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AAP News

Experts provide update on 'essential' COVID-19 vaccine trials in children, teens

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Editor's note: For the latest news on COVID-19, visit <http://bit.ly/AAPNewsCOVID19>.

Health officials expect to see progress on COVID-19 vaccine trials in adolescents over the next several months and are stressing the importance of vaccines in fighting the pandemic.

"While the overall burden of COVID may be lower among children, preventable infections, hospitalization and long-term sequelae and deaths are an important public health problem. Clinical trials to evaluate safety and immunogenicity of COVID vaccines in children are essential," Sara Oliver, M.D., M.S.P.H., a medical officer with the Centers for Disease Control and Prevention (CDC), said Wednesday at a meeting of the CDC's Advisory Committee on Immunization Practices (ACIP).

Experts at the meeting provided updates on a variety of vaccine-related issues, including pediatric trials and adult safety data. At the same time, a White House press briefing provided an update on equitable vaccine distribution.

Pediatric vaccine trials

More than 2 million pediatric cases of COVID-19 have been reported and more than 200 children have died, **according to the CDC**. The rates of reported cases are lower than any other age group, but CDC medical officer Angela Campbell, M.D., M.P.H., FPIDS, FIDSA, said there likely is a significant undercount due to many cases being mild. The CDC estimates actual case rates for children ages 5-17 years may be close to those for ages 18-49.

Children's rates of hospitalization and death also are significantly lower than adults. However, pediatricians have been concerned about a rare but serious condition linked to COVID-19 known as multisystem inflammatory syndrome in children. At least 1,659 cases have been reported nationwide and 26 children have died.

Emily Erbelding, M.D., M.P.H., director of the Division of Microbiology and Infectious Diseases at the National



Institute of Allergy and Infectious Diseases, highlighted the need for pediatric COVID-19 vaccine trials.

"The pediatric burden of disease is not as high as it is in older adults but it still is significant," Dr. Erbeling said at the ACIP meeting. "... There's a disproportionate burden among children in minority communities, and there's both direct and indirect effects to children and all of society. This burden will continue if we don't vaccinate and we just wait for herd immunity to occur over time."

The Pfizer-BioNTech vaccine has been authorized for people as young as age 16 and is the only one authorized for any youths. Pfizer recently announced that its trial in adolescents ages 12-15 is fully enrolled and it could seek authorization in the first half of this year, according to Dr. Erbeling.

Moderna's vaccine has been authorized down to age 18, and it is **enrolling adolescents ages 12-17** in trials. Janssen is expected to seek emergency use authorization of its vaccine for adults in the next several weeks and could start trials in adolescents about four to six weeks later, Dr. Erbeling said. AstraZeneca's Phase 3 trial in U.S. adults is ongoing, and it could start trials in adolescents early this year.

Over the next several months, all four companies are expected to work on planning for trials in younger children, which may involve testing vaccines at lower doses than for adults.

Vaccine safety

Roughly 23.5 million COVID-19 vaccine doses have been administered, and the country has implemented "the most intensive and comprehensive vaccine safety monitoring program in history," according to Tom Shimabukuro, M.D., M.P.H., M.B.A, a member of the CDC's COVID-19 Vaccine Task Force.

The national Vaccine Adverse Event Reporting System has received 9,096 reports. Of those, 89% were nonserious adverse events and 11% were serious. For every million doses of COVID-19 vaccine administered, about 372 nonserious adverse events and 45 serious adverse events have been reported.

Data from vaccine recipients using the new smartphone tool, the Vaccine Safety Assessment for Essential Workers, show the most common reactions are pain, fatigue, headache and myalgia.

Health officials are closely monitoring reports of anaphylaxis but said they are rare, occurring in five of every million doses of the Pfizer-BioNTech vaccine and 2.8 per million doses of Moderna vaccine.

"Overall, the safety profiles of COVID-19 vaccines are reassuring and consistent with that observed from the pre-authorization clinical trials," Dr. Shimabukuro said.

Equitable vaccine distribution

At the first COVID-19 Response Team White House press briefing today, Marcella Nunez-Smith, M.D., M.P.H., chair of the **COVID-19 Health Equity Task Force**, discussed plans to ensure equitable distribution of COVID-19 vaccine. Established within the Department of Health and Human Services (HHS), the task force will include the HHS secretary, up to 20 members from outside the federal government (to be appointed by the president) and leaders invited by the chair.

"By race, ethnicity, sexual orientation, gender identity, disability, geography and based on where you live, COVID-19 is leaving a terrible imprint on far too many communities," Dr. Nunez-Smith said.

She said the task force will make recommendations related to allocation of COVID-19 resources and relief funds, culturally aligned communication and messaging, data collection and future pandemic preparedness. Task force actions to advance equity include cutting out-of-pocket expenses for vaccines, removing barriers to



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access (e.g., through mobile vaccine clinics), boosting support for Federally Qualified Health Centers and other venues, and supporting states building equity into pandemic plans.

Other highlights from the briefing:

- HHS is amending the Public Readiness and Emergency Preparedness Act to permit doctors and nurses who retired or became inactive recently to administer the vaccine and to permit anyone licensed to vaccinate in their state to administer shots across state lines.
- Six percent of the population has received one or more doses of vaccine.
- The U.S. stockpile has only two to three days' supply of vaccine.

Resources

- [CDC guidance for health care providers on administering the Pfizer and Moderna vaccines](#)
- [AAP FAQ on COVID-19 vaccines](#)
- [AAP interim guidance on COVID-19](#)