Centers for Medicare & Medicaid Services
COVID-19 Lessons from the Front Lines
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Alina Czekai: Good afternoon. Thank you for joining our April 17th CMS Lessons from the Front Lines on COVID-19. This is Alina Czekai, leading our stakeholder engagement efforts in response to COVID-19 here at CMS.

I'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 the COVID-19. Today's call is part of our ongoing series, CMS Lessons from the Front Lines on COVID-19. Here at CMS we recognized 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 which is care for the patients in your local community.

Around the nation, providers and 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. I'd like to share some quick agency highlights with you all today before we turn to our external speakers.

Starting with in the Medicaid program, we have approved 50 emergency waivers to date, 28 emergency changes to homecare program for senior and people with disability, 9 Medicaid disaster amendments and 1 CHIP disaster amendment opens March 16th. Into Medicare, we have issued 66 Medicare blanket waivers under the 1135 authority in response to thousands of requests, so that providers nationwide can take advantage without having to submit additional paperwork or ask CMS for approval.

We also issued an emergency rule to give additional flexibilities to providers and as many of you know rulemaking typically takes several months but we issued it all in just a matter of weeks. This output has allowed us to really provide unprecedented flexibility across the healthcare system and we have set about waiving any requirement that might conjure patient care during this

emergency. And that includes restrictions on rural providers, hospitals and health systems, telehealth and the healthcare workforce.

So, today's call will focus on these expanded flexibilities and we will hear from providers who are really seizing the opportunity to innovate and transform to support our local communities. And today, we'll also be hearing from the patient community to better understand their concerns and the strategies, their advocates and caregivers are employing to mitigate the risks during the pandemic.

And today, we have built in time for plenty of audience Q&A. However, if your questions are not answered on today's call, we encourage you to continue to join our CMS COVID-19 Office Hours which occurs every Tuesday and Thursday at 5:00 p.m. Eastern. Additionally, you're welcome to e-mail us at our CMS COVID-19 inbox which is covid-19@cms.hhs.gov.

Lastly, all members of the press are always welcome to attend these calls. We do ask that they refrain from asking any questions and all press and media questions can be submitted using our media inquiries form which can be found online at cms.gov/newsroom/mediainquiries.

And today, we are joined by a number of our federal colleagues as well who are working in partnership with CMS on COVID-19 who have some brief updates to share.

At first, I'd like to turn it over to Dr. John Redd, Chief Medical Officer at ASPR which is the Assistant Secretary for Preparedness and Response. Dr. Redd, turning it over to you.

John Redd: Thank you. Good afternoon and it's a great pleasure to join Lessons from the Front Lines. I'm John Redd, I'm the Chief Medical Officer for ASPR and Dr. Kadlec (of ASPR) asked me, once the President's national disaster declaration (set up) the co-leadership of FEMA and HHS and the response, to lead the Healthcare Resilience Task Force. And it's been a great pleasure to work in great depth with CMS on issues affecting the healthcare system in the country.

And I want to give a brief update about our task force and some of the accomplishments that we made, then I'd like to stay on the call and as questions come up, I'd be very happy to answer any of them that I can. So, the Healthcare Resilience Task Force has two primary goals and we work to optimize healthcare delivery and that's primarily in terms of working on virtual and physical spaces to try to help offload the burden on hospitals who are suffering under the rigors of COVID-19.

And secondly to optimize the healthcare workforce and our primary activities there are to activate new and existing providers, reallocate staffing, provide trainings and all the while ensuring legal physical and mental health protections for the workforce. In terms of optimizing healthcare delivery, I know we're going to speak in more depth today about some of the regulatory and waiver changes that CMS has helped with.

So, I'm not going to mention too many of those but I want to mention a couple of our major thrust in terms of increasing hospital capacity. We've promulgated guidance for the Crisis Standards of Care with the National Academies along with an online hospital resource package.

A recent development this is that we are – and I hope you will be hearing more about this soon is that we are trying to have established an emergency operation centers all around the country what are known as MOCs or medical operations coordination cells.

And those are federally supported entities at emergency operation centers that can help to coordinate between large hospital systems and if needed to assist in the movement of patients from areas of overwhelming need to areas of less need to make sure that resources are distributed properly.

I also want to mention that we've recently updated our national PPE preservation guidance strategies. That's under the (group work) of a reduce, reuse and repurpose and those are being released today. We're also about to coordinate standup of telehealth measures primarily through telehealth.hhs.gov. And the last thing that I wanted to mention were we're

working on our nursing home efforts nationwide which I know is a great interest to all of you.

And last thing I would say is at under our alternate care strategies which is a toolkit that you may well have heard about, this is a way to try to offload patients who had otherwise be taking space in vitally needed critical or serious care spaces and allow patients to be supportive through their illness in nontraditional settings including at home. And we'll hear about ways that CMS has greatly facilitated these efforts.

So, that's just a quick overbrief of what our task force has been working on at the FEMA-HHS structure and I will turn it over and I'd be happy to take further questions. Thank you.

Alina Czekai: Thank you, Dr. Redd. Operator, can we please open up the lines to take some questions? Thank you.

Operator: All right, ladies and gentlemen, if you would like to ask a question, simply press star then the number one on your telephone keypad.

We have one question. For the person who pressed star one, you may now ask your question.

Ronald Hirsch: Hi, can you hear me?

Alina Czekai: We can. Thank you.

Ronald Hirsch: Oh great. You mentioned – this is Ron Hirsch with R1, you mentioned e-mail address, telehealth.hhs.gov, that is not operating nor is telehealth.cms.gov. So, I'm wondering if it's coming onboard or if he – if there's another address we should use?

John Redd: No, the answer – this is John, the answer is that it's coming. Thank you for asking that.

Ronald Hirsch: Thank you very much.

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

Operator: Ladies and gentlemen, if you would like to ask a question, simply press star then the number one on your telephone keypad.

We have one question. For the person who pressed star one, please state your first and last name. Your line is now open.

Alina Czekai: Thank you, operator. Can you please announce our guest by first and last name. Thank you so much.

Operator: We'll now proceed to the next question. Our next question comes from the line of (Laura Sullivan). Your line is now open.

(Laura Sullivan): Hi, this is (Laura Sullivan). My question is about telehealth services and I might ask – we ask you this prematurely but the other calls did have on – on Tuesdays and Thursdays have talked about lightening the restriction when a patient is unable to do telehealth due to technology restrictions and using the phone only.

We understand that there are phone only CPT codes, 99441 through 443. However, they pay significantly less than a regular E&M service. Here in West Virginia we have a significantly elderly population as well as rural counties and areas that patients don't have access to audiovisual means for visit. So, I was wondering if that is still being discussed and if there's any estimated time for an answer on that.

Ing-Jye Cheng: All right, thank you. This is Ing-Jye Cheng. I appreciate the fact that (you're) attentive to dial in to some of the other calls and this is an extremely important question. We've gotten it from a number of different providers and you're correct that there are a series of CPT codes that can be billed for telephone only services, E&M.

I would also urge people to think about the degree to which if it's technology issue or something is actually going on audio-video but it's been interrupted for whatever reason, the degree to which – the degree which a service has been performed with both the audio and visual – video component if a service can be fully perform there that can be billed as telehealth.

I think your broader question though is really the rates that we're paying for those telephone only services and the extent to which there might be other services. That could be provided using only that the audio portion on the phone and that's something that we're still working on. Unfortunately, we don't have an ETA for an answer to that yet but rest assured that if it's something that's very important and we're looking to explore all the flexibilities that we're able to tap into to do more in this front.

(Laura Sullivan): Thank you very much for answering it.

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

Operator: OK, ladies and gentlemen, if you would like to ask a question, simply press star then the number one from our telephone keypad.

Your next question comes from the line of Chris Rorick. Your line is now open.

Christopher Rorick: Yes, thank you. Chris Rorick with the American Association of Oral and Maxillofacial Surgeons. As you're aware, there are a number of office space or community-based frontline providers who are proving emergency care, essential care and recognized that hospitals are the main distribution point for PPE but we're not seeing any of that PPE trickle down to office space or community-based settings. Do you have any recommendations to ensure that these point of care settings are not overlooked for (right) the PPE distribution?

