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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  - 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

- Kathleen Dooling, MD, MPH
  ACIP Workgroup Team Lead
  Vaccine Task Force
  COVID-19 Response
  Centers for Disease Control and Prevention

- Neela Goswami, MD, MPH
  Clinical Guidelines Team Lead
  Vaccine Task Force
  COVID-19 Response
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- Tom Shimabukuro, MD, MPH, MBA
  CAPT, U.S. Public Health Service
  Vaccine Safety Team Lead
  Vaccine Task Force
  COVID-19 Response
  Centers for Disease Control and Prevention

- Katherine Shealy, MPH, IBCLC
  Vaccine Clinical Inquiry Management Team Lead
  Vaccine Task Force
  COVID-19 Response
  Centers for Disease Control and Prevention
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
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

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

Cases Total 35,665,877

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\textsuperscript{1-2}

- Lower vaccine effectiveness
  - 59--72% VE among immunocompromised people vs. 90--94% among non-immunocompromised people after 2\textsuperscript{nd} dose\textsuperscript{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

See reference slide at end
EtR Domain: Benefits and Harms
Randomized Trial of a 3rd Dose of Moderna Vaccine in Transplant Recipients (n=120)

**Benefits:**

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:

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient Population</th>
<th>Sample Size</th>
<th>Seronegative N (%)</th>
<th>Seropositive N (%)</th>
<th>Sample Size</th>
<th>Seronegative N (%)</th>
<th>Seropositive N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kamar et al.</td>
<td>Recipients of solid-organ transplant</td>
<td>99</td>
<td>59 (60)</td>
<td>40 (40)</td>
<td>59</td>
<td>33 (56)</td>
<td>26 (44)</td>
</tr>
<tr>
<td>Werbel et al.</td>
<td>Recipients of solid-organ transplant</td>
<td>30</td>
<td>24 (80)</td>
<td>6 (20)</td>
<td>24</td>
<td>16 (67)</td>
<td>8 (33)</td>
</tr>
<tr>
<td>Longlune et al.</td>
<td>Patients on hemodialysis</td>
<td>82</td>
<td>13 (16)</td>
<td>69 (84)</td>
<td>12</td>
<td>7 (58)</td>
<td>5 (42)</td>
</tr>
<tr>
<td>Epsi et al.</td>
<td>Patients on hemodialysis</td>
<td>106</td>
<td>66 (62)</td>
<td>40 (38)</td>
<td>12</td>
<td>6 (50)</td>
<td>6 (50)</td>
</tr>
<tr>
<td>Ducloux et al.</td>
<td>Patients on hemodialysis</td>
<td>45</td>
<td>5 (11)</td>
<td>40 (89)</td>
<td>5</td>
<td>3 (60)</td>
<td>2 (40)</td>
</tr>
</tbody>
</table>

- Among those who had no detectable antibody response to an initial mRNA vaccine series, 33-50% developed an antibody response to an additional dose.

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

#### Summary: Work Group Interpretations

<table>
<thead>
<tr>
<th>Balance of consequences</th>
<th>Undesirable consequences clearly outweigh desirable consequences in most settings</th>
<th>Undesirable consequences probably outweigh desirable consequences in most settings</th>
<th>The balance between desirable and undesirable consequences is closely balanced or uncertain</th>
<th>Desirable consequences probably outweigh undesirable consequences in most settings</th>
<th>Desirable consequences clearly outweigh undesirable consequences in most settings</th>
<th>There is insufficient evidence to determine the balance of consequences</th>
</tr>
</thead>
</table>
## Evidence to Recommendations Framework

### Summary: Work Group Interpretations

<table>
<thead>
<tr>
<th>Type of recommendation</th>
<th>We do not recommend the intervention</th>
<th>We recommend the intervention for individuals based on shared clinical decision-making</th>
<th>We recommend the intervention</th>
</tr>
</thead>
</table>
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

- Sara Oliver
- Jessica MacNeil
- Heather Scobie
- Amy Blain
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- Jack Gersten
- Eddie Shanley
- Hannah Rosenblum

- Amanda Cohn

- Epi Task Force:
  - COVID-NET
  - DVD Enhanced Surveillance
  - Community Surveillance
  - Seroprevalance

