



# Automated Insulin Delivery: Easy Enough to Use in Primary Care?

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There are three automated insulin delivery devices on the U.S. market, two of which are currently approved by the U.S. Food and Drug Administration. These systems have already made a significant impact for the people who use them in improving diabetes outcomes, including glycemic control and hypoglycemia prevention. This article aims to help primary care and endocrinology providers better understand the components, differences, limitations, and potential fit of these systems into clinical practice.

Diabetes is a disease of many paradoxes or tensions. Many of these issues have not been solved by technology or modern medicine, but when it comes to type 1 diabetes, the tide has turned.

Historically, managing diabetes with insulin has involved achieving a fine balance between the acute risk of severe hypoglycemic episodes (and even death) and the longer-term risk of hyperglycemia. Hyperglycemia was only hypothesized to cause long-term complications until that assumption was confirmed by the Diabetes Control and Complications Trial (DCCT) (1) for type 1 diabetes and by the U.K. Prospective Diabetes Study (2) for type 2 diabetes. It is not surprising that this great tension could cause concern and procrastination with regard to tight glycemic management among people with diabetes (PWD), who could not fine-tune their insulin regimen well enough to ensure both glycemic control and safety.

The long-term follow-up DCCT/Epidemiology of Diabetes Interventions and Complications trial (3) revealed the true inverse relationship between A1C and hypoglycemia rates for people with type 1 diabetes. Not so long ago, PWD had to rely on inconsistently absorbed insulin formulations that also likely raised the risk of hypoglycemia. There

was often poor access to and adherence with painful fingerstick blood glucose testing, as well. Exercise and regular physical activity (which has always been recommended in the treatment of diabetes) further escalated the risk for hypoglycemia. It is not difficult to see how these contradictory and competing factors could divide PWD not only from their own disease management, but also from the health care professionals who insisted that they achieve tight glycemic control.

Thankfully, much has changed in recent decades. We now have better insulins with more consistent absorption (including peakless basal insulins), insulin pumps, continuous glucose monitoring (CGM) systems, and, more recently, even algorithms that tie these devices together to achieve automated insulin delivery (AID). Many more PWD have access to these technologies than ever before. However, despite all of these improvements, data from the T1D Exchange clinic registry have not shown much (if any) A1C improvement over time at a population level. These data have shown that only 21% of adults with type 1 diabetes reached the American Diabetes Association general A1C goal of <7% between 2016 and 2018 (4), and only 37% of adults reached an A1C <7.5%. These findings were similar to those for the years between 2010 and 2012. Findings from the T1D Exchange also showed worse A1C control in adolescents and young adults in the 2016–2018 time period compared with 2010–2012 (5). However, many studies have demonstrated improvements in quality of life and decreased hypoglycemia among PWD using newer technologies (6,7). The hope is that devices with AID will finally help more PWD attain recommended A1C levels without increasing their risk of hypoglycemia.

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It is our goal to review the emerging technology of AID, explore its potential to solve some of the tensions and paradoxes described above, and discuss how it may fit into the primary care setting. We also review the currently available AID systems on the market and the limitations of their use and highlight exciting future technologies.

## Components of AID

The components that comprise an AID system include continuous subcutaneous insulin infusion via an insulin pump, a CGM system, a rapid-acting insulin analog, and an algorithm (or program) that automates the pump's delivery of the insulin based on CGM data.

### Insulin Pumps

Insulin pumps infuse rapid-acting insulin through a small subcutaneous infusion set that PWD can easily place at an appropriate infusion site approximately every 3 days. Most insulin pumps on the market deliver variable basal infusion rates that can be tuned according to a specific user's basal insulin requirements. Many PWD have a diurnal insulin response in which they consistently require less basal insulin overnight and more around dawn than during the remaining daytime hours (8). The ability to temporarily increase or decrease basal insulin delivery for illness or increased physical activity is another important attribute of pump therapy.

Bolus insulin is delivered in a pump therapy regimen at the push of a button, both preventively before meals based on estimated carbohydrate intake and correctively for high blood glucose values. Bolus calculators help determine appropriate bolus insulin doses based on the quantity of carbohydrates they will consume, their current blood glucose value, and their insulin on board (amount of active insulin remaining from their previous bolus dose). Mealtime bolus doses are based on a user's individualized insulin-to-carbohydrate (I:C) ratio. One common I:C ratio is 1:10, or 1 unit of insulin for every 10 g carbohydrate to be consumed. Corrective bolus doses are based on a person's insulin sensitivity factor (ISF), sometimes called a correction factor, which is individualized to attain the person's specific glucose target range. An ISF of 35, for example, means that 1 unit of insulin will lower blood glucose by 35 mg/dL. If a person's current glucose level was 190 mg/dL, with a glucose target of 120 mg/dL, and her ISF was 35, she would need to add 2 units of insulin to reduce her glucose by 70 mg/dL to reach the 120 mg/dL target. Individualized I:C ratios, ISFs, and glucose targets can be programmed into an insulin pump to account for variable insulin requirements throughout each 24-hour

