7. Diabetes Technology: *Standards of Care in Diabetes—2024*

*American Diabetes Association Professional Practice Committee**

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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 [CSII]) and glucose as assessed by blood glucose monitoring (BGM) or continuous glucose monitoring (CGM). Diabetes technology has expanded to include automated insulin delivery (AID) systems, where CGM-informed algorithms modulate insulin delivery, connected insulin pens, as well as diabetes self-management support software serving as medical devices. Diabetes technology, when coupled with education, follow-up, 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 Consider establishing competencies based on role in practice setting for health care professionals working with diabetes technology. **E**

7.4 The type(s) and selection of devices should be individualized based on a person's specific needs, 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, and/or physical limitations), the caregiver's skills and preferences are integral to the decision-making process. **E**

**A complete list of members of the American Diabetes Association Professional Practice Committee can be found at https://doi.org/10.2337/dc24-SINT.*

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7.5 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/sharing data (if applicable), to monitor and adjust therapy. **C**

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 payers, 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 Initiation of CSII and/or AID early, even at diagnosis, in the treatment of diabetes can be beneficial depending on a person's or caregiver's needs and preferences. **C**

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 consumerguide.diabetes.org, can help health care professionals and people with diabetes make decisions as to the initial choice of devices. 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 for 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 utilize 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/safeatschool.

Initiation of Device Use

The use of CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management (3,4). This 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. In appropriate individuals, early use of AID systems or insulin pumps may be considered. Interruption of access to CGM is associated with a worsening of outcomes (7,13); therefore, it is important for individuals on CGM to have consistent access to devices.

BLOOD GLUCOSE MONITORING

Recommendations

7.9 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**

7.10 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**

7.11 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**

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

7.13 Health care professionals should be aware of medications and other factors that can interfere with glucose

meter accuracy and provide clinical management as indicated. **E**

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 (14). 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 (15,16). 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 (17). In a subsequent analysis with updated glucose meters, 14 of 18 glucose meters met the minimum accuracy requirements (18). 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 (19) 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 (20), may also be beneficial to people with diabetes (21) 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 (22). Among those who check their blood glucose at least once daily, many report taking no action when results are high or low (23). Some meters now provide advice to the user in real time when monitoring glucose levels (24), whereas others can be used as a part of integrated health platforms (25). 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 (22,26,27).

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 to, during, and

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

Setting	FDA (287,299)	ISO 15197:2013 (300)
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. †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 (301).

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 (28).

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 targets results in lower A1C levels (29,30).

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 (31–34). 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 that of the control group (35). 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 (34). Meta-analyses have suggested that BGM can reduce A1C levels by 0.25–0.3% at 6 months (36–38), but the effect was attenuated at 12 months in one analysis (36). 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 (38). 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 (39).

Oxygen. Currently available glucose monitors use an enzymatic reaction linked to an electrochemical reaction, either glucose oxidase or glucose dehydrogenase (40). 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 (40). 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.

Table 7.2—Interfering substances for glucose meter readings

Glucose oxidase monitors
Uric acid
Galactose
Xylose
Acetaminophen
L-DOPA
Ascorbic acid
Glucose dehydrogenase monitors using pyrroloquinolinequinone cofactor (GDH/PQQ)
Icodextrin (used in peritoneal dialysis)

Interfering Substances. There are a few physiologic and pharmacologic factors that interfere with glucose readings. Most interfere only with glucose oxidase systems (40). They are listed in **Table 7.2**.

CONTINUOUS GLUCOSE MONITORING DEVICES

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

Recommendations

7.14 Real-time CGM (rtCGM) **A** or intermittently scanned CGM (isCGM) **B** should be offered for diabetes management in adults with diabetes on multiple daily injections (MDI) or CSII who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.

7.15 rtCGM **A** or isCGM **B** should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.

7.16 rtCGM **A** or isCGM **E** should be offered for diabetes management in youth with type 1 diabetes on MDI or CSII who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.

7.17 rtCGM or isCGM should be offered for diabetes management in youth with type 2 diabetes on MDI or CSII who are capable of using the devices safely (either by themselves or with a caregiver).

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.

