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Continuous Glucose and Ketone Monitoring: Making Smarter Decisions in Diabetes

Announcer:
Welcome to CME on ReachMD. This activity, titled "Continuous Glucose and Ketone Monitoring: Making Smarter Decisions in Diabetes," is provided by Primary Care Education Consortium. Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements, as well as the learning objectives.

Dr. Brunton:
Welcome to Making Smarter Decisions in Diabetes Management. I'm Stephen Brunton. I'm a family physician in rural South Carolina, and this is going to be a very important program because we've seen a tremendous change happening with regards to the technology we have for managing diabetes, and that's what we're going to talk about today.

Here are our panelists: Dr. Jim Gavin, Davida Kruger, and Eden Miller.

We have specific learning objectives for this program. After watching this webinar, you should be able to apply accurate strategies for interpreting CGM data to inform diabetes treatment decisions and support integration of CGM into clinical practice; identify patients at risk for developing diabetic ketoacidosis; incorporate recommended methods for identifying and treating patients with diabetes who develop DKA; and lastly, integrate the most recent evidence on CGM and ketone monitoring, and that includes continuous ketone monitoring to optimize care of patients with diabetes.

Well, let's start with a review of CGM with Dr. Jim Gavin.

Dr. Gavin:
I'm Dr. James Gavin, and I'm Chief Medical Officer at Healing Our Village, and I'm also Clinical Professor of Medicine at Emory University, and I serve as the Senior Consultant for Chronic Diseases for the statewide initiative of Closing the Gap in the state of Florida, and I'm very pleased to be with you today to talk about continuous glucose monitoring.

So, what is CGM, or continuous glucose monitoring? This is a technology that allows us to continuously check glucose levels. It measures glucose in the fluid—in the interstitial fluid, which is the fluid between the cells. It's not a measurement of glucose in the blood. Actually, there's a passive diffusion of glucose from the bloodstream, and there's a lag period between when glucose gets from the blood into the interstitial fluid, and the CGM readings actually lag behind blood sugar by about 10 minutes because of that diffusion process, but it greatly reduces the need for finger sticks. And the information from the transmitters that we use in CGM can be connected to mobile apps; it can be sent to your cell phone readers, insulin pumps, and connected insulin pens.

Now, one might ask the question: If these CGM units can actually give you glucose measurements minute to minute, so that you actually have a sense of where you are in your diabetes journey, why don't more patients have them? Well, about 90% of diabetes care occurs in the primary care setting. The ADA and other organizations recommend the use of CGM for many patients with diabetes. Anybody that's on insulin, anybody on glucose-lowering drugs, people who have problematic hypoglycemia, pregnancy, there are a variety of settings where CGM is recommended.

And there are many benefits associated with the use of CGM, including improved health behaviors, reduction in A1c, less

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hypoglycemia, better body weight control, reduced caloric intake, increased physical activity, and better overall treatment satisfaction, and in fact, more adherence to a personal eating plan. So there are enormous numbers of benefits, and one wonders then why don't more patients have them?

Well, for clinicians, the benefits are also numerous. We are able to give more informed treatment decisions because we see where patients are in their journey on a day-to-day, moment-to-moment basis, and we can actually see what the effects might be of events that occur in a particular patient's day. There's more engagement opportunity with the patient, greater insight into the effect of therapeutic changes. There's so much more information from CGM than the A1c can provide.

And this little inset here basically highlights the fact that the adoption gap for CGM is far worse than you might think. We see that you can cut healthcare costs by about 20% using this technology, and yet we have so few people using this technology. This is something that we desperately need to close. This is a gap that we need to close.

Now, diabetes is continuous. I describe it as a journey, and CGM is very much like a GPS for that journey. The majority of diabetes care happens between clinician visits outside of the clinical encounters. The clinical encounter may be like a filling station stop, but that's not how diabetes needs to be managed; it needs to be managed all along that journey. A1c is insufficient to reflect exactly how the journey is going. Using A1c may not be very helpful to patients for understanding exactly how their diabetes is behaving under the circumstances of their daily lives. And of course, using finger sticks with blood glucose monitoring has notable limitations because it only measures blood glucose at a single point in time, and we realize how insufficient that can be.

Prior to the development of CGM, we found out a great deal of information about just how suboptimal the use of A1c can be with respect to determining long-term outcomes, and we also found out some other things like what the effects are of things like therapeutic inertia. It turns out that when we look at data that comes from a number of studies that if glucose control as reflected by A1c was insufficient, for example, only about 50% of people were achieving an A1c of less than 7%, which was the goal A1c to prevent complications. The presence of therapeutic inertia, the reluctance of people to advance therapy in a timely and sufficiently intense fashion, actually resulted in a change in status about three years later, where that initial suboptimal glucose control as reflected by poor A1Cs, meant that 3 years later there was suboptimal glucose control. Three years later, it retained that poor control. Okay. That caused not only the appearance of complications, but the consequent economic burden that comes from poor control over a sustained period of time.

