SMART Systems Review

Current State of Automated Insulin Delivery Options for Diabetes Management: A Primer for the Clinician

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Abstract: Automated Insulin Delivery (AID) systems, which combine the use of insulin pumps with glucose sensors and software dosing algorithms, have revolutionized the management of diabetes. This review covers the components of AID systems, the benefits and limitations, and where future iterations of AID systems are headed in both type 1 and type 2 diabetes in adults and children. As AID systems become more common place, we review what clinicians of all types need to know about these systems and how we approach using these systems in people with diabetes.

Key words: Type 1 diabetes, automated insulin delivery, hybrid closed loop, continuous glucose monitoring, type 2 diabetes.

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1. Introduction

Automated Insulin Delivery (AID) systems have revolutionized diabetes management since their introduction in 2017. AID insulin pumps, also known as hybrid closed-loop insulin pumps, "smart" insulin pumps, or formerly the "artificial pancreas", combine the use of an insulin pump (which delivers subcutaneous rapid-acting insulin delivery through a cannula which is changed every 3 days without the need for concurrent long-acting insulin), a continuous glucose monitor (CGM), and a software dosing algorithm installed on the insulin pump or a smartphone to automatically adjust insulin delivery based on sensor glucose sensor values.[(1)] The "hybrid" component describes the fact that on all current systems mealtime insulin dosing is still dependent on the patient announcing meals or carbohydrate intake to trigger an insulin dose for meals.

CGMs measure glucose concentration in interstitial fluid with proprietary algorithms that convert these values into estimates of capillary glucose.[((1))] CGM has been available since the early 2000s and is now recommended to be started in all people with diabetes as soon as at diagnosis.[((1))] As the accuracy of CGM has improved so has the potential to use this data to augment insulin delivery in existing insulin pumps which previously relied on only pre-programmed insulin delivery rates throughout the day. Since 2016 the FDA has created new labeling that allows prescribed CGMs to be used for insulin dosing decisions based on sensor glucose values without the need for confirmatory capillary glucose checks.[((2))] Since CGM provides sensor glucose every one to five minutes this provides over 288 glucose data points per day to base insulin dosing decisions on as opposed to older recommendations to have 3-10 fingerstick glucose values per day. This influx of glucose

Abbreviations used in this paper: AID, Automated Insulin Delivery; CGM, continuous glucose monitor; T1D, type 1 diabetes; ADA, American Diabetes Association; T2D, type 2 diabetes; DKA, diabetic ketoacidosis.

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Table 1:

AID pump	Dexcom G6	Dexcom G7	Freestyle Libre 2+	Freestyle Libre 3+	Guardian 4	iPhone	Android Phones	Reservoir (units)	Approval Age	T2D Indication
Tandem T-slim X2 with Control-IQ	Yes	Yes	Yes	No - coming TBD	No	Yes	No	300	2 years +	Yes
Tandem Mobi with Control-IQ	Yes	Yes	No - coming TBD	No - coming TBD	No	Yes	No	200	6 years +	No
Omnipod 5	Yes	Yes	Yes	No - coming TBD	No	Yes	Yes	200	2 years +	Yes
Medtronic Minimed 780G	No	No	No	No	Yes	Yes (view only)	Yes (view only)	300	7 years +	No
Beta Bionics iLet	Yes	Yes	No	Yes	No	Yes (view only)	Yes (view only)	180	6 years +	No
Sequel Twiist with Tidepool Loop	No	No	No	Yes	No	Yes	No	300	6 years +	No
	TBD = Compability has been announced, but release date to be determined. T2D = Type 2 diabetes.									

data has allowed for more precise dosing calculations, glucose pattern detection, and modeling to predict hypo- or hyperglycemia. The benefit of CGM has been borne out in many studies showing that simply wearing a sensor translates into improved A1c and glucose values[(3-5)], but the paradigm shift has come in automating insulin infusion rates and augmenting boluses in insulin pumps with software algorithms using CGM data to target specific glucose values or glucose ranges.

