

Centers for Medicare & Medicaid Services
COVID-19: Lessons from the Front Lines
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Operator: This is conference # 6583696.

Alina Czekai: Thank you for joining our CMS Lessons from the Front Lines on COVID-19 today June 5th.

We would 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 this call is part of our ongoing series Lessons from the Front Lines.

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 question can be submitted using our online media inquiries form which can be found at [CMS.gov/newsroom](https://www.cms.gov/newsroom). Any non-media COVID-19 related questions for CMS can be directed to our e-mail which is covid-19@cms.hhs.gov.

And I'd like to begin our call today with a very brief update on the agency's latest activity. CMS continues to work to strengthen and modernize the Medicare program by bringing numerous free-market principles to bear on a program that has often been covered by overly prescriptive regulations, and we've seen it has worked. Medicare Advantage premiums are at a 13-year low and our Part D drug plans are at a seven-year low.

And most recently, we announced broad manufacturer and insurer participation in the Part D Senior Savings model which will provide many seniors with Medicare access to a broad set of insulin at a maximum \$35 co-pay for a month's supply, and we know this is very important particularly for patients living with diabetes and on today's call we will discuss diabetes care more deeply.

And in the context of the COVID-19 pandemic, since February, CMS has taken swift and unprecedented action to keep elderly nursing home residents safe, including the release of over 13 guidance documents. We have issued numerous infection control guidelines, paid for expanded testing of residents and required that families be informed of COVID-19 cases inside facilities.

And most recently, as part of President Trump's Opening Up America Again effort, we provided state and local leaders guidance on how they may reopen nursing homes in a very safe way.

In April, we instituted an unprecedented requirement that nursing homes report new coronavirus cases directly to the CDC and this allows us to have standardized data that is consistent across the entire country, and this data has formed the backbone of a national virus surveillance system.

And while patients and families have had information on COVID cases in their respective facilities, this data was recently made public this week for the very first time, and this data is being updated with a new tranche of numbers and posted publicly with searchable functionality.

Of the over 15,400 nursing homes CMS oversees for participation in Medicare and Medicaid, about 12,500 reported their data as of last week, which is about an 80 percent rate. We're really excited to see that. And we anticipate more nursing homes will report every week and nursing homes that do fail to do so are subject to enforcement actions including monetary fines.

And as always we welcome the opportunity to be able to update you all on the activity and action the agency is taking in response to COVID-19. But more importantly, we'd like to use this call as an opportunity for you all to share best practices with one another.

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, which is care for the patients in your local communities.

Around the nation, providers and local communities are innovating in response to COVID-19 and we hope to bring local innovators together to share best practices that can be scaled at the national level.

And today we are joined by physician leaders from around the country who have offered to share insights and best practices from the field, and our speakers today will discuss best practices for caring for two very important patient communities that have unique needs during the COVID-19 public health emergency and that includes patients living with diabetes and expectant mothers.

And also joining me from CMS are several of my physician and clinician leaders who have offered to share their expert perspectives throughout the conversations as well. Joining me today is Dr. Marion Couch, senior medical advisor to Administrator Seema Verma; Dr. Shari Ling, acting chief medical officer at CMS; Dr. Michelle Schreiber, director of the Quality Measurement and Value Based Incentives Group at the Center for Clinical Standard and Quality at CMS; Dr. Barry Marx, director of the Office of Clinician Engagement; and Dr. Ellen-Marie Whelan, chief population officer at the Center for Medicare and Medicaid Services.

Let's start today with our conversation on diabetes best practices. First, it's my pleasure to introduce our first speaker today, Dr. Robert Gabbay. Dr. Gabbay is the chief science and medical officer at the American Diabetes Association. Dr. Gabbay, over to you.

Robert Gabbay: Thank you so much and I want to thank CMS for organizing this call and for all of you on the line that are on the front lines of really caring for this epidemic – the pandemic that we all are dealing with.

As mentioned, I'm the chief scientific and medical officer at American Diabetes Association and recently stepped down as the chief medical officer for the Joslin Diabetes Center in Boston which is the largest and oldest diabetes care research and education center in the world.

I want to take a few moments to share some of my personal experience and best practices around caring for individuals with diabetes and COVID both on

the outpatient side and on the inpatient side, and then provide two areas where I think we can be thinking about for the future.

I think I would start by saying I'll never forget the moment on March 16th where there was a bag on my office door and found out that the first employee and first person at Joslin had been tested positive for COVID, and like many of you, that was really a game changer and we needed to quickly move our outpatient care for our 25,000 patients from 95 percent on site to 95 percent off site and remotely.

And I'll give you three examples of the types of things that we had to do which I suspect many you have been working through and have worked through in order to achieve the quality care that we want to be able to maintain.

First of all, telemedicine was obviously the answer. We started with phones, we eventually moved to video and had to instruct patients and providers on how to use this, and there are number of vendors out there that provide services that we've been able to make use of. I really want to thank CMS for their insight and support to be able to make this possible for all of us.

The second was ensuring that our patients had sufficient medication and devices and supplies, and again CMS took leadership here in liberalizing some of the documentation required to be able to get these essential treatments to manage their diabetes.

And the third was working out the flow and operational aspects to be able to handle all of the faxes and prior authorizations that we work with. And I suspect for all the clinicians on the line, if there was one wish we had amongst many, one would be to simplify and reduce the number of prior authorizations that are needed to sort of move forward.

So a little bit of – that's a little bit of the outpatient side. Let me shift to the inpatient care where we provide consultative services for diabetes. I had the experience of being on call in those early days as well and we did this all remotely quite remarkably again for safety purposes, and literally half the patients in the ICU were with diabetes and COVID.

