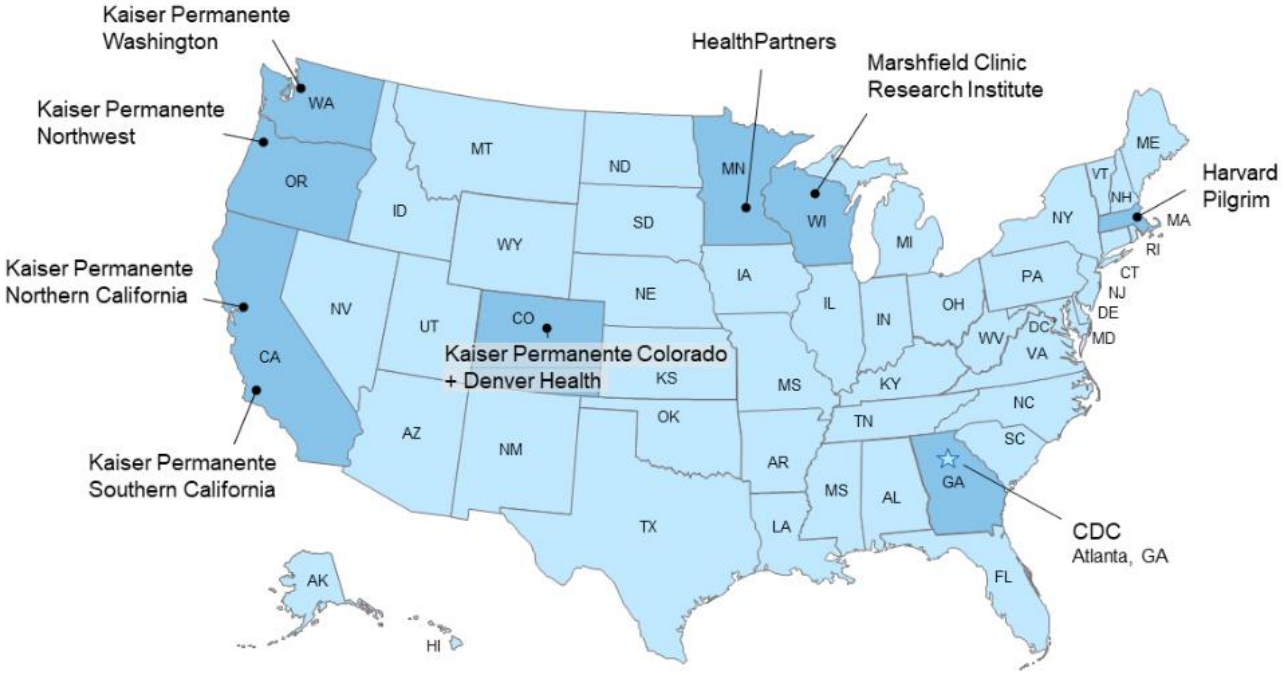

**7** participating medical research centers with vaccine safety experts

- clinical consult services*
- clinical research

*More information about clinical consults available at http://www.cdc.gov/vaccinesafety/Activities/CISA.html

# VSD

**Vaccine Safety Datalink**




- **9** participating integrated healthcare organizations
- Data on over **12 million** persons per year

# Your role

**COVID-19 vaccine safety gets stronger with your participation**

## general public

- participate in **v-safe** ✓
- report adverse event to **VAERS** ✓

## healthcare providers

- encourage patients to participate in **v-safe** ✓
- continue to report clinically important adverse events to **VAERS** ✓

# Acknowledgments

We wish to acknowledge the contributions of investigators from the following organizations:

**Centers for Disease Control and Prevention**

- COVID-19 Vaccine Task Force
- Vaccine Safety Team
- Immunization Safety Office
- Division of Healthcare Quality Promotion
- Clinical Immunization Safety Assessment Project
- Vaccine Safety Datalink

**Food and Drug Administration**

- Center for Biologics Evaluation and Research

# CDC vaccine safety monitoring

- Authorized COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**
- Strong, complementary systems are in place—both new and established

