FROM THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

COVID-19 Vaccine Updates

July/August 2023

Introduction

The SARS-CoV-2 virus emerged as a novel communicable pathogen in late 2019. By May 2023, it had caused more than 100 million COVID-19 cases and more than 1.1 million deaths in the United States and nearly 7 million deaths worldwide.[1] In 2020 and 2021, multiple candidate vaccines were rapidly developed and approved, including inactivated virus vaccines, messenger RNA (mRNA) vaccines (Pfizer and Moderna), adenovirus vector vaccines (Johnson & Johnson) and adjuvanted protein vaccines (Novavax). Computer modeling of disease transmission has estimated that vaccination against COVID-19 prevented nearly 120 million cases and more than 3 million deaths in the United States from December 2020 through November 2022.[2]

In the United States, mRNA vaccines are the most commonly administered, while relatively few doses of adenovirus vector or protein vaccines have been given.[3] Updated bivalent formulations of mRNA vaccines targeting the currently circulating SARS-CoV-2 variant became available for booster doses in fall 2022.[4] The original monovalent mRNA vaccines were phased out.

General Recommendations

- Children ages 6 months and older and adults should stay up to date with COVID-19 vaccination, including at least one dose of a bivalent mRNA vaccine.[5]
- For people ages 6 years and older who are not immuno-compromised, a single bivalent mRNA dose is enough to consider them up to date, regardless of previous vaccination status.[6]
  - Adults ages 65 and older who are not immunocompromised may receive an additional booster dose at least 4 months after their first dose of bivalent mRNA vaccine.[5]

WHAT'S NEW

As the pandemic progressed and the SARS-CoV-2 virus mutated, additional mRNA sequences targeting variant spike proteins were added to the previously authorized, effective vaccine. These new bivalent mRNA vaccines should now be used for all doses in all age groups, including primary series and booster doses.[5] Monovalent (original formulation) mRNA COVID-19 vaccines are no longer authorized by the U.S. Food and Drug Administration and should be discarded.[7]

The adenovirus vector vaccine is no longer available in the United States following the expiration of all remaining U.S. government stock on May 7, 2023.[8]

- There is no authorized vaccine for infants younger than 6 months. Pregnant and lactating people are strongly encouraged to get vaccinated to provide protection to infants too young to vaccinate.
- People who are moderately or severely immunocompromised are at higher risk for severe COVID-19 infection than the general population. They may need additional doses in their primary vaccine series, as well as additional booster doses.[5]
- Bivalent mRNA vaccines are preferred unless contraindicated.[9] The monovalent protein vaccine can be used in certain limited situations.

People Who Are Not Immunocompromised[5]

AGES 12 YEARS AND OLDER

Vaccination for COVID-19 in adolescents and adults who are not immunocompromised is now simplified.

- For **people ages 12 years and older who are unvaccinated**, a single bivalent mRNA dose is recommended and will bring them up to date.
- For **people ages 12 years and older who have had at least one dose of a monovalent mRNA vaccine or non-mRNA vaccine** in the past, a single bivalent booster dose at least 8 weeks after the last monovalent dose is recommended.

Most adolescents and adults who have already received a bivalent dose are not eligible for another shot. However, adults ages 65 and older may receive one additional bivalent mRNA booster dose at least 4 months after their first bivalent vaccine dose.

AGES 6 MONTHS THROUGH 11 YEARS

Primary dosing schedules for **children ages 6 months through 5 years** are more complex because mRNA products come in different dose strengths and the required number of doses differs based on age. All children should receive at least one dose of bivalent vaccine, but the number of doses needed varies depending on what vaccine the child has previously received. It is ideal for infants and young children to receive all doses in their primary vaccine series from the same manufacturer.

The primary dosing schedule for **children ages 6 through 11 years** more closely aligns with the schedule for adolescents and adults. A single bivalent primary dose or one bivalent booster dose at least 8 weeks after the last monovalent dose is recommended and will bring them up to date. Partially vaccinated patients ages 6 years and older may receive either brand of bivalent mRNA vaccine.

Recommended COVID-19 vaccination schedules are available on the Centers for Disease Control and Prevention website at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html.

People Who Are Moderately or Severely Immunocompromised[5]

To ensure adequate immune response, children and adults who are moderately or severely immunocompromised continue to need additional vaccine doses. Family physicians may care for patients who have immunocompromising conditions and treatments including active treatment for solid tumor cancers, current or past treatment for hematologic malignancies (e.g., leukemia, lymphoma), receipt of a solid-organ transplant and subsequent immunosuppressive therapy, primary immunodeficiency or HIV infection with CD4 cell counts less than 200/mm^3. Common immunocompromising medications include high-dose corticosteroids (i.e., 20 mg or greater of prednisone or equivalent daily for at least 2 weeks) and immunomodulatory biologic agents (e.g., tumor necrosis factor [TNF] blockers). Patients who are moderately or severely immunocompromised can self-attest and be vaccinated against COVID-19 without needing to provide documentation.