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

The choice of device should be made based on the individual's circumstances, preferences, and needs. **E**

7.18 In people with diabetes on MDI or CSII, rtCGM devices should be used as close to daily as possible for maximal benefit. **A** isCGM devices should be scanned frequently, at a 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**

7.19 When used as an adjunct to preprandial and postprandial BGM, CGM can help to achieve A1C targets in diabetes and pregnancy. **B**

7.20 Periodic use of rtCGM or isCGM or use of professional CGM can be helpful for diabetes management in circumstances where consistent use of CGM is not desired or available. **C**

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

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

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) and intermittently scanned CGM (isCGM). 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 the 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 (41,42). The frequency of scanning with isCGM devices is also correlated with improved outcomes (43–46).

Some real-time systems require calibration by the user, which varies in frequency depending on the device. Additionally, some CGM systems are called adjunctive, meaning the user should perform BGM for making treatment decisions such as dosing insulin or treating hypoglycemia. Devices that do not have this requirement outside of certain clinical situations (see BLOOD GLUCOSE MONITORING, above) are called nonadjunctive (47–49).

One specific isCGM device (Freestyle Libre 2 [no generic form available]) and three specific rtCGM devices (Dexcom G6 [no generic form available], Dexcom G7 [no generic form available], and FreeStyle Libre 3 [no generic form available]) have been designated integrated CGM (iCGM) devices (50). This is a higher standard set by the FDA so that these devices can be integrated with other digitally connected devices. Dexcom G6 rtCGM, Dexcom G7 rtCGM, and a modified version of Libre 2 and Libre 3 are FDA approved for use with AID systems. At this time, Dexcom G6 is integrated with four AID systems (t:slim ×2 with control IQ, Omnipod 5, iLet, and Mobi). Similarly, the Medtronic Guardian 3 rtCGM (no generic available) and the Medtronic Guardian 4 rtCGM 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, as long as participants regularly wore the devices (41,42,51–73). The initial studies were done primarily in adults and youth with type 1 diabetes on insulin pump therapy and/or MDI (41,42,51–54,57–67). The primary outcome was met and showed benefit in adults of all ages (41,51,52,57, 58,60,62,63,74–77), including seniors (59, 78,79). Data in children show that rtCGM use in young children with type 1 diabetes reduced hypoglycemia; in addition, behavioral support of parents of young children with diabetes using rtCGM showed the benefits of reducing hypoglycemia concerns and diabetes distress (41,66,80). Similarly, A1C level reduction was seen in adolescents and young adults with type 1 diabetes using rtCGM (65). RCT data on rtCGM use in individuals with type 2 diabetes on MDI (69), mixed therapies (70,71), and basal insulin (72,81) have consistently shown reductions in A1C levels and increases in time in range (TIR) (70–180 mg/dL [3.9–10 mmol/L]) but not a reduction in rates of hypoglycemia. 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 (13). 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 [>13.8 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 (55). In adults with type 2 diabetes using insulin, two studies were done: one study did not meet its primary end point of A1C levels reduction (82) 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 (83). 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 (84). One study in youth with type 1 diabetes did not show a reduction in A1C levels (85); however, the device was well received and was associated with an increased frequency of testing and improved diabetes treatment satisfaction (85). 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 recently reported in an RCT. In this study, 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

isCGM has been 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. In adults with diabetes, these data include results from observational studies, retrospective studies, and analyses of registry and population data (86,87). In individuals with type 1 diabetes wearing isCGM devices, most (46,86,88), but not all (89), studies have shown improvement in A1C levels. 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 (46,89,90), with persistent effects observed even after 2 years of CGM initiation (91). Some retrospective/observational data have shown an improvement in A1C levels for adults with type 2 diabetes on MDI (92), basal insulin (93), and basal insulin or noninsulin therapies (94). In a retrospective study of adults with type 2 diabetes taking insulin, a reduction in acute diabetes-related events and all-cause hospitalizations was seen (95). 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 (87).

Retrospective data from rtCGM use in a Veterans Affairs population (96) with type 1 and 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.

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 and rtCGM (97–99). In two of the studies, the primary outcome was a reduction in time spent in hypoglycemia, and rtCGM showed greater benefits compared with isCGM (97,98). In the other study, the primary outcome was improved TIR, and rtCGM also showed greater benefits compared with isCGM (99). A retrospective analysis also showed improvement in TIR with rtCGM compared with isCGM (100). 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 (101).

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 (102) and are discussed in Section 6, "Glycemic Goals and Hypoglycemia." CGM is essential for creating an ambulatory glucose profile and providing data on TIR, percentage of time spent above and below range, and glycemic variability (103). Data analysis can be burdensome without a systematic approach to its review. 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 (104–108).

