spent quite a bit of time talking to physicians who are caring for people in what's called post-COVID clinics and it's pretty clear that everyone is seeing the same thing, the same thing meaning a host of symptoms, but patients are not coming with one symptom. They are generally coming in with a cluster of symptoms and there may be different clusters of patients with different clusters of symptoms yet to be determined, but one paper, and this is I take you may know about this; this is a survey of many thousands of people that was recently published looking at people up to seven months post-symptoms and a lot of these come from that paper. So heavily neurologic, so memory/word finding difficulties, concentration difficulties. A lot of this goes under the layman's term of brain fog, along with the executive function disabilities. These will have neuropsychological abnormalities associated with them and we need to know exactly what those are to try to help develop treatments.

A lot of people with sleep disorders, a lot of pain syndromes, muscle joint pain, abnormal sensations such as tingling in the hands and feet. Headache is very prominent. Postural orthostatic tachycardia pretty prominent. Abnormal smell and taste, that's one of the earliest findings you see, the involvement of the nasal mucosa by the virus. Blurry vision, nondescript visual abnormalities yet to be defined, dizziness and balance problems, a couple of cases have been presenting with actual psychosis and a confusional state. Hopefully those remain rare.

One question there is whether it due to an autoimmune reaction that occurs due to the virus where the immune system produces antibodies against brain proteins. This is a known condition with other infections and there have been a couple of cases I think after COVID infection. We're not -- but it seems at this point to be rare

but something to really look into is whether COVID is actually producing an autoimmune condition following infection, following the infection as the cause of trouble. There as you know the signature of COVID infection is viral pneumonia.

People have shortness of breath, dry cough, chest pain. Of note, many people feel they're short of breath, but their pulmonary function tests are normal, so the cause of the symptom is unclear. Now everybody pretty much has fatigue, so it's probably 99.9% of people with these sequelae have fatigue. Most of the literature has not actually

documented post-exertion malaise but in talking to physicians around the country, they are definitely seeing it and in this report, they report it as high as 90% of people with post-exertion malaise. Remember, that's really a signature of ME/CFS along with pretty much all these symptoms in the neurological space, some in the cardiopulmonary space.

In the mental health space, one could easily understand why people who have had COVID infections might be suffering from post-traumatic stress disorder, whether they have post-acute sequelae COVID or whether they haven't, they've been through a really traumatic event and clearly if you've been through that kind of trauma, and maybe it's not just you. It may be other people in your family, questions of who spread the virus in the family in the first place, so it's a very complicated and stressful event that's happened to people and not unlikely that there would be post-traumatic stress disorder, and that's clearly happening. Lots of anxiety and depression. There is a report of a large study, electronic health records study showing an uptick in depression and dementia and sleep disorders in people who have suffered COVID infection.

There are also gastrointestinal troubles, diarrhea, decreased appetite, nausea, abdominal pain, and then there are symptoms that are hard to put in any but clearly we see this in ME/CFS as well, trouble with thermoregulation, elevated temperature, chills, flushing, sweat, sore throat, thirst. There are some skin changes and menstrual changes that have been reported. So, I think the take home point is that this is a complex disorder but it's very similar to what you would see in a group of folks with ME/CFS. The one thing we do know however that in COVID there can be tissue injury so we need to look, be careful for that and so you can get myocarditis and you can get pulmonary fibrosis in the long after the infection, and there might be other injury to other organs which we'll talk about in a second.

Now with respect to ME/CFS, we have for a long time suspected that ME/CFS, at least a large part of it, was a post-infectious condition, so many people complain of having an infectious-like illness, don't think much of it except they just don't get better or they get a little bit better and then they get a lot worse later. Now the problem in ME/CFS research is that the diagnosis isn't made till months or years after that initial event and it's

prohibitive to actually try and understand how it actually starts because the numbers just don't work. You can't take everybody who had a common cold and then follow them to see who gets ME/CFS. The difference now is we can do that with COVID because there are thousands of people who are developing COVID and the percent that are going to have trouble long term is large enough that can actually do that study, so you can look at people from the time they get infected, then follow them through to see why some people get better and other people don't, so this is a, you know, that's why this is an opportunity to really understand ME/CFS because we can do something that we always wanted to do in ME/CFS but really couldn't. Next slide.

[Slide shows NIH Services broken out into color coded boxes, information is in bullet form] So, NIH has been trying to get going and there a number of things that have been happening in the background and it's been heavily trying to look at the resources we have for COVID and other areas of research and seeing how they can be leveraged or these studies of what we call the post-acute sequelae COVID, so we have studies where there are electronic health records that have been set up to follow millions of people over time, so these can be brought to bear on the problem.

We have numerous studies that are going on in COVID in the acute condition and so that offers an opportunity to add a recovery addition to all the studies that are currently ongoing in the acute space. Now we also have some cohorts that have been established years, sometimes decades ago. Take the Framingham heart study for instance where you have lots of data on people pre-COVID, then you can get data on them during COVID and after COVID, so it allows you this kind of longitudinal data if we can move these kind of resources into the study of the long term effects of COVID. Next slide.

[Slide shows projects in bullet form] We have -- we started, gee, I think in May or June to put out supplements to projects to start looking at the longer term symptoms of COVID. This is just one to Leonard Jason at DePaul. This previous study used to look at symptoms of ME/CFS in people, kids in college, who developed mononucleosis, so it's an example of the model I was just mentioning, but now can move this to do the same thing for students who are affected by COVID. There are projects at University of

Georgia at Augusta, Cleveland Clinic, Einstein in New York, all looking at the recovery after COVID, particularly the neurologic complications that people are experiencing, and then we just we started a while ago but it just now active, a neuro-COVID database at NYU, we're hoping a place that people can put all the data with regard to the neurologic complications of COVID into a single database that's now established at NYU.

People may know that at NIH on the campus of NIH, Dr. Avi Nath and Brian Walitt and Bryan Smith have been running a study on persons with ME/CFS and one of the criteria they use, it's a subgroup really that they're studying, but it's people who started their troubles with what sounded like an infectious illness. It was never determined what the infectious illness is, but they have a series of really in-depth investigations that they have been applying to folks with ME/CFS so they now have a very similar study looking at people who are having trouble after COVID, so it's a great example here of how the ME/CFS work is actually influencing the post-COVID work. Next slide.

[Slide shows key points of study in bullet form and an image of NIH campus] Right. So this is the intramural study that I mentioned before by Avi Nath and Brian Walitt. Okay. Next slide.

[Slide shows images of the brain and key points in bullet form] So and Dr. Nath, he is a neurovirologist, actually a world-class neurovirologist and neuroimmunologist and so when COVID started, he kind of went all out to try to collect samples of brain tissue from people who died of COVID trying to understand how COVID affects the brain and so as we'll talk about in a second, it's not just the brain but the brain is affected during COVID, so during the acute infection, very common that there'll be delirium, encephalopathy, so a very severe confusional state, sometimes with depressed level of consciousness and there can be seizures as well and other neurologic complications, but it does tell you that the virus infection is somehow having some very dramatic effects on brain function.