John Redd: This is John. I can give you two answers to that. The first is that there's a huge supply chain support – actually I'll give you three answers. The first is there's a huge supply chain effort to bring in more PPE from overseas. That's the highest level effort and – but I do understand that – I understand that's taking a while to get down to the practice setting but there are big efforts afoot to try to boost the supply chain in general.

The second thing that I would say is that to try to minimize PPE use through reducing use, reusing items where possible including we have some new

cleaning strategies, particularly for masks and then for repurposing where necessary.

But, the third thing I would say is that it is possible to connect this local emergency management and it – the jurisdictions vary around the country but all states at least have their emergency operation center stood up and that it's possible to ask directly through those mechanisms. I'm not claiming any of these is easy and we are really well aware of the very, very difficult issues with PPE.

Christopher Rorick: Thank you.

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

Operator: Your next question comes from the line of (Jan Ernest). Your line is now open.

(Jan Ernest): Yes, thank you. The nursing home efforts that you mentioned, if you could provide more detail. What we are seeing in our area is facilities that have perhaps confusing guidelines related to quarantine after a case is identified, the duration of that, PPE guidance, testing guidance? And then an add-on question to that, if CMS would consider a waiver for acute care hospitals to designate swing bed, that would be a welcome relief as well. Thank you.

John Redd: Sure, I can answer some of those questions. We did just update the guidance for nursing home infection control under COVID-19 on the CDC website. And that contains several new recommendations involving management of physical spaces and some new guidance on managing employees. And as regard to the quarantine question, we're – I would actually – I think it would best if I refer you to the – to those guidance. Actually, they had been updated enough.

And regarding testing, we are in the process of kicking off as the President announced the last two days a sentinel surveillance system in nursing homes around the country. And that is an attempt to try to make sure that as this outbreak progresses over the next weeks, that we maintain awareness in nursing homes. It really is a very difficult problem and as with the previous

question, I do understand about the PPEs, the nursing homes can be very large, particularly as testing is increased.

And as regard to CMS waiver question, I would like to refer that back to my CMS colleagues.

Jean Moody-Williams: And hi, this is Jean Moody-Williams and I'll first say that – and we – with the question was just responded to, of course CMS works very closely with the CDC and follow those guidelines, and we do have opportunities to get that information out to nursing homes. We also have nursing home specific calls in which we can answer questions in which if there's any confusion about how to apply the guidelines and CDC joins us on those calls as well.

Regarding the swing bed waiver request, we are closely looking at all of those requests and we'll continue to look and I have noted your requests from this call and we've also received that from other areas. Thank you.

Alina Czekai: Thank you for your question. Operator, we'll now close this segment of Q&A and move to the next part of our agenda. Thank you.

We're now going to turn to best practices and peer to peer learning with some providers in the field. And as you know, some of our other frontline's calls, we heard from physicians mostly around ICU care and we really appreciate all of the learnings to date. Today, we're going to hear from some different voices including those of other specialties as well as patient.

Today we're joined by some obstetrics and gynecology physician from around the country. Today's doctors will all provide perspective of a group of patients who are very engaged with the healthcare system these days as these are pregnant women. And you may have seen reports the obstetric deliveries occurring while patients are on ventilators in the ICU.

I also like to note I'm joined by a number of my physician leader colleagues here at CMS including Dr. Shari Ling, our Acting Chief Medical Officer; Dr. Marion Couch, Senior Medical Advisor to CMS Administrator Verma and Dr. Michelle Schreiber, Director of Quality Measurement and Value Based

Initiative at the Center for Clinical Standards and Quality. We welcome the perspectives of all of our OB colleagues today.

And we'll first turn it over to Dr. Sharmila Makhija. Dr. Makhija is Professor and Department Chair of Obstetrics and Gynecology and Women's Health at the Montefiore Health System and Albert Einstein College of Medicine.

Dr. Makhija, turning it over to you.

Sharmila Makhija: Yes, thank you, Alina and Seema, so very much for this opportunity to share and learn from each other. I know we're limited on time, so I'll highlight our guiding principles and plans and have provided these to Alina Czekai, along with my contact details, if you need any of them in full detail.

As mentioned, I'm at Montefiore Health System in the Bronx in New York. We have six labor and delivery sites within the system including New Rochelle which as you know was one of the initial outbreak location. As all healthcare providers had been doing throughout the country, our teams had been tirelessly and bravely addressing our patient care need.

So in an effort to address protecting our patients and providers as well as to create new care delivery model, we developed several guiding principles with plans for addressing our OB clinical workforce, labor and delivery, telehealth and research. Regarding our OB workforce, we anticipated addressing both coverage of sicker patients as well as providers becoming ill.

So, we created team pods of three to four providers that work together all the time on day and night call as well as outpatient and telehealth visit. This rotation is for 14 days for direct contact clinical care, then rotated to 14 days of telehealth visits for non-contact clinical care. Our thought was that if one provider became ill, then we could limit the exposure to the rest of our providers while incorporating social distancing with rotation.

Regarding L&D guidelines, we had to balance our need to allow a visitor and support person for our OB patient on the unit with possible exposure to our providers while the PPE supplies were low. We initiated a three-phase screening process for all admitted L&D patients and their visitor which

includes the history and symptom questions, temperature check less than 100 degrees and recently implemented COVID-19 testing not only for our patients but for the visitors as well.

If a visitor is COVID-19 test negative, then they are given a surgical mask to wear and need to remain with the patient in the room during labor, delivery, recovery and now as of next week we will be allowing them to remain on the postpartum unit. Any visitor or support person who's COVID-19 positive is not allowed to stay in the hospital and all of our staff are masked with N95.

Regarding telehealth, because our goal was to limit both patient and provider exposure to COVID-19, we institute a telehealth immediately and actively work to manage our high-risk OB population of patients with devices to use at home which includes pulse oximeters, blood pressure cuffs and glucometers. By implementing clinical care that can be provided by telehealth and devices, we noted an increased utilization of telehealth care and better patient and provider satisfaction.

And over the next few weeks, we will be distributing packs of Bluetooth enabled devices to extract discreet data to be included into their medical records as well as phone access to healthcare counselors. The specific clinical diagnoses to be addressed will include preeclampsia, chronic hypertension, gestational diabetes and obesity.

This data will hopefully allow us to document the impact on healthcare health outcome metrics and will most likely limit direct patient contact care to those services that really required them such as initial visits and ultrasounds with procedures. Our intent is to change how we deliver our care, redirecting our efforts to focus on preventive care and actively managing maternal healthcare by convenient and appropriate telehealth care and to not go back to the way it was before frankly.

Regarding research, we are the lead institution analyzing a case series of almost 200 patients from three New York City hospitals to characterize birth outcomes for COVID-19 positive pregnant women. We feel this is important

to better understand the diverse population of patients we serve in order to improve the care we're delivering.

But thank you so much again for allowing us the opportunity to discuss some of our principles and I'm happy to share our guidelines with anyone who would like them. Thank you, Alina.

Alina Czekai: Thank you, Dr. Makhija. I'd now like to turn it over to Dr. Peter Bernstein, Co-Chair of ACOG District II which is New York State Safe Motherhood Initiative and he's at Montefiore Medical Center and Albert Einstein College of Medicine as well as Dr. Iffath Hoskins,, Chair of ACOG District II and Director of the Division of Obstetrics and Gynecologic Patient Safety at the NYU School of Medicine. Doctors, over to you.

Peter Bernstein: Hi, this is Peter Bernstein. Thank you for giving us the opportunity to present some of our work. I am the – also the Director of Maternal-Fetal Medicine at Montefiore Medical Center. Dr. Makhija is my Chair. And I want to describe you just a couple of things. I want to describe how we arrived at the universal testing initiative that we're currently utilizing at Montefiore Medical Health – Center.

You know, we started out by screening all women by questions and temperature when they arrive and limiting our testing to the women who were symptomatic. And then, we started noticing that we were finding women who became – develop some symptoms while they were in labor and we're testing them in labor.

And then the next step that came sort of naturally and this was well – could this be something like chorioamnionitis. Something we commonly see in labor and delivery or could this be the first sign of COVID-19 infection. And so we started swabbing women who just developed fevers in labor and we're surprised to find that they were also infected.

