

LOCAL

Kentucky kids in COVID-19 vaccine trials make 'history' in fight against virus

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LOUISVILLE, Ky. — Amelia Krause, 10, figured a simple diagram was the best way to explain to her younger brother, Drew, 8, their roles in a Louisville-based COVID-19 vaccine trial for kids.

Two-thirds of participants would get the vaccine, but the other third would get a placebo.

So, she drew a pie chart with squiggles and squares to show who would get the real shot: squiggles, "you get it," squares, "you don't."

"I got a sticky note out and drew it for him," Amelia said. "He's like, 'Oh, now I get it!'"

Amelia's drawing wound up on the cover of a medical journal, and she and her brother wound up in history as Patient 1 and 2 of a Louisville-based clinical trial, part of an international effort that led to the recent expansion of the Pfizer-BioNTech COVID-19 vaccine to children ages 5-11.

Drew was the first to enroll in June, followed by his sister, in the trial that now includes 90 children.

"It is part of history," said Dr. Gary Marshall, principal investigator for the trial held by the Norton Children's Research Institute, affiliated with the University of Louisville School of Medicine.

For Marshall, who submitted Amelia's drawing to the Journal of the Pediatric Infectious Diseases Society, the trial is the highlight of his 35-year career of treating and researching childhood diseases and vaccines.

"Nothing has been more meaningful to me than being in this trial," Marshall said. "I didn't develop the vaccine. I didn't design the protocol. But we, Norton Children's and U of L, had a small part in bringing this vaccine to approval, and that's going to save lives.

"It's one of the most rewarding things I've ever done."

'I'm helping my baby'

Parents of participants in the trial said advancing vaccine research influenced their decision, but a chance at getting their kids protected from COVID-19 was a powerful motivation.

"We wanted to help others," said Shawna Henderson, of La Grange, who has four children ages 3 through 8 enrolled in the trial. "But we also wanted to get our children vaccinated."

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She and her husband, Marty Henderson, are especially concerned about their youngest child, Rylee, 3, who has cystic fibrosis, a disease that can impair the lungs and other organs. That puts her at greater risk from COVID-19, which can attack the lungs and affect breathing.

"She is healthy, and we want her lungs to stay that way," Shawna Henderson said.

Of their three older children, Haylee, 6, and Garrett, 5, both got the Pfizer vaccine during the trial. Their older brother, Wyatt, 8, got the placebo, but was able to get the vaccine as soon as it was approved last month.

"We were so excited and happy for them," Henderson said.

The children all had different reactions to the trial process.

Wyatt, she said, was more quiet and reserved. Garrett had lots of questions.

And Haylee was very pleased about being vaccinated, saying: "I'm helping my baby," meaning her younger sister, Henderson said.

The family is still waiting to learn whether Rylee got the real vaccine or a placebo. They should learn that once the vaccine is approved for children her age, Henderson said.

The family is thrilled to be a part of the ongoing study that lasts about two years.

"The reason our world has life-saving medications is that people have volunteered to be in these trials," Henderson said.

The new 'polio pioneers'

Kentucky medical institutions and some private facilities have played a key role in COVID-19 vaccines development for children and adults, with all three vaccines approved for use having been tested in trials in the commonwealth.

Marshall, chief of pediatric infectious diseases at Norton Children's Hospital, compares the clinical trials for a children's COVID-19 vaccine to trials of the 1950s that enrolled more than 1 million kids as "polio pioneers" in a quest for a vaccine for the viral disease that caused paralysis and death.

"It was the shot heard round the world," Marshall said of the polio vaccine. "I think these COVID vaccines are another shot heard round the world."

For Amelia and Drew, who enrolled in the trial in June, it offered them an early chance to get the Pfizer vaccine that was approved in November for children ages 5-11. Prior to that, it was available only for children 12 or older.

As it turned out, Drew became a squiggle — he got the Pfizer vaccine — while Amelia ended up a square, with the placebo. But once it won federal approval last month, Amelia was able to get the two-shot vaccination as well.

Their mother, Dr. Andrea Krause, a pediatrician at Norton Children's, said her job treating very sick children hospitalized with COVID-19 motivated her and her husband, Andy Krause, to enroll their kids in the study in hopes of getting them vaccinated as soon as possible.

The Krauses were especially concerned about Drew, who recovered from leukemia, and is more vulnerable to infection.

"It's kind of selfish because I just wanted my kids protected," Andrea Krause said.

But the children also were excited by the prospect of participating in a trial they understood could make the vaccine available to more kids their age, Krause said.

"I'm proud of my kids' attitude, wanting to help others," she said. "I do think they understood this was a pretty big deal."

Marshall, she said, met with children participating in the study and told them about the polio pioneers and "that they were making history."

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The Pfizer trial in Louisville is one of about 100 sites in the United States and several other countries for children ages 6 months to 11. About 4,500 children are enrolled overall.

The trial showed the Pfizer vaccine to be very safe and highly effective for children ages 5-11 with no serious side effects, Marshall said. The vaccine remains under study for children under 5.

Henderson said she and her husband were so anxious to get their children vaccinated against COVID-19, she began researching online for trials open to kids.

She was already familiar with clinical trials because her youngest had participated in one for children with cystic fibrosis.

"We appreciate clinical trials," Henderson said. "We believe in clinical trials."

Henderson said she has found the controversy over the COVID-19 vaccines, particularly the political overtones, "exhausting."

"It's so hard when we have family and friends who disagree with vaccines, and it's political rather than scientific," she said.

Henderson said she and her husband had been prepared to go out of state if needed for a vaccine trial and were delighted to be accepted into the one at Norton Children's.

Marshall said he was overwhelmed by the response when the study opened enrollment in June, with far more people signing up than could be accommodated.

"It's like someone opened the doors and behind the doors there was a huge segment of our population that understands the science, that wants to be part of the solution and is willing to embrace the way we do that," he said. "We have to study the vaccine to make sure it's safe, to make sure it works."

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As the principal investigator overseeing the Louisville trial, Marshall said he made it a point to ask the children about why they enrolled.

The older children had a similar reply.

"The most common answer was, 'We want to help other children,'" Marshall said. "The kids actually said that. It was really incredible."

Still, some had other motives.

One participant told him "Mom says if I come here and do this we can go get McDonalds," Marshall said. Another said he'd been promised a Nerf gun.

But overall, most children seemed to grasp the importance of the study and their role in advancing a vaccine, Marshall said.

"I'm really proud that COVID can now be included in the group of things we call vaccine-preventable diseases," he said. "You don't have to get COVID. You can be vaccinated."

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