Updates and Alerts

- **COVID-19 Vaccine Authorized for Emergency Use by Food and Drug Administration (FDA)**

  See Special Section on page 6 for more information.

- **Updates to the Centers for Disease Control and Prevention's (CDC)Vaccine Storage and Handling Toolkit**

  The CDC's [Vaccine Storage and Handling Toolkit](https://www.cdc.gov/vaccines/shIELD/toolkit.html) includes a COVID-19 Vaccine Storage and Handling Addendum with information, recommendations, and resources for COVID-19 vaccine providers to follow the COVID-19 Vaccination Program Provider Agreement. This agreement includes the following protocols:

  - Store and handle COVID-19 vaccines under proper conditions
  - Monitor storage unit temperature at all times with appropriate equipment
  - Handle temperature excursions that comply with the guidance
  - Monitor COVID-19 vaccine expiration dates
  - Preserve records related to COVID-19 management for a minimum of 3 years
  - Comply with federal instructions and timelines for disposing of COVID-19 vaccine and diluent, including unused doses

  The addendum will be updated with specific information for each available COVID-19 vaccine product.

- **AAP Offers Transition Plan for new Biden-Harris Administration**

  AAP released its [Transition Plan: Advancing Child Health in the Biden-Harris Administration](https://www.aap.org/en-us/advocacy-and-policy делатьер/transition-plan-advancing-child-health-in-the-biden-harris-administration.pdf) containing 140 child health policy recommendations for the Biden-Harris administration to prioritize. One of the key policy priorities includes vaccines. Specifically, the Academy advocates the new administration:

  - Encourage children be added to COVID-19 vaccine trials to understand the safety and efficacy of the COVID-19 vaccines for children
  - Prioritize childhood vaccine administration within pediatric medical homes
  - Support efforts in restoring vaccine confidence
  - Appropriate valuation of immunization administration services
  - Allow Vaccine for Children (VFC) Program providers to use CPT code 90461
  - Reduce regulatory administrative burden associated with the VFC program.

- **Study Finds Most Americans Will Accept a COVID-19 Vaccine**

  The Kaiser Family Foundation (KFF) surveyed 1,676 adults in late November and early December 2020 for the [KFF COVID-19 Vaccine Monitor](https://www.kff.org/other/state-indicator/adult-vaccine-acceptability/) – an ongoing research project that is tracking the public’s attitudes and experiences with COVID-19 vaccination. This survey found that 71% of the respondents said they would definitely or probably get a COVID-19 vaccine, an increase in comparison to the September 2020 poll that showed 63% of the respondents were likely to get the vaccine. The survey indicated that Americans are becoming less reluctant in getting the COVID-19 vaccine. However, the survey also found that vaccine hesitancy was prevalent among Black adults, Republicans, rural residents, and individuals age 30-49.
Upcoming Meetings & Events

- **February 24-25, 2021**
  Held Virtually
  The ACIP generally holds three meetings each year at the CDC to review scientific data and vote on vaccine recommendations. Meetings are available online via live webcast. More information on ACIP meetings is available [here](#).

Resources

- **AAP EQIPP Course: Immunizations - Strategies for Success**
  The recently revised EQIPP immunization course is designed to identify immunization rates in your practice, uncover barriers to immunization delivery systems, and provide techniques to overcome those barriers using clear aims that reflect expert principles and proven quality improvement methods and tools.
  
  The online course features two tracks; the 19-23 month old track and the adolescent track with data collection activities specific to each population. The course is eligible for PI CME, NAPNAP, MOC Part 2, and MOC Part 4 credits. The course is free to AAP members. Additional course information is available [here](#).

  For rural health care providers that are non-AAP members and interested in taking this immunization course, contact Melissa Ponce at [mponce@aap.org](mailto:mponce@aap.org) by May 31, 2021 to have your course fee waived through the Supporting Pediatricians to Improve HPV and Pediatric Influenza Vaccination Rates Initiative.

- **AAP free online course – HPV Vaccine: When, Why, and How**
  AAP is offering a free, online course titled “HPV Vaccine: When, Why, and How” which addresses HPV vaccine and cancer prevention; recommending HPV vaccine; and increasing HPV vaccine rates. After completing the course, clinicians will be able to:
  - Apply communication strategies to help parents vaccinate their adolescents against HPV
  - Respond accurately and effectively to questions about HPV vaccination
  - Plan ways to update office staff on HPV vaccination’s importance, safety, timing, and contraindications/precautions

- **New Translations for Immunization Action Coalition (IAC) Screening checklists**
  The IAC has updated translations for their screening checklists for contraindications to childhood and adolescent vaccines in the following languages: Spanish, Arabic, Chinese-Simplified, French, Korean, Russian, and Vietnamese.