period. Basal insulin infusion rates, I:C ratios, and ISFs are determined largely based on each person's body weight and total daily insulin requirements (9). PWD who perform fingerstick blood glucose monitoring (BGM) or use a CGM system also generally adapt rapidly to fine-tuning their basal rates and bolus factors based on glucose data and trial and error.

Commercially available insulin pumps that offer AID, described in more detail later, include Medtronic's MiniMed 670G with SmartGuard technology and Tandem's t:slim X2 pump with Control IQ technology.

### CGM Systems

Available CGM systems fall into one of two categories: those that are intermittently scanned to provide glucose data on demand or those providing real-time data every few minutes around the clock. Real-time sensors continuously read and display glucose levels and issue alerts for high and low levels. These include the Medtronic Guardian Sensor 3 (used as a stand-alone device or integrated with the MiniMed 670G insulin pump) and the Dexcom G6 (used as a stand-alone device or integrated with the t:slim X2 pump) and are the sensors currently used in commercially available AID systems. Senseonics' Eversense 90-day implantable real-time sensor is not integrated in any of the available AID systems. Abbott's FreeStyle Libre is an intermittently scanned CGM device that only displays blood glucose when scanned by the user and has recently added real-time optional alarms for high and low glucose in the FreeStyle Libre 2 system. This system is also not integrated into any currently approved AID system.

Both the Dexcom G6 and the FreeStyle Libre CGM systems have been approved by the U.S. Food and Drug Administration (FDA) for "nonadjunctive insulin dosing" (i.e., their results do not require verification via fingerstick BGM before adjusting insulin doses), and neither one requires calibration via fingerstick BGM (i.e., they are "factory calibrated"). This nonadjunctive insulin dosing indication, in part, is why Medicare covers these two devices for insulin-requiring people with type 2 diabetes with proper documentation (see details online at <https://www.medicare.gov>). By comparison, the Medtronic's Guardian Sensor 3 and Eversense CGM sensors require 2 or more calibrations/day via fingerstick BGM to continue function.

Importantly, there is a physiologic delay between capillary (fingerstick) BGM and interstitial glucose (CGM) values that is most evident when glycemic levels are changing at a rapid rate (10,11). There is also an algorithmic delay that is based on how often a given CGM device reports blood

glucose levels. These two factors sometimes confuse health care providers and PWD, who may incorrectly view this lag time as inaccuracy.

An important concept born of the development and use of CGM is that of time in range (TIR). Generally, TIR is considered the percentage of time a person's glucose remains between 70 and 180 mg/dL (12). This metric is difficult to estimate with fingerstick BGM alone, but with CGM data, it is reported as the percentage of values that fall within that range. Whereas A1C can only give an indication of average glucose within the past 3 months, TIR better reflects extremes of glycemia (i.e., glycemic variability from hour to hour and day to day) that have been shown in many studies to be deleterious (13). TIR has also become a key metric for demonstrating the successful performance of AID devices.

### Insulin

The rapid-acting insulins currently indicated for use in insulin pumps are lispro (Humalog and Admelog), aspart (Novolog), fast-acting aspart (FiAsp), and glulisine (Apidra). However, fast-acting aspart and glulisine are not currently recommended for use in Tandem insulin pumps because of a lack of studies and the potential for crystallization (and thus “no delivery” errors) with these insulins (14).

### Algorithm

The use of a nonautomated insulin pump with a CGM system is referred to as sensor-augmented pump (SAP) therapy. In SAP regimens, the human brain acts as the “algorithm” to control insulin dosing. Although this strategy has led to significant improvements in the management of type 1 diabetes compared with fingerstick BGM (15), there are still limitations to SAP therapy. AID systems seek to address these limitations by using specific algorithms to automate the delivery of insulin based on CGM data.

