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Behind the Mask

May 13, 2022

Barr: Good Morning. Today is May 13, 2022. My name is Gabrielle Barr. I'm the archivist at the Office of NIH History and Stetten Museum. Today I have the pleasure of speaking with Dr. Pamela Guerrerio, Dr. Stella Hartono, Dr. Muhammad Khalid, Ms. Joanna Utoh, and Ms. Ellen Zektser, who are all part of the Food Allergy Research Section with the National Institute of Allergy and Infectious Diseases (NIAID). Today they are going to be speaking primarily about their studies looking at people with allergies to the mRNA vaccines. Thank you very much for being with me.

Guerrerio: Thank you for having us.

Barr: It's definitely a very important topic. To begin with, were there considerations for people with allergies in the fabrication of both the Moderna and mRNA vaccines, at least relatively common ones?

Hartono: Well, we are not involved in the vaccine development itself, so we cannot say for sure, but this vaccine actually utilizes new technologies—an mRNA that is encased in a lipid nanoparticle. We also didn't have much data initially regarding reactogenicity of the vaccine components itself. There's some data in the literature about how the lipid nanoparticle can activate and complement the immune system, but I don't think that was a major consideration for the vaccine development when they were doing it.

Barr: What were some of the allergic reactions to the first mRNA shots? Were they typical to other kinds of shots and vaccines? Do you find that people who are allergic to the mRNA vaccine are allergic to other vaccines, medication, food, etc., or did there tend not to be a correlation?

Guerrerio: Almost immediately after the mRNA vaccines were introduced into the general public—first in the U.K. and then here in the United States, there were reports of people having allergic reactions to the vaccine, with symptoms including cough, wheezing, tongue and throat swelling, skin rashes, and in a few cases, hypotension, or a drop in their blood pressure. These symptoms developed almost always within the first 30 minutes after receiving the vaccine. In some cases, individuals required treatment either in the emergency department or the hospital. These types of reactions have been reported in people who have allergic reactions to other medications, including vaccines, but the rate of these allergic reactions is somewhat higher for the mRNA vaccines—on the order of three to five cases per million doses administered, as opposed to about one case per million doses for most other vaccines. The initial reports of over 80% of people who had an allergic reaction to the first dose of the vaccine indicate that they did have a history of other allergies such as allergies to

food, insect stings, or medications, and nearly a quarter of them had a prior anaphylactic episode. At this point, we really don't know for sure what factors put an individual at higher risk for having an allergic reaction to the mRNA vaccines. There's actually another trial that just recently closed for enrollment that was led by the extramural NIH, where their goal was to ask whether people who are highly allergic or who have an underlying mast cell disorder are more likely to have a systemic allergic reaction after receiving the mRNA vaccines than people who have no allergies at all. We should have more information about this very soon.

Barr: Have you been working at all with that extramural group?

Guerrerio: We did. We certainly tried to coordinate our study and the goal was that people who reacted to their first dose in that study could then enroll onto our study to potentially receive their second dose and their booster doses. We definitely were involved in a lot of cross talk with them.

Barr: What data about allergic reactions to the vaccine were collected in the original clinical trials for both Pfizer and Moderna? Obviously, those trials were a smaller subset of the population. Did that information shape your study at all?

Hartono: Looking at the original clinical trial data for Pfizer and Moderna, they do record all the adverse events related to the vaccine. However, when I look at them, there are no reports of a systemic allergic reaction in all the clinical trial data. Again, keep in mind that in the current reported data that we have right now, it was stated that the systemic allergic reactions ranged between three to five cases per million doses. When they do a clinical trial, obviously, it was conducted with less than 100,000 participants with only half of them given a vaccine dose. We did give consideration to how rare this actually is in the general populations when we conducted our trial.

Barr: When did you begin conceiving your study that looks at those that have rare allergic reactions to the COVID-19 mRNA vaccines and what exactly was your group seeking to understand?

