RECOVER Initiative Stakeholder Briefing Transcript

September 15, 2021
12:30 – 1:00 PM EDT

Amy Patterson

Time: 00:03 – 06:21

Good afternoon everyone. Thank you, Victoria. Welcome and thanks to each of you for joining us today for the Stakeholder Briefing about the NIH RECOVER Initiative.

This is one of many steps along a journey that I hope that we'll have together in terms of delivering meaningful answers for patients and families that may be coping with the aftereffects or the long-term effects of SARS-CoV-2 infection.

I also wanted to say, before I jump in, that I'm the one speaking at the moment, but I represent a large team of people across the various Institutes and Centers at NIH who are very dedicated to working on this. And we have a few of the expert leaders from those other Institutes who have also joined today from our Neurology Institute, our Child Health Institute, or Institute of Allergy and Infectious Diseases, for example. So, they'll be on hand toward the latter portion of our session to engage in a dialogue with you.

Over the next 30 minutes, we're going to talk together about some of the key points of the public announcement that was made today about the RECOVER Cohort, the RECOVER Initiative. We're going to talk about some of the key features of the RECOVER Investigator Consortium and the national study that is being launched. And importantly, we'll also hear some brief perspectives from the Long COVID Alliance. And then we'll transition to a brief up Q&A session. That's a lot to pack in within 30 minutes, so we'll get started.

As this group is all very well aware, people who've experienced SARS-CoV-2 infection may develop a range of health problems, some of which are new, some maybe returning, or some maybe ongoing. Long COVID, as well as other kinds of post-acute sequelae of SARS-CoV-2 infection, or what we call PASC, to use a scientific term, really represent a broad and complex range of symptoms and findings. So, it's critical that we take a systematic, inclusive, and comprehensive approach to being able to fully understand and treat and even prevent PASC. And so, toward this end, we want to make sure that we have a common protocol, we have data harmonization, and we have diverse and inclusive participation. Not in a multitude of small individual studies, but really at a truly national scale.

And so, to do this, people assembled the most diverse study population possible to ensure this research is inclusive and that results are relevant for all people. And today, as you may have read in the press release, we're announcing an award of over $400 million to support this national study of Post-Acute Sequelae of SARS-CoV-2 infection and Long COVID, and what we refer to as the RECOVER Meta-Cohort Study. This award was made to NYU, that is serving as the RECOVER Clinical Science Core, and it's for the purpose of their supporting a large research consortium involving patients

and more than 100 researchers, at more than 30 institutions and hundreds of sites across the country. When we talk about the RECOVER Meta-Cohort, we're really talking about a cohort of cohorts, meaning that it unites many cohorts or groups of participants, again, from all regions of the country. And collectively, these cohorts provide that diversity, the geographic reach, that covers the age range and the clinical spectrum, that we need in order to really answer the questions. And, as you know firsthand, the clinical picture of Long COVID varies from person to person, so in recognition of this, data will be systematically collected from tens of thousands of individuals across the lifespan: adults, including pregnant individuals; children and the elderly; as well as individuals in different settings rural, urban, people presenting in Long COVID clinics or acute care settings, just to name a few. The diversity, a number of participants in the RECOVER Meta-Cohort, will allow us to comprehensively characterize this clinical syndrome and the findings and the trajectory of patients' clinical course and experience over time.

One of the key features of the RECOVER Initiative is the use of a master or a common clinical protocol of protocols for adults and pediatrics that will be used across the Meta-Cohort. So, rather than launching a multitude of small individual studies, all using different methods and terms, our goal here is to launch a harmonized study of national scale, where RECOVER Investigators use similar exams and tests and they speak the same language in reporting those results. This strategy will enable us to gather data from a large number of participants collected by different research groups across the country and to pull that data, to compare it, and to analyze it. And, ultimately, this is really the only way that will provide meaningful and broadly generalizable findings.

And importantly, we'll have created a national harmonized data and specimen resource that can be leveraged and utilized by researchers worldwide to better understand, treat, and prevent PASC. So, at this point, I'd like to hand the baton over to Dr. Stuart Katz from the NYU Grossman School of Medicine. Dr. Katz is the Principal Investigator for the RECOVER Clinical Science Core, and he'll provide an overview of the RECOVER studies and go into bit more detail. Stuart, over to you.