In the currently available AID systems, integration takes place between the pump and CGM device and mostly allows for the automatic modification of basal insulin delivery to prevent out-of-range high and low blood glucose levels. These AID systems do not meaningfully account for insulin required for food and thus still require users to manually input information for mealtime boluses, preferably timed to occur 10–15 minutes before meals. Nonetheless, it is likely that, even with an inaccurate mealtime bolus dose, automated postmeal basal rate modifications based on CGM data and individualized glycemic targets will decrease the likelihood of prolonged

hyperglycemia or hypoglycemia. The t:slim X2 pump with Control IQ AID system can also deliver automatic correction bolus doses to correct blood glucose values predicted to be or already exceeding 180 mg/dL (16). It is also reasonable to expect that these systems help to address the delayed glycemic effect of larger mixed meals that contain large amounts of carbohydrate, fat, and protein, for which adequate insulin may not be delivered from an initial mealtime bolus dose.

Because of their inability to administer mealtime insulin bolus doses, the current AID systems are considered to have “partial closed-loop” or “hybrid closed-loop” functionality. Full AID (or “fully closed-loop”) systems that account reasonably well for insulin required to prevent food-related hyperglycemia, remain a hope for the future, the realization of which is hindered by delays in absorption through the skin with current rapid-acting analog insulins. Manufacturers who are able to overcome these limitations would be able to make a more credible claim to be considered a true “artificial pancreas.”

### Currently Available AID Systems

As previously mentioned, systems that currently offer AID are the MiniMed 670G with SmartGuard technology and the t:slim X2 with Control IQ technology. Additionally, Medtronic's predecessor pump (the MiniMed 630G) and Tandem's earlier t:slim X2 Basal-IQ algorithm offer the ability to suspend basal insulin infusion in response to low or impending low glucose levels and are also integrated with their respective CGM systems. Do-it-yourself (DIY) systems that use open-source algorithm programming also exist but do not have FDA approval. In the sections below, we will briefly describe these individual systems, including their advantages and limitations, functionality, and approval status.

#### Medtronic MiniMed 670G With SmartGuard

The MiniMed 670G system was the first available hybrid closed-loop system, approved by the FDA in September 2016 for PWD  $\geq 14$  years of age (17). As such, this system is fairly conservative in its programming to automate insulin delivery and prevent hypoglycemia. It uses a sensor that must be calibrated at least twice daily for continued operation, can last 7 days, but ironically has not been approved for nonadjuvant insulin dosing based on sensor results alone. For this reason, this system is not yet covered by Medicare. Nonetheless, the pump is FDA-approved to automate basal insulin delivery based on the CGM sensor data.

This system runs in either “manual” or “auto” mode. Manual mode is similar to SAP therapy but allows some integration to automatically suspend basal delivery in response to low or impending low glucose levels. The manual mode otherwise requires (and allows for) typical conventional programming of basal infusion rates and bolus doses to meet users’ individual needs without automation to correct hyperglycemia. The auto mode functions more as a hybrid closed-loop system. In this mode, the system increases, decreases, or stops basal insulin delivery automatically in response to sensor glucose readings to attain a target of 120 mg/dL. A temporary target of 150 mg/dL can be programmed before exercise to help the system adjust infusion to avoid activity-related hypoglycemia. Preprogrammed or user-predetermined basal and correction bolus rates are not used during auto mode. However, predetermined or preferred I:C ratios are used in auto mode. In fact, after a meal bolus, basal insulin is significantly suppressed in auto mode, so meal bolus ratios often need to be significantly increased (more insulin to cover a given number of carbohydrate grams) to compensate and prevent post-meal hyperglycemia (18). Correction boluses are modified by internal programming to a target of 150 mg/dL. The system’s user guide provides more details (19).

A nonrandomized but pivotal trial that led to approval of the MiniMed 670G system involved 124 adolescents and adults and compared baseline data to 3 months on a hybrid closed-loop (AID) system with a proprietary algorithm. It found on average a 0.5% reduction in A1C (with those with higher baseline A1C values benefitting the most), a 44% reduction in time spent with blood glucose <70 mg/dL, a 40% decline in time spent in dangerous hypoglycemia (<50 mg/dL), and an 11% decline in time spent with glucose >180 mg/dL. There was an 8% improvement (from 67 to 72%) in TIR (70–180 mg/dL), which translated to nearly 2 hours more TIR per day on average (20).

### *Tandem t:slim X2 With Control IQ*

The next commercial AID to the U.S. market was the Tandem t:slim X2 with Control-IQ, which is an automated insulin pump using the Dexcom G6 sensor. This sensor has been approved by the FDA for nonadjuvant insulin dosing, is factory calibrated, and lasts for 10 days. Unlike the MiniMed 670G, this system can be updated via software uploads, still allows users’ individual preprogrammed/preferred basal rates and bolus doses for meals and corrections (adding yet another level of control over insulin delivery beyond its automated capabilities), and has automated correctional insulin capabilities. Control-IQ technology adjusts insulin delivery in several ways. The

system can decrease or suspend insulin delivery when predicted glucose values are below target, increase insulin delivery when predicted glucose values are above target, and automatically deliver up to 60% of a correction bolus dose once per hour as needed (16). The preset target for correction is 110 mg/dL. Activity override functionality allows users to use a “sleep” feature, which allows the basal algorithm to be more aggressive, and an “exercise” feature, which does the opposite.