- Data, Analytics and Visualization Task Force

- Respiratory Viruses Branch
References: Immunocompromised people and SARS-CoV-2 infection (Slide 18)

4. Hensley et al. *Intractable Coronavirus Disease 2019 (COVID-19) and Prolonged Severe Acute Respiratory Syndrome Coronavirus 2 (Sars-CoV-2 ) Replication in Chimeric Antigen Receptor-Modified T-Cell Therapy Recipient: A Case Study*. CID 2021
5. Baang et al. *Prolonged Severe Acute Respiratory Syndrome Coronavirus 2 Replication in an Immunocompromised Patient*. JID 2021
11. Lewis et al. *Household Transmission of Severe Acute Respiratory Syndrome Coronavirus-2 in the United States*. CID 2020
17. Tarhini et al. *Long-Term Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infectiousness Among Three Immunocompromised Patients: From Prolonged Viral Shedding to SARS-CoV-2 Superinfection*. [https://doi.org/10.1093/infdis/jiab075](https://doi.org/10.1093/infdis/jiab075)
References: Immunocompromised people and SARS-CoV-2 infection (Slide 19)


5. Chemaitelly et al. SARS-CoV-2 vaccine effectiveness in immunosuppressed kidney transplant recipients. medRxiv 2021.08.07.21261578; doi: https://doi.org/10.1101/2021.08.07.21261578
References: Percent of subjects with antibody response after two mRNA vaccine doses (Slide 20 - 1)

References: Percent of subjects with antibody response after two mRNA vaccine doses (Slide 20 - 2)

- Longlune, Marie Béatrice Nogier, Marcel Miedougé, Charlotte Gabilan, Charles Cartou, Bruno Seigneuric, Arnaud Del Bello, Olivier Marion, Stanislas Faguer, Jacques Izopet, Nassim Kamar, High immunogenicity of a messenger RNA based vaccine against SARS-CoV-2 in chronic dialysis patients, Nephrology Dialysis Transplantation, 2021:, gfab193, https://doi.org/10.1093/ndt/gfab193
References: Percent of subjects with antibody response after two mRNA vaccine doses (Slide 20 - 3)

- Mounzer Agha, et.al Suboptimal response to COVID-19 mRNA vaccines in hematologic malignancies patients medRxiv 2021.04.06.21254949; doi: https://doi.org/10.1101/2021.04.06.21254949
References: Percent of subjects with antibody response after two mRNA vaccine doses (Slide 20 - 4)

References: Percent of subjects with antibody response after 3 mRNA vaccine doses (Slide 29)

- Epsi et al. (2021) medRxiv doi: https://doi.org/10.1101/2021.07.02.21259913
- Ducloux., et al. (2021). Humoral response after 3 doses of the BNT162b2 mRNA COVID-19 vaccine in patients on hemodialysis.“Kidney Int. 2021 Jun 30m
  https://doi.org/10.1016/j.kint.2021.06.025 [Epub ahead of print].
For more information, contact CDC
1-800-CDC-INFO (232-4636)

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
Additional doses in immunocompromised people

**Review data:**
Assess safety, immunogenicity, and implementation

**FDA**
Regulatory allowance:
EUA amendment would allow recommendations under EUA
BLA would allow for ‘off label’ recommendations

**CDC/ACIP**
Clinical update:
Clinical considerations/recommendations for use

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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- **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.
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

Updates to additional clinical resources

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

- Kristine Schmit
- Mary Chamberland
- Kathleen Dooling
- Sara Oliver
- Kevin Chatham-Stephens
- John Omura
- Amanda Cohn
- Elisha Hall
- CDC COVID-19 Response Vaccine Task Force
For more information, contact CDC
1-800-CDC-INFO (232-4636)

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CDC Vaccine Safety Monitoring Systems

August 17, 2021

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

Immunization Safety Office

VAERS

CISA

VSD

3 core programs
VAERS is the nation’s early warning system for vaccine safety

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
- 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
Smartphone-based active safety monitoring

v-safe™
after vaccination health checker

http://cdc.gov/vsafe
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
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*

2. Clinically important health impact reported

✓ Received medical care

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

* 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

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

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

Thank you!

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:
About COVID-19 vaccine
Beyond CDC-INFO’s scope
Clinical in nature

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
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.
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
  
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

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

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

**Clinical Action**
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.
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- 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

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