Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People With Diabetes

Cari Berget,[1] Jennifer L. Sherr,[2] Daniel J. DeSalvo,[3] Ryan S. Kingman,[4] Sheri L. Stone,[5] Sue A. Brown,[6] Alex Nguyen,[7] Leslie Barrett,[7] Trang T. Ly,[7] and Gregory P. Forlenza[1]

Automated insulin delivery (AID) systems, which connect an insulin pump, continuous glucose monitoring system, and software algorithm to automate insulin delivery based on real-time glycemic data, hold promise for improving outcomes and reducing therapeutic burden for people with diabetes. This article reviews the features of the Omnipod 5 Automated Insulin Delivery System and how it compares to other AID systems available on or currently under review for the U.S. market. It also provides practical guidance for clinicians on how to effectively train and onboard people with diabetes on the Omnipod 5 System, including how to personalize therapy and optimize glycemia. Many people with diabetes receive their diabetes care in primary care settings rather than in a diabetes specialty clinic. Therefore, it is important that primary care providers have access to resources to support the adoption of AID technologies such as the Omnipod 5 System.

Advances in the past two decades in insulin formulation and insulin delivery technologies have greatly expanded treatment options for people with type 1 diabetes (1,2); however, treatment-related burdens are a significant barrier to diabetes self-care (3), and population-level improvement in glycemic control remains elusive (4).

Automated insulin delivery (AID) systems may hold promise for improving outcomes and reducing burden. These systems consist of an insulin pump, a continuous glucose monitoring (CGM) system, and a software algorithm that automatically calculates and delivers insulin based on real-time sensor glucose data, aiming to keep glucose levels at prespecified targets. This process differs from conventional insulin pump therapy (with or without concurrent use of CGM), in which insulin delivery is dictated solely by pre-programmed parameters (e.g., basal rates) and does not change unless users change it. In two meta-analyses of randomized, controlled trials with children and adults with type 1 diabetes (5,6), use of AID therapy, compared with conventional or nonautomated sensor-augmented pump (SAP) therapy, was found to increase glucose time in range (TIR), defined as the percentage of time between 70 and 180 mg/dL, by 11.1% ($P < 0.0001$, based on 22 trials) (5) and 8.5% (P not provided, based on 26 trials) (6). Furthermore, time spent in the hypoglycemic range (<70 mg/dL) was reduced by 1.9% ($P = 0.02$, based on 16 trials) (5) and 1.3% (P not provided, based on 24 trials) (6).

Current AID technologies are sometimes called hybrid closed-loop systems because they automate insulin delivery in response to real-time glycemic data, but users must still manually deliver bolus doses for carbohydrate consumption (7). Other advanced technologies are also available that contain algorithms that solely suspend pre-programmed insulin delivery to mitigate hypoglycemia (8–10). Although these are sometimes referred to as AID technologies, in this article, we use AID to refer only to systems with algorithms that calculate insulin doses and attempt to mitigate both

[1]Barbara Davis Center for Childhood Diabetes, University of Colorado, Aurora, CO; [2]Section of Pediatric Endocrinology, Yale School of Medicine, New Haven, CT; [3]Section of Pediatric Diabetes and Endocrinology, Baylor College of Medicine, Houston, TX; [4]Department of Pediatric Endocrinology, Stanford School of Medicine, Palo Alto, CA; [5]Upstate Medical University, Syracuse, NY; [6]Division of Endocrinology, Center for Diabetes Technology, University of Virginia, Charlottesville, VA; [7]Insulet Corp., Acton, MA

Corresponding author: Cari Berget, cari.berget@cuanschutz.edu

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hypoglycemia and hyperglycemia. Two AID systems—Medtronic's MiniMed 670G/770G (two models using the same algorithm) and Tandem Diabetes Care's t:slim X2 with Control-IQ technology (Control-IQ)—were introduced in the United States in 2017 and 2020, respectively (11–13). Two additional AID systems—CamDiab's CamAPS FX (14,15) and Diabeloop's Diabeloop Generation 1 (16,17)—are commercially available in Europe, but neither is currently under review by the U.S. Food and Drug Administration (FDA) or expected to become available soon in the United States. Another Medtronic AID system, the MiniMed 780G, was undergoing FDA review at the time of writing, as was the Omnipod 5 Automated Insulin Delivery System (Insulet Corp.).

With the first commercial AID system—the MiniMed 670G—barriers to use, including technical difficulties, intrusive alarms, and perceived high workload to maintain automation, hindered uptake (18–23). Therefore, ensuring that AID systems are not only effective in improving glycemia, but also easy to use is of utmost importance if people with diabetes are to realize glycemic benefits in the real world.

The Omnipod 5 System offers innovations that could help address barriers to AID therapy and reduce the overall burden of diabetes self-management (24). It consists of a wearable, tubeless, disposable insulin pump (Pod; Insulet Corp.) coupled with the Dexcom G6 CGM system (Dexcom). A model predictive control algorithm embedded in the Pod receives CGM data and computes how much insulin to deliver based on customizable glucose targets of 110–150 mg/dL that can be set for different times of day (24). Called the Omnipod Horizon Automated Glucose Control System during investigation, the Omnipod 5 System was evaluated in several early feasibility studies (25–28), as well as in more recent pre-pivotal (29) and pivotal (30) trials and was found to be safe and effective in increasing TIR and reducing hypoglycemia. Users interact with the Omnipod 5 System via a mobile application (app)on a manufacturer-provided controller or a compatible personal smartphone. The app is used primarily to activate the Pod, switch to the system's automated mode, deliver bolus doses, change glucose targets, and activate other features. Results of trials in people aged 6–70 years have been published (29,30), and trials are underway in children aged 2–5 years (NCT04476472) and individuals with type 2 diabetes (NCT04617795).

Although data from clinical trials are important to ensure safety and effectiveness, they do not prepare clinicians for implementing AID systems in clinical practice or provide insight into how best to train people with diabetes and their caregivers to use them. This article reviews the features of the Omnipod 5 System and how it compares to other AID systems available on or currently under review for the U.S. market and provides practical guidance, based on the authors' clinical and trial experience, for training and onboarding people with diabetes and using the system to personalize therapy and optimize glycemia. A comprehensive understanding of diabetes technology is important for all diabetes care providers. Because many individuals receive their diabetes care in primary care settings rather than in a diabetes specialty clinic, it is important that primary care providers, not only specialty endocrinology providers, have access to resources to support the adoption of AID technologies such as the Omnipod 5 System.

