Centers for Medicare & Medicaid Services
COVID-19 Lessons from the Front Line
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Alina Czekai: Thank you for joining our CMS Lessons from the Frontline on COVID-19 today, May 22. We'd like to begin by thanking all of you for the work you are doing day in and day out to care for patients around the nation amidst COVID-19.

This is Alina Czekai leading stakeholder engagement in the Office of CMS Administrator, Seema Verma, and today's call is part of our ongoing series, Lessons from the Frontlines.

And while members of the press are always welcome to attend these calls, we do ask that they please refrain from asking questions. All press and media questions can be submitted using our media inquiries form which can be found online at cms.gov/newsroom. Any non media COVID-19 related questions for CMS can be directed to our COVID mailbox, which is covid-19@cms.hhs.gov.

Here at CMS, we recognize that government's role during COVID-19 is to offer maximum flexibility and regulatory relief to allow you all to do what you do best: care for the patients in your local communities. Around the nation, providers in local communities are innovating in response to COVID-19, and at CMS, we hope to bring local innovators together to share best practices that can be scaled at the national level.

Today's call will focus on these expanded flexibilities, and we will hear from providers who are seizing the opportunity to innovate and transform to support their communities. Today, we will hear from providers regarding COVID-19 therapeutics, and we also have a special segment on communicating and caring for patients with serious illness.

We do encourage you to direct your questions to our guest speakers on the line, and should you have more technical questions on CMS waivers and

guidance, we encourage you to join our CMS office hours which are held every Tuesday at 5 pm Eastern.

And this week we are joined by FDA Commissioner, Dr. Stephen Hahn, and Deputy Commissioner for Medical and Scientific Affairs, Dr. Anand Shah, for an update on COVID-19 therapeutics. In addition, we are also joined by two physicians from the field who have offered to share their perspective and best practices for therapeutics during this time. But first, I'll turn it over to Commissioner Hahn.

Stephen Hahn: Thank you, Alina, and I also want to echo the thanks to all of you for being on this call as we move forward against this unprecedented global pandemic. We do continue to see signs of progress and promise, but really, that's due to the great efforts of the providers on this phone, as well as others around the globe. So thank you very much for everything that you're doing.

At FDA, we recognize the urgency of getting products to test treatments and vaccines to patients and doctors, but we also recognize that this is a balance that we have to achieve, that all of our decision making must be made upon data and science. As physicians, we realize that at times the data and science, the information we have in treating a patient may be imperfect, yet we are responsible at FDA for making decisions in that context.

We're certainly committed to helping foster the development of safe and effective medical treatments – that's a gold standard that we uphold – but also providing regulatory advice and guidance and technical assistance to developers, something that we've done throughout the COVID-19 pandemic and outbreak.

We've provided significant and, frankly, unprecedented regulatory flexibility and streamlined processes where needed, and appropriate to facilitate the development of new treatments. We have developed something called the Coronavirus Treatment Acceleration Program, which allows us to prioritize those therapies at the highest scientific backing and allowing those to go into clinical trials, or to apply for emergency use authorization.

We definitely want and emphasize that the data that comes from well performed, controlled clinical trials will provide us with the absolute best information to allow us to move forward. We're working with many different drug manufacturers, as well as academic centers, and we've provided guidance and technical expertise to expedite the clinical trials.

More than 90 drugs are being studied, and we are working with a number of vaccine sponsors. You may know that we've authorized safe to proceed for three of those vaccines to go into clinical trials and some have already done so. There are more than 144 clinical trials that have been initiated for therapeutic agents for COVID-19, and we recently issued an emergency use authorization for Remdesivir.

That particular antiviral agent had been used in other viral diseases before. I mean, it was taken off the shelf in, frankly, record time. Went through a randomized clinical trial in hospitalized patients with results showing that it reduced time to recovery. And there was a trend, although not statistically significant, toward improvement in mortality.

The data is still mature from that trial, but we felt that they were sufficient to go forward with an emergency use authorization for that drug, Remdesivir. We also need to get these data more quickly, and so we looked at how clinical trials are designed, how we can be innovative about those, but also, how we can use real world evidence.

The evidence that you all on the frontline are at, and how the data from the medical records might better inform, and more quickly inform our decisions. We need to be transparent about the information and evidence that's available – FDA is committed to being transparent about that – and to acknowledge when the data are incomplete, but we're in a position where we need to make a decision about an authorization.

Certainly, the recent information we've provided about the safety of Hydroxychloroquine, and about some of the testing equipment that we've previously authorized, is evidence of the fact that we must absolutely share data as it comes to us. I'm confident moving forward that as we gain more

answers in treatments, we'll be able to apply the lessons learned not from this, but for future health challenges as well.

Dr. Shah, my deputy here at FDA, and I are totally committed with transparency around that process in constant continuous improvement. Thank you very much for allowing me to participate and we're both very happy to answer questions. So, Alina, back to you.

Alina Czekai: Thank you, Commissioner. I'll now turn it over to Dr. Anand Shah, the Deputy Commissioner for Medical and Scientific Affairs at the FDA.

Dr. Anand Shah: Thank you, Alina, and thank you, Dr. Hahn.

I'll just offer a few additional remarks about some of the developments and therapeutics, and also offer a few comments about the progress on a vaccine. But first, I want to start with a brief mention of another important area we've made some significant progress in, and that's testing.

As all of you know, there's been a special emphasis on development and availability of accurate and reliable tests for COVID-19. Quite simply, we need to know who has the disease and who's previously had it. This is essential if we're going to understand this virus and return to a more normal lifestyle and start to reopen the economy.

Since January, we've worked with hundreds of test developers, many of whom will have submitted emergency use authorization requests to FDA for tests that detect the virus and its antibodies. Today, we have a number of reliable tests on the market and we're constantly strengthening it with updated data and evidence.

I also want to mention the FDA's work in support of the effort to facilitate the development of and access to two investigational therapies derived from human blood: convalescent plasma and hyperimmune globulin. These two antibody rich blood products are made from blood donated by people who have recovered from the virus, and they're being studied to determine if they could shorten the length, or even lessen the severity of the illness.

Dr. Hahn has already spoken about some of our work in support of the development of therapeutics. I'll say that there are a variety of therapeutic areas being evaluated for COVID-19 patients. That includes antiviral drugs, in immunotherapies that might be helpful in reducing lung inflammation and improving lung function.

I also want to mention that FDA is supporting Operation Warp Speed, which is a cross governmental effort to expedite the development and availability of therapeutics and vaccines to combat COVID-19. On vaccines, this is an important and exciting area for many reasons, not the least of which is that, ultimately, of course, a vaccine is the most likely way that we'll eventually defeat this disease.

As we work towards this goal of an approved safe and effective vaccine, FDA is providing regulatory advice, guidance and technical assistance to advance its development and availability. We're working closely with federal partners, large and small vaccine developers, researchers, manufacturers and experts across the globe to explore, expedite and incentivize the most efficient and timely development of vaccines by exploring all possible options.

