7. Diabetes Technology: Standards of Care in Diabetes—2025

*American Diabetes Association Professional Practice Committee**

Diabetes Care 2025;48(Suppl. 1):S146–S166 | https://doi.org/10.2337/dc25-S007

The American Diabetes Association (ADA) "Standards of Care in Diabetes" includes the ADA's current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care. Members of the ADA Professional Practice Committee, an interprofessional expert committee, are responsible for updating the Standards of Care annually, or more frequently as warranted. For a detailed description of ADA standards, statements, and reports, as well as the evidence-grading system for ADA's clinical practice recommendations and a full list of Professional Practice Committee members, please refer to Introduction and Methodology. Readers who wish to comment on the Standards of Care are invited to do so at professional.diabetes.org/SOC.

Diabetes technology is the term used to describe the hardware, devices, and software that people with diabetes use to assist with self-management, ranging from lifestyle modifications to glucose monitoring and therapy adjustments. Historically, diabetes technology has been divided into two main categories: insulin administered by syringe, pen, patch devices, or pump (also called continuous subcutaneous insulin infusion) and glucose as assessed by blood glucose monitoring (BGM) or continuous glucose monitoring (CGM). Diabetes technology now includes automated insulin delivery (AID) systems that use CGM-informed algorithms to modulate insulin delivery. It also encompasses connected insulin pens and diabetes self-management support software that serve as medical devices. Diabetes technology, coupled with education, follow-up, pharmacotherapy if needed, and support, can improve the lives and health of people with diabetes; however, the complexity and rapid evolution of the diabetes technology landscape can also be a barrier to implementation for people with diabetes, their care partners, and the health care team.

GENERAL DEVICE PRINCIPLES

Recommendations

7.1 Diabetes devices should be offered to people with diabetes. **A**

7.2 Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at time of diagnosis. **A**

7.3 The type(s) and 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. **E**

7.4 When prescribing a device, ensure that people with diabetes and caregivers receive initial and ongoing education and training, either in person or remotely, and ongoing evaluation of technique, results, and the ability to utilize data, including uploading or sharing data (if applicable), to monitor and adjust therapy. **C**

**A complete list of members of the American Diabetes Association Professional Practice Committee can be found at https://doi.org/10.2337/dc25-SINT.*

Duality of interest information for each author is available at https://doi.org/10.2337/dc25-SDIS.

Suggested citation: American Diabetes Association Professional Practice Committee. 7. Diabetes technology: Standards of Care in Diabetes—2025. Diabetes Care 2025;48(Suppl. 1):S146–S166

7.5 Health care professionals working with diabetes technology should ensure that competencies are established within the health care team based on their specific roles and within specific settings. **E**

7.6 People with diabetes who have been using CGM, continuous subcutaneous insulin infusion (CSII), and/or automated insulin delivery (AID) for diabetes management should have continued access across third-party payors, regardless of age or A1C levels. **E**

7.7 Students should be supported at school in the use of diabetes technology, such as CGM systems, CSII, connected insulin pens, and AID systems, as recommended or prescribed by their health care team. **E**

7.8 Recommend early initiation, including at diagnosis, of CGM, CSII, and AID depending on a person's or caregiver's needs and preferences. **C**

7.9 Standardized reports for all CGM, CSII, AID, and connected insulin devices with a minimum of a single-page report, such as the ambulatory glucose profile and weekly summary, should be available and utilized. Options for daily and weekly reports and raw data should be available. **E**

Technology is rapidly changing, but there is no one-size-fits-all approach to technology use in people with diabetes. Insurance coverage can lag behind device availability, people's interest in devices and willingness for adoption can vary, and health care teams may have challenges in keeping up with newly released technology. An American Diabetes Association resource, which can be accessed at diabetes.org/living-with-diabetes/treatment-care/diabetes-technology-guide, can help health care professionals and people with diabetes make decisions on the initial choice of device(s). Other sources, including health care professionals and device manufacturers, can help people troubleshoot when difficulties arise (1–10).

Education and Training

In general, no device used in diabetes management works optimally without education, training, and ongoing support. There are multiple resources, including online tutorials and training videos as well as written material, on the use of devices. People with diabetes vary in comfort level with technology, and some prefer in-person training and support. Those with more education regarding device use have better outcomes (1,2); therefore, the need for additional education should be periodically assessed, particularly if outcomes are not being met. Better outcomes cannot be achieved, however, without the training and education of health care professionals. The assessment of competencies in diabetes technology is crucial for prescribers, certified diabetes and education specialists, pharmacists, nurses, and anyone involved in the care of people with diabetes. These competencies are described as basic, fundamental, intermediate, and advanced and are specific to the role of each health care team member (11). In addition, the health care team's knowledge and competency are even more relevant when people with diabetes are started on advanced diabetes technologies, such as AID systems. In such situations, training is vital and should include a discussion about realistic expectations for the ability of the initiated system to achieve glucose goals, the system's features and limitations, and the best way to use the new system to maximize the benefits it can offer (12).

Use in Schools

Instructions for device use should be outlined in the student's diabetes medical management plan (DMMP). A backup plan should be included in the DMMP for potential device failure (e.g., BGM, CGM, and/or insulin delivery devices). School nurses and designees should complete training to stay up to date on diabetes technologies prescribed for use in the school setting. Updated resources to support diabetes care at school, including training materials and a DMMP template, can be found online at diabetes.org/safe-at-school-state-laws.

Initiation of Device Use

The use of CGM and BGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management (3,4). CGM use allows for close tracking of glucose levels with adjustments of insulin dosing and lifestyle modifications and removes the burden of frequent BGM. In addition, early CGM initiation after diagnosis of type 1 diabetes in youth has been shown to decrease A1C levels and is associated with high parental satisfaction and reliance on this technology for diabetes management (5,6). Training on alarm/alert settings when initiating CGM is crucial to avoid alarm overload. Early initiation of AID systems or insulin pumps should be considered, especially in youth. In an open-label, multicenter, randomized, parallel clinical trial enrolling youth with newly diagnosed type 1 diabetes, initiation of an AID system within 21 days from diagnosis showed 10% higher time in range (TIR) (70–180 mg/dL [3.9–10.0 mmol/L]) and lower A1C at 12 months versus usual care (13). In addition, use of diabetes technology overall improves A1C and increases the number of people achieving an A1C $<7\%$ (14). Interruption of access to CGM is associated with a worsening of outcomes (7,15); therefore, it is important for individuals on CGM to have consistent access to devices.

BLOOD GLUCOSE MONITORING

Recommendations

7.10 People with diabetes should be provided with blood glucose monitoring (BGM) devices as indicated by their circumstances, preferences, and treatment. People using CGM devices must also have access to BGM at all times. **A**

7.11 People who are taking insulin and using BGM should be encouraged to check their blood glucose levels when appropriate based on their insulin therapy. This may include checking when fasting, prior to meals and snacks, after meals, at bedtime, in the middle of the night, prior to, during, and after exercise, when hypoglycemia is suspected, after treating low blood glucose levels until they are normoglycemic, when hyperglycemia is suspected, and prior to and while performing critical tasks such as driving. **B**

7.12 Health care professionals should be aware of the differences in accuracy among blood glucose meters. Only meters approved by the U.S. Food and Drug Administration (FDA) (or comparable regulatory agencies for other geographical locations) with proven accuracy should be used, with unexpired test strips purchased from a pharmacy or licensed distributor and properly stored. **E**

7.13 Although BGM in people on noninsulin therapies has not consistently shown clinically significant reductions in A1C levels, it may be helpful when modifying meal plans, physical activity plans, and/or medications (particularly medications that can cause hypoglycemia) in conjunction with a treatment adjustment program. **E**

7.14 Consider potential interference of medications and substances on glucose

levels measured by blood glucose meters. **B**

Major clinical trials of insulin-treated people with diabetes have included BGM as part of multifactorial interventions to demonstrate the benefit of intensive glycemic management on diabetes complications (16). BGM is thus an integral component of effective therapy for individuals using insulin. In recent years, CGM has emerged as a method for the assessment of glucose levels (discussed below). Glucose monitoring allows people with diabetes to evaluate their individual responses to therapy and assess whether glycemic goals are being safely achieved. Integrating results into diabetes management can be a useful tool for guiding medical nutrition therapy and physical activity, preventing hypoglycemia, or adjusting medications (particularly prandial insulin doses or correction bolus doses). The specific needs and goals of the person with diabetes should dictate BGM frequency and timing or the consideration of CGM use. As recommended by the device manufacturers and the U.S. Food and Drug Administration (FDA), people with diabetes using CGM must have access to BGM for multiple reasons, including whenever there is suspicion that the CGM is inaccurate, while waiting for warm-up, when there is a disruption in CGM transmission, for calibration (if needed) or if a warning message appears, when CGM supplies are delayed, and in any clinical setting where glucose levels are changing rapidly (>2 mg/dL/min), which could cause a discrepancy between CGM and blood glucose values.

Meter Standards

Glucose meters meeting FDA guidance for meter accuracy provide the most reliable data for diabetes management. There are several current standards for the accuracy of blood glucose meters, but the two most used are those of the International Organization for Standardization (ISO) (ISO 15197:2013) and the FDA. The current ISO and FDA standards are compared in **Table 7.1**. In Europe, currently marketed meters must meet current ISO standards. In the U.S., currently marketed meters must meet the standard under which they were approved, which may not be the current standard. Moreover, the monitoring of current accuracy postmarketing is left to the manufacturer and not routinely checked by an independent source.

People with diabetes assume their glucose meter is accurate because it is FDA cleared, but that may not be the case. There is substantial variation in the accuracy of widely used BGM systems (17,18). The Diabetes Technology Society Blood Glucose Monitoring System Surveillance Program provides information on the performance of devices used for BGM (diabetestechnology.org/surveillance/). In one analysis, 6 of the top 18 best-selling glucose meters met the accuracy standard (19). In a subsequent analysis with updated glucose meters, 14 of 18 glucose meters met the minimum accuracy requirements (20). There are single-meter studies in which benefits have been found with individual meter systems, but few studies have compared meters head-to-head. Certain meter system characteristics, such as the use of lancing devices that are less painful (21) and the ability to reapply blood to a strip with an insufficient initial sample, or meters with integrated speech that can read aloud glucose levels for visually impaired individuals (22), may also be beneficial to people with diabetes (23) and may make BGM less burdensome to perform.

Counterfeit Strips

People with diabetes should be advised against purchasing or reselling preowned or secondhand test strips, as these may give incorrect results. Only unopened and unexpired vials of glucose test strips should be used to ensure BGM accuracy.

Optimizing Blood Glucose Monitoring Device Use

Optimal use of BGM devices requires proper review and interpretation of data by both the person with diabetes and the health care professional to ensure that data are used in an effective and timely manner. In people with type 1 diabetes, there is a correlation between greater BGM frequency and lower A1C levels (24). Among those who check their blood glucose at least once daily, many report taking no action when results are high or low (25). Some meters now provide advice to the user in real time when monitoring glucose levels (26), whereas others can be used as a part of integrated health platforms (27). People with diabetes should be taught how to use BGM data to adjust food intake, physical activity, or pharmacologic therapy to achieve specific goals. The ongoing need for and frequency of BGM should be reevaluated at each routine visit to ensure its effective use (24,28).

People With Diabetes on Intensive Insulin Therapies

BGM is especially important for people with diabetes treated with insulin to monitor for and prevent hypoglycemia and hyperglycemia. Most individuals on intensive insulin therapies (multiple daily injections [MDI] or insulin pump therapy) should be encouraged to assess glucose levels using BGM (and/or CGM) prior to meals and snacks, at bedtime, occasionally postprandially, prior

Table 7.1—Comparison of ISO 15197:2013 and FDA blood glucose meter accuracy standards

Setting	FDA*	ISO 15197:2013*
Hospital use	95% within 12% for BG ≥75 mg/dL 95% within 12 mg/dL for BG <75 mg/dL 98% within 15% for BG ≥75 mg/dL 98% within 15 mg/dL for BG <75 mg/dL	95% within 15% for BG ≥100 mg/dL 95% within 15 mg/dL for BG <100 mg/dL 99% in A or B region of consensus error grid‡
Home use	95% within 15% for all BG in the usable BG range† 99% within 20% for all BG in the usable BG range†	

BG, blood glucose; FDA, U.S. Food and Drug Administration; ISO, International Organization for Standardization. To convert mg/dL to mmol/L, see endmemo.com/medical/unitconvert/Glucose.php. *Data shown in the FDA column are from the FDA (298). Data shown in the ISO column are from the FDA (299). †The range of blood glucose values for which the meter has been proven accurate and will provide readings (other than low, high, or error). ‡Values outside of the "clinically acceptable" A and B regions are considered "outlier" readings and may be dangerous to use for therapeutic decisions (300).

to, during, and after physical activity, when they suspect hypoglycemia or hyperglycemia, after treating hypoglycemia until they are normoglycemic, and prior to and while performing critical tasks such as driving. For many individuals using BGM, this requires checking up to 6–10 times daily, although individual needs may vary. A database study of almost 27,000 children and adolescents with type 1 diabetes showed that, after adjusting for multiple confounders, increased daily frequency of BGM was significantly associated with lower A1C levels (−0.2% per additional check per day) and with fewer acute complications (29).

People With Diabetes Using Basal Insulin and/or Oral Agents and Noninsulin Injectables

The evidence is insufficient regarding when to prescribe BGM and how often monitoring is needed for insulin-treated people with diabetes who do not use intensive insulin therapy, such as those with type 2 diabetes taking basal insulin with or without oral agents and/or noninsulin injectables. However, for those taking basal insulin, assessing fasting glucose with BGM to inform dose adjustments to achieve blood glucose goals results in lower A1C levels (30).

In people with type 2 diabetes not taking insulin, routine glucose monitoring may be of limited additional clinical benefit. By itself, even when combined with education, this practice has shown limited improvement in outcomes (31). However, for some individuals, glucose monitoring can provide insight into the impact of nutrition, physical activity, and medication management on glucose levels. Glucose monitoring may also be useful in assessing hypoglycemia, glucose levels during intercurrent illness, or discrepancies between measured A1C and glucose levels when there is concern an A1C result may not be reliable in specific individuals (for more details, see Section 2, "Diagnosis and Classification of Diabetes"). It may be useful when coupled with a treatment adjustment program. In a year-long study of insulin-naive people with diabetes with suboptimal initial glycemic outcomes, a group trained in structured BGM (a paper tool was used at least quarterly to collect and interpret seven-point BGM profiles taken on three consecutive days) reduced their A1C levels by 0.3% more than the control group (32). A trial of once-daily BGM that included enhanced feedback from people with diabetes through messaging found no clinically or statistically significant change in A1C levels at 1 year (31). Meta-analyses have suggested that BGM can reduce A1C levels by 0.25–0.3% at 6 months (33–35), but the effect was attenuated at 12 months in one analysis (33). Reductions in A1C levels were greater (−0.3%) in trials where structured BGM data were used to adjust medications, but A1C levels were not changed significantly without such structured diabetes therapy adjustment (35). A key consideration is that performing BGM alone does not lower blood glucose levels. To be useful, the information must be integrated into clinical and self-management treatment plans.

Glucose Meter Inaccuracy

Although many meters function well under various circumstances, health care professionals and people with diabetes must be aware of factors that impair meter accuracy. A meter reading that seems discordant with the clinical picture needs to be retested or tested in a laboratory. Health care professionals in intensive care unit settings need to be particularly aware of the potential for incorrect meter readings during critical illness, and laboratory-based values should be used if there is any doubt. Some meters give error messages if meter readings are likely to be false (36).

Oxygen. Currently available glucose monitors use an enzymatic reaction linked to an electrochemical reaction, either glucose oxidase or glucose dehydrogenase (37). Glucose oxidase monitors are sensitive to the oxygen available and should only be used with capillary blood in people with normal oxygen saturation. Higher oxygen tensions (i.e., arterial blood or oxygen therapy) may result in false low-glucose readings, and low oxygen tensions (i.e., high altitude, hypoxia, or venous blood readings) may lead to falsely elevated glucose readings. Glucose dehydrogenase–based monitors are generally not sensitive to oxygen.

Temperature. Because the reaction is sensitive to temperature, all monitors have an acceptable temperature range (37). Most will show an error if the temperature is unacceptable, but a few will provide a reading and a message indicating that the value may be incorrect. Humidity and altitude may also alter glucose readings.

Interfering Substances. There are several physiologic and pharmacologic factors that interfere with glucose readings measured with either personal blood glucose meters or professional blood glucose meters used in various inpatient settings (neonatal intensive care unit, hospital wards, and intensive care unit) (37). They are listed in **Table 7.2**.

CONTINUOUS GLUCOSE MONITORING DEVICES

See **Table 7.3** for definitions of types of CGM devices.