Guerrerio: We first started to think about the trial in January 2021 after those first reports of allergic reactions came out, which of course induce a lot of fear and anxiety in our patients with allergic disease. We wrote the protocol and received the necessary regulatory approvals over the next several months, and then we enrolled our first patient in September 2021. The primary goal of our study is to determine how many people who had a systemic allergic reaction to their first dose of a mRNA COVID-19 vaccine will experience another systemic allergic reaction after they receive the second dose. Then we also hope to learn more about the mechanisms underlying these reactions. We're doing quite extensive immunologic studies as well. Finally, we're working with our colleagues in the National Institute of Mental Health (NIMH) to better understand the psychological impact of allergic reactions to the vaccine and how anxiety levels change before and after they receive their second dose. It certainly makes complete sense to us that people who had a severe reaction to the first dose may naturally be very anxious about receiving a second dose, so we want to learn as much as we can about the mental health impact of our intervention—which we hope will help us counsel patients in the future.

Barr: Will you please speak about how you all went about setting up the study, including the criteria for the participants, the logistics of your protocol, and all the different diagnostics you all use to assess patients?

Guerrerio: For this study, we are recruiting people who had a systemic allergic reaction to their first dose of either the Moderna or the Pfizer mRNA COVID-19 vaccines. We're primarily focusing on people who had more moderate to severe reactions. For people who had only a mild reaction or subjective symptoms to the first dose, we're requiring additional evidence that their reaction was truly an allergic reaction. For example, they had to have an elevation to their tryptase level, for instance. We excluded people who had a life-threatening reaction to the first dose, and those who were on certain biologic medications or systemic steroids. We don't necessarily think this will interfere with a vaccine or increase the risk of having a reaction, but primarily because it might interfere with our mechanistic studies.

For the study, participants are admitted to the ICU [intensive care unit] in the Clinical Center. We chose to do the visit in the ICU to maximally ensure that we are prepared to treat any reactions that our participant might develop. The challenges are not only attended by us as trained allergists but also the ICU team, and all the medications and equipment that we would need to treat a severe allergic reaction are present there at the bedside. We designed the study with a randomized placebo-controlled crossover design. What that means is that one day participants receive either the vaccine or the placebo, which is saltwater. Then the next day they receive whatever they didn't receive the first day. Neither the study team nor the participant knows which day they receive the vaccine and which day they receive placebo, but everyone who participates in the study will have received a second dose on one of those days. Over the course of these days, we collect a number of blood samples through an IV in their arm. We also collect urine samples as well because that's the most sensitive way to detect a number of allergic mediators that we think may be important and causing these reactions. After participants received the second dose, they usually go home. We give them a call the following week to make sure that they haven't had any other adverse reactions develop after they left the NIH—and to make sure they're doing okay. Then we also ask the participants to come back to the NIH up to three more times—first after about a month after they received the second dose of the vaccine in the ICU, so we can really look at how their immune system responded to the vaccine. Then, if they tolerated the second dose of the vaccine with no or only mild symptoms, we offer them the opportunity to come back to NIH five months later to receive the booster dose. At that visit, we also perform skin testing to the vaccine as well as the vaccine components to see if that might be helpful in identifying subjects who had a reaction to the vaccine. Their final visit to the NIH is one month after they received the booster. Our goal there is to again monitor the immune response to the booster dose.

Barr: Four days was the minimum they were observed. What was the maximum number of days and what was the average number of days for patients to stay at NIH after their shots?

Zektser: We have not had to exceed four days for the ICU admission; all of our participants thus far have done well enough to meet discharge criteria on day four.

Barr: Did you feel that patients were more anxious be in a hospital setting, or did you find patients more relaxed because they knew they were in an ICU setting getting a lot of individual attention? Or did it really vary depending on the patient?

Zektser: It depended on the patient. We do assess their anxiety, both on the day of arrival where they're not getting any intervention and then throughout their participation. In discussing with our patients, many seemed more reassured by having so many resources available to them. Being in the ICU, there's the increased medical supplies around and then just hearing different alarms—some have expressed that that can be a little anxiety inducing.

Barr: When did most people's allergic symptoms appear following their second injection, and what did those reactions look like? Were they similar to what they experienced after their first injections?