Now Dr. Nath, in his examinations, has not found virus in the brain, so he does not think the virus is actually getting into the brain infecting the cells. There's a little controversy there because there is a group from Germany who is claiming that they are seeing signs of infection, so we'll still have to see. The jury's still out, but everyone is seeing what you see in these slides which is evidence that the blood/brain barrier has broken down, and

the green here in these areas is areas where protein has been leaking out of the blood vessels into the brain, and that's very abnormal, and then after there's this leak, you can see here these cells, these little brown dots here, and here you can see them blown up.

These cells start to also accumulate and these are inflammatory cells, and they accumulate around the blood vessels that are leaked and what we know about COVID-19 is that the virus binds to a receptor called the ACE2 receptor and that receptor is present on the lining cells of the blood vessels, so we think that the major problem that we can see in the brain is related to the effect of the virus on the lining cells of the blood vessels causing leak and then inflammation. This is also seen in the heart as well and probably other organs as well. Of course, dramatically, when this gets really robust, you get clots in the blood vessels and that leads to stroke.

Now most of the people we talk to who are seeing patients in their post-COVID clinics, who have done MRI scans are not seeing stroke, but these small areas of abnormality that Dr. Nath saw would probably not get picked up on a regular MRI scan, but any big strokes would be picked up and those big strokes have occurred. Sometimes they're devastating. Next slide.

[Slide shows diagrams of affect organs] So as we think about the symptoms of people experiencing long term, we talked a little bit about the brain, but COVID actually affects all these organs and so they're -- it's kind of like, you know, a mystery where there's way too many culprits and it's -- so the question's going to really be to try and figure out who are the drivers, where are the drivers, for what the patients are experiencing. There is no shortage of potential drivers, but we really need to understand which ones are the important ones and which ones are important over the long period of time of weeks and months and which ones kind of get better quickly. Next slide.

[Slide shows title page] So I'm going to talk a little bit now about the research plans which are going at a really rapid pace so I think it was maybe two weeks ago, we, after months of planning and preparation, talking to physicians, workshops, talking to people who were affected with the condition, we came up with a plan and it's a plan that's not I would say it's a plan that is a flexible one that will allow people to go in multiple directions to understand this condition and that has to be the case because we really

don't know enough about the condition to be top-down about this so we have to be top down in some specific region which is really to ensure that this cooperation, coordination, that this has to be pretty flexible as it moves along and new data comes in.

So about two weeks ago we announced our intent to put out calls for grants and then this week, we put out the calls for the grants and I'm going to talk about those now, so the calls are out. People around the country are looking at the information we gave and hopefully writing proposals to come in. These proposals will come in as you would submit a grant except that the process for moving them forward will be much quicker than anything we do in our regular business because this is an emergency. I think someone said yesterday very astutely that if we're going to make a difference, maybe it was Mary Dimmick, that we have to intervene in this kind of acute stage and people who are chronically ill for years, it's going to be much harder to make a difference, most likely, so this is a time-sensitive effort. Next slide.

[Slide shows response information in bullet form and a box with research opportunity information] So the funding as I mentioned comes from the Coronavirus Response and Relief Supplemental Appropriations Act and it's $1.15 billion to be spent over four years for research and clinical trials related to the long-term studies of COVID-19, and as I mentioned, we're using this other transactional authority to move things much faster and also it allows flexibility so money can be moved around as the science dictates and so we'll talk about the two main components.

One is the clinical component of recruiting patients into studies and the second one are the cores that will be coordinating the research of the multiple different components, clinical components, and this was just announced this week and here's the link to look at the funding opportunities which have the explanations of what's required for the applications. Next slide.

[Slide shows key scientific questions numbered] So the goal is really simply to understand how what is going on in folks who are having trouble months after their acute infection and then figuring out what are the best treatments to reduce the suffering due to this problem. So, this key scientific questions that we think need to be

answered are to really understand what is the clinical spectrum and what's the biology that underlies recovery from the infection over time?

So for instance, people who develop the infection and get better quickly versus those who develop the infection and take five or six months to you know, opportunity to understand what is the difference in those two groups? And then to understand the people who do not fully recover, what is the natural history? Most of the docs what we talked about, talked to, are seeing that patients are still improving over time and so we're hopeful, but I would say that there is certainly concern that there could be some people who plateau and don't continue to get better, so we really have to figure out what is the driver of those different outcomes and what are the driver, the different phenotypes of patients who have prolonged symptoms and other sequelae?

Just as I mentioned first that every patient is not the same, they tend to have clusters of symptoms and why people have one cluster versus another cluster may be a clue. Not uncommon, we see the same thing in ME/CFS, and then the final question which we haven't really talked about much but I think is a responsibility of NIH and CDC to provide information on is given the millions of people who are infected by the virus, what is the effect of that infection on other conditions that are maybe common conditions such as developing dementia or developing arthrosclerosis, or developing heart failure or diabetes, all those organs, chronic kidney disease? All those organs we know are affected by the virus in the acute stage so, you know, five or ten years down the road, we need to be able to set up our research to let people know, you know, is there or is there not an effect on some of these common diseases, and then there are probably also some very rare diseases that are going to pop up. We talked about say for instance, the antibody mediated psychosis. You would really need large databases to see if that's something that's coming up mostly due to COVID infection, so setting up these databases at the site I mentioned that can follow people a long period of time is going to be important to get at that. Next slide.

[Slide shows diagram of acute and post-acute SARS-CoV-2] So in terms of the clinical side, what we're looking for is people who are acutely affected with COVID and then following them over time, trying to understand what are the drivers of recovery after

COVID? We know for instance in some people they're shedding RNA from the virus for weeks or months after the infection. Is that related to the persistent symptoms? We don't know yet but it's certainly a possibility. Is there virus, you know, hidden somewhere that we don't know about in some people than others, and so following people who had the infection, understanding how the immune system, the heart, the cognitive function, improves over time in some people and not others is really going to give us some important answers.

And then in the second group is people who are now weeks or months out from the infection still having trouble, trying to understand what is the nature of their trouble? What is really causing the shortness of breath? What is causing the cognitive difficulties, the fatigue? Is there still, you know, immune activation with cytokines that are causing fatigue? These are the kind of questions that we have been facing with the ME/CFS community for years and not come up with, you know, definitive answers, but with the numbers and the, you know, the ammunition that we're going to have now, we really have the possibility to get some answers, and I would be shocked if the answers that we get in understanding the biology underneath people who are symptoms seven months after COVID doesn't, you know, immediately parallel into trying to see if that's the case also in people who have ME/CFS from probable other infections that we don't know about. And then also these large population-based electronic health record studies are necessary to get, you know, incidence/prevalence data and also to set up to follow large numbers of people over time, look at things like long-term health consequences. Next slide.

