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**Review**

# Consensus Recommendations for the Use of Automated Insulin Delivery Technologies in Clinical Practice

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## Abstract

The significant and growing global prevalence of diabetes continues to challenge people with diabetes (PwD), healthcare providers, and payers. While maintaining near-normal glucose levels has been shown to prevent or delay the progression of the long-term complications of diabetes, a significant proportion of PwD are not attaining their glycemic goals. During the past 6 years, we have seen tremendous advances in automated insulin delivery (AID) technologies. Numerous randomized controlled trials and real-world studies have shown that the use of AID systems is safe and effective in helping PwD achieve their long-term glycemic goals while reducing hypoglycemia risk. Thus, AID systems have recently become an integral part of diabetes management. However, recommendations for using AID systems in clinical settings have been lacking. Such guided recommendations are critical for AID success and acceptance. All clinicians working with PwD need to become familiar with the available systems in order to eliminate disparities in diabetes quality of care. This report provides much-needed guidance for clinicians who are interested in utilizing AIDs and presents a comprehensive listing of the evidence payers should consider when determining eligibility criteria for AID insurance coverage.

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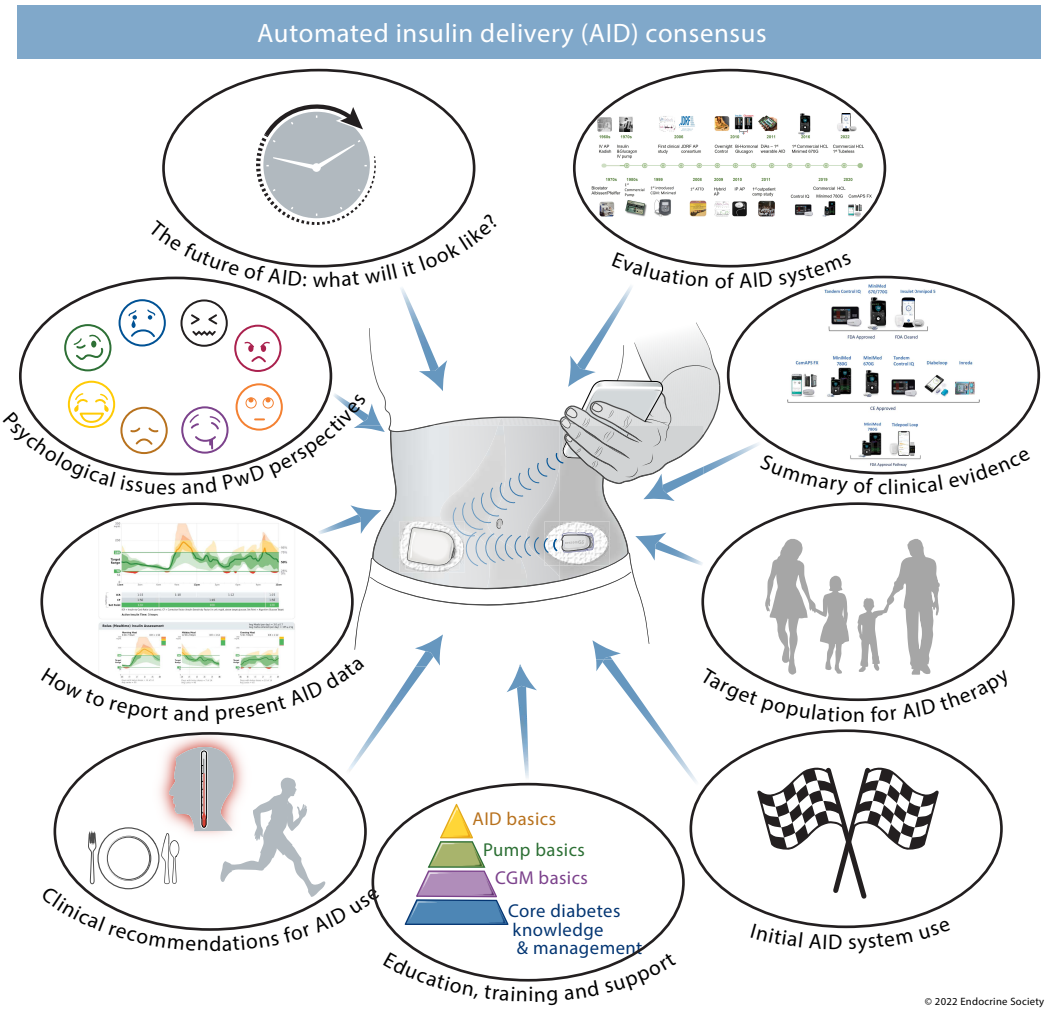
## Graphical Abstract




**Key Words:** automated insulin delivery, closed-loop, type 1 diabetes, consensus recommendations

**Abbreviations:** AID, automated insulin delivery; ATTD, Advanced Technologies & Treatments for Diabetes; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; DKA, diabetic ketoacidosis; FDA, U.S. Food and Drug Administration; GLP-1, glucagon-like peptide 1; HbA1c, glycated hemoglobin; MDI, multiple daily injections; MPC, model predictive control; PID, proportional integral derivative; PLGS, predictive low glucose suspend; PwD, people with diabetes; RCT, randomized controlled trial; SAP, sensor augmented pump; SGLT2, sodium-glucose cotransporter 2; SH, severe hypoglycemia; T1D, type 1 diabetes; TAR, time above range; TBR, time below range; TIR, time in range.

Diabetes is a chronic, demanding condition that poses a constant burden both on people with diabetes and on healthcare systems. Only a minority of persons with type 1 diabetes (T1D) meet widely accepted glycemic goals (1), demonstrating that there is an unmet need for better methods to achieve these goals. During the past 6 years, we have seen tremendous advances in automated insulin delivery (AID) technologies. Studies with various AID systems unequivocally demonstrate improvement in glycemic outcomes in people with T1D across all age groups, in all genders, and regardless of diabetes duration, prior insulin delivery modality, or baseline glycated hemoglobin (HbA1c) levels (2–6). Studies have also suggested cost-effectiveness of these systems (7–10). Yet despite the success of AIDs in improving glycemic control, guidance for integrating AID systems into clinical practice is limited. Moreover, as with all new technologies, negotiating insurance coverage for AID has been protracted.

In 2021, the Advanced Technologies & Treatments for Diabetes (ATTD) Congress organized an international panel of clinicians, researchers, and patient advocates with expertise in AID to develop clinical guidelines for initiating AID for individuals with T1D. The panel was divided into 9 working groups to address the various aspects of AID therapy, including evolution of AID; clinical evidence; determining the target population for AID use; initiation of AID; education and training; utilization of AID; AID data reporting; psychological issues/user perspective; and the future of AID. Recommendations from each working group were presented to the full panel and voted upon. This article summarizes the consensus recommendations from the panel.

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## ESSENTIAL POINTS

- AID therapy increases time in target glucose range with either no increase or a reduction in hypoglycemia compared with other diabetes therapies; AID therapy should therefore be considered for all populations with type 1 diabetes as it increases the likelihood of reaching recommended glycemic targets
- Healthcare providers need to be aware of the different AID systems available, their benefits, and their limitations, to be able to advise and support people with diabetes to increase the likelihood that the clinical benefits of AID are realized
- Commercially available AID systems still require basic diabetes management skills, including carbohydrate counting, for optimal glycemic control; opportunities to review and refresh these skills, where needed, should be sought
- Specific AID training and support for users and healthcare providers are important to maximize clinical benefits of AID therapy
- AID therapy is associated with significant improvements in quality of life and reduced burden of diabetes management for people with diabetes and their families
- Since clinical outcomes with AID therapy depend on high AID usage, consideration should be given to the usability of available AID systems; optimal AID systems require low user input to achieve excellent glycemic outcomes
- There are well documented and multifactorial racial and ethnic disparities in prescribing AID system technologies; healthcare provider preconceptions and unconscious biases about individual, family, and psychological attributes required to use AID technology effectively should be recognized and mitigated to ensure fair and equitable access to AID systems.

The purpose of this report is 2-fold: (1) to provide needed guidance to clinicians who are interested in utilizing AID; and (2) to serve as a comprehensive review of evidence for payers to consider, when determining eligibility criteria for AID insurance coverage.

## Evolution of AID Systems

Refinements in continuous glucose monitoring (CGM) technologies and dosing algorithms have led to the development of AID systems for the purpose of enhancing glucose management and minimizing burden around insulin delivery. AID systems utilize a sophisticated controller algorithm that continuously adjusts insulin delivery in response to real-time sensor glucose levels, residual insulin action and other inputs, such as meal intake and exercise announcement. The algorithm accommodates variability of insulin requirements between and within individual users. However, despite significant advances in controller algorithms in providing closed-loop insulin delivery between meals, users must still manually announce carbohydrate intake to achieve adequate postprandial insulin coverage. This is needed because current hybrid systems are not physiologic in that they rely on a delayed subcutaneous glucose signal (sensor lag time of 4 to 10 minutes) (11) and delayed subcutaneous insulin delivery into the circulation (peak insulin levels appear 45 to 60 minutes after injection) (12). Therefore, one of the major limitations for fully automated systems is the pharmacokinetics and pharmacodynamics profiles of commercially available insulins.

Currently, all commercially available AID systems are single hormone (insulin only) systems. Dual hormone AID systems, which incorporate other hormones (glucagon, pramlintide) to more closely mimic pancreatic physiology, are under development (13, 14). The addition of glucagon to an AID system may confer additional protection from hypoglycemia. Pramlintide, an analogue of amylin which is co-secreted with insulin from beta-cells, reduces postprandial glucose excursions by slowing gastric emptying and suppressing glucagon secretion.

### AID Algorithms

Several types of control algorithms have been developed, including model predictive control (MPC), proportional integral derivative (PID), and fuzzy logic (FL) controllers (15). MPC algorithms use patient-specific model parameters to calculate insulin delivery by minimizing the difference between model-predicted glucose concentrations and target glucose over a prespecified prediction time horizon. Thus, the algorithm adjusts the insulin treatment in order to bring the predicted glucose levels into the target range. PID controllers are reactive, adjusting insulin delivery by assessing glucose excursions from 3 perspectives: the proportional component calculates the deviation of measured glucose level from the target glucose; the integral component calculates the area under the curve between measured and target glucose, the third derivative component takes into account the rate of change of measured glucose, and all together dictate the amount of insulin delivered. Some PID controllers have been modified to also include feedback of a model-predicted insulin profile. A fuzzy logic control algorithm is a clinical approach to the modulation of insulin delivery based on a set of rules that imitate the line of reasoning of diabetes practitioners, which in turn are based on common medical knowledge, experience of diabetes practitioners, and known recommendations.

### Hybrid and Fully AID Systems

Current commercially available AID systems require users to manually enter prandial insulin boluses and signal exercise while automatically modulating insulin delivery. Fully AID systems, which obviate the need for carbohydrate counting and manually initiated prandial boluses, are under development at present, but the benefits in reduced user burden come at the expense of glycemic control (16). Use of truly faster insulin analogs within the AID system or glucose-lowering adjuvant therapies may make this approach more feasible in the future (*see* "The Future of AID: What Will It Look Like?"). Table 1 presents a description of commercially available AID systems. Table 2 presents some of the AID systems that are currently in development or under regulatory review.