A number of experimental designs are currently under consideration, and we're working collaboratively with manufacturers to move products forward, while ensuring that we have the safety and efficacy data needed to meet FDA standards. The process we're using is a dynamic one. It's continually informed by new data and evidence.

Very similar to the approach that we've been using in the search for therapeutic treatments. And as Dr. Hahn regularly states, the search for new products is an ongoing process that relies on research and data to continually evaluate and re evaluate whether treatments are safe and effective, through a careful and necessary balancing of risk and benefits.

I want to take a moment and thank CMS for hosting Dr. Hahn and I on today's call. We really appreciate the opportunity to have a two-way dialogue with all of you on the frontlines. And with that, I'll pass it back to CMS.

Alina Czekai: Thank you, Dr. Shah.

I'm now pleased to introduce our guest speakers today, who are national leaders addressing COVID-19 therapeutics and treatment. First, I'm pleased to introduce Dr. Magdalena Sobieszczyk. She is the Chief of Infectious Disease at New York Presbyterian/Columbia University. Dr. Sobieszczyk, over to you.

Magdalena Sobieszczyk: Wonderful, great. Thank you so very much for letting me join you this afternoon and for the opportunity just to share some thoughts and lessons learned from the frontlines and from practitioners here in New York City. And I just wanted to say that it's been – it's been an amazing experience to also, sort of, have the opportunity to communicate with many providers from across the country through a variety of calls that have been organized in many settings.

So the CDC and other government agencies and public private partnerships, because I think it's such an exactly – an exchange of ideas that really helps us make sure that we have the best resources available in terms of education, training and access to research to benefit our patients and our providers.

So yes, I just wanted to make a few thoughts and comments that are just about some of the questions that, as we know, are sort of facing clinicians and researchers, and as we are – as we're treating our patients at the frontlines. I think – and that's also, sort of, what's driving many of the research questions that are informing the clinical trials.

So one of the key questions that we, as providers, face is, you know, what – in terms of what do we target with therapeutics: the virus or the host response to the virus that we know that this can be a devastating inflammatory response that can be seen, both sort of in the mid stage and then the delayed stage of the disease.

We are still, sort of, learning a lot about what determines the rapidity and progression of the disease, and there are many clinical trials that are trying to address that as well. And the optimal timing in which to intervene on a patient – for a patient is also – is also a key question that's facing those practitioners and clinicians, as well as researchers.

I think, as we all know, kind of the framework and the key issue in providing care to our patients is providing them with the supportive care in terms of oxygenation and ventilatory, and supports, and then the therapeutics that are being investigated in clinical trials and/or through emergency use authorization are – certainly have been – have really revolutionized the way we think about COVID-19.

I have to say that with clinical trials, or certainly evaluating the different treatment strategies, as was just been – as was mentioned previously, I have to say, and I think many would agree, that conducting these clinical trials in the midst of a pandemic is both a challenge and amazing opportunity, and a great privilege.

The field is certainly learning a lot, and we as practitioners are learning a lot through the clinical trials. We are conducting and pivoting very quickly based on the results of these well conducted randomized clinical studies. And so, as you heard, and as you all know, with thanks to the emergency use authorization of Remdesivir, which is not FDA approved yet, but has been made available, it's really – it's really changed our approach to therapeutics here at the frontlines.

The other issue that many of us are still – and researchers and clinicians are grappling with is how to (notify) the host response and think about, kind of, the immune modulation that is an important component of COVID-19 disease. And there are agents that are being evaluated, such as cytokine inhibitors that are being evaluated in the context of clinical trials that are going to yield incredibly important information.

And because COVID-19 has been – as we know has been associated with this profound information, as well as a prothrombotic state, I would increase in fibrin degradation products, fibrinogen and the D dimer levels. There's also, sort of, a lot of attention that's being – that's being paid, both in clinical setting and in research to modulating those events.

And even though we don't really truly know what the true incidence of thrombosis is in these settings, there have reports of thromboembolic disease

that have been seen in COVID-19 patients, and we certainly are seeing that in patients in intensive care units, kind of, these microangiopathic events, and prothrombotic events that contribute to the increased mortality morbidity of these patients.

And so, while there are still many questions that remain about the role of coagulation markers and the complement pathway and the role of thrombolytic and anticoagulants and antiplatelet agents and complement inhibitors and what role they play in management of these patients, then I think these questions are being investigated in a very systematic fashion in the context of clinical trials.

But those very much will, sort of, guide, kind of, the – our response to COVID-19 comorbidities. And it's the use of antithrombotic agents for prevention of these venous thrombolytic events, it's certainly being investigated and being used in hospitalized settings, and is being evaluated very carefully, and a lot of attention is being paid to careful monitoring and evaluation of hospitalized patients who are at risk for these thrombotic events.

So that's, sort of, been – sort of, what's been informing a lot of our management recently here at the frontlines, kind of these – both these acute events, as well as the inflammatory prothrombotic events that we know are sequelae of this particular viral infection. Let me stop for now, and I'll be happy to take questions during the Q&A session.

Alina Czekai: Thank you so much, Dr. Sobieszczyk.

I'd now like to introduce Dr. Njeri Wainaina, associate professor of medicine and surgery at the Medical College of Wisconsin. Dr. Wainaina, over to you.

Njeri Wainaina: Thank you very much, it truly is an honor and a privilege to participate in this, and I really do appreciate the work that you're doing to bring so many people together so we can learn from one another as we try and figure out what's the best way forward. And that's what spurns our experience over here. It's – sorry, that's my pager going off, which has now stopped. I apologize for that.

One of the – we, certainly, out in the Midwest and in Wisconsin have not seen the numbers of cases that have been seen out in New York, but we've seen very similar patterns, and have gone through a similar process, I'd imagine, of trying to figure out who is getting sick, who's getting really sick. How do we predict ahead of time, and then how do we approach the disease.

Our initial approach involved, you know, going through all the literature as it was coming out at record pace, and trying to provide the best guidance for clinicians at the frontline, whether it was in the clinics, in our emergency department or in the hospital. And one of the things that we've gained from that is developing a true multidisciplinary approach, recognizing that none of us had the answer and all of us had to be nimble and closely observing what was going on.

So we've been able to develop excellent partnership between our pulmonary and critical care doctors, our cardiologists, our hematologists, our – the infectious disease group of whom I am a part, and our hospitals, as well as our outpatient clinicians as we think about the spectrum of care.

Nobody really has the answers as to what – what's the best way to treat. Should we be using an antiviral approach, should we be using more of a (inaudible) approach with convalescent plasma. Should we be addressing the inflammatory response? And it's probably a bit of all of those depending on where the patient is at what time.