| v-safe | VAERS | VSD | CISA Project |
|---|---|---|---|
|  |  |  |  |

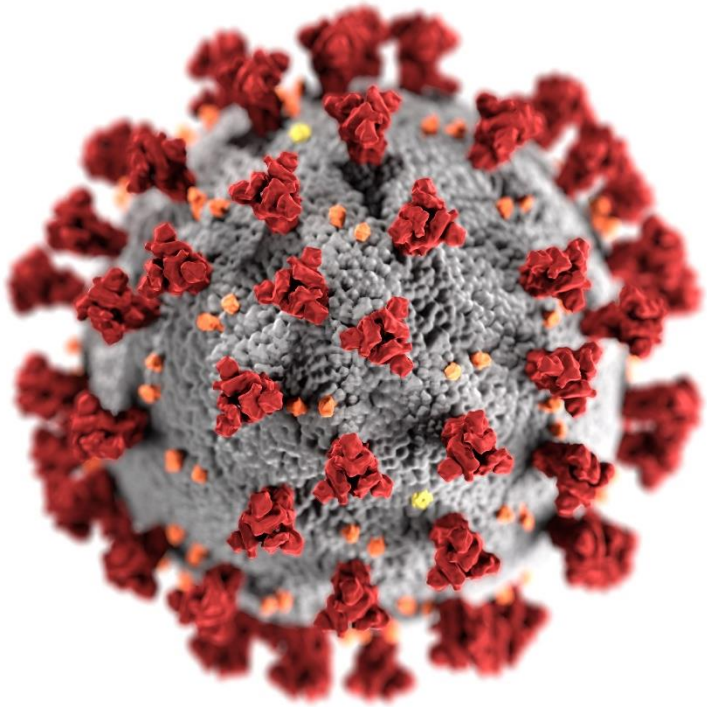




**Full list of U.S. COVID-19 vaccine safety monitoring systems**

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

# Thank you!



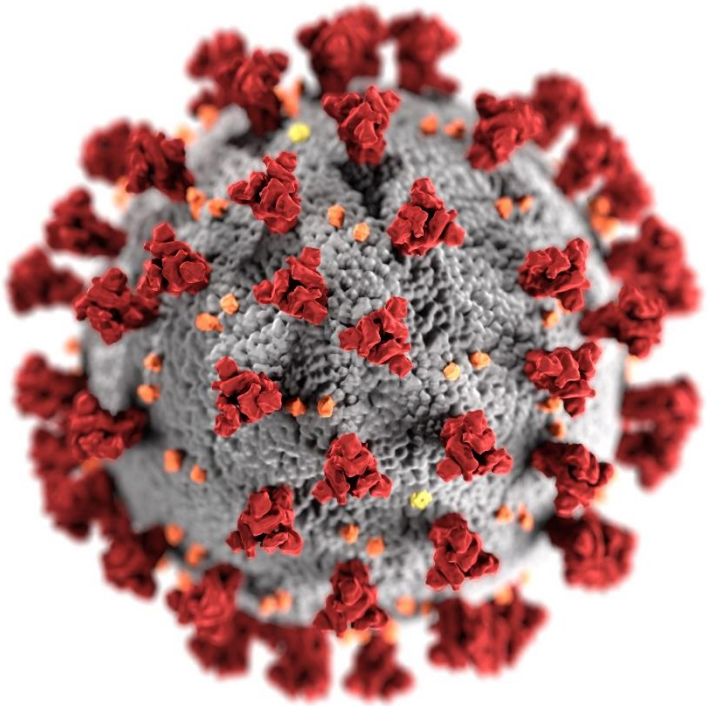
For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

# Clinician Information and Consultation Support from CDC: CDC's Vaccine Clinical Inquiries Management Team

**August 17, 2021**

**Katherine Shealy, MPH, IBCLC**
Vaccine Clinical Inquiry Management Team
CDC COVID-19 Vaccine Task Force



cdc.gov/coronavirus

# Vaccine Clinical Inquiries Management Team (VCIMT)

## **What** is VCIMT?

VCIMT is the team responsible for systematically addressing **complex COVID-19 vaccine inquiries** and also effectively coordinating escalation and management of complex inquiry escalations from CDC-INFO (CDC's national contact center) and other CDC outreach portals.

## **Where** does VCIMT sit?

COVID-19 Response Incident Manager

Vaccine Task Force

Chief Medical Officer

**VCIMT**

## **How** do inquiries get to VCIMT?

Inquirer contacts CDC*

CDC-INFO Agent ***emails*** VCIMT all inquiries that are:

**A**bout COVID-19 vaccine
**B**eyond CDC-INFO's scope
**C**linical in nature

CDC-INFO
You have questions? We have answers.
CDC's national contact center and publications fulfillment system