[Slide shows key points numbered with bulleted details] So, the plan is to try to at the end of this have maybe 10,000 cases that are well-studied with post-acute symptoms of COVID. We'd like to get an incidence/prevalence, epidemiology best we can but most of our focus is going to be trying to understand the biology of the condition and what's causing the patient's symptoms. We want to focus on children, particularly long-term neurodevelopment. I think we need to answer that question and adults including pregnant women and the elderly, particularly those who have some cognitive decline, you know, whether COVID-19 is going to push or accelerate that process of cognitive

decline with aging. We want to -- we will have a proactive community engagement as an integral element of everything we do. That's really important. We'll fail if we don't do that.

And then we'd like to get pretty quickly to design treatments and prevention strategies that can be tested in these groups of patients who are still, you know, in that subacute stage, particularly given the fact that we think that's where the most likelihood of an intervention is going to have a big effect size. We're also to try these in people who have symptoms over a longer period of time. We talked about the electronic health record study. I would add that we have written in studies on autopsy tissues, so we need to get, to understand what the effects of the virus, long-term effects are on the organ systems, we really need to be able to look under the microscope at the heart, the brain, the kidney, the other organs of the body and this is something that has been sorely missing in ME/CFS. We don't really have any good studies in this space and this I think could be a model for how we can move into understanding ME/CFS better as well. Next slide.

[Slide shows a diagram of the progression of the illness and bulleted information] So, this is what it hopefully will look like. There'll be acute cohorts, infected people or recently infected people being studied over time. There'll be people who have had symptoms already. Their infections were months ago. They'll be studied as well and followed over time, but we'll have some core tests and data collection that everybody does who participates in this effort so that we can actually then compare across the multiple different studies.

Now we are being very flexible so that these study -- these groups can come in and they'll be doing a core group assessments that we'll work out actually after they get funded, they'll have -- they can come in with a suggestion but we'll get all the groups together and we'll decide on what core -- and they will decide with us, on what core elements they'll be collecting, but also each of these groups will have their own what we call investigator initiated questions that they'll be looking at, so there might be some that are focused on the heart. There might be some focused on the brain, others on the

immune system and so as I mentioned, these will be very flexible because we don't exactly know the nature of the problem. Next slide.

[Slide shows initiative components and bulleted information] And all these form what we call the SARS-CoV-2 recovery clinic -- cohort, so we'll have those cohorts, the autopsy data and the electronic health record data and we will bring everybody together and try and, you know, really do this is as a national effort in a coordinated fashion with streamlined set of common core protocol elements, many of which are coming from the ME/CFS research that we've done and so we're really think that this is an opportunity to do things in a really high-quality, rigorous way. Next slide.

[Slide shows initiative components in bullet form] So the cores will be working to support the clinical research so there'll be a clinical coordinating center that will coordinate all the groups. There'll be a data resource center where all the data will come in and there'll be a biorepository center where samples will be coming in from all the studies, and this is important because if we don't make a quick win and figure things out, you know, in a rapid way then this material will be available for years, decades, for people to investigate and this certainly in ME/CFS has been, you know, very, very helpful. The consortium that we run is relying heavily on the biorepository and materials that have been submitted by patients thankfully to allow research to occur. But we will also have a, you know, a pretty substantial repository for the post-COVID research. Next slide.

[Slide shows quote about mandate] And then the clinical coordinating center will be mandated to set up community and patient engagement leadership board to engage patients, other stakeholders, in shaping the agenda initially and iteratively as the research questions evolve, to work with the investigators and disseminating information on the rationale and ethical basis for the studies, and then to provide feedback from the community and to get input from the community as the research moves along, so this patient engagement working group has been baked in to the research and I think is going to really help it become more successful, because we learned a lot of lessons. I think patient engagement has probably been not done appropriately in the past, but I think a lot of NIH has learned lessons how important this is and clearly we did for the post-acute sequelae COVID research. Next slide.

[Slide shows diagram of proposed workplan] And the workplan is moving out very quickly. Dr. Collins, you know, promised Congress that things would move so nothing is -- this is really going fast, so the applications will be due at the end of March.

We hope to have things funded out by potentially April and then, you know, but we will be changing things depending on how the science moves as the research evolves, and then once we have the groups, we'll also be coordinating them together, bring them together with the patient engagement group to really kind of solidify the research plans. Next slide. And I think that's it, so the -- yeah. The last slide is that there is a technical workshop on March 1st at 5 o'clock which will be instructions and discussion with people who are interested in applying. Unfortunately, applying to the U.S. government and NIH is always much more complicated than it should be, so this workshop I think will be important in clarifying a lot of the questions that people have. So, with that, I'd like to end and turn it back to Beth.

Dr. Elizabeth Unger: Thank you very much. I think one of the most exciting parts is the design that it's going to be collaborative and yeah. I think that's a lesson that we all know in this fast-moving field we need to communicate and so before we get to Andrea, who is going to really address the approaches that we've taken to communicate, I'd like to ask Dr. Jennifer Cope, who really was the leader of the long sequelae unit, just rotated off, to present some additional work that her team is leading.

Dr. Jennifer Cope: Great. Thanks Beth. Can you hear me?

Dr. Elizabeth Unger: Yes.

Dr. Jennifer Cope: Great. And let's see. Just waiting -- Next slide.

[Slide shows title page] Yeah. Yeah. There it. Okay. Well, good afternoon. Thank you for the opportunity to present here today and highlight some of the CDC COVID-19 response work on the late sequelae of COVID-19. As Beth introduced me, my name is Jennifer Cope. I'm a Medical Officer at CDC. Next slide.

[Slide shows diagram of team] And for the last two months, I've been working on a small unit within CDC's COVID-19 response structure called the late sequelae unit. I won't

bore/confuse you with a giant response org chart, but briefly we are organizationally located on the CDC COVID-19 response, on the Health Systems and Worker Safety Task Force, which is one of nine task forces on the response, and within that task force, we're one of five units on the Clinical Disease and Health Services Team, and we're a small unit of six staff now working to better understand long COVID. Next slide.

[Slide shows goals in bullet form] So for being a small unit, we do have some ambitious goals and you'll probably recognize some of this from others who have already shared but we're really being driven by what we're hearing from clinicians who are seeing these patients in increasing numbers, and while we're looking forward to the wealth of data that will come out of the NIH studies and from my epidemiology colleagues at CDC, the prospective cohort studies that Dr. Saydah talked about, we're really trying to rapidly fill some of the data gaps in the meantime. Our unit's goals include describing and defining heterogeneous late sequelae, better characterizing the many manifestations that have been reported to date, identify possible sequelae that have not been well characterized, better understand clinical practice and health care utilization for late sequelae, evaluate the frequency with which late sequelae occur, and then using that information to guide public health messaging, inform clinical treatment, and disseminate public messaging. Next slide.