Khalid: Typically, the onset of the reactions has been very rapid, likely because of the systemic route of administration. In a large majority, the symptoms basically appear within 30 minutes of receiving the dose. The earlier the onset, the more likely that the reaction will be severe. This does appear to be overall similar to the first dose reactions. In our study, we have not identified a difference in the onset of reaction after the second dose compared with the first dose. Before I explain the nature of the reactions, it is important to notice that our study can be looked at as having two phases. One phase is when they received the second dose in the ICU in a double blinded crossover placebo-controlled fashion. Then in the second phase, those who did not develop a severe allergic reaction were deemed eligible for an unblinded booster dose with less intense monitoring. But our interpretation of the second dose reactions is very limited, due to the blinding, until we complete the study.

Regardless of that, there are a few important observations in those participants that had a moderate to severe allergic reaction to the dose one and went on to receive treatment with one or more doses of epinephrine. We found that, reassuringly, not everyone who's had an allergic reaction to the first dose went on to develop an allergic reaction to the second dose. In fact, a very small number developed an allergic reaction after the second dose. These participants did develop the symptoms that were similar to what we would often think of in an allergic reaction, like itching, cough, shortness of breath, throat tightness, or low blood pressure. These reactions very rarely did require an intervention like epinephrine treatment, depending on the severity of the reaction. The more common group of patients had symptoms which were very significant but did not meet the criteria of an allergic reaction. These predominantly included throat tightness, heart racing, high blood pressure, lightheadedness, and numbness and tingling—and lacked any evidence of an allergic reaction like swelling of the face, tongue, throat, wheezing, to name a few. While some of these reactions were clearly distressing, the symptoms did improve with the reassurance and none of them required any additional interventions. Very importantly, there was another group who did not have any symptoms at all after the second dose. Despite that, they had a severe allergic reaction after the first dose. This pattern has been mirrored during their booster dose administration.

Barr: For the group that had no reaction and the group that had what would typically not be considered a reaction, do you have any idea about why they had such differences between their first dose and the second and third doses?

Khalid: This is part of what we're hoping to answer through our study. There is, as you said, a clear distinction. Until we're able to run some of the mechanistic studies, it is difficult for us to interpret at the moment. We're hoping to answer that question.

Barr: In addition to looking at the reaction, you did some mental health work. Will you please speak about how your team compiled and disseminated mental health questionnaires prior to, during the time of, and after the second dose, and what you learned from these tools?

Zektser: We partnered with our colleagues at the National Institute of Mental Health (NIMH) per the recommendation of the IRB [Institutional Review Board]. We do recognize that these reactions caused significant stress to our participants. We did want to assess the contribution of stress to their reactions. Mental health and anxiety are evaluated throughout all of our participants' study participation. The mental health team does a baseline psychiatric evaluation and disseminates a variety of validated standardized questionnaires. The mental health team is compiling the data from these different tools, and we anticipate that they will share the results with our team soon.

Barr: Do you do these mental health questionnaires with your food allergy assessments? Or have you done them with other studies before?

Guerrerio: We've done quality of life questionnaires, but we haven't specifically focused on anxiety. It'd be really interesting to do, though. We actually talked to the mental health team about that because there is a similar level of anxiety going through a food challenge in someone who's allergic, so that would be really interesting.

Barr: Have you worked with medications and vaccines before? Or do you mostly deal with food?

Guerrerio: My primary interest is food allergies. This is my first trial working on a vaccine or medication, but I know others in the group have an interest in drug allergy.

Barr: How did you choose the intervals to follow up with your patients, and what did you all discuss at these intervals? How did you decide who would receive a booster?

Utoh: As Dr. Guerrerio mentioned earlier, initially we call our patients one week after receiving their second dose to assess for any acute adverse reactions. At this point, we're expecting certain reactions to occur just as normal expected side effects of the vaccine. We're also assessing for any additional, maybe delayed, reactions or any other symptoms that would fall outside of that. We then follow up with them in person one month later to assess their immune response to the vaccine. At five months, that would be when we administer the booster and that is based on the CDC recommendations. If participants have either mild reaction or no reaction to the

second dose, then they're eligible to receive the booster. It is optional—if they elect to receive it, we do administer it at that fourth visit.

Barr: Did most of your patients who were eligible choose to go ahead with the booster?