Comparison of AID Systems

The Omnipod 5 System is the first fully on-body AID system and the only one that can be fully operated with a compatible personal smartphone (Figure 1). The control algorithm is embedded in each Pod, and CGM data are transmitted directly to the Pod every 5 minutes for use by the algorithm in calculating insulin microboluses. As a result, the handheld controller or smartphone containing the app does not need to be near the Pod for on-body insulin automation to function once the Pod and CGM have been activated. The handheld controller does need to be within range of the Pod for the user to deliver bolus doses of insulin, view pump information, and receive notifications (24).

All AID systems contain algorithms that automate insulin delivery in response to CGM data. Although there are similarities in how these systems work, there are differences in insulin automation strategies and system features that have important implications for the clinical management of each device. The features of select AID systems that are commercially available or undergoing FDA review in the United States, including the Omnipod 5 System, the MiniMed 670G/770G, the MiniMed 780G, and the Control-IQ system, are compared in Table 1 (24,31–33).

Insulin Automation Strategies

The Omnipod 5 algorithm uses total daily insulin (TDI) delivery as the basis for insulin automation, similar to the MiniMed systems, which also use a TDI-based strategy to determine microbolus insulin delivery every 5 minutes. In contrast, the Control-IQ system automatically increases or decreases pre-programmed basal rates

FIGURE 1 Components of the Omnipod 5 AID system: (left) the tubeless Pod containing the AID algorithm; (center) the app, pictured running on a smartphone; and (right) the Dexcom G6 interoperable CGM sensor. The Pod is a lightweight, waterproof (IP28), self-adhesive insulin pump that delivers insulin via an automatically inserted cannula. The algorithm receives glucose measurements every 5 minutes from the on-body CGM sensor and engages the Pod to deliver microboluses every 5 minutes based on current and projected glucose levels, aiming for a set target glucose value in its calculations. Users interact with the system through the app, which communicates wirelessly with the Pod. Actions performed via the app include completing initial setup and programming pump settings, activating and deactivating Pods, starting automated mode, using the bolus calculator/delivering boluses, enabling the Activity feature, viewing insulin delivery and CGM history, responding to system alerts and alarms, checking Pod status, and adjusting pump parameters. The app home screen displays the current CGM value and trend, the amount of IOB, information about the most recent bolus, and a link to view a CGM history graph. The bolus calculator is accessed using the circular icon near the bottom of the screen. Because the algorithm runs on the Pod and the Pod and CGM are both worn on-body and communicate directly, AID can continue uninterrupted even if the handheld device containing the app is not nearby. Image used with permission. ©2020 Insulet Corp.

in response to CGM data, although it does use TDI to scale these adjustments. Understanding how the different AID systems calculate insulin delivery, including which parameters are fixed and which are modifiable, is important for all clinicians, as this knowledge informs device tuning and therapy optimization strategies.

With the Omnipod 5 System, TDI is used to determine an "adaptive basal rate" for each user, which serves as the baseline from which the algorithm adjusts insulin delivery. During onboarding, the system estimates a user's TDI based on the programmed total daily basal insulin. This estimate, along with safety constraints built into the system for initial use, allows users to activate automated mode immediately with the first active Pod. This process contrasts with the MiniMed AID systems, which must be operated in manual mode (conventional insulin delivery) for 48 hours before activating automation, and with the Control-IQ system, which requires users to manually input the initial TDI. The Omnipod 5 System tracks TDI and, with the first Pod change, begins using actual TDI to automate insulin delivery going forward. TDI is updated with each Pod change, permitting the system to adapt to users' insulin needs across time. With this TDI-based approach, changing a person's programmed basal rates has no impact on insulin delivery once established in automated mode. In contrast, adjusting programmed basal rates in the Control-IQ system is relevant, as its algorithm incorporates that rate when determining insulin doses.

In all AID systems, algorithms calculate insulin doses aiming for either a target glucose value or range. In the Omnipod 5 System, the algorithm targets a user-programmed glucose value between 110 and 150 mg/dL, in 10-mg/dL increments, with the option to program up to eight different targets throughout the day. The MiniMed 670G/770G algorithm uses a single nonadjustable glucose target of 120 mg/dL. With the MiniMed 780G, users can choose a glucose target of 100 or 120 mg/dL but cannot program different targets throughout the day. The Control-IQ system targets a nonadjustable glucose range of 112.5–160 mg/dL during standard operation, as opposed to a single glucose target.

System Features

Each system also contains features related to exercise, sleep, and/or safety constraints that may temporarily adjust these targets. The Omnipod 5 System's Activity feature is intended to reduce the amount of insulin delivered during exercise or at other times when reduced insulin delivery may be desired for a specified period of time (e.g., when a person is sick and/or not taking food by mouth). When activated, it uses the glucose target of 150 mg/dL and adjusts algorithm-modulated insulin delivery to be less aggressive for the duration of time programmed by the user. All MiniMed AID models and the Control-IQ system have similar features for exercise, referred to as Temp Target and Exercise Activity, respectively.

TABLE 1 Comparison of Select AID Systems in the United States (24,31–33)

AID System	Onboarding	AID Strategy	Automation Adaptivity	Adjustable Parameters	System Features
Insulet Omnipod 5 System,* automated mode	Automation begins with first Pod; maximum delivery is more constrained with first Pod for safety Estimates TDI based on the programmed total basal insulin	TDI-based insulin automation Adjustable glucose targets of 110–150 mg/dL in 10-mg/dL increments, personalized for different times of day	TDI updated with every Pod change (approximately every 72 hours)	ICR, ICF, glucose targets, duration of insulin action (DIA)	**Automated Mode: Limited:** Static basal rate determined by system without any adjustments based on CGM values; activates when CGM values are missing (e.g., during sensor warm-up) and resumes full automated mode automatically once CGM values return. **Activity:** Set for 1- to 24-hour duration, with glucose target of 150 mg/dL and reduced insulin delivery
Medtronic MiniMed 670G/770G,† auto mode	48-Hour warm-up period with insulin delivery in manual mode required before user can activate auto mode	TDI-based insulin automation Glucose target: 120 mg/dL; nonadjustable	TDI updated every 6 days at midnight	ICR, DIA	**Safe Basal:** Static basal rate determined by system without any adjustments based on CGM values **Temp Target:** Set for 2- to 12-hour duration with glucose target of 150 mg/dL
t:slim X2 with Control-IQ	Weight and TDI programmed into pump before activating automation; used at onboarding to initiate automation Programmed TDI used primarily for 2-hour maximum delivery constraints (50% TDI in 2-hour period) built into system for safety purposes	Adjusts pre-programmed basal rates Target glucose range: 112.5–160 mg/dL; nonadjustable Auto-correction boluses: maximum 1/hour only if there is no user-initiated bolus in the past hour; 60% of calculated correction dose using a fixed target of 110 mg/dL	Actual TDI tracked by algorithm and primarily used to scale basal adjustments	ICR, ICF, basal rates	**Sleep Activity:** Narrows target glucose range to 112.5–120 mg/dL with no automated correction boluses; can program a sleep schedule or start/stop manually **Exercise Activity:** Changes glucose target to 140–160 mg/dL; manual start/stop—cannot program a duration of use
Medtronic MiniMed 780G,* auto mode	48-hour warm-up period with insulin delivery in manual mode before user can activate auto mode	TDI-based insulin automation Glucose target: 100 or 120 mg/dL Auto-correction boluses: maximum every 5 minutes	TDI updated every 6 days at midnight	ICR, DIA, glucose target	**Safe Basal:** Static basal rate determined by system without any adjustments based on CGM values **Temp Target:** Set for 2- to 12-hour duration with glucose target of 150 mg/dL