Pregnant and Lactating People

Growing evidence supports vaccination during pregnancy to improve maternal, fetal and neonatal outcomes. Compared to non-pregnant people of a similar age, people who are pregnant or within 6 weeks postpartum have increased risk for severe COVID-19 infection, including hospitalization, admission to an intensive care unit, need for mechanical ventilation and death.[10,11] Studies have shown that pregnant people who are vaccinated have a lower risk of stillbirth, neonatal intensive care unit admission and preterm birth than those who are not vaccinated.[12,13] Further, there is no evidence of adverse effects of vaccination unique to pregnancy, including no evidence of teratogenicity or poor perinatal outcomes.[13,14]

Pregnant and lactating people are strongly recommended to receive COVID-19 vaccination and remain up to date, with no restrictions regarding timing of doses before, during or after pregnancy.[5,15] Professional medical organizations, including the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the

American Academy of Pediatrics and the Society for Maternal-Fetal Medicine, continue to advocate for COVID-19 vaccination in this vulnerable group.[16]

Contraindications

There are only a few contraindications to COVID-19 vaccination, including the following[5,17]:

- **People who have had a severe allergic reaction to a previous dose of COVID-19 vaccine** should not receive another dose of the same vaccine type.
- **People who are allergic to polyethylene glycol (PEG)** should not receive an mRNA vaccine, but they may get a protein vaccine.
- **People who are allergic to polysorbate** should not get a protein vaccine, but mRNA vaccines are safe for them.

In addition, adults who cannot or will not receive an mRNA vaccine may get a protein vaccine. Some monovalent COVID-19 vaccine products are expired or expiring soon, so it is important to check the vaccine's expiration date prior to administration.[18]

None of the vaccines used in the United States include any preservatives, antibiotics, animal tissue (e.g., gelatin, cells) or food proteins (e.g., egg, gluten).[17] Offering 30 minutes of monitoring to patients with a history of allergic reaction to injectable medications of any kind is recommended as a precaution.[5]

Best Practices for Family Physicians

1. Standardize Your Messaging About COVID-19 Vaccines

As the world transitions into management and mitigation of endemic COVID-19, maintaining population immunity to the virus is still the most important strategy to reduce its impact. Family physicians are a trusted source of information and advice to protect patients, families and communities from the virus.

- Consider naming a vaccine champion for your practice to educate and encourage staff.
- Continue to strongly recommend and provide COVID-19 vaccines for as many eligible patients as possible in your practice. Visible high-volume COVID-19 vaccination sites have closed, so family physicians have an indispensable role in vaccinating their patients against the virus.
- If your practice does not offer COVID-19 vaccination for any reason, point your patients to www.vaccines.gov or recommend another resource to help them find COVID-19 vaccines in your area.

2. Practice Opportunistic Vaccination

It is important to take time to review your patients' risk factors and immunization history and strongly recommend getting vaccinated if they are not up to date. Most people in the United States are not up to date with COVID-19 vaccination. For example, only 17% of the total population and only 43% of adults ages 65 and older had received a bivalent booster dose as of May 2023.[3]

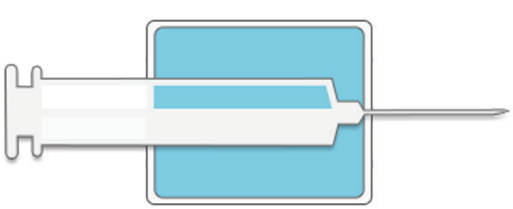
COVID-19 vaccines can be coadministered with influenza, tetanus-diphtheria-pertussis and pneumococcal vaccines. They have been added to the 2023 routine childhood immunization schedule, ensuring coverage in the Vaccines for Children (VFC) program.[19,20] COVID-19 vaccines are also covered by Medicare Part B and private insurers, and they remain no- or low-cost for patients following the expiration of the federal public health emergency on May 11, 2023.[21]

3. Plan Ahead for Fall

SARS-CoV-2 will be with us for the foreseeable future and so will the need for COVID-19 vaccines. Hopefully, summer months will offer a reprieve from the challenging surges of infections seen in the past few years. Summer also brings the planning and forecasting meetings of vaccine regulatory and advisory panels that determine the strain composition of vaccines. Similar to their annual process for the influenza vaccine, manufacturers may update COVID-19 vaccine formulations for the fall.

You can reassure your patients that there is continued safety monitoring for COVID-19 vaccines. This is also a good time to prepare for coadministration of COVID-19 vaccines with flu shots during the upcoming influenza season.