Many of them were undiagnosed diabetes and as you probably know hyperglycemia whether with or without diabetes worsens the outcomes in individuals with COVID both in terms of length of stay, and the morbidity and mortality.

And in the ICU where the sickest patients are located of course, the insulin needs are quite high and hyperglycemia is quite common, and so we needed to work on meeting a goal of minimizing the exposure of the healthcare workers in testing blood glucose because of the challenges associated with that, while at the same time reducing the variability in glucose, reducing the amount of hypoglycemia that can be a risk in the ICU as well, and overall improving glycemic goals.

And so I'll just share two quick scenarios in our solutions for them and we have published some of our early observations in diabetes care and glad to circulate that manuscript to you that has more information and more scenarios.

Look, the first scenario I want to talk about is enteral nutrition and tube feeds as you know is the mainstay of nutritional support in the ICU. We found that the best balance in the sense of minimizing exposure to glucose testing was using NPH insulin every eight hours and testing every eight hours, while at the same time using corrective regular insulin at that same frequency for high blood sugars.

Continuous glucose monitors are another option and some of my colleagues that you'll be hearing about in a moment will talk about that as well.

The second scenario is that many of these individuals are treated with high-dose steroids in the hopes of reducing the cytokine storm that comes with COVID. We found that initiating 20 unit to 30 units of NPH and that initial steroid bolus was one way to mitigate some of the extreme hyperglycemia that can occur in the setting of steroid use.

Finally, I want to bring up two issues for us to think about as we move towards recovery and more broadly talk about diabetes management. And the first is the incredible power and value of telemedicine and remote monitoring.

I think we've all seen how this has become crucial in meeting the crisis that we face with COVID.

But, clearly, this is something that requires continued support, is well accepted by patients and providers, and provides access to care to people who otherwise may not, and we look forward to that continuing and for CMS' continued leadership on this.

The second is really an example of what this call is and that's how do we disseminate best practices amongst many of the experts that are on the call today. As you know, 90 percent of people with diabetes receive their care from primary care providers, not endocrinologists like the group of us that you'll be hearing from today.

And so how do we disseminate those best practices? Call is one example of CMS' leadership and that is wonderful. The American Diabetes Association has a series of webinars on COVID and diabetes that are available free on the website. I encourage you to use them. They're very practical, brief and really informative.

And then the last thing I'll mention is an effort by the American Diabetes Association in partnership with many stakeholders around the country and that's attacking this broader issue of therapeutic inertia. Therapeutic inertia is this concept that an individual may come with blood glucose levels that are out of range, and they come to a visit and they leave without any change in their therapy.

And obviously, this is complex. There are patient factors, organizational factors, provider factors. One of the things that the ADA is taking leadership on this is launching a national program aimed at both individuals with diabetes and those that care for them to raise this issue, but also provide practical tools to be able to reduce this therapeutic inertia and improve outcomes.

And with that, I really want to thank you for the opportunity to address you and look forward to questions. Thank you very much.

Alina Czekai: Thank you so much, Dr. Gabbay. Our next speaker is Dr. Joshua Joseph from the Ohio State University College of Medicine. Dr. Joseph, over to you.

Joshua Joseph: Thank you so much and thank you to CMS for the invitation to discuss COVID-19 and diabetes with everyone today.

I'm Joshua Joseph. My passion is helping people to manage diabetes as an endocrinologist at the Ohio State University Wexner Medical Center. Additionally, I perform research to improve prevention and treatment of diabetes and build healthier communities where individuals with diabetes can thrive without the devastating long-term complications.

The COVID-19 pandemic, as mentioned by Dr. Gabbay, spur dramatic change in all our worlds, where myself and colleagues were able to synergize our roles as physician, as well as scientists in real time to improve the care of those with diabetes.

As many of you saw a paper published out of France showed that 1 out of 10 patients with diabetes die within the first seven days of hospitalization, and data from the U.S. have shown that 4 out of 10 patients hospitalized for COVID-19 have diabetes. Thus, preventing individuals with diabetes from acquiring COVID-19 and innovations in the care and treatment of type 2 diabetes are critical in this time.

I would like to focus on three challenges that we face, solutions to those challenges, and opportunities to continue to innovate during the COVID-19 pandemic and beyond. I will start with inpatient care, kind of advance towards outpatient care, and then end really with caring with communities – for communities which is really a passion of mine.

First was the challenge of caring for COVID positive diabetes patients admitted with severe hyperglycemia or DKA as Dr. Gabbay mentioned earlier, which is when your blood sugar is very high and the acidic substance called ketones really build up in the blood.

The major challenge was that using the standard of care approach of insulin infusions requires the finger sticks every hour, and with our concerns

regarding limiting the exposure to the virus by clinical care staff, this was suboptimal. To overcome this challenge, we moved the insulin infusion pumps outside of the room and connected them to the patients with longer IV lines.

Second, kudos to the FDA for allowing institutions to use CGMs in inpatient setting for monitoring glucose levels. The continuous glucose monitors are small sensors placed on the body that read glucose levels in the cellular fluid just under the skin, and the sensors transmit the readings via Bluetooth to handheld receivers that were at the nursing stations in our ICUs.

We use the system designed originally for personal use in the care of really critically-ill patients. We are starting to get back the quantitative data from that, but there are signs that the program is really working well.

The main opportunity for innovation is improving the interconnectability of the electronic medical record with these continuous glucose monitoring devices, and using CGMs in the hospital has a potential to improve care now, but also really into the future as we think about next steps.

