What Clinicians Need to Know About Pfizer-BioNTech COVID-19 Vaccination of Adolescents

Clinician Outreach and Communication Activity (COCA) Webinar

Friday, May 14, 2021
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Today’s Presenters

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  COVID-19 Response
  Centers for Disease Control and Prevention

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  Centers for Disease Control and Prevention

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  v-safe Team Co-Lead
  COVID-19 Response
  Centers for Disease Control and Prevention
What Clinicians Need to Know About Pfizer-BioNTech COVID-19 Vaccination of Adolescents

COCA Call
May 14, 2021

cdc.gov/coronavirus
COVID-19 Epidemiology among Adolescents
Trends in Number of COVID-19 Cases in the US

January 22, 2020 – May 9, 2021

Cases in US 32,571,814

https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases
Trends in COVID-19 Incidence among Adolescents 12-17 Years of Age

March 1, 2020 – April 30, 2021

>1.5 million cases among adolescents 12-17 years of age

https://covid.cdc.gov/covid-data-tracker/#demographicsovertime
As more adults are vaccinated, adolescents 12-17 years of age make up a greater proportion of total cases: 9% of cases reported in April 2021.
Cumulative Rates of COVID-19-Associated Hospitalizations by Select Age Groups — COVID-NET, Mar 1, 2020–Mar 27, 2021

Cumulative 2009 H1N1 Influenza- and COVID-19-Associated Hospitalization among Adolescents 12-17 years by MMWR week —FluSurv-NET and COVID-NET

*The 2009-2010, H1N1 pandemic season, includes data from MMWR week 15-39 of the 2008-2009 season
Trends in Number of COVID-19 Deaths in the US

January 22, 2020 – May 9, 2021

Deaths in US 578,945

https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases
COVID-19 Deaths by Age Group, NCHS
—January 1, 2020–April 30, 2021

Adolescents 12–17 years:
- **127 COVID-19 deaths**
- **1.3%** of all deaths among adolescents

[Graph showing COVID-19 deaths by age group, with specific emphasis on adolescents 12–17 years.]
Multisystem Inflammatory Syndrome in Children (MIS-C)

- Severe hyperinflammatory syndrome occurring 2-6 weeks after acute SARS-CoV-2 infection, resulting in a wide range of manifestations and complications
  - 60-70% of patients are admitted to intensive care, 1-2% die\(^1,2\)

- **3,742 MIS-C cases** have been reported to national surveillance as of May 3, 2021\(^3\)
  - Median age of 9, with 21% (804) of cases occurred in adolescents 12-17 years
  - 63% of reported cases occurred in children who are Hispanic/Latino or Black, Non-Hispanic
  - Estimated incidence of 1 to 8.5 MIS-C cases per million person-months

Severity of MIS-C by Age

Adolescents and Transmission of SARS-CoV-2

- Some studies observed similar infection rates between children and adults, while others found lower infection rates among children compared with adults\(^1,2\)

- Adolescents may be more likely to be infected than younger children (<10 years)
  - Supported by contact tracing, test positivity, and population-based seroprevalance data\(^2\)

- Secondary transmission from adolescents can and does occur
  - While SARS-CoV-2 transmission among students relatively rare, several studies suggest transmission more likely within high school than elementary school settings\(^3,4\)

- Outbreak investigations have demonstrated efficient transmission among children, adolescents, and young adults, including transmission to older household members\(^5,6\)

Public Health Problem: Summary of the available evidence

Adolescents 12–17 years of age are at risk of severe illness from COVID-19
- Over 1.5 million reported cases and >13,000 hospitalizations to date
  - Hospitalization rate higher than 2009-10 H1N1 pandemic
- Clinical presentation of MIS-C more severe in adolescents than in younger children

COVID-19 in adolescents may also indirectly impact others' health
- Adolescents contribute to transmission in households and communities
  - Including older adults at higher risk of COVID-19
- Adolescents represent an increasing proportion of recent COVID-19 cases
Safety, Efficacy and Immunogenicity of Pfizer-BioNTech COVID-19 Vaccine in Adolescents
## Clinical Efficacy

**Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds**

- The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. The efficacy was **100%**

<table>
<thead>
<tr>
<th>Population</th>
<th>Events/Vaccine (n/N)</th>
<th>Events/Placebo (n/N)</th>
<th>Vaccine efficacy (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No evidence of prior infection, ≥7 d post dose 2</td>
<td>0/1001&lt;sup&gt;a&lt;/sup&gt;</td>
<td>16/972&lt;sup&gt;a&lt;/sup&gt;</td>
<td>100.0%&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>± evidence of prior infection, ≥7 d post dose 2</td>
<td>0/1109&lt;sup&gt;a&lt;/sup&gt;</td>
<td>18/1094&lt;sup&gt;a&lt;/sup&gt;</td>
<td>100.0%&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>All available efficacy (± evidence of prior infection, post dose 1)</td>
<td>3/1120&lt;sup&gt;a&lt;/sup&gt;</td>
<td>35/1119&lt;sup&gt;a&lt;/sup&gt;</td>
<td>91.4% (72.2%, 97.4%)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Number of subjects at risk for the endpoint;  
<sup>b</sup> With a standard continuity correction of 0.5 applied, the estimated VE (95% CI) is 97.1% (51.0%, 99.8%)  
<sup>c</sup> With a standard continuity correction of 0.5 applied, the estimated VE (95% CI) is 97.3% (55.8%, 99.8%)
The geometric mean ratio (GMR) for antibodies in 12–15-year-olds compared with 16–25-year-olds was 1.76 (95% CI:1.47, 2.10), and met the noninferiority criteria.

<table>
<thead>
<tr>
<th>SARS-CoV-2 neutralization assay – NT50&lt;sup&gt;a,b&lt;/sup&gt;</th>
<th>12-15 Years</th>
<th>16-25 Years</th>
<th>Met Noninferiority Objective&lt;sup&gt;d&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>n&lt;sup&gt;c&lt;/sup&gt;</td>
<td>n&lt;sup&gt;c&lt;/sup&gt;</td>
<td>n&lt;sup&gt;c&lt;/sup&gt;</td>
<td>GMR (95% CI)</td>
</tr>
<tr>
<td>190</td>
<td>170</td>
<td>1.76</td>
<td>(1.47, 2.10)</td>
</tr>
<tr>
<td>GMT (95% CI)</td>
<td>GMT (95% CI)</td>
<td>GMT (95% CI)</td>
<td></td>
</tr>
<tr>
<td>1239.5 (1095.5, 1402.5)</td>
<td>705.1 (621.4, 800.2)</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

Abbreviations: NT50 = 50% neutralizing titer; GMT = geometric mean titer; GMR = geometric mean ratio; LLOQ = lower limit of quantitation

<sup>a</sup>Among participants with no serologic/virologic evidence (up to 1 month after second dose) of past SARS-CoV-2 infection and negative NAAT at any visit up to one month after dose two.

<sup>b</sup>Sampling time point was one month after dose two.

<sup>c</sup>Number of subjects with valid and determinate assay results for the specified assay at the given dose and sampling time point.

<sup>d</sup>Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67
Safety: Serious adverse events
Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds

- Serious adverse events (SAE) were reported in a higher proportion of recipients of vaccine versus placebo based on 5 SAEs in the vaccine group and 2 in the placebo group.
- **No deaths** were reported among any trial participants.

<table>
<thead>
<tr>
<th>Study/populationa</th>
<th>Events/Vaccine (n/N)b</th>
<th>% SAE Vaccine</th>
<th>Events/Placebo (n/N)</th>
<th>% SAE Placebo</th>
<th>Associated with vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer/BioNTech, unpublished</td>
<td>5/1131</td>
<td>0.4</td>
<td>2/1129</td>
<td>0.2</td>
<td>0</td>
</tr>
</tbody>
</table>

Serious adverse event (SAE) is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity, or is a congenital anomaly/birth defect.

a. Included all randomized participants who received at least 1 dose of vaccine
b. Data cutoff of March 13, 2021
Safety: Reactogenicity
Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds

- Local reactions within 7 days occurred in 91% of vaccine recipients
  - Pain at the injection site most common
- Systemic reactions within 7 days occurred in 91% of vaccine recipients
  - Fatigue and headache most common
- Most symptoms resolved in 1-2 days
- Severe reactions were more common in vaccine recipients; a grade ≥3 reaction (interfering with daily life) was reported by 10.7% of vaccinated versus 1.9% of placebo group
  - Fatigue, fever, headache most common
Safety
Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds

- No cases of anaphylaxis reported in the adolescent (12-15 years of age) study participants

- No cases of Bell’s palsy or facial paralysis reported in adolescent participants

- Among adolescents 12-15 years of age, 7 (0.6%) in the vaccine group had lymphadenopathy, compared to 1 (0.1%) participant in the placebo group
  - Most lymphadenopathy was local (arm or neck region), occurred on the same side as vaccination, and occurred within 2-10 days
Values and Implementation
Positive COVID-19 Vaccination Intention among Adults

† Surveys with multiple time points are shown with the same color bubble for each time point. Surveys with only one time point are shown in gray.

*Positive vaccine intentions includes persons reporting definitely, probably, or somewhat likely to get vaccinated themselves. Some surveys also included persons who already received vaccine.
Surveys of Parents (intent to have children vaccinated)

- Among parents surveyed, **46-60%** plan to get their children vaccinated\(^1\)\(^-\)\(^4\)

- **Reasons for not vaccinating**\(^2\):
  - not sure it will be safe (59%)
  - vaccine developed too quickly (59%)
  - don’t trust info being published about the vaccine (48%)
  - won’t trust right away (44%)
  - don’t have enough info (43%)

- Parents reported similar or slightly lower intent to vaccinate their children compared to intent to vaccinate themselves\(^3\)\(^,\)\(^4\)

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1. Axios/Ipsos April 2-5; Axios/Ipsos April 16-19; Calarco and Anderson preprint; WebMD March 2021.
2. National Parents Union Survey January 2021
4. Parents Together March 2021 Survey
Surveys of Parents (intent to have children vaccinated)

- Intent to vaccinate children differed by parents’ gender, age & income status
- Fathers were more willing than mothers to vaccinate their children
- Older mothers were more willing than younger mothers to vaccinate their children
- Households with higher income were more likely to report intent to vaccinate
- Households with lower income were twice as likely to say “not sure” about vaccinating their children compared to higher income households

Simonson preprint; Calarco and Anderson preprint; National Parents Union Survey January 2021; Parents Together March 2021 Survey
Values: Surveys of Adolescents and Parents
Intent to get vaccine/have children vaccinated

Adolescents 13-17 years (n=839)
- 29% Definitely will
- 22% Probably will
- 20% Not sure
- 13% Probably not
- 15% Definitely not

Parents of Adolescents 12-17 years (n=766)
- 51% Definitely/probably will get vaccinated
- 33% Definitely will
- 22% Probably will
- 19% Not sure
- 12% Probably not
- 14% Definitely not

CDC/U Iowa Survey of Parents and Adolescents, April 2021
Acceptability: Comfort with adolescent receiving COVID-19 vaccine at each site

 CDC/U Iowa Survey of Parents and Adolescents, April 2021
Implementation Objectives

- Promote adolescent vaccination as quickly and equitably as possible through a multi-pronged approach

- Jurisdictions and providers currently vaccinating adolescents 16-17 years

- Leverage current COVID-19 vaccination infrastructure to adapt over time:
  - Early summer sprint (May-June)
  - Increase access (June-July)
  - Back-to-school campaign (July-September)
Stepwise Approach to Increasing Vaccine Access for Adolescents

Augment existing infrastructure for vaccination

Strategically add providers that can reach adolescents

Apply school-focused strategies to ensure vaccination opportunities

<table>
<thead>
<tr>
<th>May</th>
<th>June</th>
<th>July</th>
<th>August</th>
<th>September</th>
</tr>
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</table>
Opportunities to Increase Equitable Access to the Pfizer-BioNTech COVID-19 Vaccine