*This system was not commercially available in the United States but was undergoing FDA review at the time of writing. †Both systems used the same AID algorithm.

Additionally, the Omnipod 5 and MiniMed systems have built-in safety modes of AID operation that are designed to automatically activate when CGM data are missing and/or constraints on minimum and maximum insulin delivery have been reached. In the Omnipod 5 System, when there is a loss of communication between the Pod and CGM sensor while in automated mode (e.g., during the 2-hour warm-up period when starting a new sensor), the system automatically enters "Automated Mode: Limited." When this occurs, the system no longer adjusts insulin delivery based on CGM data and instead delivers a static basal rate deemed safe by the algorithm based on user settings and recent insulin delivery history until the situation resolves (e.g., CGM communication resumes). There is no maximum duration for which the user may remain in Automated Mode: Limited. Of note, if insulin delivery is suspended at the time Automated Mode: Limited activates, it may remain suspended for a safe duration before the static basal rate begins. The system will resume full automated mode automatically when the CGM communication resumes. The system may also enter Automated Mode: Limited after receiving an alarm caused by minimum (e.g., insulin suspension) or maximum insulin delivery. The maximum period for insulin suspension or maximum insulin delivery is different for each user and based on individual insulin requirements and current and previous glucose values. In this instance, the Omnipod 5 System will switch from automated mode to Automated Mode: Limited before prompting users to switch to manual mode for at least 5 minutes, check their blood glucose by fingerstick to confirm CGM accuracy (although there is no requirement to enter that blood glucose result into the app), and troubleshoot potential infusion site issues before restarting automation.

The Automated Mode: Limited feature is similar to the Safe Basal feature in the MiniMed systems; however, the time constraints for minimum and maximum delivery are much longer in the Omnipod 5 System than in the MiniMed 670G/770G, making forced exits from automated mode rare. Also, Omnipod 5 System users are not required to enter fingerstick blood glucose values to return to automation, as is the case with all of the MiniMed AID models. There is no safety mode in the Control-IQ system when in AID operation. Instead, when CGM is unavailable for ≥20 minutes, the Control-IQ system reverts to manual mode and automatically resumes insulin automation when CGM becomes available.

Finally, all commercial AID systems are equipped with bolus calculators. Users can have the system suggest or can simply enter a bolus dose amount. The bolus calculator is programmed with personalized settings such as an insulin-to-carbohydrate ratio (ICR) and insulin correction factor (ICF; also known as insulin sensitivity factor). Users enter the grams of carbohydrates to be consumed and their current glucose level, and the bolus calculator determines the dose for them to deliver. The Omnipod 5 System's bolus calculator is unique in that it uses CGM trend information in addition to the CGM glucose value to calculate bolus doses. For example, a recommended bolus dose may be increased or decreased depending on whether the user's glucose trend is rising or falling, respectively. In all MiniMed AID models, the programmed ICF is used only for bolus calculations in manual mode. In auto mode, the system determines the ICF for each individual and does not use the programmed ICF for bolus calculations. The Omnipod 5 and Control-IQ systems use the programmed ICF when calculating user-initiated correction boluses via the bolus calculator in both automated and manual modes.

People Who May Benefit From AID

Most people with type 1 diabetes could benefit from AID therapy, but it is crucial to ensure that potential users have realistic expectations about what such systems can achieve. Individuals who are interested in insulin pump therapy and express trust in technological devices to manage their therapy are likely to do well with the Omnipod 5 System. Some authors have suggested that people with well-controlled diabetes (A1C <7% or TIR ≥70%), and particularly those reluctant to relinquish control of insulin delivery, may not be ideal candidates for any AID system (7). However, AID provides more than simply physiologic insulin replacement; it enables people with diabetes to achieve glycemic targets while minimizing hypoglycemia in a way that tends to lessen burden. Thus, it is feasible that anyone with insulin-treated diabetes could benefit from AID therapy.

In clinical trials, the Omnipod 5 System was found to be safe and effective across a diverse cohort of study participants (29,30). Key inclusion criteria were age 6–70 years, type 1 diabetes for ≥6 months, and an A1C <10%, with no specific requirements regarding TDI or body weight. Participants could be using any modality of insulin delivery at baseline (i.e., a multiple daily injection [MDI] regimen, a conventional insulin pump,

or another AID system). As is common in most AID system trials, potential participants were excluded for severe hypoglycemia or diabetic ketoacidosis (DKA) not caused by infusion set failure in the 6 months before enrollment, use of any noninsulin antidiabetic medication other than metformin, and pregnancy or lactation. When stratified by baseline A1C >8 or <8%, glycemic improvements were seen regardless of group, as evidenced by reductions in mean A1C and/or reduced hypoglycemic exposure in both age cohorts (6–13.9 and 14–70 years) (29,30). Although the Omnipod 5 System is under FDA review for use in people with type 1 diabetes aged 6–70 years, these attributes are likely to expand as ongoing trials in preschoolers with diabetes (2–5 years of age) and those with insulin-requiring type 2 diabetes are completed.

