FDA/CDC Issue Updates on the Use of Pfizer-BioNTech COVID-19 Vaccine Booster Doses

Issue

Following FDA expansions to the Pfizer-BioNTech COVID-19 Vaccine ("Pfizer") Emergency Use Authorization (EUA), data review and voting by the Advisory Committee on Immunization Practices (ACIP), and corresponding updates to the Interim Clinical Considerations by the CDC, **Pfizer additional (3rd) primary series doses** and **booster doses** are now ***authorized*** and ***recommended*** as follows:

- Children ages **5-11yr** having received a 2-dose Pfizer primary series AND with **moderate to severe immune compromise*** *may* receive a **single 0.2ml (Orange Cap) Additional (3rd) Pfizer primary dose** administered at least **28 days** after completion of the 2-dose series
- Individuals ages **12yr+** having received a 2-dose Pfizer primary series AND with **moderate to severe immune compromise*** *may* receive a **single 0.3ml (Purple Cap) Additional (3rd) Pfizer primary dose** administered at least **28** days after completion of the 2-dose series
- Individuals ages **12yr+** having completed a Pfizer primary series (2-3 doses) *should* receive a **single 0.3ml (Purple Cap) Pfizer booster dose** administered at least **5 months** after completion of the primary series

Pfizer Additional/Booster Dose Notable Considerations

- Heterologous ("mix and match") booster doses still allow for administering alternative available COVID-19 vaccine in eligible individuals after completion of the primary series with a different formulation.
- Adolescents age 12-17yr are currently ONLY eligible to receive Pfizer COVID-19 vaccines, and are NOT eligible for heterologous mix-and-matching to other booster dose formulations.
- Booster dose timing (interval) is based on the original primary vaccine series (i.e. Pfizer primary vaccine recipients may receive an appropriate heterologous booster ≥5 months later, regardless of booster dose formulation).
- Generally, CDC recommends the Pfizer or Moderna vaccines. J&J vaccine may be considered in some situations.
- Children ages 5-11yr have a unique Pfizer COVID-19 Vaccine formulation/dose, marked by an orange cap and label.
- * CDC provides guidance for patients/prescribers on who qualifies as moderately-severely immunocompromised.

See Page 4 for COVID-19 Vaccine Additional Dose/Booster Dose Decision Tree

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Background – Data Supporting Expanded EUA for Pfizer-BioNTech COVID-19 Vaccine Booster Doses

Per the FDA's Press Release:

A. Boosters are now authorized for people 12 years of age and older

- The agency has determined that the protective health benefits of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine to provide continued protection against COVID-19 and the associated serious consequences that can occur including hospitalization and death, outweigh the potential risks in individuals 12 – 15 years of age.
- The FDA reviewed real-world data from Israel, including safety data from more than 6,300 individuals 12 – 15 years of age who received a booster dose of the vaccine ≥5 months following completion of the primary series.
- These additional data enabled the FDA to reassess the benefits and risks of the use of a booster in the younger adolescent population in the setting of the current surge in COVID-19 cases.
- The data shows there are no new safety concerns following a booster in this population. There were no new cases of myocarditis or pericarditis reported to date in these individuals.

B. Booster interval updated to five months for people 12 years of age and older

- Since Pfizer initially submitted safety and effectiveness data on a single booster dose following primary vaccination, additional real-world data have become available on the increasing number of cases of COVID-19 with the omicron variant in the U.S.
- No new safety concerns have emerged from a population of over 4.1 million individuals 16 years of age and older in Israel who received a booster dose at least five months following completion of the primary vaccination series.
- Peer-reviewed data from multiple laboratories indicate that a booster dose of the Pfizer-BioNTech COVID-19 Vaccine greatly improves an individual's antibody response to be able to counter the omicron variant. Authorizing booster vaccination to take place at 5 months rather than 6 months may therefore provide better protection sooner for individuals against the highly transmissible omicron variant. Given the demonstrated safety and effectiveness of a booster dose when administered 5 months after primary vaccination, and the fact that a booster dose may help provide better protection against the rapidly spreading omicron variant, the FDA has determined that the known/potential benefits of administering a booster to individuals ≥12 years old and ≥5 months following completion of primary vaccination, outweighs the known/potential risks.

