

Adrian Hernandez: Hey, this is Adrian Hernandez, and welcome to the NIH Collaboratory Grant Rounds podcast. We're here to give you some extra time with our speaker, and ask some of the tough and interesting questions you want to hear most. If you haven't already, we hope you'll watch the full Grant Rounds webinar recording to learn more. All of our Grant Rounds content can be found at [RethinkingClinicalTrials.org](https://RethinkingClinicalTrials.org). Thanks for joining.

Adrian Hernandez: Hi, this is Adrian Hernandez, host for our Collaboratory Grant Rounds. And today, we're here with Emily O'Brien, who will be reflecting on a recent Grant Rounds presentation entitled HERO-TOGETHER: Building Vaccine Confidence with Long Term Outcomes Data. So Emily, thanks for joining us and doing this podcast.

Emily O'Brien: Thanks so much for having me.

Adrian Hernandez: So first of all, maybe just give an overview of what HERO is. What are the aims, and what's it intended to do?

Emily O'Brien: Yeah. So HERO-TOGETHER is a program to look at long term outcomes after vaccines in healthcare workers. And the focus for this is the COVID-19 vaccines that have recently become available under Emergency Use Authorization by the FDA, and so we're really coming from a place of having some encouraging safety and efficacy data from phase three clinical trials, but we're also acknowledging that these vaccines are new, and long term safety really comes from data and comes from having good information on how people do over time, post-vaccination.

Emily O'Brien: And so, to meet that need, we have set up a program where people can self-enroll online and then tell us through periodic surveys how they're doing, if they've had any unexpected medical care, any hospitalizations, other events of interest that we might want to investigate further. And so in addition, they'll be telling us how they're doing with respect to quality of life, and then will become part of our HERO registry for potential future research opportunities as well.

Adrian Hernandez: And you've already learned information from HERO about vaccine hesitancy from hot topics, so what are people saying? What are the healthcare workers saying about vaccines?

Emily O'Brien: Yeah, a couple of important points here. So our first poll that we did in late October, we saw more hesitancy than we might have expected. Going into this, we thought healthcare workers might be open to medical innovation than the general population and might be sort of more comfortable with the clinical trial process and the process for approval. So they might be more willing to take this new vaccine. We actually saw that about 54% of them in October said, "Yes, I would agree to be vaccinated if the vaccine were available to me at no cost."

Emily O'Brien: So that was lower than we thought. The good news is, we've seen that that is a number that can change. We repeated the poll in December, early December of 2020, exactly the same way, asked the same question. We saw that the number rose from 54% to 76%. Potential major events that could have contributed to this are press releases from phase three trials suggesting that the vaccines were highly effective. Two mRNA vaccines, one from Pfizer and BioNTech and one from Moderna were effective and safe, and then there's also obviously, a national election in November as well that had a lot of discussion around the pandemic and approaches to a vaccination, and sort of how we move forward from this.

Emily O'Brien: And so, those are both things that may have contributed to this improvement that we saw, but certainly, it's encouraging to see that people can change their minds about this and can become more vaccine-willing and accepting as time goes on. The other important piece of that is that we did see that there was variation by professional role, with paramedics, EMTs, and physicians being the most vaccine-willing at both time points, and nurses being less vaccine-willing. And so this is helpful as we start to think about where hesitancy might be most prominent, and how we might target strategies to try to improve confidence and help people feel comfortable with their decision-making process.

Adrian Hernandez: And healthcare workers on the front lines especially are under a lot of stress, dealing with COVID-19, lots of other different issues have come up in society. What's going to be the value back to healthcare workers? What's that look like?

Emily O'Brien: Yeah, so this was a really important discussion as we were planning the program. As you've mentioned, this is a group of people that have contributed a lot to keeping others healthy and safe over the past year or so, and we don't want to just capture information without also giving something back. And so, there are a couple of different things. We are offering a small amount of financial compensation to reflect the time that they'll spend filling out surveys.

Emily O'Brien: But importantly, what we heard from the HERO registry of healthcare workers is that getting information about what we were learning was really critical, and was a key driver for them to stay engaged, and they saw that as a major reason to be involved. And so we're currently planning to do the same thing here with HERO-TOGETHER, let people know what we're learning as we go instead of just having one academic publication at the end of the project, we really want to provide information back about the data in aggregate form so that the people can see what we're learning and the science that they're contributing to.