In a pivotal randomized, 6-month trial of this hybrid closed-loop system, 168 PWD were followed on the t:slim X2 insulin pump with Control-IQ technology (AID) compared with t:slim X2 pump and CGM without Control-IQ (SAP). TIR for the AID arm was 71% versus 59% in the SAP arm. During the overnight period, TIR in the AID group was 76% compared with 59% in the SAP group. Mean A1C reduction in the AID arm was 0.3% lower. Despite overall study groups having only about 2% hypoglycemia (<70 mg/dL), those on the AID system spent 13 fewer minutes per day in hypoglycemia. Notably, TIR improved at all baseline A1C levels. In a patient questionnaire at the end of the study, participants gave the AID system high ratings for usability (21).

During Tandem’s first quarter 2020 earnings call, the company revealed that >30,000 PWD had updated their previous t:slim pump to the Control-IQ technology, 15,000 new pumps were shipped, and 90% of the Tandem pumps currently in use are software updatable through a computer upload (22).

### *DIY AID Systems*

DIY AID systems are developed by a community of people living with diabetes and their caregivers using an open-source algorithm. These systems are not developed by a company and therefore are not approved by the FDA. The movement to create such systems started years before the MiniMed 670G AID became commercially available. The founders of the open-source program said, “We are not waiting” on commercial and FDA approval delays to be able to synchronize and use data from their CGM systems and insulin pumps to automate insulin delivery and thereby improve their glycemic management and lessen hypoglycemia, especially overnight.

DIY systems use FDA-approved insulin pumps (such as older versions of Medtronic pumps and older Eros versions of Omnipod patch pumps) and CGM systems, along with additional hardware to bridge the communication gap between pump and CGM (23). Beyond this interoperability, these systems allow users to decide on their glycemic management intensity.



There are different versions of DIY systems. The first such system, called OpenAPS, used a small computer to hold the algorithm, combined with radio hardware, so a phone would not be required (24). Another system, called Loop, uses an iPhone to hold the algorithm and a small radio device (RileyLink) to communicate between pump and iPhone (25). A third system, called AndroidAPS, leverages the OpenAPS algorithm on an Android phone and uses Bluetooth to enable communication directly to Bluetooth-enabled pumps without requiring additional hardware (26). These systems are the result of multiple rapid code iterations that have led to algorithms that either nearly resemble or even exceed the functionality of commercially available FDA-approved AID systems.

Thousands of people worldwide are estimated to be using DIY AID systems. Currently, there are >22,000 members worldwide in a private Facebook group known as “Looped,” which serves as a support/gathering place for those interested (including many industry employees) in these community-driven systems (27). Although DIY systems have not yet been submitted for regulatory review, there have been many studies showing improved TIR, reductions in hypoglycemia and hyperglycemia, and improved quality of life with their use (28,29). Limitations to DIY systems include the frequent use of out-of-warranty pumps, lack of formal customer support (beyond a responsive community of peers), lack of experience/trust from many health care professionals, and the time required to set up such a system.

### Limitations to AID Systems

Limitations to AID systems in general exist at multiple levels. Technical problems with AID include issues with the individual components: insulin pump, insulin, and CGM device. The AID algorithm cannot completely compensate for these individual challenges.

Typical insulin pump issues may occur occasionally and include kinked or unintentionally torn out infusion sets, malfunctioning pumps, dead batteries, and infusion site adhesion issues. Problems with insulin such as denaturing can trigger increased automated insulin infusion. Rapid-acting insulins on average can still take up to 1–2 hours to peak and 3–4 hours to clear. Because of this delay, prolonged basal reductions and infusion suspensions by the algorithm based on predicted or current hypoglycemia can lead to rebound hyperglycemia. Similarly, a delayed yet accurate mealtime bolus dose can cause an increased automated basal rate and/or premature correction bolus that can lead to rebound hypoglycemia, especially if unannounced activity or exercise occurs. As one could

imagine, balancing delayed insulin absorption and clearance with delayed carbohydrate digestion can be difficult around activity and exercise.

CGM data are also not perfectly accurate. Occasionally, the first 1–2 days of CGM glucose data can be less accurate, even with factory-calibrated sensors (30). Beyond that, the interstitial blood glucose lag is important to remember. Delays related to both insulin and CGM can be particularly difficult to navigate around higher activity levels and especially exercise. In our experience, none of the available AID systems can consistently prevent exercise-related hypoglycemia without specific and proactive interventions (which differ with each system) made by users and often determined by trial and error.

