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Cleveland Clinic Endocrinology &
Metabolism Institute Diabetes Center

***Implement and Optimize
Professional CGM using a
Standardized Approach:
the Identify, Configure, and
Collaborate Framework***

webinar

Implement and Optimize Professional CGM using a Standardized Approach: the Identify, Configure, and Collaborate Framework

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“Just try it out. You really have nothing to lose, and I think patients have so much to gain from it. Most people with diabetes have this as a covered insurance benefit. I really want it to be more widely available so more people can get the benefits from this.”

— **Diana Isaacs, Pharm.D., BCPS, BC-ADM, CDCES, FADCES**, Clinical Pharmacy Specialist, CGM Program Coordinator, Cleveland Clinic Endocrinology & Metabolism Institute Diabetes Center

The benefits of real-time continuous glucose monitoring (RT-CGM) are well established. Dexcom’s G6 Professional version (G6 Pro) can provide these benefits to patients with both type 1 and type 2 diabetes and is covered by most insurance. While integrating new technology into patient care can sometimes be daunting, using the Identify, Configure, and Collaborate (ICC) framework can ease that transition and facilitate your organization’s professional CGM program.

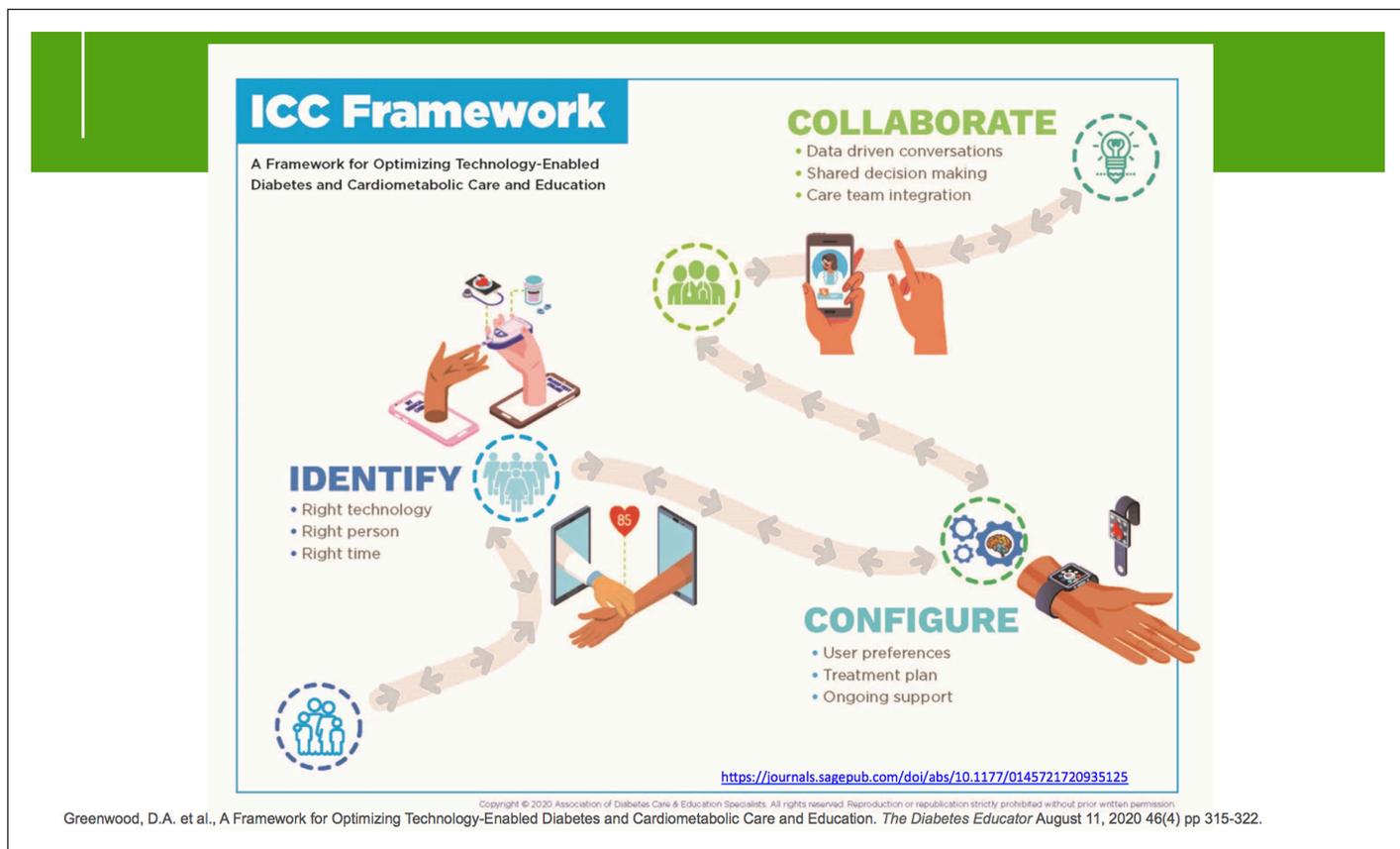
Dr. Diana Isaacs, clinical pharmacy specialist and CGM program coordinator at the Cleveland Clinic Endocrinology & Metabolism Institute Diabetes Center, as well as the Association of Diabetes Care and Education Specialists 2020 Educator of the Year, recently discussed her clinic’s success in using the Identify, Configure, Collaborate (ICC) framework and DATAA model to integrate the Dexcom G6 Pro into diabetes treatment. She and Dr. Deborah Greenwood, Dexcom’s medical science liaison for clinical education, showed how these standardized frameworks can be used elsewhere to adopt professional CGM technology.