What that means is managing glucose levels early reduces the chances of developing complication, so early control is essential. People with type 2 diabetes that achieve better glucose targets soon after diagnosis, at critical period of early in the disease, they're more likely to keep those targets in range. And the converse is also true, unfortunately—people who don't get good glycemic control early on, later on because of inertia, their targets are still not reached, and they have continued or sustained poor control.

This slide shows the inadequacy of blood glucose monitoring compared to CGM. The green dots on this glycemic pattern here represents when finger sticks were done. If a person only had to depend on their finger sticks, they'd say that they were in good control all day long. But look at what they missed. They missed the peaks and they missed those periods of low blood sugar. So blood glucose monitoring is inadequate.

And this is further reflected by what happens if you take three different patterns of blood glucose by glucose profiles, but all of these people had an A1c of 7%, the average was the same, 154. You can get to 154 or 7% in the first panel by being completely in range. Or in that middle panel, look at the peaks and valleys. And in the third panel, the variability is even greater. So you miss that variability when you don't know what your actual time in range is, and this is why A1c does not give you what you need as opposed to CGM. CGM is a game changer.

Ms. Davida Kruger:
Thank you, Jim. That was amazing. You know, when I think of what you presented, the thing that catches my eye, and I think I hope our audience will resonate with them is that that huge gap in the haves and the have-nots, and that moving forward, giving CGM makes such a huge difference for both the clinician and for people with diabetes. And hopefully, as I present in the rest of the presentations, the clinicians will want to be using CGM and prescribe it more often. Thank you so much.

So, I'm Davida Kruger. I'm a Certified Nurse Practitioner. I am at Henry Ford Health Systems in Detroit, Michigan, in the Division of Endocrinology. I focus on technology, technology, and more technology, and I do clinical research and clinical practice, and I'm here to talk to you today about CGM as a game changer. Again, the theme that we want you to go home with in terms of please prescribe this and use it in clinical practice.

So, I'm going to review the ambulatory glucose profile. Jim did refer to that, and we'll go through a little more detail. Okay, so let's start a little bit with ADA standards of care. Understand that this is a moving target; it changes annually as updates come, and that's a good

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thing because- and technology in diabetes is a moving target. And diabetes devices should be offered to people with diabetes. I think that's kind of like the end of the story. Please offer these devices to our people with type 1 and type 2 diabetes. And then real-time CGM or IS, which is intermittent scanning, which you're not going to see very much anymore, should be offered for diabetes management in adults with diabetes on basal insulin, MDI, or CSII or sulfonylureas. And Jim had referred to that as well. Sulfonylureas cause hypoglycemia. We need to protect our patients from hypoglycemia.

And then use of CGM is beneficial and recommended for individuals at high risk for hypoglycemia. When CGM first came to the market, it was all about hypoglycemia. That is not the only reason we use CGM in 2026. We use it for a great many things, and moving forward through this presentation, you're going to hear more.

And then initiation of CGM, CSII, which is an insulin pump that's not integrated, or AID, which is a pump that is integrated, or provide it to your patients early, even at diagnosis. I'm going to say that again: early, early, early. Jim showed why, and then even at diagnosis, in the treatment of diabetes, would be beneficial to our patients with diabetes. And then initiation of CGM should be offered to people with type 1 early in the disease, even at the time of diagnosis. And you will hear me say all the time, CGM is a right, not a privilege, and we need to really offer it to people with diabetes.

So, here is the AGP report. It is a one-page report. Now, when you download the data, go in and look at the data, there's about 14 pages. You don't have to get lost in 14 pages. I'm going to review one page and a smidgey more of a little bit of data, but this one page gives you the answers that you need to improve outcomes for people with diabetes.

So, let's start in the upper right-hand corner—I'm sorry, the upper left-hand corner. I don't always know my right and my left, but it's the upper left-hand corner. And what you want to look at is the number of days the sensor is active. It's recommended minimum of 14 consecutive days. Have I used less? Yes, I take what I can get. However, for the big picture, making decisions, 14 consecutive days is best. Then you can see a percentage of sensor data captured, and we want at least 70% that we can see at least 70% of that data over the 14 consecutive days.