Utoh: Up to this point, any patients who have come back for that visit have chosen to receive that booster. It's amazing. After they receive the booster, they'll receive another call and it's again to assess for any adverse reactions to the vaccine or any delayed reactions. Then finally, we follow up with them one month later to assess their immune response again, and this actually concludes their participation in the study.

Barr: You have over 100 participants and are collecting quite a lot of data. What has it been like to analyze all this data, and what observations have you made?

Khalid: We did have an accrual limit of 100, but as you can imagine, with the rarity of these reactions, it is a study that is very difficult to recruit for. We have more than 15 participants at the moment, but currently, we're still in that data gathering state. The analysis being blinded is largely to identify the nature of these reactions and any early elements that may impact safety of the patients or prompt any decisions that would require obtaining the additional studies. The study analysis is also limited, as we're in the blinded status. Expanding on the observations that we have noted, these reactions are very common among the females, predominantly affecting the young to middle-aged adults. More than half of them have a reported history of medication allergies, a prior episode of anaphylaxis, allergic rhinitis, asthma, or food allergies. There are these three groups that we're seeing where there are those who had no symptoms, a smaller group who had recurrent allergic reaction to the subsequent dose, and then a larger group who had atypical symptoms. We're hoping for this group that on one side, the explanation can be that these are driven by a neuropsychiatric pathway going through the stress of getting the vaccine. The reactions do seem to be quite significant. We hope that through this rigorous study design and analysis, we will be able to distinguish them in an objective fashion and identify if there are any distinctive pathways involved.

Additionally, we have performed skin testing to the vaccine and some components in the vaccine, such as polyethylene glycol, which was initially suspected to be behind these reactions. So far, we have not found any correlation between the skin testing, especially with the polyethylene glycol or a similar chemical, polysorbate, and development of an allergic reaction. Skin testing with a vaccine, however, may or may not correlate with the development of reactions, but we'll be able to assess that better once the study is completed. Lastly, which is very reassuring, we have observed a robust antibody response after the second dose and the booster despite a big lag between the first and second dose, which has extended up to a year for some participants. This is, of course, more profound in those who had an infection before, as many other studies have shown.

Barr: You said you had some trouble recruiting people. How did you guys go about recruiting people since it is so rare?

Khalid: Yeah. Initially we would not have that much trouble, because as soon as the news got out that we were starting this study, we received referrals from providers, especially, and other scientists who were aware of the study. Then later on, we had a press release, and we reached out to the allergists and immunologists in the community and academic settings. Dr. Guerrerio spoke in one of our national meetings of the Academy of Allergy, Asthma, and Immunology and did their podcast and several other interviews. Initially, we had a very good response, but by now, because many people have either decided to get vaccinated or otherwise, it's just becoming a little challenging to recruit further.

Barr: What are some of the long-term implications of this study? There will be more mRNA vaccines for different diseases. Will this model of being vaccinated under supervision be adapted with other kinds of shots?

Khalid: In general, allergic reactions are very difficult to study due to their unpredictable rapid nature of onset and recovery and the limited ability to perform any analysis. But our study has been carefully designed to look at these reactions in a very unbiased fashion and in a sophisticated scientific design. We do believe that it will help provide answers to some key questions, like risk of recurrence of allergic reactions to an mRNA vaccine; identifying the underlying mechanism of these reactions; identifying the biochemical, molecular, or genetic factors influencing these reactions; the ability of the skin to predict who will develop an allergic reaction; and then how the immune responses to mRNA are impacted by the variable dosing. Then, as you mentioned, this has been looked into for other platforms after the successful use in the COVID-19 vaccines. It is already being investigated to be utilized in other vaccines like influenza, HIV, and herpes, to name a few, and for its therapeutic role against the cancers. We think our study findings will likely provide insight into the nature of these reactions and how to appropriately investigate and manage them where the subsequent doses are needed. Many of our participants were considered very high risk to be vaccinated in the community, so that is why we decided to perform these challenges in a highly monitored setting like ICU. However, we do hope that the study findings will provide the guidance to the allergist and immunologist in particular, and providers in general, who can then assess the individual reactions carefully. In selected cases, they can then help them get vaccinated under supervision and with access to emergency medications.