Recommendations

7.15 Recommend real-time CGM (rtCGM) **A** or intermittently scanned CGM (isCGM) for diabetes management to youth **C** and adults **B** with diabetes on any type of insulin therapy. The choice of CGM device should be made based on the individual's circumstances, preferences, and needs.

7.16 Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals. The choice of device should be made based on the individual's circumstances, preferences, and needs. **B**

7.17 In people with diabetes on insulin therapy, rtCGM devices should be used as close to daily as possible for maximal benefit. **A** isCGM devices should be scanned frequently, at minimum once every 8 h, to avoid gaps in data. **A** People with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM. **A**

7.18 CGM can help achieve glycemic goals (e.g., time in range and time above range) **A** and A1C goal **B** in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. **E**

7.19 In circumstances when consistent use of CGM is not feasible, consider periodic use of personal or professional CGM to adjust medication and/or lifestyle. **C**

7.20 Skin reactions, either due to irritation or allergy, should be assessed and addressed to aid in successful use of devices. **E**

7.21 People who wear CGM devices should be educated on potential interfering substances and other factors that may affect accuracy. **C**

Table 7.2—Common interfering substances and/or conditions that affect glucose meters (for inpatient and outpatient use)

Substance or condition	Effects on glucose values measured by blood glucose meters
Maltose*	Falsely higher blood glucose values
Galactose	Falsely higher blood glucose values
Xylose	Falsely higher blood glucose values
N-Acetylcysteine†	Falsely higher blood glucose values
Acetaminophen	Falsely higher blood glucose values at low blood glucose levels
Dopamine	Falsely higher blood glucose values at low blood glucose levels
Furosemide	Falsely lower blood glucose values
Vitamin C	Falsely lower or higher blood glucose values
Uric acid	Falsely higher blood glucose values at very low or very high glucose levels
Hematocrit (high)	Falsely lower blood glucose values
Hematocrit (low)	Falsely higher blood glucose values

*Unmodified glucose dehydrogenase method only. †Glucose dehydrogenase monitors using pyrroloquinoline quinone cofactor (GDH/PQQ).

CGM measures interstitial glucose (which correlates well with plasma glucose, although at times, it can lag if glucose levels are rising or falling rapidly). There are two basic types of CGM devices. The first type includes those that are owned by the user, unblinded, and intended for frequent or continuous use, including real-time CGM (rtCGM), intermittently scanned CGM (isCGM), and over-the-counter CGM devices. The second type is professional CGM devices that are owned by practices and applied in the clinic, which provide data that are blinded or unblinded for a discrete period of time. The types of sensors currently available are either disposable (rtCGM and isCGM) or implantable (rtCGM). **Table 7.3** provides definitions for the types of CGM devices. For people with type 1 diabetes using CGM, frequency of sensor use is an important predictor of A1C lowering for all age-groups (38,39). The frequency of scanning with isCGM devices is also correlated with improved outcomes (40–43).

Few real-time systems require calibration by the user, which varies in frequency depending on the device. CGM systems are generally nonadjunctive, meaning they do not require BGM confirmation for treatment decisions like insulin dosing or treating hypoglycemia, except in certain clinical situations (see BLOOD GLUCOSE MONITORING, above) (44–46).

Most CGM systems are designated as integrated CGM (iCGM), a higher standard set by the FDA for integration with other digitally connected devices. Dexcom G6 rtCGM (no generic form available), Dexcom G7 rtCGM (no generic form available), FreeStyle Libre 2 Plus (no generic form available), FreeStyle Libre 3 Plus (no generic form available), and Eversense E3 (no generic form available) are FDA approved for use with AID systems. Similarly, Dexcom G6 rtCGM, Dexcom G7 rtCGM, FreeStyle Libre 2 isCGM (no generic form available), and Medtronic Simplera rtCGM (no generic form available) are approved for use with connected insulin pens (47). Currently, Dexcom G6 and Dexcom G7 are integrated with four AID systems (t:slim X2 with Control-IQ, Omnipod 5, iLet, and Mobi). Similarly, at this time in the U.S., the FreeStyle Libre 2 Plus is integrated with one AID system (t:slim X2 with Control-IQ) and the FreeStyle Libre 3 Plus with another AID system (iLet). Finally, the Medtronic Guardian 3 rtCGM (no generic form available) and the Medtronic Guardian 4 rtCGM (no generic form available) are FDA approved for use with the 670/770G and 780G AID systems, respectively.

Benefits of Continuous Glucose Monitoring

Data From Randomized Controlled Trials

Multiple randomized controlled trials (RCTs) have been performed using rtCGM devices, and the results have largely been positive in terms of reducing A1C levels and/or episodes of hypoglycemia if participants regularly wore the devices (38–41,48–51). The initial studies were done primarily in adults and youth with type 1 diabetes on insulin pump therapy and/or MDI (38,39,48,49, 52). The primary outcome was met and showed benefit in adults of all ages (38,53,54), including seniors (55–57). Data in children show that rtCGM use in young children with type 1 diabetes reduced hypoglycemia; in addition, behavioral support of parents of young

Table 7.3—Continuous glucose monitoring devices

Type of CGM	Description
rtCGM	CGM systems that measure and display glucose levels continuously
isCGM with and without alarms	CGM systems that measure glucose levels continuously but require scanning for visualization and storage of glucose values
Professional CGM	CGM devices that are placed on the person with diabetes in the health care professional's office and worn for a discrete period of time (generally 7–14 days). Data may be blinded or visible to the person wearing the device. The data are used to assess glycemic patterns and trends. Unlike rtCGM and isCGM devices, these devices are clinic-based and not owned by the person with diabetes.
Over-the-counter CGM	CGM devices called biosensors, which measure glucose continuously and display the levels at various times, have insights rather than alarms and are indicated for people with prediabetes or with diabetes not on insulin.

CGM, continuous glucose monitoring; isCGM, intermittently scanned CGM; rtCGM, real-time CGM.

children with diabetes using rtCGM showed the benefits of reducing hypoglycemia concerns and diabetes distress (38,49,58). Similarly, A1C level reduction was seen in adolescents and young adults with type 1 diabetes using rtCGM (48). RCT data on rtCGM use in individuals with type 2 diabetes on MDI (59), mixed therapies (10, 60), and basal insulin (61,62) have consistently shown reductions in A1C levels and increases in TIR (70–180 mg/dL [3.9–10 mmol/L]) but not a reduction in rates of hypoglycemia (63). Although short-term use of rtCGM in youth with type 2 diabetes did not impact short-term glucose changes or A1C improvement, users reported behavioral changes with increased blood glucose measurements, increased insulin administration, and overall improved diabetes management and quality of life (64,65). The improvements in type 2 diabetes have largely occurred without changes in insulin doses or other diabetes medications. CGM discontinuation in individuals with type 2 diabetes on basal insulin caused partial reversal of A1C reduction and TIR improvements, suggesting that continued CGM use achieves the greatest benefits (15).

RCT data for rtCGM benefits in people with type 2 diabetes not using insulin are increasing and generally have shown greater benefits of CGM compared with BGM for A1C, TIR, time below range (TBR), and time above range (TAR) as well as greater user-reported satisfaction (66). These benefits were initially reported in a study where the intermittent use of rtCGM for either one session or two sessions (3 months apart) versus control treatment showed improvement of A1C at 3 months. At 6 months, the two-session rtCGM group achieved significant A1C reduction. For both rtCGM groups, participants who measured BGM at least 1.5 times per day achieved greater A1C improvement compared with the control group (67).

In addition, rtCGM benefits were reported in a mixed population (including people not using insulin) of adults with type 2 diabetes with reduction in A1C levels, increase in TIR, and reduction of time in hyperglycemia (>180 mg/dL [>10 mmol/L] and >250 mg/dL [>13.9 mmol/L]) (10).

RCT data for isCGM are fewer but increasing. One study was performed in adults with type 1 diabetes and met its primary outcome of a reduction in rates of hypoglycemia (68). In adults with type 2 diabetes using insulin, two studies were done: one study did not meet its primary end point of A1C level reduction (69) but achieved a secondary end point of a reduction in hypoglycemia, and the other study met its primary end point of an improvement in the Diabetes Treatment Satisfaction Questionnaire score as well as a secondary end point of A1C level reduction (70). In a study of individuals with type 1 or type 2 diabetes taking insulin, the primary outcome of a reduction in severe hypoglycemia was not met and the incidence of severe hypoglycemia was not significantly different between isCGM users and the BGM group (71). One study in youth with type 1 diabetes did not show a reduction in A1C levels (72); however, the device was well received and was associated with an increased frequency of testing and improved diabetes treatment satisfaction (72). A randomized trial of adults with type 1 diabetes showed that the use of isCGM with optional alerts and alarms resulted in reduction of A1C levels compared with BGM use (9).

The benefits of isCGM for adults with type 2 diabetes not using insulin were initially reported in a multicenter, open-label, randomized (1:1), parallel-group study. At 12 weeks, A1C was significantly reduced from baseline in both groups without difference. However, at 24 weeks, the isCGM group showed a greater A1C reduction than the control group. Furthermore, there were no between-group differences in change of antihyperglycemic drugs (73). In a subsequent post hoc analysis, the isCGM group showed that the effects of isCGM were present 1 week after isCGM initiation for weekly mean glucose, glucose management indicator (GMI), percentage of TIR, percentage of TAR, and mean amplitude glucose excursion and remained stable from baseline to 12 weeks (74). Additionally, benefits of isCGM were also reported in an RCT where the use of isCGM plus diabetes education versus diabetes education alone showed decreased A1C levels and increased TIR as well as increased time in tight target range (70–140 mg/dL [3.9–7.8 mmol/L]) in the isCGM-plus-education group (8).

Observational and Real-world Studies

CGM systems are widely available in many countries for people with diabetes, and this allows for the collection of large amounts of data across groups of people with diabetes.

Data for isCGM in adults with diabetes include results from observational studies, retrospective studies, and analyses of registry and population data (75,76). In individuals with type 1 diabetes wearing isCGM devices, studies have shown improvement in A1C levels (41,77), TIR (70–180 mg/dL [3.9–10.0 mmol/L]), and hypoglycemia (41,43,75,78,79). Reductions in acute diabetes complications, such as diabetic ketoacidosis (DKA), episodes of severe hypoglycemia or diabetes-related coma, and hospitalizations for hypoglycemia and hyperglycemia, have been observed in adults with type 1 or type 2 diabetes (43,78,80), with persistent effects observed even after 2 years of CGM initiation (81). Similar reductions of acute diabetes events and all-cause inpatient hospitalizations were seen in a retrospective review of adults with type 2 diabetes treated with basal insulin or with noninsulin therapy 6 months after initiation of isCGM (82). Prospective observational as well as retrospective studies in adults with type 2 diabetes treated with MDI showed significant reduction of A1C and hypoglycemia (83) after 12 weeks of isCGM use, with increased user satisfaction (83). Similar results were seen in a retrospective study with adults with type 2 diabetes on basal insulin at 3–6 months (84). Furthermore, retrospective observational data in adults with type 2 diabetes treated with either basal insulin or noninsulin therapy have shown an improvement in A1C levels (85). Finally, a retrospective study of continued use of isCGM in adults with nonintensively treated type 2 diabetes showed reduction of A1C and GMI, increase in TIR, and reduction of TAR (>180 mg/dL) (86). Results of self-reported outcomes varied, but, where measured, people with diabetes had an increase in treatment satisfaction with isCGM compared with BGM. In an observational study in youth with type 1 diabetes, a slight increase in A1C levels and weight was seen, but the device was associated with a high user satisfaction rate (76).

Retrospective data from rtCGM use in adults (87) with type 1 or type 2 diabetes treated with insulin showed that the use of rtCGM significantly lowered A1C levels and reduced rates of emergency department visits or hospitalizations for hypoglycemia but did not significantly lower overall rates of emergency department visits, hospitalizations, or hyperglycemia.

Recent data have emerged from a real-world observational analysis of rtCGM use in adults with type 2 diabetes not treated with insulin. In this study, rtCGM benefits were observed at 6 month and 12 months versus baseline, with reduction of mean glucose levels, reduction of GMI, increase in TIR, increase in time in tight target range (70–140 mg/dL [3.9–7.8 mmol/L]), and reduction in TAR >180 and >250 mg/dL (88).

Real-time Continuous Glucose Monitoring Compared With Intermittently Scanned Continuous Glucose Monitoring

In adults with type 1 diabetes, three RCTs have been conducted comparing isCGM (without predictive alerts/alarms) and rtCGM (with predictive alerts/alarms) (84,89,90). In two of the studies, the primary outcome was a reduction in time spent in hypoglycemia, and rtCGM showed greater benefits compared with isCGM (89,90). In the other study, the primary outcome was improved TIR, and rtCGM also showed greater benefits compared with isCGM (84). A retrospective analysis also showed improvement in TIR with rtCGM compared with isCGM (91). A more recent 12-month real-world nonrandomized study compared rtCGM with isCGM in adults with type 1 diabetes. At 12 months, A1C levels, time in level 1 hypoglycemia (<70 mg/dL [<3.9 mmol/L]), and time in level 2 hypoglycemia (<54 mg/dL [<3.0 mmol/L]) were all lower in the rtCGM group than in the isCGM group; similarly, the TIR was higher in the rtCGM group than in the isCGM group (92).

Data Analysis

The abundance of data provided by CGM offers opportunities to analyze data for people with diabetes more granularly than previously possible, providing additional information to aid in achieving glycemic goals. A variety of metrics have been proposed (93) and are discussed in Section 6, "Glycemic Goals and Hypoglycemia." CGM is essential for creating an ambulatory glucose profile (AGP) and providing data on TIR, percentage of time spent above and below range, and glycemic variability (94). Standardized reports for CGM, AID, and connected insulin pens include multiple reports, each providing different degrees of information. These reports, whether single page or with raw data, should be used in clinical practice to identify CGM trends and patterns; in the setting of AID systems, these reports provide important information on insulin delivery and its suspension or modulation as well as information on automated bolus delivery that can assist the clinician in making therapy adjustments (12,94,95). However, data analysis can be burdensome without a systematic approach to its review, and CGM and AID manufacturers should aim to make device data reports as standardized as possible to reduce the burden of data analysis (12). Several efforts have been made to streamline the interpretation of CGM reports to assist health care professionals in their daily practice. These have various, but overall similar, approaches. The initial steps are focused on assessing the sufficiency and quality of data; subsequent recommendations include reviewing the presence and trends or patterns of hypoglycemia, followed by hyperglycemia patterns and trends. Some authors also suggest approaches to changing therapy plans based on the data reviewed that enable health care professionals to make a simple yet comprehensive review and plan of care even within the time constraints of office visits (96–100).

Real-time Continuous Glucose Monitoring Device Use in Pregnancy

CGM indication is now expanded to include pregnancy for Dexcom G7, FreeStyle Libre 2, and FreeStyle Libre 3, which will enhance care in this population (101,102). Prior data from one well-designed RCT showed a reduction in A1C levels in pregnant adults with type 1 diabetes on MDI or insulin pump therapy and using rtCGM in addition to standard care; CGM users experienced more pregnancy-specific TIR (63–140 mg/dL [3.5–7.8 mmol/L]) and less time in hyperglycemia (103). This study demonstrated the value of rtCGM in pregnancy complicated by type 1 diabetes by showing a mild improvement in A1C levels and a significant improvement in the maternal glucose TIR for pregnancy (63–140 mg/dL [3.5–7.8 mmol/L]), without an increase in hypoglycemia, as well as reductions in large-for-gestational-age births, infant hospital length of stay, and severe neonatal hypoglycemia (103). An observational cohort study that evaluated the glycemic variables reported using rtCGM and isCGM found that lower mean glucose, lower SD, and higher percentage of TIR were associated with lower risks of large-for-gestational-age births and other adverse neonatal outcomes (104). Another observational study in pregnancies with and without gestational diabetes mellitus (GDM) wearing blinded CGM found higher mean glucose, more time spent at >120 mg/dL and >140 mg/dL, and less time spent at 63–120 mg/dL were associated with large-for-gestational-age births and gestational hypertensive disorders, while lower mean glucose and more time spent at <63 mg/dL and <54 mg/dL were associated with small-for-gestational-age birth (105). Data from one study suggested that the use of rtCGM-reported mean glucose is superior to use of the glucose management indicator and other calculations to estimate A1C levels given the changes to A1C levels that occur in pregnancy (106). Two studies employing intermittent use of rtCGM showed no difference in neonatal outcomes in individuals with type 1 diabetes (107) or gestational diabetes mellitus (108). At this time, data are insufficient to recommend the use of CGM in all pregnant people with type 2 diabetes or GDM (109,110). The decision of whether to use CGM in pregnant individuals with type 2 diabetes or GDM should be individualized based on treatment plan, circumstances, preferences, and needs.