### Interoperability and Intraoperability

The ability of components of an AID system (CGM, insulin pump, and algorithm) to communicate accurately and interact effectively with each other is critical for achieving optimal glycemic control. This can come in the form of intra- or

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**Table 1. Commercially available AID systems**

| | Medtronic 670G/770G | Medtronic 780G | CamAPS FX | Diabeloop | Control-IQ | Omnipod 5 |
|---|---|---|---|---|---|---|
| Algorithm and approach | PID algorithm with insulin feedback with adaptive insulin limits<br>Located on pump | PID algorithm with insulin feedback with adaptive insulin limits and model based auto-corrections<br>Located on pump | Treat to target adaptive MPC algorithm (interoperable)<br>App on unlocked smartphone | Treat to target adaptive MPC algorithm<br>App on smartphone /Handheld device | Treat to range adaptive MPC algorithm (interoperable)<br>Located on pump | Treat to target adaptive MPC algorithm (interoperable)<br>Located within pod (controlled from the Omnipod 5 controller or a phone App) |
| Target glucose | Fixed target: 120 mg/dL (6.7 mmol/L)<br>Optional activity target: 150 mg/dL (8.3 mmol/L) | Target: 100 mg/dL (5.6 mmol/L) (default);<br>Customizable: 110 mg/dL (6.1 mmol/L) or 120 mg/dL (6.7 mmol/L)<br>Optional activity target: 150 mg/dL (8.3 mmol/L) | Target: 104 mg/dL (5.8 mmol/L) (default);<br>Customizable between 80 mg/dL and 200 mg/dL (4.4 mmol/L and 11.0 mmol/L)<br>Optional activity mode | Target: 110 mg/dL (6.1 mmol/L) (default);<br>Customizable from 100 mg/dL (5.5 mmol/L) to 130 mg/dL (7.2 mmol/L)<br>Zen-mode: (20–40 mg/dL, 0.5–2.2 mmol/L) higher than current target<br>Activity mode (customizable) | Fixed target range: 112.5–160 mg/dL (6.2–8.9 mmol/L)<br>Intensified overnight target range of 112.5–120 mg/dL (6.2–6.7 mmol/L)<br>Optional activity range 140–160 mg/dL (7.8–8.9 mmol/L) | Target: customizable between 110 mg/dL and 150 mg/dL (6.1 mmol/L and 8.3 mmol/L) in increments of 10 mg/dL<br>Optional activity target: 150 mg/dL (8.3 mmol/L) |
| Basal insulin delivery | Algorithm driven basal insulin delivery adjusted every 5–10 minutes based on real-time CGM data | | | | | |
| Automated correction boluses | None. Manual correction boluses targeting 150 mg/dL (8.3 mmol/L) based on control algorithm parameters not programmed sensitivity factors | Automated correction boluses targeting 120 mg/dL (6.7 mmol/L) once automatic basal reaches maximum.<br>Correction boluses based on control algorithm parameters not programmed sensitivity factors | Automated correction boluses via more aggressive basal rate adjustments<br>Optional use of "Boost" mode (user ability to temporary increase insulin delivery)<br>Manual correction boluses optional based on programmed sensitivity factors | Automated correction boluses | Automated correction boluses (60% of the calculated correction dose) if glucose predicted to exceed 180 mg/dL (10.0 mmol/L) targeting glucose of 110 mg/dL (6.1 mmol/L)<br>Manual correction boluses optional | Automated correction boluses via more aggressive basal rate adjustments<br>Manual correction boluses optional |
| Safety parameters | Maximum hourly basal insulin delivery, but not maximum total hourly delivery<br>Maximum 4 h basal insulin delivery<br>Minimum insulin delivery for 2.5 h<br>Maximum bolus amount | Maximum hourly basal insulin delivery, but not maximum total hourly delivery<br>Maximum 7 h basal insulin delivery<br>Maximum basal delivery in 24 h<br>Maximum bolus amount<br>Minimum insulin delivery for 3–6 h | Maximum insulin delivery in 24 h<br>Maximum bolus amount<br>Minimum insulin delivery for 1.5 h | Variable aggressiveness<br>A bolus for a given meal can be modulate by ± 10% increment<br>Alert for rescue carbohydrates | Maximum insulin delivery in 2 h<br>Maximum insulin delivery in 24 h<br>Maximum bolus amount | Maximum individual insulin delivery at any given time<br>Maximum bolus amount |

(*continued*)



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**Table 1.** Continued

| | Medtronic 670G/770G | Medtronic 780G | CamAPS FX | Diabeloop | Control-IQ | Omnipod 5 |
|---|---|---|---|---|---|---|
| Settings that can be modified by user/HCP | Insulin to carbohydrate ratio<br>Active insulin time<br>Temp glucose target | Insulin to carbohydrate ratio<br>Active insulin time<br>Target glucose for algorithm<br>Temp glucose target | Target system glucose<br>Insulin to carbohydrate ratio<br>Boost or Ease off—more or less aggressive algorithm | Target system glucose<br>Total daily dose<br>Algorithm treatment reactivity (aggressiveness)<br>Insulin to carbohydrate ratio | Basal insulin rates<br>Insulin to carbohydrate ratio<br>Insulin sensitivity factor<br>Temp glucose target<br>Sleep mode | Insulin to carbohydrate ratio<br>Insulin sensitivity factor (user boluses)<br>Active insulin time (user boluses)<br>Target glucose for algorithm<br>Activity glucose target with attenuated insulin delivery |
| Algorithm learning | Based on TDD and an estimate of fasting glucose and the plasma insulin concentration at the time of fasting | Based on TDD and an estimate of fasting glucose and the plasma insulin concentration at the time of fasting | Adapts to day-to-day, prandial and diurnal patterns; independent of programmed basal and sensitivity pump settings | | Based on TDD | Based on TDD, updated with each Pod change (every 3 days) |
| Compatible insulin pump | 670G/770G | 780G | Designed as interoperable controller; currently available with Dana RS, Dana I, mylife YpsoPump | Kaleido patch pump<br>Roche Accu-Chek | Designated by FDA as interoperable controller; currently available in Tandem t:slim X2 | Designated by FDA as interoperable controller;<br>Omnipod 5 ACE |
| Compatible CGM system | Guardian 3<br>Duration 7 days<br>Requires calibrations (min 4–6x/d) | Guardian 3<br>Duration 7 days<br>Requires calibrations (min 2x/d)<br>CE mark: Guardian 4, duration 7 days, factory calibrated, optional calibration | Dexcom G6<br>Duration 10 days<br>Factory calibrated, optional calibration | Dexcom G6<br>Duration 10 days<br>Factory calibrated, optional calibration | Dexcom G6<br>Duration 10 days<br>Factory calibrated, optional calibration | Interoperable iCGM currently available:<br>Dexcom G6<br>Duration 10 days<br>Factory calibrated, optional calibration |
| Data management system | Carelink; manual downloading of pump required for 670G, automated download with 770G | Carelink; automated app compatibility | Diasend; automated download | Diasend; download | t:Connect mobile; automated download | Omnipod Connect; automated download |
| Compatible insulin | Rapid only | Rapid only | Rapid and ultra-rapid | Rapid only | Rapid only | Rapid only |
| Approved indications for use | FDA and CE mark<br>7 years and upward excluding pregnancy for 670G and 2 years and upward for 770G (FDA only) | CE mark<br>7 to 80 years excluding pregnancy | CE mark<br>1 year and upward including pregnancy | CE mark<br>12–18 years (DBL4T)<br>>18 years (DBLG1)<br>excluding pregnancy | FDA and CE mark<br>6 years and upward excluding pregnancy | FDA cleared<br>2 years and upward excluding pregnancy |

(*continued*)



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**Table 1.** Continued

| | Medtronic 670G/770G | Medtronic 780G | CamAPS FX | Diabeloop | Control-IQ | Omnipod 5 |
|---|---|---|---|---|---|---|
| Other benefits | Extensive clinical experience (>200,000 users)<br>Robust training and support<br>Remote monitoring capabilities (770G) | Evidence base from clinical trials<br>Increased usability compared to 670G<br>Remote monitoring capability | Evidence base from clinical trials<br>Mobile app for remote insulin bolusing<br>Online app updates<br>Remote monitoring capability<br>Online training for HCPs and users | Remote monitoring capability—YourLoops web-based platform | Extensive clinical experience (>270,000 users)<br>FDA cleared the t:connect mobile app for remote insulin bolusing<br>Online firmware upgrade<br>Online training for HCPs and users | Evidence base from clinical trials<br>Online firmware upgrade<br>Online training for HCPs and users |

Abbreviations: CGM, continuous glucose monitoring; HCP, health care provider; MPC, model predictive control; PID, proportional integral derivate; TDD, total daily dose.

interoperability. Intraoperability describes the exchange of data and interaction within the same system provided by the same manufacturer. Interoperability facilitates the exchange of data and interaction of different AID system components, offering users increased choice and flexibility for a personalized AID system. However, this depends on commercial agreements between device manufacturers.

## Summary of Clinical Evidence

Clinical evidence supporting the efficacy and safety of AID systems has grown over the last 5 years with the introduction of multiple commercially available, and soon to become available, AID systems. As of March 2022, the U.S. Food & Drug Administration (FDA) has approved the Medtronic 670G/770G (4, 17, 18), the Control-IQ (2, 19, 20), and recently cleared the first tubeless AID system, the Insulet Omnipod 5 (21). Conformite Europeenne (CE) approval has been granted to the Medtronic 780G (5, 22, 23); CamAPS FX (6); Diabeloop (24, 25); Inreda (26); Control-IQ, and Medtronic 670G. Some systems are currently under FDA review, including the Medtronic 780G (5, 22, 23) and Tidepool Loop (27).

### Randomized Controlled Trials

Randomized controlled trials (RCTs) and single-arm studies with interventions of 3 months or longer, including children as young as 2 years and adults up to 75 years of age with T1D have been conducted (Tables 3 and 4). Some RCTs provide separate analyses for adolescents and adults allowing evaluation in specific age groups. Study designs vary from single-arm trials without a concurrent comparator to parallel-group studies and crossover randomized trials. The lack of a control group in single-arm studies limits the ability to determine how much of this achievement is attributed to AID use, as opposed to a study effect. Furthermore, some of the populations studied differ in baseline time in range (TIR; 70–180 mg/dL). Lower baseline TIR was found to be associated with a greater improvement in TIR on AID (33). These differences in study design impair the ability to do cross-study comparisons.