We then we're looking at women who developed lab abnormalities that would typically be thought to be something like HELLP syndrome but could also be signs of a COVID infection. And then, we swabbed some of those women

and were surprised to find that they were also infected and it was at that point that we began to push to swab all women arriving in labor and delivery.

And given the prevalence of the disease in our – in the community that we serve, we were discovering quite a number of asymptomatic women who were arriving on labor and delivery with the infection. And so as part of an effort to protect our patients, our staff, the families of our patients and the newborns, we moved into a situation where we wanted to not only screen all of the patients being admitted to labor and delivery but also the support persons accompanying the woman in labor.

At that point, we had already started asking visitors if they were symptomatic for COVID-19 and asking those visitors not to remain in the hospital, if they display any symptoms. The next step we went to was actually screening them once every nursing shift to see whether they had developed symptoms over the course of their loved one's admission.

And now, we're moving towards testing – actually testing all of our visitors to make sure that they're not arriving in the hospital asymptomatic but infected and asking those folks to leave. This has been something that's been well-received in our community. They understand why we're doing this and I think it's the best option, given the prevalence of the disease right now in the – for the patients that we serve.

I also like to add that with ACOG's leadership in District II, we've been holding conference calls for providers around the state to allow them to hear what their colleagues are doing around the – around the area and also we've been answering questions, sharing best practices but it's been a great way to optimize for care we're providing.

And with that, I'll hand it over to Dr. Hoskins.

Iffath Abbasi Hoskins: Thank you so much Peter and good afternoon everybody. I'm Iffath Hoskins and the – I'm also a Maternal-Fetal Medicine Specialist like my colleague, Peter. I will speak with two components, one as the Director of Safety and Quality in institution at NYU.

And also, my last few seconds, I will speak as the Chair of ACOG District II which is all of New York State. We have approximately 5,000 clinicians who are providing spectacular, state of the art care across the state of New York and I will speak on their behalf in my last few seconds.

So first in terms of our best practices at our institution, I want to start by explaining what I like on the introductory call. I know Alina said it, Dr. Redd said it, other said it, maximum flexibility while we provide the care that we think is most appropriate for all patient population. So even though Peter Bernstein and I are both in New York City, so to speak, we have very diverse patient population.

So, I want you to use that as a jumping point to show that our approach to this particular problem is slightly different. We do not do universal screening at our institution. We do screen for symptoms and you heard the question – the comments by Dr. Makhija about the symptoms that it could be fever, it could be shortness of breath, et cetera.

We do have a very loose threshold for any type of training, I'm sorry for testing, and that includes like I said a positive screen which would be the questionnaire regarding fever, cough, shortness of breath, things like that. But, we also would test people who have – presents with what we used to think were obstetrical situation such as preeclampsia.

We now know that patients can come in with abnormalities in their liver function test and we used to think that could be a component of preeclampsia, Dr. Bernstein said HELLP syndrome and now we know that it could also be a COVID hit. So, we have a very low threshold for that.

Any patient who presents in any way that we think might shift her into the algorithm of managing and training for COVID, we do that. A woman who develops a fever in the middle of her labor, we used to think it was chorioamnionitis, now we also used it to screen for COVID. So, I just wanted to explain how we do testing in terms of the screening.

The other part of it is that for the partner, the support person or whoever the patient has chosen, we only do the questionnaire screening. We – if he or she

of course a support person is symptomatic, then they go into the algorithm of needing the test. We do allow these individuals to stay with the patient, the support person. The patient gets to choose who that person is.

We do require that the person will be the same person throughout her labor process, that person cannot leave. That care person cannot be replaced by somebody else. Patient does not wear a mask if she's asymptomatic but of course I'll talk a little bit about if the patient is symptomatic and/or test positive.

So if they end – in terms of the management of the woman during labor, we have also told them, which I'll talk about in the postpartum period, but we've also told them when you come in for admission you will not be – a support person will not be leaving. So, you need to bring things like the car seat, et cetera, so there's no going back and forth.

If the patient screens positive during labor, her test came out positive and we have an approximately one to one and a half hour, our turnaround time, then that woman will be handled differently. She will get mask and she will then be handled as a COVID positive person with the precautions that are inherent to that. If the support person turns out positive because for whatever reason the support person got tested, then that person is ask to leave and that person will not come back.

We have also said that person will not be replaced by somebody else and again the intention as you heard throughout is to minimize the back and forth and the – lot of people coming in and out. When we do that, we have decided that when the patient has delivered, if she is negative both by symptoms and by screening for fever, et cetera, the support person will join her in the postpartum period as well as will her baby.

If the mother is positive, the support person – the mother will wear a mask and the support person will then not be there and the baby will be cohorted separately in our nursery. The mother can decline – this is a positive patient who has delivered. The mother can decline to let the baby go to the nursery,

then the baby will stay with the mother and there will be no interaction with others.

If that baby went to the nursery as is our staff protocol, that baby will now be (really) separated from the other babies as well. So, we allow the mother to have a say in her own care and we do tell them that at every step of the way, they have to give us – so they have to understand the pros and cons of their decision making.

I'd like to take a brief moment to talk about the staff, our physicians, our nurses, the other people who work on our labor and delivery suite. We do explain to them that there is no federal or national guideline regarding the use of N95 as personal protective equipment but we do have a very big criteria on our flow which is psychological safety. We talked about that everyday in every aspect of our care, it's almost like a separate department.

So for the under the umbrella psychological safety is our nurse, our delivering doctor wants to use the N95 and the PPE for the time of the patient's second stage of labor and specifically for the time of the delivery, then we – we had been allowing that to happen. And in our institution, we have a separate nurse for the baby.

The technical term is baby nurse and that person wears N95 as well because that is what our staff have chosen to do with the understanding that is not a federal recommendation right now. So if you can see because of maximum flexibility based on what our resources are and what our patients had shown us over these last few very difficult weeks, we have done a slightly different approach.

I want to shift for a few seconds to talk about ACOG because I represent our colleagues across New York State and it's a bidirectional best practices discussion today which I'm very proud to be part of. And I'm asking for the best practices in terms of payment for our clinicians because of COVID patients are migrating between systems, whether it's to a city or state and of best of practices and the old model, giving a global payment at the end after the delivery is hurting our financially (strapped) colleagues.

And we're asking – this is with my ACOG hat that I'm asking for federal payment systems like Medicaid, et cetera and state payment system to accept that the payment should be broken up. So whatever care is given at the site where it is given, it is reimbursed for that and then when the woman delivered, be it in a different situation or different clinician, that it pays separately.

So, it's a little bit off-topic but given that it's an ask for best practices, I wanted to also put that in, wearing my hat of ACOG District Chair for all of New York State. Again, I'm very honored to be part of this discussion and of course like my other colleagues, I'm happy to answer any questions. Thank you so much.

Alina Czekai: Thank you, Dr. Bernstein and Dr. Hoskins. I'd now like to turn it over to Dr. Denise Jamieson, Department Chair of Gynecology and Obstetrics as well as Dr. Penny Castellano, Professor and Vice Chair for Clinical Affairs both at Emory University School of Medicine. Doctors, over to you.

Denise Jamieson: Thanks so much. This is Denise Jamieson and I think Penny is going to start us off.

Penny Castellano: Thank you, Dr. Jamieson and I would like to really acknowledge and thank our colleagues from the New York area. We do appreciate and understand the speed and intensity with which your teams have had to address the pandemic. And so I will try to summarize some of the things that we had been doing here at Emory that has been the same and also emphasize a couple of additional points.

So, we similarly are a large academic-based system. We have a total of 10 owned hospitals, 3 of which have maternity services. We're also affiliated with the large city hospital, county hospital as well as a children's hospital and a VA Medical Center. And so we have a breadth of services going on at all of those sites.

From an obstetrics and GYN perspective, when we first as an institution began to address the pandemic, one of the first steps that we took was to look at our elective procedures and our elective business to decide what was appropriate to ratchet back and/or postpone/delay.

And of course that becomes a bit complicated in a very diverse specialty where you maybe doing things that are considered elective such as in vitro fertilization. But at the same time, delivering care to GYN oncology patients and obstetrical patients, some normal risk and low risk.