Second, in the outpatient clinic, we face the challenge of seeing diabetes patients virtually on a large scale as Dr. Gabbay mentioned earlier. Over the course of two to three weeks, we here as well went from seeing greater than 95 percent of our patients in-person to seeing greater than 95 percent of them virtually.

One of the opportunities that arose was retrieving data from glucometers and continuous glucose monitors so that we could adequately monitor blood glucose control during the virtual visits with the patients.

Uploading data to us in an effective manner was challenging for many patients. Patients were used to getting the devices downloaded during visits in the clinic, and our diabetes self-management and educational support team really stepped into the fray. They spent many hours with patients using instructional documents downloaded from device websites to upload the data virtually.

The system worked, but was very resource-intensive. We are now reframing our approach, working on building a culture from the beginning which encourages patients to upload data. Additionally, we are evaluating telehealth readiness assessment tools to use in our practice to determine which patients will need increased support. This is an opportunity for CMS regarding billing for diabetes telemedicine support provided by nurses which would continue to improve the care of those with diabetes.

In the virtual space, I'm sure my colleagues are seeing the same thing, we are definitely reaching individuals where they are and patients are appreciating it. Personally, I've seen many patients who were able to visit during a short break from work that did not require them to take half a day off and they were extremely grateful given the current crisis that we're in and the economic realities from that.

So, third, focusing on the community, we partnered with individuals across our organization, including physicians, nurses, government affairs, community and civic engagement along with a cadre of student organizations and community partners to engage with communities directly via a community care campaign.

Central Ohio, like many places all across this great United States, has a high rate of economic inequality. Segments of our population are made vulnerable due to challenging social determinants, structural determinants, displacements, unemployment and rapid changes related to the COVID-19 response, and I refer to those as vulnerable populations.

In Central Ohio, vulnerable populations have disproportionately higher rate of chronic diseases including diabetes. And as you have seen in the news headlines, vulnerable populations have experienced disproportionate, negative impacts during the COVID-19 pandemic.

Many of these social determinants of health also increase risk of the COVID-19 infection, including multigenerational housing, low-wage essential employment, food insecurity, neighborhood and build environments that make it difficult to effectively social distance, lower educational status that make it

harder to discern the importance of public health recommendations, and lower income that make it difficult to purchase supplies needed to prevent infection with SARS-CoV-2.

Thus, we felt it critical to support vulnerable communities through these community care kits including – in those kits, they included non-clinician isolation-grade masks, soaps and hand sanitizers. The effort was paired with an awareness campaign on social media and other forms of media through educational materials promoting physical distancing, face coverings and handwashing or sanitizing.

To do this, we selected and targeted five areas within our community and that was based on a data analysis revealing the five ZIP codes with the worst levels of health, economic opportunity and CDC social vulnerability, and that CDC vulnerability is how you can respond to something like the pandemic.

Notably, the diabetes prevalence in these ZIP codes range from 19 to 23 percent, so almost 1 out of 4 individuals to 1 out of 5 had diabetes. In these communities, we distributed 46,000 masks, 10,000 soaps and 18,000 hand sanitizers over the five-day campaign. During the distribution, many local and national, civic, governmental leaders joined us in the distribution of kits, including our own U.S. Congresswoman Joyce Beatty.

Ohio Governor Michael DeWine announced the following week on May 21st, 2020 a partnership with the Ohio Association of Community Health Centers and the Nationwide Foundation to distribute thousands of community care kits in more than 60 of Ohio's 88 counties. Thus engaging directly with vulnerable populations is another important component of diabetes prevention and treatment on a population level during COVID-19.

I would really just like to thank all my Ohio State colleagues who have worked tirelessly on these efforts during this pandemic including Dr. Brett Darrel Gray, Dr. Semin Nolan, Dr. Nowanda Olayiwola, Dr. Mark Rastetter, Adam Glover, Dr. Matthew Ringel, Janice Adbie, and Dr. Kathleen Dungan

Thank you very much for your time.

Alina Czekai: Thank you so much, Dr. Joseph. Our next speaker is Dr. Mary Korytkowski. She is an endocrinology and metabolism professor of Medicine as well as the director of Quality Improvement in the Division of Endocrinology at the University of Pittsburgh. Dr. Korytkowski, over to you.

Mary Korytkowski: Thank you very much and thank you to CMS for inviting me to serve on this panel today, as well as thank you to all the listeners who are interested in learning about more of what we are doing at our institution.

I am a professor of Medicine in Division of Endocrinology and Metabolism at the University of Pittsburgh where I work with an outstanding group of colleagues who really stepped up when this COVID pandemic first presented itself.

A lot of our work has been on the inpatient side, but a lot of our work is also on the outpatient side, and similar to some of what I've been hearing from other people, we had implemented the option of video visits for our patient population with diabetes and other endocrine disorders well before the pandemic hit, which actually placed us well for when we did switch over to video visits, we were ready.

We really did not miss a beat in terms of being able to keep up with patient visits in the clinic. What we did find is that not all patients were easily able to switch over to video visits, and so even before there was allowance for billing for phone visits, we did conduct phone visits for some of our patients who couldn't reach us through video, that speaks to the point made by Dr. Joseph where there are social determinants of health.

There are also age-related determinants of health and comfort with technology on the part of many patients, and we found that many of our patients with diabetes were relieved when we reached out to them by phone if they had difficulty connecting with us by video.

We've also continued our diabetes education program by video and phone visits. And for forms that required our signature for patients to be able to get their pump supplies, or sensor supplies, or medications, we actually used some

computer-based programs that allowed us to sign these forms remotely so that people did not lose access to their care.