In general, all the AID systems have uniformly demonstrated an increase in TIR and a reduction in mean glucose, time in hyperglycemia, and HbA1c. Overall improvement in glycemic control was similar across all age groups and was evident during both day and night. Yet even with AID use, TIR improves more overnight than during the day. TIR increased by 9% to 16% for most systems while HbA1c levels decreased by 0.3% to 0.5%, with either no change or a reduction in time in hypoglycemia. The greatest improvement in glycemic control is seen in those who have the lowest baseline TIR or highest HbA1c (33, 34). The effect on hypoglycemia has varied, also depending on the comparison group features and the amount of hypoglycemia present at baseline. In some studies, use of AID has been shown to reduce hypoglycemia even when compared to sensor-augmented pump (SAP) therapy with predictive low glucose suspend (PLGS) (5, 35). Of note, AID use resulted in reduced rates of both hypoglycemia and hyperglycemia, thus increasing TIR. This contradicts the paradigm that improving glycemic control necessarily leads to an increase in hypoglycemia (36).

### Real-World Studies

Real-world data are now also available, shedding light on true AID acceptance and performance. It is reassuring to find that

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**Table 2. AID systems under development or regulatory review**

| | Tidepool Loop | iLet (insulin only) | Inreda (insulin and glucagon) |
|---|---|---|---|
| Algorithm and approach | MPC algorithm<br>iPhone app | MPC algorithm<br>Located on pump | Insulin PID algorithm<br>Located on pump |
| Compatible insulin pump | Omnipod patch pump<br>MiniMed Medtronic | iLet pump | Inreda pump |
| Compatible CGM system | Dexcom G6<br>Medtronic Guardian Connect | Dexcom G6 | Medtronic |
| Regulatory status | FDA regulatory submission made | Not submitted | CE mark |

Abbreviations: MPC, model predictive control; PID, proportional integral derivative.

outcomes are similar to those of the pivotal studies in the means of TIR and time below range (TBR), with a modest reduction in HbA1c of 0.3% to 0.4% (35, 37–40). (Table 5). Current data also supports improved quality of life and users' reported outcomes (42–44). However, several publications on real-world use of the Medtronic 670G revealed that approximately one-third of youth starting on the 670G system discontinue use within 1 year (45, 46). Recent studies showed increased use of auto-mode on Medtronic's Advanced Hybrid AID compared to 670G (86% vs 75%, respectively) (23) and the real-world data of the use of Tandem's Control-IQ which reported 94% use of auto-mode (35).

Altogether, the data gathered provide solid evidence for the safety and efficacy of AID system use for a broad age range of PwD. Rates of acute complications such as severe hypoglycemia (SH) and diabetic ketoacidosis (DKA) were low. Of note, almost all pivotal trials exclude (or have very few) participants with a recent history of DKA or SH, thereby substantially lowering the risk of such complications. Real-world observational trials show lower rates of DKA/SH than those published in the US T1D Exchange Registry (1). Several studies also suggested improved quality of life, reduced diabetes burden, reduced fear of hypoglycemia and a return to restful sleep for PwD and family (44, 47–53), while few studies failed to find improvements in patient-reported outcomes (43, 54) (*see* "Psychological Issues and PwD Perspectives on AID Systems").

### Knowledge Gaps

Cost-effectiveness studies of AID systems are scarce. However, an analysis of the MiniMed 670G AID system vs continuous subcutaneous insulin delivery (CSII), showed that the higher acquisition costs of the AID system were offset by clinical benefits, reduced complication costs, and quality of life improvements, which represented an overall cost-effective treatment option for people with T1D (8). Similar results were reported for the MiniMed 670G AID system vs multiple daily injections (MDI) and intermittent scanned CGM (isCGM) (10). Additional data on other systems will be valuable.

Another knowledge gap is the use of AID systems in special populations. Data are accumulating on AID use in young children (< 6 years) with T1D (55–57). Several feasibility studies describe AID use in other populations, such as pregnant women with T1D (58, 59) and people with T2D (60, 61). To support AID implementation in these populations, larger and longer randomized controlled studies are needed. In addition, both RCTs and real-world studies lack racial and ethnic diversity, thereby limiting universal AID adoption (62).

## Target Populations for AID Therapy

Selecting the people who will benefit most from AID system use is essential to optimize both efficacy and safety of treatment. Table 6 presents graded evidence-based recommendations for individuals who should be considered for AID system use (American Diabetes Association [ADA] evidence-grading system) (87).

AID should be considered for all people with T1D, especially those experiencing suboptimal glycemia, problematic hypoglycemia, and/or significant glycemic variability. AID use can be particularly useful in persons at moderate to high risk for frequent and/or severe hypoglycemia (74, 88) and hypoglycemia unawareness (75, 76). Furthermore, small initial studies reported an improvement in hypoglycemia awareness with the use of AID systems (76, 77).

Additionally, lifestyle and quality of life issues should be considered when determining treatment options. As previously mentioned, evidence from numerous RCTs and real-world studies support the safety and efficacy of use of AID systems in young, school-aged pediatric populations and in adolescent/adult populations (2, 3, 5, 17, 18, 20, 23, 30, 35, 46, 56, 57, 63–67, 70–73, 89, 90). Although some studies included children from the age of 1 year, and adult populations older than 65 years (2, 4, 23, 27, 29, 35, 37, 68, 69, 89, 91), additional research is required to truly estimate the impact of AID in these age groups.

AID use can be beneficial in pregnant women (58, 60, 78–81), but the glucose targets needed during pregnancy are lower than most commercially available AID systems currently offer. The benefits of AID have also been demonstrated in insulin-naïve users with T2D in outpatient (60) and inpatient, noncritical care settings (61, 92) and in people on hemodialysis (82, 84) or with gastroparesis (83). However, additional studies are needed to confirm safety and efficacy for these populations.

Each candidate for AID use should be evaluated by their healthcare provider, to determine their ability to manage intensive insulin therapy. Factors to consider include proficiency in mealtime insulin dosing, motivation, willingness to participate in formal device training, manual dexterity/visual status, and financial/insurance status.

## Initiating AID System Use

Table 7 presents general recommendations for initiating AID use in PwD.

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**Table 3. Randomized controlled trials for commercially available AID systems**

| AID system (author & publication year) | Study design (type, duration, comparison group) | Study population (number of participants & age, mean baseline HbA1c) | Glycemic outcomes[a] | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | ΔMean sensor glucose | ΔTIR 70–180 mg/dL | ΔTBR < 70 mg/dL | ΔTBR < 54 mg/dL | ΔTAR > 250 mg/dL (or 300 or 180 mg/dL) | ΔHbA1c |
| ***Children/Adolescents*** | | | | | | | | |
| AHCL vs 670G<br>Bergenstal et al, 2021 (23) | Crossover trial, 2 13-week periods, comparison of AHCL vs 670G[b] and vs baseline[c] | N = 113, 14–29 yo, T1D, baseline mean HbA1c: 7.9%, TIR: 57% | −7 mg/dL[b]<br>−7 mg/dL: 670G<br>−14 mg/dL: AHCL | +4%[b]<br>+6%: 670G<br>+10%: AHCL | 0%[b]<br>−0.1%: 670G<br>−0.2%: AHCL | −0.04%[b]<br>+0.04%: 670G<br>0%: AHCL | −1%[b]<br>−3%: 670G<br>−4%: AHCL | −0.2%[b]<br>−0.3%: 670G<br>−0.5%: AHCL |
| AHCL<br>Collyns et al, 2021 (5) | Crossover trial, 2 4-week periods, comparison of AHCL vs PLGS | N = 33, 7–21 yo, (N = 14, 14–21 yo, N = 19, 7–13 yo), T1D, baseline mean HbA1c, TIR: NA | −13 mg/dL: 14–21 yo<br>−9 mg/dL: 7–13 yo | +14%: 14–21 yo<br>+12%: 7–13 yo | −0.4%: 14–21 yo<br>−0.7%: 7–13 yo | −0.1%: 14–21 yo<br>−0.2%: 7–13 yo | −14%: 14–21 yo<br>−11%: 7–13 yo (T > 300 mg/dL) | NA |
| Control-IQ<br>Isganaitis et al, 2020 (3) | 6-mo randomized trial, comparing CIQ with SAP | N = 63, 14–24 yo, T1D, baseline mean HbA1c: 8.1%, TIR: 52% | −18 mg/dL | +13% | −0.7% | −0.09% | −8% | −0.30% |
| Control-IQ<br>Breton et al, 2020 (20) | 16-week randomized trial, comparing CIQ with SAP | N = 101, 6–13 yo, T1D, baseline mean HbA1c: 7.7%, TIR: 53% | −13 mg/dL | +11% | −0.40% | −0.07% | −6% | −0.40% |
| CamAPS FX<br>Ware et al, 2022 (28) | 4-mo randomized trial, comparing CamAPS FX with SAP | N = 74, 1–7 yo, T1D, baseline mean HbA1c: 7.3%, TIR: NA | −13 mg/dL | +9% | +0.07% | +0.02% | −1% (T > 300 mg/dL) | −0.4% |
| ***Adults*** | | | | | | | | |
| 670G<br>McAuley et al, 2020 (4) | 6-mo randomized trial comparing 670G with MDI/CSII | N = 120, ≥ 25 yo, T1D, baseline mean HbA1c: 7.4%, TIR: 55% | −13 mg/dL | +15% | −2.0%<br>Median | −0.6%<br>Median | −2.9%<br>Median | −0.4% |
| Control-IQ<br>Brown et al, 2019 (2) | 6-mo randomized trial, comparing CIQ with SAP | N = 168, 14–71 yo, T1D, baseline mean HbA1c: 7.4%, TIR: 61% | −13 mg/dL | +11%<br>All the group<br>+10%<br>N = 105, 25–71 yo | −0.9%<br>−2.2% | −0.1% | −5.3% | −0.33% |
| CamAPS, FX<br>Tauschmann et al, 2018 (6) | 3-mo randomized trial, comparing CamAPS FX algorithm with SAP | N = 86, ≥ 6 yo, T1D, baseline mean HbA1c: 8.3%[d], TIR: NA | −15 mg/dL | +11%<br>All the group<br>+10%<br>N = 44, ≥ 22 yo | −0.8%<br>−0.5% (<63 mg/dL) | −0.1% (<50 mg/dL) | −1.4% (T > 300 mg/dL) | −0.36%<br>−0.3% |
| CamAPS FX<br>Boughton et al, 2022 (29) | 4-mo randomized trial, comparing CamAPS FX with SAP | N = 37, 60 yo and older, T1D, baseline mean HbA1c: 7.4%, TIR: 70% | −13 mg/dL | +9% | −0.1% | −0.0% | −0.7% (T > 300 mg/dL) | −0.2% |
| Diabeloop.<br>Benhamou et al, 2019 (24) | Crossover trial, 2 12-week periods, comparing Diabeloop with SAP | N = 68, ≥ 18 yo, T1D, baseline mean HbA1c: 7.6%, TIR: NA | −9 mg/dL | +9% | −2.4% | −0.5% (<50 mg/dL) | −4.3% | −0.15% |

Abbreviations: AHCL, advanced hybrid AID; AID, automated insulin delivery; CSII, continuous subcutaneous insulin delivery; HbA1c, glycated hemoglobin; MDI, multiple daily injections; mo, month; SAP, sensor-augmented pump, TAR, time above range (>180 mg/dL [>10.0 mmol/L], >250 mg/dL [13.9 mmol/L); TBR, time below range (<70 mg/dL [<3.9 mmol/L], <54 mg/dL [<3.0 mmol/L); TIR, time in range (70–180 mg/dL [3.9–10 mmol/L]), yo, years old.