Additionally, we have the social and emotional piece of patients having some fear, if they're healthy OB patients of coming into a health center where they may be patients who are sick with something that could be contagious. So, we quickly look at our appointment schedules and we began to make modifications, understanding that we wanted to delay what we could was elective, address what we needed to that was considered non-elective and work with our surgical colleagues across all of our hospitals to make sure that we had triage all of our work appropriately.

Similarly, to what Dr. Makhija described, we became concern about the health and preservation of our workforce. There are some skill sets in obstetrics that do not easily translate into other specialties and so ability to back up and cross-cover is not always easy. And we therefore, did a very similar approach to a 14-day in-house, 14-day out of house rotation.

We split into two teams but in doing that we consolidated our office practices down, so that we had the minimal number of staff and the minimal number of exam rooms involved and continue then our inpatient services at the three sites. That we do maternity in our own system and the one affiliated site where we do maternity but all of that team did a 14-day on 14-day out of house rotation.

What we quickly learned was that during that out of house rotation, we had to be somewhat prescriptive about what our faculty, staff, residents and fellows would be doing. And so assigning virtual education processes to those teams during their off-week, making sure that we had a robust telemedicine methodology became very important, specifically for some of our subspecialties.

And then, giving our research teams and our trainees a method to continue their educational experience became again somewhat prescriptive to the point

that we actually track everyone's activity on a weekly basis, making sure that we know the amount of time that they have been devoting to those different activities.

Similarly, to what we heard from our colleagues, we tried to pare down some of the things that probably were more tradition than evidence-based for maternity care, decreasing the number of face-to-face visits, coordinating visits with ultrasound. We have leveraged telemedicine to help implement our no visitor policy in all of our ambulatory clinics. That was a bit of a disappointment to pregnant moms who were having ultrasounds and wanted their family members to be able to see the ultrasound picture.

So, we have used telemedicine to be able to involve the family members from afar. Similarly, to what we heard from colleagues, we are doing screening of both patients and in our maternity wards, we do allow one visitor. We are not yet doing universal testing but we do a symptom screen and of course if there are screen positive visitors, they are asked to excuse themselves.

I think the only other thing that I will add from our experience is that we have had very focused part of our department on provider wellness. And we have realized that emphasizing that, probably double down during this experience has been really important for all of our learners, trainees and our faculty.

So given the time, let me pause there and see if Dr. Jamieson would like to add anything to what I described for our system. And again, thank you in acknowledging our colleagues in New York and thank you for giving us the honor of presenting our experience today.

Denise Jamieson: Thanks so much Dr. Castellano. Just briefly since I'm the last OB-GYN speaker, I wanted to just comment that from this call it's really remarkable that similar approaches had been taken across the country. Part of this is our efforts to informally share best practices nationally. So, I participate on weekly calls with OB-GYN departments across the county and that's really helped us to share best practices.

And as you can tell, we've all been innovating as we go along and really implementing a lot of new approaches in short order. So, many of us who

were not that involve in telehealth have developed telehealth. We are looking at rapidly developing rapid testing approaches on labor and delivery which reminds me of when we implemented rapid HIV testing quite some time ago on labor and delivery but this is happening a lot faster.

We're optimizing the use of PPE. We are now paying a lot more attention to correct and consistent use of PPE and we're also paying a lot more attention to the wellness of our physicians and staff. So, I'm hoping that these developments in these important areas will survive post COVID and will be long term improvements to how we deliver OB-GYN care. Thank you.

Alina Czekai: Thank you and thank you to all of our speakers for sharing their insights and best practices. At this time, we'd now like to open up the lines, so you have the opportunity to ask questions of our guest speakers today. And again if you have questions on other topics or topics address at the top of the call, we encourage you to direct those questions to our inbox at covid-19@cms.hhs.gov.

Operator, we'll now open up the lines for questions. Thank you.

Operator: All right, ladies and gentlemen, at this time, if you would like to ask a question, simply press star then the number one on your telephone keypad.

Your first question comes from the line of (Alicia Daniel). Your line is now open.

Alina Czekai: Hi. What is your question please?

(Alicia Daniel): Hi, sorry, I was on mute. I'm going to direct my question to the inbox. I want to thank everyone for taking the time to share their experiences (for) all that everyone is doing on the frontline. So, thank you.

Alina Czekai: Thank you so much. Next question please.

Operator: Your next question comes from the line of (Daniel Hegg). Your line is now open.

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

Operator: We will now proceed to the next question. We have a question from Christine LaRocca. Your line is now open.

Christine LaRocca: Thank you so much. This is Christine LaRocca. Can you hear me?

Alina Czekai: We can. Thanks for joining Christine.

Christine LaRocca: Excellent, thanks. I'm a geriatrician, a Medical Director at Telligen and I want to say hi to Jean Moody-Williams. Thank you for this great call. I actually had a comment to the initial presentation. Is it OK to ask a question about that?

Alina Czekai: Sure. We can take that.

Christine LaRocca: Great. So, I just wanted to raise – what's great about these calls is that we can raise issues that we're hearing from providers in the field. And I just wondered if there was an opportunity to address who pays for COVID-19 testing on the day of hospital discharge. It's my understanding that the day before your discharge is your last inpatient day and hospitals would be concerned about not getting paid for running a test, a COVID-19 test on the day of discharge.

The reason this is important is we're hearing about tension about hospitals trying to discharge inpatient to SNFs and SNF is not accepting these patients without negative COVID-19 test results. And for background, I think we all know that a number of SNFs are experiencing outbreaks, staff shortages, PPE shortages, testing challenges and challenges establishing separate locations designated to the care for COVID-19 residents.

So as such, it's not unreasonable that SNFs maybe requesting two-negative test results. Is this something that could be considered making sure that there's payment for test performed on the day of hospital discharge?

Ing-Jye Cheng: Hi, this is Ing-Jye Cheng. That's a really good question. I don't have an answer for you right now and I'm actually going to follow up back through

with Alina here to make sure we get the answer written up and posted. Because, I'm sure you're not the only person who has this question.

Christine LaRocca: Thanks so much.

Ing-Jye Cheng: Sure.

Alina Czekai: Thank you for your question. Other questions for our presenters. Thank you.

Operator: Your next question comes from the line of (Andrea Sullivan). Your line is now open.

Alina Czekai: Hi. What is your question, please?

(Kyle), we'll take our next question please.

Operator: We will now proceed to the next question. Your next question comes from the line of (Denise Egan). The line is now open.

(Denise Egan): Hi, thank you. This question also refers to the earlier presentation. I thought I heard that there were 55 waivers specifically for home health agencies and I was trying to locate them and as well, are there any criteria for discharge from a long-term care facility to home?

Jean Moody-Williams: Hi, this is Jean Moody-Williams and all of our waivers – it's a great question, so that everyone knows that all of the waivers that we have can be found, if you go to cms.gov, there's a big banner there with the COVID-19 symbol. If you click on that, right about in the middle of the page you'll see waiver and there you'll have them all listed.

There are a number of waivers not specifically – there are some specific to home health but I think that total number that you're quoting was a total number and I encourage you to read through them all because they may not at first glance seem to be relevant to your particular discipline but they do – many of them overlapped. So, I encourage you to at least glance at all of the waivers and then there are some that are going to be specific to your discipline.

These are blanket waivers and what that means is if you see – if it says blanket waivers, you do not have to apply to those waivers. They automatically apply to you and your situation but if you don't see one and that – what you're looking for, we are happy to accept that, those requests. Thank you.

(Denise Egan): Thank you.

Shari Ling: And this is Shari Ling. Sorry, I was going to just add to Jean's response. So, this is Dr. Ling, just to say that the spirit of the waiver is flexibility, so that you all out there, taking care of our beneficiary, you can actually remain focus on exactly what their needs are. So, individual decisions will be made that are in the best interest for each and every beneficiary. So, they are flexible, they are meant to be applied in a way that help support you making those decisions, so thank you so much.

(Denise Egan): Thank you.

Jean Moody-Williams: Yes and I'm going to add to – I'm going to add to Shari's response as well, I mentioned the waivers but I also want to call your attention to the guidances that are there. We issued a number of guidances and within – because you did have a second question, within those guidances, we have recommendations for discharge, whether that be discharge to the nursing home, discharge to home, home health, all of those. So, please take a look at those as well, thanks.