Although CGM systems for use in pregnancy do not require calibrations and are approved for nonadjunctive use, when using CGM in diabetes and pregnancy, determination of glucose levels by finger stick may be necessary in certain circumstances, such as in the setting of hypoglycemia or hyperglycemia outside the recommended CGM goal ranges (63–140 mg/dL [3.5–7.8 mmol/L]) during pregnancy.

Use of Professional Continuous Glucose Monitoring and Intermittent Use of Continuous Glucose Monitoring

Professional CGM devices, which provide retrospective data, either blinded or unblinded, for analysis can be used to identify patterns of hypoglycemia and hyperglycemia (111,112). Professional CGM can be helpful to evaluate an individual's glucose levels when either rtCGM or isCGM is not available to the individual or they prefer a blinded analysis or a shorter experience with unblinded data. It can be particularly useful in individuals using agents that can cause hypoglycemia, as the data can be used to evaluate periods of hypoglycemia and make medication dose adjustments if needed. It can also be useful to evaluate periods of hyperglycemia.

Some data have shown the benefit of intermittent use of CGM (rtCGM or isCGM) in individuals with type 2 diabetes on noninsulin and/or basal insulin therapies (60,73). In these RCTs, people with type 2 diabetes not on intensive insulin therapy used CGM intermittently compared with those randomized to BGM. Both early (60) and late improvements in A1C levels were found (60,73).

Furthermore, in a real-world study, the use of professional CGM in individuals with type 2 diabetes not on insulin at baseline and at 6 months of follow-up resulted in lower A1C at 6 months as well as a shift toward greater use of glucose-lowering medications with cardiometabolic benefits, such as sodium–glucose transporter 2 inhibitors and glucagon-like peptide 1 receptor agonists (113). Use of professional or intermittent CGM should always be coupled with analysis and interpretation for people with diabetes along with education, as needed, to adjust medication and change lifestyle behaviors (114–116).

Side Effects of Continuous Glucose Monitoring Devices

Contact dermatitis (both irritant and allergic) has been reported with all devices that attach to the skin (20,117,118). In some cases, this has been linked to the presence of isobornyl acrylate, a skin sensitizer that can cause an additional spreading allergic reaction (119–121). It is important to ask CGM users periodically about adhesive reactions, as tape formulations may change over time. Patch testing can sometimes identify the cause of contact dermatitis (122). Identifying and eliminating tape allergens is important to ensure the comfortable use of devices and promote self-care (123–126). The PANTHER Program offers resources in English and Spanish at www.pantherprogram.org/skin-solutions. In some instances, using an implanted sensor can help avoid skin reactions in those sensitive to tape (127,128).

Substances and Factors Affecting Continuous Glucose Monitoring Accuracy

Sensor interference due to several medications/substances is a known potential source of CGM sensor measurement errors (**Table 7.4**). While several of these substances have been reported in the various CGM brands' user manuals, additional interferences have been discovered after the market release of these products. Hydroxyurea, used for myeloproliferative disorders and hematologic conditions, is one of the most recently identified interfering substances that cause a temporary increase in sensor glucose values discrepant from actual glucose values (129–134). Similarly, substances such as mannitol and sorbitol, when administered intravenously or as a component of peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of sensor glucose (135). Therefore, it is crucial to routinely review the medications and supplements used by the person with diabetes to identify possible interfering substances and advise them accordingly on the need to use additional BGM if sensor values are unreliable due to these substances.

INSULIN DELIVERY

Insulin Syringes and Pens

Recommendations

7.22 For people with insulin-requiring diabetes on multiple daily injections (MDI), insulin pens are preferred in most cases. Still, insulin syringes may be used for insulin delivery considering individual and caregiver preference, insulin type, availability in vials, dosing therapy, cost, and self-management capabilities. **C**

7.23 Insulin pens or insulin injection aids are recommended for people with dexterity issues or vision impairment or when decided by shared decision-making to facilitate the accurate dosing and administration of insulin. **C**

7.24 Offer connected insulin pens for people with diabetes taking multiple daily insulin injections. **B**

7.25 FDA-approved insulin dose calculators/decision support systems may be helpful for calculating insulin doses. **B**

Injecting insulin with a syringe or pen (136–147) is the insulin delivery method used by most people with diabetes (142,148), although inhaled insulin is also available. Others use insulin pumps or AID devices (see INSULIN PUMPS AND AUTOMATED INSULIN DELIVERY SYSTEMS, below). For people with diabetes who use insulin, insulin syringes and pens both can deliver insulin safely and effectively for the achievement of glycemic goals. Individual preferences, cost, insulin type, dosing therapy, and self-management capabilities should be considered when choosing among delivery systems. Trials with insulin pens generally show equivalence or small improvements in glycemic outcomes compared with using a vial and syringe. Many individuals with diabetes prefer using a pen because of its simplicity and convenience. It is important to note that while many insulin types are available for purchase as either pens or vials, others may be

Table 7.4—Continuous glucose monitoring device interfering substances

Medication	Systems affected	Effect
Acetaminophen		
>4 g/day	Dexcom G6, Dexcom G7	Higher sensor readings than actual glucose
Any dose	Medtronic Guardian	Higher sensor readings than actual glucose
Ascorbic acid (vitamin C), >500 mg/day	FreeStyle Libre 14 day, FreeStyle Libre 2, FreeStyle Libre 3	Higher sensor readings than actual glucose
Ascorbic acid (vitamin C), >1,000 mg/day	FreeStyle Libre 2 Plus, FreeStyle Libre 3 Plus	Higher sensor readings than actual glucose
Hydroxyurea	Dexcom G6, Dexcom G7, Medtronic Guardian	Higher sensor readings than actual glucose
Mannitol (intravenously or as peritoneal dialysis solution)	Senseonics Eversense	Higher sensor readings than actual glucose
Sorbitol (intravenously or as peritoneal dialysis solution)	Senseonics Eversense	Higher sensor readings than actual glucose

available in only one form or the other, and there may be significant cost differences between pens and vials (see **Table 9.4** for a list of insulin product costs with dosage forms). Insulin pens may allow people with vision impairment or dexterity issues to dose insulin accurately (149–151), and insulin injection aids are also available to help with these issues. (For a helpful list of injection aids, see living-with-diabetes/treatment-care/diabetes-technology-guide). Inhaled technosphere insulin can be useful for people with diabetes, providing an alternative method of insulin delivery with very fast onset of action. In a recent randomized clinical trial, the use of technosphere inhaled insulin showed lower postprandial hyperglycemia than subcutaneous rapid-acting analog insulin (152).

The most common syringe sizes are 1 mL, 0.5 mL, and 0.3 mL, allowing doses of up to 100 units, 50 units, and 30 units, respectively, of U-100 insulin. Some 0.3-mL syringes have half-unit markings, whereas other syringes have markings in 1- to 2-unit increments. In a few parts of the world, insulin syringes still have U-80 and U-40 markings for older insulin concentrations and veterinary insulin, and U-500 syringes are available for the use of U-500 insulin. Syringes are generally used once but may be reused by the same individual in resource-limited settings with appropriate storage and cleansing (151).

Insulin pens offer added convenience by combining the vial and syringe into a single device. Insulin pens, allowing push-button injections, come as disposable pens with prefilled cartridges or reusable insulin pens with replaceable insulin cartridges. Pens vary with respect to dosing increment and minimal dose, ranging from half-unit doses to 2-unit dose increments, with the latter available in U-200 insulin pens. U-500 pens come in 5-unit dose increments. Some reusable pens include a memory function, which can recall dose amounts and timing. Insulin pens, once started, can be kept in use for variable durations, based on the type of insulin, usually for 28 days, ranging from 14 to 56 days. Needle thickness (gauge) and length are other considerations. Needle gauges range from 22 to 34, with a higher gauge indicating a thinner needle. A thicker needle can give a dose of insulin more quickly, while a thinner needle may cause less pain. Needle length ranges from 4 to 12.7 mm, with some evidence suggesting that shorter needles (4–5 mm) lower the risk of intramuscular injection with erratic absorption and possibly the development of lipohypertrophy. When reused, needles may be duller and thus injections may be more painful. Proper insulin injection technique is a requisite for receiving the full dose of insulin with each injection. Concerns with technique and use of the proper technique are outlined in Section 9, "Pharmacologic Approaches to Glycemic Treatment."

Connected insulin pens are insulin pens with the capacity to record and/or transmit insulin dose data. Insulin pen caps are also available and are placed on existing insulin pens and may assist with calculating insulin doses and by providing a memory function. Some connected insulin pens and pen caps can be programmed to calculate insulin doses, can be synced with select CGM systems, and can provide downloadable data reports. These pens and pen caps are useful to people with diabetes for real-time insulin dosing and allow clinicians to retrospectively review the insulin delivery times and, in some cases, doses and glucose data to make informed insulin dose adjustments (153). A quantitative study showed that people with diabetes preferred connected pens because of their ability to log insulin doses and glucose levels automatically (153). In a multicenter RCT in people with type 1 diabetes, the use of an insulin pen cap was associated with improved glycemic outcomes at 6 weeks in the insulin cap group, with an increase in TIR and decrease in GMI and TAR (154). A systematic review of connected insulin pens or pen caps showed improvement of glucose outcomes whether as A1C reduction, TIR increase, or hypoglycemia reduction (155). A recent real-world study with multinational data collected from 3,954 adults with diabetes using a connected pen and CGM validated the fact that treatment engagement with a connected insulin pen is positively associated with glycemic outcomes. On the other hand, missing as little as two basal doses or four bolus insulin doses over a 14-day period would be associated with a clinically relevant decrease in TIR of ≥5% (156).

Bolus calculators have been developed to aid dosing decisions (157–162). These systems are subject to FDA approval to ensure safety and efficacy in terms of algorithms used and subsequent dosing recommendations. People interested in using these systems should be encouraged to use those that are FDA approved. Health care professional input and education can be helpful for setting the initial dosing calculations with ongoing follow-up for adjustments as needed.

Insulin Pumps and Automated Insulin Delivery Systems

Recommendations

7.26 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 **A** and other types of insulin-deficient diabetes **E** who are capable of using the device (either by themselves or with a caregiver). Choice of an AID system should be made based on the individual's circumstances, preferences, and needs. **A**

7.27 Insulin pump therapy, preferably with CGM, should be offered for diabetes management to youth and adults on MDI with type 2 diabetes who can use the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs. **A**

7.28 Individuals with diabetes who have been using CSII should have continued access across third-party payors. **E**

Insulin Pumps

Insulin pumps have been available in the U.S. for over 40 years. These devices deliver rapid-acting insulin throughout the day to help manage glucose levels. Most insulin pumps use tubing to deliver insulin through a cannula, while a few attach directly to the skin without tubing (pods or patch pumps), and these systems have been approved for use in type 1 and type 2 diabetes. AID systems, which can adjust insulin delivery rates based on sensor glucose values, are preferred over nonautomated pumps and MDI in people with type 1 diabetes and have largely replaced the use of nonintegrated or standard insulin pumps. Recently, one AID system was approved for use by people with type 2 diabetes.

Historically, studies that compared MDI with insulin pump therapy were relatively small and of short duration. However, a systematic review and meta-analysis concluded that pump therapy has modest advantages for lowering A1C levels (−0.30% [95% CI −0.58 to −0.02]) and for reducing severe hypoglycemia rates in children and adults (163). Real-world data on insulin

pump use in individuals with type 1 diabetes show benefits in A1C levels and hypoglycemia reductions as well as total daily insulin dose reduction (164). There is no consensus to guide choices on which form of insulin administration is best for a given individual, and research to guide this decision-making process is needed (163). Thus, the choice of MDI or an insulin pump is often based on the characteristics of the person with diabetes and which method is most likely to benefit them. DiabetesWise (diabeteswise.org/), for individuals with diabetes, DiabetesWise Pro (pro.diabeteswise.org/), for health care professionals, and the PANTHER Program (pantherprogram.org/device-comparison-chart) have helpful websites to assist health care professionals and people with diabetes in choosing diabetes devices based on their individual needs and the features of the devices. Newer systems, such as sensor-augmented pumps (SAPs) and AID systems, are discussed below.

Adoption of pump therapy in the U.S. shows geographical variations, which may be related to health care professional preference or center characteristics (165,166) and socioeconomic status, as pump therapy is more common in individuals of higher socioeconomic status, as reflected by private health insurance, family income, and education (165,166). Given the additional barriers to optimal diabetes care observed in disadvantaged groups (167), addressing the differences in access to insulin pumps and other diabetes technologies may contribute to fewer health disparities.

Pump therapy can be successfully started at the time of diagnosis (168). Practical aspects of pump therapy initiation include assessment of readiness of the person with diabetes and their family, if applicable (although there is no consensus on which factors to consider in adults [169] or children and adolescents with diabetes), selection of pump type and initial pump settings, individual and family education on potential pump complications (e.g., DKA with infusion set failure), transition from MDI, and introduction of advanced pump settings (e.g., temporary basal rates and extended bolus, square-wave bolus, or dual-wave bolus).

Older individuals with type 1 diabetes benefit from ongoing insulin pump therapy. There are no data to suggest that measurement of C-peptide levels or antibodies predicts success with insulin pump therapy (170,171). Additionally, the frequency of follow-up does not influence outcomes. Access to insulin pump therapy, including AID systems, should be allowed or continued in older adults as it is in younger people.

Complications of the pump can be caused by issues with infusion sets (dislodgement and occlusion), which put individuals at risk for ketosis and DKA and thus must be recognized and managed early (172). Other pump skin issues include lipohypertrophy or, less frequently, lipoatrophy (173) and pump site infection. Discontinuation of pump therapy is relatively uncommon today; the frequency has decreased over the past few decades, and its causes have changed (174). Current reasons for attrition are problems with cost or wearability, loss of insurance, dislike of the pump, suboptimal glycemic outcomes, or mood disorders (e.g., anxiety or depression) (175).

Insulin Pumps in Youth

The safety of insulin pumps in youth has been established for over 15 years (176). Studying the effectiveness of insulin pump therapy in lowering A1C levels has been challenging because of the potential selection bias of observational studies. Participants on insulin pump therapy may have a higher socioeconomic status that may facilitate better glycemic outcomes (177) than MDI. In addition, the fast pace of development of new insulins and technologies quickly renders comparisons obsolete. However, RCTs that compared insulin pumps and MDI with rapid-acting insulin analogs demonstrated a modest improvement in A1C levels in participants on insulin pump therapy (178,179). Observational studies, registry data, and meta-analyses have also suggested an improvement in glycemic outcomes in participants on insulin pump therapy (180–182). Data suggest that insulin pumps reduce the rates of severe hypoglycemia compared with MDI (182–185).

There is also evidence that insulin pump therapy may reduce DKA risk (182,186) and diabetes complications, particularly retinopathy and peripheral neuropathy in youth, compared with MDI (169). In addition, treatment satisfaction and quality-of-life measures improved on insulin pump therapy compared with MDI (187). Therefore, insulin pumps can be used safely and effectively in youth with type 1 diabetes to assist with achieving targeted glycemic outcomes while reducing the risk of hypoglycemia and DKA, improving quality of life, and preventing long-term complications. Based on shared decision-making by people with diabetes and health care professionals, insulin pumps may be considered in all children and adolescents with type 1 diabetes. In particular, pump therapy may be the preferred mode of insulin delivery for children under 7 years of age (188). Because of a paucity of data in adolescents and youth with type 2 diabetes, there is insufficient evidence to make recommendations.

Common barriers to pump therapy adoption in children and adolescents are concerns regarding the physical interference of the device, discomfort with the idea of having a device on the body, therapeutic effectiveness, and financial burden (180,189).

Sensor-Augmented Pumps

SAPs (or partial closed-loop systems) consist of three components: an insulin pump, a CGM system, and an algorithm that automates insulin suspension when glucose is low or is predicted to go low within the next 30 min. Predictive low-glucose suspend systems have been shown to reduce time spent with glucose $<$70 mg/dL without rebound hyperglycemia during a 6-week randomized crossover trial (190). Similar results were seen in additional studies in adults and children with reduction of hypoglycemia (191–193). SAPs have now been largely replaced by AID systems, which offer superior benefits for glycemic outcomes; nevertheless, some AID systems can still be used in either low-glucose suspend mode or predictive low-glucose suspend mode.

Automated Insulin Delivery Systems

AID systems consist of mainly three components: an insulin pump, a CGM system, and an algorithm that determines insulin delivery. Based on the model and brand of currently FDA approved AID systems, the algorithm can be hosted in the pump body, in an insulin pod, or on a phone app. All AID systems on the market today integrate with one or more CGM systems and adjust insulin delivery either by modulating the preprogrammed basal rates or by replacing the basal rates with microboluses or microdoses of insulin every 5 min.