- Pfizer-BioNTech COVID-19 vaccine characteristics
  - Submitted new data to FDA supporting stability of vaccine when stored for up to one month (31 days) at 2-8°C¹
  - Encourage strategies to efficiently utilize doses and support local redistribution, smaller tray sizes would improve access (e.g., smaller providers, rural areas)

- Need for 2-dose series
  - In adults, ~3-8% missed the second dose of a 2-dose series, but differences were seen by jurisdiction, race/ethnicity, and age²

- Multipronged approach to improve access
  - Primary care providers serving adolescents, FQHCs, rural health clinics, community health centers, children’s hospitals, pharmacies, school-located vaccination clinics

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Vaccine Policy
Pfizer-BioNTech COVID-19 Vaccine Among Adolescents
Policy Question

- Should vaccination with Pfizer-BioNTech COVID-19 vaccine (2-doses, IM) be recommended for persons 12-15 years of age under an Emergency Use Authorization?
The Pfizer-BioNTech COVID-19 vaccine is recommended for persons 12–15 years of age in the U.S. population under the FDA’s Emergency Use Authorization.
Clinical Considerations
Interim clinical considerations for COVID-19 vaccines

- Recommendations apply to the use of the Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines under the Food and Drug Administration’s (FDA) Emergency Use Authorization (EUA)

- Clinical considerations are being updated to include guidance for adolescents and recommendations regarding vaccine coadministration and vaccination after Multisystem Inflammatory Syndrome in Children (MIS-C) and Adults (MIS-A)

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
## Pfizer-BioNTech Dosing and Administration

<table>
<thead>
<tr>
<th>Authorized age groups</th>
<th>≥ 12 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of doses in series</td>
<td>2 doses</td>
</tr>
<tr>
<td>Interval between 1\textsuperscript{st} and 2\textsuperscript{nd} doses*</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Dose volume</td>
<td>0.3 ml</td>
</tr>
<tr>
<td>Route</td>
<td>Intramuscular</td>
</tr>
</tbody>
</table>

\*If it is not feasible to adhere to the recommended interval, the second dose may be administered up to 6 weeks (42 days) after the first dose.
Consent

▪ The federal government does not have specific requirements for medical consent for vaccination.

▪ States/jurisdictions have medical consent laws that address the circumstances requiring and the processes for obtaining consent.
  – These laws vary across jurisdictions.
  – Providers may also be subject to policy requirements for consent within their own organizations.

▪ Sites administering vaccines should follow current state/jurisdictional policies and practices for other routine immunizations in this age group.

Coadministration

- COVID-19 vaccines were previously recommended to be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns.

- However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized for use by FDA for use under EUA.

- Although data are not available for COVID-19 vaccines administered simultaneously with other vaccines, extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.

[https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html)
Coadministration

- COVID-19 vaccines and other vaccines **may now be administered without regard to timing**. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
Coadministration

- It is unknown whether reactogenicity is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines.

- When deciding whether to coadminister another vaccine(s) with COVID-19 vaccines, providers should consider:
  - whether the patient is behind or at risk of becoming behind on recommended vaccines
  - their risk of vaccine-preventable diseases (e.g., during an outbreak or occupational exposures)
  - the reactogenicity profile of the vaccines

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
Coadministration

- If multiple vaccines are administered at a single visit, administer each injection in a different injection site.
- For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.
- Best practices for multiple injections include:
  - Label each syringe to identify the vaccine it contains.
  - Separate injection sites by 1 inch or more, if possible.
  - Administer COVID-19 and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

https://www.cdc.gov/vaccines/covid-19/clincial-considerations/index.html
Routine Adolescent Vaccines

- Updated coadministration recommendations may facilitate catch up vaccination of adolescents.

- As of May 2, 2021, overall VFC provider orders (other than influenza) are down by **11.7 million doses** compared with 2019.

- This gap is largest in vaccines primarily given to adolescents.
  - Tdap – down **18.9%**
  - HPV – down **19.3%**
  - Meningococcal conjugate vaccine – down **15.1%**
Multisystem Inflammatory Syndrome in Children (MIS-C) and Adults (MIS-A)

- MIS-C and MIS-A are severe hyperinflammatory syndromes occurring 2-6 weeks after acute SARS-CoV-2 infection, resulting in a wide range of manifestations and complications.