The ICC Framework

The ICC framework (see Figure 1) was designed to provide a standardized approach for incorporating technology into clinical practice. Dr. Greenwood explained that the framework is applicable on both personal and organizational levels. On the personal level, ICC relates to the individual patient:

- **Identify** the right technology for the right person at the right time
- **Configure** the technology based on user preferences and the treatment plan (e.g., what support will the patient need, what alarms/alerts will work best for them)
- **Collaborate** using the data to drive discussions and shared decision-making that engages the person with diabetes and the whole care team.

Figure 1: The ICC Framework



This same framework applies to integrating technology into the organizational care setting, whether that is a single office or a large health system. From this “30,000-foot level,” Dr. Greenwood said, ICC means “we’ll be *identifying* key assessments, planning, and process requirements to start a professional CGM program. Then, we’ll *configure* the essential tools, workflows, and training requirements. And then finally, we’ll *collaborate* with both the care team—to evaluate the program’s success and outcomes—and also with the person with diabetes on how they’re using their CGM data.”

Benefits of Professional CGM

Providing an overview of CGM, Dr. Greenwood advised that CGM is supported by American Diabetes Association (ADA) standards of care. Dexcom RT-CGM has been shown to lower A1C, help reduce both hypo- and hyperglycemia, increase time in target range, and provide patients with improved quality of life and well-

being. Although there is more research focused on personal, RT-CGM use by people with type 1 diabetes, Dr. Greenwood noted several studies have identified professional CGM benefits for people with type 2 diabetes, including studies that uncovered episodes of asymptomatic hypoglycemia, nocturnal hypoglycemia, and postprandial hyperglycemia. Also, “retrospective studies of type 2 diabetes found that professional CGM improved A1C when there was a focus on behavior change and treatment modifications based on the CGM data.”

Dexcom G6 Professional CGM can be used in two modes. “Unblinded” mode provides an experience similar to personal, RT-CGM. Patients get alerts and alarms. They can see their RT-CGM data in real time on their smartphone and see how food and activity choices are affecting their glucose and can make treatment decisions for lows and highs. In “blinded” mode, the patient does not see their data in real-time,

but they review their data after the 10-day session with the healthcare provider using Dexcom CLARITY clinic software. In both cases, “along with diabetes self-management, education and support, CGM can help identify patterns and trends to change treatment and health behaviors in people with type 1 and type 2 diabetes using retrospective data,” according to Dr. Greenwood.

Dexcom’s G6 Pro is authorized for use in ages two and up, and it has up to a 10-day sensor wear. It has the same sensor accuracy as the personal Dexcom G6. In blinded mode it is authorized for use in people without diabetes. Dr. Greenwood noted significant advances from the Dexcom G4 Pro: The G6 Pro is disposable, which eases workflow and is a particular boon in the age of COVID-19. It is factory calibrated, approved to make treatment decisions, and providers can view the most recently available data when shared via the Dexcom CLARITY Clinic software.