Then here's the thing that's newer to our thought process: the glucose management indicator. People confuse it with A1c because we now actually use it instead of in a lot of situations. But it's the assessment of glycemic control for the time covered, often used as an A1c comparison, although they may not match. So, don't get lost in they didn't match. So, what the GMI looks at is the period of time that you're looking at the AGP. So, we're looking at 14 days. The GMI is a GMI for that 14 days. Then glucose variability. Jim talked about that with the A1c, that roller coaster kind of effect. We want to get rid of that roller coaster effect, and so the lower the glucose variability, the flatter the blood sugars, the more comfortable life is for a person with diabetes, and we want it equal to or less than 36.

Then on the right-hand side, we're looking at target above range, and that is the blood sugar is greater than 180. The blood sugar is greater than 250. As an aggregate, we want that less than 25%. Then we're looking at time in range. We want that 70 to 180, at least 70%. More is better. And then time below, less is better. And you're looking at less than 70 and less than 54, and we really want that to be less than 5% of the total aggregate of the data. And again, less hypoglycemia keeps our patients safer.

And then what you're looking at in the next panel down is a summary of the glucose values over the entire reported period. So, it takes 14 days' worth of data, makes it look like 24 hours. So, you can now focus on where changes need to occur. So, when you're looking at that, the green bar is your 70 to 180. Above that would be the higher numbers. Below that is obviously your hypoglycemia. In a perfect world, that blue line would be as flat as possible, and that's your glucose variability. This page is going to get you where you need to go.

But let's look at this particular patient. Look at that time in range. It's 81%. The GMI is 6.8%, and we've got 14 days of data, 89%. We see this and we say, "Whoop, our job's done. Look at the hypoglycemia. There's 1% of hypoglycemia." Now, I know I said we're looking for less than 5%, but I'd like to look for 0 to protect that patient. So, I'm going to look at that data. I'm looking at what's happening to that patient. A couple of hours after breakfast, they're having hypoglycemia. They're on long-acting glargine. I'm going to lower the glargine, try to get rid of that 1%. The time in target will probably go up a smidgey, and that's great too. And then I'll protect that patient from hypoglycemia. I can get all of that by just looking at this page. I can look at the target. I can look at where the low blood sugars are, and I can make a difference in that person's medications that will help prevent them from hypoglycemia.

And then there is a third section below the AGP report, and that's the glucose daily report. What's wonderful about that is that I can look at each individual of those 14 consecutive days, and I can see is there a pattern? I can say, look, look, look! You're always low Saturday morning. What happens Friday night? Or you're always high Thursday. Is that your pizza night? And it helps the person with diabetes make behavioral changes. This data is not just for me; it's more important for them because they can look at it 365 days a year, and if they see patterns that need to be changes, they can make lifestyle changes.

We have plenty of research that shows that just giving a sensor to a person with diabetes, no medication changes, improves their A1c.

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Why? Because they make behavioral changes. So, that's your AGP, your whole one-page report that you can live with and make changes. You honestly don't need more to improve the outcome for people with diabetes.

But I'm going to show you a little bit more. If there's patterns on a particular day, I can actually go in and look at where the low blood sugars are and what the numbers were, and I can say, look, on this particular person, it seems to be happening after breakfast, so I am going to make a change for that individual.

Okay, so for my money again, a patient should all be wearing CGM. I don't know how I practice without it. Plus, it's more important that they go home and have it. Minimum of 14 to 15 days for me to make decisions. And if their insurance is not covering it, we often offer professional samples so that periodically we get to look at their data, and then they can make a decision if their insurance isn't covering it whether they can put it in their lives anyway with a cash price.

Okay, so when I think of AGP, I think of a three-step process: determining if action is needed based on the aggregated metrics such as time in range. Are they having any low blood sugar? My eyes always go to hypoglycemia first. Fix the hypoglycemia first, and then identify where action is needed by reviewing the overall and daily AGP curves, noting times of day with patterns of low or high glucose, and looking for gaps when the patient may not be routinely monitoring. Before CGM, how often did you get overnight blood glucoses unless the patient was having hypoglycemia? Even 2 to 3 hours after a meal, when did we get those? So, looking where you otherwise would not have that opportunity, and act on the patterns of low and high, helping that person make adjustments and changes.

I'm now going to pass it on to Eden.

Dr. Miller:
Oh, Davida, I love that. I always get so much information from you when I look at the interpretation of AGP. And Jim, you did such a great job of teeing up CGM. I'm Dr. Eden Miller, a family medicine specialist. I have my fellowship in diabetology and obesity medicine, I work with my sweet husband in our clinic, Diabetes and Obesity Care, in Bend, Oregon.

And so now I'm going to pivot just a moment and go a little bit broader into the technology space. We're going to cover a little bit of automated insulin delivery systems as well as over-the-counter continuous glucose monitors.