As far as downloading material, those patients who are tech-savvy and are able to download their pump data and their sensor data to be ready for us at the time of the visits. Even before the pandemic hit, we did switch over to this program called Tidepool that allows downloading of multiple – of data from multiple different sensors and pump so the nurses are not having to learn many different programs that are associated with each proprietary pump or meter, and that has really facilitated our ability to obtain data from our patients.

We do send data – the information for how to download these data out to them ahead of the visit so they are able to do so. If they are not able to do so, whether it's by a video visit or a phone visit, we asked them what their blood glucose are at home the old fashion way who don't use – the inability to capture their downloaded data as a reason not to get their glucose needs are, even if the only question we can get from there is whether or not you're having low blood sugars or high blood sugar symptoms.

So that is – another aspect of outpatient management that I wanted raise is that we have received a lot of calls from our patients who are fearful that they are at higher risk for developing COVID. And to my knowledge in the literature, there is no evidence that people with diabetes at any higher risk for getting COVID, but that they are at risk for more severe illness if they do contract the disease.

So we re-emphasized the CDC guidelines for how to protect themselves from contracting the illness and provide them with that reassurance that they are not more likely to get that and that has been reassuring to many of our patients.

I do want to turn now to the inpatient area. At University of Pittsburgh Medical Center which is part of the University of Pittsburgh system, we prepared for an onslaught of patients which I will tell you we had not really seen here in Western Pennsylvania as have been seen in so many other parts of the country.

We do have cases, but we prepared early by looking at previously established guidelines for inpatient glycemic management that were in place at our institution to see if they needed to be revised in light of the COVID pandemic. What we paid attention to with looking at whether anything needed to be revised is that there may be a lot of patients coming into the institution and this was also a time when we wanted to limit the contact for healthcare personnel with patients, acknowledging that inpatient glycemic management is an interaction-heavy disease where your blood sugars need to be monitored and insulin needs to be administered according to mealtime.

And for patients in critical care units on IV insulin infusions, often they have their blood glucose monitored hourly, if not every two hours in order to adjust their insulin. So we did modified things a bit and submitted a guideline to the hospital that allowed transition to basal-bolus insulin regimen with similar glycemic goals for what we have with the IV insulin infusions, but might be associated with less patient contact.

What we have found is that we really have not yet to use this so much because we have not been overwhelmed with patients, and that patients who do need IV insulin infusion have been getting them. In those situations in the critical care areas, the nurses – one nurse is assigned to the patient and rather than a nurse coming in and out of the room multiple times, there is another nurse who is assigned to work with the nurse in the room to bring them any supplies that they may need.

Another area that we've visited was the issue of patients admitted with diabetic ketoacidosis or who might develop this diabetic ketoacidosis when they were in the hospital. Usually our protocol for managing DKA is we use IV insulin infusion, but we have used the protocol that has subcutaneous insulin administration administered every two hours, with similar rates of fluid resuscitation as well as monitoring the fluid and electrolytes, again as a way of decreasing the contact between nurses and patients.

But, overall, we found, looking backwards now, that we really have not yet to change things as much as we thought we would have to. We have management protocols for inpatient glycemic management both in the main

hospital for the UPMC system as well as at all outside hospitals. And there was some thought that introducing too many changes may add a lot of stress in an already stressful environment as people were working to take care of the patients in this new pandemic.

Another question that came up very early, particularly following the allowance on the part of the FDA to use continuous glucose monitoring devices in the hospital with remote monitoring of patients, allowing data to be transmitted to the nursing stations, we did visit whether or not we wanted to do this in our hospital setting.

We had some enthusiasm for doing this and met with our critical care medicine colleagues to see if this would be something of interest there. The decision at least for now was not to pursue that. It was felt that it would be too stressful to nurses to learn a home new technology at our institution. There are publications about using continuous glucose monitoring in the hospitals in non-critical care as well as some critical care units, but we have not been doing that and we've been using just regular bedside glucose monitoring.

However, if a patient comes into the hospital with their own continuous glucose monitoring device, we do have a protocol in place that allows patients to use it through the course of their hospitalization provided that they provide the information they're getting from their CGM device to nursing, and provided that they are awake and alert enough to use it, and provided that they're not being exposed to radiation or medication that could damage the machine or interfere with the readings from these devices such as uses of high-dose Tylenol, high doses of vitamins, or high doses of vitamin C.

So a few notes here, in the guidelines that we put out early in the pandemic, we had criteria for when to seek consultation with the endocrine and diabetes services if they were not able to achieve control with the guidelines that were presented for basal-bolus or IV insulin management. We did this in a way to limit the number of consultations or limit the number of people coming in contact with these patients.

However, many of our inpatient consults have also become virtual inpatient consultations. We are now talking about changing that back to rounding in the hospital, but at the present time, we are still doing predominantly virtual consultations with patients.

So two other areas I want to address is the issue with diabetes self-management in the hospital. This question has been raised in the ADA guideline for hospitalized patients with diabetes. Most of the publications in this area come from patients who were admitted to the hospital with insulin pumps, which we do have a protocol in place for patients who were admitted with insulin pumps.

But the very first condition of this protocol is that patients be cognitively intact and physically able to manage their pumps while in the hospital and that it is not exposed to conditions that could possibly damage the equipment, but so as for some but not all patients similar to what we see with the continuous glucose monitoring.

Another issue for us even addressing these guidelines was with attention to nursing personnel who are providing the most direct patient care to these patients in the hospital and we feel need to be protected. So that is the reason for the – that is the reason for why many of the protocols were meant to decrease the amount of time nurses have to spend particularly in many places where adequate protective equipment may not be widely available.