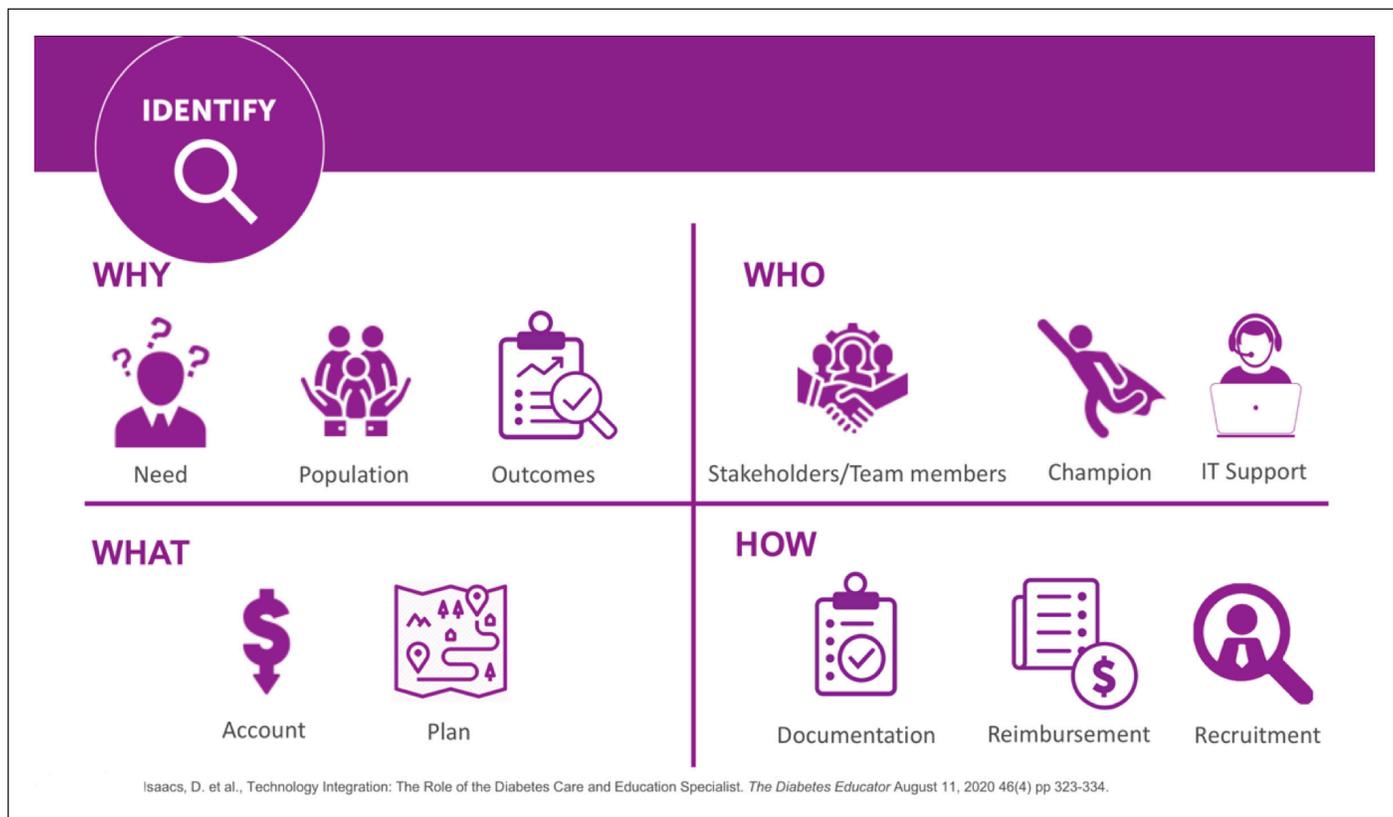
Using the ICC Framework to Integrate Professional CGM Technology

With the benefits of the professional CGM clearly identified, Dr. Greenwood turned the presentation over to Dr. Isaacs, who discussed integrating the Dexcom G6 Pro at the Cleveland Clinic Diabetes Center using the ICC framework (see Figure 2). According to Dr. Isaacs, the Identify step has several components:

- Identify the need the technology should meet
- Identify the target patient population
- Identify hoped-for outcomes and how success is measured
- Identify stakeholders, team members, champions

Identifying the need, Dr. Isaacs said, is identifying the “why” behind the program. For diabetes care, that includes helping patients lower their A1Cs to less than 7% , as recommended by the American Diabetes Association. “We know it’s really a struggle,” said Dr. Isaacs. Diabetes needs a lot of management, and it is

Figure 2: ICC Framework in Action



important to make diabetes education “fun and exciting because when people hear ‘education,’ they’re like, ‘I know what I need to know.’” So a key to integration was developing related education programs that allow for discovery learning.

Next, identify patients for the program. Although Dr. Isaacs believes any patient not using a personal CGM could benefit from using the Dexcom G6 Pro, “if you have a large population of people with diabetes, you may not be ready to let the floodgates open.” Dr. Isaacs believes a targeted approach can be a good starting point, including targeting people with A1Cs over 9%, those with A1Cs that are discordant with glucose readings, or patients who don’t bring in their glucose readings. So, there is a wide variety of possible target populations.

Then, it’s important to identify what kind of outcomes you hope to see for the target population, e.g., “what do we hope to see if we’re including people with A1Cs that are higher?” In that population, Cleveland Clinic measured A1Cs in type 1 and type 2 patients prior to use of the device and then three months later. They found the mean A1C reduction was 0.8%. They also found tremendous improvements in patients’ confidence to manage and treat hypoglycemia, check blood glucose regularly, and eat regular meals.

Finally, identify stakeholders and team members. At Cleveland Clinic, diabetes care and education specialists were the driving force behind starting the professional CGM program, but, noted Dr. Isaacs, other stakeholders are also needed. For example, Cleveland Clinic’s program includes pharmacists with pharmacist-led CGM interpretation. As well, because this is a technology-based program, IT needs to be involved. Of course, key in the stakeholder identification process is identifying a champion. That, said Dr. Isaacs, “is huge.” It’s important to have a champion with enthusiasm for the program, “if you can get at least one person who

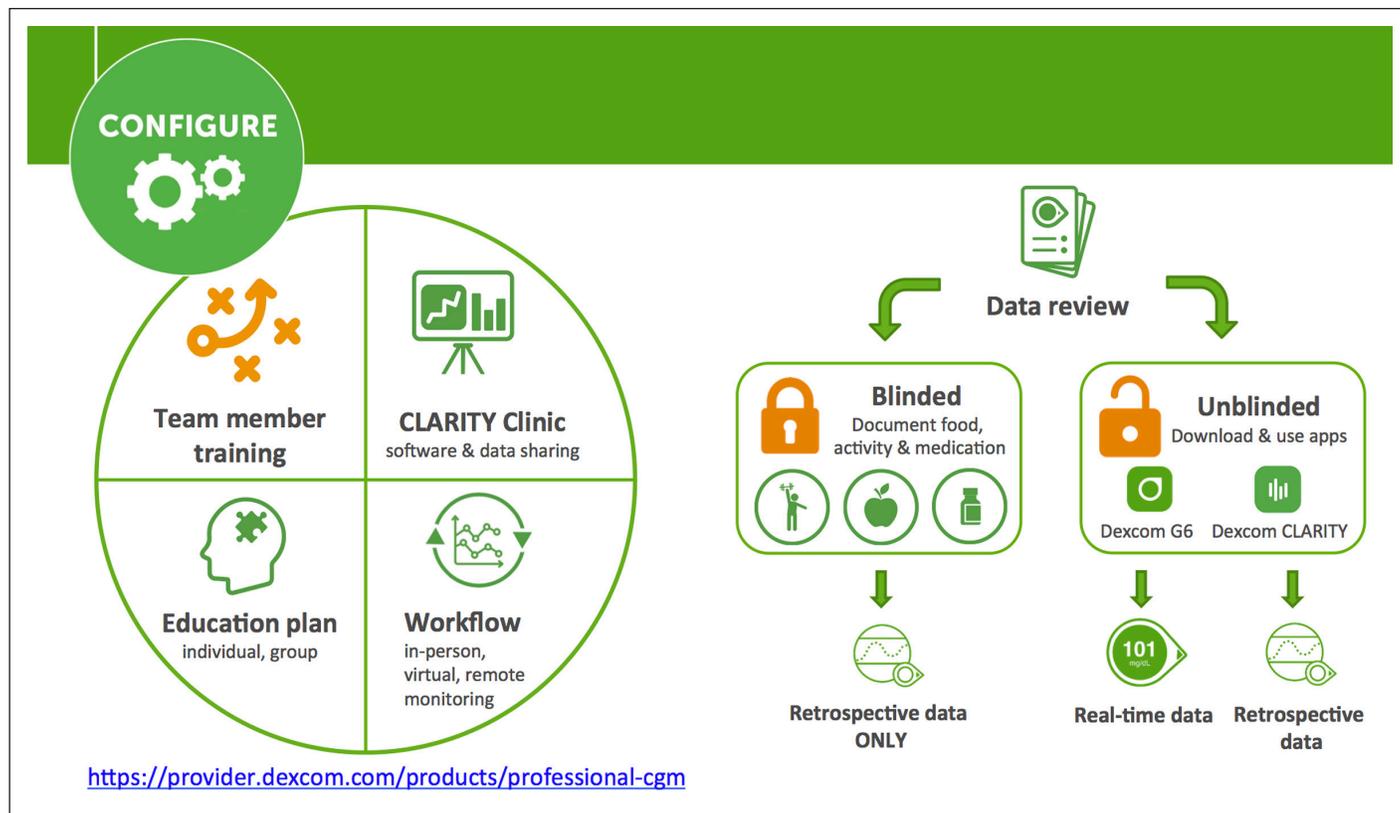
is excited about driving it, then you can have a lot of success.” She noted later that the Cleveland Clinic team was so excited about the program, “I think our passion was contagious.” If starting from a base where knowledge about professional CGM is limited, she suggested utilizing the resources discussed in the presentation to help others understand the value of it. Understanding can help dissolve barriers and get things moving forward.