[Slide shows graphic if strategies in blue boxes] We're using multiple strategies to achieve these goals with our ultimate goal of getting to a standard -- to standardized terminologies and definitions for long COVID. In the following slides, I'll go into detail about how we plan to characterize and identify long COVID, assess the frequency with which it occurs, and then our efforts to coordinate with partners and outreach and communication efforts for both the public and clinicians. Next slide.

So first I'd like to talk about how we're characterizing it using healthcare administrative data and chart reviews. We are currently working with a single medical center to do chart abstractions on patients testing positive for SARS-CoV-2 from March through November 1st, 2020 who have at least one follow-up visit 14 or more days after their initial diagnosis. Chart review will abstract data on demographics, comorbid conditions,

types of follow-up visits, and the symptoms reported at the follow-up visits, any hospitalizations occurring in the follow-up period as well as pertinent labs or imaging.

So, this is essentially our pilot study and then we hope to, using a contract mechanism, scale up to do a medical -- to do medical chart abstractions at three post-COVID clinics. We've also established a partnership with a nationwide physical rehabilitation provider to examine data from patients enrolled in their post-COVID recovery clinics. We think this is a unique opportunity to analyze richer data on functional status of COVID patients in recovery. Next slide.

[Slide shows key points in bullet form] We have several analyses using healthcare administrative data in various stages of progress. First, we have collaborated with an integrated healthcare system to examine healthcare utilization and clinical characteristics of non-hospitalized patients four weeks or more after testing positive for SARS-CoV-2. Knowing that a lot of the current literature has been primarily focused on follow-up among hospitalized COVID patients, we've chosen to examine lab-confirmed SARS-CoV-2 infected adults not hospitalized in the first 28 days after initial diagnosis, who had continuous enrollment in the health care system in the previous 12 months. We used three letter ICD-10 diagnostic codes as the level of analysis and performed a 12-month retrospective review at the patient level to determine whether those codes were new. The analysis was a longitudinal follow-up from 28 to 180 days to determine healthcare utilization related to preexisting and new diagnoses, describe the most common preexisting and new diagnoses and calculate diagnosis visit rates over time.

We expect these results to be published soon in CDC's Morbidity and Mortality Weekly Report, or MMWR. Another project that is close to publication, hopefully also in MMWR, is a retrospective matched cohort analysis using the Premier health care database which contains longitudinal in-patient and hospital-based outpatient discharge data from more than 800 facilities in 45 states covering approximately a quarter of all U.S. hospital admissions, and it currently includes approximately 370,000 COVID patients. The analysis examines late onset conditions 31 to 120 days after the initial COVID illness. We've also been able to work with PCORnet which is the National Patient-Centered Clinical Research Network that allows for on-demand rapid queries of a large clinical

network of patients and our query is to examine COVID patients in the months after diagnosis. We've just received results from this initial query and are currently reviewing the findings. Both Premier and PCORnet include pediatric populations, allowing us to examine data on this population for which very little has been reported so far related to late sequelae COVID. Next slide.

[Slide shows key points in bullet form] We are also working to assess frequency of late symptoms using patient surveys. We plan to administer surveys to people who have tested positive for SARS-CoV-2 with questions asking about when they tested positive, what their acute COVID symptoms were, symptoms they are currently experiencing, if any, healthcare seeking for those symptoms, and their mental health and functional status pre and post-COVID. We're currently working with several state health departments to administer surveys to cases using their state line list data. We also have funding approved for a contract to do an internet panel survey with a group of people who report testing positive for SARS-CoV-2 as well as a comparison who report not testing positive. We've developed a questionnaire that where possible, uses standardized and validated questions to enable comparisons to pre-COVID data. Next slide.

[Slide shows a graphic of the different agencies] Our unit has been involved in the coordination of efforts to work towards common terminology and definitions for long COVID, along with Dr. Saydah and Dr. Unger's groups at CDC. We participated in WHO's meeting on February 9th to begin the process of developing an internationally standardized definition for what WHO is calling post-COVID condition.

We have also been meeting weekly with a group of NIH colleagues to discuss issues around definition development and determine next steps. Next slide.

[Slide shows images from the website] The main way we communicate what we currently know about long term effects of COVID-19 is through our web content with sites aimed at both the general public and clinicians. We are actively working to update the clinician-focused web content to reflect the latest on what is known about long COVID and describe the early efforts to establish terminology and definitions. We have also used additional mechanisms to reach clinicians.

On January 16th, we participated in the CDC IDSA clinician call to give an overview of long COVID. Following that, on January 18th, we used CDC's clinician outreach and communication activity, or COCA call, to provide an overview of long COVID and arranged for two clinician speakers who have established post-COVID clinics at their medical centers, one a pulmonologist and one a neurologist.

Going forward as more data becomes available, we will assess the need for additional presentations using these mechanisms. Next slide.

[Slide shows closing slide and contact information] We realize this work represents only a fraction of what is needed to fully understand long COVID and we look forward to partnering both internally at CDC and with other federal agencies, academic groups, and patient advocacy organizations to better understand the long-term effects of COVID-19 illness. Thank you.

Dr. Elizabeth Unger: Well, thank you so much, Jennifer. That was very good and concise and I'd like to now turn to Dr. Andrea Lerner, and we invited her because she was involved, one of the co-leaders in organizing the workshop in early December which I think really kicked off our ability to collaborate across multiple agencies, and so we thought she would be in a good position to address that topic. Thank you.

Dr. Andrea Lerner: [Slide shows title page] Thank you so much, Dr. Unger, and thanks for inviting me to this meeting today. I'll be speaking to you all about cross agency communication and collaboration in the area of long COVID, post-acute COVID, and I'm going to touch on some similar themes that you've heard Dr. Cope mention and also Dr. Koroshetz before me. So, I'm a Medical Officer at the National Institute of Allergy and Infectious Diseases, which is one of the institutes of NIH. Next slide, please. Next slide, please.

[Slide shows screen grab of virtual workshop and key points in bullet form] Oh, great. So as Dr. Unger mentioned, I was going to start off by just speaking about our workshop that we held on December 3rd and 4th of last year to look at -- the title of the workshop was Workshop on Post-Acute Sequelae of COVID-19.This was an online, a virtual workshop, that's available on the NIH videocast website if you'd like to watch, but

basically the goal of this workshop was to really gather knowledge on what was known about post-acute effects of COVID-19 at the time and also identify some of the key gaps in knowledge and key questions that needed to be answered, and as Dr. Unger mentioned, this workshop really did bring together a lot of folks from different spheres so within the U.S. government, NIH, CDC.