Stuart Katz

Time: 06:22 – 11:18

Alright, thanks Dr. Patterson. I will just also mention that I'm the one representing the NYU Clinical Science Core today, but also there are three principal investigators myself, Leora Horowitz and Andrea Troxel, and an incredible team of individuals that we've been working with to bring us to this day. So, you've heard that the RECOVER Consortium is a network that involves hundreds of researchers, with enrollment sites across the country, in fact in all 50 states, and this was brought together by the NIH. And the role of the NYU Langone Health Clinical Science Core is to bring together all the researchers and all the other stakeholders, including our patient and caregiver stakeholders, in pursuit of a unified mission, which is to better understand PASC and to develop new approaches for diagnosis and treatment.

So, it's a big task, and in order to get there, we are planning to enroll tens of thousands of recertification participants over the next 12 months. And I'm going to add that this is really an unprecedented scale and pace of enrollment, which is supported by this large network of researchers and sites across the country. And the recruitment of a large number of participants is necessary to provide accurate estimates, but of the rate or the risk of PASC after COVID, also different types of PASC—we think there may be more than one type of PASC—and also the identification of risk factors for PASC and, finally, to better understand potential mechanisms. All that comes together under this clinical science coordination.

To ensure that the RECOVER study findings are relevant to all Americans with PASC, the RECOVER Consortium willing or participants that match the diversity of the US population from across the lifespan so, including children, adults, and women exposed to SARS-CoV-2 during pregnancy and their babies. So again, we have specific protocols that have been tailored for each of these different groups, but we also have harmonized as much as possible the scientific goals and the data collection among these different populations. So, in addition to leading the scientific development for all these protocols and collaboration with the NIH and investigator, patient, and caregiver stakeholders, the other role of the Clinical Science Core is to administer and oversee the implementation of these studies. So, the first step of that is to finalize the selection of the study sites and to activate those study sites. So we're in the final stages of that process and we will be posting information about the selected research locations and study investigators on the recovercovid.org website later this month.

Our goal is to bring the opportunity for participation RECOVER studies to communities across the country to make it easier for people with PASC to join in our search for answers and new treatments.

People with interest in learning more about the RECOVER studies can register now on the website to receive more information about participation and RECOVER studies. I also want to just highlight how important our collaboration with patients, caregivers, and other patient representatives have been, in the genesis of the RECOVER protocols today. So, from the very start, we were working with patients, caregivers, and other patient representatives to develop these protocols. Very, very important insights were provided that were very important in the final versions of these protocols. And, now that we're going to start to move into the enrollment phase, we will convene a national panel which will be led by patients and caregivers to provide ongoing guidance on the RECOVER study progress and our Clinical Science Core will also lead patient engagement efforts at the local level, at the communities, to foster patient and caregiver collaborations with the RECOVER researchers across the country. So, our goal here is to promote collaboration and transparency with patients' caregivers and all community stakeholders in order to build trust and really maximize the beneficial effects of the RECOVER studies on public health.

So, I'm going to stop there, and I'm going to pass the baton to Emily Taylor from the Long COVID Alliance.

Emily Taylor

Time: 11:20 – 15:45

Hello. Thank you so much, Stuart, and it's a pleasure to be here with this team today. I'm wearing a couple hats in my representation today. First, my name is Emily Taylor. I am the Director of Advocacy and Community Relations for Solve M.E., a nonprofit that has been in existence since 1987, working on myalgic encephalomyelitis or chronic fatigue syndrome. And in addition to that, I'm also a caregiver for a loved one in my family who got a virus in 2008 and never recovered. So, I'm very familiar with a lot of the symptoms and challenges that so many people are experiencing as a result of being infected with SARS-CoV-2.