Other identification considerations may include, for example, procurement, reimbursement, and recruitment. As noted by Dr. Isaacs, “Who’s going to come to your program? You could plan the most amazing program in the world, but how is anyone going to know about it?” At Cleveland Clinic, diabetes care and education specialists approached current patients, but other efforts included creating fliers and conducting outreach at staff meetings to introduce the program. It was important that everyone was on board and understood “this is a new service, we’re trying to help your patients.”

Dr. Isaacs emphasized that the program doesn’t have to be large at the outset, “you can order one reader and four CGM sensors to start off with and you can pilot it. And that’s essentially what we did.” As Dr. Isaacs recalled, only two of the potential four initial patients participated, but “it was a great opportunity to pilot it.” She also noted that initial up-front investment is minimal. So, you can start with a very small pilot program, tweak it from there, and “then you can decide to ramp up your volume and everything.”

Regarding configuration (Step 2 of the ICC framework), Dr. Isaacs explained, “You’ve identified you want to do this, you’ve got a good plan in place, but what are the steps to actually configure what is all happening and everything?” (See Figure 3.) Considerations include workflow and team member training. This includes identifying the personnel responsible for placing the

Figure 3: Configuration



sensors on people and training them. It’s important those team members feel comfortable. The same is true for personnel downloading the data and those helping patients learn to use the Dexcom G6 smartphone app, Dexcom CLARITY app and Dexcom CLARITY Clinic software. Ideally, Dr. Issacs suggested, all team members should wear a sensor; “if you’ve got the opportunity to just wear it, you see it in action, and you see what your patients are actually being able to see.”

Another configuration consideration is whether a patient should use the device in blinded or unblinded mode. Cleveland Clinic will usually choose unblinded mode because “people learn in real- time what happens to their numbers.” There are certain times, however, when blinded mode may be preferred, for example, when you want to see someone’s true glucose variability without them changing behaviors. As Dr. Isaacs noted, “While alerts are wonderful, if they get those alerts, that is going to impact the percentage of time of hypoglycemia. So if you’re

really trying to get that true estimate, that could be a time you go with blinded.” As well, if a person does not have a compatible smart device, blinded mode will be necessary. Cleveland Clinic has handouts for patients with common FAQ information, and there are separate handouts designed for people using blinded and unblinded mode because of their different considerations.