- The mechanisms of MIS-C and MIS-A are not well understood but include a dysregulated immune response to SARS-CoV-2.
Clinical Considerations for People with a History of MIS-C or MIS-A

- Children with MIS-C have high antibody titers to SARS-CoV-2; however, it is unknown if this correlates with protection against reinfection and for how long protective antibody levels persist.

- It is unclear if people with a history of MIS-C or MIS-A are at risk for recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or in response to a COVID-19 vaccine.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
Clinical Considerations for People with a History of MIS-C or MIS-A

- People with a history of MIS-C or MIS-A may choose to be vaccinated.
- Considerations for vaccination may include:
  - Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function
  - Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
  - Level of COVID-19 community transmission and personal risk of reinfection
  - Lack of safety data of COVID-19 vaccines following these illnesses
  - Timing of any immunomodulatory therapies

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
Clinical Considerations for People with a History of MIS-C or MIS-A

- Current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

[https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html)
Clinical Considerations for People with a History of MIS-C or MIS-A

Healthcare personnel or health departments can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project if they have complex COVID-19 vaccine safety questions not readily addressed by CDC guidance.

Contraindications for COVID-19 Vaccines

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine
- Known polysorbate allergy is no longer a contraindication to mRNA vaccination but is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
Syncope (fainting)

- Syncope (fainting) may occur in association with any injectable vaccine.

- Procedures should be in place to prevent falling injuries and manage syncopal reactions following vaccination.

- All people are recommended to be observed following vaccination for at least 15 minutes; patients should be seated or lying down during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

https://www.cdc.gov/vaccinesafety/concerns/fainting.html
Observation Period Following Vaccination

- History of immediate allergic reaction (any severity) to a vaccine or injectable therapy
- Contraindication to a different type of COVID-19 vaccine
- History of anaphylaxis (due to any cause)

All other persons

30 minutes
15 minutes
Additional resources
Additional Tools

- Additional tools to identify persons with contraindications and precautions to vaccination

Interim Considerations

- Preparing for the potential management of anaphylaxis at COVID-19 vaccination sites

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html
CDC Resources

Learn more with **CDC’s COVID-19 vaccine tools and resources**. Find information for COVID-19 vaccination administration, storage, reporting, patient education, and more.

- **COVID-19 Vaccination:** [https://www.cdc.gov/vaccines/covid-19/index.html](https://www.cdc.gov/vaccines/covid-19/index.html)
- **For Healthcare Professionals:** [https://www.cdc.gov/vaccines/covid-19/hcp/index.html](https://www.cdc.gov/vaccines/covid-19/hcp/index.html)
COVID-19 Vaccine Communication Resources

- Toolkit for Medical Centers, Clinics, and Clinicians
  https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

- Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit
Your Patients Need to Hear from You!

- You are the most trusted resource for your patients in making health decisions. **Your strong recommendation to get a COVID-19 vaccine is one of the most important factors in your patients’ decision to accept vaccination.**

- Engaging in Effective COVID-19 Vaccine Conversations
  
  [https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html](https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html)
Making a Strong Recommendation to Get a COVID-19 Vaccine

- Make it clear to your patients that you recommend COVID-19 vaccination for them.
- Tell your patients how important COVID-19 vaccines are to **protect their health, as well as the health of their family and friends.**
- COVID-19 vaccines are new, and it’s understandable that your patients may have questions. Your answers can help them make an informed decision about getting vaccinated.
- Make it clear that you understand they may have questions, and you want to answer them, so they feel confident in choosing to get vaccinated.
- If you are not currently offering COVID-19 vaccination, send them to [www.vaccines.gov](http://www.vaccines.gov) to find a location.
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.
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- Next Scheduled COCA Calls:
  - **Thursday, May 20**: Lyme Disease Updates and New Educational Tools for Clinicians
  - **Thursday, May 27**: Underlying Medical Conditions and Severe COVID-19
  - **Thursday, June 3**: Evaluating and Caring for Patients with Suspected Long COVID
  - 2:00 PM-3:00 PM ET

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