Financial limitations related to reimbursement also exist. Pumps, CGM sensors, and AID systems are quite expensive and mostly only feasible for continued use by individuals with insurance. Even DIY systems require users to pay yearly fees for a software development license and the initial costs for any hardware required to connect their pump and algorithm.

“Alert fatigue” refers to the concept of having too many low and high glucose prompts from the pump, CGM device, or AID algorithm itself (31). These systems vary in terms of which alarms can be silenced, and the alarm for severe low glucose is designed to always stay on for safety and to comply with FDA regulations. However, other alarms are customizable.

Despite these limitations, recommended solutions for these issues are generally both practical and reasonable and include timely premeal bolus dosing, accurate carbohydrate counting, understanding of delays in insulin absorption and the effect of exercise on glycemia, and the use of accurate, pretested basal and bolus settings for systems that allow such settings. Clearly, PWD must still be actively and cognitively involved in the use of these systems at various levels despite their hybrid automated functionality.

### Which AID System Is Best for a Given Person With Diabetes?

All of this information provided above raises some important questions, many of which have not been answered in randomized clinical trials. Which PWD would do better without an AID system (assuming they may do better with multiple daily insulin injections or separate insulin pump with CGM devices), and how does one determine which AID system is right for a given person when indicated? The

specific benefits and limitations of each AID system help to define its individual utility.

Much of this information provided below comes from our own clinical and personal experiences with these systems. We also devised a 10-question survey to poll local, national, and a few international endocrinologists, diabetologists, and experienced diabetes educators who care for PWD and train them on the use of insulin pumps and CGM systems to further validate our own experiences. We received 60 responses to the survey. Figure 1 lists the survey questions (with provider groups polled listed in the legend), and Table 1 includes a tally of key responses. Full survey results, including respondent comments, are available online from <https://www.surveymonkey.com/results/SM-ZWFQLR6N7>.

In our survey, most respondents had experience with all three systems. Many preferred the Tandem system overall because of the features of the Dexcom G6 CGM device, the effective algorithm, ease of use, reduced burden/better quality of life, and FDA approval (as opposed to a DIY system). Most respondents valued the ability to share CGM data using the Dexcom system in users with hypoglycemia unawareness. Those with hypoglycemia who have no compelling need to share CGM data also may do well with the MiniMed 670G system as long as they can tolerate the required calibrations and alerts (32).

Many respondents preferred the Tandem and DIY systems for PWD who want the most intensive control of their glucose and insulin delivery. Of note, 5% chose “no AID” for this specific reason. An observational study using data from the T1D Exchange clinic registry revealed that >30% of PWD discontinued using the Medtronic system mostly because of forced exits from auto mode, frequent alarms, sensor inaccuracy, and skin adhesion difficulties (33).

Interestingly, when it came to DIY systems, 62% of respondents were comfortable with their patients using them, but only 17% were able or willing to help set up such a system because of time constraints, complexity, and liability issues related to such systems not being approved by the FDA. Those not able or willing to help set up a system were still willing to help adjust insulin settings in the algorithm based on glycemic trends. The biggest complaints regarding DIY systems were their onerous set-up process, their lack of FDA approval, difficulty downloading glycemic data/trend information from them, and the need for PWD to carry a separate device to use them.

It is relevant to note that expectations and education regarding the use of any AID system are paramount to

promote usage and prevent frustration, especially in PWD who think these technologies will “do all the work” to manage their diabetes. In a study involving 32 people with type 1 diabetes after 4–5 days of using the MiniMed 670G system, focus group analysis revealed that participants were willing to use the system, despite some hassles and limitations, if that use led to perceived health benefits (32).

Beyond insulin pump, CGM system, AID device, and DIY websites, there are also many other websites, blogs, and social network groups that help PWD navigate the market and decide which pump and/or CGM system fits their lifestyle best and whether AID is a good option for them (Table 2).

### The Future of AID, Especially in the Primary Care Setting

In the near future, we believe there are several AID systems in the pipeline that will offer more choice, improved usability, and even more automation. Some of these features, particularly those involving ease of use and insurance coverage, may be especially appealing for primary care providers (PCPs) and the PWD who depend on them for diabetes care. More device interoperability may also emerge.

