

PES **PEDIATRIC ENDOCRINE SOCIETY**

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COVID-19 Vaccination for Children with Endocrine Disorders

A statement by PES Drugs and Therapeutics Committee

On May 10, 2021, the United States Food and Drug Administration (FDA) approved the Pfizer-BioNTech COVID-19 vaccine for adolescents 12-15 years of age based on an Emergency Use Authorization. This was a welcome advance that makes ~87% of the U.S. population now eligible for a COVID-19 vaccine.

Although children are less likely to get a severe COVID-19 infection than older individuals, infections in children are not uncommon. While most of these infections cause mild symptoms, some children may develop a severe inflammatory syndrome called multisystem inflammatory syndrome in children (MIS-C). Some children also experience prolonged fatigue, respiratory complications, and gastrointestinal problems that may last long after the initial COVID-19 infection. Avoiding infection will prevent the risk of these COVID-19-related complications.

Similar to the dosing regimen for those 16 years and older, the Pfizer-BioNTech COVID-19 vaccine is administered as a series of two doses given 21 days apart. The FDA evaluated data on over 1,100 children who received the vaccine and over 1,100 children who received placebo. The vaccine was 100% effective in preventing infection and produced immunity similar to that seen in older age groups. Starting 7 days after the second dose, no cases occurred in those who received the vaccine. The most common side effects were pain at the injection site, tiredness, headache, chills, muscle pain, fever, and joint pain. Symptoms typically lasted for 1-3 days, and except for pain at the injection site, they were more common after the second dose. Of note, patients with a history of COVID-19 infection with or without MIS-C were not included in the trial. Per current recommendations, patients with a history of COVID-19 infection should also be vaccinated. Those who developed MIS-C may consider getting the vaccine after recovery and at least 90 days after the diagnosis of MIS-C if benefits outweigh risks. Based on experience with adults, some vaccine recipients may not experience side effects and this does not relate to (or reflect) vaccine efficacy. Patients who have had an allergic reaction to any component of the Pfizer-BioNTech COVID-19 vaccine should not get the vaccine.

Please refer to Center for Disease Control's website as well as any applicable regional laws, rules and regulations for the most up-to-date information on mask-wearing and social-distancing guidelines for fully vaccinated individuals. We are still in very early stages of understanding the durability of protection from the vaccine against current and future variants of COVID-19 and there is inadequate evidence at this time to provide formal recommendations regarding this.

This vaccine does not have any known hormonal effects and hence should not interfere with puberty, growth, or other hormonal processes of the body. At this time, the COVID-19 vaccine is not associated

with an increased risk of side effects in patients with diabetes mellitus (DM) or other endocrine disorders. However, there are limited data on vaccine protection in immunocompromised individuals and those taking immunosuppressive medications; such patients should ask their healthcare provider/s if they need to continue masking and social distancing after vaccination. The Pfizer-BioNTech vaccine has not been associated with an increased risk of thrombosis. There is currently no recommendation to discontinue or change contraceptive methods or estrogen/progestin therapy in adolescent girls or women who have received or plan to receive any of the currently approved COVID-19 vaccines. There is also no link between COVID-19 vaccination and pregnancy loss or infertility.

Considerations for patients with endocrine disorders, including diabetes mellitus or other underlying medical conditions:

About 1 in 5 patients in the pediatric vaccine study trial had an underlying medical condition, some of whom had diabetes. Half of the subjects had obesity. Patients with autoimmune conditions were also eligible to participate. However, no data are currently available regarding the safety and efficacy of COVID-19 vaccines specifically in people with autoimmune conditions. Similarly, no data are available for conditions such as adrenal insufficiency or growth hormone deficiency. There are no known contraindications to the vaccine in individuals taking growth hormone injections based on expert opinion.

The Pfizer-BioNTech COVID-19 vaccine may be administered without regard to timing of corticosteroid treatment (including hydrocortisone, prednisone, prednisolone, dexamethasone, and fludrocortisone). Thus, patients with adrenal insufficiency can take the vaccine at any time irrespective of their medication timing. Patients with adrenal insufficiency/Addison disease do not require pre-treatment with stress doses before vaccination. However, if they develop fever, chills and/or extreme fatigue after a COVID-19 vaccine dose, it is prudent to take stress doses of their glucocorticoid medication (typically 2-3 times their maintenance/daily dose) for at least 24 hours after resolution of symptoms/fever. Patients with diabetes may need to monitor blood glucose levels more frequently and/or check for ketones if feeling unwell after vaccine administration

Pfizer-BioNTech plans to monitor vaccine trial participants for up to 2 years after the second dose for any long-term side effects and will report these findings to the FDA. On June 25th 2021, after an extensive review of relevant information, the FDA announced that the Pfizer-BioNTech (and Moderna) vaccines were associated with a risk of myocarditis and pericarditis, particularly following the second dose. Hence, if patients develop symptoms of chest pain, shortness of breath or rapid heartbeat after vaccination, they should seek immediate medical attention. Patients should discuss any concerns related to the COVID-19 vaccine and underlying endocrine disorders with their endocrinologist or primary care physician.

Addition resources/ reference:

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use> accessed on May 19th 2021

<https://www.cdc.gov/media/releases/2021/s0512-advisory-committee-signing.html> accessed on May 19th 2021

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html> accessed on July 7th 2021

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/underlying-conditions.html> accessed on May 24th 2021

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#underlying-conditions> accessed on May 24th 2021

<https://abcnews.go.com/Health/teens-now-covid-vaccines-experts-impact-fertility/story?id=77673356> accessed on May 19th 2021

<https://www.fda.gov/media/148542/download> accessed on May 24th 2021

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care?utm_source=redirect&utm_medium=web&utm_campaign=int accessed on June 10, 2021

https://www.britishfertilitysociety.org.uk/wp-content/uploads/2021/02/Covid19-Vaccines-FAQ-1_3.pdf accessed on July 7th 2021

<https://www.cincinnatichildrens.org/patients/coronavirus-information/vaccines/fertility> accessed on July 7th 2021