So one thing we are certain of is that supportive care is the foundation of taking care of these patients, providing the oxygenation and ventilatory support as needed. But as important is identifying which patients may be able to get better on their own without this early being in the hospital which, you know, turned out to be the majority. But, you know, constantly watching who we have and how they're doing was really our best intervention and the ability to be nimble and adjust our approaches as we got more and more information.

We're privileged to be able to participate and continue to enroll in different clinical trials where we can get the best possible information as to what truly

works and who it works in as opposed to just relying a hundred percent on initial impressions, recognizing that we have individual biases.

I think I'll stop my comments at that and return to CMS and I'm happy to take questions as well.

Alina Czekai: Thank you so much, Dr Wainaina, and I really appreciate your perspective. Operator, let's open up the phones for some questions focused on therapeutics for either the FDA or our guest speakers today. Thank you.

Operator: Ladies and gentlemen, we will now begin the question and answer session. If you have a question, please press star, then the number 1 on your telephone keypad. Again, please press star, then the number 1 on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

Once again, ladies and gentlemen, if you have questions, please press star, then the number 1 on your telephone keypad. Again, please press star, then the number 1 on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

Our first question is from Edward Yu of (inaudible). Your line is now open.

Edward Yu: Thank you very much. I really appreciate these calls. My question is about the vaccine development. What we would like to learn more is – there are a multitude of companies internationally going into this.

What is the governmental agencies going to do to help us to sort through – among those that are going to hit the market, how do we know which one works the best and we have that issue now with the antibody testing and antigen testing test and we just want to make sure that when we get to the vaccine treatment stage, that we have some way of determining which of these products will be the most effective one. Thank you.

Stephen Hahn: This is Steve Hahn from the FDA. That's a really excellent question. As you can imagine, there is a difference between the vaccines and the antibody test with respect to the number and the different operating characteristics.

Nonetheless, your point about the fact that some vaccines may have a different level of SKC than other is spot on.

Certainly from our point of view at FDA, when we issue an approval or an authorization – and that is not yet known what will happen. Obviously it will depend upon the data – we will use the data that we receive to provide guidance with respect to the indication which patients, how often to give it and at what times.

And so that will be part of our either authorization or approval process. Very similar to what we did with Remdesivir where we specified the patient population that the authorization applied to. So we will do the same with the vaccine. We will likely receive applications from a number of different vaccine makers and that will be one of our jobs as we sort through the data that they provide us. Thank you.

Alina Czekai: Thank you. We'll take our next question please.

Operator: The next question is from Tracey Russell of Canyon Home Care. Your line is open.

Tracey Russell: Yes. Thank you for taking my question. I have a question about the thrombolytic events that you guys are seeing and considering we work in home care and we work with the elderly, which are about the most highly affected people, is there anything that we can do in a preventative way?

Should we be managing their blood levels to ensure appropriate clotting factors in case there's infection or anything like that?

Magdalena Sobieszczyk: This is Magda Sobieszczyk, if I may answer that question and others can weigh in as well. So I think that's an excellent question and, as we sort of mentioned, many, many, many patients with COVID-19 actually do have, you know, sort of a mild disease course which may not necessitate hospitalization, in which case we don't even see these patients in the hospital but you're probably managing them from afar.

The current recommendations in terms of managing laboratory testing for individuals who are not hospitalized and that who do have COVID-19, there's really no data that would support checking and monitoring levels of D dimers or platelet counts of fibrinogen.

And that's a little bit different in individuals who are hospitalized just because these markers are often times are measured in the course of their hospitalization but are really – and this has been discussed by experts in the field and has (inaudible) into the guidance that's been provided by the NIH in terms of there's really no, you know, evidence to support the necessity for measuring these coagulation markers.

But I think advising patients about taking just kind of the usual precautions as we do in sick individuals and making sure they're remaining ambulatory to the extent possible would be prudent. Others can weigh in as well.

Njeri Wainaina: This is Njeri Wainaina. I would agree with that, that in the outpatient setting with mild disease there really is no rule for treatment or for any prophylaxis outside of what the patient usually would be on. Many of these patients are likely to be on baby aspirin for primary or secondary prophylaxis of their chronic medical conditions.

So patients who are coming back to the nursing home or being newly admitted to the nursing home after having been in the hospital with COVID, there may be a group that are higher risk that may have required prophylaxis against venous thromboembolism or thromboembolic phenomenon.

And there's even a smaller group that – really high risk that have been treated and may continue with therapeutic anti-coagulation when they come out. Other than those groups, it would basically be their routine treatment, their routine – aspirin, for instance, and any other anti-coagulants they may be on.

And of course emphasis on ambulation, both for prophylaxis against thromboembolism and to get them – to treat any condition they may have from having been in the hospital.

Alina Czekai: Thank you for your question. And thank you again Commissioner Hahn and Deputy Commissioner Shah for joining us as well as our terrific guest speakers today.

We will move to our next segment which is focused on communicating and caring for patients with serious illness. And today we are joined by providers in the field as well as patient advocates who are going to speak to this topic today. And I'm also joined by a number of my CMS colleagues who will offer their expert perspective throughout the conversation as well.

And joining me from the agency is Dr Marion Couch, Senior Medical Advisor to Administrator Seema Verma, Dr Michelle Shriver, Director of the Quality, Measurement and Value Based Incentives Group at the Center for Clinical Standards and Quality at CMS, Dr Barry Marks, Director of the Office of Clinician Engagement and Dr Michael Lipp, Chief Medical Officer at the Center for Medicare and Medicaid Innovation.

And moderating this segment is Dr Shoshana Ungerleider. She is the founder of the End Well Foundation and she is passionate about improving how people are cared for throughout the continuum of life which we know is especially important during these unprecedented times. Dr Ungerleider, I'm pleased to turn it over to you.

Shoshana Ungerleider: Thank you, Alina. I appreciate you having me and the rest of my colleagues. So, as you mentioned, I'm an internist and the founder of End Well and we're non-profit and really focused on transforming the culture, the care, the policy and perceptions around how we address the end of life experience which is of course inclusive of serious illness care, death and dying, care giving, as well as grief and loss.

And I'm really pleased to be joining you alongside my colleagues who you'll hear from shortly. It's critical that during this very challenging time that we consider, you know, how might COVID-19 present new avenues for care.

So today we curated this group of experts from across the country who are going to take us through various elements of the patient journey, starting with a serious illness diagnosis.

And this ideally starts with access to high quality palliative care for patients and families facing a life-limiting illness and in these times and beyond, you know, how can we create the right conditions for telemedicine given that the circumstances don't always allow for in-person visits.

How can we keep the patient experience at the center of the conversation? If a patient becomes (inaudible) eligible, what does that look like during this era of physical distancing and what are the best practices around providing hospice, whether at home, in a facility or in a hospital?

And then finally the need to address really the provider experience during these unimaginably stressful times is paramount. How can we create a medical culture that supports clinicians when we're experiencing burnout and grief at significant numbers?

