# Transcript Module 4

**[0:16] Dr. Carol Wysham:**

Welcome to Module 4, "Closing the Loop: From Home Glucose Monitoring to Continuous Glucose Monitoring to Automated Insulin Delivery Devices." I'm Dr. Carol Wysham, Clinical Professor of Medicine at the University of Washington. Dr. Cobry, would you introduce yourself?

**[~0:30] Dr. Erin Cobry:**

Yes, I'm Erin Cobry, Associate Professor of Pediatrics at the Barbara Davis Center for Diabetes at the University of Colorado.

**[~0:42] Dr. Carol Wysham:**

For the last 30 years, self-monitoring of blood glucose has been the standard of care for monitoring our patients with diabetes. However, it has notable limitations. It measures just one point in time, and if we're lucky enough to get any monitoring data at all, it's usually just in the morning. It misses important information on glycemic fluctuations, so the patient and the healthcare provider can make dosing errors. In most of our experience, patients often forget to bring their meters or logbooks, so we're basing our information on what they tell us verbally.

CGM devices, on the other hand, collect continuous data, so we can see what blood sugars are doing throughout the day because it's continuously streamed. Many national and international organizations now recommend CGM for all patients with diabetes, particularly those on insulin. Diabetes is continuous, and it's really hard to measure glycemia with a single time point.

**[1:41] Dr. Carol Wysham:**

There are many benefits of CGM versus SMBG. Starting on the left of the slide, time in range is the most actionable metric. The ADA now recognizes it as a key glycemic outcome and considers it complementary to the A1C. Having the AGP as well as the TIR lets us engage patients in the office and use shared decision making about their management. TIR reflects daily glucose stability, not just averages.

It has been found in multiple studies to be associated with improvement in A1C, or at least reduction in hypoglycemia. In type 1 diabetes in the GOLD trial, there was significant improvement in TIR with CGM. In the DIAMOND trial, in type 1 and type 2 on MDI, CGM users had improved TIR with less time above range. Real-world registries confirm this. Most recently, the INTERMITTENT-type trial in type 2 diabetes not on insulin showed reduced A1C and improved glucose control quality as measured by TIR. We're also beginning to see evidence that TIR is inversely associated with risk of microvascular complications: higher TIR, fewer complications.

**[3:36] Dr. Carol Wysham:**

On the right side of the slide is important information about hypoglycemia. Remember that hypoglycemia can be related to falls, cognitive impairment, cardiovascular events and mortality. In studies in both type 1 and type 2, CGM is uniformly associated with a reduction in hypoglycemia without deterioration in A1C. In the MOBILE trial, in patients with type 2 diabetes on basal insulin, they showed not only decreased hypoglycemia but an overall improvement in A1C.

**[4:15] Dr. Carol Wysham:**

To remind you, our clinical goals with CGM start with time in range, defined as blood sugars between 70 and 180. The goal in most patients with type 1 and type 2 diabetes is greater than 70% time in range. In older adults or patients at high risk for hypoglycemia complications, we can loosen that to greater than 50%. We also need to focus on hypoglycemia reduction. In most type 1 and type 2 patients we want less than 4% of time under 70 and less than 1% under 54 mg/dL.

In the older, more vulnerable adult, you might consider less than 1% under 70 as your target. And importantly, we need to address treatment burden in our patients and minimize it as much as possible.

**[5:15] Dr. Erin Cobry:**

We're going to shift gears now and talk about automated insulin delivery systems, including core concepts and use by patient type. Automated insulin delivery builds on the foundation of continuous glucose monitoring. This figure illustrates the three essential components of every AID system. First is the CGM data. The CGM provides real-time glucose values and trends. It's the system's sensory input, and without accurate, timely CGM data, automation can't function. Sensor reliability, warm-up periods and calibration requirements all influence performance.

Second is the insulin pump, the action arm of the system. It delivers basal insulin adjustments and, depending on the system, may support automated correction boluses. Pump infusion site issues, including occlusions, adhesion problems or aging sites, remain a major source of variability.

Third is the control algorithm. The algorithm is the brains of the system. It continuously interprets CGM data, predicts future glucose trajectories, and adjusts insulin delivery to keep glucose in the target range. Each commercial system uses a different algorithmic approach, but they all rely on accurate inputs and consistent pump function. When it works well, AID reduces glycemic variability, increases time in range and decreases user burden.

But the system is only as strong as its weakest link. Sensors must be worn, accurate and communicate with the pump. Pump usage, including keeping the battery charged and managing infusion sets, and user engagement all affect success.