Another issue is the use of some medications. Some of you may be familiar with the study that's being done called REMAP where a variety of interventions, pharmacologic interventions are being studied in these patients, two of which have an impact on glycemic management; one that was addressed by Dr. Gabbay which is the use of high doses of hydrocortisone in these patients, which is one of the protocols that's being used in this REMAP program. But it's also part of the critical care of these patients in many institutions and can have a major impact on glycemic control.

Another is the now infamous drug hydroxychloroquine which has been proposed as one of the agents for treating these patients. Two mixed reviews

in the literature, there is not wide awareness of the fact that this drug actually improves insulin sensitivity and may even have an impact on beta cell function, and has been associated with reductions in glucose. And so some patients with diabetes who are receiving this agent may actually require less insulin on this drug and others.

So why did we do all these? Well, we know that glycemic control helps reduce the risk of hospital complications, reduces hospital length of stay and plays a major role in long-term outcomes in our patients. We don't have literature specific to COVID patients that's paying attention to good glycemic control in the hospital impacts outcomes.

But there have been several observational studies to date that have shown that patients who were admitted to the hospitals who have higher blood sugar at the time of admission have poor outcome. This really speaks to the need to help our patients achieve optimal levels of glycemic control in the outpatient setting as well as in the inpatient setting.

And finally, I would just like to call your attention to a paper that it published online today in the Journal of Clinical Endocrinology and Metabolism that summarizes a lot of what I had covered as well as what others have covered and are likely to cover in additional presentations that will occur this morning.

So I thank you for your attention and I appreciate the opportunity to speak to you.

Alina Czekai: Thank you so much, Dr. Korytkowski. I really appreciate you for touching protection on both outpatient and inpatient care for patients with diabetes during COVID-19.

Our final speaker in this segment is Dr. Marie McDonnell. She is the director of the Brigham Diabetes Program at Brigham and Women's Hospital. Dr. McDonnell, over to you.

Marie McDonnell: Thank you, Alina, and I really do want to thank my colleagues on this call and also my colleagues here at home in Boston for their work and participation in their communities as Dr. Joseph highlighted so beautifully. And also national

and international forums I know my colleagues have been part of to develop and spread these best practices because I think we are now learning we will need them going forward.

I also want to recognize our patients with diabetes, and hopefully we'll get to Q&A and be able to hear from not only our clinicians but some patients perhaps who already know – we already know as endocrinologists these patients have to be so resilient to survive and thrive in their condition. And I have found my patients to be inspiring me to go forward because it's been so challenging, so we need to recognize the strength of this patient population.

So I thought it would be helpful in the short time to highlight a unique set of issues that COVID brought to our diabetes patient population. We were and we continue to be a hotspot here in Boston, Massachusetts, and recently our hospital system had approximately 3,000 patients total in the hospital over the course of the pandemic and we know about 30 percent of them actually had hyperglycemia or diabetes so this has been an enormous burden on our team. And as Dr. Korytkowski identified, our teams have been incredibly flexible in using – applying their brilliance and talent to this crisis.

So our initial concern was actually the patients who would be inadvertently or actually on their own accord of disconnected from usual care. We were immediately alerted to the fact that patients were calling to cancel appointments and we understood that with the confusion around telemedicine, there would be no shows. And we didn't have a method to track patients who were disconnected from us, and in fact, I've learned that most practices don't.

So we developed immediately a patient tracker which is a simple online or shared – shareable database that was developed by one of our team members and then utilized by our clinical nursing team to identify patients who were canceled or they did not show. And the idea behind this – and they would go out and connect with these patients by phone or by video.

And the concept here was to make sure that we weren't missing patients who would subsequently require more urgent care due to lack of what we think is so incredibly important which is that routine care some of our patients coming

in regularly every three months. So in those calls, they determine medication requirements, other missed appointments for which there are concerned symptoms that they're not seeking care for.

So, overall, we actually identified 420 patients who they just didn't keep their appointments, they didn't know how to do it, or they weren't sure what was happening; and about 900 patients canceled either proactively or as we transition to telemedicine, there were some hiccups. So we've contacted these patients and we have identified those who need help, and this has resulted in numerous episodes of educating patients with virtual education including videos and also online education in their language which has become a challenge as well.

The other piece I need to lay is our care of patients who were seen in the emergency room. We have a program here at Brigham and Women's Hospital that was started at Boston University that is designed to connect patients with diabetes in the emergency room to diabetes management and care should they not require hospitalization.

And of course, during COVID, the utilization of beds was critical because at one point as we mentioned – as was mentioned, about half of the ICU beds were COVID and/or of the ICU beds with COVID, half of them had diabetes and many patients were in ICU for a long time so access to beds for appropriate patients is critical.

So we have the rapid follow-up program from the ED where in this case we have to convert it to a virtual follow-up program whereby a nurse would be contacted to set up a virtual visit that would include whatever the patient needed. But this could include often insulin teaching by video which we've all now developed unique skills around.

And now we're working to identify methods to assess that educational tool because there are no standards around telemedicine-delivered education and that is something I'd hope to partner with my colleagues on.

Another aspect I'd like to highlight is what was happening in the hospital. As many – as we've heard that the hospital was certainly burdened, but in terms

of patients with diabetes, we have to come up with unique strategies because the management of COVID -related hypoglycemia is unique.

We noticed early on that insulin requirement were up to four to five times than we would normally expect in an intensive care unit patient; and hence we did develop quickly with our colleagues in ICU and our diabetes team that subcutaneous insulin protocol that was used quite frequently to assist with glycemic control as an alternative to intravenous insulin, which as you've heard requires very close monitoring by the nurse at the bedside.

And it turns out it was utilized not only by us, but we actually published it on an open access COVID protocol website and it was used by other institutions certainly not to replace usual protocol, but rather as an option for management of patients in the ICU when intravenous insulin therapy was not practical, or possibly the opportunity was there to use subcutaneous instead.