So our work at End Well is showing that earlier, better communication with patients and families facing serious illness is not only good for patient outcomes, families also feel more supported, report less trauma and it of course can reduce clinician distress as well.

So with that, I'm pleased to introduce you to our first speaker, Dr Michael Fratkin, a palliative care physician, the CEO and founder of Resolution Care Network. He lived in rural Northern California and is a pioneer in the use of telemedicine for palliative care and how we can best leverage technology to connect with our patients. So with that, Dr Michael Fratkin, over to you.

Michael Fratkin: Thank you so much, Shoshana. Thank you, Commissioner Hahn and others and the federal government working so hard to figure out what works and what does not work in response to the medical treatment of people with this terrible coronavirus.

There's two things I really want to get across today. One is that telemedicine is better than real life and has been and I'll explain why I think that. And number 2, I will also want to emphasize that it's an important element of a rapid communication response.

So we have been doing palliative care in the home with a team for about 5 years and what we've discovered with the use of telemedicine is that there are two major directions that make it better than real life.

One is that people don't have to do the things that are necessary to deliver themselves as patients to the settings where we've centralized the delivery of health care. They don't have to get up in the morning. They don't have to get dressed. They don't have to have a family member take half a day off work.

They don't have to fight with traffic. They don't have to get through the front door and into the waiting room where they're confronted by other very sick people and a clipboard and the whole experience of becoming identified as a patient. And they don't have to return themselves to home.

All those practical things are out of their way. As it relates to home-based care, they don't have to deal with an invasion of their home by health care professionals with a sort of asymmetrical power structure.

What they have to deal with is the click of a light once the technology has been facilitated and poof there's a health care professional with their attention held and just seeing them.

The more subtle aspects of how it's better I can't really outline in 5 minutes but I want you to recognize that these technologies are access to leveling of the power structure. And when you're working with people not to manage what's the matter with them but to explore what truly matters to them. This window, this framing of the encounter, is a whole new setting for health care.

So I think there's two things that I hope will be durable after this terrible experience we're all going through together. Number 1 is that telemedicine is here to stay. And number 2, that in the face of mortality that each and every one of us, all the participants in the call, all the speakers, the commissioner, everybody is faced with a threat to their mortality.

And my hope is the idea of getting extra person-centered support in that context makes a little bit more sense to people going forward. So palliative care should be elevated in your attention as you think about what the lived

experience of serious illness is and that telemedicine technologies are adequate and exceptional at providing you access to being there with the people you're caring for in their homes.

Shoshana Ungerleider: Thank you, Michael. I am now pleased to introduce Adam Hayden who is a writer, a patient advocate and an organizer for the brain tumor community. Adam was diagnosed with glioblastoma in 2016 and since that time has really become a patient advocate, publishing issues germane to medical education, to survivorship, philosophy, illness and testifying regularly in Washington D.C. So with that, Adam, over to you.

Adam Hayden: Great. Terrific. Thanks so much, Dr Ungerleider. Thanks to CMS and thanks also to the FDA. I shared with the organizers leading up to this call that my community, a nonprofit national brain tumor society, was recently invited to an FDA listening session to hear from the patients that are impacted by brain tumors and central nervous system cancers. And so really hats off to the FDA and to CMS and of course to all the frontline clinicians gathered today.

Hey, so I just want to provide – so as someone who is living with a serious illness – and I should mention my spouse in fact is an inpatient occupational therapist. She works for a county hospital where we live and she is currently recovering from an infection of COVID-19 that she did most likely contract working on the frontline.

So this issue is timely and urgent really for our family and for the whole community. I just want to share three – I think a peek maybe behind the curtain of the patient experience for those with serious illness, I think dovetailing on some of what Dr Fratkin just shared.

Speaking to telemedicine, there's the provider, the clinician experience but then of course we're curious about the patient experience as well. So I think the first thing of the three points I want to share – the first is that, you know, those with serious illness, we do possess kind of a special wisdom.

And I know that's a bit of a head-scratcher for some people but, you know, it is the reality of facing our bodies as they change and, you know, the function

we were once used to perhaps is different after treatment or after a serious illness.

But through those changes we begin to pick up what does matter most and what is my life really about? And that daily sort of wrestling with our mortality does give us a little bit of wisdom.

So I think the first thing to promote here is that the serious illness community, we are interested in being partners through change. I think one of the ways that we've been vocal throughout the advocacy community is to remind folk that certain public health guidelines that are recommended, that it is in your personal interest but really it is to the benefit of the community that we enact those changes and that we embrace them.

And so I think that responsible acceptance of public health recommendation, folks with serious illness, some of the wisdom that we have is to encourage other people to embrace those changes, not to be fearful or intimidated or resistant but instead to see how acting and responsibility for our community is really one of the most important meaningful actions that we can take.

The second thing that I just wanted to share with everyone is an extension of that wisdom but a little bit more on the ground, that we are good at overcoming obstacles to accessibility. So of course in a person with a real life example, after my surgical resection, you know, I had a long road to recovery. I was a wheelchair user immediately following resection of a pretty big tumor, a 7-centimeter mass in my right parietal lobe.

But, you know, graduating from a wheelchair to a walker to a cane, that's sort of a real life overcoming of accessibility obstacles but, you know, accessing social media, accessing a virtual support group, the serious illness community has been active for a while, so I think that’s another thing just to lift up – is that many of the patients that you are interfacing with may already have some experience with using tools like telemedicine, or accessing through Twitter chat or Facebook support groups, there's a vast, kind of, peer to peer support network, and you can tap into those networks.

So maybe you don’t want to participate – you'd be welcome to, of course, but you can still, sort of, scroll and scroll and find and see, so there are Twitter support communities rallied around disease with specific hashtags, so regardless of your specialty, you may tap into certain cancer-specific support groups, for example.

You can locate their hashtags. You can scroll through their Twitter chat timeline, and you can learn the on-the-ground truth from members of the communities that you support. So I think that’s important to remember, this idea of a physician and patient divide, I think, in the realm of technology, where we are today, we can help to bridge those gaps, and to learn the wisdom that we each and all have to share.

I think the third point that I want to make before kind of wrapping up here, is just to address the telehealth or telemedicine visits specifically. There are two really common worries that I've heard expressed by members of my community, so this may be helpful for clinicians on the call to understand how they may manage the expectations of the patients during the encounter.

I think the first thing that I hear is, you know, is a full exam even possible in this setting? And we know that for many conditions, you need a physical examination. That’s very important. I also want to emphasize that that touch in a clinical encounter is really reassuring to patients, but knowing that that’s not accessible or available to many of us today, the first thing is, can we do a full exam?

And in the brain tumor community, you can do things like walk around in front of the webcam to check gait stability. You could talk to – invite partners to the telemedicine visits, and to sort of inquire about changes in memory or behavior, things like that. Checking symptom logs – many caregivers or care partners in our community help to keep a notebook where they track symptoms for their patients.

