Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



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Vision: To be the Healthiest State in the Nation

Guidance for Pediatric COVID-19 Vaccines

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Florida recognizes that parents should always be empowered to make the best health decisions for their children. It is essential that health care practitioners review all data to evaluate risks and benefits unique to each patient when determining what health care services to provide, including the administration of COVID-19 vaccines. These decisions should be made on an individual basis. As the risks of administering a COVID-19 vaccine to healthy children may outweigh the benefits, the Florida Department of Health has issued the following guidance:

Based on currently available data, healthy children aged 5 to 17 may not benefit from receiving the currently available COVID-19 vaccine. The Department recommends that children with underlying conditions are the best candidates for the COVID-19 vaccine.

At the present time, there are certain risks to consider that may outweigh benefits among healthy children with no underlying conditions:

- Limited risk of severe illness due to COVID-19
- High prevalence of <u>existing immunity</u> among children
 - Absence of data informing benefit of COVID-19 vaccination among children with existing immunity.
- In clinical trials, higher than anticipated <u>severe adverse events</u> occurred among those receiving the COVID-19 vaccine.
- Reduced COVID-19 vaccine efficacy among children 5-17
- Risk of myocarditis due to the COVID-19 vaccine

For children with underlying health conditions or comorbidities, COVID-19 vaccines should be considered in consultation with your health care practitioner. Parents are encouraged to discuss the risks and benefits with their children's health care practitioner when evaluating whether their child should receive a COVID-19 vaccine, particularly for children with underlying health conditions or comorbidities.

In general, healthy children with no significant underlying health conditions under 16 years old are at little to no risk of severe illness complications from COVID-19. For adolescents 16 to 17 years of age, the risk of myocarditis due to the COVID-19 vaccines may outweigh the benefits.

Healthy Children Ages 5 to 11

In a <u>clinical</u> trial, there were no cases of severe illness among children ages 5 to 11 among any placebo recipients or COVID-19 vaccine recipients. A <u>study conducted out of New York</u> determined that COVID-19 vaccine efficacy declined 84%, from 68% to 12%, over a span of two months for children aged 5 to 11.

Healthy Adolescents Ages 12 to 17

The <u>same study</u> determined that COVID-19 vaccine efficacy declined 40%, from 85% to 51%, over a span of two months for adolescents ages 12 to 17. There is also concern for the risk of myocarditis and pericarditis in children, especially among adolescent boys. <u>One study found the highest rates of myocarditis</u> among males ages 12 to 15, followed by adolescent males ages 16 to 17 years old.

FDA Vaccines and Related Biological Products Advisory Committee

During FDA's Vaccine Advisory Committee, multiple advisors voiced concerns over COVID-19 vaccination among healthy children. This debate can be found <u>here</u>.

FDA Advisor Dr. Mark Sawyer: "We're all concerned about the myocarditis issue, and I do think the model has overestimated the hospitalizations prevented. I do think we need it as a tool for high-risk children."

FDA adviser Dr. James Hildreth: "I do believe children at high risk should be vaccinated but vaccinating all the children to achieve that just seems a bit much for me."