[a]Reported glycemic metrics are mean differences between groups for randomized trial.

[b]Comparison between 2 AIDs.

[c]Glycemic metrics estimated from reported means in each group

[d]Differences reported from rank tests.



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**Table 4. Single-arm studies for commercially available AID systems**

| AID system (author & publication year) | Study design (type, duration, comparison group) | Study population (number of participants & age, mean baseline HbA1c) | Glycemic outcomes[a] | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | ΔMean sensor glucose | ΔTIR 70–180 mg/dL | ΔTBR < 70 mg/dL | ΔTBR < 54 mg/dL | ΔTAR > 250 mg/dL (or 300 or 180 mg/dL) | ΔHbA1c |
| ***Children/Adolescents*** | | | | | | | | |
| 670G Bergenstal et al, 2016 (17)<br>Garg et al, 2017 (30) | 3-mo single-arm study | N = 30, 14–21 yo, T1D, baseline mean HbA1c: 7.7%, TIR: 60% | −5 mg/dL | +7% | −1.5% | −0.2% | −1% (T > 300 mg/dL) | −0.6% |
| 780G<br>Carlson et al, 2022 (22) | 3-mo single-arm study | N = 39, 14–21 yo, T1D, baseline mean HbA1c: 7.5%, TIR: 62% | −6 mg/dL | +6% | −1% | −0.3% | −1.6% | −0.5% |
| 670G<br>Forlenza et al, 2019 (18) | 3-mo single-arm study | N = 105, 7–13 yo, T1D, baseline mean HbA1c: 7.9%, TIR: 56% | −7 mg/dL | +9% | −1.7% | −0.5% | −3% | −0.4% |
| 670G<br>Forlenza et al, 2022 (31) | 3-mo single-arm study | N = 46, 2–7 yo, T1D, baseline mean HbA1c: 8.0%, TIR: 56% | −12 mg/dL | +8% | −0.1% | 0% | −4% | −0.5% |
| Omnipod 5[b]<br>Brown et al, 2021 (21) | 3-mo single-arm study | N = 112, 6–13 yo, T1D, baseline mean HbA1c: 7.7%, TIR: 53% | −23 mg/dL | +16% | −0.4% | −0.1% | −9% | −0.7% |
| Omnipod 5[b]<br>Sherr et al, 2022 (32) | 3-mo single-arm study | N = 80, 2–6 yo, T1D, baseline mean HbA1c: 7.4%, TIR: 57% | −14 mg/dL | +11% | −0.3% | +0.1% | −6% | −0.6% |
| ***Adults*** | | | | | | | | |
| 670G Bergenstal et al, 2016 (17) | 3-mo single-arm study | N = 94, 22–75 yo, T1D, baseline mean HbA1c: 7.3%, TIR: 69% | +2 mg/dL | +5% | −3% | −0.5% (<50 mg/dL) | −0.5% (T > 300 mg/dL) | −0.5% |
| 780G<br>Carlson et al, 2022 (22) | 3-mo single-arm study | N = 118, 22–75 yo, T1D, baseline mean HbA1c: 7.5%, TIR: 71% | −4 mg/dL | +4% | −0.9% | −0.3% | −1% | −0.5% |
| Omnipod 5<br>Brown et al, 2021 (21) | 3-mo single-arm study | N = 129, 14–70 yo, T1D, baseline mean HbA1c: 7.2%, TIR: 65% | −8 mg/dL | +9% | −1.6% | −0.4% | −4% | −0.4% |

Abbreviations: TAR, time above range (>180 mg/dL [>10.0 mmol/L], >250 mg/dL [13.9 mmol/L); TBR, time below range (<70 mg/dL [<3.9 mmol/L], <54 mg/dL [<3.0 mmol/L); TIR, time in range (70–180 mg/dL [3.9–10 mmol/L]).
[a]Reported glycemic metrics are mean change from baseline to follow-up for single-arm studies (comparison of study period with baseline).
[b]Omnipod 5 is expected to be commercially available during 2022.



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**Table 5. Key real-world studies**

| Closed-loop system (author & publication year) | Study design (type, duration, comparison group) | Study population (number of participants & age, mean baseline HbA1c) | Number of participants by age category | Glycemic outcomes (start to end of study) | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | ΔMean sensor glucose | ΔTIR 70–180 mg/dL | ΔTBR < 70 mg/dL | ΔTBR < 54 mg/dL | ΔTAR > 250 mg/dL | ΔHbA1c |
| 670G<br>Stone MP et al, 2018 (37) | 3-mo retrospective, CareLink system data comparing baseline | N = 3141, >7 yo, T1D, no baseline HbA1c | N = 2066, 22–60 yo<br>N = 649, ≥ 60 yo | −7 mg/dL<br>−6 mg/dL | +8%<br>+6% | −0.7%<br>−0.4% | −0.1% | −2.7% | |
| | | | N = 105, 7–13 yo<br>N = 244, 14–21 yo | −17 mg/dL<br>−10 mg/dL | +11%<br>+8% | +0.5%<br>−0.3% | | | |
| 670G<br>Akturk et al, 2019 (38) | 6-mo retrospective single-center study comparing study period with baseline SAP use | N = 127, 21–68 yo, T1D, baseline mean HbA1c: 7.6% | | −12 mg/dL | +11% | −1% | −0.2% | −0.5% | −0.4% |
| 780G<br>Da Silva et al, 2022 (40) | 2-mo retrospective, CareLink system data comparing study period with baseline | N = 812, T1D, baseline mean estimated HbA1c: 7.2% | No data | −15.7 mg/dL | +12% | −0.3% | −0.1% | −4.2% | −0.4% |
| Control-IQ<br>Breton & Kovatchev 2021 (35) | 12-mo retrospective, real-world observational study, comparing study period with baseline (PLGS)** | N = 9010, 6–91 yo, T1D or T2D, baseline mean estimated HbA1c: 7.3% (N = 7813 T1D) | N = 5616, 19–63 yo<br>N = 1773, >63 yo | −13 mg/dL<br>−12 mg/dL | +10%<br>+9% | −0.8%<br>0% | +0.1%<br>0% | −3%<br>−2% | −0.3%<br>GMI for all group |
| | | | N = 716, 6–13 yo<br>N = 905, 14–18 yo | −15.5 mg/dL<br>−13 mg/dL | +12%<br>+12% | +0.1%<br>+0.1% | +0.1%<br>+0.1% | −5%<br>−6% | |
| Control-IQ<br>Messer et al, 2021 (41) | 6-mo prospective, real-world single-center comparing study period with baseline | N = 191, children and adolescents with T1D, baseline mean HbA1c: 7.6% | | −12.5 mg/dL | +9.4% | −0.4% | 0% | −4.3% | −0.3%<br>GMI |
| Loop Open Source<br>Lum et al, 2021 (27) | 6-mo prospective, real-world observational study comparison of study period with baseline** | N = 558, 1–71 yo, T1D, baseline mean HbA1c: 6.8% | | −10 mg/dL | +7% | −0.2% | −0.05% | −2% | −0.3% |

**Time in range change from baseline estimated from median.
Abbreviations: GMI, glucose management index; HbA1c, glycated hemoglobin; mo, month; yo, years old.



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**Table 6. Summary of recommendations: target populations**

- Strongly consider recommending AID systems to all people with T1D to improve glycemic control
  - School-aged children (7–14 years) (2, 3, 5, 20, 46, 63–67) **A**
  - Adolescents/Adults (3, 6, 68) **A**
- Consider recommending to:
  - Older adults (above 65 years) (2, 29, 68, 69) **B**
  - Preschool children (<7 years) (31, 32, 56, 57, 70–73) **B**
  - People with moderate/severe hypoglycemia and hypoglycemia unawareness (74–77) **C**
  - Pregnancy complicated with T1D (58, 60, 78–81) **C**
  - People with comorbidities: chronic renal failure and gastroparesis (82–84) **C**
- Consider recommending appropriate AID systems to people with other types of diabetes treated with intensive insulin therapy (multiple daily injections or pump therapy):
  - People with type 2 diabetes (60, 61) **C**
  - People after pancreatectomy **E**
  - People with cystic fibrosis–related diabetes (85, 86) **C**
- Use of AID under supervision should be allowed in hospital settings if not contraindicated by clinical status or treatment needs **E**

### The Optimal Time to Initiate AID

Early initiation of diabetes technologies in recently diagnosed PwD has been shown to improve and sustain long-term glycemic control, and thereby perhaps reduce the risk of diabetes-related complications (93–95). Moreover, tight glycemic control from disease onset in people with T1D may help to preserve beta-cell function (96). There are no definitive data to support the benefit of early initiation of AID systems on long-term metabolic control or beta-cell preservation (97). Studies are underway to examine the safety and efficacy of early AID adoption in adults and children newly diagnosed with T1D (98, 99). Likely benefits of early initiation include long-term glycemic control, long-term device acceptance, durable use, and a particular benefit for preschool age (100).

### Setting Up the AID System

AID settings should be selected according to individualized glycemic targets, based on recently acquired CGM metrics (101). In poorly controlled individuals, using the highest system glucose target possible for the first few weeks is suggested. When determining the settings, the healthcare provider should use conservative estimates to ensure prevention of hypoglycemia. The information needed for initiating the AID system and the parameters that affect automated insulin delivery differ widely across different AID systems. Clinical judgment should be used where programmed regimens do not result in optimal glycemic outcomes. Requirements for initiating AID for specific systems are provided in Table 8.