C. A third primary series dose for certain immunocompromised children ages 5 through 11

Children 5 through 11 years of age who have undergone solid organ transplantation, or who have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise, may not respond adequately to the two-dose primary vaccination series. Thus, a third primary series dose has now been authorized for this group. This will now allow these children to receive the maximum potential benefit from vaccination.

- The FDA previously authorized a third primary series dose for use as part of the primary immunization series in individuals 12 years and older. The potential effectiveness of an additional dose in children 5 through 11 years of age was extrapolated from data in adults.
- The agency used prior analyses conducted as part of the authorization process for healthy children to inform safety in this population and determined that the potential benefits of the administration of a third primary series dose at least 28 days following the second dose of the two-dose regimen, outweighed the potential and known risks of the vaccine. To date, the FDA and CDC have seen no new safety signals in this age group.

Timeline of Recent Events

FDA/CDC Issue Updates on the Use of Pfizer-BioNTech COVID-19 Vaccine Booster Doses

1/3/22: **FDA** publishes a press release detailing 3 EUA amendments for the Pfizer-BioNTech ("Pfizer") COVID-19 Vaccine:

- **A.** Pfizer booster interval (from completion of primary vaccine series) shortened from ≥6 months to ≥5 months.
- **B.** Authorization for additional (3rd) Pfizer primary series dose for select immunocompromised individuals dropped from ≥12yr to include children ages 5 – 11yr (note, different formulation and dose for children).
- **C.** Minimum authorized age for Pfizer booster dose dropped from ≥16 years to ≥12yr.

1/4/22: CDC updates interim clinical considerations to back EUA expansion items **A** and **B**:

- Recommends shortening Pfizer booster dose interval to ≥5 months.
- Recommends additional (3rd) Pfizer primary series dose for select immunocompromised individuals to include children ages 5 – 11yr (note, different formulation and dose for children).

1/5/22: **ACIP** convenes to review data on EUA expansion item **C**; votes 13-1 to endorse Pfizer booster dose in ages ≥12yr

1/5/22: **CDC** endorses ACIP's recommendation on EUA expansion item **C** and updates interim clinical considerations accordingly.

Additional Resources

- **PFIZER-BIONTECH COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine** (*updated 01/03/22*)
- **MODERNA COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine** (*updated 12/09/21*)
- **JANSSEN COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine** (*updated 12/14/21*)
- **CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States**
- **CDC's COVID-19 Vaccine Booster Shots**

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COVID-19 Vaccine Additional Dose/Booster Dose Decision Tree

