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COVID-19 Vaccine Bivalent Boosters

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Introduction

As the United States (U.S.) moves into the next phase of the coronavirus disease-2019 (COVID-19) pandemic, some individuals may question the need for COVID-19 booster vaccines during the upcoming fall and winter influenza season. Challenges to adequate immunization include inequitable vaccine distribution, lack of vaccine confidence, waning immunity, and the emergence of viral variants.[1] This newsletter will discuss the new COVID-19 bivalent booster vaccines, barriers to immunization, and tips for improving vaccine confidence.

Benefits of COVID-19 Vaccination:

- Reduce severity of illness
- Reduce risk of hospitalization
- Decrease risk of death

COVID-19 Primary Monovalent Vaccine Recommendations

Four COVID-19 vaccines are U.S. Food and Drug Administration (FDA)-approved to prevent COVID-19: Pfizer-BioNTech, Moderna, Novavax, and Johnson & Johnson's Janssen (J&J/Janssen). The Centers for Disease Control and Prevention (CDC) recommends the J&J/Janssen COVID-19 vaccine only be considered in certain situations due to the risk of serious, but rare adverse events, including thrombocytopenia and Guillain-Barre syndromes.[2] Individuals who are candidates for the J&J/Janssen vaccine include those who have had a severe reaction to an ingredient of the Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines); who would otherwise remain unvaccinated due to limited access to mRNA COVID-9 or Novavax vaccines; or who want to receive the J&J/Janssen COVID-19 vaccine despite safety concerns.[2]

The CDC recommends COVID-19 monovalent primary series vaccines for individuals ages 6 months and older, and COVID-19 monovalent boosters for individuals ages 5 years and older.[3] The monovalent vaccines only target the original SARS-CoV-2 alpha strain of the virus. Getting a COVID-19 vaccine after recovering from COVID-19 infection provides added protection against COVID-19.[3] CDC has stated the next vaccination can be delayed for 3 months from when symptoms started or, if individuals did not have symptoms, when they received a positive test.[4] Moderately or severely immunocompromised individuals have different recommendations for COVID-19 vaccines, including boosters.[3] This guidance can be accessed at the CDC website. Unless there are specific contraindications, vaccine providers should also offer to administer any other vaccines to eligible individuals at the time of the healthcare visit.[3]

COVID-19 Bivalent Booster Vaccine Recommendations

The initial monovalent mRNA Pfizer and Moderna vaccines induce short-term neutralizing antibody responses and protective efficacy.[1] However, the high initial serum neutralizing antibody titers induced by mRNA vaccines begin to wane by 3 to 6 months and decline further by 8 months, with a half-life of about 60 days.[1] The waning of immunity with mRNA vaccines is correlated with increased breakthrough infections in vaccinated persons.[1] In late 2021, the highly transmissible omicron (B.1.1.529) variant emerged and became the most prevalent virus globally.[1] In contrast to the 4 mutations in delta, omicron has more than 50 mutations, including more than 30 mutations in the spike protein, which result in substantial escape from neutralizing antibody responses elicited by vaccination or prior infection with a non-omicron variant.[1] Original monovalent vaccines may not provide robust protection against infection or transmission of currently circulating omicron subvariants.[1] The most important goal of COVID-19 immunization is to provide long-term protection against severe disease, including hospitalization and death.[3]

The FDA recently issued Emergency Use Authorization (EUA) for two new bivalent COVID-19 booster vaccines from Moderna and Pfizer-BioNTech that combine spike proteins from the original alpha variant and the omicron BA.4 and BA.5 subvariants, which match the virus strains currently circulating.[5,6] Pfizer-BioNTech's bivalent booster is authorized for individuals 12 years and older,[6] whereas Moderna's bivalent booster is authorized for individuals 18 years and older.[5] Dosing parameters for both vaccines are presented in **Table 1**. In late September 2022, Pfizer requested the FDA to expand use of its updated COVID-19 booster vaccine to children ages 5 to 11. Moderna also submitted a request for FDA authorization of its booster to children and adolescents aged 6 years and older. Both vaccines may be administered at least 2 months since the last COVID-19 primary vaccination or monovalent booster, regardless of the number of booster doses previously received.[5,6] Pfizer-BioNTech and Moderna monovalent vaccines are no longer authorized for use as a booster dose in individuals 12 years of age and older.[5,6] With the arrival of the updated boosters, CDC is reframing what it means to be up-to-date with COVID-19 vaccination. If individuals have completed the primary series and the most recent booster recommended by the CDC, they have completed the immunization series for COVID-19.