## Education, Training, and Support

A rigorous, comprehensive, consistent, and structured education curriculum for AID must be of high priority for all AID systems and must be individualized for each PwD. The following recommendations present the essential elements that should be considered in providing education and training to

**Table 7. Summary of recommendations: initiating AID use**

- Make AID systems available to all people with T1D (2, 3, 7, 8).
- Initiation of AID can be done with in-clinic or digital/virtual training; further research is warranted on how to design, implement, and evaluate individual training programs, including required follow-up and long-term glycemic outcomes.
- Ensure that the PwD and their care partners can demonstrate proficiency in intensive insulin therapy knowledge and skills before initiating AID.
- Individualize training in AID based on each PwD's current therapy:
  - MDI + blood glucose monitoring
  - MDI + CGM
  - CSII + blood glucose monitoring
  - CSII + CGM (as nonintegrated and integrated components)
  - AID system
- Personalize training and follow-up based on the PwD/family, health care settings, etc.
- Consider starting people with T1D who are "*technology naïve*" on either an insulin pump or CGM before transitioning to AID. In some cases, the insulin pump and CGM can be initiated simultaneously.
- Advise people with T1D who are transitioning from prior insulin pump therapy to AID to use current pump settings if glycemic control is acceptable; however, pump parameters (basal rate, bolus settings) may need reassessment.
- Address insulin to carbohydrate ratios (ICRs), correction doses, basal rates, accounting for ratio of basal/TDD as well carbohydrate intake (eg, low carb diets).
- Individualize the approach to AID depending on the AID system, considering target glucose, active insulin time, etc.
- Provide fundamental guidance regarding hypoglycemia and hyperglycemia treatment with AID, exercise management, switching to open loop or MDI (for "pump vacation"), sick day management, etc (*see* "Clinical Recommendations for AID Use" section).
- Particular attention should be paid to use of adjunctive therapies (eg, SGLTs), and whether continuing such therapy is safe or feasible.
- The diabetes care team should discuss limitations and benefits for AID use:
  - Set realistic expectations for AID system user requirements: handling mealtime boluses/timing; handling CGM and pump use; handling exercise with pre-, during, and post- exercise adjustment as needed; manual insulin delivery during CGM warm-up, loss of connectivity, etc.
  - Review published data on the expected benefit on glycemic outcomes, improvement in overnight glucose control, restful sleep.
- Considerations should be made when initiating AID for people with long diabetes duration (especially those with eating disorders) and/or suboptimal control:
  - Potential transient worsening of retinopathy with need for ophthalmologic care prior to initiation of AID along with close follow-up with ophthalmology.
  - Potential temporary neuropathic pain, insulin edema, increase in microalbuminuria and other microvascular complications.

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**Table 8. Recommendation for preparation and initiation of AID system**

| | Medtronic 670G/770G/780G | Tandem Control-IQ | CamAPS FX | Insulet OP5 |
|---|---|---|---|---|
| **Preparation before starting AID** | • Set up realistic expectation, assess user willingness to learn and adapt to new technologies<br>• In individuals who are CGM naïve, initiation of CGM 1–2 weeks prior to commencing AID may be helpful<br>• In individuals using MDI, initiation of pump (along with CGM) and education on infusion set issues, early recognition and treatment of ketosis diabetic ketoacidosis, 1–2 weeks prior to commencing AID may be helpful<br>• Training videos may be helpful to understand AID system and its requirements | | | |
| **Information needed to start AID** | TDD from 3–7 days of using the Medtronic AID pump | Body weight and TDD, basal profile, CHO:I ratios, CF's | Body weight and TDD | Basal profile, CHO:I ratios, CF's, AIT |
| **Recommended initial settings** | • Basal rate does not play role in auto mode but is needed for manual mode and it should be reduced by 10% if it constitutes more than 50% of TDD<br>• ICR should be strengthened by 10%<br>• AIT between 2–4 hours (shorter AIT is better) | • Optimize the basal rate (general guide is 50% of TDD)<br>• Set up sleep activity which narrows glucose targets to 112.5–120 mg/dL (6.3–6.7 mmol/L), best to extend beyond usual breakfast bolus time | • Optimize the basal rate (general guide is 50% of TDD should be basal)<br>• Extended bolus feature must be on when using Dana pumps<br>• Maximum bolus should be set at 50% of TDD<br>• Daily maximum should be 3 times the TDD for Dana pumps | • Basal rate does not play role in auto mode but is needed for manual mode and it should be reduced by 10% if it constitutes more than 50% of TDD |
| **Glucose targets** | • 670G/770G is 120 mg/dL (6.7 mmol/L), nonadjustable<br>• 780G can be 100 mg/dL (5.6 mmol/L) or 120 mg/dL (6.7 mmol/L); may use 120 mg/dL (6.7 mmol/L) initially in a person with high A1c or in children and older adults | • A control to range algorithm with daytime range of 112.5 to 160 mg/dL (6.3–8.9 mmol/L), and sleep target range of 112.5 to 120 mg/dL (6.3–6.7 mmol/L) | • Set individualized glucose targets between 80–200 mg/dL (4.4–11.1 mmol/L) | • Individualized glucose targets between 110–150 mg/dL (6.1–8.3 mmol/L), can be programmed throughout a day (up to 8 segments) |
| **AID adaptivity** | • TDD updated daily with fading memory over 6 days<br>• Adjusts CF, basal rates | • TDD uses 6-day average to adjust algorithm aggressiveness | • Continually adapts independent of pump settings | • Occurs with each pod change; first pod is constrained, after first pod, then full adaptivity<br>• Estimates TDD by multiplying programmed basal insulin by 2 |
| **Autocorrection** | • None with 670G/770G<br>• Every 5 minutes with 780G | • Can occur 1 hour after a previous bolus: 60% of calculated to a target of 110 mg/dL (6.1 mmol/L) | • None (algorithm tuned not to need bolus autocorrection) | |
| **Modifiable factors to optimize AID** | • ICR and AIT | • Basal rate, correction factor, and ICR, sleep duration, and timing<br>• Exercise- targets glucose at 140–160 mg/dL (7.8–8.9 mmol/L) | • None – algorithm independent of pump settings | • ICR, and correction factor, glucose targets<br>• AIT is only for user-initiated bolus (with corrections and food boluses). Pump's AIT is not used for auto mode insulin delivery |
| **Exercise** | • Temp target to 150 mg/dL (8.3 mmol/L), programmable duration | • Target glucose is 140–160 mg/dL (7.8–8.9 mmol/L), stops basal at 80 mg/dL (4.4 mmol/L)<br>• Currently must be manually stopped (no duration setting) | • "Ease-off" – target glucose increased by 40 mg/dL (2.2 mmol/L), and insulin sensitivity increased programmable for 10 min to 24 hours (can also be preplanned) | • "HypoProtect" target is 150 mg/dL (8.3 mmol/L<br>• All basal/bolus/corrections are 50%<br>• Duration is programmable for 1–72 hours |

(*continued*)



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**Table 8**. Continued

| | Medtronic 670G/770G/780G | Tandem Control-IQ | CamAPS FX | Insulet OP5 |
|---|---|---|---|---|
| **Reverse correction if below target** | • With 780G uses "safe bolus" | • No | • Yes | • Yes, but can be toggled off |
| **Extended bolus** | • No | • Yes, current max time is 2 hours | • No | • No |
| **Use of CGM trend in bolus calculation** | • No | • No | • No | • Yes |

Abbreviations: AIT, active insulin time; CF, correction factor; CGM, continuous glucose monitor; ICR, insulin to carb ratio; TDD, total daily insulin dose.

individuals who are initiating AID. Table 9 presents recommendations for patient training and education.

## Training for AID Systems

It is important to emphasize that transition to AID systems should be individualized. In general, persons who are CGM naïve will benefit from several days of CGM use before commencing AID. This period can be used for education on alarms, trend arrows, and data interpretation for optimization of insulin therapy, which may allow for better starting parameters for AID transition. CGM user engagement requires insertion of sensors, replacing sensors when failures occur, and knowledge on how to troubleshoot sensor failures. This education is vital to avoid burnout, frustration, and to optimize successful device use. Those who are naïve to CSII therapy should follow existing protocols for switching from MDI to CSII therapy, considering 1 to 2 weeks of SAP therapy before commencing AID. Education for CSII-related eventualities such as alternating pump insertion sites, replacing infusion sets, and how to troubleshoot pump occlusions are advised. Pump users should consider using SAP mode for several days if switching from a different pump brand, allowing for adaptation both to the user interface and to the bolus calculator that may require insulin dose adjustments. It is recommended that PwD and care partners demonstrate understanding of the AID system features, how to use them, and how to troubleshoot. Initial training can be successful when delivered face-to-face, by videoconference (107–110), and with supporting roles for e-learning, video, simulation apps, and combined approaches. Where applicable, industry should continue their essential role in certifying trainers to provide initial device training.

## Emphasize Choice and Personal Reasons

PwD should have the opportunity to assess the full benefit and burden of available AID systems to decide if and which device is most suitable for them. Educational support, personal resources, age/licensing/availability/insurance, and personal preferences need to be considered, and unbiased sources should be heavily utilized by PwD (eg, clinical educators, noncommercial entities such as JDRF, ADA, Association of Diabetes Care & Education Specialists [ADCES], Diabeteswise.org, or BDCPantherDiabetes.org).

## Prioritize Comprehensive Education

PwD must be trained and assessed for proficiency on general diabetes management, carbohydrate counting, insulin pump use, and CGM use in order to use an AID system safely. We recommend the creation and use of a universal pre-AID checklist or framework to comprehensively review essential education. AID training is not just technical and cannot be separated from the overall management of diabetes. It is actually adding on the tip of the pyramid of education. The base is the core diabetes knowledge and management education, CGM basics, insulin pump basics, and on the top is the AID basics education. Table 10 presents a comprehensive pre-AID education checklist.

It is helpful for PwD to know how to check progress they are making when using an AID system, both through reports on their mobile devices, on their personal cloud-based accounts, or eventually their electronic health record AID

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**Table 9. Summary of recommendations for training and education**

- Advise users to consistently wear the CGM, respond to system alerts, and perform actions as needed to stay in AID mode as much as possible for optimal glycemic control.
- Proactively address user expectations (102–104): AID systems may take several weeks to perform optimally, and PwD need time to acclimate to the system. Psychological considerations such as learning to develop trust in the automated system as well as having realistic expectations for glycemic control should be proactively addressed prior to AID start and on an ongoing basis.
- Reinforce the importance of maintaining self-management skills, including blood glucose checking, ketone checking, administering a syringe or insulin pen injection, regular review of default basal insulin delivery settings, calculating a correction dose of insulin in case of system malfunction, identifying diabetes emergencies, and carrying supplies to handle them (102, 104).
- Remind users how to recognize signs of infusion set failure: in cases of sustained hyperglycemia above 250 mg/dL, and/or after a bolus insulin correction, the glucose level does not drop by at least 50 mg/dL within 1 hour of treatment (105). (*see* "Clinical Recommendations for AID Use" section for more information on pump malfunction).
- Emphasize the importance of understanding the benefits of pre-meal bolusing and AID response to postprandial hyperglycemia. Encourage users to bolus accurately for all meals and snacks (104, 106). Educate users, in case a meal bolus was missed, to give half of the meal bolus amount or not to bolus at all, depending on when they remembered the missed bolus (*see* "Clinical Recommendations for AID Use" section for more information on bolusing).
- Advise users to consider treating hypoglycemia with less carbohydrates than usual, and respond to system cues such as CGM arrows, CGM trend, and insulin on board (104). Remind users that the AID system may have reduced/suspended insulin prior to hypoglycemia.
- Assist users in setting CGM alerts to be actionable and not a nuisance. (*see* "Clinical Recommendations for AID Use" section for more information on alert fatigue).
- Educate users about the risk of trying to "trick the system." Using techniques such as entering fictitious carbohydrates, overriding bolus calculators, taking extra insulin outside of the system, etc, can lead to increased glucose lability and decreased system performance.
- Counsel PwD how to handle their AID system in special situations (illness, exercise, pregnancy). Users may consider transitioning to open loop in circumstances where more manual control is desired (eg, ketones, steroid bursts, sports competition, pregnancy, altered mental status, etc). When disconnecting their AID system for more than 15–30 minutes, advise users to suspend insulin delivery so AID does not try to automate insulin while disconnected.