Now, one of the things I want to kind of set a foundation for many of you, and I'm so glad you're here learning about technology incorporation and diabetes, but I also want to break down some barriers, and that is when we look at automated insulin deliveries or pump integrations with CGM, a lot of times we think of those individuals with type 1 diabetes, but I want to expand your horizon a bit. And as we are going through this briefly, looking at these integrated connective systems, I want you to think about all persons with diabetes, because you know allowing the data from a CGM to incorporate into an insulin pump, the two of them work in tandem, can be such a game changer for persons with diabetes, and those AID systems are so advanced. I always say it remembers you have diabetes when you don't want to, and so pairing that real-time data with those real-time needs for insulin really reduce the risk of both hyperglycemia and especially hypoglycemia, which really translates into improved time in range without the increased risk.

So you know these integrations and pass-throughs and all that, you know who plays with who, is constantly changing. So much changing that just a couple days ago, one of the iLet Beta Bionic Pancreas is now integrating in the future with Eversense. I mean, this stuff by the time we even review it at the end of the presentation is going to be outdated. So the reality is, is try to keep up.

This is a lovely graphic looking to say what are some of the options. Do you notice a pattern here? A lot of the CGMs are starting to integrate with multiple pumps, right? But in certain circumstances, as you can see, some of the pumps only integrate with particular types of sensors. So put it as a cheat sheet. You know, match the technology, the sensor to the individual. Match the pump to the individual, so everyone is having an experience that they feel most comfortable with.

As we continue to navigate the two options of standard of care, and so as Davida said, CGM is a right, not a privilege. I would also say that expanding coverage is allowing us to get that. And it isn't always the same. The standards of care that are set aside by the American Diabetes Association for the integration of technology in CGM may not always match the coverage in your area with both insurance companies, Medicaid. But one thing CGM has been doing in the world of CMS is that expanded coverage. No longer do we have to prove all the finger sticks. No longer do you have to be on multiple daily injections. And so you know this is a very good resource. I just did a presentation yesterday where they said, "Do you have some of the recommendations or requirements for adding CGM, getting it covered for those on Medicare?" And so this is important because many of those patients will qualify, and I've seen some pretty low percentages that there might only be like 20% of people who fall into the CMS category for coverage are even getting CGM.

So we're really encouraging you to try and identify those people. It's going to be life-changing for them. It's going to help you navigate their care, and it's going to be covered.

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So now let's pivot to over-the-counter. This is something that many of our colleagues are not aware of. Some are, but I'll tell you, individuals out there are getting these. And so having that shared discussion, having that opportunity that they own their own biometrics, they are aware of it. And so you can see, kind of from left to right, there are different options, different wear time, different downloads, different export, and you know ability, and so be familiar with this. You know, the costs are relatively the same; they're kind of price pointed the same, but they also have different indications. And what we mean by that is we want those individuals that are not on insulin. They are all for adults, but those who really want to manage their glycemic health and manage some of those things that are ever changing. And for me, I think it's a great new way to look at how data can deal with disease prevention, it can deal with engagement in lifestyle, and all of those different opportunities for health.

So there are individuals that are going to go for that over-the-counter CGM, and so be aware in your clinical practice. You know, there's lack of insurance coverage. Those people that have a family history of diabetes concerned about pre-diabetes—I'm going to put a little teaser in here—be on the lookout. In the next year, you're going to see quite a bit of chatter regarding the use of CGM metrics for direction, predictive types of graphics for who is at risk for developing diabetes, because this is a very large group of people, 115 million people in the U.S. that are defined as having pre-diabetes. And what are some of the things that can improve that or change the trajectory or prevent it? It's lifestyle intervention. It's weight loss. And so as Jim talked about, we see how CGM can improve those different things in your life that you can have control over.

We see some, you know, fitness bloggers and athletes and all of those different individuals trying to improve their health, and that's why we're really trying to create consensus and direction. Because sometimes I do see some of those influencers throwing out their data that really doesn't have a lot of scientific basis, so we're really trying to provide that.

Other metabolic disorders that have issues; not only that, those with early type 1 diabetes. We're starting to see consensus panels that are wanting individuals to monitor their glucose to make sure that they're going to be aware if they change, or those individuals who just want to live better and have hypoglycemia and they want to smooth out all of how they're feeling.

And so I'm going to now turn it over to Jim Gavin to talk about diabetic ketoacidosis. We got to revisit this, Jim. Thanks for brushing us up on that.

Dr. Gavin:
So thanks very much, Eden and Davida. You both have provided excellent insight into what levels and extent of information can be gotten from CGM, who actually needs this and the enormous benefit that can derive for a broad spectrum of patients by using CGM.