One additional technical requirement for using the Omnipod 5 System is the need to have a smartphone (iPhone or Android) on which to install the Dexcom G6 app. The Omnipod 5 app can be downloaded onto a compatible smartphone, or users may opt to use the manufacturer-provided controller with the app preloaded. However, individuals who do not have a compatible smartphone on which to use the Dexcom G6 app would not be able to operate the Omnipod 5 system in automated mode. The Dexcom G6 mobile app (not the Dexcom G6 receiver) is used to start CGM sensor sessions. Once the CGM sensor session is active on the G6 mobile app, the user connects the CGM to the Omnipod 5 system by entering the Dexcom transmitter serial number into the Omnipod 5 app to enable AID use. Once a sensor session is active and the CGM is connected to the Pod, CGM data will be displayed in the Omnipod 5 app. The sensor will communicate directly to the Pod to automate insulin delivery. However, users will need to keep the Dexcom G6 app within range to receive CGM alerts, if desired, as all CGM alarms originate from it. The Omnipod 5 System does include alerts for urgent low glucose (<55 mg/dL) that will sound even if the Dexcom G6 app is not within range.

Clinicians can facilitate success with the Omnipod 5 System for people with diabetes by taking steps before initiation to ensure that individuals are fully knowledgeable and prepared to use the system. Taking care to optimally program settings at therapy initiation is also important to appropriately activate the system for the first time. Fine-tuning settings and providing support and education in an ongoing manner will help to optimize therapy moving forward.

Preparing for Onboarding

Educating Users and Setting Expectations

Before onboarding people with diabetes to the Omnipod 5 System, it is beneficial to review basic diabetes self-management, insulin pump, and CGM education for all potential users regardless of previous experience. People planning to use the system should receive training on managing Pod infusion sites and a framework for troubleshooting persistent hyperglycemia, including checking ketones and changing Pods. Perhaps most importantly, potential users should have realistic expectations and be committed to carrying out the self-care tasks required for success.

Because mealtime insulin delivery is not automated, users should program and deliver bolus doses, ideally by using the bolus calculator, which will require them to estimate and enter the total grams of carbohydrates they will consume. Thus, a review of how to read Nutrition Facts labels on packaged foods and count carbohydrates in meals and snacks is important.

Troubleshooting Hyperglycemia and Infusion Site Failure

All insulin pump technologies rely on insulin infusing effectively through a small cannula inserted in the subcutaneous tissue. In the Omnipod 5 System, the infusion cannula is contained within the Pod and automatically inserted under the skin during Pod activation. Inserting the Pod in the same location repeatedly may result in accumulation of scar tissue (lipohypertrophy) and impair insulin absorption (34,35). Users should be educated to replace the Pod every 2–3 days and to rotate its placement on their arms, buttocks, abdomen, and legs in locations with sufficient subcutaneous tissue. They should avoid wearing the Pod in areas with skin scarring or irritation and should also avoid areas where skin creases or folds such as the waistline.

Although these measures will help to ensure adequate insulin absorption, infusion site failure may still occur and is a common problem with insulin pump use (36,37). Infusion site failure is characterized by hyperglycemia that persists despite increased insulin delivery. It may occur when a cannula becomes kinked, occluded, or dislodged or as a result of local inflammation at the infusion site, and it increases the risk of DKA. Thus, it is essential for people with diabetes and their caregivers to know how to troubleshoot hyperglycemia when using an insulin pump to prevent DKA.

With the Omnipod 5 System, if hyperglycemia (e.g., glucose >250 mg/dL) persists for >90–120 minutes after a user-initiated correction bolus, a Pod infusion site issue should be suspected, ketones should be checked to assess for DKA risk, and the Pod should be replaced. In some cases, if ketone levels are elevated, an injection of rapid-acting insulin should be given with a syringe or insulin pen before replacing the Pod, and glucose and ketone levels should be monitored every 1–2 hours until ketones return to normal levels. If insulin is given by syringe or pen, users should be advised that the algorithm will be unaware of the insulin on board (IOB; active insulin remaining from previously delivered insulin) from that injection. Therefore, clinicians might consider suggesting that users switch from automated mode to manual mode for 2–4 hours after delivering the injection (until the insulin from the injection is no longer active) before returning to automated mode, although this precaution may not always be necessary.

Ensuring Realistic Expectations

Setting realistic expectations before initiating AID therapy is especially important. Many individuals may expect an AID system to take over the entire insulin regimen for them (38–40), and this is not a realistic expectation of the Omnipod 5 System or any other commercially available AID system. Unrealistic expectations of technology can increase the likelihood of user dissatisfaction and therapy discontinuation, in addition to suboptimal glycemia (41–43). Users should expect to wear both a CGM sensor and Pod continuously to maximize time in automation and to bolus for meals. Clinicians should provide users with anticipatory guidance on the system's limitations and on potential problems such as infusion site failure, pump malfunction, and skin irritation (44). Users will also need to be prepared to respond to CGM alarms and manage situations such as a lost sensor signal.

Overall, people with diabetes must understand that AID will help them improve their overall glycemia but will not eliminate all hypo- and hyperglycemic excursions. Although these systems include glucose target values or ranges, helping people understand that the true goal is increased TIR is essential. Agreeing on an individualized TIR target will help them assess their success with the system and determine whether they should reach out to their clinician to optimize their settings. It is best to conceptualize AID as a tool to help improve diabetes management and reduce self-care burden, but not as a means of eliminating the need for self-care.

Finally, although patients need to understand when to intervene with manual boluses, clinicians should also discuss with users the need to learn to trust the system when using AID. Some people who are accustomed to closely controlling their own insulin delivery may need reassurance that the algorithm has been rigorously tested and was found to safely deliver insulin based on current glucose values and trends, while also taking into account factors such as IOB and patient-specific parameters.

Programming the System

The Omnipod 5 System can operate in manual mode as a conventional insulin pump or in automated mode as an AID system. Users can manually switch between automated and manual mode by simply toggling between modes in the main menu on the handheld controller. The mode of insulin delivery (manual or automated) is displayed in the top right corner of the home screen, making it clear which mode is active at any given time. Onboarding involves programming various parameters in the system's app. Although some of these parameters are only relevant when the system is operating in manual mode, most also have implications for automated mode (Table 2).