Lastly, I just want to mention that outside of specialty care, there is a large world of patients who were disconnected from their diabetes care and have disconnected from even primary care. And we are seeing more and more patients entering their primary care practices either through telemedicine or in person with very poorly controlled diabetes. This is in the setting of weight gain and other I think behaviors that have been promoted through COVID, and in addition, stress and fear around their individual communities and the impact on especially our communities of color.

So we do know that we have to expand our telemedicine practice to include our primary care colleagues in managing the most complex cases, starting insulin remotely, et cetera, and I think we're inspired now by this challenge to work more closely with them. So I really do like the idea of a formal assessment of telemedicine readiness for our patients and I think that we would join Dr. Joseph in that mission as well.

So again thank you so much for including me in this and I will hand it back over to you, Alina.

Alina Czekai: Thank you so much, Dr. McDonnell, and thank you for reminding all of us about the resiliency of that patient population and really all patients facing chronic disease during the COVID-19 public health emergency.

So before we open it up to questions from the audience, I'd like to invite my CMS colleagues to ask any questions to our speakers today, or share any comments or thoughts that you might have as you've listened to our terrific presentations today. So any questions or comments from my colleagues?

Barry Marx: Hi, this is Barry Marx. First, I'd like to thank all of our speakers today for their time, and their experiences and expertise on this call.

It's a question really for any or all of the speakers. Obviously, telemedicine has been of enormous importance in the circumstances of the COVID-19 public health emergency. As we look ahead and as communities across the nation are starting to open up, are there lessons learned from the experience with providing virtual care for patients with diabetes mellitus that are informing decisions about when and how to return to face-to-face care as opposed to what the role should be going forward of virtual care? And thank you.

Robert Gabbay: This is Bob Gabbay. I can share a couple of observations and it's a great question. Now, I would throw out three things.

One, I think it's more challenging to do telemedicine with new patients and that's where we've struggled the most. The feedback from patients have been that because they already have a relationship with us, it's easy to do this remotely, and so think that's a challenge to sort out.

I also think the other observation is that continuous glucose monitoring which has really been game changer in the management of diabetes. We found that we can initiate that remotely and there are some digital health companies that are doing work in that arena as well. And so whereas we would have thought that had to be – learning a skill had to be on site, it doesn't seem necessarily be the case.

And the third piece that I would mention that we have struggled with is laboratory data. Our specialty in management of diabetes is so dependent on getting that kind of information and seamlessly getting that in a way that can populate into an electronic health record, allow tracking and reporting in population health still is a challenge.

Mary Korytkowski: This is Mary Korytkowski. I would like to add that what these video visits or this telemedicine has helped us understand is that we can actually use it to our advantage.

One of the very treacherous areas for many people with diabetes is when they transition from the inpatient to the outpatient area. There is often confusion if their diabetes medications are the same. If they are discharged home on steroids, they may not be advised to taper their insulin or other diabetes medications downward as they taper the dose of steroids, or they may not understand completely how to follow what are often complex instructions for insulin management at home.

So we are actually using what we've learned from how effective telemedicine can be to apply this to our discharged population. We've had a discharge clinic in place for a while, but there is a very high no-show rate likely because these people are still ill and it's hard for them to make yet another visit for what may not have been their primary reason for hospitalization.

So we are now converting these post-discharge visits to video telemedicine visits which we hope is going to help in the long run reduce risk of hospital readmission as we might be able to identify problems early. This is something we're just starting.

Marie McDonnell: If I might add, this is Marie from Boston. I just wanted to say that I think the future of virtual care in diabetes is bright in the sense that we are now realizing that it is useful in the scenario Mary brought up.

But also I think it belongs mostly in interim care, I think the new patient assessment we do have some concerns about missing some details not just in the physical exam, the most important of which are probably the cardiac and the foot exam, or the peripheral vascular exam. But also in technique and

perhaps specifically insulin technique, for example, we've had so many cases of patients not learning proper technique and it's hard to assess that virtually entirely well.

And on that note, I think that our challenge – one of the challenges I see for virtual education inpatient training is that we do need good tools to say – to assess our quality in the sense that if we do teach patients virtually, how can we ensure that they learned what they needed to learn and they can apply that knowledge in the same way as we have already been able to assess in the outpatient setting. There's a lot of literature in-person – from in-person education including group education.

I think we need to open up a new area of investigation around how best to perform virtual education and care.

Alina Czekai: Thank you so much. Any other questions or comments from my CMS colleagues before we open up the lines? Great. Operator, let's take some questions from our phone attendees. Thank you.

Operator: Thank you. As a reminder, to ask a question over the phone, please press star then number 1 on your telephone keypad. Again, that is star 1 on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

If anyone wants to ask a question, please press star 1 on your telephone keypad. Speakers, I'm seeing no questions in the queue, please continue.

Alina Czekai: Great, thank you, operator, and thank you to our terrific speakers today sharing best practices on diabetes care. I really appreciate you all taking time out of your schedules to share best practices, what you're seeing in your communities with other providers around the country.

Our next topic today is prenatal care during COVID-19. As a nation, we are still learning about the virus particularly related to its effect on pregnant women and infants. And today we'll examine this topic through a use case on caring for TennCare Medicaid patients and this initiative attacked tremendous results in Tennessee and today we're pleased to offer a forum to learn about this initiative.

Today we are joined by Dr. Connie Graves from the Tennessee Maternal Fetal Medicine Clinic and she was one of the leaders in Tennessee championing this initiative in her state. So Dr. Graves, I'm pleased to turn it over to you.