**[7:05] Dr. Erin Cobry:**

AID is now used across different clinical populations. For people with type 1 diabetes, AID is increasingly considered the standard of care. Key considerations that influence glycemic outcomes with AID include meal bolus timing, insulin infusion site issues, and ensuring appropriate

expectations. Even with automation, and because of the insulins available today, delayed or missed meal boluses remain the most common pitfall. Algorithms can compensate partially, but not fully. Infusion set failures or poor absorption can rapidly degrade system performance, so routine site rotation and troubleshooting are essential. And while most users experience improved time in range and less hypoglycemia, education on system limitations is critical.

**[8:09] Dr. Erin Cobry:**

AID use in type 2 diabetes is also expanding, but thoughtful selection is still important. Individuals already on basal-bolus therapy may transition more easily to AID, but basal-only users may also benefit from automated systems, with or without intermittent bolus dosing, if appropriate. Several studies are underway on AID in type 2 diabetes without bolusing.

AID can reduce regimen complexity in type 2 diabetes, especially for people with high variability or difficulty with manual dose adjustments. Tools that support bolus estimation or titration of pump settings can help bridge gaps in numeracy, carbohydrate estimation or confidence.

**[8:58] Dr. Erin Cobry:**

Not all users adopt full automation immediately or consistently, and in some cases partial or intermittent automation may be beneficial. One use case for partial automation would be someone on basal-bolus injections who supplements nights with automation to improve glycemic levels when there is less variability in activity and carbohydrate intake. No currently available system offers this, but it may be an option in the not-too-distant future. For people transitioning from MDI to AID, it's very important to focus early on education about pump basics, infusion sets and algorithm expectations. Even after starting AID, there may be occasions when people revert to multiple daily injections, because AID may not work for everyone all the time. For example, they may want to come off the pump while traveling or on vacation, especially around beaches, or for sports, in particular contact sports. They may also come off during illness or device issues. So users should know how to revert safely to manual dosing, and ideally continue using a CGM regardless of the method of insulin delivery. Across all groups and ages, combining AID and dosing guidance supports safer, more confident insulin use and can reduce cognitive burden for patients and caregivers.

**[10:27] Dr. Carol Wysham:**

I'd like to move on to CGM use in patients on basal insulin. Most patients have coverage for CGM when starting basal insulin, and for Medicare there are no prerequisites of home glucose monitoring before qualifying for CGM. Very important: for those on Medicare, prescriptions need to be sent to a durable medical equipment provider, not a pharmacy.

One benefit of using CGM at the start of basal insulin is that you can use it for titration. CGM titration can use the same fasting-glucose-based regimens but has additional benefits. Patients gain a lot of information about the impact of food and activity on their glucose profiles. CGM also shows the potential for lower blood sugars later in the day that might alter the recommended titration. For instance, if their fasting sugar is 160 and you want to increase the dose, but you see blood sugars later in the day approaching 80, you might increase by a smaller amount or wait a few days.

An important reason for fasting hyperglycemia is high post-dinner excursions. CGM lets us see that and approach the dinner-time glucose rather than continuing to increase basal insulin.

**[12:09] Dr. Carol Wysham:**

What about CGM in patients not on insulin? Many studies now show that people with type 2 diabetes not on insulin can improve glucose control considerably just through behavior change and recognizing patterns, not necessarily requiring any change in therapy. If they start seeing hypoglycemia or untreated hyperglycemia, adjustments can be made based on the data.

Patients on CGM can expect reduced postprandial excursions and improved glucose control with ongoing weight loss. If they're on insulin, they can lower their doses based on CGM data and be instructed how to do that on their own. There may be residual hyperglycemia that needs prandial insulin or further lifestyle changes. The AGP is a very important coaching tool. In the office, you can show it to patients, talk through the options and what you're seeing, and work with them to decide the best therapy.

**[13:26] Dr. Carol Wysham:**

Let's put this to work with a case. Janice is a 68-year-old woman with a 19-year history of type 2 diabetes complicated by kidney disease and neuropathy. She comes in saying she's having some low blood sugars and doesn't feel well. Her medications include metformin, empagliflozin, glipizide and insulin glargine 22 units at bedtime. She checks her glucose in the morning and when she has symptoms. She says she has no hypoglycemia symptoms unless her blood sugar drops below 60, but she has had at least three episodes of unprovoked hypoglycemia below 54, mostly in the early morning hours.