Generally, individuals with type 1 diabetes require 40–50% of their TDI as basal insulin and 50–60% as bolus insulin (45). Although programmed basal infusion rates are not used in automated mode, each user must set a basal program to be used if the pump is operating in manual mode and to initiate AID for the first time. When transitioning a patient from an MDI regimen to the Omnipod 5 System, clinicians may calculate an initial basal rate using the estimated TDI the patient currently receives. Commonly, 75–80% of the TDI a patient receives with MDI is used to estimate the starting basal rate (e.g., reduce TDI on MDI by 20–25%, then estimate the basal rate to equal ∼50% of the reduced TDI) (46). Rapid-acting insulin is generally more efficient than long-acting insulin; therefore, the user's TDI needs may be less on an insulin pump compared with MDI. Alternatively, clinicians may estimate TDI based on the patient's body weight; TDI generally ranges from 0.4 to 0.8 units/kg/day, with higher doses typically required during puberty or in individuals with obesity or a sedentary lifestyle. When starting automated mode for the first time, the algorithm estimates users' TDI based on their programmed basal

TABLE 2 Programmable Settings in the Omnipod 5 AID System

Parameter Name	Available Settings	Description	Implications for Automated Mode
Basal Program	Up to 24 segments per basal program, from 0 units/hour to user-set maximum basal rate in 0.05-unit/hour increments	In manual mode, the Pod will deliver basal insulin at the programmed rates.	The Basal Program is only used *once* when initiating therapy to estimate a user's TDI and determine an adaptive basal rate for AID. After the first Pod change, the algorithm uses actual TDI and updates TDI with each Pod change thereafter. The pre-programmed basal program is then irrelevant except in manual mode and has no further effect on automated delivery of insulin.
Target Glucose	Maximum of 8 segments per day from 110 to 150 mg/dL in 10-mg/dL increments	The Target Glucose is the glucose value the algorithm aims for when calculating insulin delivery and the value the bolus calculator aims for when calculating correction bolus doses.	Target Glucose is the primary parameter that affects automation. Insulin delivery will generally increase if glucose is predicted to rise above the target and decrease or suspend if glucose is predicted to fall below the target. If glucose is trending downward, insulin delivery may be decreased or suspended, even if the current glucose value is above target. If glucose is trending upward, insulin delivery may be increased, even if the current glucose value is below target.
Activity	Can be set for a duration of 1–24 hours	The Activity feature temporarily reduces AID. It may be used to reduce the amount of insulin delivered with exercise or in other situations in which hypoglycemia risk may be increased.	While Activity is enabled, the algorithm targets a glucose level of 150 mg/dL (instead of the programmed Target Glucose) and additionally reduces insulin delivery. To reduce insulin on board with exercise, it is best to turn on this feature 1–2 hours before the start of exercise. Keeping it activated for up to 12 hours after exercise may be useful if delayed hypoglycemia is a concern.
Duration of Insulin Action (DIA)	A single setting is programmed from 2–6 hours in 30-minute increments	This setting informs the pump how long a bolus is actively working to reduce glucose. It is used to calculate the IOB remaining from past meal and correction boluses.	The DIA programmed by users is only used to calculate IOB accrual from user-delivered boluses. This setting does not influence how IOB is calculated from AID; the algorithm uses its own method to determine IOB accrual from AID. When the algorithm increases insulin delivery in response to hyperglycemia, this insulin will factor into IOB and be subtracted from user-initiated boluses, in addition to the IOB from user-given boluses. As a result, correction boluses may be smaller than expected due to the additional IOB being taken into account from AID.
Correction Factor	Up to 8 segments per day of 1–400 mg/dL in 1-mg/dL increments	This setting informs the pump of the user's ICF—by how many mg/dL glucose is expected to drop from the delivery of 1 unit of insulin. It is used by the system's bolus calculator in calculating correction boluses.	The programmed ICF does not influence AID; it is only used for user-initiated correction boluses. This setting may need to be modified to improve the efficacy of user-initiated correction boluses when using the automated mode.
Insulin to Carb (IC) Ratio	Up to 8 segments per day of 1–150 g carbohydrate/unit of insulin in 0.1-g increments	This setting informs the bolus calculator of the user's ICR—how many grams of carbohydrate are covered by 1 unit of insulin. It is used by the bolus calculator to calculate mealtime boluses.	A user's ICR may need to be changed to optimize postprandial glucose control. Because the system reduces and/or suspends insulin delivery if glucose is trending down or below target, there is often little to no IOB leading up to mealtimes. With little IOB before meals, users may benefit from a stronger ICR when using an AID system compared with an MDI regimen or conventional pump therapy, in which static basal insulin infusion occurs regardless of glucose level, resulting in more pre-meal IOB.

Continued on p. 176 »

« Continued from p. 175

TABLE 2 Programmable Settings in the Omnipod 5 AID System *(Continued)*

Parameter Name	Available Settings	Description	Implications for Automated Mode
Correct Above	Up to 8 segments per day from target glucose level to 200 mg/dL in 1-mg/dL increments	This setting is the glucose level at which the bolus calculator may calculate a correction dose.	This value has no influence on AID. It may be adjusted to affect user-given correction boluses.
Minimum Glucose for Calc	50–70 mg/dL in 1-mg/dL increments	This setting defines a minimum glucose value at which the pump will allow use of the bolus calculator.	This setting has no influence on AID. It may be adjusted to ensure a safe glucose value when delivering a bolus.
Reverse Correction	On or off	When reverse correction is turned on, the bolus calculator will reduce the mealtime bolus amount when the current glucose value is below the target glucose.	When in automated mode, users may consider turning reverse correction off if glucose is often below their target at mealtime and they are experiencing post-meal hyperglycemia. Turning the reverse correction off will ensure that users receive their full bolus dose for carbohydrates.
Extended Bolus	On or off	Turning on this parameter will allow users to extend a bolus delivery over 0.5–8 hours when the pump is in manual mode.	Extended boluses are not available in automated mode even if the parameter is turned on in the pump settings. Extended boluses can only be given in manual mode.
Temp Basal	On or off	When turned on, this feature will allow users to program a temporary basal rate of delivery or to increase or decrease the programmed basal delivery by a percentage (0–100%) when in manual mode.	Temporary basal rates are not available in automated mode, even if this feature is turned on in the pump settings. Temporary basal rates can only be used in manual mode.
Maximum Bolus	0.05–30 units	This setting defines the upper limit for a bolus dose. The pump will not deliver more than the maximum bolus amount programmed by a user.	The Maximum Bolus setting has no influence on AID. It is only relevant for user-delivered bolus doses.
Maximum Basal Rate	0.05–30 units/hour	This setting defines the maximum basal rate the pump will allow in manual mode. Usually this is set to twice the highest user-programmed basal rate to allow for temporary basal rate increases as needed in manual mode.	The programmed Maximum Basal Rate has no impact on AID. The algorithm determines maximum delivery for each user when in automated mode.

rates. Therefore, when preparing to onboard someone who is not already on pump therapy, it is recommended to input a basal program that is equal to ∼50% of TDI, while still representing basal delivery that would be safe and effective in manual mode. For individuals transitioning from an alternative insulin pump to the Omnipod 5 System, basal settings may be transferred directly from the previous device, in most cases. However, clinicians should review historic insulin delivery (i.e., use of temporary basal rates) to assess each person's true basal insulin delivery and alter the programmed basal settings for the Omnipod 5 System as needed.