So I think managing expectations, helping to assure our patients that yes, a full exam is possible, when we’re conducting this encounter via telemedicine, and to remind patients – there's a terrific neuro-oncologist, Dr. Ashley

Sumrall, who is involved in our community. She had a really terrific kind of Tweet thread, talking about her preparations for a visit, whether that's telemedicine or assessed in the office, her preparation is the same. She goes through the chart. She prepares to meet with the patient.

I think that that helps to calm the nerves, to know the preparation of the visit, of the encounter, doesn't change just because it's telemedicine. It's just a different mode, but the same care is available, so I think that that's a helpful thing.

The final, sort of, worry that I've heard expressed is that we miss the hug. So, I know not everyone is a hugger, but as I've thought about this, we do need a tactile sensation to sort of come along with us through the virtual encounter, so I've been brainstorming. Is it something like a rubbing stone, is there something that patients may have available to them in their home that can associate a tactile experience with the visit?

That may be a way for thinking about surrogate endpoints or thinking about surrogate hugs. What's a way to encourage some sort of physical connection to the visit, regardless of the physical barriers that we have, like conducting a visit through telemedicine.

So, those are the three insights, I thought. We've got wisdom. We want to share it. Find us on social media. You can learn about the ground truth and then help to manage expectations around the telemedicine visit. So that's it from me. I think I'll turn it back over to Dr. Ungerleider. Thanks so much.

Dr. Shoshana Ungerleider: Thank you, Adam. Our next expert is Dr. Sonali Wilborn. She's the Chief Medical Officer of Heart of Hospice, and she'll share how their team built the first inpatient hospice unit for a patient with COVID in New Orleans, in just ten days, and then talk about the important of creating ways for people to be with their loved ones at the end of life, in person, or even virtually. So over to you, Dr. Wilborn.

Dr. Sonali Wilborn: Hey, Shoshana. Good afternoon. First of all, thank you for having me on this call, and also, thank you to CMS staff and Alina and the rest of the team

for putting together these calls. I think it's incredibly important. What I'd like to do today is really to take a few minutes to address three things.

One is, to tell you a little bit about what it is that we did at Heart of Hospice and why it was important. The second thing I'd like to talk about is really the impact this is having on our patient population, especially the seriously ill patient population who are institutionalized, and the third thing is, really talk a little bit about our long-term hopes and wishes, if there is some good that comes out of the COVID-19 pandemic, and all of that we're facing today. I'll talk to you a little bit about what that hope would be.

So let me start by telling you real quickly a little bit about our organization. So, Heart of Hospice is an experienced hospice and palliative care organization, and we've been in business for several years. We have a pretty significant presence in five of the southern states in our country, with the Louisiana market being our largest. We care for over 1,700 patients across our five states, and in Louisiana, we care for over a thousand patients across the state.

But the one thing that I will say to you, right from the onset of the pandemic, it was not even a question to us that it was important for us as a hospice and a palliative care organization, to take care of COVID patients. We didn't have a hesitation or a pause recognizing there was a need to bring end of life care to these patients, especially patients who are frail, elderly, multi-morbid patients who are certainly known to have a high mortality from this disease.

So, the way we went about it is that we aggressively created a COVID-19 internal task force that met on a daily basis, and in addition to that, one of the key things that we did, we aggressively sourced PPE so we could keep our staff safe in the event we were able to care for COVID-19 patients.

Around the time – this was towards the end of March – what we were noticing in one of our major markets, which was New Orleans, that there was a significant uptick in COVID-19 cases. What we were hearing from our colleagues in the front lines, in the ICUs, hospitals, we'd be hearing that the

New Orleans hospitals were being inundated with multiple COVID-19 patients.

We also heard about the fact that the ERs and the intensive care units were full. Patients who were unlikely to recover from COVID-19 were actually unfortunately dying in the hospitals and the ERs, in the ICUs, on the medical floors, sometimes in waiting rooms, without the benefit and the support of family at the bedside, and certainly without the benefit of hospice and end of life support.

And what we have also heard, because we're certainly a part of our community, we've heard from multiple family members who have lost loved ones, and they were clearly traumatized by the experience of not being able to be present during their loved ones' final moments.

So, recognizing this need, on one of our COVID-19 task force calls, we had this crazy idea, and I still remember to this day the date it was. It was April 1st, when we floated the idea of putting up what we referred to as a pop-up hospice inpatient unit, which was going to be dedicated to caring for COVID-19 patients, especially COVID-19 patients that were hospitalized and unlikely to recover.

So, what was incredible about this is that our CEO, Carla Davis, who is extremely forward-thinking – there was a pause on the line when we came up with this crazy idea, and she said, you know, even though this is the craziest idea I've heard, let's go ahead and run with it and see if we can make this happen.

Our intent with this pop-up inpatient unit, was to ease the burden on the hospital system, free up the beds and the critical resources, while bringing true end of life care, if you will, and symptom management patience to these patients in a hospital, and to do it in a setting which is similar to a hospital, but with the benefit of hospice providers taking care of them, and also with the benefit of safely allowing family members to be at their bedsides.

So, once we had this idea and had the go-ahead from our leader, we decided, multiple members of the senior leadership team basically started working at it

from several different angles. What I will tell you is that we had incredible help and support from the Louisiana State Department, from Palmetto GBA, basically in helping us process through things that – normally in a traditional world, the regulatory environment prevents it from happening as quickly as it did, but with the support from these agencies, what we were able to do is really get license.

We got our 855 approved, and we had the state walkthrough, literally from day one of idea, and took our very first patient 14 days after that. What I'd also like to do is recognize that we've had incredible support from the healthcare – from the administration, who have certainly identified that there is a need in the healthcare – in the community, and has mobilized resources.

They've implemented the CARES Act, and with the advocacy of NHPCO, we've had increased telehealth access, we've had the ability to practice across state lines. We've seen the removal of the three-day hospital stay, to get patients into nursing homes, so there's been an incredible amount that's been done by the administration to support bringing care to patients out in the community.

What I'd like to share with you is that to date we have cared for 144 COVID-19 positive patients across our communities, and 64 of those patients, we actually brought to the inpatient unit, and were able to bring end of life care to them, and allow them to pass in peace and comfort, with their family members at the bedside.

What has also been incredible about this journey is that we've had over 60 plus staff members from across our different sites, who have come to the New Orleans hospice inpatient unit and basically cared for these patients, and not one of our staff members has actually become sick or has been exposed to the virus, so PPE certainly works and has been incredible in helping keep our families and our patients and our staff safe.

A couple of additional things that I'd like to address before turning the call over back to Shoshana, is the impact that COVID-19 has had on patients. We certainly recognize that there's going to be widespread impact, not only on the

patients, certainly on families, and certainly, significantly on our institutionalized patients who are suffering from COVID-19, not because of the disease itself, but also because of being isolated, with the decreased functionality, the greater need for therapy that they are not able to get to, the higher mortality and morbidity that they're impacted with.