(Denise Egan): I will. Thank you. I did notice in the blanket waivers, there's reference to – for a physician whose privileges are expiring that there's a waiver for that. But, I didn't see anything, and I could have missed it, about facilities credentialing staff as they're being hired.

Jean Moody-Williams: Yes, we have – I have to take another look at that – much of the credentialing I believe – I don't know if there's anyone else on that can address that. I thought we had addressed that and then much of that is also left at the local and state level which we of course will look forward to them. But, we will look to see what else is available for credentialing.

(Denise Egan): Thank you.

Alina Czekai: Thank you for your questions. And on the topic of flexibilities and waivers, I think that's a natural segue to our next section and that is hospitals without walls and telehealth. Two other major pieces of flexibility that CMS has offered during this time of COVID-19.

So, first I'd like to introduce one of our speakers today and that's Dr. Eric Dickson. Dr. Dickson is the President and Chief Executive Officer at the University of Massachusetts Memorial Health Care. Dr. Dickson, we like to turn it over to you to share some of your perspectives on hospitals without walls. Thank you.

Eric Dickson: Thank you so much for the opportunity and say hello to all my fellow caregivers out there and thank them for the terrific work they're doing in dealing with this COVID-19 crisis. I think all healthcare systems as they look at the potential of number of patients that are COVID-19 positive coming into their facilities have to asked themselves very early questions about surge capacity for their ICU, for their acute care beds, are they going to have skilled nursing facility space, (where) are the homeless that are COVID positive go, psychiatric patients, detox patients.

We almost have to develop a healthcare system within your healthcare system to be able to deal with this. And for us, the biggest challenge was acute care space and having a flexible space that was almost an open care as sometimes we have to shift things around. So, what we decided was to create a 216 bed field hospital in an exhibition hall of basically over the course of eight days.

We looked at multiple different options, dorms, hotel space, we're very worried about putting COVID positive patients behind a closed door. We didn't have a closed hospital to choose from and we knew that the staffing was going to be relatively meager compared to our standards that we have within the hospital. A field hospital where a person can walk down the line and see 10 patients over the course of a couple of minutes is ideal for surge space for us.

So, we found an open exhibition hall and decided that was the place to build the hospital. This is a COVID only space, such that once you come in, you're

in your PPE, you're in it until you leave the hospital. Everybody is positive, so there's going to be no spread of infection between patients at least for the coronavirus but we're all so very aware of spreading other diseases between patients which is a real consideration.

Some of the early decisions that we have to – had to make is how to license the space and did we want to see acute care patients there. We chose to just make it additional inpatient unit of our hospital. We were able in a matter of days, to the flexibility of some of the waivers and state government, to get the space licensed. How you're going to staff it? We decided to staff with internal medicine physicians and residents, many of which came out of ambulatory practices which were much slower.

We didn't have nurses that we could send there except for around the clinics, so we did have to bring in some travelers. And then, we had almost 1,000 nursing students, pharmacy students, respiratory therapy students volunteer – we put out a public call to be patient care assistants. The patients that they're taking care of there had to be on 6 liters nasal cannula oxygen or less. And the first thing we said to figure out and the last thing we finally got done was how to supply oxygen to the patients.

You're talking about 50,000 square feet of empty space that fortunately had power in the floor but no oxygen. Bedside liquid oxygen systems are a consideration, oxygen concentrated, if you can get them, are a consideration, and pipe-in oxygen from a liquid system that can provide you the 50 psi necessary to run a vent would be ideal.

We couldn't get all 216 beds done in time, so we decided that we would have 50 beds with the standard pipe-in oxygen that could run a ventilator, anything else we needed and we're able to supply the rest of the beds with concentrators and bedside liquids systems. If you have to do this, the day one, start thinking about how you're going to provide oxygen to the patients because it will be your hardest problem to solve.

IT, you're going to use downtime procedures in a paper medical record and feed that into your electronic record afterwards or can you get it wired in time.

Our team decided that they could do an epic built for the field hospital in a matter of a couple of days and get it hardwired off the existing network that was in the exhibition hall, such that we could run all of the electronic health record on computer on – computers on wheels.

Pharmacy, are you going to ship in from one of your main hospital campuses, the daily medications that patients need, what you're going to have on site, are you going to have a code cart, a resuscitation area. We went to further than we probably had to in terms of the number of medications that we stocked as a field hospital.

And it was just that our pharmacy had a can do attitude and was able to put up, pyxis machines necessary to had almost all of the daily medications that the patient would need as well as things for a sedation for example. Because we're staffing with internal medicine physicians that primarily were working in an ambulatory environment beforehand, we decide we needed some backup in terms of resuscitation or the patients that would deteriorate on the floor.

And we didn't have anesthesiologists, a nurse anesthetist or emergency physicians because they're all managing the ICU surge and the emergency department surge. So, we used the paramedic setup and station paramedics right at the field hospital that could help stabilize and quickly transport a patient if necessary. To date, we only had to do that once.

Labs, what do we want to have for labs available to you? X-ray, we're able to have portable x-ray set up in point of care of labs but most labs continue to be sent out from there. And one of the things we didn't think of until it came to us at first, discharge planning. We have now discharged more patients than we admitted and that took some time to set up as well. I think through all of this, it's important to think about sending somebody to a field hospital and creating a positive patient experience.

And the way that we've been able to do this is by giving people what they didn't have in the hospital locked into a room, freedom to get up, walk around, take a shower. We had portable showers brought in. They all get iPads and have Netflix and the means of communicating with their family. And many of

the patients that had been at the field hospital that were moved from a hospital originally where they're really locked into a room the whole time, think it was actually a better patient experience.

They can actually interact with one another, something that wasn't happening in our hospital. Overall, we've been able to take care of many acute care patients there but also be able to flex the space for things like almost positive COVID patients, detox patients when necessary. We took a section that was for prisoners that were COVID positive for a period of time. And what has given us a flexible space to be able to move things around and give us time to set up other specific areas within the hospitals.

And that's all I have. If you want to see a video of our field hospital, just go to UMass Memorial Field Hospital DCU, put into Google, go to umassmemorial.com and we have a nice overview that it's designed to help others that are going to set up similar hospitals, get that done. Thank you.

Alina Czekai: Terrific. Thank you so much Dr. Dickson for sharing your insights for Massachusetts. I'd now like to turn it over to Dr. Scott Shipman. Dr. Shipman is the Director of Clinical Innovation and Director of Primary Care Initiatives at the American Association of Medical Colleges and he'll be touching on telehealth this afternoon. Dr. Shipman?

Scott Shipman: Thank you very. It's a pleasure to join the conversation today. So, I will be talking briefly about what my team and others have done to implement a tool in clinical practice called an e-consult. Whether you're a primary care provider or subspecialists, you've undoubtedly had experience with fragmented communication or poor coordination between PCPs and specialists. And this fragmented care can create inefficiencies at best and negatively impacts patients at worst.

Beyond this access to specialty care is often challenging, even the best of times and much of the country, patient wait times for specialty visits are often measured in weeks, if not months. And beyond the long wait time, many patients lived a significant distance from the nearest specialist which is – which creates a further impediment for them to accessing needed care.

So, sometimes doctors will resort to curbside consult as a workaround to get clinical advice, whether they do this – when they run in to colleagues in the stairwell, at the hallway or more often these days with the phone call or e-mail or a message in the in-basket of the electronic medical record or EMR. Unfortunately, as a mechanism for a consultation, curbside is often suffered from a lack of important clinical information or timing for the consultation is inconvenient for either the PCP or the specialists.

They typically are not documented in the medical record and there's no reimbursement for the time and advice that's provided. So, a new clinical tool often called an e-consult has emerged in the past few years that really overcomes each of those limitations of curbside. Just to level set, an e-consult as I'm talking about is an asynchronous or store-and-forward exchange between two clinicians typically from a PCP to a specialist. There's a variety of different approaches to using e-consults out there.

I find that the tools most useful when it's built into the EMR were clinician can order that e-consult in a similar way that they would place a referral. Unlike a referral, an e-consult avoids the need for the patient to be seen by or established a relationship with the specialist when that's not necessary for clinical care.