The system's Temp Basal feature, which allows users to temporarily change their basal insulin delivery for a defined duration, is only available in manual mode. When in automated mode, the algorithm automatically adjusts basal insulin based on CGM data. Other parameters that are only used in manual mode include the extended bolus and maximum basal rate settings. The latter influences the maximum basal delivery a user can program when in manual mode and has no impact on maximum delivery constraints in automated mode.

Users must also program bolus calculator settings, including their ICR, ICF, duration of insulin action, and target and "correct above" glucose values (the value above which the bolus calculator may calculate a correction dose). The bolus calculator uses these settings to determine mealtime boluses when total grams of carbohydrate are entered and correction boluses when a current glucose value is entered. These initial settings may be transferred from a user's prior regimen, in most cases, or may be estimated from TDI using established guidelines (e.g., the rule of 1,800 for ICF and the rule of 500 for ICR [47]). Importantly, users may benefit from stronger ICRs that will cover consumed carbohydrates with more insulin when using AID compared with MDI or nonautomated insulin pump therapy (48). The dynamic nature of AID often results in less IOB leading up to mealtimes than with nonautomated insulin delivery; therefore, a 10–25% increase in mealtime bolus insulin dose may help to optimize postprandial glucose control for some individuals, especially youths (48,49). However, adjustments to mealtime insulin doses should be tailored to each person, and bolus timing and insulin sensitivity should be considered.

In addition to their use in calculating correction boluses, the programmed target glucose values are also used by the algorithm in automated mode to calculate insulin delivery. Users can personalize their target settings between 110 and 150 mg/dL, in 10-mg/dL increments, throughout the day. Initial targets should be customized by evaluating users' current versus desired glycemic control, while balancing their TIR goal with their comfort level at a given target. In general, a lower target usually equates to more TIR and lower mean glucose, whereas a higher target equates to less TIR, higher mean glucose, and reduced hypoglycemia risk (29,30).

The system's Activity feature is only available in automated mode and can be enabled by users for times of increased hypoglycemia risk, such as during and after aerobic exercise or during illness. It is an optional feature, and its use is not required for automated mode to function. Clinicians may choose to address this feature at a follow-up visit rather than at the initial training to avoid information overload. For exercise, it is likely best to enable the Activity feature 1–2 hours in advance to reduce IOB when exercise begins. Users may also find it helpful to extend the duration for several hours after exercise, if delayed hypoglycemia is a concern.

Initiating Automated Mode

Once parameters are programmed, a Pod is activated, and an active CGM session is started, users are ready to switch on the system's automated mode in the app. With the first Pod, automated mode estimates TDI based on the user's basal program and operates under conservative maximum delivery constraints for safety. With the first Pod change, the algorithm uses actual TDI and is less constrained in maximum delivery, and thereafter the user's TDI is updated with each subsequent Pod change. Given the adaptive nature of the Omnipod 5 System, it is important to explain to users that their glycemic control will improve across time and that it may take a few days to a few weeks for the system to optimize insulin delivery as it adapts to their TDI. As with other AID systems, clinicians should review users' glucose data and insulin delivery within the first few weeks of use to assess whether any parameters (e.g., ICR, ICF, and glucose targets) should be altered to optimize TIR.

Adjusting Parameters With Continued Use

Although the Omnipod 5 System's algorithm was shown in the pivotal trial to be adept at optimizing TIR and reducing hypoglycemia risk (30), the diabetes care team continues to play an important role in educating people with diabetes and personalizing their insulin therapy. Below, we present several vignettes of common clinical scenarios in which therapeutic modifications to address specific issues can help to optimize AID therapy.

Addressing Post-Meal Glucose Excursions

Vignette 1

Teresa is a 16-year-old girl with type 1 diabetes. She is independent in her diabetes self-care but has a history of missing mealtime boluses, which has hindered her achievement of glycemic targets. Using the Omnipod 5 System, her TIR has improved compared with her previous SAP therapy regimen but is still just 50%. She is experiencing persistent hyperglycemia after meals, and her pump report indicates that she is delivering, on average, only 1.5 meal boluses per day.

Therapy Adjustments

Although the system's algorithm will increase insulin delivery with rising glucose levels, this automated response is not sufficient to fully counter post-meal glucose excursions. Thus, Teresa still needs to bolus before eating to reduce postprandial hyperglycemia and increase her TIR. Given her propensity for missing boluses, the clinician believes she would benefit from more parental involvement. The clinician explains to Teresa and her parents the importance of continuing to deliver mealtime boluses when using an AID system and facilitates collaborative problem-solving to identify strategies to increase bolus consistency that involve parental support and shared responsibility.

Vignette 2

Devon is an 8-year-old boy who was diagnosed with type 1 diabetes 4 years ago and recently transitioned from SAP therapy to the Omnipod 5 System. His glucose values have been stable overnight, with levels of 90–110 mg/dL upon waking most mornings. However, he is experiencing significant glycemic variability after breakfast, including hyperglycemia 1–2 hours post-meal and hypoglycemia another 1–2 hours later, after receiving a correction bolus. His mother, Janet, reports bolusing every morning when Devon starts to eat breakfast. She is concerned that the AID algorithm is not aggressive enough in response to hyperglycemia and reports frequently overriding the bolus calculator for correction doses to try to bring his glucose values back into range.

Therapy Adjustments

With the Omnipod 5 System, insulin delivery is often suspended if glucose levels are trending down or below the glucose target. This is the case with Devon in the early-morning hours, resulting in minimal IOB leading up to breakfast and making bolus timing crucial for managing post-meal glycemic excursions. The clinician advises bolusing 15–20 minutes before breakfast instead of at the start of the meal to ensure that the bolus insulin is active when Devon starts to eat to mitigate the sharp rise in glucose that he has been experiencing postprandially.

The AID system increases insulin delivery in response to hyperglycemia, resulting in additional IOB, which has been occurring with Devon after breakfast. To help prevent hypoglycemia, this IOB is subtracted from correction bolus calculations. However, Janet has been overriding the bolus calculator to deliver a correction dose similar to what she would have given him when using SAP therapy, and that is causing hypoglycemia. Explaining that correction bolus calculations on this system may be smaller than Janet expects because of the automated delivery of insulin and advising her to trust the system and follow the bolus calculator recommendations will likely help to prevent hypoglycemia.

Vignette 3

James is a 37-year-old man who has been using the Omnipod 5 System for 1 month. He is doing well, with glucose levels usually at target before meals. However, he is experiencing post-meal hyperglycemia that persists for 2–3 hours after eating, despite the fact that he is giving meal boluses 15–20 minutes before eating. James is wondering how to improve his glycemia after meals.