The AAFP's Immunizations and Vaccines webpage (aafp.org/vaccines) provides information and resources to support your efforts to get your patients up to date on vaccinations.



References

1. World Health Organization. WHO coronavirus (COVID-19) dashboard. Updated May 10, 2023. Accessed May 11, 2023. https://covid19.who.int/
2. Fitzpatrick MC, Moghadas SM, Pandey A, et al. Two years of U.S. COVID-19 vaccines have prevented millions of hospitalizations and deaths. The Commonwealth Fund. December 13, 2022. Accessed May 11, 2023. https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations
3. Centers for Disease Control and Prevention. COVID-19 vaccinations in the United States. Updated May 11, 2023. Accessed May 11, 2023. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-pop5
4. Rosenblum HG, Wallace M, Godfrey M, et al. Interim recommendations from the Advisory Committee on Immunization Practices for the use of bivalent booster doses of COVID-19 vaccines — United States, October 2022. *MMWR Morb Mortal Wkly Rep.* 2022;71(45):1436-1441.
5. Centers for Disease Control and Prevention. Interim clinical considerations for use of COVID-19 vaccines in the United States. Updated May 12, 2023. Accessed May 23, 2023. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
6. Centers for Disease Control and Prevention. Stay up to date with COVID-19 vaccines. Updated May 23, 2023. Accessed May 23, 2023. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html
7. Coronavirus (COVID-19) update: FDA authorizes changes to simplify use of bivalent mRNA COVID-19 vaccines. News release. U.S. Food and Drug Administration. April 18, 2023. Accessed May 11, 2023. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines
8. Centers for Disease Control and Prevention. Janssen (Johnson & Johnson) COVID-19 vaccine. Updated May 10, 2023. Accessed May 23, 2023. https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html
9. Centers for Disease Control and Prevention. FAQs for the interim clinical considerations for COVID-19 vaccination. Updated May 12, 2023. Accessed May 23, 2023. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html
10. Ellington S, Strid P, Tong VT, et al. Characteristics of women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status—United States, January 22-June 7, 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(25):769-775.
11. Allotey J, Stallings E, Bonet M, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. *BMJ.* 2020;370:m3320.
12. Watanabe A, Yasuhara J, Iwagami M, et al. Peripartum outcomes associated with COVID-19 vaccination during pregnancy: a systematic review and meta-analysis. *JAMA Pediatr.* 2022;176(11):1098-1106.
13. Fell DB, Dimanlig-Cruz S, Regan AK, et al. Risk of preterm birth, small for gestational age at birth, and stillbirth after COVID-19 vaccination during pregnancy: population based retrospective cohort study. *BMJ.* 2022;378:e071416.
14. Ruderman RS, Mormol J, Trawick E, et al. Association of COVID-19 vaccination during early pregnancy with risk of congenital fetal anomalies. *JAMA Pediatr.* 2022;176(7):717–719.
15. Centers for Disease Control and Prevention. COVID-19 vaccines while pregnant or breastfeeding. Updated October, 20, 2022. Accessed May 11, 2023. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html
16. Statement of strong medical consensus for vaccination of pregnant individuals against COVID-19. News release. American College of Obstetricians and Gynecologists. August 9, 2021. Updated September 14, 2021. Accessed May 11, 2023. https://www.acog.org/news/news-releases/2021/08/statement-of-strong-medical-consensus-for-vaccination-of-pregnant-individuals-against-covid-19
17. Centers for Disease Control and Prevention. Overview of COVID-19 vaccines. Updated November 1, 2022. Accessed May 23, 2023. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html
18. Centers for Disease Control and Prevention. Administration of Novavax COVID-19 vaccines. Reviewed May 17, 2023. Accessed May 25, 2023. https://www.cdc.gov/vaccines/covid-19/info-by-product/novavax/administration.html
19. Wodi AP, Murthy N, McNally V, et al. Advisory Committee on Immunization Practices recommended immunization schedule for children and adolescents ages 18 years or younger — United States, 2023. *MMWR Morb Mortal Wkly Rep.* 2023;72(6):137-140.
20. Centers for Disease Control and Prevention. VFC detailed questions and answers for parents. Reviewed December 17, 2014. Accessed May 25, 2023. https://www.cdc.gov/vaccines/programs/vfc/parents/qa-detailed.html
21. Medicare.gov. Medicare & coronavirus. Accessed May 11, 2023. https://www.medicare.gov/medicare-coronavirus

Author: Laura Elizabeth Morris, M.D.

This publication is funded under the AAFP's "Improving Adult Immunization Rates Among Racial and Ethnic Minority Populations" project, which is supported by a Cooperative Agreement from the Centers for Disease Control and Prevention (6 NU66IP000681-02-01). (The author is solely responsible for the content and does not necessarily represent the official views of the CDC.)

HOPS2305421