The first commercially available AID system, the Medtronic 670G, was released in 2017 and its primary automation was adjusting basal insulin delivery rates to target a glucose of 120 mg/dl.[(6)] When glucose was projected to become hyperglycemic, basal insulin infusion would increase. Conversely, when glucose was approaching hypoglycemia, insulin infusion was decreased or suspended. As the first to market AID system, the 670G had conservative restrictions on its CGM and algorithm, which created a user experience that caused many patients to stop using automation features.[(7)] Subsequent iterations on AID have maintained safety while creating a more user-friendly patient experience in addition to adding automation features such as automated insulin correction doses on top of basal rate modulation for hyperglycemia and more aggressive correction insulin doses for post-meal hyperglycemia.[(8)]

AID systems have been shown to be safe and effective by decreasing both hyperglycemia *and* hypoglycemia in people with type 1 diabetes (T1D) in multiple clinical trials for patients as young as 2 years old.[(7-11)] We are now in an era where people with diabetes are routinely achieving better glycemic results and endorsing improved quality of life[(12)] with the use of AID systems compared to other treatment regimens such as multiple daily injections or non-automated pumps. This is further supported by multiple professional societies recommending the use of AID as standard of care in T1D care, including the American Diabetes Association (ADA) Standards of Care 2025 which state with grade A evidence that "AID systems should be the preferred insulin delivery method to improve glycemic outcomes and reduce hypoglycemia and disparities in youth and adults with type 1 diabetes."[(1)] Similar statements of support for AID use are seen in the guidelines and consensus reports published by the International Society for Pediatric and Adolescent Diabetes (ISPAD)[(13)] and the European Association for the Study of Diabetes (EASD).[(14)]

Table 2:

Device	Adults or Adults/Adolescents							
	Source	TIR 70-180 mg/dL (%)	Change in TIR (%)	Mean SG (mg/dL)	HbA1c (%)	TAR >250 mg/dL (%)	TBR <70 mg/dL (%)	TBR <54 mg/dL (%)
Medtronic 670G	Garg - DTT - 2017*	68.8 / 67.2	+5.0 / +6.8	148.3 / 158.5	6.8 / 7.1	1.3 / 2.8 *	3.4 / 2.8	0.6 / 0.5 *
Medtronic 780G	Carlson - DTT - 2021	75.1 / 72.7	+4.2 / +10.3	147 / 150	7.0 / 7.1	4.3 / 5.6	2.3 / 2.4	0.5 / 0.6
Tandem Control IQ	Brown - NEJM - 2019	71	+11	156	7.06	5.2	1.58	0.29
Insulet OP5	Brown - DC - 2021	73.9	+9.3	154	6.78	5.8	1.32	0.23
Beta Bionics iLet	Russell - NEJM - 2022	65	+11	164	7.3	8.5	1.8	0.3
CamAPS Fx	Tauschmann - Lancet - 2018	65	+10.8	160	7.4	3.5	2.6	0.3
Tidepool Loop	Lum - DTT - 2021	73	+21	147	6.5	5	2.8	0.4
TIR = CGM Time In Range. SG = sensor glucose. GMI = Glucose management indicator, a CGM derived estimate of 3 month glucose. TAR = Time Above Range. TBR = Time below Range. *The Garg 670G trial reported TBR <50 mg/dL instead of <54 mg/dL and TAR >300 mg/dL instead of >250 mg/dL								

In this overview, we will review the current systems that clinicians may see people with diabetes using, clinical trial results from major AID studies in both adults and children, their recent approval for use in Type 2 Diabetes (T2D) and pregnancy, how people with diabetes and their providers choose which system to use, future improvements in the technology, , and what the non-endocrinologist must know about these systems.