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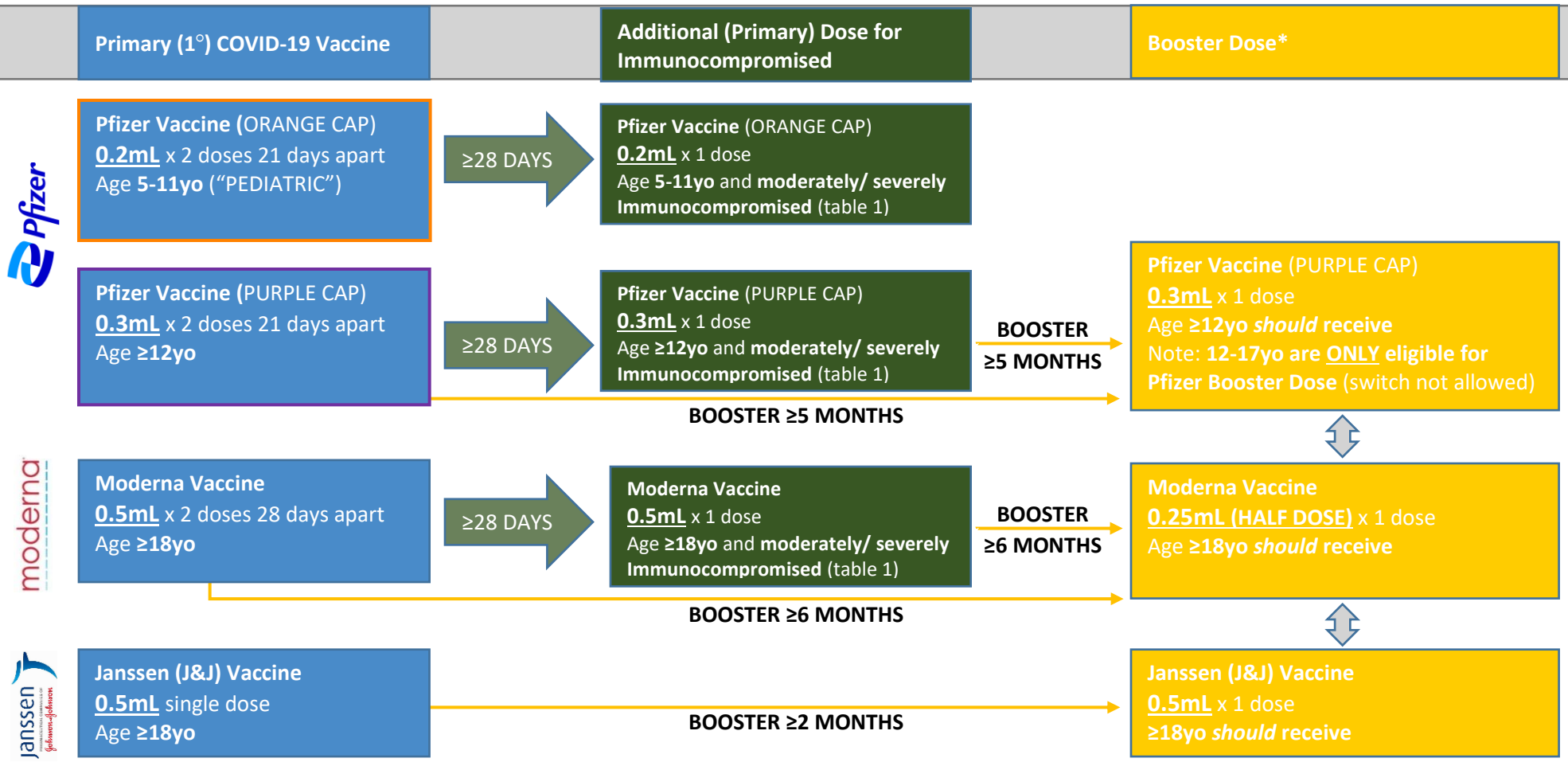

Table 1. CDC Definition of Moderate to Severe Immunocompromise

Undergoing active cancer treatment Organ transplant recipient
Stem cell transplant recipient ~2 years
Taking medication to suppress the immune system
Moderate or severe primary immunodeficiency
Advance or untreated HIV infection
Active treatment with high dose corticosteroids

Primary mRNA vaccine recipients meeting criteria for additional dose(s) should get a matching mRNA vaccine to the primary series. If not feasible, giving either one of the mRNA vaccines is appropriate.

* FDA authorized **heterologous ("mix and match") booster doses**, allowing for an alternative available COVID-19 vaccine to be used as a booster dose in eligible individuals after completion of 1° vaccination.

Booster dose timing (interval) is based on the original 1° vaccine series (i.e. Pfizer 1° vaccine recipients may receive a booster ≥5 months later, regardless of booster dose formulation).

CDC recommends the Pfizer or Moderna (mRNA) vaccines as generally preferred. J&J vaccine may be considered in some situations.

For informational purposes only. Information is subject to change and users should reference primary FDA EUA Factsheets and the CDC Interim Clinical Considerations for COVID-19 Vaccines for current information. PharMerica© January 5, 2022.