### Insulet's Omnipod and Horizon AID

The Omnipod patch pump differs from traditional tubed pumps in a few ways that already make the device more appealing for primary care. Unlike traditional pumps, which use tubing connected to an infusion set, the Omnipod sits directly on the body. The disposable pod is filled with insulin before being placed on the body (usually on the upper arm) and is discarded after 3 days. In 2019, Insulet launched a pay-as-you-go model for Omnipod, allowing users to effectively try the system at no extra cost. This contrasts with traditional pumps, which require a large upfront investment and lock-in to a 4-year warranty. Additionally, the subscription-based Omnipod can be accessed through a pharmacy (as opposed to a durable medical equipment supplier, as with other pumps), improving the experience for patients and providers. Many find the one-piece, no-needle Omnipod pump to be easier to teach, learn, and use than traditional pumps, which have multiple components, including pump, reservoir, tubing, and infusion sets. These features have made Omnipod especially popular in pediatric settings and with pump-naïve users and people with type 2 diabetes (34).

### **AUTOMATED INSULIN DELIVERY (AID) SURVEY**

**1. Do you have experience using AIDs in your practice for T1Ds on pump/CGM (Medtronic 670G, tandem tslim x2 with control IQ, and DIY systems)? Which one (s)?**

- Medtronic 670G
- Tandem control IQ
- DIY (Loop, Open APS, AndroidAPS)
- None

**2. If so please rank them in terms of your favorite (#1 being favorite).**

- Medtronic 670G
- Tandem control IQ
- DIY systems

**3. Please explain why your #1 choice is your favorite and #3 choice least favorite.**

**4. Which AID would you recommend to a patient with hypoglycemia unawareness who lives alone?**

- Medtronic 670G
- Tandem control IQ
- DIY-system
- Other (please specify)

**5. Which AID would you recommend for a T1D who wants intensive control and still wants control over their own insulin delivery?**

- Medtronic 670G
- Tandem control IQ
- DIY-system
- None
- Other (please specify)

**6. Which T1D would you not recommend an AID (assuming they would do better on any CGM and any pump without automated insulin delivery)?**

**7. Which of these have your Medtronic 670G users complained about?**

- system requirements to keep automated (i.e., calibrations, etc.)
- technical issues (sensor/transmitter/pump)
- adhesive issues with pump infusion or CGM
- alert fatigue (cannot stop trivial alerts)
- doesn't help prevent exercise-related lows
- prevents intensive glycemic control
- other (please specify)

**8. Which of these have your Tandem control IQ users complained about?**

- system requirements to keep automated (i.e., calibrations, etc.)
- technical issues (sensor/transmitter/pump)
- adhesive issues with pump infusion or CGM
- alert fatigue (cannot stop trivial alerts)
- doesn't help prevent exercise-related lows
- prevents intensive glycemic control
- other (please specify)
- 

**9. In your experience which of these AIDs is most often discontinued or switched away from?**

- Medtronic 670G
- Tandem control IQ
- DIY-system
- too little experience to answer
- other (please specify)

**10. Are you comfortable allowing your T1D patients to use DIY systems, and if so, do you help them set the system up? Comments about complaints using this system as well welcomed.**

**FIGURE 1** AID survey. Groups polled included three Facebook groups: Your Endo Doctors (2,331 members nationally), Diabetes Technology Clinicians (474 members nationally), and Tristate Endocrinology (24 members from Cincinnati, OH), as well as the large Diabetes Technology Community of Interest Group of the Association of Diabetes Care & Education Specialists and a small international group of endocrinologists contacted individually via e-mail message.

**TABLE 1** Responses to AID Provider Survey (N = 60)

Question	Topic	Medtronic	Tandem	DIY	None	Other
1	Experience with system	98.33	93.33	60.00	1.67	–
2	Favorite system	6.90	83.93	16.00	–	–
	Least favorite system	58.62	0.00	32.0	–	–
3	Explain why favorite	*	*	*	–	–
	Explain why least favorite	*	*	*	–	–
4	Preferred AID for patients with hypoglycemia unawareness or who live alone	18.33	90.00	18.33	–	5.00*
5	Preferred AID for intensive and individual control	8.33	55.00	51.67	6.67	11.70*
6	Patients for whom you would not recommend AID*					
7, 8	Complaints about AID systems					
	System requirements	95.00	3.77	–	–	–
	Technical issues	83.33	35.85	–	–	–
	Adhesion issues	46.67	33.96	–	–	–
	Alert fatigue	85.00	26.42	–	–	–
	Exercise-related hypoglycemia	43.33	24.53	–	–	–
	Prevention of intensive control	56.67	16.98	–	–	–
	Other	*	*	†	–	–
9	AID systems most often discontinued or switched away from	91.67	1.67	3.33	–	3.33*
10	Comfort level and complaints with DIY*					

Data are % respondents. \*Full responses can be found in the full survey results, available online from <https://www.surveymonkey.com/results/SM-ZWFQLR6N7>. †See online responses to question 10.

