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

American Diabetes Association Professional Practice Committee*

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**

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

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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.

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