Abbreviations: AID, automated insulin delivery; CGM, continuous glucose monitoring; CL, closed loop; PwD, people with diabetes.

summary reports. Further, PwD need to anticipate new challenges and learning opportunities with AID systems and to expect the need for clinical follow-up early after AID initiation.

### Implement Universal Early Follow-Up

PwD are at increased risk for discontinuing devices in the first 3 to 6 months of use (45, 65, 68); therefore, early clinical follow-up is essential, but often not defined or consistent with routine diabetes follow-up (111, 112). Diabetes teams should consider creating "Initial Device Optimization" follow-up plans for new AID device users to: (a) assess system use; (b) reinforce appropriate expectations; (c) optimize insulin dosing and behavior; (d) provide troubleshooting; and (e) gain trust in the system. These topics should be universally covered, but the content and timing can be personalized to the needs of the user, ideally within the first 2 to 4 weeks after device initiation. This could be accomplished through phone calls with data review, videoconference, or in-person visits with their diabetes team. Additional use and creation of e-learning, and training videos may be useful. Although there are no data related to worsening or occurrence of neuropathy with AID initiation, there may be a need for retinal checks and/or retinal stabilization before and after initiation of AID in people with suboptimal glycemic control.

### Clinical Roles

There is no universal role differentiation between diabetes providers, diabetes educators, and other members of the healthcare team with AID systems, as every practice environment is different. All clinicians should be aware of how AID systems work (104) and could benefit from brief training videos, webinars, demonstration devices, step-by-step tools, and device simulation apps (102, 113). Additionally, practices or regions should consider the role of "Diabetes Technology Specialists" to provide more specific troubleshooting and device optimization strategies to support other clinicians and PwD. Consider the development of a standard curriculum, clarifying the scope of this role, and possible certification programs to formalize this role.

### Routine Clinical Assessment

Diabetes clinicians must be able to provide competent clinical assessment of AID use for routine care (33, 102). Table 11 presents a proposed standard approach for clinical practice, which includes 4 key components. Clinical AID tools should be developed to standardize these principles across AID systems and models of care.

## Clinical Recommendations for AID Use

AID systems are labeled for efficacy and safety based upon manufacturer-specified instructions. PwD should be advised that actions such as entering fictitious carbohydrates, performing postprandial meal boluses, manual insulin bolus corrections, or overriding recommended doses unless educated to do so (eg, during prolonged exercise after a meal) can lead to glucose instability, increased hypoglycemic risk, and destabilized systems.

We should reconsider the traditional concepts of "basal" insulin and "bolus" insulin, which become less useful with AID, as both types of insulin delivery are used to mitigate hypoglycemia and hyperglycemia and contend with carbohydrate consumption. Instead of basal-bolus we suggest using the terms of *user-initiated* and *algorithm modulated insulin delivery*. Importantly, all current commercial AID systems still

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**Table 10. Pre-AID comprehensive education checklist**

| |
|---|
| **Core diabetes knowledge** |
| Insulin action time |
| Blood glucose and blood ketone testing |
| Importance of proper nutrition |
| Importance of physical activity |
| Treating hypoglycemia |
| Carbohydrate counting |
| Checking in witd psychological concerns around diabetes and diabetes care |
| **Insulin pump basics** |
| Set changes and site rotation |
| Connecting and disconnecting infusion set or tubing (if applicable) |
| Bolus insulin vs basal insulin |
| Data interpretation |
| Physical activity and sport, holiday, alcohol, menstrual cycle, etc management |
| Infusion set failures, manual injections, checking ketones, emergency management |
| **Continuous glucose monitoring basics** |
| Sensor changes and site rotation |
| Connecting, pairing, programming components |
| Calibrating (if applicable) |
| Using CGM information (trend line, trend arrows, alerts, data sharing, downloads) |
| **AID (prior to device training)** |
| Understanding tde different CL system options to weigh tde burden and benefit of each one to tde PwD |
| Importance of maintaining knowledge of diabetes management principles described above |
| Expectations of CL |
| How CL differs from open loop insulin tderapy |
| Importance of early follow-up witd clinical team after starting CL |

Abbreviations: AID, automated insulin delivery; CGM, continuous glucose monitoring; CL, closed loop; PwD, people witd diabetes.

require user-initiated bolusing for carbohydrate intake. Pump settings (such as insulin action time, basal rates, etc) are handled differently in the various AID systems, dissimilarities which preclude our ability to provide general recommendations. Refer to Table 8 for system specifications. The following are general recommendations for use of AID systems (should be tailored individually). (Table 12). Recommendations for AID adjustments for physical activity are presented in Table 13.

## How to Report and Present AID Data

Internationally agreed upon standardization of CGM metrics, targets, and a report to visualize them were published and endorsed by a wide range of diabetes associations and endocrine societies (101, 119–121). The use of AID systems is based on CGM data, and its success may be measured in improved CGM outcomes such as TIR. As the use of AID grows, it is therefore important that clinical teams receive AID data reports with consistent and familiar data displays (122). Data should be provided in a way that assists with appropriate modification of insulin delivery settings.

**Table 11. Proposed approach to the assessment of AID use**

| | |
|---|---|
| *1. System descriptions* | Clinicians can be provided with a brief summary of device information, using **CARES** framework (provides information on how each system **C**alculates insulin delivery, which parameters can be **A**djusted, when users should **R**evert to traditional insulin pump settings, critical **E**ducation points, and key aspects of the sensor and **S**haring capabilities of the system) (104, 114) or other. |
| *2. How to ASSESS glycemic information* | Clinicians can explain how they interpret CGM data, including TIR, TAR, TBR, mean glucose, Glycemic Management Index (GMI) and glycemic variability (101, 115). |
| *3. How to OPTIMIZE AID settings* | Clinicians can explain which settings/parameters can be changed, best practices for insulin dose titration as applicable to the system, comparing AID basal to open loop basal. |
| *4. How to GUIDE behavioral recommendations* | Clinicians can explain bolus behavior, use of special modes, frequency of infusion set changes (33). |

An academic panel of experts in AID system development, research, or clinical use collaborated to generate a template for an AID system data report. The standardized 2-page "Automated Insulin Delivery Report" (AID Report) (Fig. 1) template was arranged to make sure that the clinically most important glucose and insulin metrics are shown at the very top of the first page (upper panel). The middle panel of the first page contains the Ambulatory Glucose Profile (AGP) chart that has become the standardized way to represent aggregated CGM data, usually over 14 days. The bottom panel of the first page contains the bolus (mealtime) insulin assessment with average meals per day and average carbs entered per day indicated at the top of the section banner. Each mealtime displays a glucose profile created when one or more insulin boluses is delivered within the specified mealtimes.

The second page of the report shows detailed daily glucose profiles (Fig. 2). Most clinicians want to see records over a useful period of time, commonly 14 days, and there will likely be further pages of daily views, as requested. Note, only 1 daily profile is shown for illustrative purposes.

AID systems differ in the way glucose is controlled and insulin is delivered. Therefore, modification of the report might be needed according to the specific system features. The report aims to present the relevant data and metrics that can assist the health care provider in decision making and in adjustment of the system parameters that can be modified.

## Psychological Issues and PwD Perspectives on AID Systems

An increasing number of trials with AID systems incorporate psychosocial variables among their outcome measures. Improvements in patient-reported outcomes have not been consistent (48–51, 123, 124), yet all studies showed there

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**Table 12. Summary of recommendations for use of AID system**

- *User-initiated bolus for meal:carbohydrate ratio (ICR) settings are important:*
  - For hybrid AID systems which use ICR for meal bolus, the ICR should be evaluated routinely after initiation by assessing post-meal glucose excursions and aiming for <60 mg/dL (<3.3 mmol/L) increase compared to pre-meal, similar to the recommendations for open loop systems.
  - Some systems benefit from more aggressive ICR (eg, numerically lower ICR) by 10 to 20% (116, 117) as compared to open loop settings to help minimize post-meal glucose excursions.
- *User-initiated bolus timing for meals:*
  - Timing user-initiated insulin boluses prior to carbohydrate intake is especially important, as AID will automatically increase algorithm modulated insulin delivery after an initial rise of glucose levels, so a bolus delivered either during or after carbohydrate consumption could lead to insulin stacking and hypoglycemia.
  - Generally, user-initiated meal boluses should be given in advance of a meal (usually 10–20 minutes) unless there is incipient hypoglycemia, gastroparesis, or high protein/fat meal. Faster insulins may shorten the timing of the bolus. Adjunct therapy and meal composition may also influence timing.
  - In situations where a meal bolus is missed or delayed, consider giving half the bolus 30–60 minutes after the start of the meal, or if more than 60 minutes have elapsed from start of the meal a user-initiated correction bolus can be given, based on the glycemic rise (eg, the system-recommended correction bolus only).
  - While some systems have the ability to give an extended bolus, the clinical utility may be limited in most AID systems. This is due to the fundamental algorithm modulated insulin delivery (AMID) that is the hallmark of these systems, which will inevitably increase algorithmic insulin delivery for persistently elevated glucose that can be seen after certain meals, like those with high fat content.
  - Low carbohydrate intake may be used to improve glycemic control for adults using AID (118).
- *Exercise management:*
  - Setting a higher glucose target, ideally well before starting the activity (up to 1 to 2 hours in advance), particularly for prolonged aerobic exercise. This temporary target can be canceled at the end of exercise or be maintained post exercise if post-exercise hypoglycemia is a concern.
  - Minimizing activity at times of peak bolus insulin action appears to increase AID efficacy around exercise. To facilitate this, a pre-meal bolus dose can be reduced by approximately 25% to 75% if prolonged exercise is anticipated within 3 hours of a meal.
  - If the pump is disconnected during exercise, insulin delivery should be suspended so that the algorithm does not account for algorithm modulated insulin delivery that is not delivered to the person with diabetes.
- *Carbohydrates before exercise:*
  - Advise users against consuming carbohydrates 15 to 60 minutes prior to exercise, unless glucose is trending toward hypoglycemia because AID systems will respond by automatically increasing insulin delivery which might increase the risk for hypoglycemia during the activity. However, this recommendation should be individualized, and carbohydrates can be suggested in the following circumstances:
  - Advise 15 g carbohydrate if glucose is <120 mg/dL (6.7 mmol/L), 10 minutes pre-exercise, especially for moderate intensity exercise.
  - Simple carbohydrates can be taken at exercise onset, or just prior to exercise as long as the temporary target is set. Carbohydrate feeding during a prolonged exercise activity, without entering the carbohydrate intake into the AID, may be needed to help maintain glycemia and help with endurance performance. If the AID function is suspended during the activity (ie, if the pump is set to "open loop" or "standard" mode), carbohydrates can be taken freely before and/or during exercise to increase or maintain a desired glucose target.
  - Summary table for exercise management is provided in Table 13.
- *Treatment of hypoglycemia event (>15 minutes at <70 mg/dL, hypoglycemia alert event):* (119)
  - Start hypoglycemia event treatment with 5–10 g carbs with an exception for hypoglycemia with exercise, or in case of significant over-estimation of carbs/meal bolus.
  - Wait for 15 minutes before re-treating hypoglycemia to avoid oscillating glucose levels.
- *Treatment of hyperglycemia event and ketones:*
  - In case of sustained hyperglycemia, it is recommended to measure blood glucose (by glucometer), monitor ketones and perform a set change.
  - As with all insulin pumps, DKA remains a concern due to potential infusion set failure. A user-initiated correction bolus might be needed.
  - A correction may be more effective using an insulin pen/syringe, as in case of set failure and multiple correction attempts, IOB may be falsely elevated thus preventing an additional bolus.
  - If giving a corrective insulin injection, advise users that the AID should be turned off for 2 to 4 hours that insulin-on-board (IOB) is accurate.
- *Sick days treatment:*
  - Advise users to consider stopping AID and move to open loop sick day management plans (eg, monitor ketones and increase open loop insulin), especially in case of elevated ketones and glucose levels within normal range.
  - Before small procedures (such as gastroscopy) AID can be used with a temporary glucose target or hypoglycemia protect mode.
- *Types of insulin:*
  - A rapid-acting insulin is recommended for AID systems. Using ultra-rapid analogs may be considered for a greater clinical advantage in PwD who tend to miss meal boluses or prefer to bolus immediately before a meal (if approved for use in the system).
- *Tuning open loop settings:*
  - Adjustments to open loop settings should be performed for times when PwD may need to use, or choose to use, open loop therapy.
  - If a PwD is going off AID for extended periods, consider using more conservative ICR settings as a method to avoid hypoglycemia, since ICR are often intensified for optimal AID performance.
  - Multiple daily injection regimens should be available when switching from AID to MDI in case of pump failure or pump break.
- *Avoiding alarm fatigue:*
  - Advise users that minimizing alarms to those that require immediate attention can help avoid alarm fatigue.
  - Clinicians need to assist users to develop plans to respond to alerts (for example, advising that fewer carbohydrates will be needed to treat hypoglycemia while on an AID system).
  - One suggestion is to start with hypoglycemia only alerts (at a lower threshold of 65–70 mg/dL [3.6–3.9 mmol/L]), and add hyperglycemia alerts if tolerated (starting higher, 250–300 mg/dL [13.8–16.7 mmol/L]).
- *Glycemic targets with AID:*
  - Although many PwD are able to achieve currently recommended targets for time in range, separate targets for AID are currently not recommended. However, these may be subject to change as the technology evolves and should be customized according to the individual PwD.