Whether or not she recognizes a nighttime reaction, she often wakes with headaches. She denies severe hypoglycemia. Her exam shows obesity and changes consistent with peripheral neuropathy. Her labs show an A1C of 7.2, an eGFR of 44, and macroalbuminuria with an ACR of 327.

**[14:43] Dr. Carol Wysham:**

At this visit we discontinued her glipizide and ordered a CGM. Under Medicare criteria, two or more glucose levels below 54 qualify for CGM approval. She returned for follow-up with a diabetes educator, sensor placement and connection to the clinic CGM account.

**[15:06] Dr. Carol Wysham:**

One month later we reviewed her CGM report. She's off glipizide at this point, but from her TIR you can see she's still having considerable hypoglycemia. Our goal for a woman at this age is less than 1%. In her AGP, her glucose is dropping overnight, with a lot of hypoglycemia in the early morning hours and a lot of hyperglycemia after meals. Looking at this data, we decided to lower her glargine dose to 15 units and moved it to the morning, since some studies suggest less nocturnal hypoglycemia with morning glargine. Alternatively, we offered her the chance to add or switch to a GLP-1 receptor agonist or dual agonist, with the potential to aggressively taper off the glargine.

She was interested in this. Given her CKD stage 3 and significant proteinuria, we started semaglutide 0.25 mg weekly, with appropriate counseling on side effects, titration and nutrition.

**[16:28] Dr. Carol Wysham:**

She returned, and after titrating semaglutide to 1 mg we were able to discontinue her glargine. Her TIR is now 80% and she has no values below 70. Her GMI, or estimated A1C, is 6.7%. I'm sure many of you have seen similar results in patients you've started on a dual agonist or GLP-1 receptor agonist in place of insulin.

**[16:58] Dr. Erin Cobry:**

Let's take a look at Jessica, a 16-year-old with type 1 diabetes for 10 years. She has been using multiple daily injections with a CGM, and her A1C has hovered around 8% for several years. She recently chose to transition to an AID system to improve between-meal and overnight glucose and reduce the burden of daily injections. Her glucose has improved overall, but she continues to struggle with post-meal spikes. This is a common pattern when users adopt AID. The system can automate basal adjustments, often beautifully. But mealtime behaviors still drive a large portion of glycemic outcomes.

**[17:41] Dr. Erin Cobry:**

Jessica's CGM trace shows classic examples of late and missed meal boluses. Rapid-acting insulin takes 20 to 30 minutes to start working and peaks around 90 minutes. AID systems are glucose-responsive, meaning they only increase insulin after glucose begins to rise. When a meal bolus is missed, as you can see on the right, glucose spikes sharply and stays elevated for several hours while the algorithm cautiously increases insulin to avoid stacking and rapid drops. Often the user then needs to give additional correction insulin to bring glucose back into range. When a bolus is late, as you can see on the left, the spike is still significant, and the combination of rising algorithm-driven insulin plus the delayed manual bolus can lead to initially prolonged hyperglycemia followed by delayed hypoglycemia from excess insulin delivery. These patterns explain why Jessica continues to see post-meal highs despite overall improvement with AID. Focusing on the timing of insulin dosing at meals will greatly benefit her and avoid significant postprandial hyperglycemia.

**[18:57] Dr. Erin Cobry:**

Here we see that she is now dosing before meals and before the glucose spikes. However, she still has prolonged hyperglycemia after meals, triggering frequent algorithm-driven insulin delivery to mitigate those highs. This suggests her insulin-to-carb ratio is too weak, meaning her meal bolus isn't sufficient for the carbohydrate load. The next step is strengthening the insulin-to-carb ratio, which helps the meal bolus match the meal, reducing the burden on the algorithm and improving postprandial control.

**[19:31] Dr. Erin Cobry:**

With tuned AID settings and targeted behavior changes, Jessica's glucose pattern stabilizes significantly. Key elements include consistent pre-meal bolusing, optimized insulin-to-carb ratios,

reliable infusion sites, and understanding how the algorithm responds to the glucose signal and trends it receives. When these components are aligned, AID systems can deliver excellent glycemic outcomes and reduce daily management burden.

**[20:00] Dr. Erin Cobry:**

Jessica's case illustrates the core message: AID can be powerful, but it works best when paired with strong mealtime habits and tuned settings.

I want to close by saying thank you for participating in this session. We hope it was helpful for your clinical care of people with diabetes. Please make sure to check out the other ACT Now modules to learn more about continuous glucose monitoring.