Barr: How would your group like to proceed with this type of research in the future? This study is wrapping up, but there always seems to be more questions, so one study brings on another.

Hartono: The two main questions that we would like to have answers to are: What is the mechanism underlying this systemic reaction? Is it an IgE-mediated reaction, similar to what you experience during a seasonal or food allergy? Or is it something else that’s completely different, involving other immune components, like preformed antibodies like IgG or IgM, mast cells, or some other factors that we cannot quite yet identify? The second question is: What is the component of the vaccine that acts as an antigen or trigger for these reactions? To do this, we'll be doing a lot of laboratory analysis and not trying to rely on transcriptomic and proteomic analysis to identify which of the pathways get activated during the reactions, and then confirming it with possibly in vitro study.

Barr: What have been some difficulties in operating the study that you have been involved in, and what do you each feel that you have learned and gained from being a part of this study?

Guerrerio: We probably all have answers to this, but for me, the study required an incredible amount of coordination among so many different people. It was our group, the Pharmacy Department, the Department of Laboratory Medicine, the ICU staff, the Vascular Access Team, and multiple people in multiple different labs within and outside our institute who are processing samples for the study. It was just an enormous feat each time a patient comes in, but it was successful because every one of these groups, and everybody who's been involved in the study, has always been willing to go above and beyond to make the study happen. In that sense, it's been just a really remarkable experience.

Hartono: At least for me, as a clinical fellow, I actually learned a lot from being involved in this study. I always wanted to learn about how to design clinical trials, but this is a little different in a sense—it is high risk. We know that these patients are going to have had reactions before and have a propensity to develop anaphylactic reactions again. We don't know [what's going to happen]. It has involved coordinating with a lot of teams. We have to talk with the ICU team. Samples need to get to the lab and in a timely manner because all of these are time sensitive assays. Patient recruitment can be challenging. On the lab analysis standpoint, I was hoping to learn more about system biology and bioinformatics. This is a great opportunity for me to learn and I really thank them for letting me be a part of it.

Khalid: I would echo that. Some of the other challenges that I can recall are when we were in the process of designing the study. From that time on, there was minimal to no literature with only anecdotal evidence of what is going on with these reactions. We had to be extra vigilant, not only about following the design very carefully, but also to adapt very quickly and make changes based on any new evidence. Just to give you a sense of that, our protocol was approved in July. Since then, in the last 10 months, we've amended our study vertical five times, at least, to include the changes based on this new information—for example, inclusion of the booster after the CDC recommendation, and then lowering the age group in our study to 16 years once the vaccine was approved for the group. Another challenge was definitely the screening because of the difference in interpretation of these reactions as allergic in nature. We did receive lots of interest, but unfortunately, due to our defined criteria in the study, we could not include many of those participants—as much as we wanted to, they just did not qualify or have an allergy.

Barr: Was it a challenge? Everyone got the same version of the Moderna vaccine, but both Moderna and Pfizer are supposedly in the process of updating their vaccines for the fall, so is that something that your group has been considering dealing with?

Guerrerio: In our study, we only give the Pfizer vaccine. That's how we decided to define it. Actually, most people have had a reaction to the first dose of the Pfizer. The study will conclude after the booster dose is given. That will be the approved Pfizer dose that we're using for that as well. We're hoping to be able to answer this question for people who have had allergic reactions. Hopefully, we can tell them that it would be safe to get any

additional vaccinations that are recommended by the CDC from here on out, either in their allergist's office or some other monitored setting.

Barr: What were each of your roles in the study, and how did you offer your own expertise to organizing and conducting this protocol?

Zektser: I'm a registered nurse, and I function as the nurse study coordinator for this protocol. My role includes a lot of different tasks, including recruiting, screening, consenting the patients, enrolling the patients, and communicating with them. I also coordinate all of the study tasks and requirements and ensure that our study procedures are occurring as described in the protocol. I handle all of our lab specimens during the challenges. I ensure that our team is adhering to our protocol, submit reportable events as needed, complete the regulatory requirements, and I fill in during other situations.

Barr: Were the patients' families allowed to accompany them?