Insulet's Omnipod Horizon AID system is currently in a pivotal trial with a potential launch in the United States in 2021. The system being studied uses Dexcom's G6 CGM with the Omnipod pump and an algorithm developed by Insulet. It will include automated basal rates and correction boluses. Meals and exercise will still require manual bolus dosing and adjustments. For ease of use, Insulet plans to bring smartphone control to the Omnipod Horizon system, allowing users to deliver bolus doses or adjust insulin delivery using their personal smartphones, a feature long requested by many pump users (35). Presumably, the smartphone connectivity will also mean that CGM and pump data can be uploaded to the Cloud wirelessly, another ease-of-use improvement for clinicians and PWD who use remote monitoring. Because the Omnipod pump will store the algorithm and communicate directly with the Dexcom G6, the system will work even when a smartphone/pump controller is not nearby.

### Improvements to Existing Systems

#### Medtronic's MiniMed 780G

Medtronic's next AID system, the MiniMed 780G, is expected to launch in the United States in 2021, possibly

after starting in Europe in 2020, and will represent a significant upgrade over the now 4-year-old MiniMed 670G system. MiniMed 780G will include automatic correction boluses and an adjustable glucose target down to 100 mg/dL. The system will also have fewer alarms and simpler operation than the 670G. Medtronic is targeting ambitious >80% TIR and >99% time spent with closed-loop control goals for 780G users. The 780G will also add Bluetooth connectivity to the pump, allowing users to view pump data on their phones, upload pump data wirelessly, and update their pump wirelessly. These upgrades will make this system more attractive to providers by addressing many of the complaints noted previously regarding the 670G.

It will use the same Guardian CGM device as the 670G, which requires two fingersticks per day and has a 7-day wear time. The FDA is currently reviewing the Guardian CGM for nonadjunctive insulin dosing and, if approved, users will be able to deliver insulin bolus doses based on their CGM reading alone, without fingerstick BGM confirmation (36). The fingerstick calibrations and lack of customization may continue to be a disadvantage for Medtronic's AID system users, as Medtronic's pump will only work based on values from Medtronic CGM systems.



**TABLE 2** Websites, Online Forums, and Blogs Focusing on Type 1 Diabetes

- DiaTribe: <https://diatribe.org>
- A Sweet Life: <https://asweetlife.org>
- Beyond Type 1: <https://beyonddiabetes.com>
- Diabetes Strong: <https://diabetesstrong.com>
- Integrated Diabetes Services: <https://integrateddiabetes.com>
- T1D Exchange-Glu: <https://myglu.org>
- dLife: <https://dlife.com/>
- TypeOneNation: <https://www.jdrf.org/community/typeonenation>
- SixUntilMe: <https://sixuntilme.com/wp>
- TCOYD: <https://tcoyd.org>
- JDRF: <https://www.jdrf.org>
- American Diabetes Association: <https://diabetes.org>
- Association of Diabetes Care & Education Specialists: <https://www.diabeteseducator.org>
- Children with Diabetes: <https://childrenwithdiabetes.com>

### Tandem's Next Generation AID

Since Tandem launched its Control-IQ AID system in January 2020, the company has announced a series of iterative updates adding several features that may make the device more appealing for use in primary care. A smartphone app for the t:slim X2 pump has recently launched and allows wireless data uploads of pump and CGM data for simplified remote patient monitoring in primary care. Later, potentially in late 2020 or early 2021, Tandem also plans to incorporate smartphone pump control (e.g., for delivering bolus doses and adjusting basal infusion rates).

Tandem also has plans to bring a fully closed-loop system with complete basal and bolus automation (i.e., automatic dosing for meals and exercise as well as for basal insulin and correctional doses) to the market in 2021 (37). Such a system would certainly be useful in the primary care setting for patients who require bolus insulin doses in addition to basal insulin. However, high upfront costs and perceived implementation difficulties remain a challenge for PCPs.

### Nonprofits, Dual Hormone Systems, and More

Outside of the three big players (Insulet, Tandem, and Medtronic), small start-up companies such as Beta Bionics and the nonprofit Tidepool Project have plans to bring their own AID systems to market.

Tidepool is a nonprofit group working on an AID algorithm-only closed-loop system. It plans to submit a variant of the DIY Loop app mentioned above to the FDA as an officially supported app available from the Apple App Store. Currently, Tidepool has partnerships with Medtronic, Dexcom, and Insulet, suggesting the app will be compatible with those companies' pumps and CGM systems when Tidepool Loop becomes available. Tidepool has a 12-month observational study of Loop users, which will likely be part of its FDA application submission (38).