A related issue is which reports you want to see regularly. Dr. Isaacs noted, “You can get really crazy with the data and you could print out 10 pages if you want, but usually you don’t need that.” At Cleveland Clinic, they’ve chosen three standard report pages they consider both valuable and easy for patients to understand. Those are printed to share and are added to the patients’ electronic medical records. The one-page Dexcom CLARITY G6 Pro Report is a simplified report that is very easy for healthcare providers to use.

Finally, configure the workflow for patient interaction. There are many different options to implement

professional CGM in a clinic or health system. The Cleveland Clinic uses a two-part shared medical appointment, where four to six patients come in together to receive their sensors and, Dr. Isaacs joked, you can “sneak in diabetes education.” Patients learn about A1C goals and talk about treatment of hypoglycemia and hyperglycemia. As well, they receive education on use of the Dexcom G6 and CLARITY apps. This can be done via the handouts discussed above, but “if you have the time,” Dr. Isaacs noted, “it is nice to walk people through the apps and just make sure it’s really set up correctly.”

In the second group appointment, patient’s CGM reports are shared on a screen and discussed. Of course, Dr. Isaacs emphasized, the patients sign HIPAA agreements to share their data within the group. While some people may be reticent to do so, Cleveland Clinic has found these group appointments extremely beneficial. She noted, “There’s so many commonalities in people’s data. The classic ‘during the week I eat cereal and on Sundays I eat eggs.’ Well, that’s so interesting. When you look at someone’s report and you see during the week, there’s a huge spike every day at breakfast and then the day they eat eggs, there’s not that spike. And that’s a great conversation piece.” Overtreatment of hypoglycemia is another oft-seen commonality. The primary benefit of the group appointment, says Dr. Isaacs, is the peer support: “People really find it empowering,” and “what they learn is that no one’s perfect, that everyone is really struggling with similar things.” Indeed, many patients exchange phone numbers and stay in touch after the professional CGM experience, which is, she noted, “one of the reasons I just love this model.”

Dr. Isaacs emphasized that “this is definitely not the only way you can do this, and especially during COVID, I understand why a lot of people would have reservations about doing it this way.” In fact, her clinic now limits groups to two people at a time for that very reason. Individual appointments are also always an option.

To limit how many times patients have to appear in person, virtual or telephone visits can be used to review data after it’s been downloaded.

Collaboration, the final step in the ICC framework, “is really where that rich exchange of information happens and we apply it.” As with configuration, there are actually two aspects to collaboration: Collaboration with the team and collaboration with the patient.

With the team, there should be ongoing assessment of the program to optimize outcomes. It’s a constant process of reviewing what’s working well and what’s not. For example, some patients are not suited to the group appointment setting. After a few “flops,” Cleveland Clinic refined their process to identify which referred patients would be a good fit for group appointments. Other logistical issues, such as billing and coding, can take time to perfect. For example, Dr. Isaacs, a pharmacist with a collaborative practice, is authorized to conduct interpretations, but is not considered an approved Medicare “provider.” As a result, there were questions about how to bill for her work. The team decided to have interpretation notes cosigned by the referring provider, which “now works seamlessly.”*

Collaboration with the patient relies on the professional CGM data to drive discussions and action planning. Dr. Isaacs assured participants, “This is something that you get really good at over time, the more you look at these reports and these interpretations where you’ll just get so comfortable with them, you’ll look at them and it’ll be clear, become clear what the patterns are.” This leads to productive discussions and shared decision-making that supports the patient both in the here and now and moving forward. “I think,” said Dr. Isaacs, “one of the successes with our program and why we have seen improved outcomes is it’s, yes, wearing a professional CGM itself is amazing, but it’s what you do with the data, and then what is that next step?”

* The reimbursement information provided is intended for informational purposes only and is not a guarantee of coverage and payment. Healthcare professionals are encouraged to contact their local payers with questions related to coverage, coding, and payment.