We had people from WHO who attended the workshop and participated. There were members of the research community, the clinical community, and the patient community, so it was an event that brought a lot of folks together and next slide, please.

[Slide shows key points in bullet form] And the rationale for why the workshop was held in the first place and the rationale for further study of post-acute, or long COVID, really is that, and this has been mentioned already but with such an enormous burden of SARS-CoV-2 infection, obviously if only if even a small proportion of people are having persistent effects following their initial infection, that's a significant public health issue. This is a distinct opportunity to understand longitudinal effects following, you know, known SARS-CoV-2 infection and also as has been mentioned in this meeting, there's the potential to take what is learned about post-acute or long COVID and apply that to other cases of instances of ongoing symptoms or signs where a viral infection is known or maybe not known but suspected. Next slide.

[Slide shows key points in bullet form] So some of the fundamental gaps and questions that were identified at the December workshop really was as we've heard, the need for common vocabulary, terminology, and case definitions, knowing what the epidemiology of, you know, post-acute, long COVID, is, so including the incidence and prevalence of all of the different various phenotypes when we talk about people who are recovering from SARS-CoV-2 infection and also in diverse communities and across the lifespan.

So, there's a need to describe what are the various phenotypes or kind of categories, for lack of a better term, of conditions that we're seeing following SARS-CoV-2 infection? What's the full clinical spectrum and what's the natural history of those different conditions? Next slide.

[Slide shows questions in bullet form] Some more fundamental questions that came from the workshop, what are the pathophysiological mechanisms of disease, and I say mechanisms because I'm sure we're probably dealing with a heterogeneous collection of conditions when we say post-acute COVID. What are risk factors for having a prolonged recovery from COVID-19, such as underlying comorbidities, how severe your initial disease was, viral factors, perhaps host genetics, host immune response? And that's obviously not a complete list. And also how do therapeutics -- if you receive a therapeutic for COVID-19 during the early part of your disease, how does that -- or a vaccine -- how does that alter outcomes? Next slide.

[Slide shows key points in bullet form] So, as I mentioned, the workshop really started off some nice, interagency and also international communications and collaborations, so both CDC and WHO participated in the December workshop along with, you know, people from other communities, as I mentioned, and as Dr. Cope mentioned, we at the NIH, we have ongoing discussions with CDC regarding approaches to terminology, case definitions, and research approaches as well, so there's definitely communication going on there because this is an area that's important to both agencies.

With regards to WHO, as Dr. Cope mentioned, they recently held a meeting that we were able to -- both of our groups were able to participate in and they have developed an ICD-10 code for what they refer to as post-COVID condition, and they also have shared a case reporting form so that more information can be learned about this entity, about post-COVID condition, post-acute COVID, long COVID. Next slide.

[Slide shows key points in bullet form] So steps forward, with regards to communication and collaboration, as Dr. Koroshetz just went into great detail about, the NIH has launched the PASC initiative, so PASC refers to post-acute sequelae of SARS-CoV-2 infection, so the term that we're using for our research initiative, and these initial research opportunity announcements are out there and we are going to be developing a collaborative research consortium that we hope to have involvement with our partners as well as other, you know, clinicians and researchers to answer key questions about post-acute COVID, long COVID. And we're going to continue to engage with key stakeholders, so including WHO, CDC, clinicians, and the patient community, and there

is ongoing collaborations and knowledge sharing between workshop participants that we're going to continue to facilitate. Next slide.

[Slides shows thank you] And I think that actually is my last slide. So yeah, I think really my take home points here is that this is an area that's important to NIH and I know CDC, WHO, and others, and communication and collaboration between our agencies is something that we're all working towards and continue to do, so thank you.

Dr. Elizabeth Unger: Thank you so much, and now I just want to ask for the participants' forbearance to stay a little bit past our planned break because I'd like to give Dr. Sadie Whittaker time to give her presentation. She's speaking on behalf of the Long COVID Alliance and I'd like to be sure she has the time she needs. Would that be okay with everyone? Okay. I saw at least a couple of nods so Sadie, could you?

Dr. Sadie Whittaker: [Slide shows title page] Yes. I'd be happy to and thank you, everybody for staying a little bit longer. I promise it won't be more than a few minutes, and thank you, Beth and thank you, Vicky for inviting us to talk today. We're excited to tell you about the work we're doing with the Long COVID Alliance as well as the registry. I know they're looking for the slides, but I can make a start whilst you're scrolling through.

So, I think really Emily, who some of you know, in our group who's the head of advocacy was one of the first in our organization to say, you know, this is common. There's something -- this long COVID is common. We need to get on top of it, and so we started talking to a number of the groups, a number of the grassroot organizations, medical centers, other groups who are looking at this to understand what they were doing, how they were tracking this and at some point we decided we would formalize it and so we established this Long COVID Alliance that we set up. We put a press release out for actually yesterday, and if you skip, I think we can skip this second slide.

[Slide shows organizations in the alliance] We don't need to tell everybody on this call that. This talks a little bit about what the alliance does, so it's really open to anyone who wants to join. It's advocates, scientists, disease experts, drug developers, and the goal really is how do we learn from each other? How do we pool resources to do a better

job? And there's two aspects to this. One is based in the advocacy world and then the other is to accelerate research and one of the first things that Emily really spearheaded was this money from to secure long COVID research clinical trials, so that was a pretty exciting moment I think for this group. You see some of the organizations on the right hand side of the slide. Since the release went out, we actually now have 93 people who are signed up to be part of this alliance so there's a lot of appetite for it and I think there's a lot of exciting work we can do by working together.

Next slide please.

[Slide shows alliance priorities in bullet form] These are some of the key priorities. Ensure meaningful participation from individuals who are suffering with long COVID. Health equity obviously is a big one. We all know that COVID has disproportionately affected people of color and so we're anticipating long COVID is also going to have an impact there. How do we address that? Data harmonization is my kind of soapbox. Anyone who's heard me speak about the registry has heard me talk about how important data harmonization is. If we can get enough people collecting data in the same way, we can understand things a lot easier. I talked about leveraging existing knowledge and infrastructure. I think those in the ME/CFS world have such a lot to contribute to what we're seeing now with long COVID and so how do we leverage that? And then obviously, connecting policy makers with patients and researchers to advance some of those policy goals and increase awareness. Next slide.

[Slide shows global goal] Within the Long COVID Alliance, we have this global data collaborative that Allison and I have been working on, and the goal here is to how do we create the global big dataset by working with others? How do we harmonize how we collect data, and how do we get people to agree to share their data so that we can aggregate it to get to the largest amount of information possible?