We're now going to move to an extreme of sorts of glycemic control, poor glycemic control, and that is what happens when we get to a situation of diabetic ketoacidosis. Why do we worry about this condition? We worry about diabetic ketoacidosis—we're just going to say DKA, which is how it's popularly referred to. It's a serious complication of diabetes. It's life-threatening. It can actually be a source of mortality. It's a condition that develops when the body can't produce enough insulin, and insulin, of course, is what helps glucose get into the cells. And now you have to change your energy source because glucose is not available because of the lack of insulin, and fat starts to break down. Counterregulatory hormones go up, and that accelerates not only the production of fatty acids, but the conversion of those fatty acids into acidic bodies in the bloodstream, beta-hydroxybutyrate, and then we see acetyl acetoacetate and things like that.

Type 1 diabetes is a situation where DKA occurs in 30 to 40% of patients at the time of diagnosis. It's often a presenting symptom. In type 2, we have a group of people who actually are ketosis prone, called Flatbush diabetes. But we can also see it as people get older; they have type 2 longer, they have insulin deficiency. And then there is a group of people on SGLT2 inhibitors where we see euglycemic ketoacidosis.

Now, the symptoms are very, very striking for DKA. Very thirsty, urinating a lot, feeling a need to throw up, nausea, belly pain, weak, feeling tired, short of breath, and fruity scented breath—acetone breath as people sometimes describe it—being confused. And you should be aware of the fact that these are symptoms that can come on really quickly, sometimes within a 24-hour period, and this can very often, as I said earlier, be the first sign of the development of the onset of type 1 diabetes.

Now, if we look at the risk factors for DKA, persons with type 2 make up a significant minority of DKA, and you might think this is reasonable because if it's principally a matter of not having enough insulin as a principal defect in this condition, then people with type 2 diabetes are going to be much less likely to have this than people with type 1 diabetes. In older adults, the incidence is roughly 5 to 7 per 100,000 person-years. In the ketosis-prone type 2 diabetes or the Flatbush type 2 patients, these are specific types patients that are prone to ketosis, and it can actually cause DKA. And then there are those patients who have been misdiagnosed as type 2, but they actually have type 1 diabetes.

Now, the factors that precipitate DKA, well, very often infections. We saw a surge of DKA during the COVID pandemic. There are times

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when people miss their medications or they miss their insulin doses. And we see a new group of people in recent years, those who are on SGLT2 inhibitors who lower glucose but through a non-insulin-dependent mechanism.

DKA is on the rise, and that's unfortunate. We see data from the CDC that show increased DKA hospitalizations, and this is even true for people with type 2 diabetes. And this is potentially due to a number of factors that we've seen on the rise recently, things like COVID and SGLT2 use.

The burden is significant. There's a problem with a lack of self-monitoring. But why are we seeing this? Well, it turns out less than 20% of people test their ketone levels even when they actually know that their blood sugars are greater than 300. These are the people who are directly in harm's way for DKA; 38, almost 40%, never test their ketones, even when they feel nauseated, they have classical symptoms, nauseated, they're vomiting; 45% never test their ketones even when they are clearly affected by some illness, they have a fever. So we have a problem with people actually doing monitoring that's required to detect DKA when it's happening.

And this is why we see this increased prevalence of DKA, and we see these data, for example, which reflects that. That in the left panel, you see that even though over this period of time between 2017 and 2024, serious or severe hypoglycemia has basically maintained pretty level. That hasn't changed very much. What has changed is the opposite extreme. DKA is on the rise in the pediatric type 1 diabetes patient population. And in the right panel we see that there is an impressive rise in pediatric DKA and type 1 patients, and this is particularly true, you see, in that age group shown with the blue lines. It's true for everybody, okay, but the rise is impressive, with 12% —96% of these episodes required inpatient management. They had to be hospitalized. So it's an economic burden as well as a serious problem of illness.

Now, if we look at the increased prevalence of DKA and type 2, we also see a rise. On the left panel, you see that hump in the middle. Well, clearly, that's the COVID surge. We see that there was a great deal of DKA that happened during the period of COVID. And you see that that's in the 12- to 17-year-olds had the highest risk of DKA in the type 2 pediatric population. And they see that in the adult population on the right, the trends are going up for everybody. But the 18- to 34-year-olds show evidence of the greatest risk for increased rates of DKA.

We need better strategies. We absolutely need earlier means of detecting and better ways of following the clinical course of DKA. It doesn't matter what age group you're in, we need better tools. And what we do know is this: that when we look at DKA, you're seeing changes in two key metabolites. You're seeing changes in the rates of rise of glucose because hyperglycemia is a serious causative factor, or one of the serious findings that we see in the presence of DKA and of course the ketonemia, but these things don't always change in the same way or at the same rate. There's a lot of variability here.

Now, you can see in each of these panels that you see panels where glucose levels rise faster than the ketones, all the way to the other extreme where the ketones rise faster than the glucose, and then there are such circumstances where the ketones and the glucoses basically rise at the same rate, or they stay flat.