- **MenACWY: You’re Not Done if You Give Just One: Give 2 Doses to Strengthen Protection**
  The IAC and Sanofi Pasteur’s collaborative project – [MenACWY: You’re Not Done If You Give Just One: Give 2 Doses to Strengthen Protection](#) — aims to bring awareness of the low completion rate for MenACWY, as less than 50% of teens have received the second dose of the vaccine. Through the project’s website, providers can find a variety of resources to increase rates for the MenACWY booster. Resources will guide providers on measuring immunization success and how to recommend MenACWY. In addition, the website provides resources for adolescent immunizations, specifically for vaccinating teens at the 16-year-old visit.
Featured Research Findings

Study: Children with vaccine-hesitant parents less likely to receive flu vaccine

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Melissa Jenco, News Content Editor

Nearly 20% of U.S. children have a parent who is hesitant about childhood vaccines, and these children are significantly less likely to receive a flu vaccine, according to a new study.

The findings come as health officials warn about both flu and COVID-19 circulating and follow a flu season that set records for pediatric deaths and hospitalizations.


The study found:

• 26% of parents in 2018 and 20% in 2019 expressed hesitancy about childhood vaccines;
• 6% used a nonstandard childhood vaccination schedule;
• 23% in 2018 and 19% in 2019 said concerns about the number of simultaneous childhood vaccines impacted their decision to vaccinate;
• 27% in 2018 and 22% in 2019 said concern about serious, long-term side effects impacted their decision to vaccinate;
• 15% in 2018 and 14% in 2019 said they know someone with a serious long-term side effect from vaccination; and
• 17% in 2018 and 14% in 2019 said their doctor or health care provider was not their most trusted source of information about childhood vaccines.

Black parents were significantly more likely than White parents to be hesitant about childhood vaccination and side effects, according to the study.

During the 2018-'19 season, about 41% of children with vaccine-hesitant parents received a flu vaccine compared to 67% of children whose parents were not vaccine-hesitant. The difference was nearly the same the year before.

The findings follow a 2019-'20 season in which 195 children died of flu, a new record for a regular flu season. Hospitalization rates for children 4 and under were at a record high, even surpassing the 2009 H1N1 pandemic, and rates for children ages 5-17 were higher than any recent regular season.

"Consistently monitoring changes in VH (vaccine hesitancy), including socioeconomic differences in VH, could inform immunization programs in targeting interventions, provide resources to facilitate provider-patient vaccine conversations, and ultimately increase confidence in vaccinations and improve vaccination coverage to protect children from disease," authors wrote. Their conclusions do not necessarily represent the official position of the CDC.

Resources

• AAP policy "Recommendations for Prevention and Control of Influenza in Children, 2020–2021"
• AAP resources to help pediatricians prepare for flu season during the COVID-19 pandemic
• Information from the CDC about flu
• CDC's VaccineFinder website
• Information for parents on flu vaccine from HealthyChildren.org
• AAP News stories on flu
• Information on flu from the AAP Red Book
Pediatricians discuss ways to prepare ahead of COVID-19 vaccination of children

While children have not yet been assigned a priority group for the COVID-19 vaccination, pediatricians can take steps to prepare, advised two experts involved with the process.

Three immediate actions that pediatricians can take include learning about the vaccine, preparing themselves and staff to be immunized and sharing vaccine communications expertise, according to James Campbell, M.D., M.S., FAAP, AAP Committee on Infectious Diseases member, and Lisa Costello, M.D., M.P.H., FAAP, AAP West Virginia Chapter president and member of the AAP Committee on State Government Affairs.

Drs. Costello and Campbell answered questions about the COVID-19 vaccine at a virtual town hall, hosted by the Academy and moderated by Anne Edwards, M.D., FAAP, AAP chief population health officer.

Dr. Costello, who is an adviser to the pandemic response in West Virginia, said pediatricians are “prime immunizers,” who are well-versed in ways to communicate with patients about vaccines.

“... We as pediatricians should be getting immunized and our staffs should be getting immunized. It's going to be important to build confidence now, so that can hopefully have a trajectory long term,” she said.

Pediatricians are valuable leaders in their communities because they have the most experience of any physician when it comes to navigating vaccine communications, addressing patients' concerns, and promoting follow up on booster doses, Dr. Costello said.

The AAP West Virginia Chapter recently conducted a survey to help determine the best approaches to vaccine communications. Results indicated that people trust their doctor and organizations like the AAP to provide reliable information about vaccines and vaccine safety, she said.

The chapter is working on ways to coordinate communications and educate the community, including via an open letter to West Virginians signed by more than 30 medical organizations. The letter emphasizes that health care providers trust the vaccine and urges residents to get immunized when it is their turn.