The DATAA Model

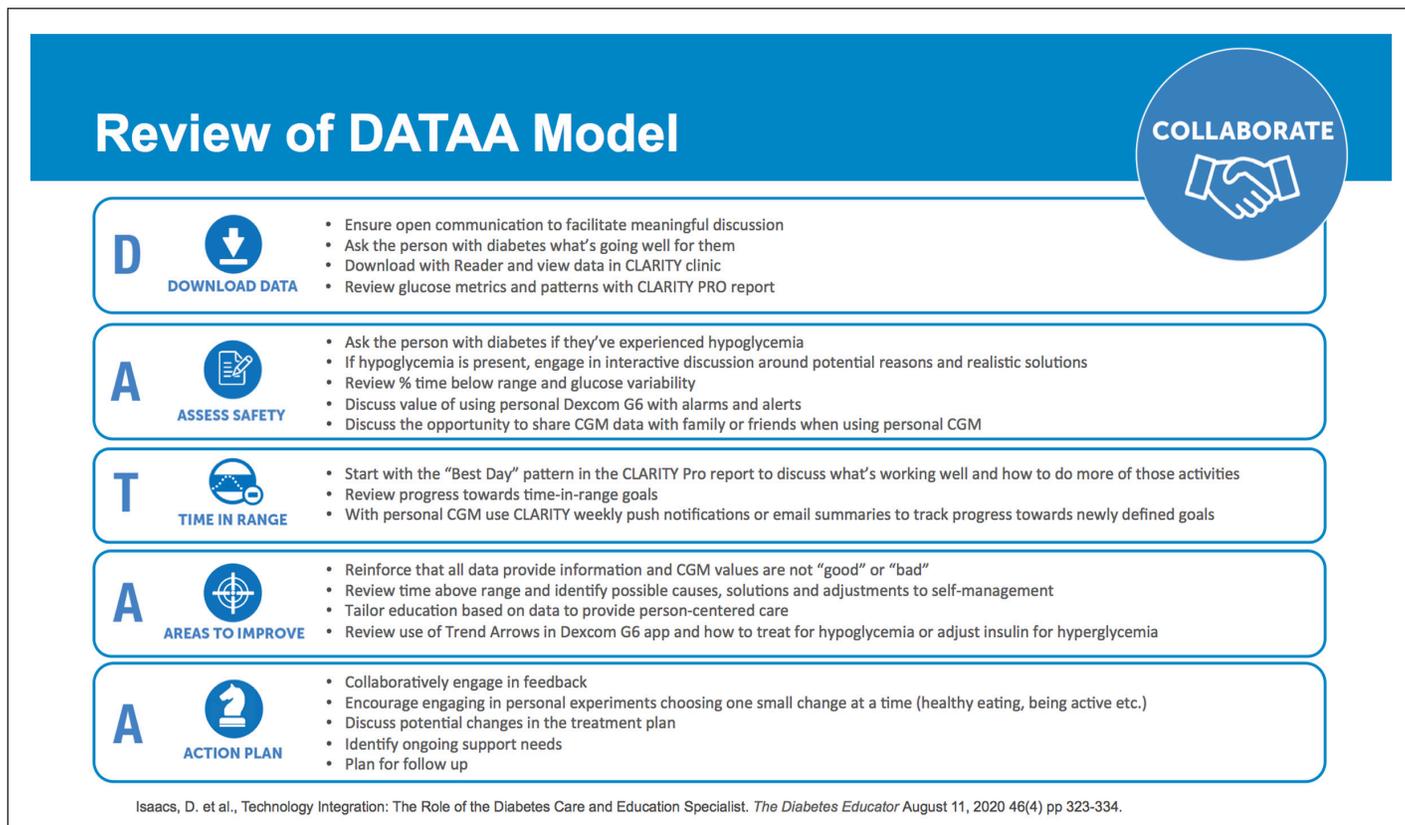
In response to that question, Dr. Isaacs shared the DATAA Model, which she and other diabetes care and education specialists developed specifically for collaborating with patients using CGM data and published in the August 2020 issue of *The Diabetes Educator* (see Figure 4).