Table 1. COVID-19 Bivalent Booster Dosing (as of 9/22)

Manufacturer	Dose	Age
Pfizer-BioNTech	30 mcg/0.3 mL	≥ 12 years
Moderna	50 mcg/0.5 mL	≥ 18 years

The FDA based its decision for EUA of these bivalent vaccines on extensive safety and effectiveness data for each of the monovalent mRNA COVID-19 vaccines.[5,6] Clinical trials of both bivalent vaccines are ongoing. Influenza vaccines have long used a similar process that omits requirements for new clinical trials because the influenza virus mutates from year to year. As with all vaccines, safety monitoring will continue to be ongoing process through the FDA and CDC.

Of concern is whether individuals will choose to receive the bivalent booster dose. As of September 2022, CDC data show that while more than 262 million individuals within the U.S. (79% of the total population) have received their original primary vaccine series, only 109 million individuals, or half of those eligible, have received their booster vaccine.[7] There are disparities in first and second booster coverage by age group, sex, race and ethnicity; urban-rural classification; and primary series vaccine product.[8]
Booster and second booster dose vaccination coverage rates were lowest among the youngest age groups; males; Black, Hispanic, and multiracial persons; residents of rural counties; and Janssen primary series recipients.[8] Among age groups, the lowest booster dose coverage was among children aged 5–11 years (15.6%), followed by that among adolescents aged 12–17 years (33.4%).[8] Children aged 5–11 years were recommended to receive a booster dose most recently, which might partially explain the low coverage in this group.[8]
Understanding the factors contributing to low booster and second booster dose coverage among Black, Hispanic, and multiracial populations, and designing interventions to address these factors, is crucial to ensuring equitable access to COVID-19 vaccination.[8]

COVID-19 booster vaccines are fully covered under the Oregon Health Plan.

Find COVID-19 Vaccine Administration Sites

Vaccination Barriers

Children may face barriers in getting vaccinated not only for COVID-19 but for routine childhood vaccines, including:

- Children who are unable to establish routine care with a pediatrician — such as those who are experiencing limited access to housing or those who live in remote areas.[9]
- Children living in congregate settings — such as those who are incarcerated or detained or those who live in group homes.[9]
- Children historically and currently marginalized when it comes to healthcare — such as those in racial and ethnic minority groups or households with lower incomes.[9]
- Children who are non-English speakers, immigrants, or with undocumented status.[9]
- Children with developmental disabilities — such as cerebral palsy, autism spectrum disorder, or an intellectual disability.[9]
- Children who have special healthcare needs — such as lung, heart, or kidney disease, an immune system problem, malignancy, diabetes, some blood diseases, or conditions of the muscular or central nervous system.[9]

Improving immunization begins with taking a complete vaccination history from every patient.[10] Oregon's ALERT Immunization Information System is the best place to find immunization records for people who were vaccinated in Oregon. Individuals of all ages who are not up-to-date with their immunizations should be vaccinated, if eligible.[10] Pharmacists in Oregon can administer any vaccine to adults and children aged 7 years and older approved by the CDC Advisory Committee on Immunization Practices (ACIP) when done in accordance with current pharmacy immunization protocols.[11]

Vaccine Confidence

Increasing vaccine confidence is critical to protect against vaccine-preventable diseases.[10] Reasons for decreasing confidence varies, but should be addressed on a case-by-case basis.[10] Some people believe vaccines are no longer necessary while others lack trust in the health care system.[10] Some merely have concerns about vaccines and can be positively influenced by education and awareness, while other are adamantly opposed to vaccines altogether.[10] Others will allow vaccinations required for school while refusing others.[10] In 2021, most children received an influenza vaccine in a provider's office, but factors such as language, insurance status, and ability to take time off work reduces the ability from families to go to their primary care provider regularly.[9] Based on experience with influenza immunization challenges, alternative strategies are needed to reach children with COVID-19 vaccine boosters.[9]

All public health professionals and federal, state, and local partners are encouraged to:

- Use a health equity lens when framing information about health disparities.[9]
- Consider key communication principles: use person-first language (e.g., "a person with diabetes" instead of "a diabetic"); avoid unintentional blaming; use preferred terms for select population groups and communities while recognizing that there is not always consistent agreement on these terms.[9]
- Consider how communications, messages, and products are developed and look for ways to improve health equity and inclusivity.[9]
- Increase patient's vaccine confidence by using a motivational interviewing approach.[9]

Conclusions

The COVID-19 pandemic appears to be transitioning from a hyperacute phase to an endemic phase.[1] Recently approved COVID-19 bivalent booster vaccines will provide additional protection against contracting severe viral disease from emerging variants. Addressing barriers to vaccination and increasing vaccine confidence are vital to improving immunization.

Additional Information:

Health Education and Communication Tools

CDC Interim COVID-19 Immunization Schedule

Oregon Health Authority Pharmacy Immunization Protocols

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