Therapy Adjustments

As previously mentioned, the Omnipod 5 System reduces and/or suspends insulin delivery if glucose is trending down or below target, resulting in little IOB leading up to mealtimes. As a result, many individuals may need stronger ICRs with AID therapy compared with nonautomated insulin delivery regimens (48). James' clinician explains this and recommends strengthening his ICR by 10–20% (e.g., changing the ICR from 20 to 18) to improve post-meal glycemia. The clinician also recommends turning off James' reverse correction setting. This will enable the bolus calculator to deliver a full meal bolus, even if the glucose level is below the target.

Maximizing Nighttime TIR

Vignette 4

Kristi is a 7-year-old girl with type 1 diabetes, who was diagnosed at 2 years of age and is transitioning from SAP therapy to the Omnipod 5 System. Two years ago, she experienced a severe hypoglycemic event, resulting in a seizure while she was sleeping; since then, her

family has been fearful of nocturnal hypoglycemia. To allay their fear, they have adopted a strategy of permissive hyperglycemia, keeping Kristi's glucose values between 180 and 250 mg/dL overnight. At bedtime, she eats a snack without insulin if her glucose is <180 mg/dL, and after she falls asleep, her caregivers wake her up to give her fast-acting carbohydrates if her glucose drops to <120 mg/dL.

Therapy Adjustments

Given Kristi's history of severe hypoglycemia at night, it may be helpful to set the nighttime target (9:00 p.m. to 7:00 a.m.) to 150 mg/dL when initiating the Omnipod 5 System. As the family adapts to and learns to trust the algorithm, the clinician may consider slowly lowering the nighttime target to 140, 130, 120, or 110 mg/dL. The system will reduce or suspend insulin delivery when glucose values are dropping to help prevent hypoglycemia. Therefore, as the family becomes more comfortable, the provider may counsel them to avoid giving extra carbohydrates at bedtime unless Kristi's glucose is in a lower range (e.g., <90 mg/dL) and avoid fast-acting carbohydrate treatment overnight unless her glucose is <70 mg/dL. When making these incremental changes, the clinician must balance Kristi's risk and her caregivers' fear of hypoglycemia with the benefit of increased overnight TIR and improved user/caregiver quality of life.

Vignette 5

Maria is a 60-year-old woman who has had type 1 diabetes for 50 years. She has had hypoglycemia unawareness for several years, putting her at risk for severe hypoglycemia. She is also hard of hearing and often does not wake up to her CGM alerts overnight. Maria's doctor would like her glucose levels to be 130–180 mg/dL overnight to reduce her risk of hypoglycemia. During the daytime, Maria would like more aggressive glycemic management than during the nighttime.

Therapy Adjustments

The Omnipod 5 System allows users to personalize their insulin delivery by choosing the target glucose value the algorithm aims for when automating insulin delivery. Because of Maria's hypoglycemia unawareness and concern about not waking to alarms overnight, her physician sets her overnight glucose target to 150 mg/dL to provide more protection against nocturnal hypoglycemia. During the day, Maria's physician sets the target lower, to 120 mg/dL. The clinician knows she can set different target glucose values for specific times of day to optimize glycemia. Therefore, she explains to Maria that these targets can be adjusted as needed across time to meet her personal diabetes management goals.

Approaching Exercise

Vignette 6

John is a 27-year-old man with longstanding type 1 diabetes who is using the Omnipod 5 System. He recently began training for a triathlon. He has been using the Activity feature during training, which has helped him manage his glycemia during exercise, but has been experiencing nocturnal hypoglycemia. He wakes up to his alerts and treats the hypoglycemia but asks for advice on preventing this problem.

Therapy Adjustments

The clinician explains that John's nighttime hypoglycemia is most likely related to his increased physical activity, which can boost insulin sensitivity for 12–18 hours or longer post-exercise. Strategies to mitigate nocturnal hypoglycemia after exercise include raising the glucose target from 110 to 130, 140, or 150 mg/dL overnight; keeping the Activity feature enabled overnight after intense training days; and eating a small bedtime snack with ~15 g complex carbohydrates and protein (with no bolus) after afternoon or evening exercise sessions.

Vignette 7

Aaron is a 14-year-old boy with growing independence in his glucose management. An avid athlete, he gets 2 hours of aerobic exercise at practices 5 days per week. He remembers to enable the Activity feature on his Omnipod 5 System 1–2 hours before each practice. He also eats a bagel or similarly high-carbohydrate snack just before taking the field. Despite these preventive actions, he still experiences hypoglycemia during practice and frequently has to stop and treat with fast-acting carbohydrates. His parents are concerned that the Activity feature has not prevented hypoglycemia and worry that it will be more difficult for him to compete at the level of physical performance required for high school athletics.

Therapy Adjustments

When reviewing data from pump downloads, the clinician notices that Aaron boluses for each of his pre-exercise snacks. The clinician points out that these boluses are directly countering the system's efforts to decrease IOB. The bolus associated with each snack is equal to roughly

4 hours of standard basal delivery, an amount of IOB that the Activity feature is unable to compensate for during exercise.

Strategies to mitigate exercise-induced hypoglycemia include enabling the Activity feature 1–2 hours before activity, as Aaron has been doing, and also ensuring that there is minimal IOB from user-given boluses. Depending on the expected intensity or duration of the planned aerobic exercise, the clinician advises Aaron to reduce the size of his pre-exercise snack bolus by 20–50% or to omit the bolus altogether, if necessary. If his pre-exercise glucose is <120–150 mg/dL, the clinician advises him to consume 15 g fast-acting carbohydrates at the start of exercise, without a bolus, to help prevent hypoglycemia.

Vignette 8

Michelle is a 45-year-old woman using the Omnipod 5 System who takes brisk walks for exercise two to three times per week and attends a strength training class two times per week. She enables the Activity feature 1–2 hours before each walk and workout but has had inconsistent results. Her glucose is generally stable after walks, but she has had a consistent pattern of hyperglycemia after strength training.

Therapy Adjustments

Different forms of exercise affect glucose management differently. The Activity feature works well for aerobic exercise, during which reduced insulin delivery may help reduce the risk of hypoglycemia, but it may not be necessary for anaerobic exercise, during which counter-regulatory hormones may cause hyperglycemia. Michelle's clinician discusses the different types of exercise with her and advises that she continue using this feature for her walks but stop using it during her strength training classes.