The modulation of insulin delivery is done by increasing, decreasing, or pausing insulin based on the CGM feedback, the predicted direction of the glucose levels, and the speed with which the

glucose levels are changing. Different AID systems modulate insulin based on predicted glucose levels at various times, most commonly 30 min or 1 h. Currently available AID systems have either fixed glucose targets or adjustable glucose targets, generally ranging from 100 to 120 mg/dL, with some exceptions where glucose targets can be adjusted up to 150 mg/dL. Glucose targets are generally set up for 24 h but can also be adjusted in some systems with up to eight segments per day. All current AID systems provide automated correction doses, whether embedded in the microdose adjustments every 5 min or by providing additional correction boluses whose doses are dependent on the various types of algorithms with variable frequency and threshold glucose based on the type of control algorithm. Most AID systems can be used in manual mode, although this is generally not recommended, as the benefits of CGM modulation may be partially or totally lost. However, use of AID in manual mode may be necessary in some circumstances, therefore it is important to review and reassess manual-mode settings periodically. Current AID systems still require manual entry of carbohydrates for meal announcements or qualitative meal estimation announcements to calculate prandial doses.

Adjustments for physical activity are available in most AID systems currently on the market. These can be programmed in various time increments. In general, the glucose target is raised to prespecified levels based on AID systems, and these are often accompanied by more conservative insulin delivery to reduce the risk of hypoglycemia in the setting of increased insulin sensitivity other than physical activity, such as prolonged fasting or NPO status for procedures. Of note, some systems may still give autocorrection boluses if the glucose levels rise above a certain threshold even while the exercise/activity mode has been enabled. Details on the available AID systems and their features can be found at pantherprogram.org/device-type.

AID systems have largely replaced other methods of continuous subcutaneous insulin delivery due to the advantages they offer in insulin modulation and sophistication of algorithms to adjust insulin doses and minimize hypoglycemia and hyperglycemia.

Data From Pivotal Trials

All currently FDA-approved AID systems were tested for safety and efficacy in their pivotal trials in children and adults with type 1 diabetes (194–206). These studies were conducted either as a single arm of manual mode followed by automated mode of a specific AID system or as an RCT comparing the AID system to an SAP and/or usual care. Regardless of the study design, all AID system pivotal trials that examined individuals 2 years old or older, including older adults, have consistently demonstrated superiority to either standard insulin delivery (or manual mode for the single-arm studies) or SAP and/or usual care (for the randomized trials), with consistent improvement in A1C, increase in TIR, especially overnight, as well as reduction of time spent in hypoglycemia (207–219). The greatest improvements were seen with AID when used in individuals with the highest baseline A1C or lowest TIR (220). These systems may also lower the risk of exercise-related hypoglycemia (219) and have been shown to have psychosocial benefits (221–225). A review of the literature on the health and economic value of AID systems in individuals with type 1 diabetes found that AID systems are cost-effective (226). AID is rapidly becoming the standard of care for people with type 1 diabetes and should be the preferred method of insulin delivery in these individuals. The decision to use AID systems should be made based on the preference of the person with diabetes and the selection of individuals (and/or caregivers) who are capable of safely and effectively using the devices.

Data From Real-world Studies

Data from real-world studies on AID systems have become available and continue to increase rapidly. These studies include large numbers of users, at times even 30-fold higher than the number of people studied in AID pivotal trials (227). It is important to emphasize that for some AID systems all data are automatically collected to the database (228), whereas for other systems data are collected based on voluntary sharing to the database by AID users. A recent systematic review of AID real-world studies, with 20 studies representing 171,209 individuals, substantiated the results observed in the pivotal trials and have confirmed the clinical benefits of AID systems in people with type 1 diabetes. Newer systems have shown increased time spent in automation, and the real-world studies have retrospectively analyzed longer duration of system use compared with their respective pivotal trials, with most analyses occurring for more than 6 months and an average duration of 9 months (227).

Benefits include improvement in A1C levels, TIR, and other glucometrics as well as psychosocial benefits (229–234).

Finally, real-world data showed that AID systems provide the same glycemic benefits to Medicare and Medicaid beneficiaries with type 1 and type 2 diabetes, emphasizing that access to this technology should be made available regardless of A1C levels and should be based on the individual's needs (235).

Automated Insulin Delivery Systems in Pregnancy

The use of AID systems in diabetes and pregnancy presents particular challenges, as the current FDA-approved AID systems (except for one that has been FDA approved but is not yet commercially available) have glucose goals that are not pregnancy specific and do not have algorithms designed to achieve pregnancy-specific glucose goals. Initiating or continuing AID systems during pregnancy needs to be assessed carefully. Selected individuals with type 1 diabetes should be evaluated as potential candidates for AID systems in the setting of expert guidance. Recent data have shown the clinical benefits and safety of AID use, even though only one study used an AID system with a pregnancy-specific glycemic target. This study, a multicenter, controlled trial, enrolled pregnant women with type 1 diabetes before 14 weeks' gestation and randomized them by week 16 to the AID system or standard care (MDI with CGM or standard insulin pump therapy with CGM). The primary outcome of time spent in the pregnancy-specific target range of 63–140 mg/dL was found to be 10.5% higher in the AID group versus standard care ($P < 0.001$). The secondary outcomes were also met, with less time spent above range (>140 mg/dL) in the AID group, greater overnight time in target range, and lower A1C (236). There were no differences in the number of preterm births, birth weight, neonatal complications, or admission to the neonatal intensive care unit.

Additional data were reported from a pilot RCT of SAP without automation versus assisted hybrid closed-loop therapy in pregnant women with type 1 diabetes that enrolled participants in the first trimester and randomized them at 14–18 weeks'

gestation. This system did not have pregnancy-specific glucose targets; however, the results showed that the time in hypoglycemia <54 mg/dL did not differ between groups. Time at <63 mg/dL was lower in the hybrid closed-loop group, whereas percentage of the pregnancy-specific TIR was greater in the SAP group in the third trimester, with similar safety and adverse pregnancy outcomes between groups (237). There were no statistically significant differences in measures of glycemic risk or in measures of glycemic variability between the hybrid closed-loop and the SAP groups at any point during pregnancy or postpartum (238). In another study with an AID system with a lowest glucose target of 100 mg/dL, participants were randomized to AID or standard of care in the first trimester and for the rest of gestation. The 24-h percentage of pregnancy-specific TIR was not different between groups, but the overnight percentage of pregnancy-specific TIR was higher in the AID group while using assistive techniques. Time spent below range was lower over 24 h and overnight in the AID group as well. Quality-of-life metrics were improved in the AID group in this study (239).

Therefore, if the decision is made to use AID systems without pregnancy-specific targets in selected pregnant individuals, then using assistive techniques, such as the combination of SAP mode (or manual mode) and hybrid closed-loop mode at different time points in pregnancy or throughout the day or entering fake carbohydrate boluses, should be considered and applied as needed to achieve intended goals (240). See Section 15, "Diabetes and Pregnancy," for more details.

Insulin Pumps and Automated Insulin Delivery Systems in People With Type 2 and Other Types of Diabetes

Traditional insulin pumps can be considered for the treatment of people with type 2 diabetes who are on MDI as well as those who have other types of diabetes resulting in insulin deficiency, for instance, those who have had a pancreatectomy and/or individuals with cystic fibrosis (241–245). Similar to data on insulin pump use in people with type 1 diabetes, reductions in A1C levels have been reported in some studies (243,246). More recently, real-world reports have shown reduction of A1C levels and reduction of total daily insulin dose in individuals with type 2 diabetes initiating insulin pump therapy (247). Use of insulin pumps in insulin-requiring people with any type of diabetes may improve user satisfaction and simplify therapy (171,241).

For people with diabetes judged to be clinically insulin deficient who are treated with an intensive insulin therapy, the presence or absence of measurable C-peptide levels does not correlate with response to therapy (171). A low C-peptide value should not be required for insulin pump coverage in individuals with type 2 diabetes.

The use of insulin pumps and AID systems in type 2 diabetes is still limited, and at this time only one system is FDA approved for use in type 2 diabetes. Nevertheless, data are increasing; a small, single-arm prospective study in adults with type 2 diabetes who were on MDI and started an AID system revealed improvement of TIR by 15% at 6 weeks (248). Similar findings were reported in a randomized controlled, crossover trial of adults with type 2 diabetes previously treated with conventional insulin pump therapy plus CGM. While on the AID system (5 weeks), the TIR increased by a mean of 15%, with a decrease in TAR (>180 mg/dL and >250 mg/dL) and GMI. Of note, an increase in total daily insulin dose was noted in the subjects while on the AID system (249), whereas other studies have shown either nonsignificant trends for a lower total daily dose of insulin in the AID group (250) or a reduction of total daily insulin in the AID group previously using MDI (251). Finally, a recent RCT of older adults with type 2 diabetes who used MDI but were unable to manage insulin therapy on their own revealed an increase of TIR of 27% over 12 weeks of AID system use in addition to tailored home health care services (250). Real-world studies have also shown benefits of these technologies in adults with type 2 diabetes (235,251).

Alternative insulin delivery options in people with type 2 diabetes include disposable patch-like devices, which provide either a continuous subcutaneous insulin infusion of rapid-acting insulin (basal) with bolus insulin in 2-unit increments at the press of a button or bolus insulin only, delivered in 2-unit increments, used in conjunction with basal insulin injections (242,244, 252,253). Use of an insulin pump as a means of insulin delivery is an individual choice for people with diabetes and should be considered an option in those who are capable of safely using the device.

Open-Source Automated Insulin Dosing

Recommendation

7.29 Support and provide diabetes management advice to people with diabetes who choose to use an open-source closed-loop system. **B**

Open-source automated insulin dosing (OS-AID) algorithms provide the precise code that governs their operation, so health care professionals and people with diabetes can have a more complete understanding of risks and benefits (254). Any commercial entity could provide the source code for their interoperable automated glycemic controller, but most choose not to. OS-AID algorithms are largely designed, maintained, and curated by people with diabetes and their loved ones. Thousands of people with diabetes use these algorithms with cleared CGM systems and insulin pump components. The information on how to set up and manage these systems is freely available online.

OS-AID is the preferred term when referring to any open-source system (commercial or otherwise). It is important to note that the term "DIY" is not reflective of any aspect of these community-driven systems. No individual person has written all the code for these algorithms, and a large percentage of users do not build the software themselves (255). There are two main available algorithms, the OpenAPS algorithm and the Loop algorithm, which have been implemented on a variety of platforms.

The OpenAPS heuristic algorithm (implemented on a system on a chip in OpenAPS, Android smartphones as AndroidAPS, and iPhone as iAPS/Trio) is supported by large real-world studies (256) and a multicenter RCT (257). The OpenAPS algorithm is the only AID system to support unannounced meals. In a single-center study of adolescents with type 1 diabetes randomized to AndroidAPS with quantitative carbohydrate announcements, qualitative announcements, and no announcements, TIR was preserved across groups (258).

Loop, an open-source model predictive control algorithm, is implemented on iPhones as an app. Prospective real-world data from 558 adults and children with type 1 diabetes on this system (255) was used to support the FDA clearance of a variant called Tidepool Loop (259).

Both the Loop and OpenAPS algorithms offer direct management of algorithm aggressiveness through conventional pump settings. Therefore, it is advisable that health care professionals understand and offer support in tuning settings for these safe and effective technologies (254). This may include, for example, the adjustment of basal rates, insulin-to-carbohydrate ratios, or insulin sensitivity factors. As with any AID system, a backup insulin treatment plan is advisable.

Digital Health Technology

Recommendation

7.30 Consider combining technology (CGM, insulin pump, and/or diabetes apps) with online or virtual coaching to improve glycemic outcomes in individuals with diabetes or prediabetes. **B**

Increasingly, people are turning to the internet for advice, coaching, connection, and health care. Diabetes, partly because it is both common and numeric, lends itself to the development of apps and online programs. Recommendations for developing and implementing a digital diabetes clinic have been published (260). The FDA approves and monitors clinically validated, digital, and usually online health technologies intended to treat a medical or psychological condition; these are known as digital therapeutics, or "digiceuticals" (fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications) (261). Other applications, such as those that assist in displaying or storing data, encourage a healthy lifestyle or provide limited clinical data support. Therefore, it is possible to find apps that have been fully reviewed and approved by the FDA and others designed and promoted by people with relatively little skill or knowledge in the clinical treatment of diabetes. There are insufficient data to provide recommendations for specific apps for diabetes management, education, and support in the absence of RCTs and validation of apps unless they are FDA cleared.

An area of particular importance is that of online privacy and security. Established cloud-based data aggregator programs, such as Tidepool, Glooko, and others, have been developed with appropriate data security features and are compliant with the U.S. Health Insurance Portability and Accountability Act of 1996. These programs can help monitor people with diabetes and provide access to their health care teams (262). Consumers should read the policy regarding data privacy and sharing before entering data into an application and learn how they can manage the way their data will be used (some programs offer the ability to share more or less information, such as being part of a registry or data repository or not).

Many online programs offer lifestyle counseling to achieve weight loss and increased physical activity (263). Many include a health coach and can create small groups of similar participants on social networks. Some programs aim to treat prediabetes and prevent progression to diabetes, often following the model of the Diabetes Prevention Program (264,265). Others assist in improving diabetes outcomes by remotely monitoring clinical data (for instance, wireless monitoring of glucose levels, weight, or blood pressure) and providing feedback and coaching (266–271). There are text messaging approaches that tie into a variety of different types of lifestyle and treatment programs, which vary in terms of their effectiveness (272,273). There are limited RCT data for many of these interventions, and long-term follow-up is lacking. However, in a real-world observational study in individuals with type 2 diabetes treated with basal insulin, oral medications, or no medications, the use of a digital health solution and rtCGM resulted in reductions of GMI and TAR >180 and >250 mg/dL as well as an increase in TIR by 15% and participation in a least one engagement activity per week (274). Therefore, even with limited data, for an individual with diabetes, opting in to one of these programs can be helpful in providing support and, for many, is an attractive option.

Inpatient Care

Recommendations

7.31 In people with diabetes wearing personal CGM, the use of CGM should be continued when clinically appropriate during hospitalization, with confirmatory point-of-care glucose measurements for insulin dosing and hypoglycemia assessment and treatment under an institutional protocol. **B**

7.32 Continue use of insulin pump or AID in people with diabetes who are hospitalized when clinically appropriate, with confirmatory point-of-care blood glucose measurements for insulin dose decisions and hypoglycemia assessment and treatment. This is contingent upon availability of necessary supplies, resources, and training, ongoing competency assessments, and implementation of institutional diabetes technology protocols. **C**

Individuals who are comfortable using their diabetes devices, such as insulin pumps and CGM, should be allowed to use them in an inpatient setting if they are well enough to take care of the devices and have brought the necessary supplies (273,275–278). People with diabetes who are familiar with treating their own glucose levels can often adjust insulin doses more knowledgeably than inpatient staff who do not personally know the individual or their management style. It is crucial that, when people with diabetes in the inpatient setting need to temporarily disconnect or interrupt their device use for a procedure or imaging studies, etc., the care team is particularly careful to not discard these devices or stop their use without ensuring that an alternate method of insulin delivery has been initiated, if these are insulin delivery devices, and to ensure that close glucose monitoring is continued by finger stick. Therefore, it is particularly important that the use of diabetes devices while in the inpatient setting should occur based on the hospital's policies for diabetes management and use of diabetes technology, and there should be supervision to ensure that the individual is achieving and maintaining glycemic goals during acute illness in a hospitalized setting where factors such as infection, certain medications, immobility, and changes in nutrition can affect insulin sensitivity and the insulin response (279–281).

With the advent of the coronavirus disease 2019 pandemic, the FDA exercised enforcement discretion by allowing CGM device use temporarily in the hospital for patient monitoring (282). This approach has been taken to reduce the use of personal protective equipment and more closely monitor patients so that health care personnel do not have to go into a patient room solely to measure a glucose level (283–286). Studies have been published assessing the effectiveness of this approach, which may ultimately lead to the approved use of CGM

for monitoring hospitalized individuals (277,286–295). When used in the setting of a clinical trial or when clinical circumstances (such as during a shortage of personal protective equipment) require it, CGM can be used to manage hospitalized individuals in conjunction with BGM. Point-of-care BGM remains the approved method for glucose monitoring in hospitals, especially for dosing insulin and treating hypoglycemia. Similarly, data are emerging on the inpatient use of AID systems and their challenges (277,296, 297). For more information, see Section 16, "Diabetes Care in the Hospital."

The Future

The pace of development in diabetes technology is extremely rapid. New approaches and tools are available each year. It is difficult for research to keep up with these advances, because newer versions of the devices and digital solutions are already on the market by the time a study is completed. The most important component in all these systems is the person with diabetes. Technology selection must be appropriate for the individual. Simply having a device or application does not change outcomes unless the human being engages with it to create positive health benefits. This underscores the need for the health care team to assist people with diabetes in device and program selection and to support their use through ongoing education and training. Expectations must be tempered by reality—we do not yet have technology that completely eliminates the self-care tasks necessary for managing diabetes, but the tools described in this section can make it easier to manage.