Connie Graves: Good afternoon. Can everyone hear me?

Alina Czekai: Yes, we can, Dr. Graves. Thank you.

Connie Graves: Thank you very much for this opportunity to kind of talk about some of the things that we did in our state regarding prenatal care and COVID-19.

I think one of the big – one of the big help in our state was our TennCare in particular was very instrumental and thoughtful about how we can meet the needs of our patient population during this time. However, I will tell you that there were a number of challenges for us because one of the things we did not know about COVID-19 was whether or not it would have the same effect on pregnancy as H1N1 had which was particularly devastating to pregnant women especially from a pulmonary standpoint.

So I kind of just wanted to go through some things that we did with prenatal care to make sure that our patient needs were met. Now, we are a high risk practice, so many of our patients really do need to have care during their pregnancy.

ACOG put out some statements about spacing prenatal care, but many of our patients have complications such as diabetes, heart disease and hypertension which cannot be overlooked during this time; and because they have these complications, not only does it affect them from a pregnancy standpoint, it affects their fetus as well.

So one of the first things that we did is actually we started by aggressively looking for a – we have had some experience in our office with telehealth through the misfortune of one of my partners being out for a year, and then just to kind of tell a story when she was out on setting, my nurse practitioner who was going to the office broke her ankle. So we were able – and we had a

schedule full of patients and so we were able then to already look at telehealth and some telehealth platform.

But one of the things that we really wanted to make sure in our telehealth platform is that our patients – it would be easy for our patients to access because we are in Tennessee and we realized that we have some limitations. One of our limitations often is our patient's access especially in rural areas even to Internet. And then if they can access the Internet, how they can access this through the Internet. And so we wanted to make sure that our telehealth platform was very easily accessed without the patient needing a computer.

And so once we instituted that, we then converted many of our patients to telehealth. Some of the safety things and some of the safety initiatives that we did from the beginning is that after we consulted with the CDC for which I have been a member in the past is we barred all partners from coming to visits.

Often in the prenatal realm, people bring their mothers, their kids, their husbands, especially to our office that performs a lot of ultrasound, but we banned them from our office, so only the patient could come into the office. Not only could only the patient come to the office, but she had to call our front desk and then be allowed to be admitted to the office. And upon entering the office, the patient was given a mask and her temperature was taken, and she was asked appropriate questions regarding COVID-19 just as if she were in a hospital setting before entering the office.

All of our staffs were then asked to wear masks in order to protect the patient and as I reported before, all of our patients were also asked to wear masks in order to protect us. Once the protocol for patients being seen in the office was established, we then established protocols for patients being seen by telehealth.

And we have a fantastic nurse practitioner who is the millennial who I call her the telehealth – she's the telehealth worker, and so she actually volunteered to pilot telehealth at home and was able to really see patients on this platform.

One of the things that – the way we decided who needed to come to the office versus those who did not need to come to the office is we've really looked at what their history was. And if they had a history of diabetes and we were just seeing them for diabetes care and we weren't seeing them for anything else that day like an ultrasound for fetal growth or antenatal testing, those patients were offered telehealth visits.

We created a file and e-mail for the patient to e-mail her blood sugars to our office prior to the visit and then we would download that into the patient's medical records so we could review them with the patient when she came for her visit. This allowed us to then see patients who really needed to have continued management of her glucose.

I know many of my colleagues are on the line from the diabetes, they're like, “Man, you're seeing them every two weeks for pregnancy.” Diabetes and pregnancy really needs to be tightly managed and is associated with fetal stillbirth when it's not well taken care of.

In addition to that, we then started seeing preconception counseling over the telehealth being used as well which was very helpful for a lot of our patients who were thinking of getting pregnant and also for patients who we knew because it was COVID-19 and they were on quarantine would end up getting pregnant prior to them being able to get back into the office.

One of the most helpful things was that, however, the TennCare approached us regarding providing blood pressure cuffs to our patients in the postpartum period and maybe even during their antenatal care. If you're aware of the data, hypertensive disease in pregnancy is particularly a problem and managing these patients is particularly a problem.

There have been studies that showed that remote blood pressure monitoring is very helpful in this particular patient population and increases their compliance especially in the postpartum period when many patients get readmitted for preeclampsia and much of the maternal morbidity and mortality occur from stroke and cardiovascular disease.

So we were exploring the opportunities for us to be able to provide this blood pressure cuffs so that when we tell people to come back in a week or five days to check their blood pressure, then they can do that over the phone and we can be – and we're able then to do telehealth visits over the phone. I will tell you that this has been a success and we're really actually looking forward to continuing this program.

I have said to my colleagues in a number of times if you have a baby and you were at home, and people were there and you were trying to get adjusted to taking care of the baby, and going out, trying to get to – and getting the baby to their pediatrician appointment, going out to your doctor, your OB doctor for a follow-up blood pressure check would be a low-take level down on your list. But when we have this ability for patients to monitor their blood pressures at home, it has been particularly successful.

I'm going to share a story of a patient who I saw at one of the hospitals who was one of the members. She actually left the hospital. She had severe postpartum hypertension and preeclampsia. She left the hospital on six blood pressure medications. We have been monitoring – we have been seeing her weekly because most of these women will not need to – continue to need six blood pressure medications.

But I have been monitoring her weekly through telehealth. She has not had to come to the office and she's been able to breastfeed her baby and have her baby on her chest during the visits in the comfort of her home, and we have been able to manage her blood pressure and wean her medications appropriately without her ever having to come down to the hospital for a visit. And so those are some of the things that we have been able to do during this COVID time.