Real-time Continuous Glucose Monitoring Device Use in Pregnancy

Recently, CGM indication has been expanded to include pregnancy for Dexcom G7, FreeStyle Libre 2, and FreeStyle Libre 3, which will enhance care in this population (109,110). 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 (111). 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 (111). An observational cohort study that evaluated

the glycemic variables reported using rtCGM and isCGM found that lower mean glucose, lower standard deviation, and a higher percentage of TIR were associated with lower risks of large-for-gestational-age births and other adverse neonatal outcomes (112). 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 (113). Two studies employing intermittent use of rtCGM showed no difference in neonatal outcomes in individuals with type 1 diabetes (114) or gestational diabetes mellitus (115). At this time, data are insufficient for recommending the use of CGM in all pregnant people with type 2 diabetes or GDM (116,117). 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 targets (63–140 mg/dL [3.5–7.8 mmol/L]) during pregnancy.

Use of Professional and Intermittent 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 (118,119). 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 (70,120). In these RCTs, people with type 2 diabetes not on intensive insulin therapy used CGM intermittently compared with those randomized to BGM. Both early (70) and late improvements in A1C levels were found (70,120). 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 (121–123).

Side Effects of Continuous Glucose Monitoring Devices

Contact dermatitis (both irritant and allergic) has been reported with all devices that attach to the skin (18,124,125). In some cases, this has been linked to the presence of isobornyl acrylate, a skin sensitizer that can cause an additional spreading allergic reaction (126–128). 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 (129). Identifying and eliminating tape allergens is important to ensure the comfortable use of devices and promote self-care (130–133). The Panther Program offers resources in English and Spanish at pantherprogram.org/skin-solutions. In some instances, using an implanted sensor can help avoid skin reactions in those sensitive to tape (134,135).

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 (136–141). 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 (142). 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

7.23 For people with insulin-requiring diabetes on 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

Table 7.4—Continuous glucose monitoring devices 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
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

therapy, cost, and self-management capabilities. C

7.24 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

7.25 Connected insulin pens can be helpful for diabetes management and may be used in people with diabetes taking subcutaneous insulin. E

7.26 FDA-approved insulin dose calculators/decision support systems may be helpful for calculating insulin doses. C

Injecting insulin with a syringe or pen (143–159) is the insulin delivery method used by most people with diabetes (149,160), 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 are both able to deliver insulin safely and effectively for the achievement of glycemic targets. 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 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 (161–163), and insulin injection aids are also available to help with these issues. (For a helpful list of injection aids, see consumerguide.diabetes.org/collections/injection-aids). Inhaled insulin can be useful in people who have an aversion to injection.

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 1- to 2-unit increment markings. 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 (163).

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. 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 in order to make informed insulin dose adjustments (164). A quantitative study showed that people with diabetes preferred connected pens because of their ability to log insulin doses and glucose levels automatically (164).

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."

Bolus calculators have been developed to aid dosing decisions (165–170). 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

7.27 AID systems should be offered for diabetes management to youth and adults with type 1 diabetes A and other types of insulin-deficient diabetes E who are capable of using 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 Insulin pump therapy alone with or without a sensor-augmented pump low-glucose suspend feature should be offered for diabetes management to youth and adults on MDI with type 1 diabetes A or other types of insulin-deficient diabetes E who are capable of using the device safely (either by themselves or with a caregiver) and are not able to use or do not choose an AID system. The choice of device should be made based on the individual's circumstances, preferences, and needs. A

7.29 Insulin pump therapy can be offered for diabetes management to youth and adults on MDI with type 2 diabetes who are capable of using 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

7.30 Individuals with diabetes who have been using CSII should have continued access across third-party payers. 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. 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.

Most studies that compare MDI with insulin pump therapy have been 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 (171). 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 (172). There is no consensus to guide choosing which form of insulin administration is best for a given individual, and research to guide this decision-making process is needed (171). Thus, the choice of MDI or an insulin pump is often based upon the characteristics of the person with diabetes and which method is most likely to benefit them. DiabetesWise (diabeteswise.org/) and 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 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 (173,174) 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 (173,174). Given the additional barriers to optimal diabetes care observed in disadvantaged groups (175), 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 (176,177). 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 [178] or children and adolescents with diabetes), selection of pump type and initial pump settings, individual/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/square/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 (179,180). 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 place individuals at risk for ketosis and DKA and thus must be recognized and managed early (181). Other pump skin issues include lipohypertrophy or, less frequently, lipoatrophy (182,183) and pump site infection (184). Discontinuation of pump therapy is relatively uncommon today; the frequency has decreased over the past few decades, and its causes have changed (184,185). Current reasons for attrition are problems with cost or wearability, loss of insurance, dislike for the pump, suboptimal glycemic outcomes, or mood disorders (e.g., anxiety or depression) (186).

