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Moderna, Pfizer Test mRNA Experimental Biologics on Children

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On Dec. 10, 2020, American biotechnology company Moderna, Inc., which is pioneering the development of experimental messenger RNA (mRNA) therapeutics and vaccines, gave a 12-year old a dose of the company's mRNA-1273 vaccine in a Phase 2/3 study of the new vaccine. Moderna CEO Stephane Bancel said, "Our goal is to generate data in the spring of 2021 that will support the use of mRNA-1273 in adolescents in advance of the 2021 school year".[1]

Moderna was granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) on Dec. 18, 2020 for administration of the experimental COVID-19 biologic to adults 18 years or older. The estimated study completion date is June 30, 2022.[2]

Moderna Admits Struggling to Find Tweens and Teens Willing to Sign Up

Moderna needs to enroll at least 3,000 adolescent participants to provide valid safety and efficacy data, and to get authorization from the FDA for the COVID-19 biologic to be administered to children as young as age 12.[3] However, by mid-January, the company acknowledged it was struggling to find enough adolescent volunteers,[4] which will potentially delay FDA authorization for the mRNA coronavirus vaccine to be given to this age group.[5]

Moncef Slaoui, PhD, the scientific head of the previous administration's Operation Warp Speed COVID-19 vaccination program expressed concern about having trouble getting adolescent volunteers to enroll in clinical trials. On Jan. 12, 2020 he said that, while a vaccine trial in adults is accruing 800 volunteers per day, the teen trial is getting only about 800 per month.[6]

The Moderna teen trial, called TeenCove, expects to enroll adolescents at up to 15 sites nationwide.[7] Katherine Luzuriaga, MD, principal investigator at the University of Massachusetts Medical Center, one of the 15 clinical trial sites, said study participants will receive either the experimental biologic or a saline placebo in a 2:1 ratio.

Those receiving the experimental biologic will receive two doses of 100 micrograms each, given 28 days apart, as is authorized for adults. Participants will be followed for one year after receipt of the second dose.[8] They're hoping to enroll children from diverse communities, especially those in Black and other minority communities which reportedly have been the most severely affected by COVID-19. Study participants must be between 12 and 17 years old, in good health, and have never tested positive for COVID-19.

In its "Frequently Asked Questions" section, TeenCove states that, "compensation for your family's time will be available. We realize it takes time to come for study visits, so we want to make sure this is not too much of a burden for you and your child. The study site will review these details with you."[9]

"Hard for Parents to Justify" Enrolling Children in COVID-19 Clinical Trials

Yvonne Maldonado, MD, an infectious disease specialist at Stanford University School of Medicine and chair of the committee on infectious diseases for the American Academy of Pediatrics (AAP), said it's crucial to get vaccine data for children of all ages. She said, "Many of us want to see kids vaccinated—for their own safety of course, but also because it really reduces the chain of transmission." She observed that the fact that COVID-19 is usually so mild in minors makes it hard for parents to justify enrolling their kids in trials. "If the disease were something that was very clearly impacting them in a hugely negative way, you'd probably see more interest there," she said.[10]

On Jan. 22, 2020 Pfizer, Inc. announced it had finished enrolling children between 12 and 15 years old in a study testing its COVID-19 biologic, as they seek to expand the shot's use among different age groups. The study, which was announced in October, had enrolled over 2,000 participants, a Pfizer spokeswoman said in an emailed statement to *Reuters*.[11]

To Test or Not to Test COVID-19 Vaccines in Children?

Nationwide through Jan. 31, 2021, the U.S. Centers for Disease Control and Prevention (CDC) reported there were 267 deaths attributed to COVID-19 in ages 0-17, which accounted for less than 0.1 percent of all deaths in the U.S since the beginning of the pandemic. Persons over 65 years of age accounted for 81 percent of all deaths.[12]

Waiting until vaccines appear safe to test them in children is a common practice, as children's biological responses to vaccination can be different than adult responses. Some doctors think testing in children should begin sooner than later, continuing the current overall push to expedite the development and distribution of COVID-19 vaccines to all age groups. Others have argued that because children are less likely to have severe complications or die if they become infected with SARS-CoV-2, the risks of testing COVID-19 vaccines on them could actually be greater than those posed by the severe disease symptoms the shots are designed to prevent.[13]

The FDA convened a panel of outside experts for its Vaccines and Related Biological Products Advisory Committee (VRBPAC) that met on Oct. 22, 2020 to review data and advise the agency on candidate coronavirus vaccines. Members of the FDA advisory committee expressed several serious concerns about the testing and approval process. Luigi Notarangelo, MD, chief researcher at the National Institutes of Health (NIH) said:

> I think children at this point should not be considered for use of this vaccine until there is sufficient evidence that it's safe for them, and what we've been presented today does not provide that.[14]