2. Current AID Systems

At time of publication there are five FDA-approved or FDA-cleared commercial AID systems in USA (listed in alphabetical order): Beta Bionics iLet, Insulet Omnipod 5, Medtronic MiniMed 780G, Tandem T:slim X2 and the Tandem Mobi both with Control-IQ technology. Two other systems, the Sequel twiist insulin pump with Tidepool Loop[((15))], and the CamAPS FX algorithm[((16))] which doesn't yet have a compatible insulin pump in the USA, have received FDA clearance but at time of publication have not been released commercially.

Many systems, but not all, are compatible with the Dexcom or Abbott Freestyle Libre CGM sensors. The Medtronic system is only compatible with Medtronic's Guardian glucose sensors or its recently FDA cleared Simplera Sync sensor.Medtronic [(17)] has also announced an agreement with Abbott to develop a Medtronic-compatible Abbott glucose sensor in the future.[((18))] Another FDA approved glucose sensor, the Senseonics Eversense implantable sensor available for ages 18 years and up, is not currently compatible with existing AID systems, but in 2024 received FDA interoperable CGM designation and may have future plans to integrate into existing AID systems.[((19))] Clinicians should note that the benefits of CGM have not been studied in over-the-counter CGM introduced by Dexcom and Abbott in 2024, nor are they compatible with any AID system (i.e. Dexcom Stelo, Abbott Libre Rio and Lingo).

Table 1 summarizes the currently available systems and glucose sensors with which they are compatible, how much insulin each system holds, as well as the ages they are approved for. Lastly it shows which systems have compatibility with iPhone or Android phone apps that may allow remote dosing control of the pump or just remote data review. Figure 1 shows examples of what the AID pump looks like along with example CGM sensors by Abbott and Dexcom.

Both randomized and non-randomized trials of AID systems show improvement in Hemoglobin A1c as well as glucose sensor metrics in contrast to traditional non-automated pump therapy and multiple daily injections (Table 2). Glucose sensor results using today's generation of AID systems have started to achieve similar results despite different underlying algorithms and study of different age ranges and populations. Details are listed in Table 2 of each pivotal study[((6-8, 20-23))], with many systems achieving glucose sensor Time in Range, 70-180mg/dl above 65%, and Time Below Range less than 70mg/dl to less than 3% per day. Note that these trials were of different designs and durations with different baseline characteristics for each study population. The results are thus not appropriate for head-to-head comparison on "superiority" of a given system over another, but rather to summarize the general benefits of the technology. Overall, these results either meet or are approaching consensus glucose goals for patients with diabetes according to the ADA Standards of Care 2025[((24))] (i.e. Time in range goal above >70%, time below range goal <4%)

Figure 1

Real world evidence shows similar or even improved results when compared to clinical trials in thousands of patients (Table 3[((25-28))]), with all systems achieving or being just below the aforementioned consensus CGM glycemic metrics in real life use settings.

Table 3:

Device	Source	TIR 70-180 mg/dL (%)	Mean SG (mg/dL)	GMI (%)	TAR >250 mg/dL (%)	TAR >180 mg/dL (%)	TBR <70 mg/dL (%)	TBR <54 mg/dL (%)	Users
Medtronic 780G	Da Silva - DTT - 2022	76.2	144.4	6.8	4.2	21.3	2.5	0.5	4,120
Tandem Control-IQ	Breton - DTT - 2021	73.6	152	6.9	4.6	24.3	1.1	0.2	9,010
Insulet Omnipod 5	Forlenza - DTT - 2024	67.7	160	7.2	not reported	30.6	1.6	0.4	37,640
CamAPS FX	Alwan - JDST - 2023	72.6	151	6.9	5.2	24.7	2.3	0.4	1,805

TIR = CGM Time In Range. SG = sensor glucose. GMI = Glucose management indicator, a CGM derived estimate of 3 month glucose. TAR = Time Above Range. TBR = Time below Range.