Now, these have important management implications because you do want to know, for example, when the ketones are really exceeding the rate of rise of the glucose. These are people in whom you really want to make sure that you stay on top of them, and with respect to the insulin replacement and the hydration that you give them because you need to monitor these people quite closely because acidemia is a very serious problem clinically when you have patients with DKA. So if you have more information, then you actually can actually control the interventions that you're using to control the outcomes for these patients much better.

Why then is the ability to continuously monitor not just glucose but ketones so important? Well, we see that there are many, many patterns in DKA which are characterized by changes in ketone levels that occur out of phase with the glucose. It's important to know that because you know that you need to more closely monitor that and in some instances intensify the therapy that you're giving patients.

So, ketone monitoring is critical for early detection of DKA, but it's rarely done in practice. Traditional methods using blood ketone measurements rarely ever done by people. Using ketone urinary ketone measurements, it's very, very difficult to do in a way that gives you accurate information. There can be lag periods depending on how long the ketones have been in the urine. Remember, you have a conversion of beta-hydroxybutyrate. You have acetoacetate coming out in the urine. So there are all kinds of problems that can give you misguided information or inaccurate information if you depend on urine rather than blood ketone. But blood ketones need to be accurately measured, and sometimes that's difficult to do. And ketone sticks are expensive. Okay.

Continuous ketone monitoring is poised to address these limitations, and the devices that have been approved and designed with many expert recommended what we call desirable characteristics for ketone testing. Now we are able to announce that a continuous glucose ketone monitoring device has been approved by the FDA. This is a new announcement that we're going to hear more about from Eden

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because it is such an important tool in this universe of DKA. Eden?

Dr. Miller:
You know, that was so good of a reminder to bring us back to the fact that ketones have been so far behind glucose monitoring. I mean, you just mentioned about how you're using the urine stick, and so I think about the continuous ketone monitoring is really a way for ketones to level up. It's going to fill in a lot of knowledge gaps that we've had for quite some time. You mentioned the misdiagnosis of individuals, and I know that you share the excitement that I have looking forward to this new FDA-approved duo sensor.

So, as you mentioned, it's breaking news. It is FDA approved in both the U.S. and Europe. It's not available yet, but we anticipate either by the end of this year or the early next year, we will have the first of its kind integrated. We're not talking two sensors, two monofilaments; we're talking one sensor, two areas, one to monitor glucose, one to monitor ketones through the interstitium in real-time fashion. Just like we're used to continuous glucose monitoring, we're going to have continuous ketone monitoring. And what's the goal? The goal is to provide ongoing information, early detection that could potentially lead to diabetic ketoacidosis and allow us to identify and mitigate these, so it really has a great opportunity.

Now, one of the things that I presented at the ADA this year was just like you mentioned about the stakeholders, you know, all those experts, all of those. We are thinking, many of us, my colleagues have been involved in this project, and we were like, you know, what would you want a continuous ketone monitor to do? Right? Would you want it to be accurate? And we've seen great accuracy. What kind of displays do you want? Real-time. How often? This is going to be every minute, but you don't want to be bothered by too many alarms, right? We also want to know that the monitoring of the ketones could allow for intervention. When should you alarm? Could they be optional? What are the levels? Reliability that they're going to provide the information in a real-time manner and also convenient? Not two sensors, but one calibrated by the factory, so we don't, you know— because guess what? You know, that's one thing that hasn't really come up, you know, many of the sensors we're talking about are non-calibrated because of how good they are factory calibrated. But we're not going to be peeing on sticks to calibrate a continuous ketone monitor. We're not going to be doing that. And then cost-effective and available. And who should be provided or the ability to have those? So all of those things are being designed. All of those things are being incorporated into it.

And one of the things that I've been seeing, kind of as a tagline with the continuous ketone monitor, is because some of our colleagues are afraid there's going to be what we call alert burden, you don't want your ketone monitor to go off. But if your ketone monitor does go off, it's like your check engine light. You need to be aware of it and we need to have a lot of education about how to mitigate it and how to intervene.

Now, this formulation of this sensor really is on the foundation of a lot of data and how the dual glucose ketone monitor can impact real world. We had great data. Richard Bergenstal did a lot of this data. Jenn Sherr did a lot of this data. We looked at different cases, even those with type 2 diabetes, like the 62-year-old female who had chronic kidney disease. And to your point, Jim, how the glucose and the ketones sometimes are independent of each other, so that's the opportunity for learning. I'm not saying that when glucose rises, ketones don't, but we're really going to learn from an individual standpoint how continuous ketones shift depending on glucose levels, states of stress.