Another thing that we enacted in our office was when a patient is exposed, we have – our call doesn't tell us that she has a positive COVID test. We have a way in our office of tracking our contacts. It goes to the HR person, the HR person then sends it to me as the medical director, and then everybody who was exposed in the office from the medical assistant to the sonographers which spend a large amount of time with patients are actually informed.

And if we feel like a COVID testing is appropriate so that our staff does not end up being exposed, then that has been a value to us as well in this time. We have had patients just like everyone else, Tennessee has not been as hot of a bet as they thought we're going to be, but we've had a number of patients.

And one of our patients actually who was diabetic, hypertensive and overweight actually ended up on the ventilator, and I'm happy to say that with convalescent plasma and remdesivir, she is still pregnant at 20 – excuse me, about 25 weeks gestation. But she had been in our office prior to that and we were able to trace those contacts. But more importantly, we were also able to continue her continuity of care in the hospital.

I think our challenges in providing remote prenatal care and remote care for patients is again many of the challenges that have been mentioned before, mostly the language barrier. Many of our patients speak Spanish. Our particular telehealth system has where you can join the call so you can actually put the interpreter on the line with you and the patient which has been helpful.

Some of us, including myself, speak enough Spanish to get to especially a diabetic pregnant or hypertensive visit with the patient. But it has been those things I think that have made us successful in being able to provide care for our patient population while minimizing their contact with us, our contact with them, but not sacrificing optimal patient care for these really high risk women who should not be abandoned and cannot be abandoned during this time.

Alina Czekai: Thank you so much, Dr. Graves. I really appreciate your perspective. Do any of our CMS physicians or clinicians have any questions or comments on Dr. Grave's presentation?

Michelle Schreiber: Alina, hi, it's Michelle Schreiber. First of all, Dr. Graves, thank you so much for the wonderful work that you're doing. I have a question about testing, do you have a protocol for – or a recommendation around testing pregnant patients or certainly when they get closer to being ready to deliver

testing patient, and does that then have implications for things like postpartum care, breastfeeding or something like that? Thanks.

Connie Graves: Yes, Michelle, you must have been in my meeting yesterday. So we actually have started testing all elective procedures; that is vaginal delivery and cesarean section. We have started testing them for COVID and should the patient be positive, then unfortunately her support person cannot attend, especially her partner, or her partner cannot attend to her delivery.

In addition to that, we just had some discussion yesterday about how to maintain breastfeeding as the CDC has recommended and maintain patient separation and adequately staff women who need to be isolate. And so we decided that what we would do is we would try – because these patients won't have a support person, we will try to – we're going to place the isolette in the room with the patient, have one-on-one nursing when possible, and allow the patient to breastfeed with a mask and then place the baby – the staff will place the baby back into the isolette.

But this is – this is really challenging because not all hospitals in our city and anything that – anybody knows anything about Nashville where they're kind of the healthcare capital. So they're three large systems in the city and we're the only one testing at this time. But we hope to get some good data.

Our surgical – elective surgery started testing and they said it was only like 0.1 percent of their patients. But in Nashville, our Hispanic population has been hit quite hard. And in fact, there were two or three patients with COVID on our antepartum negative pressure area yesterday. So we're hoping to get some better data about how it's affecting different populations in the city.

Michelle Schreiber: Thanks so much.

Alina Czekai: Thanks, Dr. Schreiber for your question. Any other questions from my CMS colleagues?

Ellen-Marie Whelan: Yes, this is Ellen-Marie Whelan from CMS Medicaid. I also want to echo our thanks for, first of all, the fabulous work you're doing and they are being

so creative caring for your patients and for taking the time today to share your stories with us.

I'm wondering if you are aware of any specific flexibility that Tennessee Medicaid allowed that helps support the work that you were doing. We got some I think state folks on the line and they might like to hear how the Medicaid ...

Connie Graves: Yes, Tennessee Medicaid was great actually. They were very – they were very much involved and actively involved in making sure there will be a reimbursement for remote – for our remote ability – for our telehealth visits and for some of our – on occasions for even some home visits. So that was really very helpful to us.

And again like I said, they were also very vocal and very helpful in supporting this call for blood pressure cuffs for our patients and wanting to make sure that their members were well taken care of. So I want to go on record and just thanking them for being creative as well and actually thinking about how to best care for this patient population.

Ellen-Marie Whelan: Thank you. That's really helpful. Thanks.

Alina Czekai: Thanks, Dr. Whelan.

Connie Graves: So I will say this, for the provider, if you're not – if we're not going to be reimbursed and not going to be reimbursed at least at the same level, and I think that they actually reimbursed us a little bit better. I think a lot of providers are hesitant – we're hesitant to move into this realm. But I actually – I had several providers calling me on the phone asking us how we were getting this done. So I think our ability as a high risk office to get this done actually trickles down to many of our generalists as well.

Alina Czekai: Terrific, thank you. Operator, let's take some questions from the phone. Thank you.

Operator: Thank you. As a reminder, to ask a question over the telephone, please press star then the number 1 on your telephone keypad. Again, to ask a question, please press star 1 on your telephone keypad.

Speakers, I'm seeing no questions from the phone lines, please continue.

Alina Czekai: Great, thank you, operator, and thank you again, Dr. Graves, for sharing your best practices and all that you're doing for expecting mothers and their infants in Tennessee.

And thank you everyone for joining our call today. Please do continue to direct your questions or comments related to COVID-19 to our CMS e-mail box, which is covid-19@cms.hhs.gov.

As always, we appreciate all that you are doing for patients and their families around the country as we address COVID-19 as a nation. Have a safe and healthy weekend.

Operator: Ladies and gentlemen, this concludes the conference. You may now disconnect.

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