What we are also seeing, unfortunately, in these instances, because of the way that things are structured, we're seeing hospice and palliative care providers in many instances are not able to get into hospitals and get into nursing homes to care for these patients. This is leading to patients basically dying alone, without the support of families and also without the support, oftentimes, of aggressive symptom management, which we certainly see there is a need for.

I'd like to close by saying, if there is a few things that we'd like to see happen going forward, is really to continue to have a plan to allow for greater access of hospice and palliative care support in hospitals, nursing homes, where the sickest cohort of our patients reside. I'd also like to see if we can come up with creative ways to actually encourage hospice utilization in the nursing home community, especially for patients that might be COVID-19 positive and are extremely symptomatic, without a negative impact on their reimbursement.

We also want to promote and encourage advanced care planning. As some of my colleagues previously have shared, it is really a patient's right to choose, and now more so than ever, having an advanced care plan, making sure the patient's wishes are addressed and heard, I think, is key.

I'd like to end and conclude by saying that hospice and palliative care certainly has a larger role to play in caring for patients who are chronically ill, both now, in dealing with the COVID-19 pandemic, and certainly beyond it, especially as it relates to patient outcomes and overall patient experience. I think there's a huge role that we have to play.

In conclusion, I'd like to reiterate how incredible it has been to be on this call with the leaders who have spoken on the call before me, leaders of the healthcare system, and how grateful I am for the work that the administration

and the rest of you on this call are doing on the front lines to keep our patients and community safe. With that, Shoshana, I'll turn it back to you. Thank you.

Dr. Shoshana Ungerleider: Thank you. Our final expert is Dr. Sunita Puri. She is an author and the Medical Director of the Palliative Medicine and Supportive Care service at the University of Southern California in Los Angeles, where she also serves as the Chair of the Ethics Committee, so she'll share why addressing physician distress in the area of COVID is still critical now more than ever. Dr. Sunita Puri, over to you.

Dr. Sunita Puri: Thank you so much, Shoshana, and thank you to CMS and all of my colleagues in the field of palliative care for the beautiful work you're doing. What I would like to address today actually dovetails nicely with Sonali's comments, but I'd like to shift the focus from patient grief to provider grief.

The experience of physician grief amid COVID, how COVID has exposed the grief we have always experienced in medicine, and the lack of rituals for physicians to explore their feelings are the topics I'd like to discuss with you today. I'd also like to suggest, from my experience as a writer and author, that writing may actually be a useful tool for people to explore their individual grief, which now is less isolating and more deeply connected to the grief of the world.

So, what is grief? Grief is our reaction to profound loss, and it's not just emotional. It can have really profound physical, cognitive and spiritual effects as well. Elisabeth Kubler Ross and her five stages of grief are what we are taught in medical school to interpret and help people through their own experience of grief, but we don't turn that lens on ourselves. We're not taught to, and even though there are five stages of grief, denial, anger, bargaining, depression and acceptance, these don't happen in a linear fashion and may continue to cycle through our lives for a while.

Grief is a process. It's something that's fully (inaudible) and it can be our companion throughout life, depending on the magnitude of the loss, and although sometimes people feel when they are grieving they are so isolated, because they are grieving something that keeps them stuck while the world is

moving forward, and grief can have many permutations. We can feel it from anything from a loss of a relationship, to the loss of a parent, to most relevant in this discussion, the loss of a patient.

There are so many stories and images in the news these days about how physicians are overwhelmed, traumatized, and grieving in patient care, especially when so many patients come into the hospital, often in the later stages of dying of COVID, and that paralyzes us, as providers, because we are trained to save.

We are less capable of contending with what it means to reach the limits of our capabilities in a pandemic that is overwhelming, and as I mentioned earlier, one of the strange silver linings of this pandemic is that it has forced us to reconsider how grief and overwhelm and trauma have always been a part of healthcare providers' experience, and it's been highlighted by this pandemic, both for the public, but also for institutions in our own field, which have not always known how to address and make space for how physicians interpret loss.

So, in medicine, we are witnessing situations we couldn't have imagined, losing patients quickly, witnessing particular forms of suffering and sudden death, feeling inadequate in our work, due to the sheer volume and complexity of patients presenting, and our feelings of depression and anxiety from what is being asked of us.

In addition to that, we're trying to support families of patients who can't visit them, who can't be with them. We're witnessing the suffering of patients, from their lack of ability to connect, and their ongoing fear and uncertainty about this virus, and we're collectively struggling with a lack of connection, anticipatory and complicated grief, and a lack of rituals to help us in moments of grieving.

I think, a term that I actually recently learned is the concept of disenfranchised grief, which is a type of grief we commonly experience in healthcare, because it refers to grief that we're not in some way allowed to contend with publicly,

so we as healthcare providers are taught to absorb the grief and suffering of others, and not to necessarily look closely at how that affects us.

I want to suggest that literature, both the reading and writing of it, can help. We have evidence that writing and journaling in med students' pre-clinical years actually help with maintaining a sense of empathy for patients later in their clinicals and throughout their careers.

Journaling and writing is often used in different forms of therapy. It really forces us to articulate what's in our heads to nobody but ourselves at first. If I asked everybody on this call to write one sentence about something you had recently grieved and we shared our sentences with each other I think you would undoubtedly find a person who's writing or voice echoed your own.

Because the point of writing is to connect the personal and the universal, it's an incredibly powerful tool for us as individuals but also deeply healing for us as a collective whole, particularly at this times because it may be the ultimate form of connection during these disconnected times.

And what writing forces us to do is to step away from the stiff upper lip and performative parts of being a physician, particularly these days. It asks of us the opposite which is not to be stringent and kind of very much in our heads and in our minds and focused on others.

It asks of us to step back from all of that and in true reflective and supportive writing what I ask of people is to just start writing, images, thoughts, phrases they don't have to be complete sentences because we need to articulate what's in our minds. After when we are grieving, we are left for questions and answers that we tell ourselves because we are desperately searching for explanations.

But in the process of writing we can step away from the need for an explanation and simply allowed what has happened to be and learn to be with it. Yesterday I took care of a patient who died of alcoholic liver disease and whose family was not able to visit.

We had a devastating family meeting over Zoom and when they came in and we transitioned to comfort care I couldn't even hug them. This is perhaps the tip of the iceberg of my own experience with grief and loss and the witnessing of suffering with others and not knowing where to put the suffering I bear because of the combination of those factors.

But I went home and I journaled and it was a bunch of phrases, something like James Joyce something like stream of consciousness. But telling the story to myself at first let me go on with my evening unburdened. Rituals are a sequence series of events performed at a given occasion and they can be weddings or baptisms, funerals, or the tending of the dead body in a particular way.