Zektser: Depending on the timing of the patient's admission, the different policies in the ICU reflected what was going on with COVID in the community. Most of the time, our participants were able to have one visitor during visiting hours. Some of them chose to have someone and some of them chose not to. Many of them did travel from different areas in the country and so were unable to bring somebody with them.

Barr: That must've been very hard on you to deal with all that.

Hartono: Yeah, I have to say like without Ellen, I don't know what we would do.

Utoh: My name is Joanna, and I'm a family nurse practitioner. I work with the team. During the initial inpatient visit, and the day we administer the booster; I work with the team to record and assess for the onset, progression, and potential resolution of any symptoms or physical findings. When we do skin testing on visit four, the day they receive the booster, I assist with that process. I primarily see the patients during their follow up visits to address any adverse effects they may have had, and to ensure relevant data, such as symptoms, medical problems, medications, or physical findings are all documented in a clear and systematic way. I'm a very methodical and thorough person, so I have learned with this protocol that it is extremely important to be clear and concise and make sure that you're doing things systematically, in order to ensure that accurate data is collected so we can provide appropriate recommendations at the end of the study.

Khalid: I'm a clinical fellow in allergy and immunology, and as my primary research project, the study is very close to my heart. I'm very grateful and honored to have led the clinical side of the study under the supervision of Dr. Guerrerio, who deserves the most credit for exceptional leadership in getting this study done successfully, and our amazing team who has put all their heart and soul into making it happen. Personally, I've been involved from the time the study started in writing the protocol design of the study, designing the skin testing protocol and the treatment strategies for the allergic reactions, leading the patient recruitment and screening, performance of the challenges, performance of the skin testing, evaluating patients during their visits, as well as

coordinating within our team and with other groups like the pharmacy, the laboratories, and other investigators, to ensure the smooth completion of the visit. I have also been leading the clinical data analysis and have presented the preliminary data in multiple internal meetings. I'm looking forward to presenting these findings once we complete the study. For me, this has been a very rewarding and invaluable experience of performing such high-quality clinical research and in such dire times.

Hartono: I am involved in other clinical sites. I'm the one that's leading the laboratory sites, trying to identify the mechanism underlying these reactions and determining what the trigger is for all these allergic reactions. Unfortunately for me, we can't really start doing this analysis until the study is "un-blinded." I have been working quite a lot just trying to get all the laboratory samples. We have multiple laboratories involved in these studies. It's been an honor being in the lab working with this team. Everyone's working very, very hard. I'm very excited to, hopefully in a couple of months, get started on working really hard at analyzing the data.

Guerrerio: As a PI [principal investigator], my job is really to oversee this study and ensure that it's conducted within the regulatory guidelines. But as you can see and as you've heard, I am one tiny piece of this huge puzzle. The thing I've learned is just how much these types of trials rely on teamwork. For me, that's been one of the most enjoyable aspects of the whole process. I had an incredible team to do this trial with, so that's made it a lot of fun.

Barr: Was it just you guys, or were there other people that were part of the lab that assisted you in your work?

Hartono: Oh, there's a lot.

Guerrerio: Lots of other people—it's probably 40 or 50 people that are all involved in making this study happen, and that's directly involved. We certainly received help from the protocol navigators and the DIR [Division of Intramural Research]—and so many other people that I don't think I could even list all who have contributed to this. It's been an undertaking like I've never been a part of before.

Barr: Will you please speak about some of the other COVID-19 research and initiatives you've been involved in or would like to get involved in?

Guerrerio: I was involved with a study that would aim to really try and better understand the Multisystem Inflammatory Syndrome in Children, or MIS-C, which is a potentially life-threatening complication that can occur in some cases weeks after an asymptomatic or even mild COVID infection, and mostly affects children. The goal of this study was really to try to define blood and cellular signatures that correlate with the severity of MIS-C.

Khalid: I was involved in the determination of the clinical outcomes of patients with immunodeficiency, in particular the STAT3 [signal transducer and activator of transcription 3] and PGM3 [phosphoglucomutase 3] deficiency, to see how they've done after contracting COVID-19 infection. We interviewed these patients and then just followed their clinical course to observe for any complications, because there was this concern that these patients in particular are at high risk for having adverse outcomes. We found that these outcomes were in

fact not worse, as originally expected, and most of these patients actually did really well and only have a mild course of disease without any major complications.