And so, we've been talking for the past several months to lots of different groups and asking them hey, could you tell us how you're collecting data? This is how we're doing it. Can we try and collect it in a similar enough way? Will you share what you learn? Are you willing to aggregate? So we've been having those kinds of conversations over the

past several months and it's really, you know, the centerpiece for us, and you can go to the next slide.

[Slide shows numbered steps in the registry and details] The centerpiece for us in this is our registry, so we established this registry. We're calling it You and ME, launched in May of last year and it's both patient recorded data and biological samples. When we launched in May, it was open to people with ME/CFS and controls, and then in December, we opened it to long COVID, and so we're collecting data from both people who had long-term effects of COVID and those who don't as a comparison group. So the goal's really here obviously to understand what's going on in ME/CFS. In long COVID, it's to understand susceptibility and resilience to long-term effects, and then the benefit we have with this is that we can compare the two, right?

We can look at similarities and differences between long COVID and ME/CFS. The thing that kind of drives us is the principles you see at the bottom here, so we want to collaborate. We want to work with others. Co-creation, so we created the way that we collect data, the design of the registry with the community and we continue to evolve it.

We continue to survey people and speak to individuals and finesse that, and then we want to make the information within the registry a way to empower individuals who have either long COVID or ME/CFS so, you know, we allow them -- we have created an approach where they can download the information, share it with their doctors. Through the symptom tracking app I'm going to talk about in a couple of slides, you can see your symptoms on an ongoing basis and see how different activities can impact that symptomology. So just briefly, let's look on the right. You enter the registry. You sign up. You complete some baseline surveys. You can download a mobile symptom tracking app that we'll show you shortly, and that dataset, the data from the app and registry is aggregated together so you have a really complete picture of longitudinal data for that individual.

We'll ask participants to provide biological samples and then that all of that data in aggregate will be made available to researchers who can submit proposals that will be vetted through a peer review panel. So next slide, please.

[Slide shows graphic of data collection over 6 months in boxes for every 3 months] I'm going to give you an overview over the next few -- couple slides of how we're collecting it in ME/CFS and how we're collecting it in long COVID. We really wanted to align the two obviously so that we could do that comparison between the two cohorts, so this is an overview of what we're collecting at month 0, 3, and 6, and how we came up with this was we went to everybody in the ME/CFS community and said how are you doing it, how are you doing it, how are you doing it, and Allison actually did this incredible crosswalk and so we aligned it as closely as possible with others in the community, and then if you scroll to the next slide, the long COVID is on the next slide. It's not changed on my end.

[Slide shows data collection at each interval in different boxes] Thank you. It's very, very similar, right? -- because we wanted to be able to compare cohorts, the main difference being that we are collecting data more frequently for the post-COVID, primarily because of insights that we got from that community that the symptomology's changing quite rapidly over time. Next slide.

[Slide shows images from tracking app] Okay. And this is a bit of an overview of the symptom tracking apps where you see on the left-hand side the different symptoms you can add. You can take symptoms away. You slide them across with the slider. You can have treatments. On the right-hand side in the middle there you see how you can add life events, and then you can capture a general wellness score, so this is not all the screens. I just wanted to give you a quick snapshot of kind of some of the symptoms that are used in the tracker, and we, like I said, we created this with the community. We did go back and share this with the long COVID community and make tweaks according to their needs as well. Next slide.

[Slide shows breakdown of collaboration in table form] I mentioned that data harmonization, and this is obviously one of the first focuses of that global data collaborative. This just gives you a snapshot of how we do it, so we've been talking to AHA and recovery core, just sort of seeing okay, what do you collect? What are the variables you're looking at? What are the time points? And doing this kind of crosswalk.

So, we have we have this for ME/CFS and we have with this for long COVID and we'd be happy to share and make it available, and you know, a lot of you are collecting data.

I think the more transparent we can be about how we're all doing it, that the closer we can get to harmonization. Next slide. The next two slides give you a snapshot of some of the data. So overall, we have 2,730 people in the registry.

We have 2,054, so this number has gone up since I shared these slides earlier in the week and this shows you a snapshot of ME/CFS. Obviously, we need to do a better job of enrolling people of color and that's a primary focus for us this first part of the year, but this is an inter -- for us, I think it's really interesting to be able to already see the patterns in age and functional status, and we're actually working with a statistical group over the coming months to do more analyses. We have all this information. We have more than a million data points already just in this cohort alone and so we have a ton of information and we want to start digging into it and starting to understand what we have in there and reporting that out as soon as possible. Next slide.

[Slide shows graphics breaking down gender and sex with percentages with tables and charts] This is the COVID-19 for comparison, so I mentioned we opened this about six months later in December so we have 335 when I shared these slides, but now we have 360, so we're ticking up and we're working with a lot of the grassroots COVID organization to help us pulse out, you know, links to the registry through their online groups. Similar demographics in terms of race and ethnicity and then you see the age distribution is a little bit different than the ME/CFS and the functional status is skewing more towards moderate and severe, which if you remember in the ME/CFS is a little more severe.

So still relatively small numbers but already pretty interesting information that we're getting out, and then the next slide just talks a little bit about the case criteria, if you want to jump to that one.

[Slide shows case definitions] So we do have the long COVID individuals complete a symptom questionnaire that has an algorithm that's pegged to the case criteria, so this is based on about 350 individuals with long COVID, so there's about 29%, 28, 29%

meet at least one case criteria and then if you see the table on the right-hand side, so these are not slices of a pie, some of these like represent the same individual, so of the 350, about 12.5 meet Canadian, 12.5 IoM, 17 Fukuda, and 24 ICC.

Part of the reason we think that difference we're seeing in ICC is because obviously it doesn't have the six-month cutoff, and so our data is still fairly new. Like I said, we opened in December, so obviously, that number is skewing a little higher, so we're anticipating that once we get past the six-month mark, the numbers of the other criteria may also tick up. So that was my last slide. I don't know how you want to do questions, Beth, but hopefully that gives you a snapshot of kind of what we're doing in the registry and our symptom-tracking app. Thank you so much.

Dr. Elizabeth Unger: I do think the data management question and common data elements are going to be a continuing process and theme and it's great that you've assembled some of that information. I think that there is also web bases that have been compiled by several groups. Maybe we could get those all pulled together for the community. So I think according to our schedule we'll take a little break and in the interest to be sure that we do have discussion time, perhaps just a five-minute break this time. Would that be okay? All right. So come back at 2:40 and see you then.

Dr. Elizabeth Unger: I guess best way is just to start. Christine, could you?

Christine Pearson: Yup. Hi, everybody again. So just a couple things housekeeping before I begin. We have about 35 questions logged, so if we could try to, those who are answering, keep your answers shortish but complete. That'd be great, and I'm going to try to hit ones that have been asked by multiple people in the interest of getting the most people's questions addressed.

So, there is a question. There were a couple questions related to vaccination for COVID among people who have ME/CFS and whether or not there are concerns about that, health concerns related to that.