They give us a place to work out our most complex emotions, we don't have rituals in medicine to make space for grieving, to make space for connecting with each other or just with ourselves over what we witness. I want to suggest if hospitals and medical groups can try to develop rituals or writing, if individual physicians can start to develop rituals of writing, that may open a space to let out what we have been holding within for so long, not just in COVID but in our entire careers and I'm happy to take questions later, thank you.

Shoshana Ungerleider: Thank you all I am going to turn it back over to Alina for the next bit of the program on the call here.

Alina Czekai: Thank you so much Dr Ungerlider and thank you to our guest speakers in this segment. I think this piece of the agenda was particularly powerful and important and before we open up to questions from the lines, I'd like to invite my CMS colleagues to ask any questions or share comments with our presenters today.

Michael Lipp: Hi this is Michael Lipp I just want to take a moment to thank our guest speakers really powerful comments and really appreciated the comments and I was particularly interested in asking questions about the impact of telehealth, particularly for patients with serious illness and heard some comments around

one of the drawbacks of telehealth as been kind of lack of having a tactile experience.

Lack of being able to do a full physical exam but on the flipside maybe balancing a power structure with patients and some of the efforts related to patients needing to get into the office, getting dressed, having family members take them – they may be unburdened with that.

I'm curious of any thoughts on particularly older patients with serious illness, their ability to use their technology and comfort level with using it for these types of evaluations. I wondered if you could tell us a little bit about that.

Male: Yes, I can. Thank you, Michael. You know, I had the preconceived notion that older folks would somehow persistently resist acquisition of this, an adoption of this (inaudible). While it's true that I think that there may be more resistance I think that I can say pretty safely that the older patients and the folks that were most resistant to our transition to 100 percent tele palliative care delivery are also the people most enthusiastic about what it adds to their lives and experience quality of life.

I think older folks are excited for things that really deliver those kinds of pragmatic improvements. The folks that it remains quite difficult to work with are folks that have a substantial cognitive impairment or lack someone to assist them with monkeying about with the gizmo itself.

When you can add that assistance and support and walk them through it with good humor, almost universally people recognize for themselves just experientially the advantages of connecting from the comfort of their home without having to travel. Older folks seem to be most excited about it in my experience.

Michael Lipp: That's really helpful, thank you.

Alina Czekai: Thank you Dr. Lipp are there questions or comments from my CMS colleagues?

Female: Operator let's take some questions from the phone, thank you.

Operator: As a reminder, ladies, and gentlemen if you have questions please press star one on your telephone keypad. Again, if you have questions you may press star one on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

Once again ladies and gentlemen if you have questions please press star one on your telephone keypad. The first question is from Sarasha Kapula, University of New Mexico your line is open.

Sarasha Kapula: Hi, this is Sarasha Kapula thank you for all the information today and I have a question regarding the home-based care. I know with the 1135 waiver and the hospital without borders we are allowed to do more of that. With the hospitals trying to make use of that is there need for more beds out of the hospital as we are filling up the beds in the hospital?

What is the likelihood of this continuing after the COVID considering that this takes a lot of investment into the audio-visual devices as well as the home monitoring, thank you.

Alina Czekai: Thank you for your question, do we have any of our CMS colleagues or subject matter experts who would like to address that? I'm happy to address it if not. Well, thank you for your question we really appreciate you asking about our continued efforts to give the healthcare system unprecedented flexibility during this time.

The agency is currently looking into these flexibilities that we have offered so we don't have any news that we can share with you today but please do continue to receive our updates and visit the CMS website where you can find additional information, so thank you we'll take our next question please.

Operator: Once again ladies and gentlemen if you have questions please press star then the number one on your telephone keypad. The next question is from Ladawn Lynch of Javida Health your line is open.

Ladawn Lynch: Hi I was calling in regard to the telehealther listening in and the advocate was very – in response to the telemedicine that, that worked really well. But when

the woman spoke about her writing it's the lack of connection – the lack of connection is going to be missed if we call telehealth or somebody calls telehealth and they actually get different doctors that they get to call into.

How do we know that we're going to get the same doctor that has done a physical on us that we've gone to for years and then we get different people at different times and they don't know our case except what's been read of – of what the last person actually put into the EMR system that's going to now be everywhere.

So I think my concern would the lack of connection, would definitely be that especially with the older patients population and then in regards to the pop up tents or the little pop up hospitals. The majority of those weren't even used and when they were used, I don't know about New Orleans but I'm in Florida, they weren't even used but they got to bill for those.

And a lot of those staff members and the parking lots were empty because everybody was being sent home. But if we look at the impacts of the allotments that everybody received for the COVID-19 funds that were paid out by CMS and everybody for these pop up tents and telehealth equipment and services that they're providing that's quite a bit of funds that are going back to the community health services, the rural health centers and it's not going back to the patients that actually suffered from COVID-19.

So, I think the disconnect – there's a lack of connection with telehealth is definitely going to be there, if we're going to get multiple doctors and they may not even be in our state.

Male: I'm happy to respond to that if that's OK?

Alina Czekai: Sure.

Male: It turns out that health systems and delivery models all around the country have been rapidly adopting the use off telemedicine technology and with that is not just the gizmos themselves but a series of workflows that each of those organizations must use to fulfill the mission of their delivery model.

So, the kinds of continuity that you're asking for are highly valued by many, many health systems whether in primary care, whether in specialty care or in our organization in palliative care. So those kinds of disconnections are not intrinsic to the technology in any way, the people that our team sees have continuous and longitudinal relationships that stretch over months and sometimes even years for people that are seriously ill.

As do in our local community the primary care providers who I'm assisting in making these technologies serve their delivery model for primary care in a community clinic structure. So, the technology itself does not interrupt any kinds of those relational continuity issues and in fact in our issues it's actually enhanced our ability to stay connected to the same people with the same team.

Alina Czekai: And I'll just …

Ladawn Lynch: Are those the people during clinical trials or are those into – are they calling the same, you know, if your have the health insurance and I call the back of my number on my card or somebody calls the back of their number on their card are they guaranteed to get that?

You guys have them as pilots or clinical trials or testing these patients out to see how they'll do, educating them on stuff just like the other person that chimed in it is very difficult to get them use, you know, this new technology and understanding how to actually do it.

So, one, are we going to get the same telehealth person every single time, will they know me? I think that's going to a major concern moving forward but I appreciate all of your guys time and I'll just leave it at that.

Female: And I just want to address really quickly ...

Male: (Inaudible)

Female: ... sorry Michael, the comment about the pop-up units. So just real quickly wanted to address that, the pop up unit that we initiated was really a hospice unit to provide care – end of life care to patients that were dying as a result of COVID and our inpatient hospice unit which was 15 beds has been running at about 85 per cent capacity since then. So, we'd had a significant amount of

use come off of it and we thought the resources that we put towards an organization towards that were extremely well utilized.

Alina Czekai: Terrific, thank you for your question and comment. We'll take our next question please.

