



**ACIP**  
***(Advisory Committee on  
Immunization Practices)***  
**and CDC**  
**Recommendations**

**Christine Hahn, MD**

**CVAC 12/18/2020**



IDAHO DEPARTMENT OF  
HEALTH & WELFARE



## The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

*Weekly* / December 11, 2020 / 69(49):1857-1859

*On December 3, 2020, this report was posted online as an MMWR Early Release.*

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- ACIP convened on December 1, 2020, in advance of the completion of FDA's review of the Emergency Use Authorization application, to provide interim guidance to federal, state, and local jurisdictions on allocation of initial doses of COVID-19 vaccine.
- ACIP recommended that, when a COVID-19 vaccine is authorized by FDA and recommended by ACIP, both **1) health care personnel and 2) residents of long-term care facilities** be offered vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a).
- The interim recommendation might be updated over the coming weeks based on additional safety and efficacy data from phase III clinical trials and conditions of FDA Emergency Use Authorization.



- Health care personnel are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials.
- LTCF residents are defined as adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently.



## Final - December 11, 2020

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)  
Centers for Disease Control and Prevention  
Atlanta, Georgia 30329  
December 11 and 12, 2020

<u>AGENDA ITEM</u>	<u>PRESIDER/PRESENTER(s)</u>
<b>Friday, December 11, 2020</b>	
12:00 Welcome & Introductions	Dr. José Romero (ACIP Chair) Dr. Amanda Cohn (ACIP Executive Secretary, CDC)
12:30 Agency Updates CDC, CMS, FDA, HRSA, IHS, NIH, ODP	
1:00 Coronavirus Disease 2019 (COVID-19) Vaccines Introduction BNT162b2 Development Program	Dr. Beth Bell (ACIP, WG Chair) Dr. William Gruber (Pfizer)
2:15 <i>Break</i>	
2:30 GRADE: Pfizer-BioNTech COVID-19 vaccine Work Group interpretation and n Discussion	Dr. Julia Gargano (CDC/NCIRD)
5:00 Adjourn	
<b>Saturday, December 12, 2020</b>	
11:00 Welcome & Introductions	
11:30 Coronavirus Disease 2019 (COVID-19) Vaccines Introduction Evidence to Recommendation Framework Clinical Considerations	
1:15 Public Comment	
2:30 <b>VOTE</b> Pfizer-BioNTech COVID-19 Vaccine Amendment to 2021 Child and Adolescent Immunization Schedule Amendment to 2021 Adult Immunization Schedule	Dr. Sara Oliver (CDC/NCIRD)
3:00 Adjourn	

## Policy Question

- Should vaccination with Pfizer-BioNTech COVID-19 vaccine (2-doses, IM) be recommended for persons 16 years of age and older under an emergency use authorization?



## Morbidity and Mortality Weekly Report (*MMWR*)

CDC



### The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer–BioNTech COVID–19 Vaccine — United States, December 2020

*Early Release* / December 13, 2020 / 69

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[https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s\\_cid=mm6950e2\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s_cid=mm6950e2_w)  
<https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>



## Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine

On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an [interim recommendation](#) for use of the Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 in persons aged 16 years and older. The Pfizer-BioNTech COVID-19 vaccine is a lipid nanoparticle-formulated, nucleoside-modified mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19).

These CDC clinical considerations are informed by [data](#) submitted to the Food and Drug Administration for Emergency Use Authorization (EUA) of the vaccine, other data sources, [general best practice guidelines for immunization](#), and expert opinion. In addition to the following considerations, the [EUA conditions of use](#) and storage, handling, and administration procedures described in the [prescribing information](#) should be referenced when using the Pfizer-BioNTech COVID-19 vaccine.

### Administration

The Pfizer-BioNTech COVID-19 vaccine series consists of two doses (30 µg, 0.3 ml each) administered intramuscularly, three weeks apart. Doses administered within a grace period of ≤4 days (i.e., between day 17 and 21) are considered valid; however, if the second dose is administered earlier than day 17, it does not need to be repeated. If more than 21 days have elapsed since the first dose, the second dose should be given at the earliest opportunity; the series does not need to be repeated.

### Interchangeability with other COVID-19 vaccine products

The Pfizer-BioNTech COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products and efficacy of a mixed-product series have not been evaluated. Persons initiating vaccination with Pfizer-BioNTech COVID-19 vaccine should complete the series with this product. If two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. Recommendations may be updated as further information becomes available or other vaccine types (e.g., viral vector, protein subunit vaccines) are authorized.

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### Appendix: Triage of persons presenting for Pfizer-BioNTech COVID-19 vaccination

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	<ul style="list-style-type: none"> <li>Immunocompromising conditions</li> <li>Pregnancy</li> <li>Lactation</li> </ul>	<ul style="list-style-type: none"> <li>Moderate/severe acute illness</li> </ul>	<ul style="list-style-type: none"> <li>None</li> </ul>
ACTIONS	<ul style="list-style-type: none"> <li>Additional information provided*</li> <li>15 minute observation period</li> </ul>	<ul style="list-style-type: none"> <li>Risk assessment</li> <li>Potential deferral of vaccination</li> <li>15 minute observation period if vaccinated</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
ALLERGIES	<ul style="list-style-type: none"> <li>History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies</li> <li>History of allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis)</li> <li>Family history of anaphylaxis</li> <li>Any other history of anaphylaxis that is not related to a vaccine or injectable therapy</li> </ul>	<ul style="list-style-type: none"> <li>History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine)</li> <li>History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy</li> </ul>	<ul style="list-style-type: none"> <li>History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine</li> </ul>
ACTIONS	<ul style="list-style-type: none"> <li>30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause</li> <li>15 minute observation period: Persons with allergic reaction, but not anaphylaxis</li> </ul>	<ul style="list-style-type: none"> <li>Risk assessment</li> <li>Potential deferral of vaccination</li> <li>30 minute observation period if vaccinated</li> </ul>	<ul style="list-style-type: none"> <li>Do not vaccinate</li> </ul>

\* See Special Populations section for information on patient counseling in these groups



- Training opportunities, webinars, toolkits announced/released

<https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf>

- [COVID-19 vaccination website for healthcare professionals](#)
- [Pfizer-BioNTech COVID-19 Vaccine webpage](#)
- Slides from CDC Partner call Sunday Dec 13: <https://www.cdc.gov/vaccines/covid-19/planning/index.html>.
- [COVID-19 vaccine information for consumers](#)
- CDC COVID-19 Vaccination Provider Agreement at [COVID-19 Vaccination Provider Requirements and Support | CDC](#)