Dr. Elizabeth Unger: Could someone from the response answer that? Do we have that information?

Dr. Jennifer Cope: All right. We -- Yeah, I can. I'm sorry. This is a question about people with ME/CFS getting vaccinated or people with long COVID or both?

Christine Pearson: With ME/CFS in terms of if there are potential health complications related to that.

Dr. Jennifer Cope: Okay. Well, I'm by no means an ME/CFS expert, but I can tell you from a -- just generally, from the response standpoint, you know, questions about getting vaccinated are really CDC mostly refers those to a conversation for the patient to have with their physician and go through the risks and benefits.

That being said, we know there's, you know, this is all very early. These vaccines have just come out and so there's not a lot to go on, but as far -- to my knowledge ME/CFS is not a contra indication to being vaccinated and CDC is encouraging everyone who can get vaccinated to do so.

Dr. Walter Koroshetz: Yeah, I would agree. Walter. You know, we don't have really good data so we can't say anything definitive but we haven't heard that ME/CFS folks have been particularly worsened by the vaccine as compared to anybody else. You can definitely get some pretty nasty symptoms for a couple of days after the vaccine and it may be that some ME/CFS may last longer from what we've heard, anecdotal. There also are anecdotal reports that the vaccine has made some of the symptoms go away so it's really -- we really don't know the answer.

Dr. Sadie Whittaker: And we just integrated actually a survey into the registry that's going to capture vaccination data, type of vaccination and response for both the ME/CFS and the long COVID cohorts so we'll be able to have data on that quite quickly I think.

Christine Pearson: Great.

Dr. Walter Koroshetz: The neurologic conditions, the only folks that there's hesitancy in is if their symptoms came on after vaccination, so maybe if someone's symptoms came on -- of ME/CFS came on after vaccination, that might be a special instance.

Christine Pearson: Great. Great, thank you. So I think this one, actually the next question actually sort of relates to that and it's something I've been wondering as well so and that is how long or how many patients will it require before we have a statistically sound assessment of the percentage of long haul patients who have ME/CFS?

Dr. Walter Koroshetz: Sadie's going to get the answer to that one quicker than anybody else.

Dr. Sadie Whittaker: So I won't speak from our data but I will tell you from the people who started tracking COVID the earliest was the [inaudible] of King's College and they partnered with ZOE Health to monitor kind of the acute part of the disease and what they're reporting is that it's about 10%, so they have data on at least a couple million people in the U.K., and of that 10%, it's all people who managed the disease at home. None of that cohort were at ICU, in the ICU or had really severe symptoms in the acute phase, so that's the best data point that I've seen on that.

Dr. Nancy Klimas: And that mirrors the Dubbo study in Australia for ME/CFS post-EBV/Q fever, Ross River virus was 11%, so it's not a bad guesstimate that we're looking at about 10 to 11%. Right. Yeah, and that [inaudible] several [inaudible]. [inaudible] The question is when we will have the answers. I would imagine about a year we'll have enough data back to have a first stab at that answer for the CDC study that we're doing.

Dr. Walter Koroshetz: I would say also that people who have ARDS in intensive care unit, even if it's not COVID, they, about 75% are still impaired at a year, so those folks, they're going to have a long recovery. It may be different from people who didn't get hospitalized and are having symptoms, but, you know, that's a population that everyone's known about for years.

Dr. Nancy Klimas: Yeah. And I think that hospitalized versus not hospitalized is an important cut point in our prospective work to look at outcomes.

Dr. Walter Koroshetz: Right.

Christine Pearson: Thank you. And so then were a couple people who asked about questions related to PEM and so it was how did or do the different long COVID studies ask about PEM? Did they equate it to post-exertional fatigue, quote feeling worse after exertion unquote, or in a more detailed way? I'm concerned any and all post-exertional symptoms are being interpreted as PEM.

Dr. Elizabeth Unger: Yeah. That's a complicated question and I think the challenge with post-exertional malaise is both its importance and its poor definition. And what people not familiar with ME/CFS don't usually ask about post-exertional malaise so it's very difficult to find it in the records. There's no coding of that as a symptom in the ICD codes and so there does need to be a lot of education around what is meant when you ask the questions. We have been suggesting using a question similar to the one that's in CDC symptom inventory which does talk about the extent of worsening after physical or mental exertion of symptoms, but it is a -- it's a very important question and one that I think will continue to require more work, and others want to comment?

Dr. Walter Koroshetz: Just to say that I mentioned from the long -- from the patient-led research for COVID survey study, they did get specific about post-exertion malaise asking, you know, questions what's the delay between the effort and the sickness and how long did it last and anyway, their estimate is like 90% of the people they thought had post-exertion malaise.

Ben Hsu-Borger: That's a striking [inaudible]. And I think it's not a coincidence that like the patient-centered studies are the ones to then capture and zone in and identify these things to be tracked. So, I guess I just have kind of a little bit broader question to ask about this like a lot of these presentations have been great. It's been great to hear like all the details of how NIH and CDC are moving forward. It gives, you know, a lot of hope for the [inaudible] situation and the things we can learn from it. I guess, you know, connecting it back to day one, just my broader question of how are -- given all we know about the difficulties, and especially difficulties in electronic health records and real world data, of like capturing ME/CFS and like so the need of this, you know, PASC initiative to and what CDC is doing to do move very fast and do research because we

do need it very fast but I did not hear a lot of -- I have a lot of questions and worries about whether we are actually going to capture.

We're going to do a bunch of research, but are we going to appropriately capture people with ME/CFS given all the constraints that we've talked about and that we know all the difficulties in doing, you know, evidence-based, in doing research whether people are even looking for post-exertional malaise or how it's defined, so given that this stuff is -- this is a unique, kind of once in a lifetime opportunity to research and get answers to these post-viral questions but how are we -- what are the things that are being done to make sure that -- in within the PASC initiative and others, we will be able to know people with ME/CFS will be identified clearly and that we're -- I'm certain there are a lot of good ME/CFS researchers who know this disease, who will apply, you know, Dr. Whittaker, what she talked about and like the different definitions that you're tracking but the concerns about all the researchers who the many clinicians and researchers who don't understand the disease and then won't design research that would appropriately capture these people at this one shot we have to do it and so how can we deal with that problem?

Dr. Elizabeth Unger: And that's a -- it's a good question. I would say at CDC it's been the ME/CFS program has been integrated very closely with the studies that are tracking the long-term sequelae and we've had numerous conversations and we're basing our recommendations on questions and surveillance based on things that we used in the multi-site clinical assessment of ME/CFS when we worked with seven ME/CFS experts, clinicians, but this can't be over-emphasized and I think the NIH's secret to success is the fact that they are asking everybody to be collaborative and to be dialoguing over these things and that and they have a patient advocacy group overseeing it and so I think that is again a secret to trying to address this concern, and it's one that we in the ME/CFS program at CDC have been very intentional about being sure that the right information is captured because you're correct, if you don't look for it, it'll be difficult to find it. And Charmian, you have your hand raised.