Barr: In addition to being scientists, you're also individuals who've been living through these interesting times. What have been some personal opportunities and challenges that the pandemic has presented for each of you?

Utoh: I moved from Houston and started my new role in the Food Allergy Research section at NIH in January of 2020. I was in the orientation process when everything shut down due to the pandemic. This presented several challenges. It made it very difficult to get trained in food allergies. I primarily practiced in family medicine for seven years prior. Basically, I just had to lean into all the changes and the uncertainty and learn to be very flexible and willing to take on new things as they were coming my way. As our team shifted away from food allergy to focus on the CoFAR [Consortium of Food Allergy Research] study, I was very hesitant, but quickly appreciated how unique the opportunity was. I am extremely grateful that our team has been able to work so well together to ensure that patients in our study are actually getting additional protection by receiving these additional doses, and grateful that as a team we are providing excellent clinical care. The pandemic has allowed me to expand my role as a nurse practitioner and to make a meaningful contribution to society. For that, I'm honored.

Barr: How have you guys been dealing with your food allergy patients during the pandemic?

Utoh: We've been able to see some of our food allergy patients, just not to the level we were before—so not as many visits as we were seeing before—to ensure the safety of our patients. Then, of course, when the CoFAR study began, priorities shifted a little bit. We're still able to see some of our food allergy patients, but again, there's just not as much time to be able to dedicate to them at this moment. As we're winding down with enrollment, we're able to bring back a lot of these patients. We're very, very excited that this summer we're going to be able to start seeing more and more food allergy patients.

Hartono: I also moved from Houston to here around July 2020 to begin my fellowship in allergy and immunology at the NIH. Obviously, it was very unexpected. I was coming in here thinking I was going to do research related to primary immunodeficiency, but with COVID it actually shifted my interest into things like adverse events to drugs and monoclonal antibodies—because when you start looking at the literature, there's not that much known about these things.

Zektser: For me, the greatest opportunity has been to be able to work on this study. It has been such a wonderful learning opportunity. As everyone mentioned, I have to echo that the teamwork and collaboration is just phenomenal. The amount of support that our team provides has been really great. At the end of a week, where we've completed a [inaudible] and we're able to get a patient vaccinated, they're so grateful for that vaccination—and we're so grateful for their participation. It's just wonderful to see. For challenges—similar challenges to what the rest of the world is experiencing, like childcare, uncertainty, or things changing at the drop of a hat. We had a couple patients scheduled to go—we put in so much effort to get them scheduled—and

then they needed to be rescheduled because of increases in cases in the community. We just had to be flexible and shift gears regularly.

Khalid: Just like Sarah mentioned, I moved from Memphis in July of 2020 when I started my fellowship. Even during the last few months of my residency training, I was involved in caring for the patients who had the severest COVID-19 in the ICU. This by itself was extremely tough at that time because of the limited protective equipment. There was no targeted treatment available, and the hospitals were overwhelmed. Then, the week before I started my fellowship, I unfortunately lost my mother to COVID-19.

Barr: I'm so sorry to hear that.

Khalid: Thank you. The constant fear of bringing this disease home to my family, after losing a family member, was always haunting. They were big challenges to overcome, but I feel very fortunate to be at NIH. Being part of this study has provided me the sense of fulfillment and pride that I'm able to make some difference by contributing my very small part in advancing the science. I am just very grateful to be a part of this amazing institute and learn from the best in the field.

Guerrerio: For me too, it's just been a lesson in flexibility and resiliency. As I mentioned, this is my first vaccine study I've done. I'm a pediatrician, actually, so I don't usually do trials with adults either. But this is what the public needed, and we know that vaccines are people's best protection against COVID-19. Just being a part of that and, as Ellen said, being able to get people vaccinated, is an incredible feeling and certainly makes all the work worth it.

Barr: Definitely. Well, thank you all so much for being with me and for all your work. Is there anything else that any of you would like to share or add at this time?

Geurerrio: Thank you for having us. We really appreciate the opportunity.

Barr: I wish each of you all the best, and I hope that you and your families continue to stay safe and healthy. I look forward to the results!

Geurerrio: Thank you.