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?
## 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>
<tbody>
<tr>
<td>Type of recommendation</td>
<td>We do not recommend the intervention</td>
<td>We recommend the intervention for individuals based on shared clinical decision-making</td>
<td>We recommend the intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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The Pfizer-BioNTech COVID-19 vaccine is recommended for persons 16 years of age and older in the U.S. population under the FDA’s Emergency Use Authorization.

For purposes of ACIP’s role under the Affordable Care Act, ACIP recommends vaccination with COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine.
ACIP Vote – Interim Recommendation
Amendment to 2021 Adult and Child/Adolescent Immunization Schedule

Recommend the proposed amendment to the 2021 Adult and Child/Adolescent immunization Schedules
ACIP Vote – Interim Recommendation
Amendment to 2021 Adult Immunization Schedule

Additional Information

- **At risk for hepatitis A virus infection**: 2-dose series HepA or 3-dose series HepA, HepB as above
  - **Chronic liver disease** (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
  - **HIV infection**
  - **Men who have sex with men**
  - **Injection or noninjection drug use**
  - **Persons experiencing homelessness**
  - **Work with hepatitis A virus** in research laboratory or with nonhuman primates with hepatitis A virus infection
  - **Travel in countries with high or intermediate endemic hepatitis A** (HepA, HepB, Twinrix) may be administered on an accelerated schedule of 0, 1, 6 months

**COVID-19 Vaccination**
ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine. Interim ACIP recommendations for the use of COVID-19 vaccines can be found at [https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html](https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html)

**Hemophilia type B vaccination**

**Special situations**
- **At risk for hepatitis B virus infection**: 2-dose (HepB series) or 3-dose (Engerix-B, Recombivax HB) series or 3-dose series HepA, HepB (Twinrix) as above
  - **Chronic liver disease** (e.g., persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice upper limit of normal)
  - **HIV infection**
For vaccine recommendations for persons 19 years of age or older, see the Recommended Adult Immunization Schedule.

Additional information

**COVID-19 Vaccination**
ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologies License Application for the particular vaccine. Interim ACIP recommendations for the use of COVID-19 vaccines can be found at [https://www.cdc.gov/vaccines/hcp/acip-recs/vaccines.html](https://www.cdc.gov/vaccines/hcp/acip-recs/vaccines.html).

- Consult relevant ACIP statements for detailed recommendations at [www.cdc.gov/vaccines/hcp/acip-recs/index.html](https://www.cdc.gov/vaccines/hcp/acip-recs/index.html).

The repeat dose should be spaced after the invalid dose by the recommended minimum interval. For further details, see Table 3-1, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html](https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html).

- Information on travel vaccine requirements and recommendations is available at [http://www.cdc.gov/travel/](http://www.cdc.gov/travel/).