References

1. Broos B, Charleer S, Bolsens N, et al. Diabetes knowledge and metabolic control in type 1 diabetes starting with continuous glucose monitoring: FUTURE-PEAK. J Clin Endocrinol Metab 2021;106: e3037–e3048
2. Yoo JH, Kim G, Lee HJ, Sim KH, Jin S-M, Kim JH. Effect of structured individualized education on continuous glucose monitoring use in poorly controlled patients with type 1 diabetes: a randomized controlled trial. Diabetes Res Clin Pract 2022;184:109209
3. Champakanath A, Akturk HK, Alonso GT, Snell-Bergeon JK, Shah VN. Continuous glucose monitoring initiation within first year of type 1 diabetes diagnosis is associated with improved glycemic outcomes: 7-year follow-up study. Diabetes Care 2022;45:750–753
4. Patton SR, Noser AE, Youngkin EM, Majidi S, Clements MA. Early initiation of diabetes devices relates to improved glycemic control in children with recent-onset type 1 diabetes mellitus. Diabetes Technol Ther 2019;21:379–384
5. Prahalad P, Ding VY, Zaharieva DP, et al. Teamwork, targets, technology, and tight control in newly diagnosed type 1 diabetes: the Pilot 4T Study. J Clin Endocrinol Metab 2022;107:998–1008
6. Tanenbaum ML, Zaharieva DP, Addala A, et al. "I was ready for it at the beginning": parent experiences with early introduction of continuous glucose monitoring following their child's type 1 diabetes diagnosis. Diabet Med 2021;38:e14567
7. Addala A, Maahs DM, Scheinker D, Chertow S, Leverenz B, Prahalad P. Uninterrupted continuous glucose monitoring access is associated with a decrease in HbA1c in youth with type 1 diabetes and public insurance. Pediatr Diabetes 2020;21: 1301–1309
8. Aronson R, Brown RE, Chu L, et al. IMpact of flash glucose Monitoring in pEople with type 2 Diabetes Inadequately controlled with non-insulin Antihyperglycaemic ThErapy (IMMEDIATE): a randomized controlled trial. Diabetes Obes Metab 2023;25:1024–1031
9. Leelarathna L, Evans ML, Neupane S, et al.; FLASH-UK Trial Study Group. Intermittently scanned continuous glucose monitoring for type 1 diabetes. N Engl J Med 2022;387:1477–1487
10. Grace T, Salyer J. Use of real-time continuous glucose monitoring improves glycemic control and other clinical outcomes in type 2 diabetes patients treated with less intensive therapy. Diabetes Technol Ther 2022;24:26–31
11. Patil SP, Albanese-O'Neill A, Yehl K, Seley JJ, Hughes AS. Professional competencies for diabetes technology use in the care setting. Sci Diabetes Self Manag Care 2022;48:437–445
12. Phillip M, Nimri R, Bergenstal RM, et al. Consensus recommendations for the use of automated insulin delivery technologies in clinical practice. Endocr Rev 2023;44:254–280
13. Boughton CK, Allen JM, Ware J, et al. The effect of closed-loop glucose control on C-peptide secretion in youth with newly diagnosed type 1 diabetes: the CLOuD RCT. Efficacy Mech Eval 2024;11:8
14. Karakus KE, Akturk HK, Alonso GT, Snell-Bergeon JK, Shah VN. Association between diabetes technology use and glycemic outcomes in adults with type 1 diabetes over a decade. Diabetes Care 2023;46:1646–1651
15. Aleppo G, Beck RW, Bailey R, et al.; Type 2 Diabetes Basal Insulin Users: The Mobile Study (MOBILE) Study Group. The effect of discontinuing continuous glucose monitoring in adults with type 2 diabetes treated with basal insulin. Diabetes Care 2021;44:2729–2737
16. Nathan DM, Genuth S, Lachin J, et al.; Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977–986
17. King F, Ahn D, Hsiao V, Porco T, Klonoff DC. A review of blood glucose monitor accuracy. Diabetes Technol Ther 2018;20:843–856
18. Brazg RL, Klaff LJ, Parkin CG. Performance variability of seven commonly used self-monitoring of blood glucose systems: clinical considerations for patients and providers. J Diabetes Sci Technol 2013;7:144–152
19. Klonoff DC, Parkes JL, Kovatchev BP, et al. Investigation of the accuracy of 18 marketed blood glucose monitors. Diabetes Care 2018;41:1681–1688
20. Pleus S, Ulbrich S, Zschornack E, Kamann S, Haug C, Freckmann G. Documentation of skin-related issues associated with continuous glucose monitoring use in the scientific literature. Diabetes Technol Ther 2019;21:538–545
21. Grady M, Lamps G, Shemain A, Cameron H, Murray L. Clinical evaluation of a new, lower pain, one touch lancing device for people with diabetes: virtually pain-free testing and improved comfort compared to current lancing systems. J Diabetes Sci Technol 2021;15:53–59
22. Burton DM, Enigk MG, Lilly JW. Blood glucose meters and accessibility to blind and visually impaired people. J Diabetes Sci Technol 2012;6: 242–245
23. Harrison B, Brown D. Accuracy of a blood glucose monitoring system that recognizes insufficient sample blood volume and allows application of more blood to the same test strip. Expert Rev Med Devices 2020;17:75–82
24. Miller KM, Beck RW, Bergenstal RM, et al.; T1D Exchange Clinic Network. Evidence of a strong association between frequency of self-monitoring of blood glucose and hemoglobin A1c levels in T1D exchange clinic registry participants. Diabetes Care 2013;36:2009–2014
25. Grant RW, Huang ES, Wexler DJ, et al. Patients who self-monitor blood glucose and their unused testing results. Am J Manag Care 2015;21: e119–e129
26. Katz LB, Stewart L, Guthrie B, Cameron H. Patient satisfaction with a new, high accuracy blood glucose meter that provides personalized guidance, insight, and encouragement. J Diabetes Sci Technol 2020;14:318–323
27. Shaw RJ, Yang Q, Barnes A, et al. Self-monitoring diabetes with multiple mobile health devices. J Am Med Inform Assoc 2020;27:667–676
28. Gellad WF, Zhao X, Thorpe CT, Mor MK, Good CB, Fine MJ. Dual use of Department of Veterans Affairs and Medicare benefits and use of test strips in veterans with type 2 diabetes mellitus. JAMA Intern Med 2015;175:26–34
29. Ziegler R, Heidtmann B, Hilgard D, Hofer S, Rosenbauer J, Holl R, DPV-Wiss-Initiative. Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes. Pediatr Diabetes 2011;12:11–17
30. Garber AJ. Treat-to-target trials: uses, interpretation and review of concepts. Diabetes Obes Metab 2014;16:193–205
31. Young LA, Buse JB, Weaver MA, et al.; Monitor Trial Group. Glucose self-monitoring in non-insulin-treated patients with type 2 diabetes in primary care settings: a randomized trial. JAMA Intern Med 2017;177:920–929
32. Polonsky WH, Fisher L, Schikman CH, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study. Diabetes Care 2011;34:262–267
33. Malanda UL, Welschen LMC, Riphagen II, Dekker JM, Nijpels G, Bot SDM. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. Cochrane Database Syst Rev 2012;1:Cd005060
34. Willett LR; ACP Journal Club. Meta-analysis: self-monitoring in non-insulin-treated type 2

diabetes improved HbA1c by 0.25%. Ann Intern Med 2012;156:JC6–12
35. Mannucci E, Antenore A, Giorgino F, Scavini M. Effects of structured versus unstructured self-monitoring of blood glucose on glucose control in patients with non-insulin-treated type 2 diabetes: a meta-analysis of randomized controlled trials. J Diabetes Sci Technol 2018;12:183–189
36. Sai S, Urata M, Ogawa I. Evaluation of linearity and interference effect on SMBG and POCT devices, showing drastic high values, low values, or error messages. J Diabetes Sci Technol 2019;13:734–743
37. Sacks DB, Arnold M, Bakris GL, et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Diabetes Care 2023;46:e151–e199
38. Tamborlane WV, Beck RW, Bode BW, et al.; Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med 2008;359:1464–1476
39. Tumminia A, Crimi S, Sciacca L, et al. Efficacy of real-time continuous glucose monitoring on glycaemic control and glucose variability in type 1 diabetic patients treated with either insulin pumps or multiple insulin injection therapy: a randomized controlled crossover trial. Diabetes Metab Res Rev 2015;31:61–68
40. Hansen KW, Bibby BM. The frequency of intermittently scanned glucose and diurnal variation of glycemic metrics. J Diabetes Sci Technol 2022;16:1461–1465
41. Urakami T, Yoshida K, Kuwabara R, et al. Frequent scanning using flash glucose monitoring contributes to better glycemic control in children and adolescents with type 1 diabetes. J Diabetes Investig 2022;13:185–190
42. Lameijer A, Lommerde N, Dunn TC, et al. Flash glucose monitoring in the Netherlands: increased monitoring frequency is associated with improvement of glycemic parameters. Diabetes Res Clin Pract 2021;177:108897
43. Hohendorff J, Gumprecht J, Mysliwiec M, Zozulinska-Ziolkiewicz D, Malecki MT. Intermittently scanned continuous glucose monitoring data of polish patients from real-life conditions: more scanning and better glycemic control compared to worldwide data. Diabetes Technol Ther 2021;23:577–585
44. Aleppo G, Ruedy KJ, Riddlesworth TD, et al.; REPLACE-BG Study Group. REPLACE-BG: a randomized trial comparing continuous glucose monitoring with and without routine blood glucose monitoring in adults with well-controlled type 1 diabetes. Diabetes Care 2017;40:538–545
45. Friedman JG, Cardona Matos Z, Szmuilowicz ED, Aleppo G. Use of continuous glucose monitors to manage type 1 diabetes mellitus: progress, challenges, and recommendations. Pharmgenomics Pers Med 2023;16:263–276
46. Klonoff DC, Gabbay M, Moon SJ, Wilmot EG. Importance of FDA-integrated continuous glucose monitors to ensure accuracy of continuous glucose monitoring. J Diabetes Sci Technol 2024:19322968241250357
47. Medtronic. Medtronic announces FDA approval of Simplera CGM and global partnership with Abbott. Accessed 16 August 2024. Available from https://news.medtronic.com/2024-08-07-Medtronic-announces-FDA-approval-of-Simplera-TM-CGM-and-global-partnership-with-Abbott
48. Laffel LM, Kanapka LG, Beck RW, et al.; CDE10. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. JAMA 2020;323:2388–2396
49. Strategies to Enhance New CGM Use in Early Childhood (SENCE) Study Group. A randomized clinical trial assessing continuous glucose monitoring (CGM) use with standardized education with or without a family behavioral intervention compared with fingerstick blood glucose monitoring in very young children with type 1 diabetes. Diabetes Care 2021;44:464–472
50. New JP, Ajjan R, Pfeiffer AFH, Freckmann G. Continuous glucose monitoring in people with diabetes: the randomized controlled Glucose Level Awareness in Diabetes Study (GLADIS). Diabet Med 2015;32:609–617
51. Gubitosi-Klug RA, Braffett BH, Bebu I, et al. Continuous glucose monitoring in adults with type 1 diabetes with 35 years duration from the DCCT/EDIC study. Diabetes Care 2022;45:659–665
52. Sequeira PA, Montoya L, Ruelas V, et al. Continuous glucose monitoring pilot in low-income type 1 diabetes patients. Diabetes Technol Ther 2013;15:855–858
53. Friedman JG, Coyne K, Aleppo G, Szmuilowicz ED. Beyond A1C: exploring continuous glucose monitoring metrics in managing diabetes. Endocr Connect 2023;12:e230085
54. Teo E, Hassan N, Tam W, Koh S. Effectiveness of continuous glucose monitoring in maintaining glycaemic control among people with type 1 diabetes mellitus: a systematic review of randomised controlled trials and meta-analysis. Diabetologia 2022;65:604–619
55. Pratley RE, Kanapka LG, Rickels MR, et al.; Wireless Innovation for Seniors With Diabetes Mellitus (WISDM) Study Group. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: a randomized clinical trial. JAMA 2020;323:2397–2406
56. Miller KM, Kanapka LG, Rickels MR, et al. Benefit of continuous glucose monitoring in reducing hypoglycemia is sustained through 12 months of use among older adults with type 1 diabetes. Diabetes Technol Ther 2022;24:424–434
57. Bao S, Bailey R, Calhoun P, Beck RW. Effectiveness of continuous glucose monitoring in older adults with type 2 diabetes treated with basal insulin. Diabetes Technol Ther 2022;24:299–306
58. Van Name MA, Kanapka LG, DiMeglio LA, et al. Long-term continuous glucose monitor use in very young children with type 1 diabetes: one-year results from the SENCE study. J Diabetes Sci Technol 2023;17:976–987
59. Beck RW, Riddlesworth TD, Ruedy K, et al.; DIAMOND Study Group. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. Ann Intern Med 2017;167:365–374
60. Ehrhardt NM, Chellappa M, Walker MS, Fonda SJ, Vigersky RA. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. J Diabetes Sci Technol 2011;5:668–675
61. Martens T, Beck RW, Bailey R, et al.; MOBILE Study Group. Effect of continuous glucose monitoring on glycemic control in patients with type 2 diabetes treated with basal insulin: a randomized clinical trial. JAMA 2021;325:2262–2272
62. Price DA, Deng Q, Kipnes M, Beck SE. Episodic real-time CGM use in adults with type 2 diabetes: results of a pilot randomized controlled trial. Diabetes Ther 2021;12:2089–2099
63. Jancev M, Vissers TACM, Visseren FLJ, et al. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetologia 2024;67:798–810
64. Manfredo J, Lin T, Gupta R, et al. Short-term use of CGM in youth onset type 2 diabetes is associated with behavioral modifications. Front Endocrinol (Lausanne) 2023;14:1182260
65. Chesser H, Srinivasan S, Puckett C, Gitelman SE, Wong JC. Real-time continuous glucose monitoring in adolescents and young adults with type 2 diabetes can improve quality of life. J Diabetes Sci Technol 2024;18:911–919
66. Ferreira ROM, Trevisan T, Pasqualotto E, et al. Continuous glucose monitoring systems in noninsulin-treated people with type 2 diabetes: a systematic review and meta-analysis of randomized controlled trials. Diabetes Technol Ther 2024;26:252–262
67. Moon SJ, Kim K-S, Lee WJ, Lee MY, Vigersky R, Park C-Y. Efficacy of intermittent short-term use of a real-time continuous glucose monitoring system in non-insulin-treated patients with type 2 diabetes: a randomized controlled trial. Diabetes Obes Metab 2023;25:110–120
68. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. Lancet 2016;388:2254–2263
69. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline J-P, Rayman G. Flash glucose-sensing technology as a replacement for blood glucose monitoring for the management of insulin-treated type 2 diabetes: a multicenter, open-label randomized controlled trial. Diabetes Ther 2017;8:55–73
70. Yaron M, Roitman E, Aharon-Hananel G, et al. Effect of flash glucose monitoring technology on glycemic control and treatment satisfaction in patients with type 2 diabetes. Diabetes Care 2019;42:1178–1184
71. Davis TME, Dwyer P, England M, Fegan PG, Davis WA. Efficacy of intermittently scanned continuous glucose monitoring in the prevention of recurrent severe hypoglycemia. Diabetes Technol Ther 2020;22:367–373
72. Boucher SE, Gray AR, Wiltshire EJ, et al. Effect of 6 months of flash glucose monitoring in youth with type 1 diabetes and high-risk glycemic control: a randomized controlled trial. Diabetes Care 2020;43:2388–2395
73. Wada E, Onoue T, Kobayashi T, et al. Flash glucose monitoring helps achieve better glycemic control than conventional self-monitoring of blood glucose in non-insulin-treated type 2 diabetes: a randomized controlled trial. BMJ Open Diabetes Res Care 2020;8:e001115
74. Hayase A, Onoue T, Kobayashi T, et al. Improved glycemic control after the use of flash glucose monitoring accompanied by improved treatment satisfaction in patients with non-insulin-treated type 2 diabetes: a post-hoc analysis of a randomized controlled trial. Prim Care Diabetes 2023;17:575–580
75. Deshmukh H, Wilmot EG, Gregory R, et al. Effect of flash glucose monitoring on glycemic control, hypoglycemia, diabetes-related distress, and resource utilization in the Association of