Instead the e-consult creates a reliable and standardized and documented exchange between providers that allows them – the patient that is to be managed by the personal physician that they know and trust but with timely access to an expert's advice and guidance when that's necessary. At the AAMC, we had been working with health systems around the country to establish an e-consult program that we called Project CORE, it stands for Coordinating Optimal Referral Experiences.

And today has been implemented in something over 30-large health systems in about 20 states across the country. And then Project CORE, we're finding about 80 percent of PCPs come to use e-consults on a regular basis, so they really do find this to be a useful in clinical practice and we have most specialties participating at most of the centers that have implemented this. So, it's available really across the board.

An important thing about the CORE model is both the PCP and the specialist receive a credit or reimbursement for the work they do when they complete any consult, recognizing the specialists for the time and reviewing the case and providing their expert guidance. And also, recognizing the PCP for taking ownership of the problem for posing the question and then carrying out specialist guidance typically without a subsequent visit for the patient after the guidance has been given.

We like to say that e-consults really create a win, win, win, win for different stakeholders including patients, providers, health systems and payers and I'll briefly focus on two of these today, the patient and the provider. On average, a patient is going to save more than – about $100 in out-of-pocket and opportunity cost for every specialty visit that's averted by an e-consult. There's no need (to) say time off work to go see someone or travel somewhere new for care.

Yet, they still get it but from the specialist who reviews their case personally and provides that personal advice to their PCP who can then translate it and decide with the patient how to go forward. And rather than waiting about a month or so for the visit with the specialist, e-consults typically answered about a day.

PCP, specialist benefits from having a reliable structure for effective communication with standard expectations for each provider. PCPs get timely access to specialty guidance when it's needed, allowing them to provider more comprehensive care for their patient population, while specialists are able to serve more patients more efficiently and they get reimbursed for it unlike curbside consults.

CMS created two new CPT codes in 2019 for a so-called interprofessional electronic consultation, codes 99451 and 99452, that enabled both the PCP and the specialists to be reimbursed by Medicare for an e-consult much like we set up in the Project CORE model. Commercial payers are also beginning to follow suit.

Now e-consults have an important role to play during the COVID crisis to reduce unnecessary exposure for both patients and providers. In addition to avoiding the unnecessary specialty visits in an ambulatory setting that I described so far, we have a number of health systems that are now looking to use e-consults for a subset of their inpatient consultations where a physical exam isn't essential and telehealth video capabilities may not be practical in every instance.

We fully appreciate CMS's work in adding flexibility to many of the regulatory restrictions that could have otherwise restricted the ability of e-consult to the tool during pandemic and we look forward to continuing to work with CMS on this going forward. Thank you very much.

Alina Czekai: Thanks very much Dr. Shipman. Also discussing telehealth today, we have Dr. Karen Rheuban. Dr. Rheuban is the Medical Director at the Office of Telemedicine at the University of Virginia, go Hoos. Dr. Rheuban, over to you.

Female: Well (hello), wah-hoo.

Karen Rheuban: OK, well good afternoon and thank you for the opportunity to join you today. The University of Virginia is home to a longstanding telemedicine program through which we support clinical consultations and followup visits, tele-ICU care, remote patient monitoring, store-and-forward services, Project CORE, e-consults and virtual education to patients and providers.

Our 150-site network across Virginia includes community and critical access hospital, skilled nursing and long-term care facility, federally qualified health centers, free clinics, medical practices, correctional facilities, schools and EMS providers. We offered telemedicine services across more than 60 different clinical subspecialties.

In addition, as a state designated special pathogen hospital following the Ebola outbreak in 2015, we developed a model we referred to as (Isocom) in which we configured all rooms within our special pathogens unit with video conferencing to reduce provider exposure, improve the patient experience and conserve PPE.

Although our telemedicine program has primarily been externally-facing, last year heartened by both the relevant provisions of the 2019 Medicare Physician Fee Schedule that Scott referred to and by clear messages from our patients seeking new models of care, we underwent a multistakeholder strategic planning effort to further expand our virtual care offering. The COVID-19 Public Health Emergency catapulted us into action to rapidly scale all elements of our strategic plan.

The 1135 waivers and changes implemented in the recent COVID-19 interim final rule have further enabled us to advance that plan. Our state Medicaid program has taken similar expansive action. For those policies changes, we are truly grateful. Our clinics have rapidly transformed ambulatory care by replacing in-person visits with virtual care provided to the homes of our patients.

Last week we enabled more than 1,500 virtual visits daily. We also provide telephone services as well. Within our hospital, we've configured more than 80 isolation rooms with (Isocom's) cart. This enables our own clinicians to provide video-based consults from health system locations other than directly within the special pathogens unit or in our other isolation rooms.

We're about to launch a new direct to consumer urgent care portal to our emergency physicians to decrease emergency room visits. We greatly expanded our remote patient monitoring programs not just for high-risk patients with chronic illness but also for pregnant women and also for our COVID-19 positive patients. Those latter patients, if symptomatic, are monitored by our nurse practitioners every four hours using video conferencing to the home and biometric devices.

In some cases, we are also monitoring patients with multifunction remote examination tool. We great expanded our external-facing relationships with long-term care facilities where a significant number of outbreaks in Virginia and across the nation have occurred.

As an example earlier this week following an urgent request from one long-term care facility, about an hour from here, with 90 percent of their patients

testing positive, we rapidly delivered a telemedicine card and executed an agreement that same day, enabling our clinicians to make daily round and provide consultative support. And we have since admitted at least seven or eight patients from that facility.

We've ramped up our ambulatory Project CORE, yey Scott, e-consult program, so also provide inpatient e-consult and we have implemented a COVID-19 Project ECHO statewide program.

These transformations were not easy and required an all hands on deck approach supported at the top by UVA senior leadership and by our clinicians working in partnership with telemedicine, health IT, our billing and compliance team, patient registration staff, contracting, our analytics group and of course most importantly our patients.

I might also add as a HRSA designated telehealth resource center and it – ours is called the Mid-Atlantic Telehealth Resource Center but resource centers span the entire nation, we've see our own request for technical assistance and training increased by more than 1,000 percent in the last few weeks. Our website is matrc.org and we offered it to anyone across the country.

There's still much work to be done to train providers on the use of telemedicine. As such, we will also implore our federal partners to ensure that many of the digital health reforms and investments rapidly scaled in response to this public health emergency will endure. Likely will be a cyclic nature of COVID-19 or in preparation for any future public health emergency, healthcare providers and systems must be ready. Thank you.

Alina Czekai: Thank you so much Dr. Rheuban. I really appreciate your insights on how you're implementing telehealth in Virginia. I think in the interest of time we will move to our next topic on the agenda.

And I know if you have questions on telehealth which I know many of you do in the field, we encourage you to continue to join our CMS COVID-19 Office Hours and again those calls are every Tuesday and Thursday at 5:00 p.m. Eastern and they are open to anyone in the field to come in and ask questions

of our CMS subject matter experts. So, thanks again to Doctors Dickson, Shipman and Rheuban.

And next, we'll move on to our next topic on the agenda and we'll be hearing from our colleagues at the FDA, Dr. Jenny Gao, for a discussion on COVID-19 clinical trial conduct and she'll also be leading a discussion with the patient community. We'll be hearing from the cancer community, cystic fibrosis community, diabetes and arthritis.

So without further adieu, Dr. Gao, I will turn it over to you.

Jennifer Gao: Good afternoon and thank you for inviting me to speak today. My name is Jennifer Gao. I am the Associate Director for Education at the FDA Oncology Center of Excellence. I'll keep my remarks brief in the interest of time. I think one of the greatest things (of) working at the FDA is being able to work together and collaboratively and there's been an incredible all hands effort as we together address the COVID-19 Public Health Emergency.

Altogether, more than 15 guidances had been developed across the FDA centers. These are getting release without public comments, so that we can get the information out in weeks rather than sometimes months to years is that what they can take. I want to briefly highlight the conduct of clinical trials guidance which is available online.

This guidance was most recently updated yesterday with additional question and answer section, discussing remote monitoring for trials, conduct, obtaining consent and many other topics. I encourage you to go online and check it out. The guiding principle for this guidance is really to ensure the safety of all trial participants.