These clinical scenarios illustrate the importance of diabetes education and personalization of therapy to optimize outcomes for individuals with type 1 diabetes. By educating people with diabetes on key self-care behaviors and modifying system parameters, clinicians can help them increase TIR while reducing their burden of care.

Providing Ongoing Support and Education: Lessons From the Pivotal Trial

Even after individuals gain confidence in using the Omnipod 5 System, they will still look to their diabetes care providers for ongoing support as they encounter new situations and likely will also need continuing education and review of basic information about how the system operates.

Revisiting Expectations

Although candidates for the Omnipod 5 System should have realistic expectations before starting therapy, people with diabetes and caregivers may sometimes need reminding that AID therapy is not a "set-it-and-forget-it" proposition, and their active involvement is still required. Conversely, some may find it more challenging than they imagined to relinquish control over any part of their insulin delivery. In either case, clinicians should review the importance of allowing the algorithm to determine their insulin needs over time and of continuing to administer their own mealtime doses (guided by the bolus calculator).

Troubleshooting Forced Exits From Automated Mode

Improvements in glycemia directly correlate to the amount of time spent in automated mode when using an AID system (50). Therefore, helping people with diabetes maximize the amount of time in automated mode is key to achieving successful outcomes. In the Omnipod 5 pivotal trial (30), the percentage of time spent in automated mode was among the highest of any commercial AID system trials to date. Children spent a median of 96.4% (interquartile range [IQR] 93.8–97.7%), and adults spent a median of 96.7% (IQR 93.4–98.0%) of total study time in automated mode (mean ± SD 95.2 ± 4.0% and 94.8 ± 6.0% of time in children and adults, respectively) (30,51–56). This high use of automated mode is encouraging, as it suggests that users did not experience many obstacles to sustaining automated mode use over the 3-month trial period. An active Pod and CGM sensor are all that is required to activate and sustain automated mode in the Omnipod 5 system. Additionally, the system's minimum and maximum delivery constraints, which apply different logic than those of the MiniMed 670G/770G models, result in very few system exits from automated mode, and use of the factory-calibrated Dexcom G6 CGM system eliminates the need for user calibration to maintain automated mode function.

If users are consistently wearing their CGM sensor, forced exits from automated mode are rare, and their causes are few. If automated mode has been maintained at maximum delivery or suspended for an excessive

period of time, the system will revert to manual mode to ensure user safety. For exits that occur when maximum delivery is exceeded, basic pump troubleshooting is recommended (e.g., ensuring that the Pod is securely adhered to skin, checking for insulin leaking from the Pod site, and checking ketones). If no problem is found, a correction bolus should be delivered, and automated mode should be immediately restarted. For exits that occur because of prolonged insulin suspension, users should check their blood glucose with a glucose meter to ensure that CGM is accurate, after which automated mode can be resumed. If the CGM is not accurate, the CGM system should be calibrated to ensure safe insulin delivery, and automated mode should be resumed once CGM accuracy is confirmed.

As previously mentioned, one unique feature of the Omnipod 5 System is that the Pod and the Dexcom G6 app each receive data directly from the CGM sensor. Poor communication between the Pod and the sensor could result in the system switching from full automated mode to Automated Mode: Limited for safety. Both devices should be on the same plane of the body (i.e., within the same line of sight) to help ensure optimal communication between the CGM and the Pod. Having one device on the buttocks and the other on the front of the thigh or one on the stomach and the other on the buttocks may hinder communication, as this would require communication through the body. Educating users about recommended device proximity can help to optimize device communication.

Abandoning Preconceptions

Participants in the Omnipod 5 pivotal trial were representative of AID system users previously described by Boughton et al. (57). As these authors noted, some individuals who clinicians initially thought would be the most comfortable with AID were actually more likely to interfere with their system's functioning, whereas others who were predicted to have more challenges fared better because they refrained from interfering with the automated process. Thus, it may be wise to disregard preconceptions about which individuals or families may or may not adapt well to AID therapy and instead consider it for any interested individual who may benefit from improved glycemia and has had sufficient self-care education.

With time, individuals who struggle to trust the system usually become more comfortable, and most users easily adapt to the technology from the outset. One 6-year-old girl who had been using an MDI regimen and a Dexcom G6 CGM system before enrollment in the pivotal trial had rare hypoglycemia and TIR of 24% despite her parents' exemplary dose calculations and delivery. By trial completion, she still had rare hypoglycemia, but her TIR had improved to 70% with the Omnipod 5 System. Another participant was a 70-year-old woman who had previously used SAP therapy with Medtronic insulin pump and CGM systems and was diligent with self-management. However, even with the hypoglycemia prevention features on her pump enabled, she experienced hypoglycemia 5% of the time and had a TIR of 69% before enrolling. After more than 1 year with the Omnipod 5 System, she had 0% hypoglycemia and a TIR of 76%. Although these are just two examples, they are representative of findings in the pivotal trial—specifically, that trial participants from all age-groups and with varying circumstances experienced improvements in glycemic control and satisfaction with the system.

Summary

The Omnipod 5 System, the first fully on-body AID system, offers several features not commercially available in the United States for intensive insulin management in people with diabetes. Undergoing review for FDA clearance at the time of writing, it is the only AID system that can be fully operated from a compatible smartphone app and the only one with which users can set different glucose targets between 110 to 150 mg/dL for different times of day. Furthermore, the system distinguishes itself from others by factoring in glucose trend as well as current glucose value when calculating bolus doses. Clinicians can lay the groundwork for success with the system by helping users set realistic expectations, ensuring that they receive the necessary education, and appropriately programming the system before initiation. After implementation, modifying parameter settings to fine-tune insulin delivery and providing ongoing support will further personalize therapy to improve glycemic management and health outcomes.

NOTE ADDED IN PROOF

Between initial publication of this article online and its publication in print, the U.S. Food and Drug Administration cleared the Omnipod 5 AID System for use in the United States but required a change in the name and description of one system feature. The authors therefore requested several revisions that were made to the online version and are also reflected here. The revisions were as follows:

- The feature originally called "HypoProtect" is now called "Activity," and its description now reflects its function in reducing the amount of insulin delivered rather than specifically in preventing hypoglycemia.

- The Activity feature is now referred to as being "enabled" rather than "activated."
- Mentions of "blood glucose" have been changed to "glucose" except when referring specifically to fingerstick glucose measurements.

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AUTHOR CONTRIBUTIONS

C.B. wrote the manuscript. D.J.D., R.S.K., and S.L.S. contributed to select sections of the manuscript. All authors reviewed and edited the manuscript. C.B. is the guarantor of this work and, as such, had full access to all the data reported and takes responsibility for the integrity of the article content.

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