3. AID Use in Type 2 Diabetes

Two AID systems are now cleared for use in adults with Type 2 Diabetes. The Omnipod 5 system received FDA clearance for use in adults with T2D using insulin in July 2024. This was the first AID system approved for T2D use in the United States. Trial results showed a statistically significant decrease in A1c of 0.8%, with a greater 2.1% decrease in those with baseline A1c above 9%. CGM time in range was increased by 20%, or roughly 5 hours per day, without significantly increasing time below 70 mg/dl.[(29)] Notably, total daily insulin dose was significantly decreased on Omnipod 5 AID therapy compared to insulin injections.

In Spring 2025, the Tandem Control-IQ algorithm was also FDA cleared for use in T2D. A randomized control trial of 319 adults with T2D on insulin showed that those who were randomized to AID use had significantly improved A1c and Time in Range without any significant increase in hypoglycemia.[(30)] Aside from minor modifications to maximum weight and total daily insulin dose, the algorithms for these systems are unchanged for use in T2D.

4. Use During Pregnancy and Pregnancy Algorithms

As of now, pregnant women with T1D who are using AID systems in the United States are using these systems off-label as they do not have pregnancy-specific glucose targets or an indication for use during pregnancy. The CamAPS FX algorithm was recently approved in the United States. It has many years of use in the United Kingdom and is already available in multiple European countries. When available in the US, it will be the first system with an indication for use during pregnancy for people with T1D. Additional tailored AID algorithms for pregnancy are under development, addressing the unique glycemic targets and variability seen in glucose and insulin needs during each trimester for T1D during pregnancy.[(31)] ADA Standards of Care do recommend use of AID in pregnant women with T1D "when used with assistive techniques and working with experienced health care teams."[(32)]

5. "How I do it" – A Primer for the Non-Endocrinologist

While head-to-head trials comparing AID systems have been proposed, such efforts are subjected to bias, only compare two given systems, and are not likely the basis on which people with diabetes should select a device. We do not believe that there exists evidence to say there is one system that is best for everyone. Our center has patients using every one of the commercially available systems. Choosing the appropriate system relies on shared decision making with the person with diabetes and their care partners, and ultimately the best system for each individual is the one they have access to and will consistently use. ADA Standards of Care highlight individual and caretaker considerations, "*...selection of devices should be individualized based on a person's specific needs, circumstances, preferences, and skill level. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., a young child or a person with cognitive impairment or dexterity, psychosocial issues, and/or physical limitations), the caregiver's skills and preferences are integral to the decision-making process."[(1)]*

Important considerations in this choice include:

- Patient and caregiver preferences regarding a more hands-on experience where settings can be fine-tuned versus a hands-off experience with fewer settings to tweak
- Desire to have a tubed pump versus a tubeless "patch pump" design (example: Omnipod 5 or Tandem Mobi with shorter tube option)
- Daily insulin dose volumes (Table 1 shows how some systems hold less insulin, which may mean more frequent pump refills)
- Insurance coverage
- Specific glycemic patterns or insulin dosing behaviors that may be better addressed by certain algorithm features, the latter of which is best addressed by endocrinologist with experience in diabetes technology
- In children the pump size and available surface area on the skin should be considered for adhesives

Helpful resources to learn the details between systems and guide decision making include:

- Barbara Davis Center for Diabetes's Panther Program website (www.pantherprogram.org): up-to-date device comparison charts and tools for providers to understand the settings and reports for each AID system. It also has point-of-care tools to help interpret glucose and device reports and guide which insulin adjustments are recommended for specific glycemic patterns.
- Stanford University's DiabetesWise website (www.diabeteswise.org): another resource which is more patient facing and allows users to input features that they seek and it will recommend AID systems that may be a better fit to their desired features. A provider-facing version of DiabetesWise (www.pro.diabeteswise.org) also includes information on insurance coverage and where prescriptions should be sent.

- Association of Diabetes Care and Education Specialists (ADCES)'s DanaTech website (https://-www.adces.org/education/danatech/home): geared for any type of provider or support staff with courses on primary care clinic use, insurance coverage, billing tips, and device comparisons.