Dr. Costello planned to use social media to share information with her community. She said serving as a role model has been an effective way to encourage patients, especially those with vaccine hesitancy. “They saw a doctor they trust get it and now they want to get it,” she said. “As pediatricians, we would love all these people saying, 'when can I get my shot?'”

Being knowledgeable about how the Pfizer-BioNTech and Moderna messenger ribonucleic acid (mRNA) vaccines work will allay concerns people may have about side effects, contraindications or allergic reactions, said Dr. Campbell, who has been involved with COVID-19 vaccine testing.

The vaccines’ ingredients include mRNA, a lipid nanoparticle, sugar and salts. They do not contain preservatives, adjuvants or antibiotics. They are not made in eggs and do not have latex in the membrane, Dr. Campbell said.

The second dose of the Pfizer-BioNTech vaccine should be given at 21 days and the second dose of the Moderna vaccine should be given at 28 days, but Dr. Campbell said pediatricians should not worry if the second dose is not administered exactly 21 or 28 days after their first dose.

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Pediatricians discuss ways to prepare ahead of COVID-19 vaccination of children

There is only one known contraindication, Dr. Campbell said. “The only stated contraindication at this point is known severe allergic reaction to a component of the vaccine. It’s unlikely that we’re going to have a pre-existing known severe allergy to a component in the vaccine. ... It’s not unexpected that we’re going to see an occasional allergic reaction when we are vaccinating this many people.”

Dr. Campbell said more vaccine trials in children are needed to make sure that there are not any side effects that are pediatric-specific. There is no known biomarker to predict an immune response that leads to multisystem inflammatory syndrome in children (MIS-C). He hypothesized that protection from COVID-19 by vaccination may protect against the sequelae, including MIS-C. He also noted that multisystem inflammatory syndrome in adults (MIS-A) has been common in young adults with COVID-19 disease, but has not been observed in young adults who received the vaccine in clinical trials.

Another area being studied involves transmissibility of the virus by those who are fully immunized. “We currently only know that the vaccine prevents disease. We don’t know about preventing infection,” Dr. Campbell said, adding that pediatricians should continue to communicate the importance of wearing a mask, physical distancing and hand hygiene.

Right now, pediatricians should focus on making sure their patients are caught up on routine childhood immunizations, Dr. Campbell said. He worries that other highly contagious diseases, like measles, pertussis and influenza, could return once children return to school and families resume traveling and other pre-pandemic routines.

“Do what you can now, while you’re waiting for COVID-19 vaccine, to work with your practices, your families ... to get everybody up to date,” he said.

Dr. Costello added, “We need to continue what we’re already doing to prevent the spread the best we can. ... Being optimistic and hopeful is going to help us continue to push on.”

Resources

- Connecting with the Experts: A COVID-19 Townhall Series
- COVID-19 Vaccine: Frequently Asked Questions
- Food and Drug Administration fact sheet for Pfizer-BioNtech vaccine
- Food and Drug Administration fact sheet for Moderna vaccine
- Centers for Disease Control and Prevention COVID-19 Vaccination Communication Toolkit

AAP Childhood Immunization Flipchart – Get it for your practice!

The AAP Childhood Immunization Support Program has developed a Childhood Immunization Flipchart. The flipchart is designed for use by pediatricians and other primary care providers during clinical encounters with patients and families to aid them in conducting efficient, productive conversations about childhood vaccination and giving a strong recommendation for childhood vaccines. It focuses on vaccines routinely provided to children from birth through age 6 years and contains family-friendly infographics and detailed speaking points that providers can use, for each of the 10 vaccines recommended in childhood.

If you would like to request copies of this flipchart to use with patients/families, please do so here. We are currently mailing copies. The flipchart user guide will include suggestions for limiting germ spread, while using the flipchart during the COVID-19 pandemic.
COVID-19 Vaccine Now Available for Adults and Older Children

Currently, there are two vaccines authorized for the prevention of COVID-19 in the United States (US). In December, the US Food and Drug Administration’s (FDA’s) Vaccines and Related Biological Products Advisory Committee (VRBPAC), a group that is comprised of independent scientists and public health experts (including several pediatricians), met twice to review and discuss data and voted to recommend an emergency use authorization (EUA) for the COVID-19 vaccine from Pfizer/BioNTech and the COVID-19 vaccine from Moderna. FDA leaders approved the EUA shortly after each meeting.

The Centers for Disease Control and Prevention’s (CDC’s) Advisory Committee on Immunization Practices (ACIP) also met after each EUA was issued. This group also reviewed and discussed data, and voted to issue recommendations regarding the use of COVID-19 vaccines. Continue reading for details on each vaccine.