There was also another 59-year-old male with type 2 diabetes on the SGLT2 inhibitor. We mentioned those with type 2 diabetes at risk because SGLT2s can facilitate ketosis. I don't want people to be worried about them. They're amazing drugs with cardio-kidney-metabolic reduction, but sometimes in different states, they can cause ketones to rise, so we can be mindful of that. And then, of course, those with type 1 diabetes. I don't care what age you are if you are at risk for that. You know, in my case, I've had type 1. I've never had DKA, but that doesn't mean that I won't be at risk for that. And so we see issues of a 73-year-old with type 1 using an AID system and how the ketones may change depending on the glucose. Oh, I can't contain my excitement of how much we're going to be learning going forward.

And so, many of us did get the opportunity and have set a foundation in the past regarding ketone management algorithm, and this was just recently published, both the international and the ADA consensus panel looking at this process of having ketone conversations. We need to identify who needs to be mindful of ketones. Now, I want to stop there for a moment because sometimes we don't know who should be doing it, so we really have to cast a little wider net because maybe you know that person in your practice who developed ketones, and you went, "Oh, I never thought they would have that happen." So really, kind of broaden your scope just a little bit to those individuals at risk. You know, steroid shots and SGLT2s or insulin deficiency, in my opinion, all persons with type 1 diabetes.

How should we do it? Whether you're able to acquire a continuous ketone monitor, you know, Jim talked about how hard it is to get those self-monitoring blood ketone strips. They're expensive, they're hard to get, they expire, or whether an individual would concomitantly benefit from a continuous glucose and ketone monitor. And I think it's going to be just like Davida said. You know, you

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know, all persons with diabetes on insulin, it should be a right to have a continuous ketone monitor, and then becomes our opportunity for knowledge. What do we do with it? How do we get patients educated? How do we set the alarms? How do we— and take time to do that, don't feel like you're behind, understand it's going to take some. And then how do we manage that appropriately?

It's also going to be individualized. I want us to understand it's going to be an individualized ketone plan for the person to mitigate it at home, to communicate. But hey, either way, it's going to be a heads-up because that is what we want. We want to not be blindsided by ketones that are lurking in the background. And so you can see here many of my colleagues, including myself and Davida, had that opportunity with ISPAD to co-formulate with them the recommendations. Those are things

that are available, and they're ongoing in their availability as well because now a secondary consensus panel through the American Diabetes Association really talked at a high level about have a ketone plan. Start with the conversation, mention it. Right? What is a ketone? Many of our patients, even our colleagues, don't know what a ketone is. Have those meaningful conversations. Write out the plan. Give them education. Tell them when to seek emergency care, when to call you, what to do at home. What are some of the mitigations that you could do individually for their needs? And then, do they have a history? Are they at risk for that? Because I think additional interventions, especially with a continuous ketone monitor, and that is going to be those arrows. But also, if individuals can only obtain the urinary types of ketones, you need to understand the different colors and how to give them information to monitor their own health, their own ketone production when it is bulk trace or mild. Don't forget, overnight fasts often can cause mild ketosis, which is nutritional, but it's when it gets into the danger area. Greater than 6, 1, 1.5, for sure, 3 and above are those things that we want to be mindful of.

And then now trend arrows, just like we have trend arrows with CGM and hypoglycemia, right? You have a particular glucose, you're trending down. You want to take action. Now we have a particular ketone level. You're trending up. You need to pause. You need to notice the alert. Look at your own condition. Have those conversations with your colleagues because these are these ongoing things. This is one of the graphic that I just helped develop to try to distill down where is it going? What should you do? What is your action? What are those colors? And so we're going to be very versed in this, just like we are with time in range, and time in target, and all of those things. It's just another opportunity for ketones, continuous ketone monitoring to level up with glucose. So we've kept the colors and the arrows similar, so you understand. But you're going to have to review some of those new levels because many of my colleagues don't realize what a ketone is, what a mild elevation, moderate, and severe are, and how to act.

And there's going to be action plans. We will have information for healthcare providers. We'll have information for patients. We have even those for nurses and school nurses and CDC ESs and all of the different interventions. PharmDs and you know another group, you ER physicians out there, be aware; there are going to be these sensors walking through. They're highly accurate. They're going to be your best friend. Utilize them. Trust them. You know, tell the patient good job for monitoring this because we want to avoid hospitalization and in some cases death. I mean, I think it's going to be great to be able to have a mitigation plan.