Initial device start-up training is provided by the pump companies or clinic staff. Successful use of these systems requires more frequent follow-up in the first few weeks and months of AID use in contrast to every 3 to 6-month visits patients traditionally have with endocrinologists. Providers will need access to online data review websites that CGM and AID system companies use:

- Dexcom Clarity
- Abbott LibreView
- Medtronic CareLink
- Tandem Source
- Insulet Discover
- third-party data review platforms like Tidepool or Glooko

Recent iterations of these sites may highlight glycemic patterns based on time of day, insulin dosing frequency, and percent time per day patients are using the closed-loop features. Once these reports are available for review, we recommend referencing the Panther Program point-of-care tools to help the provider analyze these reports and make insulin dosing adjustments best fit for each AID system. Device company representatives can assist with setting up an account for the clinic and train how to use each data review website.

6. Challenges In Current AID Systems

While AID systems have advanced significantly, challenges remain. These include:

- Device access: As of the end of 2022, only about 35% of people with T1D were using AID systems according to data collected by the largest clinic registry for patients with T1D in the United States, with minority groups having even lower use.[(33)] Barriers to uptake are multifactorial, but one modifiable limitation is insurance coverage and device cost.
- The need for on-time meal boluses triggered by the patient and the added burden of accurate carbohydrate counting.
- Delays in insulin action due to the lag between subcutaneous injection and absorption into portal and systemic circulation.
- Occlusions that can happen in the infusion set cannula, leading to insulin deficiency and the possibility of diabetic ketoacidosis (DKA) if not recognized within several hours. This is more acute because patients on pumps only use rapid-acting insulin and do not have any long-acting insulin in their system.
- Skin irritation that can happen with medical adhesives or allergies to plastic cannulas or steel needles.
- Limitations in CGM accuracy in specific settings (i.e. medication interference with high dose acetaminophen or ascorbic acid), lag time when serum glucose is rapidly changing[(34)], falsely low readings when CGMs are compressed on the body such as laying in bed[(35)], or FDA authorization to use these devices in hospital settings.
- Limitations in insulin pump hardware computing memory and processing speed to handle more advanced resource-intensive dosing algorithms.[(36)]

Some people with diabetes choose to stay on multiple daily insulin injection regimens because of the above. If they are achieving glycemic goals on an injection regimen, this is a reasonable option as long as CGM and AID systems have been discussed and offered to the patient.

7. Where The Field Is Going Next: Full Closed-Loop AID

Trials are underway on future systems with fully closed-loop algorithms (instead of hybrid closed loop) that forgo the need for manual meal dosing by automating meal dosing entirely.[(37, 38)] Multiple groups are working in this area. One such system developed at the University of Virginia has completed early multicenter pilot studies in 2024-2025 with preliminary results being announced at the Advanced Technology and Therapeutics conference and the American Diabetes Association Scientific Sessions in summer 2025.[(39)]

Beta Bionics' iLet system has served as a segue to this next generation by requiring only meal size estimates (usual, more than, or less than size meals) instead of specific entry of grams of carbohydrates which requires the patient to do mathematics at each meal.[(22)] The iLet's machine-learning algorithm observes glucose rise post-meal and the amount of insulin delivered over the next 4 hours and adjusts meal dosing every 24 hours based on this data.

Other designs in development include the use of emerging ultra-rapid insulins or dual-hormone designs with the inclusion of glucagon to decrease the incidence of hypoglycemia more effectively. Beta Bionics' iLet was initially developed as dual insulin and glucagon system, and the dual-

hormone design achieves more time with euglycemia with less hypoglycemia.[(40)] While the insulin-only system is commercially available, pivotal trials for the dual-hormone model are still pending. Other trials have investigated the use of amylin infusions to slow gastric emptying and decrease post-prandial glucose rise.[(41)] Systems with intraperitoneal delivery of insulin are being investigated as one way to make up for the slower onset of action of subcutaneous insulin injection.[(42)]

Another area of research is the use of additional analytes such as serum ketones with a continuous ketone sensor[(43)], or the use of wearable devices to measure metrics like heart rate[(44)] or detection of meal consumption by hand motions[(45)] that can be added to AID algorithms to improve glucose time in range. At time of publication, no commercially available AID systems use any other data input aside from CGM glucose value.