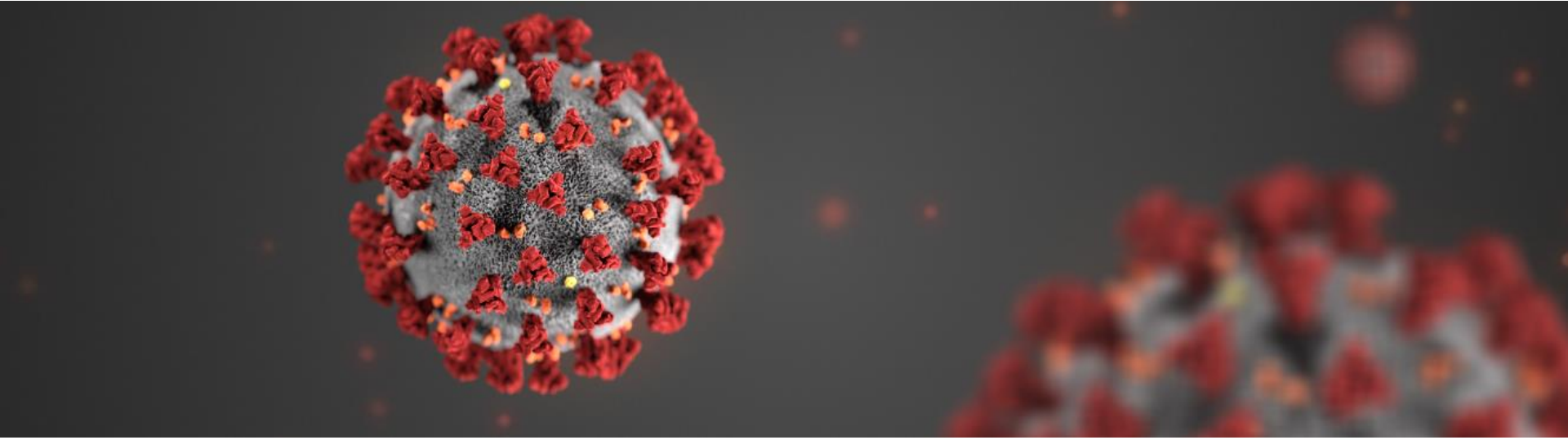
1-800-CDC-INFO
cdc.gov/cdc-info/

## **What** does VCIMT do?

REPLY DIRECTLY ***via email*** that CDC receives from clinical, public health, and other jurisdictional partners

ASSIST OTHERS across CDC's COVID-19 Response that ask for help in addressing questions, inquiries and TA requests from partners

IDENTIFY and ADDRESS content gaps, emerging issues, communication priorities, collaboration opportunities



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# 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 COCA Call Will Be Available On-Demand

- **When:** A few hours after the live call
- **What:** Video recording
- **Where:** On the COCA Call webpage at

https://emergency.cdc.gov/coca/calls/2021/callinfo_081721.asp

# Upcoming COCA Calls & Additional COVID-19 Resources

- Continue to visit https://emergency.cdc.gov/coca to get more details about upcoming COCA Calls, as we intend 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

- Sign up to receive weekly ***COVID-19 Science Updates*** by visiting cdc.gov/library/covid19/scienceupdates.html?Sort=Date%3A%3Adesc

# COCA Products & Services


COCA Call Announcements contain all information subscribers need to participate in COCA Calls. COCA Calls are held as needed.


Monthly newsletter that provides information on CDC training opportunities, conference and training resources, the COCA Partner Spotlight, and the Clinician Corner.


As-needed messages that provide specific, immediate action clinicians should take. Contains comprehensive CDC guidance so clinicians can easily follow recommended actions.

# COCA Products & Services

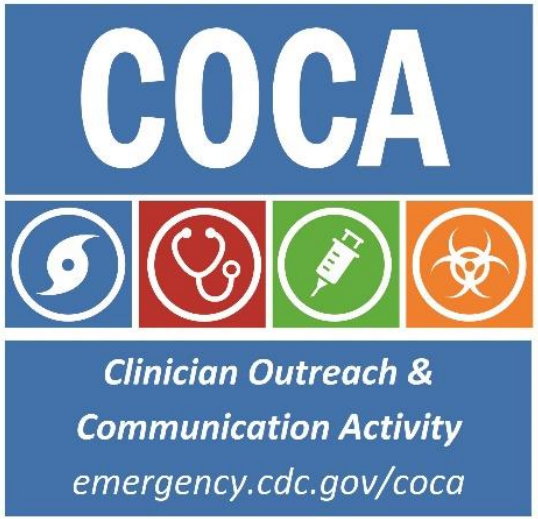

Monthly newsletter providing updates on emergency preparedness and response topics, emerging public health threat literature, resources for health professionals, and additional information important during public health emergencies and disasters.


Informs clinicians of new CDC resources and guidance related to emergency preparedness and response. This email is sent as soon as possible after CDC publishes new content.


CDC's primary method of sharing information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories.

# Join COCA's Mailing List

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




emergency.cdc.gov/coca/subscribe.asp

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