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To: Maine Immunization Providers
From: Maine Immunization Program
Subject: Updated Interim Clinical Considerations for COVID-19 Vaccination Guidance
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As of Feb. 19, 2022, nearly 215 million people in the U.S. have been vaccinated with COVID-19 vaccines, and nearly 93 million have received a booster dose.

COVID-19 vaccines have undergone—and will continue to undergo—the most intensive safety monitoring in U.S. history. Evidence from the hundreds of millions of COVID-19 vaccines already administered in the U.S., and the billions of vaccines administered globally, demonstrates that they are safe and effective.

Following a thorough evaluation of the latest safety and effectiveness data, CDC is providing new information to help healthcare providers recommend the optimal COVID-19 vaccination schedule based on the individual patient. This updated guidance is specific to the mRNA (Pfizer-BioNTech or Moderna) COVID-19 vaccine primary series and is only for some patients who are not yet vaccinated.

Updates include the following:

- People ages 12 through 64 years who are not are not moderately or severely immunocompromised—and particularly males ages 12 through 39 years—may benefit from getting their second mRNA COVID-19 vaccine dose 8 weeks after their first dose, instead of after the FDA-approved or FDA-authorized 3-week (Pfizer-BioNTech) or 4-week (Moderna) interval. The potential benefits of this extended interval are two-fold:
 - Stronger immune response—Data show that a longer interval between the first and second doses may give the body a chance to build a stronger immune response, increasing the effectiveness of these vaccines.
 - Further minimization of the already rare risk of adverse events—[New studies](#) have shown the small risk of myocarditis and pericarditis associated with mRNA COVID-19 vaccination—mostly among males between the ages of 12 and 39 years—might be reduced with a longer interval.

It's important to note that patients who meet these criteria and have already received their primary mRNA series at the 3-week (Pfizer-BioNTech) or 4-week (Moderna) interval remain well-protected—especially if they have received a booster dose—and do **not** need to repeat any doses.

The extended interval is **not** recommended for all people ages 12 through 64 years, and there are situations where providers should continue to recommend the 3-week (Pfizer-BioNTech) or 4-week (Moderna) intervals between primary doses. These include when there is concern about high levels of community transmission, and among people who are moderately or severely immunocompromised. In addition, the extended interval is not recommended for anyone ages 65 years or older.

Healthcare providers are a valued and trusted source of health information and can play a key role in a patient's decision to get vaccinated. This new guidance is intended to help inform clinical decision-making by giving providers additional information to tailor vaccine recommendations based on the patient.

The interval between COVID-19 mRNA vaccine doses is best determined by considering the balance of risks and benefits, based on the individual’s age and health conditions. Regardless of the interval between the first and second dose, [data](#) show mRNA vaccines remain [highly effective](#) at reducing the risk of hospitalization or serious complications from COVID-19 infection.

The COVID-19 vaccination primary series schedule, with updates highlighted:

Primary series vaccine manufacturer	Age group	Number of doses in primary series	Number of booster doses	Interval between 1 st and 2 nd dose *	Interval between primary series and booster dose
Pfizer-BioNTech	5–11 years	2	NA	3 weeks	N/A
Pfizer-BioNTech	≥12 years	2	1	3-8 weeks**	≥5 months
Moderna	≥18 years	2	1	4-8 weeks**	≥5 months
Janssen	≥18 years	1	1	NA	≥2 months

*For the vaccination schedule for people who are moderately or severely immunocompromised, see [Table 3](#).

**An 8-week interval may be optimal for people ages 12 years through 64 years, and especially for males ages 12 through 39 years, who are not moderately or severely immunocompromised. A shorter interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second dose remains the recommended interval for: people who are moderately or severely immunocompromised; adults ages 65 years and older; and others who need early protection due to increased concern about community transmission or risk of severe disease.

Below is a list of resources and upcoming informational activities related to the recommendation:

- Updated [Interim Clinical Care Considerations for COVID-19 Vaccination](#)
- COCA call, 2/24/22 - https://emergency.cdc.gov/coca/calls/2022/callinfo_022422.asp

Q & A:

Q: Can you explain this new guidance that CDC is providing related to dose intervals for mRNA primary series vaccination?

A: CDC is providing healthcare providers with additional information to factor into COVID-19 vaccine recommendations for their patients. Some people ages 12 through 64 years—and especially males ages 12 through 39 years—may benefit from getting their second mRNA COVID-19 vaccine dose 8 weeks after receiving their first dose, instead of after the FDA-approved or FDA-authorized 3 weeks (Pfizer-BioNTech) or 4 weeks (Moderna). Recent safety and effectiveness [data](#) illustrate that a longer time interval between the first and second mRNA COVID-19 vaccine dose gives the body a chance to build a stronger immune response, increasing the effectiveness of these vaccines, and offering individuals greater protection against COVID-19. A longer interval between primary doses can also help lower the rare risk of myocarditis and pericarditis following vaccination. Although rare, some cases have been reported—mostly among adolescent and young adult males—after receiving the Pfizer-BioNTech or Moderna vaccines.

Q: For whom might an 8-week interval between the 1st and 2nd doses of mRNA COVID-19 vaccines be especially optimal?

A: The 8-week interval is optimal for patients ages 12 through 64 years—and particularly males ages 12 through 39 years—who are not moderately or severely immunocompromised, and for whom there is not increased concern about community transmission or severe disease.

Q: Would an interval between the 1st and 2nd doses of mRNA COVID-19 vaccines longer than 8 weeks be even better?

A: Extending the interval beyond this time has not been shown to provide additional benefits.

Q: Are mRNA vaccine doses administered later than the recommended interval valid?

A: mRNA vaccine doses administered at any time after the recommended interval are valid and do not need to be repeated.

Q: For whom might the FDA-approved or FDA-authorized 3- or 4-week intervals between 1st and 2nd doses of mRNA COVID-19 vaccines continue to be optimal?

A: Vaccine providers should continue to recommend the 3- or 4-week interval for patients who are at higher risk of having an inadequate response to the first mRNA vaccine dose (such as people who are moderately or severely immunocompromised), patients who are at higher risk for severe complications of COVID-19 (such as adults ages 65 years and older), and patients who need rapid protection, such as during high levels of community transmission. Providers can help patients determine the best interval between vaccine doses by examining their balance of benefits and risks.

Q: Why are children ages 5-11 years not recommended to consider a longer interval between the 1st and 2nd doses of mRNA COVID-19 vaccines?

A: There are currently no data available for children younger than age 12 years regarding any impact of intervals longer than 3 weeks between the 1st and 2nd doses of the Pfizer-BioNTech COVID-19 vaccine, which is an mRNA vaccine. Children younger than 12 years are not eligible for any other COVID-19 vaccine at this time.