You can see that it's based on glucose, but sometimes it's not based on glucose and just based on ketone level, hydration, hydration, hydration. Find the problem. Find what's the contributing factor. Make a course direction change, whether it's insulin to administer, whether it's a pump-type failure, whether it's an SGLT2, whether that sweet orthopedic surgeon gave you a steroid shot and the next thing you know you started to smoke a little bit and burst into flames. Have that ability to be mindful with your health and start to enact that, continue that ketone plan that your healthcare provider gives for patients. Because I think just like Davida said, if you're on insulin, if you're at risk for DKA, you should use a dual glucose ketone sensor because it's going to prevent these complications. But we're also in a territory that we haven't seen before.

We're going to learn so much about ketones in the next year, so stay tuned. I think it's a new area. I often say it's like a place we haven't been to before. We're exploring new areas of metabolism. For sure, those with type 1 and type 2 diabetes on pump, children, pregnancy, big- big time of development of insulin changing needs, so those SGLT2s, we're going to have to unpack that. If you've had DKA once, you're going to be on a continuous glucose ketone sensor.

And as we unpack the different things, there are many things that we see in the future. Right? Ketones for heart failure. They like it. You know, mental health disorders. So, oh, I can barely contain my enthusiasm because there's a lot that's out there.

So, Davida, let's talk about the healthcare team and see how we can all be in this together.

Ms. Davida Kruger:
Thank you, Eden. That was marvelous. I love the overview, and I think you're right. There's such exciting time to come, so stay tuned.

But in order for us to get this accomplished, we really need to think about the healthcare team and efficient and appropriate uses of that team to get continuous glucose monitoring in the hands of everybody, also for us to get keto monitoring and also education for people

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with diabetes.

So, thinking about the healthcare team and the use of CGM, we know Jim shared it. I shared a little bit about it, the relatively low adoption of CGM, that has to change. Insulin delivery devices and other diabetes technologies among clinicians is of concern, given the improvement shown with their use. And the fact is, if we use these devices, we can provide better healthcare for people with diabetes, and it actually makes my life better and easier. I know it's not all about the clinician, but if I can have this information, I can share that with the person with diabetes and make changes.

Adoption of CGM can seem to be daunting tasks. Underutilization of these tools is often driven by time constraints within an office, insufficient staff support, lack of awareness of the significance and consistent clinical benefit provided by these technologies. But I'll tell you, direct-to-consumer is pushing that envelope in a good way because our patients are seeing it on TV and they're coming in saying, "Why don't I have this? I want CGM." That is precisely why the healthcare team is so important in this process.

And look at everybody: nurse coordinators, social workers, psychologists, advanced practice people, NPs and PAs, clinical pharmacists really have stepped up over the last couple of years to help with technology, diabetes care and education specialists, school nurses, dietitians. All of these have a component that then help in terms of the team approach and helping to institute CGM and improve outcomes.

And the CGM is a wake-up call for both the practice and the patient. And thinking about how your clinic is going to initiate this, I can't tell you how to initiate it in your practice, but look around and see whose hands can be in this pot and help you stir it to get what you need. Thinking about application of the sensor, obtaining the sensor, prior authorization, all of those things we've got patterns for, and it's easier now than it's ever been before. And we don't want that to trip you up. So think about who in your workflow can help.

And be out front. You know, think about it ahead of the appointment. Before COVID, we didn't connect everybody in our clinic. During COVID, the first 3 weeks we went crazy calling everybody, making sure they were connected. It's not difficult to do. There are websites. You have in your clinic, people have their passwords. You give a code to the patient, they're now connected to you in your practice. And it's going to be easier because now EMRs are adopting it where I write the prescription, as soon as the patient has product, they're connected to my EMR, and the data is then uploaded. So look at that as well. And be familiar with all products available, whether the patient has a reader or they're using the app, make sure the patient is connected to you and go from there.

So think about your workflow ahead of time and make sure that before the patient arrives, you know who's going to do what. In my clinic, when someone comes in, if they're not directly already uploaded, our MA's can take their readers and make sure we have the data when I walk into the exam room. But really understand that this data is really going to help you help the patient manage their diabetes, and then when they go home at night, they can own their own diabetes, which is so important.

Dr. Brunton:
We hope this has been a useful program for you, and we have several key takeaways. Clinicians should seek to empower patients and members of the healthcare team to utilize CGM data for improved clinical care of patients. CGM offers numerous benefits to patients and clinicians, including increased engagement in diabetes care, improved health behaviors, better indicators of glucose management, and improved clinical outcomes. Every patient with diabetes will benefit from using CGM. CGM insurance coverage is possible for many, and cash price is often affordable. Over-the-counter CGM devices are newer technologies that may help patients access CGM, though there are limitations in glucose measurement ranges and data sharing, and they should be considered. And lastly,

CGM and ketone monitoring is a new FDA-approved tool that may help prevent and manage DKA. To receive your certificate, use the URL or the QR code below. And we hope this has been a helpful program. Thank you for your attention.

Announcer:
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