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**Table 13. Adjustments for physical activity in AID**

| Type of Exercise | Before Exercise | During Exercise | After Exercise | Overnight |
|---|---|---|---|---|
| Aerobic | Reduce basal rate with 'exercise target' 1–2 hours prior | Reduce basal rate with 'exercise target' or suspend insulin delivery[a] | Reduce basal rate with 'exercise target' 0–6 hours after | 'Exercise target' overnight (up to 6 hours) as necessary And/Or Uncovered bedtime snack |
| Aerobic & Anaerobic | Reduce bolus amount by 0%–25% in 1–3 hours prior (maybe up to 75% is prolonged exercise is anticipated) | In case glucose level is below 120 mg/dL, consume 10–20 g carbohydrates at start or 10 min prior[b] Carbohydrates as needed | Reduce bolus up to 50% at post-exercise meal | |
| Anaerobic | May not need insulin adjustments | May not need insulin adjustments | Reduce bolus or cancel exercise target | |

[a]Confirm insulin pump suspension.
[b]Avoid consuming carbohydrates 15–60 minutes prior to exercise (can be given as needed during exercise)
Prepared by Laurel H Messer.

was no deterioration, if not an improvement, in quality of life (QoL). Some have reported a significant reduction in fear of hypoglycemia (50, 124) and others have found a reduction in diabetes distress and increased quality of sleep (53). Many PwD as well as their care partners, including parents, spouses, adult children of PwD, and other caregivers, feel that AID has been "life-changing" and restores a greater sense of well-being, and that they have great hope for the next steps toward full automation of insulin delivery (125).

A major issue in sustainable AID use is supporting user acceptance and helping the users to integrate AID use into their daily lives and to address the numerous challenges accompanying long-term AID use. In addition, user expectations should be acknowledged by different health care providers. Because many of these challenges are psychological and behavioral in nature, further research is needed to develop strategies that effectively address these issues. Table 14 presents recommendations, gaps, and opportunities.

It is well-established that there are considerable disparities in healthcare delivery, access to structured diabetes education, uptake of diabetes technologies, and achievement of diabetes-related treatment targets across gender, geographic area, racial/ethnic groups, and level of social deprivation (127, 128). Although the use of new technology has been proven to be beneficial in clinical trials, participation in such trials has so far lacked the necessary diversity across ethnicity, socioeconomic status, and health literacy. One explanation for this may be that research has largely been conducted through academic medical centers, posing a barrier to participants who are unable to travel to these centers partly due to social determinants of health. However, other factors may also play a role, such as providers' bias in recruiting study participants and the use of clinical sites whose population either does not include or includes few members of racial/ethnic minority groups. The importance of including minorities in clinical studies, beyond the generalizability of outcomes, is contribution to device development along with improved propagation and marketing policies to increase AID use among underrepresented groups (62).

In 2020 and 2022, the FDA published guidelines on how to enhance population diversity in clinical trials. These include specifying enrollment targets according to race/ethnicity, choosing clinical sites in geographic areas that will enable representation of minority populations, and including a diverse study team of health care providers to help in recruitment (129). Recently, leading journals are required to provide detailed racial/ethnic distributions in reports of clinical trials and it is hoped that this would lead to more representation of minorities in trials in the future (130, 131). Still, there is a need to create regulation and reporting procedures that will promote inclusion and diversity in clinical trials in addition to multidisciplinary stakeholder engagement in disparities research (132).

Inequalities in technology access have not been overcome, and the reasons for this beyond the socioeconomic status are poorly understood (133, 134). Unfortunately, many healthcare systems make access to diabetes technologies in general, and AID systems in particular, very difficult to obtain and maintain. Advocacy efforts are required to make diabetes technology and AID systems available to all people with diabetes who would benefit from their use. Failure to achieve equity and access to AID systems may translate into a 2-tiered system of diabetes care based on who can, and cannot, access diabetes technology.

Moving forward, to support access to AID systems, all clinicians working with PwD will have to become familiar with the available systems. Appropriate education should be developed that is high in quality, efficient, and accessible. Coordination and cooperation across professional organizations should be encouraged to maximize impact and reach. Shared professional resources should be encouraged. Greater coordination, cooperation, and partnership will be the key to providing adequate support and equip clinicians with the required skills so they may confidently offer their patients the best diabetes technologies available, including AID systems. It is clear that this technology has brought positive life-changing experiences for many users.

## The Future of AID: What Will It Look Like?

There are several directions for the future development of the next generation of AID systems:

### AID Component Interoperability

In December 2019, the FDA authorized the first interoperable AID controller (135). According to the FDA press release: "*This authorization paves the way for Integrated CGMs (iCGMs) and alternate controller-enabled insulin pumps (ACE pumps) to be used with an interoperable automated glycemic controller as a complete automated insulin dosing system.*" Other algorithms will follow and, together with

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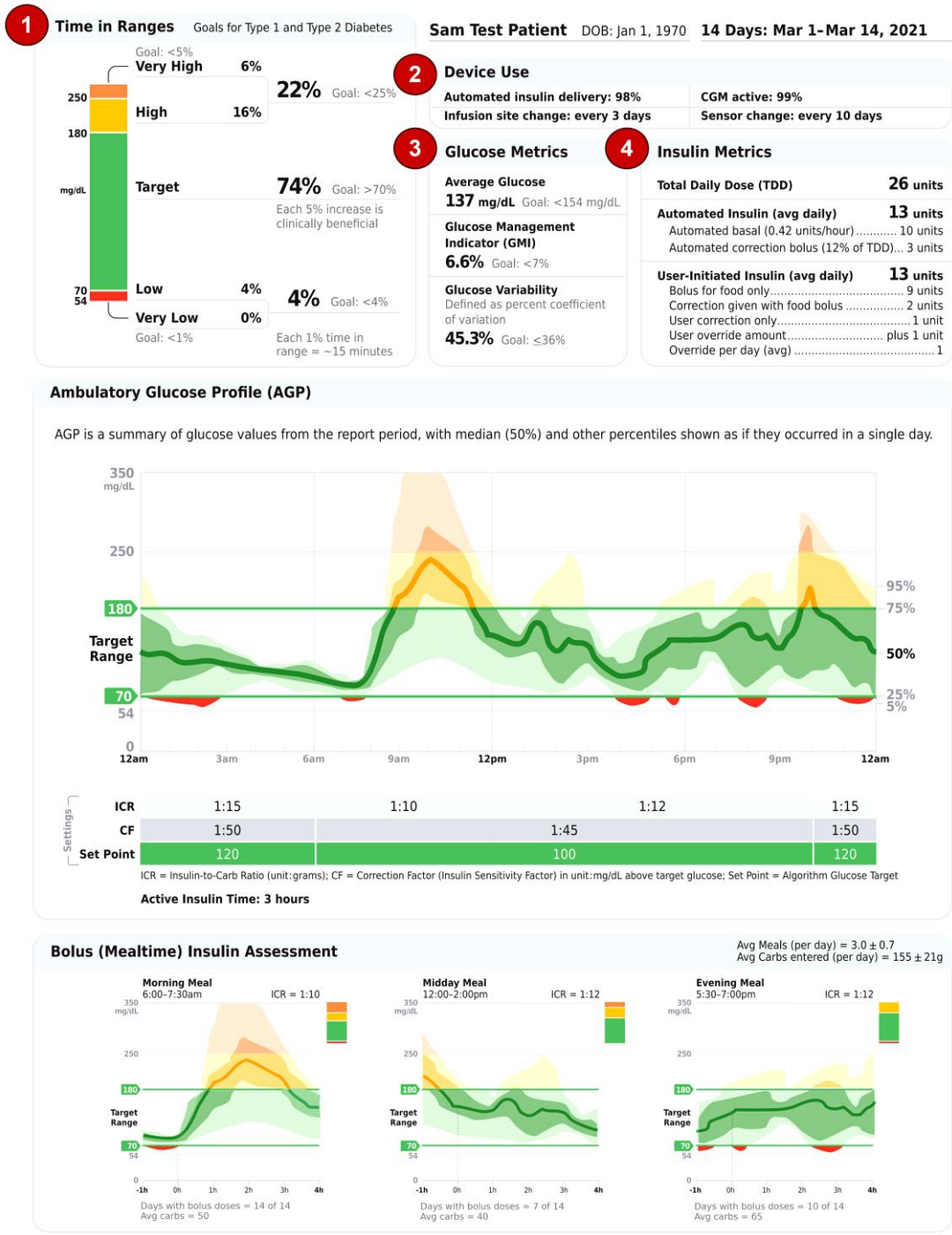