To illustrate the DATAA model in practice, Dr. Isaacs shared a case study: A 63-year old male with type 2 diabetes for 17 years. Other conditions include visual impairment (which made self-checks of glucose difficult), recent pancreatitis (which limited use of some agents like GLP-1 receptor agonist and DPP-4 inhibitors), and chronic kidney disease with albuminuria. Medications prior to G6 Pro use were 65 units of insulin glargine every evening and 10 milligrams of Glipizide twice a day (before breakfast and before dinner). His last A1C was 9%, serum creatinine was 1.8, and GFR was 46.” He readily agreed to using the Dexcom G6 Pro in unblinded mode, using his smartphone and both the Dexcom G6 and CLARITY apps.

First, “you’ve got to get the data right.” Once you **download the data**, it’s time to orient the person with diabetes to what it all means, what these key metrics are in a very objective way. Dr. Isaacs emphasized, it’s not about “saying ‘this is good,’ ‘this is bad,’ but just ‘these are numbers. This is information.’” After eight days of monitoring, the Ambulatory Glucose Profile (AGP) report showed time in target range of 70 mg/dL to 180 mg/dL was 51.4% (target is 70% or more), and the patient was above 180 mg/dL 48.6 % of the time (goal is to be less than 25%). Another key data point was coefficient of variation. The goal for that metric is under 36%, which means that glucose is relatively stable and there’s not a lot of variability between hyper- and hypoglycemia. The patient was within target, at 34%.

Assessing safety (Step 2), overall, there was zero percent hypoglycemia, but, said Dr. Isaacs, “I never assume that that means that my patient didn’t have any lows, because ... he’s getting alerts.” It’s possible that the patient got an alert and was able to prevent a

Figure 4: DATAA Model



hypoglycemic event. In fact, the data showed a drop overnight to 70 mg/dL that had caused an alarm.

Next is **time in range** (Step 3). Dr. Isaacs advised, “The key here is you focus on what’s positive, what’s working well.” Focus on the day or the time period where time in range was highest. Dr. Isaacs acknowledged, providers “want to fix things,” but from a patient perspective, “it doesn’t feel good to be pointing to things that aren’t working well. If we focus on the things that are already working well and try to repeat more of that, we often get to have more success.” Using the AGP report, Dr. Isaacs identified the day that was highest in range, so “we talk through what he ate that day, his level of activity, which it turns out, he was more active that day.” They also discussed medication doses. Dr. Isaacs highlighted the importance of time in range: A 5% increase in time in range is clinically meaningful, and a 10% increase has been shown to decrease A1C by 0.5%. One of the reasons to target 70% or more time in range, Dr. Isaacs advised, is because that generally leads to an A1C of around or just below 7%.

Next, is **areas to improve** (Step 4). The reports can help identify patterns and, in this case, the report showed a pattern overnight where glucose was going up, then decreasing. Discussion led the patient to disclose that he was snacking in the evening, but noticed he was not snacking as much during the day, especially while wearing the CGM. He also indicated that, while he did not miss any medication doses, he was taking his second dose of Glipizide at bedtime instead of before dinner, which, Dr. Isaacs explained, could potentially contribute to the overnight decline.

The final step in the DATAA Model is the **action plan** collaboration. “We decided we were going to decrease his insulin glargine because of those drops happening overnight.” They also decided to address the snacking. As Dr. Isaacs explained, “If you can curb that snacking or even pick foods instead of popcorn (which he was eating a lot of), switching to nuts ... a food that doesn’t have as

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much of an impact on the glucose, then often you’re able to decrease that.” They also had an educational dialog about taking Glipizide before dinner instead of right before bed to improve effectiveness. They set follow-up with a diabetes care and education specialist.

The patient “was so happy wearing the device.” He particularly liked the alerts and the ability to have his smartphone speak to him from his Dexcom G6 app—“Hey Siri, what’s my glucose?”—avoiding issues related to his visual impairment. After initial follow-up, he obtained a personal CGM, “which has really facilitated his ability to monitor.” The patient was able to achieve an 81% time in range, a significant improvement. This case study is consistent with Dr. Isaacs’ general experience: “99% that [use the Dexcom CGM Pro] go on to get personal CGM because they were already interested and they see the value of it.”

When asked to provide one tip about a professional CGM program, Dr. Isaacs provided this advice: “Just do it. get the equipment, try it out, try it on a couple patients, and just get your feet wet with it and see. And then you may come up with ideas. Maybe you’ll come up with your own kind of innovative way to do this. But just try it out. You really have nothing to lose. And I think patients have everything to gain.”



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