Adrian Hernandez: Terrific. I know this is being done in a different way, a different model, so-called siteless. What's that mean, especially in the setting where healthcare workers are actually often at sites?

Emily O'Brien: Yeah. So this was really an interesting sort of design to put together. What we recognized was that it was important that we get this up and running quickly

and also that we're able to meet people where they are. And so acknowledging that healthcare workers, some obviously work in large academic medical centers, and some are working in other smaller, more rural settings, we wanted to make sure that an opportunity was available to all of them to participate in this effort.

Emily O'Brien: So we have several institutions that we've partnered with where we'll have navigators who are physically present on site and are able to answer some high level questions on the study, and also to provide key information about the goals of the project. But in addition to that, we are open to enrollment from any healthcare provider, no matter where they are in the country. As long as they meet our inclusion criteria, they can be part of the study. And so, this is really important.

Emily O'Brien: As we think about the evidence that comes from this, we want to make sure that it's representative of the entire healthcare worker community, not just those who work in large academic settings. And so we have a number of different recruitment strategies to try to really bolster enrollment outside of the sort of traditional academic health system, but then also have the navigators to complement that, who are present at these large vaccination locations. So hopefully, we'll get a good variety of people both with respect to role and with respect to demographics and geographic region, and we'll be able to have more generalizable findings as a result.

Adrian Hernandez: Great. And there are a lot of initiatives around COVID-19 vaccines. And how is this different from those other initiatives? How is it complementary?

Emily O'Brien: Yeah, so I think the first question that has come up as we've talked about what we can really add is the phase three trial participants are still contributing data and we're learning more about long term outcomes in those populations, which is absolutely true. But when we talk about real world evidence, it's important for us to emphasize how populations that are broader can actually give us new understanding and new knowledge that isn't available in other data sets.

Emily O'Brien: And so the example that we point to with HERO-TOGETHER is that phase three trial populations excluded immunocompromised individuals as well as pregnant and breastfeeding women. And so, this is a key opportunity for us to learn from people who might fall into those categories who are making their own decisions without a whole lot of data, sort of what things look like over time. And so the breadth of the population is a big one. We also have verification of events from a clinical [inaudible 00:09:24] ascertainment committee that will adjudicate any hospitalizations or other events that we see through medical record reviews. So we'll have really robust event information relative to something like an administrative claims only data set.

Emily O'Brien: An extensive list of adjustment variables, we'll be asking people to tell us about their medical history so when we do comparisons, we can be really confident

that anything that we see has been adequately adjusted for some of the potential key risk factors. And then as I previously mentioned, we want people to know that what we're learning from their data and that they're contributing to the science, and one way to do that is to show them what we're learning. And so the return of results is going to be another key piece of this, that they're not just reporting data that is then sort of internally assessed and they don't get to really see what's happening. It's really about sharing and building this community where we can show what we're finding as we go.

Adrian Hernandez: Terrific. And last question, if someone wants to join who's a healthcare worker or wants to refer a friend or family or a workmate, where do they go?

Emily O'Brien: They should go to [HEROSResearch.org](https://HEROSResearch.org), that's one word, [HEROSResearch.org](https://HEROSResearch.org) and look for the link to HERO-TOGETHER. You can also find us on social media, we're on Twitter and we would love to partner with you and hear from you about your experience signing up. So please get in contact with us. We are very eager to hear how the experience is for people, and are hopeful that you'll join us. So, thanks.

Adrian Hernandez: Emily, thanks for sharing your insights about this important program, and also helping address major issues around COVID-19 health and vaccinations.

Emily O'Brien: Thank you.

Adrian Hernandez: And thanks, everyone, for listening to this podcast. Please join us for our next podcast, as we continue to highlight interesting issues and big changes in the research world. Thanks for joining us.

Adrian Hernandez: Thanks for joining today's NIH Collaboratory Grant Rounds podcast. Let us know what you think by rating this interview on our website and we hope to see you again on our next Grant Rounds, Fridays at 1:00 PM Eastern Time.