As the senior staff member of the Long COVID Alliance, you can learn more about us at longcovidalliance.org. We are a network of patient advocates, scientists, disease experts, and drug developers, who have joined together to leverage our collective knowledge and resources to educate policymakers, educate our partners at NIH, and to accelerate research to transform our understanding of post viral illnesses. SOLVE M.E. co-founded the Long COVID Alliance with two amazing partners, the COVID-19 Advocacy Project and the Pandemic Coalition, in February of this year, in order to help create a mechanism and a collaborative space for diverse participation and representation—especially to include the millions of patients and researchers who have already been working on these important issues for decades.

The Long COVID Alliance has not had the opportunity to completely review today's announcement and we look forward to sharing our feedback, our guidance, and expertise with NIH and their partners.

The LCA and our members are really excited to elevate the patient voices and establish research in this process.

Here's a sum of our priorities for this important work that we see the NIH continuing to elaborate and expand on.

First is ensuring meaningful participation of the patient voice – nothing about us, without us. We feel that there's a lot of areas for improvement in this process. Second, is, as was already discussed confronting systemic bias and racism in the Long COVID response. We've already heard from many patients that these systemic and racist barriers are still impacting and plaguing both the research and patient care today. And last but not least, most importantly, delivering evidence-based treatments to patients as quickly as possible.

There are several things we believe that the NIH can use, and mechanisms that can be used, to help do this, in addition to the amazing work that their RECOVER Initiative has announced today. The first is leveraging existing post disease knowledge and infrastructure. As I described, there are a lot of overlaps with existing illnesses that we've been researching for years, for decades even, and we can expedite the process of delivering these treatments to patients by leveraging that knowledge.

Expediting public and private partnerships is another priority of the Long COVID Alliance. We do not like the silos that have existed in many of these fields, and we really see the RECOVER Initiative as a mechanism to break down those barriers, bring

these resources together, and work collaboratively towards quick solutions that will help patients' quality of life today.

And last but not least, facilitating data harmonization. As many of the scientists on this call know and respect that data in silos, comparing apples to apples, is so critical and all of this data, we believe in the big data dream that can come together and through machine learning, through our advanced understanding and processes, we can bring all of this diverse data into a centralized location. We encourage the NIH to keep this data available, public, open source, and, of course anonymized to protect patients' identities, but so that others can assist by using their mechanisms in their own resources to help apply answers to the data that is found through this process.

The key question that we have for the NIH today is: How can we as Long COVID Alliance and the diverse membership we include, work together to ensure that patient voices are at the center of this important work to combat misinformation that's been so prevalent on the Internet and to be valued partners in the development of these new initiatives and this diverse research cohort, so that we can find answers and get people well as soon as possible?

Thank you, again, for this opportunity to share these thoughts. I look forward to being your partner and our continued efforts together.

Lenora Johnson

Time: 15:47 – 17:48

Thank you, Emily. We are very grateful to have the Long COVID Alliance as a partner and appreciate the effort to be able to engage and continue to work with you all throughout the RECOVER Initiative.

As we go into the Q&A, and we already have some questions coming in through the Q&A feature of the chat, I just want to make sure I take the opportunity to also, in addition to Drs. Katz and Patterson, to introduce some of the other leaders across NIH that are leaning in heavily on the RECOVER Initiative. Dr. Rohan Azra is the Acting Deputy Director of Extramural Research at the National Institute for Child Health and Development. We have also Dr. Andrea Learner, Medical Officer within the Office of the Director at the National Institute of Allergy and Infectious Diseases. We also have Dr. Clint Wright who is the Director of Clinical Research at the National Institute of Neurological Disorders and Stroke, and of course I want to just recognize my colleague as a Communication Director from the National Institute of Neurological Disorders and Stroke, as well.

That set of introductions gives you a sense of the breath of the RECOVER Initiative. It is truly an NIH-wide initiative. And many, many, many across the NIH have been dedicating much much, much time, energy, effort, over the last several months to get to this point. And so, at this point in time I'd like to turn to some of your questions.

I want to start with what I think is probably the most important question as Mark indicates: Most of us with Long COVID only have one question, when can we expect a cure or when will there be a cure?

So, I'd like to just ask either Drs. Patterson or Katz to walk through what happens first, next, and the trajectory as we work toward testing different ways to get to a cure.