**Pfizer-BioNTech COVID-19 Vaccine – manufactured by Pfizer**

- Recommended for **persons 16 years of age and older** in the US
- Messenger RNA (mRNA) vaccine given in two doses, 21 days apart
- Intramuscular (IM) administration
- Requires diluent
- Stored at -80°C to -60°C
- **Efficacy:**
  - The companies conducted randomized, placebo-controlled trials with more than 40,000 people including 283 adolescents ages 16 and 17 years.
  - During the trials, 170 people were infected with COVID-19, eight of whom had received the vaccine and 162 who had received the placebo, resulting in a calculated efficacy of 95%.
  - Efficacy was similar across age groups and ethnicities.
- **Safety:**
  - This vaccine was found to be safe – and two months of follow-up found mostly mild or moderate systemic reactions.
  - Most common reactions included injection site reactions, fatigue, headache, muscle pain, joint pain, and fever.
    - These are typical of an immune response.
    - These reactions were more common in people under 55 years of age and after the second dose.
  - Other reactions
    - Among those who received the vaccine during trials, four reported cases of Bell’s Palsy, but it was not determined if the vaccine was the cause.
    - Sixty-four participants who received the vaccine during trials experienced lymphadenopathy.
    - There was one report of a shoulder injury from either the vaccine or vaccine administration during trials.
  - Safety data for the 16-17 year-old population showed small percentages of systemic reactions – injection site pain, fatigue, pyrexia, chills and headache.

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**Resources**

- Read related articles from [AAP News](#)
- [AAP interim COVID-19 guidance](#)
- [AAP FAQ on COVID-19 vaccines](#)
COVID-19 Vaccine Now Available for Adults and Older Children
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Moderna COVID-19 Vaccine – manufactured by Moderna TX, Inc.

- Recommended for persons 18 years of age and older in the US
- mRNA vaccine given in two doses, 28 days apart
- IM administration
- No diluent required
- Stored at: -25°C to -15°C (-13°F to 5°F). Vaccine vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days before vials are punctured. After 30 days, remove any remaining vials from the refrigerator and discard following manufacturer and jurisdiction guidance on proper disposal.

- Efficacy
  - Moderna conducted randomized, placebo-controlled trials with just over 30,000 adults.
  - During trials, 196 people were infected with COVID-19, 11 of whom had received the vaccine and 185 of whom had received the placebo, resulting in a calculated efficacy of 94%.
  - Efficacy was similar across subgroups.
  - All 30 cases of severe COVID-19 occurred in the placebo group.

- Safety
  - This vaccine was found to be safe, and like the Pfizer-BioNTech vaccine, reactions were typically mild to moderate and quickly resolved.
  - The most common reactions were pain at the injection site, fatigue, headache, myalgia, arthralgia, nausea/vomiting, chills and fever.
    - These reactions were more common after the second dose and in people under age 65.
  - Other reactions
    - A case of intractable nausea/vomiting and two cases of facial swelling in people who had dermal fillers were reported.
    - Three cases of Bell’s palsy were reported among those who received the vaccine. Like with the Pfizer-BioNTech vaccine, it was not clear whether the vaccine caused them. The FDA will be studying this issue.
    - Lymphadenopathy was reported more frequently in those who received the vaccine compared to those who received the placebo.

COVID-19 Vaccines and Children

At the FDA VRBPAC meeting for the Pfizer-BioNTech vaccine, some members offered concerns that there was not enough data to include its use in children ages 16-17 in the EUA — others believed the benefit outweighed the risk. As of early January, only the Pfizer-BioNTech vaccines has been authorized for those age 16-17 years; neither vaccine has been authorized for use in children under the age of 16. To date, Pfizer has enrolled children down to age 12 and its EUA for vaccination indications down to age 16 was recently approved. Moderna has started a similar study, as has Janssen and AstraZeneca. We anticipate that studies including younger children will begin soon (perhaps over the next couple of months).

The AAP has advocated for the inclusion of children and pregnant women in COVID-19 vaccine trials, including letters to the FDA, and the VRBPAC, a press release and comments submitted to VRBPAC for its meeting to consider EUA of the Moderna COVID-19 vaccine.

Populations Prioritized for Vaccination by ACIP

The CDC ACIP set the following prioritizations for vaccination against COVID-19:

- Phase 1a — health care personnel (including employees at long-term care facilities) and residents of long-term care facilities
- Phase 1b — frontline essential workers (non–health care workers) and persons aged ≥75 years
- Phase 1c — persons aged 65–74 years, persons aged 16–64 years with medical conditions that increase the risk for severe COVID-19, and essential workers not previously included in Phase 1a or 1b
- Phase 2 — all other persons aged ≥16 years not already recommended for vaccination in Phases 1a, 1b, or 1c.