Operator: The next question is from Suzanne Clifford of Inspiring Transformations; your line is open.

Suzanne Clifford: Yes, thank you so much this has been very useful. We're actually creating a local health department as we speak and so this is extremely helpful information. We really believe there's a lot more need for data and resources for end of life and maybe it's out there and just hard to find but as providers, hospice, families are making difficult decisions about end of life the quality of life post COVID is unclear.

And so how do we collect data quickly so that we can help families and providers understand what is it going to take to be able to survive this and what kind of quality of life could you face afterwards. And I know we can't predict and we don't know but the more data that we have for things like that so that families can make the decision to, you know, do we do a DNR?

What is the right decision at this point? And then also for both providers and families are there some good journaling resources out there or can the wonderful speaker who talked about that quickly create one that we can use? Thank you.

Sunita Puri: So, I'm happy to take a stab at your questions, this is Sunita Puri. First of all, certainly I can definitely send you some journaling prompts and resources that might really help your staff and your patients and families whether they're dealing with COVID or not.

I think secondly, regarding your question about how recovery from COVID looks like. So at our hospital at University of Southern California our palliative care team actually auto consults on every patient with COVID who enters the ICU and we know that's a small fraction of all of the patients who get COVID in the United States.

But what I've seen with recovery from COVID is that, first of all time on the vent can be very variable and we know that the longer you're on the ventilator and in the ICU the harder your recovery is going to be. A lot of patients with COVID also have ARDS or Acute Respiratory Distress Syndrome and recovery from that, from both a breathing and a functional standpoint takes generally a long time.

So, I think, you know, and we have data out of Wuhan regarding CPR that shows that of one center there only person out of 136 patients survived CPR in the ICU. So generally speaking, I think some of the studies we have now, even if they're out of other countries or centers that take care of more sick patients, I think they're still useful in guiding discussions about CPR and ventilation.

I don't know of any studies that have really looked at quality of life post COVID for all comers, per se. But I think, at least our collective experience amongst the med centers in Southern California is that, number one because this virus is still not totally understood. Some of our recommendations about decisions that could impact quality of life are really based on prior experience with things like acute respiratory distress syndrome and length of time in the ICU.

Secondly I think those, you know, families do ask what life is going to look like after COVID and part of our rule on palliative care is to help support their decision making through the extreme uncertainty that comes with this. Thirdly, I think what's always helpful in these discussions is to say that even though we don't exactly know what your quality of life is going to be.

One of the things that you're always allowed to do is make different decisions than the ones you're making right now regarding your treatment if your quality of life with treatment is not where you want it to be. So, I hope that helps, I think there's still so much uncertainty about how to guide decisions in the long term, rather than in the short term admission to the hospital or ICU, but we do have a lot of data on recovery from being in an ICU, being on a vent, potentially being paralyzed because your oxygenation is so bad, and we

can extrapolate from some of those data of post ICU syndromes, in particular, to help guide patient decisions.

Suzanne Clifford: Yes, I think that's really helpful. I'm really interested in, like, do oxygen levels impact cognition long term and quality of life, and I know we're really early, but I – if we are going to have another wave of this, I think it's going to be important to figure those things out for family members whose loved one said, "I want to have a good quality of life", or, you know, "I don't want to be here anymore," it's really hard to make those decisions with the data we have.

And so, I know we don't have a lot of the data that I want yet, but I hope some great researcher's listening that can start to collect some of that wonderful data.

Sunita Puri: Totally agree.

Alina Czekai: Thank you so much for your question. We will take our final question today. Thank you.

Operator: The last question is from David Baird of the Coalition to Transform Advanced. Your line is open.

Davis Baird: Terrific, thank you. And thanks so much to all the speakers today and to the organizers of the call from CMS and the administration.

So, you know, given that we've just heard, you know, from a number of different perspectives about how important it is now for patients, families and providers to be having advanced care planning conversations in this environment, I wanted to kind of open it up and ask any of the speakers, but also those on the line from CMS, are there additional policy actions that CMS or other agencies might take to increase access to these conversations.

You know, some really good work has been done so far. We at the Coalition to Transform Advanced Care we're really pleased that advanced care planning is now going to be able to be reimbursed using (inaudible) only means. So I'm just curious if anyone has thoughts about additional policy actions that

could be taken to, you know, increase access, or even socialize how important these conversations are right now in this environment. Thank you.

Alina Czekai: Thank you so much for your comment. I'd invite any of my CMS colleagues to address.

Michael Lipp: Hi, this is Michael Lipp. And so, I appreciate the comments, and I think this would go along with some of the other flexibilities that we're, kind of, actively looking at in light of the pandemic and considering, kind of, post pandemic, which would be the – which of these we should consider moving forward with, or which would make more sense in the light of the PHE. But I appreciate the comments and these are things that we're actively working on.

Davis Baird: Perfect.

Alina Czekai: Thank you.

Sunita Puri: I can offer a few thoughts. I don't want to hog time though, so really briefly, I think you're right, that in order for advanced care planning discussions to be more widely done, there needs to be a cultural change in the community and a cultural change within medicine.

We're just not taught how to have these discussions, and so palliative care specialists like myself and everyone else on the line, we're often called upon to help in moments of crisis. I think part of the cultural change needs to be that doctors and patients expect to have these discussions upstream, not in moments of crisis in the hospital, because that's generally what happens, at least in the health care systems I've worked in.

So trying to find a way to normalize these discussions, the way we normalize domestic violence screening, for example, in the inpatient and outpatient setting, I think that needs to become an expectation that the doctors will do and that patients are prepared for. I think that's going to be a very, very long process of change.

So one thing that has worked here is that we have triggers for advanced care planning discussions that we offer especially to outpatient oncologists and

primary care doctors. So if patients meet certain criteria, like new diagnoses of stage 3A, B or 4 cancers, that's a trigger to have an advanced care planning discussion. And if it goes south, they can refer to our clinic.

But I think part of what it means to do this well is to empower all physicians at all stages of training and practice on how to have these discussions, when to have these discussions, and to know that having these discussions doesn't mean "giving up". It means planning for all possibilities and managing uncertainty, which is really what I think – I think, truly, that's healing for both physicians and patients.

Davis Baird: Thank you.

Alina Czekai: Thank you so much. And thank you everyone for joining our call today. Another thanks to our tremendous guest speakers. As always, we appreciate you all finding time to connect with your peers and learn from one another as we address COVID-19 together.

And, in the meantime, you can continue to direct your questions or comments to our COVID-19 mailbox, which is covid-19@cms.hhs.gov. As always, please don't hesitate to reach us with any questions. Thank you again for all that you're doing for patients and their families around the country as we address COVID-19 as a nation.

This concludes today's call, have a great rest of your day.

Operator: Ladies and gentlemen, this concludes today's conference call, thank you for participating. You may now disconnect. Have a good day.

End