Pressure to return children to school may make testing vaccines in children more urgent, but Anthony Fauci, MD, the nation's top infectious disease expert, states it's "an extra added benefit when we get the vaccine for the kids," but that it is not a prerequisite for reopening. That sentiment has been echoed by many teachers' groups and medical experts. "There's very little concern or sense that school shouldn't be open because the kids aren't vaccinated," said Colin Sharkey, the executive director of the Association of American Educators.[15]

"This year has been the strangest anyone has ever experienced," said Lisa Brown, a mother whose 15 year-old son is enrolled in the adolescent arm of the Pfizer mRNA study. "It's important for this age group to get vaccinated so that they can go back to school, and things can go back to normal."[16]

Many parents are "more afraid of COVID than the vaccine," according to Laurie Evans, whose 16-year-old daughter is enrolled in the Pfizer study.[17] But fear is only one element that would attract the thousands of American families Pfizer and Moderna need to enroll children for pediatric clinical trials. Many medical researchers and health officials are also emphasizing the concept that enrolling in COVID-19 vaccine experiments and getting vaccinated is for "the greater good," suggesting that "getting a vaccine, when it's available, is not just about you. It's about protecting your grandmother who has diabetes and Uncle Sean, who is immune-compromised."[18]

Limited Long-Term Follow-Up of Pfizer, Moderna COVID-19 Biologics

So far, both the Pfizer and Moderna mRNA COVID-19 biologics are believed to be generally tolerable, with most of the reported short-term side effects including fever, chills, fatigue, headache and injection site pain and swelling.[19] However, clinical trials only included thousands of participants followed up for a few months. Important safety data won't be available until they have been followed for many more months and even years.

Pfizer and Moderna have promised to collect and disclose follow-up clinical trial safety and efficacy information when it becomes available.[20] However, long-term follow-up for conditions such as cancer and autoimmune diseases will become difficult, if not impossible, if the vaccine makers hasten to offer their vaccines to the placebo groups, which will completely erase the ability for researchers to compare or evaluate potential long term differences in health outcomes among the vaccinated and placebo groups.

Moderna and Pfizer executives have both suggested that the COVID-19 vaccine clinical trial participants, who received a placebo, should be vaccinated.[21]

The challenge of keeping children in the study long enough to evaluate longer-term consequences of the vaccine is well articulated by mother Laurie Evans. She is concerned that the two-year commitment to which her daughter agreed as a COVID-19 vaccine clinical

trial participant means that, if she received a placebo, she might be discouraged from getting the actual vaccine when it is approved since that would compromise the ongoing research.

Her daughter is also concerned about that scenario, especially if her school requires students to be vaccinated in order to attend. Evans reports that Pfizer has been surprisingly vague on that point so far and has not yet spelled out what it will expect from placebo recipients.

Vaccine Experiments on Children Have Cruel Past

From 1950 to 1972, Saul Krugman, MD conducted hepatitis vaccine trials on disabled children aged five to ten years old at the Willowbrook State School on Staten Island in New York. One parent, Dianna McCort, said she was "desperate" to find a placement for her daughter. She described how Dr. Krugman offered to jump the long waitlist and put her daughter in the newer, cleaner research wards with more staff, but only if she allowed her daughter to be enrolled in the hepatitis B vaccine experiments.

"I did feel coerced," McCort said, "I felt like I was denied help unless I took this [opportunity]." Dr. Krugman also told parents that since hepatitis was already prevalent at Willowbrook, their children may as well have the chance to not contract hepatitis B by getting the experimental hepatitis B vaccine.[22]

Willowbrook was one in a long line of human experiments on children, prison inmates, people in mental health facilities, and minority populations in the U.S.. In 1974, the National Research Act was passed in an effort to create regulations that protected subjects in human research trials. The Act created an ethics task force, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Vaccine experiments carried out without parental consent on babies and young children in Mother and Baby homes in Ireland during the 1960s violated the Nuremberg Code created by an international war crimes commission after horrific Nazi experiments on children during World War II were discovered. Patrick Meenan, MD, who led the vaccine program in Ireland and was also a key government advisor on the issue, stated: "There was a tradition of doing testing in orphanages. You went to where the material was to put it crudely."[23]

"Mistakes with vaccines can erode the public's trust"

In the Philippines, 600 child deaths are currently under investigation after children received the Sanofi-Pasteur dengue vaccine, Dengvaxia. Fourteen government officials have been indicted for acting with "undue haste" in procuring the vaccine and launching the mass immunization campaign before the clinical trials were finished.

The debacle in the Philippines offers a key lesson for governments and manufacturers when it comes to approving and selling new vaccines. Physician and bioethicist Keymanthri Moodley, who directs the Centre for Medical Ethics and Law at Stellenbosch University in South Africa, advises researchers and public health officials to "slow down" because mistakes with testing vaccines can erode the public's trust and have long-term consequences for the health of an entire country. He said,

> When a vaccine goes wrong, it creates fear and anxiety in terms of the public, especially the parents. That fear can impact negatively on the established immune programs that are actually safe and work very well.[24]

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Notes

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