British Clinical Diabetologists (ABCD) nationwide audit. Diabetes Care 2020;43:2153–2160
76. Charleer S, Gillard P, Vandoorne E, Cammaerts K, Mathieu C, Casteels K. Intermittently scanned continuous glucose monitoring is associated with high satisfaction but increased HbA1c and weight in well-controlled youth with type 1 diabetes. Pediatr Diabetes 2020;21:1465–1474
77. Tyndall V, Stimson RH, Zammitt NN, et al. Marked improvement in HbA1c following commencement of flash glucose monitoring in people with type 1 diabetes. Diabetologia 2019;62:1349–1356
78. Nathanson D, Svensson A-M, Miftaraj M, Franzén S, Bolinder J, Eeg-Olofsson K. Effect of flash glucose monitoring in adults with type 1 diabetes: a nationwide, longitudinal observational study of 14,372 flash users compared with 7691 glucose sensor naive controls. Diabetologia 2021;64: 1595–1603
79. Charleer S, De Block C, Van Huffel L, et al. Quality of life and glucose control after 1 year of nationwide reimbursement of intermittently scanned continuous glucose monitoring in adults living with type 1 diabetes (FUTURE): a prospective observational real-world cohort study. Diabetes Care 2020;43:389–397
80. Roussel R, Riveline J-P, Vicaut E, et al. Important drop in rate of acute diabetes complications in people with type 1 or type 2 diabetes after initiation of flash glucose monitoring in France: the RELIEF study. Diabetes Care 2021;44:1368–1376
81. Riveline J-P, Roussel R, Vicaut E, et al. Reduced rate of acute diabetes events with flash glucose monitoring is sustained for 2 years after initiation: extended outcomes from the RELIEF study. Diabetes Technol Ther 2022;24:611–618
82. Miller E, Kerr MSD, Roberts GJ, Nabutovsky Y, Wright E. Flash CGM associated with event reduction in nonintensive diabetes therapy. Am J Manag Care 2021;27:e372–e377
83. Al Hayek A, Al Dawish M, El Jammal M. The impact of flash glucose monitoring on markers of glycaemic control and patient satisfaction in type 2 diabetes. Cureus 2021;13:e16007
84. Visser MM, Charleer S, Fieuws S, et al. Comparing real-time and intermittently scanned continuous glucose monitoring in adults with type 1 diabetes (ALERTT1): a 6-month, prospective, multicentre, randomised controlled trial. Lancet 2021;397:2275–2283
85. Wright EE, Kerr MSD, Reyes IJ, Nabutovsky Y, Miller E. Use of flash continuous glucose monitoring is associated with A1C reduction in people with type 2 diabetes treated with basal insulin or noninsulin therapy. Diabetes Spectr 2021;34:184–189
86. Al Hayek AA, Al Dawish MA. Use of flash glucose monitoring and glycemic control in patients with type 2 diabetes mellitus not treated with an intensive insulin regimen: 1-year real-life retrospective cohort study. Adv Ther 2023;40: 2855–2868
87. Karter AJ, Parker MM, Moffet HH, Gilliam LK, Dlott R. Association of real-time continuous glucose monitoring with glycemic control and acute metabolic events among patients with insulin-treated diabetes. JAMA 2021;325:2273–2284
88. Layne JE, Jepson LH, Carite AM, Parkin CG, Bergenstal RM. Long-term improvements in glycemic control with Dexcom CGM use in adults with noninsulin-treated type 2 diabetes. Diabetes Technol Ther. 21 June 2024 [Epub ahead of print]. DOI: 10.1089/dia.2024.0197
89. Reddy M, Jugnee N, El Laboudi A, Spanudakis E, Anantharaja S, Oliver N. A randomized controlled pilot study of continuous glucose monitoring and flash glucose monitoring in people with type 1 diabetes and impaired awareness of hypoglycaemia. Diabet Med 2018;35:483–490
90. Hásková A, Radovnická L, Petruželková L, et al. Real-time CGM is superior to flash glucose monitoring for glucose control in type 1 diabetes: the CORRIDA randomized controlled trial. Diabetes Care 2020;43:2744–2750
91. Sandig D, Grimsmann J, Reinauer C, et al. Continuous glucose monitoring in adults with type 1 diabetes: real-world data from the German/Austrian prospective diabetes follow-up registry. Diabetes Technol Ther 2020;22:602–612
92. Radovnická L, Hásková A, Do QD, et al. Lower glycated hemoglobin with real-time continuous glucose monitoring than with intermittently scanned continuous glucose monitoring after 1 year: the CORRIDA LIFE study. Diabetes Technol Ther 2022;24:859–867
93. Danne T, Nimri R, Battelino T, et al. International consensus on use of continuous glucose monitoring. Diabetes Care 2017;40:1631–1640
94. Battelino T, Danne T, Bergenstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the International Consensus on Time in Range. Diabetes Care 2019;42:1593–1603
95. Simonson GD, Criego AB, Battelino T, et al. Expert panel recommendations for a standardized ambulatory glucose profile report for connected insulin pens. Diabetes Technol Ther 2024;26:814–822
96. Szmuilowicz ED, Aleppo G. Stepwise approach to continuous glucose monitoring interpretation for internists and family physicians. Postgrad Med 2022;134:743–751
97. Isaacs D, Cox C, Schwab K, et al. Technology integration: the role of the diabetes care and education specialist in practice. Diabetes Educ 2020;46:323–334
98. Rosenfeld C, Blevins T, Aleppo G, et al. Expert roundtable on continuous glucose monitoring. Endocr Pract 2022;28:622–627
99. Lee GS, Lupsa BC. Continuous glucose monitoring for the internist. Med Clin North Am 2021;105:967–982
100. Johnson ML, Martens TW, Criego AB, Carlson AL, Simonson GD, Bergenstal RM. Utilizing the ambulatory glucose profile to standardize and implement continuous glucose monitoring in clinical practice. Diabetes Technol Ther 2019;21:S217–S225
101. Akturk HK; American Diabetes Association Diabetes Technology Interest Group. Recent advances in diabetes technology and activities of the American Diabetes Association Diabetes Technology Interest Group. Clin Diabetes 2024;42:316–321
102. Dexcom, Inc. Dexcom G7 Continuous Glucose Monitoring System. Integrated Continuous Glucose Monitoring System, Factory Calibrated. Accessed 14 August 2024. Available from https://fda.report/PMN/K213919
103. Feig DS, Donovan LE, Corcoy R, et al.; CONCEPTT Collaborative Group. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet 2017;390:2347–2359
104. Kristensen K, Ögge LE, Sengpiel V, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes: an observational cohort study of 186 pregnancies. Diabetologia 2019;62:1143–1153
105. Durnwald C, Beck RW, Li Z, et al. Continuous glucose monitoring-derived differences in pregnancies with and without adverse perinatal outcomes. Obstet Gynecol 2024;144:684–696
106. Law GR, Gilthorpe MS, Secher AL, et al. Translating HbA1c measurements into estimated average glucose values in pregnant women with diabetes. Diabetologia 2017;60:618–624
107. Secher AL, Ringholm L, Andersen HU, Damm P, Mathiesen ER. The effect of real-time continuous glucose monitoring in pregnant women with diabetes: a randomized controlled trial. Diabetes Care 2013;36:1877–1883
108. Wei Q, Sun Z, Yang Y, Yu H, Ding H, Wang S. Effect of a CGMS and SMBG on maternal and neonatal outcomes in gestational diabetes mellitus: a randomized controlled trial. Sci Rep 2016;6:19920
109. García-Moreno RM, Benítez-Valderrama P, Barquiel B, et al. Efficacy of continuous glucose monitoring on maternal and neonatal outcomes in gestational diabetes mellitus: a systematic review and meta-analysis of randomized clinical trials. Diabet Med 2022;39:e14703
110. Wyckoff JA, Brown FM. Time in range in pregnancy: is there a role? Diabetes Spectr 2021; 34:119–132
111. Ajjan RA, Jackson N, Thomson SA. Reduction in HbA1c using professional flash glucose monitoring in insulin-treated type 2 diabetes patients managed in primary and secondary care settings: a pilot, multicentre, randomised controlled trial. Diab Vasc Dis Res 2019;16:385–395
112. Ribeiro RT, Andrade R, Dulce Nascimento do Ó, Lopes AF, Raposo JF. Impact of blinded retrospective continuous glucose monitoring on clinical decision making and glycemic control in persons with type 2 diabetes on insulin therapy. Nutr Metab Cardiovasc Dis 2021;31:1267–1275
113. Nemlekar PM, Hannah KL, Norman GJ. Association between change in A1C and use of professional continuous glucose monitoring in adults with type 2 diabetes on noninsulin therapies: a real-world evidence study. Clin Diabetes 2023;41: 359–366
114. Fantasia KL, Stockman M-C, Ju Z, et al. Professional continuous glucose monitoring and endocrinology eConsult for adults with type 2 diabetes in primary care: results of a clinical pilot program. J Clin Transl Endocrinol 2021;24:100254
115. Simonson GD, Bergenstal RM, Johnson ML, Davidson JL, Martens TW. Effect of professional CGM (pCGM) on glucose management in type 2 diabetes patients in primary care. J Diabetes Sci Technol 2021;15:539–545
116. Ulrich H, Bowen M. The clinical utility of professional continuous glucose monitoring by pharmacists for patients with type 2 diabetes. J Am Pharm Assoc (2003) 2021;61:e76–e82
117. Herman A, de Montjoye L, Baeck M. Adverse cutaneous reaction to diabetic glucose sensors and insulin pumps: irritant contact dermatitis or allergic contact dermatitis? Contact Dermatitis 2020;83:25–30
118. Rigo RS, Levin LE, Belsito DV, Garzon MC, Gandica R, Williams KM. Cutaneous reactions to continuous glucose monitoring and continuous subcutaneous insulin infusion devices in type 1

diabetes mellitus. J Diabetes Sci Technol 2021;15:786–791
119. Kamann S, Aerts O, Heinemann L. Further evidence of severe allergic contact dermatitis from isobornyl acrylate while using a continuous glucose monitoring system. J Diabetes Sci Technol 2018;12:630–633
120. Aerts O, Herman A, Bruze M, Goossens A, Mowitz M. FreeStyle Libre: contact irritation versus contact allergy. Lancet 2017;390:1644
121. Herman A, Aerts O, Baeck M, et al. Allergic contact dermatitis caused by isobornyl acrylate in Freestyle Libre, a newly introduced glucose sensor. Contact Dermatitis 2017;77:367–373
122. Hyry HSI, Liippo JP, Virtanen HM. Allergic contact dermatitis caused by glucose sensors in type 1 diabetes patients. Contact Dermatitis 2019;81:161–166
123. Asarani NAM, Reynolds AN, Boucher SE, de Bock M, Wheeler BJ. Cutaneous complications with continuous or flash glucose monitoring use: systematic review of trials and observational studies. J Diabetes Sci Technol 2020;14:328–337
124. Lombardo F, Salzano G, Crisafulli G, et al. Allergic contact dermatitis in pediatric patients with type 1 diabetes: an emerging issue. Diabetes Res Clin Pract 2020;162:108089
125. Oppel E, Kamann S, Heinemann L, Reichl F-X, Högg C. The implanted glucose monitoring system Eversense: an alternative for diabetes patients with isobornyl acrylate allergy. Contact Dermatitis 2020;82:101–104
126. Freckmann G, Buck S, Waldenmaier D, et al. Skin reaction report form: development and design of a standardized report form for skin reactions due to medical devices for diabetes management. J Diabetes Sci Technol 2021;15:801–806
127. Deiss D, Irace C, Carlson G, Tweden KS, Kaufman FR. Real-world safety of an implantable continuous glucose sensor over multiple cycles of use: a post-market registry study. Diabetes Technol Ther 2020;22:48–52
128. Sanchez P, Ghosh-Dastidar S, Tweden KS, Kaufman FR. Real-world data from the first U.S. commercial users of an implantable continuous glucose sensor. Diabetes Technol Ther 2019;21:677–681
129. Heinemann L. Interferences with CGM systems: practical relevance? J Diabetes Sci Technol 2022;16:271–274
130. Tellez SE, Hornung LN, Courter JD, et al. Inaccurate glucose sensor values after hydroxyurea administration. Diabetes Technol Ther 2021;23:443–451
131. Szmuilowicz ED, Aleppo G. Interferent effect of hydroxyurea on continuous glucose monitoring. Diabetes Care 2021;44:e89–e90
132. Pfützner A, Jensch H, Cardinal C, Srikanthamoorthy G, Riehn E, Thomé N. Laboratory protocol and pilot results for dynamic interference testing of continuous glucose monitoring sensors. J Diabetes Sci Technol 2022;18:59–65
133. Lorenz C, Sandoval W, Mortellaro M. Interference assessment of various endogenous and exogenous substances on the performance of the Eversense long-term implantable continuous glucose monitoring system. Diabetes Technol Ther 2018;20:344–352
134. Denham D. Effect of repeated doses of acetaminophen on a continuous glucose monitoring system with permselective membrane. J Diabetes Sci Technol 2021;15:517–518
135. U.S. FDA. Summary of safety and effectiveness data (SSED). Continuous glucose monitor (CGM), implanted, adjunctive use 2018. Accessed 14 August 2024. Available from https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048B.pdf
136. Piras de Oliveira C, Mitchell BD, Fan L, et al. Patient perspectives on the use of half-unit insulin pens by people with type 1 diabetes: a cross-sectional observational study. Curr Med Res Opin 2021;37:45–51
137. Machry RV, Cipriani GF, Pedroso HU, et al. Pens versus syringes to deliver insulin among elderly patients with type 2 diabetes: a randomized controlled clinical trial. Diabetol Metab Syndr 2021;13:64
138. Korytkowski M, Bell D, Jacobsen C, Suwannasari R, FlexPen Study Team. A multicenter, randomized, open-label, comparative, two-period crossover trial of preference, efficacy, and safety profiles of a prefilled, disposable pen and conventional vial/syringe for insulin injection in patients with type 1 or 2 diabetes mellitus. Clin Ther 2003;25:2836–2848
139. Asche CV, Shane-McWhorter L, Raparla S. Health economics and compliance of vials/syringes versus pen devices: a review of the evidence. Diabetes Technol Ther 2010;12(Suppl 1):S101–S108
140. Singh R, Samuel C, Jacob JJ. A comparison of insulin pen devices and disposable plastic syringes–simplicity, safety, convenience and cost differences. Eur Endocrinol 2018;14:47–51
141. Frid AH, Kreugel G, Grassi G, et al. New insulin delivery recommendations. Mayo Clin Proc 2016;91:1231–1255
142. Lasalvia P, Barahona-Correa JE, Romero-Alvernia DM, et al. Pen devices for insulin self-administration compared with needle and vial: systematic review of the literature and meta-analysis. J Diabetes Sci Technol 2016;10:959–966
143. Slabaugh SL, Bouchard JR, Li Y, Baltz JC, Meah YA, Moretz DC. Characteristics relating to adherence and persistence to basal insulin regimens among elderly insulin-naïve patients with type 2 diabetes: pre-filled pens versus vials/syringes. Adv Ther 2015;32:1206–1221
144. Chandran A, Bonafede MK, Nigam S, Saltiel-Berzin R, Hirsch LJ, Lahue BJ. Adherence to insulin pen therapy is associated with reduction in healthcare costs among patients with type 2 diabetes mellitus. Am Health Drug Benefits 2015;8:148–158
145. Ahmann A, Szeinbach SL, Gill J, Traylor L, Garg SK. Comparing patient preferences and healthcare provider recommendations with the pen versus vial-and-syringe insulin delivery in patients with type 2 diabetes. Diabetes Technol Ther 2014;16:76–83
146. Asche CV, Luo W, Aagren M. Differences in rates of hypoglycemia and health care costs in patients treated with insulin aspart in pens versus vials. Curr Med Res Opin 2013;29:1287–1296
147. Luijf YM, DeVries JH. Dosing accuracy of insulin pens versus conventional syringes and vials. Diabetes Technol Ther 2010;12(Suppl 1):S73–S77
148. Hanas R, de Beaufort C, Hoey H, Anderson B. Insulin delivery by injection in children and adolescents with diabetes. Pediatr Diabetes 2011;12:518–526
149. Pfützner A, Schipper C, Niemeyer M, et al. Comparison of patient preference for two insulin injection pen devices in relation to patient dexterity skills. J Diabetes Sci Technol 2012;6:910–916
150. Reinauer KM, Joksch G, Renn W, Eggstein M. Insulin pens in elderly diabetic patients. Diabetes Care 1990;13:1136–1137
151. Thomas DR, Fischer RG, Nicholas WC, Beghe C, Hatten KW, Thomas JN. Disposable insulin syringe reuse and aseptic practices in diabetic patients. J Gen Intern Med 1989;4:97–100
152. Hirsch IB, Beck RW, Marak MC, et al.; INHALE-3 Study Group. A randomized comparison of postprandial glucose excursion using inhaled insulin versus rapid-acting analog insulin in adults with type 1 diabetes using multiple daily injections of insulin or automated insulin delivery. Diabetes Care 2024;47:1682–1687
153. Seo J, Heidenreich S, Aldalooj E, et al. Patients' preferences for connected insulin pens: a discrete choice experiment among patients with type 1 and type 2 diabetes. Patient 2023;16:127–138
154. Gomez-Peralta F, Abreu C, Fernández-Rubio E, et al. Efficacy of a connected insulin pen cap in people with noncontrolled type 1 diabetes: a multicenter randomized clinical trial. Diabetes Care 2023;46:206–208
155. Cranston I, Jamdade V, Liao B, Newson RS. Clinical, economic, and patient-reported benefits of connected insulin pen systems: a systematic literature review. Adv Ther 2023;40:2015–2037
156. Danne TPA, Joubert M, Hartvig NV, Kaas A, Knudsen NN, Mader JK. Association between treatment adherence and continuous glucose monitoring outcomes in people with diabetes using smart insulin pens in a real-world setting. Diabetes Care 2024;47:995–1003
157. Bailey TS, Stone JY. A novel pen-based Bluetooth-enabled insulin delivery system with insulin dose tracking and advice. Expert Opin Drug Deliv 2017;14:697–703
158. Eiland L, McLarney M, Thangavelu T, Drincic A. App-based insulin calculators: current and future state. Curr Diab Rep 2018;18:123
159. Breton MD, Patek SD, Lv D, et al. Continuous glucose monitoring and insulin informed advisory system with automated titration and dosing of insulin reduces glucose variability in type 1 diabetes mellitus. Diabetes Technol Ther 2018;20:531–540
160. Bergenstal RM, Johnson M, Passi R, et al. Automated insulin dosing guidance to optimise insulin management in patients with type 2 diabetes: a multicentre, randomised controlled trial. Lancet 2019;393:1138–1148
161. Schneider JE, Parikh A, Stojanovic I. Impact of a novel insulin management service on non-insulin pharmaceutical expenses. J Health Econ Outcomes Res 2018;6:53–62
162. Huckvale K, Adomaviciute S, Prieto JT, Leow MK-S, Car J. Smartphone apps for calculating insulin dose: a systematic assessment. BMC Med 2015;13:106
163. Yeh H-C, Brown TT, Maruthur N, et al. Comparative effectiveness and safety of methods of insulin delivery and glucose monitoring for diabetes mellitus: a systematic review and meta-analysis. Ann Intern Med 2012;157:336–347
164. Aleppo G, DeSalvo DJ, Lauand F, et al. Improvements in glycemic outcomes in 4738 children, adolescents, and adults with type 1 diabetes initiating a tubeless insulin management system. Diabetes Ther 2023;14:593–610
165. Lin MH, Connor CG, Ruedy KJ, et al.; Pediatric Diabetes Consortium. Race, socioeconomic status, and treatment center are associated with insulin