**Figure 1.** Automated Insulin Delivery Report: Page 1. **Upper Panel,** 1, The upper left section contains the clinically important time in ranges (bar) and internationally recognized goals to allow the clinician to quickly ascertain the overall level of glucose management. 2, The essential device use information, including percentage of time AID and CGM were active, along with infusion set and sensor change information, is at the top of the first page to alert the clinician of any data sufficiency or safety concerns. 3, The middle upper panel contains essential glucose metrics, including average glucose, glucose management indicator (GMI), and glucose variability calculated as percentage coefficient of variation. 4, The final component of the upper panel is a table containing detailed insulin metrics divided by how the insulin is delivered, either automatically by the AID system (called automated insulin) or user-initiated insulin delivery. Automated insulin metrics include the average amount of insulin delivered per day and the calculated average units per hour. In addition, the daily average automated correction bolus delivered along with the calculated percentage of total daily dose (TDD) is listed. Detailed insulin metrics describing the average user-initiated amounts of bolus insulin given for food, correction insulin given with the food bolus, and correction only insulin are listed. In addition, the average amount of user overrides insulin delivered per day and average overrides per day are listed. **Middle Panel,** Below the AGP are the AID system settings, including the insulin to carbohydrate (ICR) (1 unit insulin/g CHO), correction factor (CF) (or ISF, Insulin Sensitivity Factor) (1 unit insulin/mg/dL or 1 unit insulin/mmol/L), algorithm glucose set point and active insulin time (that may or may not be adjusted depending on the AID system). **Lower Panel,** The mealtime glucose metrics begin 1 hour before the meal to show the user's average glucose level prior to the meal and ends 4 hours after the start of the meal. The start of the meal is the time when the user-initiated bolus is delivered. The number of days with meal boluses recorded is listed to help identify mealtimes where user-initiated bolus insulin may have been omitted. The average amount of carbs per mealtime is also listed. Of note, automated correction boluses may have also been delivered (in AID systems that have this feature) during the post-meal period and may be reflected in the late post-meal period.

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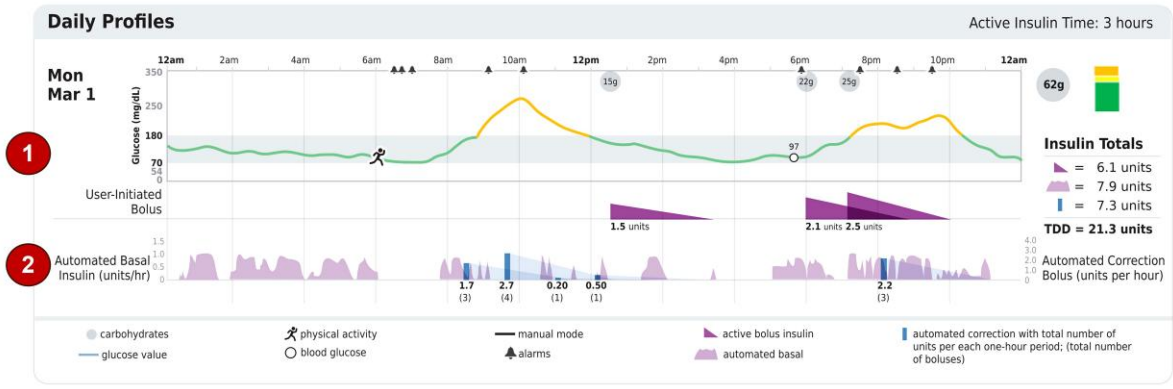


**Figure 2.** Automated Insulin Delivery Report: Page 2. 1, The top part of the daily profile displays the CGM tracing and is color coded to match the time in ranges bar (eg, green when in target range of 70 to 180 mg/dL, red when less than 70 mg/dL ang gold when above 180 mg/dL). The user-entered carbohydrate is shown above the CGM tracing in gray circles and total amount of carbohydrates is shown on the bar right. Just below the glucose tracing is the amount of user-initiated bolus insulin in dark purple with the common "insulin sail" to show that active bolus insulin is available. 2, The lower section of the daily profile contains the automated basal insulin tracing in light purple with the left y-axis showing the rate in units/hour and the automated correction boluses delivered with the right y-axis showing units per hour. The total amount of correction boluses delivered in each 1-hour period of the day is shown by the thin blue line with the number of corrections in that hour shown in parenthesis below the total insulin amount. Total insulin amount for each day is shown on the right of each daily profile using icons to designate how the insulin was delivered along with the TDD.

iCGM and ACE pumps, will create an ecosystem of AID components that can be mixed and matched. Regulatory agencies across the world are reviewing this issue and we are confident that positive steps will be taken. Nevertheless, challenges will remain; thus, academic and corporate groups should continue working on a global interoperability standard.

## Better Insulin Time-Action Profiles

The delay associated with insulin absorption from the subcutaneous insulin depot into the bloodstream is still a bottleneck. Thus, virtually all commercial AID systems are "hybrid," necessitating meal and exercise announcements to achieve glycemic targets. Insulin analogs that are absorbed faster are becoming increasingly available (136), and it is assumed that faster insulin will contribute to better glucose control. However, several studies of insulin delivery via insulin pump or AID found that this assumption is not necessarily accurate in terms of TIR; ultra-rapid insulin provides a modest advantage over rapid insulin analogs, at best, or no advantage (137, 138). Future studies will show whether proper adaptation of the AID control algorithms to ultra-rapid insulin will result in clinically significant changes.

Alternative routes of insulin delivery are being explored to improve postprandial glycemic control, and initial results are promising, reporting on intraperitoneal (IP) insulin delivery (139, 140) or pre-meal inhaled insulin (Afrezza) when added to an AID system (141).

## Fully Automated AID Systems

The progress in this direction is directly related to better insulin time-action profiles, alternative routes of insulin delivery, novel control algorithms, and adjunctive agents (eg, glucagon, amylin, glucagon-like peptide 1 [GLP-1], and sodium-glucose cotransporter 2 [SGLT-2] therapies). Additional inputs, such as motion sensing, meal detection, and disturbance anticipation can be employed to control post-meal hyperglycemia and exercise-related hypoglycemia. Funding agencies are actively supporting research on sensors that could provide additional signals, eg, active insulin, lactate, or ketones, although the utility of these additional signals will still be subject to the pharmacokinetics of subcutaneous insulin delivery.

Multi-hormone closed-loop systems, which include AID plus glucagon (13), pramlintide (14) or adjuvant medications such as GLP-1 receptor agonists (142) and SGLT-2 inhibitors (143, 144) to further improve postprandial hyperglycemia, are under investigation. Of note, the data suggest that the control algorithm in these systems may need to be adaptive to the physiological changes caused by some of these medications, thereby increasing technological complexity and regulatory barriers for multi-hormonal systems.

## AID Usability

The size, shape, battery life, physical specifications, and additional customizations of the AID hardware and software will remain critical to system acceptance by the users (145). The stability and safety of data communications, both locally between system components and the user's smartphone, and between the AID system and the Cloud, is critical as well. Convenience and longevity of the infusion sets or tubeless insulin delivery devices must continue to improve—currently, the infusion set is the weakest link in most AID systems. User burden may be reduced with implanted sensors and combined insulin delivery glucose sensing platforms. And last but not least, AID affordability and reimbursement by health care systems will remain the gateway to system adoption.

## The Future Technology Vision

Cloud databases will play an increasingly important role to support data sharing, virtual clinic visits, and remote access and will allow the deployment of data science tools, such as pattern recognition, neural networks, deep learning, and artificial intelligence. In silico preclinical trials have been, and will continue to be, used for rapid and cost-effective testing of new ideas (146). Merging large databases with in silico models will create a comprehensive virtual environment for experimenting with new system components prior to their deployment in clinical trials. A most promising application of Cloud databases and data science tools is the use of adaptation

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**Table 14. Summary of recommendations, gaps and opportunities: addressing psychological and behavioral issues**

**Recommendations**

- AID clinical trials should include participants from diverse populations to ensure equitable access; to improve sustainable engagement in poor areas; to reduce healthcare disparities and make this technology more broadly accessible to underserved areas.
- Trials should pivot away from the typical participants of past studies who tend to be quite "tech-savvy" and have already adopted use of devices such as CGM and insulin pumps. Studies of the processes involved in AID adaptation and adoption in these groups will likely reveal an even more urgent need for PwD education and support, as well as programs to address psychosocial barriers to technology use.
- Engaging primary care is essential for bringing AID technology as a viable option to the full quorum of PwD to ensure they can consider its use. This will require not only industry support, but also increased education.
- Specific support should be available to all clinicians caring for people with diabetes, including the necessary resources to make AID systems viable options in as many clinical settings as possible. This support should also focus on improving workflow and reducing HCP burden.
- AID systems must be used to focus on reducing time spent on diabetes self-management, increasing well-being. The avoidance of medicalizing psychosocial outcomes must be emphasized.

**Opportunities/Gaps**

- AID systems can be used to detect daily glucose fluctuations related to psychological stress. Algorithms can be improved accordingly, as user experience is taken into account during algorithm development (126).
- Future research should consider the role of AID in PwD with eating disorders and other vulnerable groups.
- Further work exploring AID associated improvement for children and families is necessary. Improvement should be quantified and contextualized in terms of potential reduction of risk of intended self-injury and suicidal acts.
- Studies evaluating long-term health benefits of AID related to improved glycemia are needed (such as reduction in diabetes-related complications, neurocognitive outcomes, etc).

Abbreviations: AID, automated insulin delivery; CGM, continuous glucose monitoring; PwD, people with diabetes.

technologies that can "learn" and personalize the response of an AID system to the individual. Preliminary work showing the potential of adaptation is already published (147), and a long-term vision for AID personalized medicine strategy has been presented (148). AID key discreet data and the presented consensus report need to be directly integrated into the electronic health record (EHR). This integration is most important for ease of access by clinicians, ease of communication with PwD, and for population health management (case management). Smart insulin pens connected with CGM will enable a kind of AID for people who prefer to use MDI therapy.

## Summary

Given the associated improvements in glycemic control and quality of life measures, clinicians should strongly consider use of AID systems in PwD who would benefit from this technological option. We recommend that payers support usage of AID systems and other emerging technologies that reduce diabetes burden and improve patient-reported outcomes. Furthermore, studies have suggested long-term cost saving for health care systems using these systems. Therefore, we strongly recommend that all payers (government and private) should reimburse/cover AID systems along with initial and ongoing AID education and training to support the management of people with T1D. Failure to reimburse diabetes technologies such as AID systems will deprive many individuals with T1D who would benefit from this valuable technology and may result in increased disparities in diabetes outcomes due to racial and social inequities (149, 150).

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