There are protocol modifications, protocol deviations we expect to see but we want safety to be paramount and to be at the forefront while at the same time make any flexibility and trying to making this a trial (integrity) and rigor as possible. The guidance provides some high-level overview. This was specifics on common issues because sponsors will have questions and we, they wants them to be able to have a documented go-to for some of these topics.

We understand that there will be many specific questions (partaking) to protocols or the risk specific study or it would be (inaudible) for the sponsors to come and speak to the FDA and discuss things such as changes in efficacy endpoints, the patient eligibility criteria and such. But again, the key point from this guidance is the trial should really assure the safety of patients and the trial participants is forefront.

With that, I'd like to turn over to our panel section. We have experts from the FDA and I'm honored to be joined by patient advocate who will provide very valuable perspectives. And with that, I'll turn it over to Ms. Nasso to kick us off.

Alina Czekai: Great. Thanks so much. We'll start with Shelley Fuld Nasso. Shelley is the Chief Executive Officer at the National Coalition for Cancer Survivorship. Shelley, we love to hear your remarks from the cancer community. Thank you.

Shelley Fuld Nasso: Great. Thank you so much for inviting me. So, the National Coalition for Cancer Survivorship is a patient advocacy organization and we advocate on behalf of the nearly 17 million cancer survivors in the United States, many of (them) with long-term physical and emotional side effects from their cancer treatments.

On behalf of everyone in NCCS, I want to express our gratitude to the healthcare providers on the frontline of caring both for COVID-19 patients as well as trying to – as the patients with other health conditions who need the continuity of care during this crisis.

So, we hear from cancer survivors that they feel both uniquely challenged because of concerns about the risks and also in a strange way uniquely prepared for this time because of what they have endured for their cancer experience. We've been collecting questions from patients and survivors on how to manage their health during this crisis and also providing information, resources and answers to questions on our website, canceradvocacy.org.

We partnered with the American Society of Clinical Oncology to address clinical questions from patients and survivors. And we've launched a series of webcast and – webinars and podcasts. Our first webinar last week with Dr. Otis Brawley covered questions about risks for survivors and the completed treatment, cancer care for patients currently in treatment, the (series) and outcomes, disruptions to clinical trials and clinical research and ration of care.

And yesterday, we have the webinar on managing anxiety, stress and grief during this difficult time. We had an overwhelming response from these webinars with survivors, advocates, healthcare professionals and public health officials. So, clearly there is a hunger for more information and it's also clear from the questions we're receiving from patients and survivors that the care is palpable.

Some of it we're hearing for cancer survivors and patients currently in treatment include fear of increase risks for contracting COVID-19 and poor outcomes due to the history of cancer treatment and the compromised immune system and delays in screening and diagnostic testing, fear of navigating a stressed healthcare system and in receiving care at a hospital or facility where COVID-19 patients are being treated, changes in the risk benefit assessment for adjuvant therapy with decisions to forgo adjuvant therapy, resulting in higher risk of recurrence in the future.

What we're hearing from patients is that they really need a clear explanation of why treatment decisions may have change based on the personalized assessment at the risk and benefit. We're also hearing about their stress of social isolation, concern for cancer survivors who do not have access to technology for telehealth or for social connection, concern about rationing decisions, particularly a response system guidance that terminal cancer patients would receive only supportive care.

Many people live with stage 4 cancer for years and so the guidelines really should not discriminate against any blanket group of patients and should recognize the distinction between terminal cancer and stage 4 cancer. And we're also hearing concerns about plans to reopen the economy and return to work. NCCS is joined with other patient groups to advocate for expansion of

paid leave for people who have underlying health conditions that put them at higher risk for returning to work.

Thank you for inviting us to join and again our resources could be found at patientadvocacy.org.

Alina Czekai: Thank you so much Shelley. We'd now like to turn it over to Mary Dwight. Mary is the Senior Vice President and Chief of Policy and Advocacy at Cystic Fibrosis Foundation. Mary, over to you.

Mary Dwight: Thanks so much for having me and again we want to echo – I'm actually going to echo a lot of the things that Shelley just said but I also want to echo our thanks to frontline providers. It was really fascinating to hear your experiences. As some of you may not be familiar with cystic fibrosis or it's been a long time since you've seen cystic fibrosis, I want to just provide a very quick snapshot of the disease.

It's a rare genetic disease that affects multiple systems of the body, primarily the lungs and the digestive tract and while it's important to note that chronic lung infection has been hallmark of CF for a long time. When the Cystic Fibrosis Foundation was established in 1955, children with the disease were not expected to live to be kindergarteners.

But thanks a lot of advances in treatments including highly effective new therapies and an extremely well-coordinated multidisciplinary care model, the improvements in care has been quite dramatic. And the median (inaudible) age that survive for people with a cystic fibrosis in the U.S. is approaching 50 years of age. We're very optimistic that with advances in therapies such as some of these promising new drugs, we really expect that age will continue to climb which is an important note to a point I'm going to come back later.

So much like Shelley spoke to about what they're hearing from the cancer survivorship community, we are hearing an awful lot from our patient community to a variety of resources and inputs including frontline case management of (protocol) compass where we're getting calls in from our community. They have questions that range from the basics of the virus,

specifically the experience of COVID-19 for people with cystic fibrosis which has been overall encouraging.

One of the components of the Cystic Fibrosis Foundation is that we really are in many ways is the medical specialty society for the disease and that includes one of the oldest and largest patient registries in the world. We used that registry to tract the experience of COVID-19 with cystic fibrosis and had been collaborating with many of our international peers. We know about 15 people with CF is with COVID-19 in the U.S. and about 80 globally.

And the good news there is that most had been able to stay home and recover with few hospitalizations. Unfortunately, there had been two deaths globally but again I want to reiterate that many of these folks have – that had COVID-19 and cystic fibrosis have recovered including some with quite low lung function below at FEV1 (25). And there's no evidence to suggest that people living with cystic fibrosis cannot make a full recovery from COVID-19.

The (experiment) I mentioned that CF has hallmark of lung infections and that means in many ways the CF community has been well trained to handle the current situation that so many of Americans find themselves in now with a lot of experience protecting themselves for things like physical distancing in cold and flu season and for the extensive infection prevention and control strategy. That it happens in CF care naturally and including care at home.

So, the community continues to have questions about how to take care of themselves and the precautions that family should take. And so I want to reiterate the point that Shelley mentioned on advancing paid leaves for those more vulnerable patients out in our community that will be an essential step to take as we return to the “new normal.” The CF community also like the cancer community is very concerned about some of the care rationing or triage plans that are cropping up in states and institution.

It's been quite alarming to see that several states have created regional triage plans that reflects outdated, understanding of cystic fibrosis that ignores several of the significant improvements I mentioned earlier, and neglect to take in account there – a lot of the new therapies that we've seen have really

transformed the disease. We are quite clear that any plan that uses outdated or inaccurate information to disadvantage people with cystic fibrosis is unacceptable.

And that the mere presence of CF should never disqualify someone from lifesaving care. I also want to reiterate the comments from the previous panels about the advantage of the telehealth. This is something that has been emerging in cystic fibrosis care. As I mentioned, infection prevention is quite critical in routine CF care and so the move to telehealth is something that's been promising in our care delivery for some time.

And really the concern here is – there's an opportunity here as we accelerate assistance with telehealth but there's also some concerns about the stability of some very important multidisciplinary team that's really brought for so many of the positive changes in cystic fibrosis. We need to make sure that there are considerations across the board to be able to deliver effective multidisciplinary telehealth in cystic fibrosis. Things like equipment like spirometers and data collection will be quite critical.

The community is also curious about what the impact for the sole spectrum of CF care will look like in the telehealth setting all the way from newborn screening which is critical to diagnose the disease to the other side of the fence of transplant. And it's those kinds of services that some of our community still require will still be available. And it's very important to continue to emphasize the importance of mental and emotional wellness and care.

And last but not least, the ability of our community to reach their care provider and their care team, so we're not only invaded by COVID-19 but are also being redeploy in their institution. The collaboration and co-production of care is essential in a chronic disease like CF and it's going to be essential to make sure to maintain those connections. So, thank you so much for including us and I look forward to any questions.

Alina Czekai: Thank you, Mary. We very appreciate your perspective. I'll next turn it over to Dr. Sanjoy Dutta. He's the Vice President of Research at the Juvenile Diabetes Research Foundation. Turning it over to you doctor.

