

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Hearing on
The Long Haul: Forging a Path Through
The Lingering Effects of COVID-19

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Good morning, Chair Eshoo, Ranking Member Guthrie, and distinguished Subcommittee members. Thank you for your sustained commitment to the National Institutes of Health. I'm grateful for this opportunity to discuss with you the best research approach to understanding post-acute sequelae of SARS-CoV-2 infection or PASC. That includes the array of symptoms often referred to as "Long COVID", the recovery process of organs injured during the acute infection, and the question of whether the COVID-19 pandemic will increase the risk of developing common diseases in the future.

We've all heard and read the troubling stories about COVID-19 survivors who are suffering for months after they recover from the acute infection caused by SARS-CoV-2. These people suffer with a wide variety of symptoms that can affect almost every system in the body and last for months. Fatigue, 'brain fog' or difficulty thinking, abnormal sleep patterns, shortness of breath, persistent loss of taste and smell, muscle pain, and the list goes on. Not everyone has the same symptoms or in the same severity. Even those who had an asymptomatic infection can experience these long-term effects. Children can also be affected with long COVID.

Late last year, we outlined the substantial research needed, not just to understand the long-term effects of SARS-CoV-2 infection, but to try to find treatments or prevention strategies. Congress appropriated \$1.15 billion for this work in December 2020. Since that time, we've called together experts from the fields of infectious diseases, neuroscience, cardiology, pulmonology, mental health, and more to design a fast, flexible, comprehensive research initiative. Today I'll walk through those plans with you.

Before I do, I want to pause for a moment and speak directly to the patient community. Some of you have been suffering for over a year, with no answers, no treatment options, not even a prediction of what your future may be. Some of you have even faced skepticism about whether your symptoms are real. I want to assure you—I hear you and I believe you. If you hear nothing else today, hear that we are working to get you answers.

First, we have to understand the basics: how frequently do SARS-CoV-2 survivors experience long-term effects? Is there any correlation between the severity of the initial illness and the likelihood of ongoing symptoms?

New data arrives every day, but preliminary reports suggest that up to 30 percent of patients recovered from SARS-CoV-2 infection may have some form of longer-term health impairment. To get a solid measure of the prevalence of PASC in the population, we will need to recruit tens of thousands of patients. For that to provide the answers we need, we must make sure that we are recruiting a diverse set of COVID survivors:

- A good mix of female and male
- People of all races and ethnicities
- Individuals across the lifespan from children to older adults
- Patients who experienced mild, moderate, or severe illness as well as no symptoms at all
- Patients who experienced COVID-19 before there were therapies available and patients who received monoclonal antibodies, remdesivir, dexamethasone, and other interventions
- Patients who were infected by the initial strain of SARS-CoV-2 and those being infected by emerging virus variants.

To do this complex kind of recruitment rapidly, we are launching a meta-cohort: essentially leveraging some existing cohorts (or groups of research participants) as well as forming new ones that we can knit together in ways that make their data comparable and collectively powerful for answering pressing questions about this virus.

We want to leverage existing longitudinal community-based cohorts. Examples include the Framingham Heart Study, the All of Us study, or a cohort based at a health system. These groups already include tens of thousands of participants on whom we have years-worth of clinical data, diagnostic scans, and outcomes before, during, and after SARS-CoV-2 infected some portion of their participants. In addition, they will be well situated to follow persons over long time periods and determine if there will be effects of COVID-19 pandemic on the future health of Americans.

Second, we want to leverage COVID-specific patient cohorts. Tens of thousands of Americans signed up for research trials to test vaccines and therapeutics. They are already being meticulously monitored for COVID-19 with detailed notes on their personal observations of their health and clinical data about treatments and responses.

Finally, we need a special cohort for children and adolescents. We know that, very rarely, some children exposed to SARS-CoV-2 develop a serious disorder known as multisystem inflammatory syndrome in children or MIS-C. But we also are learning that children can suffer from PASC, and we need to know more about those impacts on their physical or neurocognitive development.

We'll need to be flexible so that additional patients can be enrolled as new virus variants emerge and different therapies become the standard of care.

We have already had a robust response from the medical research community to our call for research proposals to better understand, treat, and ultimately prevent PASC. We have received hundreds of research applications that feature the kinds of cohorts I mentioned. They are being evaluated jointly using Other Transactions Authority. This authority provides the ability to engage partners in collaborative innovation and problem solving, and the much-needed flexibility to rapidly evolve our research approach in response to new findings and emerging scientific needs. We expect to make awards in the next few weeks.

Next, we have to bring the cohorts together with common clinical research protocols, ensuring that data are collected in standardized formats from each of the research participants to enable the most powerful comparisons.

Patients will have an active role at every level and stage of this research. We are planning listening sessions to help guide the future of the PASC Initiative. As we recruit patients to take part in research, we will be asking them to share their health information via mobile health apps and wearable devices. Patients will be able to identify new features of PASC, track their symptoms over time, and

provide real world updates. Patients are the experts on what they have experienced, and this will be a way to quickly bring information directly to researchers.

Now, how can we begin to bring all the diverse stories of PASC together into a coherent picture that explains who is at risk and how to prevent and treat it? Coordination, consistency, and cooperation will be key. We will apply these strategies to rapid data sharing, communicating our findings quickly back to the patient and the research community, and engaging the best minds in interpreting the results. By conducting the studies to better understand the clinical spectrum and biology underlying recovery from acute SARS-CoV-2 infection, in parallel with studies of new approaches to treatment and prevention, we can make great strides toward helping those who are suffering now.

Before concluding, I have to emphasize that a critical way to limit the future toll of PASC is to be sure that the number of new cases of COVID-19 is brought down to zero as quickly as possible. Even for young people who consider their risks of acute disease to be low, the long term consequences can be quite serious. So the recognition of PASC is one more reason to seek vaccination of all adults as quickly as possible, and to continue stringent use of public health measures like mask wearing in the meantime.

PASC and the individuals suffering from it can no longer be a hidden toll of the pandemic. We must bring this circumstance to the forefront of our fight against the COVID-19 pandemic. NIH has already initiated this effort and aims to pursue answers with all of the energy and creativity that the scientific community can muster. Thank you for your time today. I look forward to your questions.