Amy Patterson

Time: 17:51 – 20:33

Thank you, Lenora. I'll start us off and then pass the baton to Stuart.

We are already thinking about ways in which to solicit ideas about potential candidate interventions, ways to evaluate them and prioritize them, key features of the trials in terms of their overall design—again, so that we have studies that are truly powered to provide the evidence base needed to deliver safe and effective interventions for patients. In parallel with this activity, which is in draft and development form right now, we will be engaging with the RECOVER Consortium, inclusive of investigators and the patients that will be participating as part of that activity in terms of conceptualizing the framework for trials – and this work is beginning now and will continue over the next several months.

In parallel, as the RECOVER Initiative moves forward and gathers data about symptomatology, clinical course, risk factors, also gathers data and specimens that shed light on the biology that underpins what patients are experiencing, we'll be able to discern potential targets for those interventions and really more strategically focus our clinical trial interventions.

So that's a long way of saying that there's sort of a multi-pronged approach right now to preparing, tilling the soil, if you will, for being able to be prepared to launch trials within the next year, to year and a half, and much sooner than that if we see a signal or sub something that looks promising. And we'll also add that one of the things that the RECOVER Initiative will be doing is looking at the clinical course of patients who have received different types of interventions during the acute phase. Because we think that this could offer clues as to what might be effective in terms of either preventing or mitigating some of the symptoms of some of the immune modulators, for example, or the monoclonal antibodies – have they had an impact on the clinical course after the acute phase? But, Stuart over to you. What would you add or modify from that?

Stuart Katz

Time: 20:34 – 22:09

I will just add also the role of vaccinations. So we will be collecting that information. We will be able to discern whether in fact vaccination has any detectable effects on the course of PASC. But I think more broadly, one of the charges of the Clinical Science Core is to prepare for future clinical trials, which would use the same RECOVER research infrastructure as the platform for those clinical trials and we will have working group committees that are part of the current RECOVER efforts. And again, I will mention that we will have patients, caregivers, and other patient representative on all of those committees.

The committee that's the most important with regard to this question is what we're calling a Study Design Committee, which will be looking at the data as it comes in at regular intervals. And we'll be looking to see: are there early detectable signals that could be used to start the planning of clinical trials of future interventions? And the other part that's important in terms of addressing these questions is, as I pointed out, that we're front loading our enrollment, so that we're talking about tens of thousands of persons participating within the next year. So we are doing everything we can in order to detect a signal as early as possible and then to have the planning in place to be able to turn that – as quickly as possible – into a clinical trial.

Lenora Johnson

Time: 22:14 – 22:41

Dr. Katz, I just want to follow up because you talk a little about enrollment and there are several questions that discuss or are around enrollment. When will we see studies first starting to enroll participants? Will enrollment cover rural participants? And will enrollment address specific other participants with other diseases?

Stuart Katz

Time: 22:42 – 24:05

So, we expect the enrollment to start in about a month. As I mentioned, there are numerous sites across all 50 states, and there are both urban, suburban, and rural communities. We've actually structured the enrollment in such a way that there's additional efforts in areas either that are defined as rural or perhaps that are medically underserved, where people may have less access to studies like this. So, there's going to be extra efforts to reach out to those communities, so that we can enroll people from all different types of communities across the country. Our enrollment criteria are based on history of COVID infection, with or without any symptoms at the time, with or without subsequent symptoms.

But we are not enrolling groups of individuals from other disease states at this point in time. So our enrollment is focused on people have had some evidence of a PASC/SARS-CoV-2 infection and appropriate control groups. But that would be unexposed individuals, as opposed to other control groups or specific disease populations. That's the current structure of the study design.

Lenora Johnson

Time: 24:08 – 24:23

Great, thank you. There are a couple of questions around the protocols, Dr. Patterson, that speak to what they are, where they are, can they be made available or public?

Amy Patterson

Time: 24:24 – 24:54

I'm going to turn that over to Stuart in a second. But we will be making available the protocols and then also publishing a design paper and more readily accessible synopsis. But, Stuart, over to you for the details about that.

