

COVID-19 Evidence Digest 05/28/21

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 (MMWR)

Bottom Line: The Pfizer-BioNTech COVID-19 vaccine has been approved for emergency use by the Food and Drug Administration (FDA) and is recommended by the Advisory Committee on Immunization Practices for adolescents aged 12–18 years.

Details: Adolescents aged 12–17 years account for a growing proportion of new COVID-19 infections and hospitalizations. The cumulative COVID-19-associated hospitalization rate for adolescents aged 12-17, as of May 1, 2021, was 51 per 100,000 population, which was higher than the 2009 H1N1 pandemic (23.9 per 100,000 population). On May 10, 2021, the FDA expanded the Emergency Use Authorization (EUA) for use of the Pfizer-BioNTech vaccine to include adolescents aged 12-15 years. On May 12, 2021, the Advisory Committee on Immunization Practices also made a recommendation to use the Pfizer-BioNTech vaccine for prevention of COVID-19 among those aged 12–15 years. The Pfizer-BioNTech vaccine has already been approved and recommended for use in those aged ≥16. The vaccine was found to be safe and 100% effective in a phase two/three clinical trial of 2,200 adolescents aged 12-15 years. Efforts to provide equitable access to vaccinations among adolescents should be considered, particularly among populations with disproportionate COVID-19 morbidity and mortality. Health care providers and community leaders need to be engaged in reducing barriers to vaccine access and hesitancy among adolescents, parents, and guardians. The EUA Fact Sheet should also be provided to recipients and parents or guardians by providers prior to vaccination.

Key Takeaways:

- The Pfizer-BioNTech vaccine is the first COVID-19 vaccine to be approved and recommended for use in adolescents aged 12–15 years and has been found to be effective against symptomatic COVID-19.
- Efforts to ensure equitable distribution of the vaccine among adolescents should be made, while working to reduce barriers to vaccine confidence.

COVID-19 VaST Work Group Technical Report – May 17, 2021 (CDC)

Details: On May 17, 2021 the Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Safety Technical (VaST) Work Group met and reviewed real world COVID-19 vaccine safety data, including reports of myocarditis following mRNA vaccines in adolescents and young adults. They noted that there were relatively few reports to date, that rates of myocarditis reports following COVID-19 vaccination did not differ from expected rates, but that information on the reports of myocarditis should be shared with providers to enhance recognition and management of myocarditis cases. VaST noted that cases seemed to occur: 1) predominantly in adolescents and young adults, 2) more often in males than females, 3) more often following dose two than dose one, and 4) typically within four days after vaccination.

BNT162b2 mRNA COVID-19 vaccine effectiveness in the prevention of SARS-CoV-2 infection: a preliminary report (J Infect Dis)

Bottom Line: BNT162b2 (Pfizer-BioNTech) mRNA vaccine was highly effective at preventing both symptomatic and asymptomatic SARS-CoV-2 infection in healthcare workers.



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Details: In this study, 2,034 healthcare workers (HCW) in Italy were evaluated for vaccine effectiveness at preventing symptomatic and asymptomatic SARS-CoV-2 infection. All HCW were offered vaccine and those who accepted and completed the vaccine series were compared to those who declined. All asymptomatic HCWs were routinely screened every 14 days for SARS-CoV-2 infection using nasopharyngeal swab molecular tests.

Of the 2,034 HCW included, 1,607 HCW were in the vaccinated group and 427 were in the unvaccinated group. During an average follow up of 60.5 days 121 infections were recorded, of which 64 in the unvaccinated group (14 asymptomatic, 50 symptomatic) and 54 in the vaccinated group (17 asymptomatic, 37 symptomatic). The SARS-CoV-2 infection rate was higher in the unvaccinated group compared to the vaccinated group (incidence rate ratio: 0.22; 95% CI: 0.15–0.32). Estimated vaccine effectiveness for PCR-confirmed infection was 61.9% during the 14–20 days after the first dose, 87.9% during the 21–27 days after the first dose, and 96% ≥7 days after the second dose.

Key Takeaways:

- Real world effectiveness of the BNT162b2 mRNA vaccine was demonstrated in a large cohort of Italian HCWs who completed the vaccine series, as compared to HCWs who declined the vaccine.
- Both symptomatic and asymptomatic SARS-CoV-2 infections were less common in the vaccinated group as compared to the unvaccinated group.
- Estimated vaccine efficacy for PCR confirmed infection was 96% ≥7 days after receiving the second dose of the vaccine.

<u>COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021</u> (MMWR)

Bottom Line: Vaccine breakthrough infections of COVID-19 have only occurred in a small fraction of all vaccinated persons, and account for a small percentage of all COVID-19 cases.

Details: As of April 30, 2021, approximately 101 million persons in the United States had been fully vaccinated against COVID-19. A total of 10,262 SARS-CoV-2 vaccine breakthrough infections had been reported from 46 U.S. states and territories as of April 30, 2021. Among these cases, 6,446 (63%) occurred in females, and the median patient age was 58 years (interquartile range = 40–74 years). Based on preliminary data, 2,725 (27%) vaccine breakthrough infections were asymptomatic, 995 (10%) patients were known to be hospitalized, and 160 (2%) patients died. Among the 995 hospitalized patients, 289 (29%) were asymptomatic or hospitalized for a reason unrelated to COVID-19. The median age of patients who died was 82 years (interquartile range=71–89 years); 28 (18%) decedents were asymptomatic or died from a cause unrelated to COVID-19. The proportion of reported vaccine breakthrough infections attributed to variants of concern has also been similar to the proportion of these variants circulating throughout the United States.

Key Takeaways:

 Even though FDA-authorized vaccines are highly effective, breakthrough cases are expected, especially before population immunity reaches sufficient levels to further decrease transmission.



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- To date, breakthrough infections account for only a small percentage of all COVID-19 cases, and the age and sex distribution of reported breakthrough infections reflects the fully vaccinated U.S. population.
- The proportion of reported vaccine breakthrough infections attributed to variants of concern has also been similar to the proportion of these variants circulating throughout the US.