pump therapy in youth in the first year following diagnosis of type 1 diabetes. Diabetes Technol Ther 2013;15:929–934
166. Willi SM, Miller KM, DiMeglio LA, et al.; T1D Exchange Clinic Network. Racial-ethnic disparities in management and outcomes among children with type 1 diabetes. Pediatrics 2015;135:424–434
167. Redondo MJ, Libman I, Cheng P, et al.; Pediatric Diabetes Consortium. Racial/ethnic minority youth with recent-onset type 1 diabetes have poor prognostic factors. Diabetes Care 2018;41:1017–1024
168. Berghaeuser MA, Kapellen T, Heidtmann B, Haberland H, Klinkert C, Holl RW, German Working Group for Insulin Pump Treatment in Paediatric Patients. Continuous subcutaneous insulin infusion in toddlers starting at diagnosis of type 1 diabetes mellitus. A multicenter analysis of 104 patients from 63 centres in Germany and Austria. Pediatr Diabetes 2008;9:590–595
169. Peters AL, Ahmann AJ, Battelino T, et al. Diabetes technology-continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2016;101:3922–3937
170. Gill M, Chhabra H, Shah M, Zhu C, Grunberger G. C-peptide and beta-cell autoantibody testing prior to initiating continuous subcutaneous insulin infusion pump therapy did not improve utilization or medical costs among older adults with diabetes mellitus. Endocr Pract 2018;24:634–645
171. Vigersky RA, Huang S, Cordero TL, et al.; OpT2mise Study Group. Improved HBa1c, total daily insulin dose, and treatment satisfaction with insulin pump therapy compared to multiple daily insulin injections in patients with type 2 diabetes irrespective of baseline c-peptide levels. Endocr Pract 2018;24:446–452
172. Wheeler BJ, Heels K, Donaghue KC, Reith DM, Ambler GR. Insulin pump-associated adverse events in children and adolescents–a prospective study. Diabetes Technol Ther 2014;16:558–562
173. Ucieklak D, Mrozinska S, Wojnarska A, Malecki MT, Klupa T, Matejko B. Insulin-induced lipohypertrophy in patients with type 1 diabetes mellitus treated with an insulin pump. Int J Endocrinol 2022;2022:9169296
174. Wong JC, Boyle C, DiMeglio LA, et al.; T1D Exchange Clinic Network. Evaluation of pump discontinuation and associated factors in the T1D Exchange Clinic Registry. J Diabetes Sci Technol 2017;11:224–232
175. Wong JC, Dolan LM, Yang TT, Hood KK. Insulin pump use and glycemic control in adolescents with type 1 diabetes: predictors of change in method of insulin delivery across two years. Pediatr Diabetes 2015;16:592–599
176. Plotnick LP, Clark LM, Brancati FL, Erlinger T. Safety and effectiveness of insulin pump therapy in children and adolescents with type 1 diabetes. Diabetes Care 2003;26:1142–1146
177. Redondo MJ, Connor CG, Ruedy KJ, et al.; Pediatric Diabetes Consortium. Pediatric Diabetes Consortium type 1 diabetes new onset (NeOn) study: factors associated with HbA1c levels one year after diagnosis. Pediatr Diabetes 2014;15:294–302
178. Doyle EA, Weinzimer SA, Steffen AT, Ahern JAH, Vincent M, Tamborlane WV. A randomized, prospective trial comparing the efficacy of continuous subcutaneous insulin infusion with multiple daily injections using insulin glargine. Diabetes Care 2004;27:1554–1558
179. Alemzadeh R, Ellis JN, Holzum MK, Parton EA, Wyatt DT. Beneficial effects of continuous subcutaneous insulin infusion and flexible multiple daily insulin regimen using insulin glargine in type 1 diabetes. Pediatrics 2004;114:e91–e95
180. Sherr JL, Hermann JM, Campbell F, et al.; T1D Exchange Clinic Network, the DPV Initiative, and the National Paediatric Diabetes Audit and the Royal College of Paediatrics and Child Health Registries. Use of insulin pump therapy in children and adolescents with type 1 diabetes and its impact on metabolic control: comparison of results from three large, transatlantic paediatric registries. Diabetologia 2016;59:87–91
181. Jeitler K, Horvath K, Berghold A, et al. Continuous subcutaneous insulin infusion versus multiple daily insulin injections in patients with diabetes mellitus: systematic review and meta-analysis. Diabetologia 2008;51:941–951
182. Karges B, Schwandt A, Heidtmann B, et al. Association of insulin pump therapy vs insulin injection therapy with severe hypoglycemia, ketoacidosis, and glycemic control among children, adolescents, and young adults with type 1 diabetes. JAMA 2017;318:1358–1366
183. Haynes A, Hermann JM, Miller KM, et al.; T1D Exchange, WACDD and DPV Registries. Severe hypoglycemia rates are not associated with HbA1c: a cross-sectional analysis of 3 contemporary pediatric diabetes registry databases. Pediatr Diabetes 2017;18:643–650
184. Pickup JC, Sutton AJ. Severe hypoglycaemia and glycaemic control in type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion. Diabet Med 2008;25:765–774
185. Birkebaek NH, Drivvoll AK, Aakeson K, et al. Incidence of severe hypoglycemia in children with type 1 diabetes in the Nordic countries in the period 2008-2012: association with hemoglobin A 1c and treatment modality. BMJ Open Diabetes Res Care 2017;5:e000377
186. Maahs DM, Hermann JM, Holman N, et al.; National Paediatric Diabetes Audit and the Royal College of Paediatrics and Child Health, the DPV Initiative, and the T1D Exchange Clinic Network. Rates of diabetic ketoacidosis: international comparison with 49,859 pediatric patients with type 1 diabetes from England, Wales, the U.S., Austria, and Germany. Diabetes Care 2015;38:1876–1882
187. Opipari-Arrigan L, Fredericks EM, Burkhart N, Dale L, Hodge M, Foster C. Continuous subcutaneous insulin infusion benefits quality of life in preschool-age children with type 1 diabetes mellitus. Pediatr Diabetes 2007;8:377–383
188. Sundberg F, Barnard K, Cato A, et al. ISPAD Guidelines. Managing diabetes in preschool children. Pediatr Diabetes 2017;18:499–517
189. Commissariat PV, Boyle CT, Miller KM, et al. Insulin pump use in young children with type 1 diabetes: sociodemographic factors and parent-reported barriers. Diabetes Technol Ther 2017;19:363–369
190. Forlenza GP, Li Z, Buckingham BA, et al. Predictive low-glucose suspend reduces hypoglycemia in adults, adolescents, and children with type 1 diabetes in an at-home randomized crossover study: results of the PROLOG trial. Diabetes Care 2018;41:2155–2161
191. Wood MA, Shulman DI, Forlenza GP, et al. In-clinic evaluation of the MiniMed 670G system "suspend before low" feature in children with type 1 diabetes. Diabetes Technol Ther 2018;20:731–737
192. Beato-Víbora PI, Quirós-López C, Lázaro-Martín L, et al. Impact of sensor-augmented pump therapy with predictive low-glucose suspend function on glycemic control and patient satisfaction in adults and children with type 1 diabetes. Diabetes Technol Ther 2018;20:738–743
193. Brown SA, Beck RW, Raghinaru D, et al.; iDCL Trial Research Group. Glycemic outcomes of use of CLC versus PLGS in type 1 diabetes: a randomized controlled trial. Diabetes Care 2020;43:1822–1828
194. Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. JAMA 2016;316:1407–1408
195. Garg SK, Weinzimer SA, Tamborlane WV, et al. Glucose outcomes with the in-home use of a hybrid closed-loop insulin delivery system in adolescents and adults with type 1 diabetes. Diabetes Technol Ther 2017;19:155–163
196. Tauschmann M, Thabit H, Bally L, et al.; APCam11 Consortium. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial. Lancet 2018;392:1321–1329
197. Ekhlaspour L, Forlenza GP, Chernavvsky D, et al. Closed loop control in adolescents and children during winter sports: use of the Tandem Control-IQ AP system. Pediatr Diabetes 2019;20:759–768
198. Buckingham BA, Christiansen MP, Forlenza GP, et al. Performance of the Omnipod personalized model predictive control algorithm with meal bolus challenges in adults with type 1 diabetes. Diabetes Technol Ther 2018;20:585–595
199. Renard E, Tubiana-Rufi N, Bonnemaison-Gilbert E, et al. Closed-loop driven by control-to-range algorithm outperforms threshold-low-glucose-suspend insulin delivery on glucose control albeit not on nocturnal hypoglycaemia in prepubertal patients with type 1 diabetes in a supervised hotel setting. Diabetes Obes Metab 2019;21:183–187
200. Forlenza GP, Ekhlaspour L, Breton M, et al. Successful at-home use of the Tandem Control-IQ artificial pancreas system in young children during a randomized controlled trial. Diabetes Technol Ther 2019;21:159–169
201. Anderson SM, Buckingham BA, Breton MD, et al. Hybrid closed-loop control is safe and effective for people with type 1 diabetes who are at moderate to high risk for hypoglycemia. Diabetes Technol Ther 2019;21:356–363
202. Forlenza GP, Pinhas-Hamiel O, Liljenquist DR, et al. Safety evaluation of the MiniMed 670G system in children 7-13 years of age with type 1 diabetes. Diabetes Technol Ther 2019;21:11–19
203. Karageorgiou V, Papaioannou TG, Bellos I, et al. Effectiveness of artificial pancreas in the non-adult population: a systematic review and network meta-analysis. Metabolism 2019;90:20–30
204. Wadwa RP, Reed ZW, Buckingham BA, et al.; PEDAP Trial Study Group. Trial of hybrid closed-loop control in young children with type 1 diabetes. N Engl J Med 2023;388:991–1001
205. McVean J, Forlenza GP, Beck RW, et al.; CLVer Study Group. Effect of tight glycemic control on pancreatic beta cell function in newly diagnosed