Stuart Katz

Time: 24:56 – 26:06

Right, so yes, we do plan to make the protocols public. We intend to share all the data elements that we will be collecting to promote collaboration with other scientists, here and internationally. And beyond releasing the protocols, every document that comes out of the Clinical Science Core in support of this RECOVER Initiative will be written in plain language, so that all the patient participants will be able to access the core information of the things we're doing in in language that's not highly technical in nature. We think this is this is really, really important. This is done routinely for consent forms, so we're taking this beyond that, to really every single document that will involve patient participants, which is essentially every step of the research process. We will develop plain language and technical documents and they'll be released together.

Lenora Johnson

Time: 26:10 – 26:13

Great, thank you for that.

Alissa Gallagher

Time: 26:13 – 26:32

Thanks, and we also have a couple questions in the chat related to treatments moving forward into trials. This might be another great question for you, Dr. Katz and Dr. Patterson: What is the mechanism to have a potential treatment considered as a candidate for future trials?

Amy Patterson

Time: 26:33 – 26:34

Stuart, do you want to take that one, or do you want me to start?

Stuart Katz

Time: 26:35 – 28:08

So, what I'll say is that we have another one of our working group committees that we are developing, is what's traditionally called Ancillary Studies Committee, which is the idea of collaborating with investigators who may not yet be part of the RECOVER

Initiative. And that traditionally is related to an investigator who may be looking to get additional funds for specific research question, but for this initiative we're really taking that further. We are now starting to bring together clinic investigators at PASC clinics, other citizen scientists that are parts of advocacy organizations, and we're going to create a forum where all these individuals will be able to interact with the core of the existing RECOVER Initiative. And a big component of that will be to bring in new ideas, including new therapeutic ideas, that will be evaluated in a specific standardized review process that will lead to a prioritization for the actual selection of interventions for clinical trials. So, we want to have a process in place to make sure that we're looking at the best evidence base and also the most promising treatments.

Lenora Johnson

Time: 28:11 – 28:33

Great, I see that we have time for maybe one more question. I think there is a question around the capacity of mobile health that was mentioned in the press release, and what that gives the RECOVER Initiative? We'll take that as the last question, and maybe Amy?

Amy Patterson

Time: 28:33 – 30:57

Sure, yes, so mobile health and digital health platforms are a vital component of the RECOVER Initiative. So, in addition to accessing information from patients through exams and tests in the clinic, we will also be looking across at electronic health records. But, in addition, we are going to be leveraging the power of mobile health technology to provide us with a way to enable participants to engage in the research in a relatively low burden. In other words, to bring RECOVER to them. Because they, in essence, can hold access in the palm of their hand through a phone or on their wrist, with a watch, and interact, record symptoms. Some of the personal sensor technology enables almost real time monitoring of some of the symptoms, heart rate, etc. And this will be an integral component of the cohort studies. We recognize that not everyone has a device, and so part of the RECOVER Initiative will be to provide devices to a fair fraction of the participants. We won't be able to do it for everyone, but we're going to do our best to get a large number of devices out there. And we'll also be selecting a mobile health platform that is workable on a variety of devices that patients may already have, so that if they already have a phone or smartwatch, or what have you, they can interact with the application readily.

This is important because we think it's going to enable us to broaden our reach, to reach deeper into communities, and again importantly to have a way to interact, push information out, share with patients, and also hear directly from them in a really ongoing basis. And importantly, it represents a relatively low burden way for patients to be able to participate in the research endeavor.

Lenora Johnson

Time: 30:59 - 32:00

Thank you. Again, I'd like to thank all of our presenters who have been able to carve out this time to make sure that we reach the community that's most affected by Long COVID. We will continue to engage. There have been a number of questions we've not been able to get to in this time. We are capturing them, we will evolve answers for them, and make them available on recovercovid.org.

For those that want to continue to keep up with the initiative, recovercovid.org is where all of the information at this time, will be stored. In addition, those that are interested in providing their name and contact information for potential enrollment and studies as they evolve, that is done on that site, as well.

So, with that, we want to thank you for joining us today, and we look forward to continuing to engage going forward. So, best, have a great afternoon.

Alissa Gallagher:

Time: 32:00 – 32:02

Thank you.