Beta Bionics is another AID company that plans to develop a dual-hormone (insulin and glucagon) AID system. The system will also have easy setup, requiring body weight only (no programming of other information such as a user's I:C ratio or ISF), and the system will "learn" over time via artificial intelligence. Users will not need to count carbohydrates; rather, they will only need to describe meals as containing more, less, or the same amount of carbohydrates as in a meal requiring a usual bolus dose. An insulin-only version of Beta Bionics' AID system, iLet, could be submitted to the FDA as soon as late 2020, with the bihormonal version planned for a few years later (39).

### Recommendations for Primary Care

Now is a great time for PCPs to become more familiar with AID technologies. PCPs may choose to play an active role implementing these systems within their own clinical practice or may choose to provide guidance to PWD who want to learn more and more effectively collaborate with local specialists.

We have already witnessed incredible improvements in not only quality of life, but also patient care and the efficiency of office visits related to the use of AID in clinical practice. These improvements include AID-related A1C lowering, less difficulty managing labile blood glucose levels and their consequences, and simpler review of glycemic data. Most PCPs do not have direct access to certified pump trainers; however, those who want to pursue the use of these systems can seek assistance from representatives of the respective device companies to assist with insurance authorization and successful implementation.

It is clear to us, and our survey respondents, that PWD who have overall good glycemic control with minimal hypoglycemia (generally as evidenced by an A1C <7% or  $\geq 70\%$  TIR)—especially those who want complete control over insulin delivery and those who do not want the bother of alerts, alarms, or having a pump attached to their body—are not the best candidates for AID.

Unfortunately, as evidenced by T1D Exchange registry data, most people with type 1 diabetes do not achieve goal A1C and TIR (5). For this reason, many people with type 1 diabetes could greatly benefit from AID.

It is also clear that fear of hypoglycemia is a barrier to achieving goal A1C (40) and TIR targets. AID could also potentially help alleviate this fear for all PWD on intensive insulin therapy.

In our experience and based on the survey results discussed here, Tandem's AID system is generally considered to be more user-friendly and has more options for personalized programming and trouble-shooting. However, with the Medtronic system, especially when the user can maintain auto mode, very few parameters can be adjusted by the provider. Much information, including a user's percentage of time spent in auto mode and TIR can be reviewed on the pump itself (i.e., in the device history menu) without the need for a complete download of the pump to guide therapy. For users who are able to spend most of their time using the system's auto mode and have a high TIR, little further review of parameters or data are necessary, freeing up time during clinic encounters to focus on other important medical issues.

Although the DIY systems are fascinating and their use is becoming more widespread, they are unlikely to be recommended and used in primary care clinics without an endocrinology referral. This situation may change when and if such systems receive FDA approval and become simpler to set up and use.

## Conclusion

Three AID systems are now on the U.S. market, and they have already made significant contributions to improving the lives of PWD. Each AID system has its own features, subtleties in functionality, and limitations, making it important for clinicians and PWD to research and understand which one may be the best fit for their specific needs and characteristics. In our opinion, not all people with type 1 diabetes prefer or do better with AID.

As AID becomes more commonplace, we anticipate that the national median A1C will at last decrease, and TIR will improve, especially among people with type 1 diabetes. These technologies have already helped users to intensify glycemic control without increasing the risk of hypoglycemia, as indicated by improved TIR. It is not uncommon to hear personal testimonies and to see daily CGM data graphs revealing 80–100% TIR with the use of AID.

In our opinion, these systems are not necessarily “ready for prime time” for use in most primary care clinics because of the complexities involved in using and incorporating all of their components. Exceptions to this opinion would include PCPs who care for PWD who are already successfully using AID and prefer to condense their medical care to their PCP office, as well as PCPs with a special interest in the care of patients with type 1 diabetes.

We hope that, one day soon, these systems will be commonplace and simple enough to initiate for any person with diabetes, even by clinicians who are inexperienced in their use. Future enhancements of the available devices and newer AID systems in the pipeline are heading in this direction. It is also our hope that this article has not only helped to educate readers about AID technologies, but has also shared valuable resources to help navigate this topic more effectively with colleagues and patients.

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## AUTHOR CONTRIBUTIONS

M.H. researched, wrote, and revised the manuscript. B.H. and L.B. researched and revised the manuscript. A.C. wrote the section on the future of AID. K.C. reviewed and revised the manuscript. M.H. is the guarantor of this work and, as such, had full access to all of the material presented and references cited and takes responsibility for the integrity and accuracy of this review.

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