Sanjoy Dutta: Thank you so much for this opportunity. JDRF was the leading charitable organization, funding type 1 diabetes research globally. Type 1 diabetes is a chronic autoimmune disease and with people must test their blood glucose and take insulin in order to stay alive. Blood sugar testing is even more significant when a person is ill, to reduce the risk of complications which can be brought on by illness.

We greatly appreciate the opportunity to briefly share today the impact of COVID-19 on our community. For people with diabetes, it is vitally important to continue to vigilantly manage diabetes during this crisis. Diabetes emergencies will still happen during this time and cannot always be avoided. It is important that in these cases people are encouraged to seek the care they need at a hospital in ways that lessen the fear of virus transmission.

From what we know, people with type 1 diabetes with well controlled disease are not more susceptible to contracting COVID or at higher risk of complications from the virus. But, those with diabetes and other medical conditions such as heart or kidney disease do seem to be at higher risk. If someone with diabetes contracts COVID, their glucose levels may be one of the first things to be affected. Being extra diligent with the glucose control is necessary to help the body focus on fighting the virus.

A particular importance of diabetes management for people who had (been) hospitalized. Hospital staff usually performed fingerstick blood glucose measurement for hospitalization but this requires hands on contact increasing risk of virus exposure and use of PPE. Therefore, this may be (reduce) which can have many other clinical consequences.

JDRF were strongly encouraging all hospitals to do two things. One, allow use of glucose monitoring devices patients bring with them to the hospital. Two, procure continuous glucose monitor which allows for remote monitoring

of glucose levels, greatly reducing hands on contact and PPE for patients who do not have their own.

(MJ) has recently made this possible by communicating the continuous glucose monitor manufacturer that they are not objecting to them providing their products to hospitals and also releasing an FAQ on use of (home) meal glucose meters in the hospital. Importantly, two continuous glucose monitor manufacturers have announced their products are now available to hospitals, some being donated.

Another area of where we're seeing an impact is with insulin (active) for pump and continuous glucose monitor. Medicare and some commercial insurer required documentation for various criteria for coverage. In the current situation, much of those documentation is not possible to obtain or provide and therefore people with diabetes may not be able to obtain the devices they need.

We strongly recommend that during this crisis, CMS and other insurers waived documentation requirement and allow DME supplier to provide the devices based from the secured e-mail or phone in verbal order.

In closing, JDRF is continuously communicating information on COVID-19 and C1B to our community through our website. So, I refer you there for more information and once again thank you for the opportunity to provide the voice of people effected with diabetes on behalf of JDRF.

Alina Czekai: Thank you so much Dr. Dutta and certainly not last but certainly not least, excuse me, we have Guy Eakin. Guy is the Senior Vice President of Scientific Strategy at the Arthritis Foundation to share some perspective from his patient community. Thank you.

Guy Eakin: So, thank you very much for the opportunity to speak today, representing 54 million people simultaneously living with arthritis and within the societal and medical changes that are made necessary by COVID-19.

I do want to begin with the story. It's from our Arthritis Foundation volunteer, (Lauren) in Georgia. She's a 911 dispatcher living with autoimmune arthritis.

In her words and like so many in our community, she says that health to me starts mentally but it's (have) to do. And so in a critical way but like other, she's managing her health in an enclosed workspace while managing other people's emergency and that comes at a cost.

So, like the comments made by earlier presenters, we're seeing an increase in anxiety and depression played out in the Arthritis Foundation data. So for over a year, we've been collecting our Live Yes! INSIGHTS, patient reported outcomes measures and it's chronicled how arthritis affects symptoms including social and mental health. This was created by more than 100 patients and volunteers to best describe a life lived with arthritis. It now has more than 12,000 users.

So when we look at the COVID-19 pandemic, we're seeing anxiety measures jumping 20 percent with similar increases in depression averaging about 10 percent when compared with the same time period last year. We're also seeing 30 percent increases in our help line usage. And so at the request of patients and I'll use the example of a woman, (Stephanie) in New Jersey, who noted that access to support group is challenging.

We're beginning to offer more support groups in our Live Yes! Arthritis Network to an increasing number of patients. So, that Live Yes! Arthritis Network is making connections traditionally in person but now we're dramatically increasing our online presence, empowering people to live their best life in response to the statistics that we're discussing.

And of course why is this so vital? I mean we can talk about healthcare interruption, its suspension as others had mentioned but our – many of our patients are relying on ongoing physical therapy. They're relying on infusions, counseling and employments, et cetera.

Much of which is being altered or suspended and we have amazing advances and virtual employments are becoming an option. Those procedures with hands on care and team medicine is being sacrificed as mentioned by Dr. Dwight at the Cystic Fibrosis Foundation.

And then, even with these clinic-based appointments are received, it requires additional calculations of risk. So (Rebecca), a patient in Colorado framed this perfectly when she explained to us that, look, I've always been very careful in public. I'm disinfecting, sanitizing, washing my hands frequently but I had rheumatoid arthritis for over 18 years. I catch infections and viruses so easily but now with the COVID-19 crisis, I have such anxiety about even going into public places because I'm at such a high risk. It's just an added layer of anxiety.

So on this call, we're all aware of drug shortages and in our community we are thrilled to learn that medications, they're familiar to the arthritis community such as hydroxychloroquine but also others including expensive and difficult to manufacture biologics could possibly be solutions to the global pandemic.

Unfortunately, there's no silver bullets and our community is documenting COVID-19 positive patients on antirheumatics including hydroxychloroquine. There's also a very real concern that increased demand for these drugs to help treat COVID-19 has exacerbated their already limited availability and this is an access we're trying to preserve by working within the drug supply chain at the Arthritis Foundation.

Unfortunately, we know also that in many cases, there are no alternative medications. Hydroxychloroquine in particular is a cornerstone therapy in lupus and the only medication shown to increase survival. So, offering another patient story, (Michelle) in Alabama is the mother of a child (Caitlin) who is her 13-year-old daughter who's living with a complicated juvenile idiopathic arthritis that has lupus-like features.

She's contraindicated for biologics. Hydroxychloroquine is the only safe medication for her. It is their miracle. It's been the difference between a wheelchair and walking. (Michelle) went recently to the pharmacy and was told that this maybe their last refill on (Caitlin's) miracle drug because it was being touted in the news as COVID's miracle drug.

So, (Michelle) called 12 different pharmacies near her hometown with no success and we helped, at the Arthritis Foundation, share the story with The

Wall Street Journal which on April 5th quoted to (Michelle) saying I had even one pharmacy suggest I contact Mexico and Canada for my – for my hydroxychloroquine supply. So, staggering as that maybe, another patient, (Winona) in California kind of sums this up best to say, I would be happy to give up my dose to save a life but it's not been proven to save lives.

And so today, limited data support COVID-related efficacy for the drugs that are under testing including hydroxychloroquine. And as we began to see glimmers of hope in other medications, our shared goal needs to be underscored by an imperative to preserve access to these medications for all those patients whose lives depend on them.

So, it's really my distinct honor to share this experiences of the Arthritis Foundation patient communities in this very challenging and rapidly evolving times and I'll return it back to our moderators.

Alina Czekai: Thank you so much Mr. Eakin. It's always really valuable to us here at CMS and across the federal government to hear from the patient and caregiver community. So, we really look forward to including you all on these calls moving forward.

And I know we're pressed for time today. So, I'd really like to thank all of our speakers. I'm really grateful to you all for sharing your insights and best practices not only with us here at CMS and FDA but also with one another. We hope that you find these calls to be an opportunity and a way for you to share best practices and what you're seeing maybe with doctors or clinicians across the country.

And we hope that you all will continue to take advantage of our many of other opportunities for question and answer with our CMS subject matter experts. So, please be on the lookout for those invitations both for other care site specific call, this series and our Office Hours which are every Tuesday and Thursday at 5:00 p.m. Eastern.

And in the meantime, please continue to direct your e-mail questions to covid-19@cms.hhs.gov. Again, thank you for all that you were doing for patients

and their families around the country and I hope you have a restful weekend. Thank you.

Operator: This concludes today's conference call. You may now disconnect. Thank you for your participation.

End