Another consideration is the size and body surface area required to wear these devices. Miniaturization of both infusion sets and CGM sensors or the combination of both devices into one device is another improvement still under development.[(46)]

8. What The Non-Endocrinologist Needs to Know

All people with T1D should be offered AID systems regardless of baseline glucose control or previous insulin pump use if they are interested in the technology. People with T2D who are on daily insulin regimens now also have the option of using these systems. Previous dogmas of requiring people with diabetes to achieve a certain baseline A1c threshold, glucose testing frequency, or number of insulin doses per day are being replaced by promoting early use of CGM and AID systems in *all* people with diabetes open to using them.

Outpatient providers can ask their patients with diabetes what diabetes devices they are using, if any. If they aren't using CGM yet but are open to it, providers should feel empowered to order prescriptions for these themselves if the patient is not yet established with a diabetes care team. For people with T2D not requiring insulin, the over-the-counter (OTC) CGM options may help increase CGM use. While out of pocket is lower, the OTC options are not typically covered by insurance.

Starting insulin pumps and AID systems is best done working alongside an endocrinologist; however, there are models of primary care doctors starting the Beta Bionics iLet in primary care offices as it only needs a patient's body weight to start the system.[(47)]

Currently use of these devices in the hospital setting depends on each hospital's policy. With the support of an endocrinology or diabetes management team they have been used successfully. Studies are in process to obtain FDA approval of CGM for inpatient use. As these systems undergo further study in inpatient settings, hospital providers will increasingly see AID systems and CGM used in inpatient settings.

The only absolute contraindications requiring the removal of an AID system in inpatient settings include MRI due to the on-body metal, during treatment with an insulin IV drip like for DKA, or if AID/CGM devices will contaminate a surgical field.[(34)] Regarding MRI, the Abbott Libre 2 and 3 Plus CGMs are now cleared for MRI use, although the insulin pumps are not. Otherwise, AID systems should be left on, and workarounds exist such as temporarily disconnecting or covering devices with lead aprons during CT scans or X-rays. People with diabetes or their family members can show medical staff how to disconnect and temporarily remove these devices as needed. If the system is removed and will not be put back on within 2 hours, subcutaneous or IV insulin must be given urgently to prevent ketone formation in people with type 1 diabetes. People on insulin pumps who are disconnected from their pumps are at risk of developing DKA sooner than those on insulin injections due to the lack of background long-acting insulin which pump users do not require.[(48)] Pumps should not be disconnected for more than 2 hours without a plan to give insulin injections to patients with T1D.

Primary care providers, subspecialists, and hospitalists should not stop nor discourage the use of diabetes technology like AID and CGM. Instead, they should be advocates, facilitating the needs of their patients and working with them to optimize their health. Due to the complexities and rapid advancements in this field, discussion with the endocrinology team or glucose management team should happen if issues arise to ensure smooth transition off or back onto these systems.

9. Conclusion

Automated insulin delivery systems have been transforming T1D management, offering significant improvements in glycemic control and patient quality of life. Their use in people with T2D using insulin is a recent advancement with a large patient base for potential growth. Use of CGM is allowing for more precise assessments of glycemic control between the 3-month averages the A1c has offered. AID is allowing for improved glucose control over the lifetime of diabetes, which will likely decrease the incidence of micro and macrovascular complications in people with diabetes.

This field is advancing rapidly in an exciting manner. Much has happened in the eight years since the first system became available in 2017. As the field progresses toward fully closed-loop systems and more automation of device settings and easier patient onboarding, non-endocrinologist physicians may see a larger role in supporting device start and optimizing care especially in regions where endocrinologists are fewer in number. Familiarity with current

offerings and future directions ensures patients receive the best available diabetes care using this technology.

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