Dr. Walter Koroshetz: Can I just say from NIH, you know, Adrian and Vicky are the ones who are telling people what they have to collect so I think we'll be in good shape. They don't do it, they don't get the money.

Dr. Elizabeth Unger: Charmian?

Charmian Proskauer: Yes, I –

Ben Hsu-Borger: I'm sorry, but Dr. Kor -- I'm sorry, Dr. Koroshetz, just and I hate to interrupt you Charmian, but like when I read you through the ROA for the PASC, like there's no -- there's mention of this as a dysautonomia]. There's no mention of ME/CFS. I guess I'm not clear. I like a lot of what I hear in the presentation, but when I look at the documentation of the ROAs, like ME/CFS feels like it could have called out or identified or given some clarity that would at least point people in the right direction and that's why when I look at the actual notice of funding, I have a lot of questions.

Dr. Vicky Whittemore: If I could respond. I don't think it -- yeah. If I can respond. As Dr. Koroshetz described, once the grants are awarded, NIH is bringing all of those investigators together to harmonize the protocol, harmonize what will be collected, and you can be assured that ME/CFS and ways to diagnose and identify ME/CFS will be a part of that. So, what the ROAs are looking for are the investigators who will then all be brought together to develop those protocols and the data elements that will be collected. So, we're not expecting in those initial applications for all of that to be detailed. That will come after the groups are funded. Thank you.

Dr. Elizabeth Unger: Charmian?

Charmian Proskauer: Yeah. I just want to build on what Ben said. It gets back to the structural issues that we were talking about yesterday. Difficulties and limitations in ICD coding for instance. When I look at the idea of looking at electronic health records, I know that ICD codes are missing. You pointed out already that the symptom -- there's no symptom code for post-exertional malaise. That's a huge omission and also the medical education, training doctors to recognize the symptoms of ME/CFS is something we've been struggling with for 30 or 40 years and that's not going to go away I guess. There are also are some seems like some limitations in the epidemiological approach,

for example, requiring a positive COVID test is going to leave out a lot of the longer term patients who would be exhibiting symptoms perhaps that could be very illuminating right now. We don't have to wait another two or three months. Some people may get symptoms of long COVID after an asymptomatic case of long COVID and I know the antibody tests are not all that accurate, might not be the only way to identify whether someone who's exhibiting long COVID symptoms might have had a asymptomatic infection.

And finally, anecdotally, what we know from a lot of ME/CFS patients is the symptoms, the recurring symptoms don't always occur after the first infection. It may be the second infection. It might take two hits to activate the immune system or whatever causes the underlying biology of ME/CFS systems but very often people who become sick with ME after a cold or bronchitis or some seemingly minor infection might have a history of mononucleosis for example or something that we know often is a trigger, so these kind of subtleties, I know they may be not the majority of cases but they should still should -- we should think about these things.

Dr. Elizabeth Unger: Thank you. I think it's -- there's so many questions. There's no one study that's going to be able to address all of this. Pat, you have your hand up for a comment.

Pat LaRosa: Yes. My face disappeared by I'm still here. I'd -- thank you Dr. Whittemore for saying that the ME/CFS will not be forgotten because that's really the feel I kept getting today was that well, they don't know what patients had before they got sick, so there's no way to research it and we heard yesterday that there might be subsets, but still we have this huge community of several million people that have no answers and I'm thrilled that post-COVID is being addressed immediately but I would hope that the ME/CFS community is going to benefit from it, that we will see treatments and acknowledgement and education which I know is the whole purpose for these two days, so thank you for everyone's efforts. I hope it all follows through.

Dr. Elizabeth Unger: Yeah, thank you. We do too. Christine, can we squeeze in another question?

Christine Pearson: I think we can. So, this is one I think we got asked multiple times and I know was a question yesterday as well, which is how will you ensure that the cohorts are truly representative of those most affected by COVID including black, Latinx, and Native American/Alaska Natives, as well as people with disabilities and chronic illness? Okay.

Dr. Elizabeth Unger: Dr. Saydah, looks like you wanted to comment.

Dr. Sharon Saydah: Yeah, no. I was just going to try and address that question, and I agree this is vitally important that our cohorts are as representative as possible and as diverse as possible. For the cohorts that we've initiated, you know, we are doing -- for the INSPIRE for example, we have specific outreach in multiple languages for participants to try and ensure that we have a broad representation there. We've included the American Indian populations in the Southwest as one of our groups and we have other studies that -- one which we actually didn't mention but includes six different healthcare centers throughout the U.S. with an aim to include both people who have access to healthcare and those who might not have access to healthcare for these studies.

Dr. Walter Koroshetz: I'll just add from the NIH side that this has been something that has been focused on for quite a while, particularly in the vaccine space, so there's a big effort to reach out to African-American, Hispanic, Native American populations with regard to vaccine education, and even before that there was a diagnostic testing program that NIH ran also had a large component of it, it was called RADx-UP, to bring the testing research to underrepresented groups and the vaccine work as well.

We work with companies to improve their diversity of the populations that were in the vaccine studies, so there is actually an infrastructure now that allows us hopefully to be more successful that we can now adopt for the post-acute work. That's kind of our plan.

Dr. Elizabeth Unger: Good point. Thank you. I think we are at the hour. I've had a couple of the panelists let me know by chat that they need to leave. So Dr. Damon –

Christine Pearson: Beth, can I jump in real quick with a housekeeping --

Dr. Elizabeth Unger: Sure. -- thing? We have gotten a lot of questions about whether or not we can share the slides as that might be more useful for the patient communities. I think that as long as all of the speakers are fine with that, we can do that. There was also a question asked about posting them on the website. That is a little trickier due to some of the rules we have about posting things, but we will look into that, but for those of you who have asked and for those who have been on the call, if you would like those, the slides, we can provide those. And then also, I know yesterday NIH said that they would be happy to answer questions directed to them that we didn't get to and we will be doing that as well, so apologies for those that we weren't able to get to. There's just -- it seems like there's never enough time for this, so thank you. Dr. Damon?

Dr. Inger Damon: Okay. So I guess just a final thank you to everybody who presented, participated, asked questions, you know, contributed through the chat and Q&As. Really appreciate the open dialogue and moving forward in this area of work and really understanding the interface of long COVID and ME/CFS and how we move both diseases forward to better understand treatment and ultimately hopefully prevention methods, so thanks, everybody.

Dr. Elizabeth Unger: Yes. Thank you. Till we meet again.

Dr. Walter Koroshetz: All right. Very good. Thank you, everyone.