pediatric type 1 diabetes: a randomized clinical trial. JAMA 2023;329:980–989
206. Cordero TL, Dai Z, Arrieta A, et al. Glycemic outcomes during early use of the MiniMed 780G advanced hybrid closed-loop system with Guardian 4 sensor. Diabetes Technol Ther 2023;25:652–658
207. Kaur H, Schneider N, Pyle L, Campbell K, Akturk HK, Shah VN. Efficacy of hybrid closed-loop system in adults with type 1 diabetes and gastroparesis. Diabetes Technol Ther 2019;21:736–739
208. Brown SA, Kovatchev BP, Raghinaru D, et al.; iDCL Trial Research Group. Six-month randomized, multicenter trial of closed-loop control in type 1 diabetes. N Engl J Med 2019;381:1707–1717
209. Sherr JL, Buckingham BA, Forlenza GP, et al. Safety and performance of the Omnipod hybrid closed-loop system in adults, adolescents, and children with type 1 diabetes over 5 days under free-living conditions. Diabetes Technol Ther 2020;22:174–184
210. Lal RA, Basina M, Maahs DM, Hood K, Buckingham B, Wilson DM. One year clinical experience of the first commercial hybrid closed-loop system. Diabetes Care 2019;42:2190–2196
211. Kovatchev B, Anderson SM, Raghinaru D, et al.; iDCL Study Group. Randomized controlled trial of mobile closed-loop control. Diabetes Care 2020;43:607–615
212. Beck RW, Russell SJ, Damiano ER, et al. A multicenter randomized trial evaluating fast-acting insulin aspart in the bionic pancreas in adults with type 1 diabetes. Diabetes Technol Ther 2022;24:681–696
213. Messer LH, Buckingham BA, Cogen F, et al. Positive impact of the bionic pancreas on diabetes control in youth 6-17 years old with type 1 diabetes: a multicenter randomized trial. Diabetes Technol Ther 2022;24:712–725
214. Castellanos LE, Russell SJ, Damiano ER, et al.; Bionic Pancreas Research Group. The insulin-only bionic pancreas improves glycemic control in non-Hispanic White and minority adults and children with type 1 diabetes. Diabetes Care 2023;46:1185–1190
215. Russell SJ, Beck RW, Damiano ER, et al.; Bionic Pancreas Research Group. Multicenter, randomized trial of a bionic pancreas in type 1 diabetes. N Engl J Med 2022;387:1161–1172
216. Kruger D, Kass A, Lonier J, et al. A multicenter randomized trial evaluating the insulin-only configuration of the bionic pancreas in adults with type 1 diabetes. Diabetes Technol Ther 2022;24:697–711
217. Lynch J, Kanapka LG, Russell SJ, et al. The insulin-only bionic pancreas pivotal trial extension study: a multi-center single-arm evaluation of the insulin-only configuration of the bionic pancreas in adults and youth with type 1 diabetes. Diabetes Technol Ther 2022;24:726–736
218. Ekhlaspour L, Raghinaru D, Forlenza GP, et al. Outcomes in pump- and CGM-baseline use subgroups in the international diabetes closed-loop trial. J Diabetes Sci Technol 2023;17:935–942
219. Sherr JL, Cengiz E, Palerm CC, et al. Reduced hypoglycemia and increased time in target using closed-loop insulin delivery during nights with or without antecedent afternoon exercise in type 1 diabetes. Diabetes Care 2013;36:2909–2914
220. Boughton CK, Hovorka R. The role of automated insulin delivery technology in diabetes. Diabetologia 2024;67:2034–2044
221. Weissberg-Benchell J, Hessler D, Polonsky WH, Fisher L. Psychosocial impact of the bionic pancreas during summer camp. J Diabetes Sci Technol 2016;10:840–844
222. Troncone A, Bonfanti R, Iafusco D, et al. Evaluating the experience of children with type 1 diabetes and their parents taking part in an artificial pancreas clinical trial over multiple days in a diabetes camp setting. Diabetes Care 2016;39:2158–2164
223. Barnard KD, Wysocki T, Allen JM, et al. Closing the loop overnight at home setting: psychosocial impact for adolescents with type 1 diabetes and their parents. BMJ Open Diabetes Res Care 2014;2:e000025
224. Carlson AL, Sherr JL, Shulman DI, et al. Safety and glycemic outcomes during the MiniMed advanced hybrid closed-loop system pivotal trial in adolescents and adults with type 1 diabetes. Diabetes Technol Ther 2022;24:178–189
225. Weissberg-Benchell J, Vesco AT, Shapiro J, et al. Psychosocial impact of the insulin-only iLet bionic pancreas for adults, youth, and caregivers of youth with type 1 diabetes. Diabetes Technol Ther 2023;25:705–717
226. Mathieu C, Ahmed W, Gillard P, et al. The health economics of automated insulin delivery systems and the potential use of time in range in diabetes modeling: a narrative review. Diabetes Technol Ther 2024;26:66–75
227. Considine EG, Sherr JL. Real-world evidence of automated insulin delivery system use. Diabetes Technol Ther 2024;26:53–65
228. Forlenza GP, DeSalvo DJ, Aleppo G, et al. Real-world evidence of Omnipod 5 automated insulin delivery system use in 69,902 people with type 1 diabetes. Diabetes Technol Ther 2024;26:514–525
229. Amigó J, Ortiz-Zúñiga Á, de Urbina AMO, et al. Switching from treatment with sensor augmented pump to hybrid closed loop system in type 1 diabetes: impact on glycemic control and neuropsychological tests in the real world. Diabetes Res Clin Pract 2023;201:110730
230. Chico A, Navas de Solís S, Lainez M, Rius F, Cuesta M. Efficacy, safety, and satisfaction with the Accu-Chek Insight with Diabeloop closed-loop system in subjects with type 1 diabetes: a multicenter real-world study. Diabetes Technol Ther 2023;25:242–249
231. Benhamou P-Y, Adenis A, Lebbad H, et al. One-year real-world performance of the DBLG1 closed-loop system: data from 3706 adult users with type 1 diabetes in Germany. Diabetes Obes Metab 2023;25:1607–1613
232. Benhamou P-Y, Adenis A, Lablanche S, et al. First generation of a modular interoperable closed-loop system for automated insulin delivery in patients with type 1 diabetes: lessons from trials and real-life data. J Diabetes Sci Technol 2023;17:1433–1439
233. Beck RW, Kanapka LG, Breton MD, et al. A meta-analysis of randomized trial outcomes for the t:slim X2 Insulin pump with Control-IQ technology in youth and adults from age 2 to 72. Diabetes Technol Ther 2023;25:329–342
234. Grassi B, Gómez AM, Calliari LE, et al. Real-world performance of the MiniMed 780G advanced hybrid closed loop system in Latin America: substantial improvement in glycaemic control with each technology iteration of the MiniMed automated insulin delivery system. Diabetes Obes Metab 2023;25:1688–1697
235. Forlenza GP, Carlson AL, Galindo RJ, et al. Real-world evidence supporting Tandem Control-IQ hybrid closed-loop success in the Medicare and Medicaid type 1 and type 2 diabetes populations. Diabetes Technol Ther 2022;24:814–823
236. Lee TTM, Collett C, Bergford S, et al.; AiDAPT Collaborative Group. Automated insulin delivery in women with pregnancy complicated by type 1 diabetes. N Engl J Med 2023;389:1566–1578
237. Polsky S, Buschur E, Dungan K, et al. Randomized trial of assisted hybrid closed-loop therapy versus sensor-augmented pump therapy in pregnancy. Diabetes Technol Ther 2024;26:547–555
238. King J, Buschur E, Snell-Bergeon J, et al. Glycemic variability in pregnant individuals using assisted hybrid closed-loop therapy versus sensor-augmented pump therapy. J Diabetes Sci Technol 2024;18:1260–1262 19322968241260050
239. Benhalima K, Beunen K, Van Wilder N, et al. Comparing advanced hybrid closed loop therapy and standard insulin therapy in pregnant women with type 1 diabetes (CRISTAL): a parallel-group, open-label, randomised controlled trial. Lancet Diabetes Endocrinol 2024;12:390–403
240. Szmuilowicz ED, Levy CJ, Buschur EO, Polsky S. Expert guidance on off-label use of hybrid closed-loop therapy in pregnancies complicated by diabetes. Diabetes Technol Ther 2023;25:363–373
241. Grunberger G, Sze D, Ermakova A, Sieradzan R, Oliveria T, Miller EM. Treatment intensification with insulin pumps and other technologies in patients with type 2 diabetes: results of a physician survey in the United States. Clin Diabetes 2020;38:47–55
242. Grunberger G, Rosenfeld CR, Bode BW, et al. Effectiveness of V-Go for patients with type 2 diabetes in a real-world setting: a prospective observational study. Drugs Real World Outcomes 2020;7:31–40
243. Layne JE, Parkin CG, Zisser H. Efficacy of a tubeless patch pump in patients with type 2 diabetes previously treated with multiple daily injections. J Diabetes Sci Technol 2017;11:178–179
244. Raval AD, Nguyen MH, Zhou S, Grabner M, Barron J, Quimbo R. Effect of V-Go versus multiple daily injections on glycemic control, insulin use, and diabetes medication costs among individuals with type 2 diabetes mellitus. J Manag Care Spec Pharm 2019;25:1111–1123
245. Leahy JJL, Aleppo G, Fonseca VA, et al. Optimizing postprandial glucose management in adults with insulin-requiring diabetes: report and recommendations. J Endocr Soc 2019;3:1942–1957
246. Reznik Y, Cohen O, Aronson R, et al.; OpT2mise Study Group. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): a randomised open-label controlled trial. Lancet 2014;384:1265–1272
247. Carlson AL, Huyett LM, Jantz J, Chang A, Vienneau T, Ly TT. Improved glycemic control in 3,592 adults with type 2 diabetes mellitus initiating a tubeless insulin management system. Diabetes Res Clin Pract 2021;174:108735
248. Levy CJ, Raghinaru D, Kudva YC, et al. Beneficial effects of Control-IQ automated insulin delivery in basal-bolus and basal-only insulin users with type 2 diabetes. Clin Diabetes 2024;42:116–124
249. Borel A-L, Lablanche S, Waterlot C, et al. Closed-loop insulin therapy for people with type 2 diabetes treated with an insulin pump: a 12-week

multicenter, open-label randomized, controlled, crossover trial. Diabetes Care 2024;47:1778–1786
250. Reznik Y, Carvalho M, Fendri S, et al. Should people with type 2 diabetes treated by multiple daily insulin injections with home health care support be switched to hybrid closed-loop? The CLOSE AP+ randomized controlled trial. Diabetes Obes Metab 2024;26:622–630
251. Davis GM, Peters AL, Bode BW, et al. Safety and efficacy of the Omnipod 5 automated insulin delivery system in adults with type 2 diabetes: from injections to hybrid closed-loop therapy. Diabetes Care 2023;46:742–750
252. Winter A, Lintner M, Knezevich E. V-Go insulin delivery system versus multiple daily insulin injections for patients with uncontrolled type 2 diabetes mellitus. J Diabetes Sci Technol 2015;9:1111–1116
253. Bergenstal RM, Peyrot M, Dreon DM, et al.; Calibra Study Group. Implementation of basal-bolus therapy in type 2 diabetes: a randomized controlled trial comparing bolus insulin delivery using an insulin patch with an insulin pen. Diabetes Technol Ther 2019;21:273–285
254. Braune K, Lal RA, Petruželková L, et al.; OPEN International Healthcare Professional Network and OPEN Legal Advisory Group. Open-source automated insulin delivery: international consensus statement and practical guidance for health-care professionals. Lancet Diabetes Endocrinol 2022;10:58–74
255. Lum JW, Bailey RJ, Barnes-Lomen V, et al. A real-world prospective study of the safety and effectiveness of the loop open source automated insulin delivery system. Diabetes Technol Ther 2021;23:367–375
256. Braune K, Gajewska KA, Thieffry A, et al. Why #WeAreNotWaiting–motivations and self-reported outcomes among users of open-source automated insulin delivery systems: multinational survey. J Med Internet Res 2021;23:e25409
257. Burnside MJ, Lewis DM, Crocket HR, et al. Open-source automated insulin delivery in type 1 diabetes. N Engl J Med 2022;387:869–881
258. Petruzelkova L, Neuman V, Plachy L, et al. First use of open-source automated insulin delivery AndroidAPS in full closed-loop scenario: Pancreas4ALL randomized pilot study. Diabetes Technol Ther 2023;25:315–323
259. Braune K, Hussain S, Lal R. The first regulatory clearance of an open-source automated insulin delivery algorithm. J Diabetes Sci Technol 2023;17:1139–1141
260. Phillip M, Bergenstal RM, Close KL, et al. The digital/virtual diabetes clinic: the future is now-recommendations from an international panel on diabetes digital technologies introduction. Diabetes Technol Ther 2021;23:146–154
261. Fleming GA, Petrie JR, Bergenstal RM, Holl RW, Peters AL, Heinemann L. Diabetes digital app technology: benefits, challenges, and recommendations. A consensus report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group. Diabetes Care 2020;43:250–260
262. Wong JC, Izadi Z, Schroeder S, et al. A pilot study of use of a software platform for the collection, integration, and visualization of diabetes device data by health care providers in a multidisciplinary pediatric setting. Diabetes Technol Ther 2018;20:806–816
263. Chao DY, Lin TM, Ma W-Y. Enhanced self-efficacy and behavioral changes among patients with diabetes: cloud-based mobile health platform and mobile app service. JMIR Diabetes 2019;4:e11017
264. Sepah SC, Jiang L, Peters AL. Translating the Diabetes Prevention Program into an online social network: validation against CDC standards. Diabetes Educ 2014;40:435–443
265. Kaufman N, Ferrin C, Sugrue D. Using digital health technology to prevent and treat diabetes. Diabetes Technol Ther 2019;21:S79–S94
266. Öberg U, Isaksson U, Jutterström L, Orre CJ, Hörnsten Å. Perceptions of persons with type 2 diabetes treated in swedish primary health care: qualitative study on using eHealth services for self-management support. JMIR Diabetes 2018;3:e7
267. Bollyky JB, Bravata D, Yang J, Williamson M, Schneider J. Remote lifestyle coaching plus a connected glucose meter with certified diabetes educator support improves glucose and weight loss for people with type 2 diabetes. J Diabetes Res 2018;2018:3961730
268. Wilhide Iii CC, Peeples MM, Anthony Kouyaté RC. Evidence-based mHealth chronic disease mobile app intervention design: development of a framework. JMIR Res Protoc 2016;5:e25
269. Dixon RF, Zisser H, Layne JE, et al. A virtual type 2 diabetes clinic using continuous glucose monitoring and endocrinology visits. J Diabetes Sci Technol 2020;14:908–911
270. Yang Y, Lee EY, Kim H-S, Lee S-H, Yoon K-H, Cho J-H. Effect of a mobile phone-based glucose-monitoring and feedback system for type 2 diabetes management in multiple primary care clinic settings: cluster randomized controlled trial. JMIR Mhealth Uhealth 2020;8:e16266
271. Levine BJ, Close KL, Gabbay RA. Reviewing U.S. connected diabetes care: the newest member of the team. Diabetes Technol Ther 2020;22:1–9
272. McGill DE, Volkening LK, Butler DA, Wasserman RM, Anderson BJ, Laffel LM. Text-message responsiveness to blood glucose monitoring reminders is associated with HbA1c benefit in teenagers with type 1 diabetes. Diabet Med 2019;36:600–605
273. Shen Y, Wang F, Zhang X, et al. Effectiveness of internet-based interventions on glycemic control in patients with type 2 diabetes: meta-analysis of randomized controlled trials. J Med Internet Res 2018;20:e172
274. Kumbara AB, Iyer AK, Green CR, et al. Impact of a combined continuous glucose monitoring-digital health solution on glucose metrics and self-management behavior for adults with type 2 diabetes: real-world, observational study. JMIR Diabetes 2023;8:e47638
275. Umpierrez GE, Klonoff DC. Diabetes technology update: use of insulin pumps and continuous glucose monitoring in the hospital. Diabetes Care 2018;41:1579–1589
276. Yeh T, Yeung M, Mendelsohn Curanaj FA. Managing patients with insulin pumps and continuous glucose monitors in the hospital: to wear or not to wear. Curr Diab Rep 2021;21:7
277. Galindo RJ, Umpierrez GE, Rushakoff RJ, et al. Continuous glucose monitors and automated insulin dosing systems in the hospital consensus guideline. J Diabetes Sci Technol 2020;14:1035–1064
278. Houlden RL, Moore S. In-hospital management of adults using insulin pump therapy. Can J Diabetes 2014;38:126–133
279. Avari P, Lumb A, Flanagan D, et al. Insulin pumps and hybrid close loop systems within hospital: a scoping review and practical guidance from the Joint British Diabetes Societies for Inpatient Care. J Diabetes Sci Technol 2023;17:625–634
280. McCall AL, Lieb DC, Gianchandani R, et al. Management of individuals with diabetes at high risk for hypoglycemia: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2023;108:529–562
281. Tian T, Aaron RE, Yeung AM, et al. Use of continuous glucose monitors in the hospital: the Diabetes Technology Society hospital meeting report 2023. J Diabetes Sci Technol 2023;17:1392–1418
282. U.S. Food and Drug Administration. Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (revised), 2020. Accessed 15 August 2024. Available from https://www.fda.gov/media/136290/download
283. Davis GM, Faulds E, Walker T, et al. Remote continuous glucose monitoring with a computerized insulin infusion protocol for critically ill patients in a COVID-19 medical ICU: proof of concept. Diabetes Care 2021;44:1055–1058
284. Sadhu AR, Serrano IA, Xu J, et al. Continuous glucose monitoring in critically ill patients with COVID-19: results of an emergent pilot study. J Diabetes Sci Technol 2020;14:1065–1073
285. Agarwal S, Mathew J, Davis GM, et al. Continuous glucose monitoring in the intensive care unit during the COVID-19 pandemic. Diabetes Care 2021;44:847–849
286. Galindo RJ, Aleppo G, Klonoff DC, et al. Implementation of continuous glucose monitoring in the hospital: emergent considerations for remote glucose monitoring during the COVID-19 pandemic. J Diabetes Sci Technol 2020;14:822–832
287. Ushigome E, Yamazaki M, Hamaguchi M, et al. Usefulness and safety of remote continuous glucose monitoring for a severe COVID-19 patient with diabetes. Diabetes Technol Ther 2021;23:78–80
288. Korytkowski MT, Muniyappa R, Antinori-Lent K, et al. Management of hyperglycemia in hospitalized adult patients in non-critical care settings: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2022;107:2101–2128
289. Longo RR, Elias H, Khan M, Seley JJ. Use and accuracy of inpatient CGM during the COVID-19 pandemic: an observational study of general medicine and ICU patients. J Diabetes Sci Technol 2022;16:1136–1143
290. Davis GM, Spanakis EK, Migdal AL, et al. Accuracy of Dexcom G6 continuous glucose monitoring in non-critically ill hospitalized patients with diabetes. Diabetes Care 2021;44:1641–1646
291. Baker M, Musselman ME, Rogers R, Hellman R. Practical implementation of remote continuous glucose monitoring in hospitalized patients with diabetes. Am J Health Syst Pharm 2022;79:452–458
292. Wright JJ, Williams AJ, Friedman SB, et al. Accuracy of continuous glucose monitors for inpatient diabetes management. J Diabetes Sci Technol 2022;17:1252–1255
293. Spanakis EK, Urrutia A, Galindo RJ, et al. Continuous glucose monitoring-guided insulin administration in hospitalized patients with diabetes:

a randomized clinical trial. Diabetes Care 2022;45:2369–2375
294. Singh LG, Satyarengga M, Marcano I, et al. Reducing inpatient hypoglycemia in the general wards using real-time continuous glucose monitoring: the glucose telemetry system, a randomized clinical trial. Diabetes Care 2020;43:2736–2743
295. Fortmann AL, Spierling Bagsic SR, Talavera L, et al. Glucose as the fifth vital sign: a randomized controlled trial of continuous glucose monitoring in a non-ICU hospital setting. Diabetes Care 2020;43:2873–2877
296. Pelkey MN, Boyle ME, Long A, Castro JC, Cook CB, Thompson B. Hybrid closed-loop insulin pump technology can be safely used in the inpatient setting. Endocr Pract 2023;29:24–28
297. Madhun NZ, Galindo RJ, Donato J, et al. Attitudes and behaviors with diabetes technology use in the hospital: multicenter survey study in the United States. Diabetes Technol Ther 2023;25:39–49
298. U.S. Food and Drug Administration. Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use. Guidance for Industry and Food and Drug Administration Staff, September 2020. Accessed 19 August 2024. Available from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoring-blood-glucose-test-systems-over-counter-use
299. U.S. Food and Drug Administration. Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use: Guidance for Industry and Food and Drug Administration Staff, September 2020. Accessed 15 Aug 2024. Available from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/blood-glucose-monitoring-test-systems-prescription-point-care-use
300. Pardo S, Simmons DA. The quantitative relationship between ISO 15197 accuracy criteria and mean absolute relative difference (MARD) in the evaluation of analytical performance of self-monitoring of blood glucose (SMBG) systems. J Diabetes Sci Technol 2016;10:1182–1187