Insulin Pumps in Youth

The safety of insulin pumps in youth has been established for over 15 years (187). 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 (188) versus 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 (189,190). Observational studies, registry data, and meta-analyses have also suggested an improvement in glycemic outcomes in participants on insulin pump therapy (191–193). Data suggest that insulin pumps reduce the rates of severe hypoglycemia compared with MDI (193–196).

There is also evidence that insulin pump therapy may reduce DKA risk (193,197) and diabetes complications, particularly retinopathy and peripheral neuropathy in youth, compared with MDI (178). In addition, treatment satisfaction and quality-of-life measures improved on insulin pump therapy compared with MDI (198,199). 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 (200). 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 (191,201).

Sensor-Augmented Pumps

Sensor-augmented pumps (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, and these systems have been approved by the FDA. The Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial of 247 people with type 1 diabetes showed that sensor-augmented insulin pump therapy with a low-glucose suspend function significantly reduced nocturnal

hypoglycemia over 3 months without increasing A1C levels (61). In a different sensor-augmented pump, predictive low-glucose suspend reduced time spent with glucose <70 mg/dL from 3.6% at baseline to 2.6% (3.2% with sensor-augmented pump therapy without predictive low-glucose suspend) without rebound hyperglycemia during a 6-week randomized crossover trial (202). These devices may offer the opportunity to reduce hypoglycemia for those with a history of nocturnal hypoglycemia. Additional studies have been performed in adults and children that show the benefits of this technology (203–205).

Automated Insulin Delivery Systems

AID systems increase and decrease insulin delivery based on sensor-derived glucose levels to mimic physiologic insulin delivery. These systems consist of three components: an insulin pump, a CGM system, and an algorithm that determines insulin delivery. All AID systems on the market today adjust basal delivery in real time, and some deliver correction doses automatically. While insulin delivery in closed-loop systems eventually may be truly automated, currently used AID systems require the manual entry of carbohydrates consumed or qualitative meal estimation announcements to calculate prandial doses, and adjustments for physical activity must be announced in most systems. Multiple studies using various systems with varying algorithms, pumps, and sensors have been performed in adults and children (206–218). Evidence suggests AID systems reduce A1C levels and improve TIR (219–231). They may also lower the risk of exercise-related hypoglycemia (231) and may have psychosocial benefits (232–236). The use of AID systems depends 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.

The data from real-world studies on AID systems have substantiated the results observed in RCTs and have confirmed the clinical benefits of AID systems in people with type 1 diabetes. Benefits include improvement in A1C levels, TIR, and other glucometrics as well as psychosocial benefits (237–242).

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 (243).

Automated Insulin Delivery Systems in Pregnancy

The use of AID systems in diabetes and pregnancy presents particular challenges, as none of the current FDA-approved systems have glucose goals that are pregnancy specific or 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. Moreover, if the decision is made to use these systems in selected pregnant individuals, then using assistive techniques, such as the combination of sensor-augmented pump mode and hybrid closed-loop mode at different time points in pregnancy or throughout the day, should be considered and applied as needed to achieve intended goals (244). See Section 15, "Diabetes and Pregnancy," for more details.

Insulin Pumps 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 (245–249). Similar to data on insulin pump use in people with type 1 diabetes, reductions in A1C levels have been reported in some studies (247,250). 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 (251). Use of insulin pumps in insulin-requiring people with any type of diabetes may improve user satisfaction and simplify therapy (180,245).

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 (180). 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; however, real-world studies have shown benefits of these technologies in these individuals (243,252).

Alternative insulin delivery options in people with type 2 diabetes may include disposable patch-like devices, which provide either a CSII 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 (246,248,253,254). 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.

Do-It-Yourself Closed-Loop Systems

Recommendation

7.31 Individuals with diabetes may be using systems not approved by the FDA, such as do-it-yourself closed-loop systems and others; health care professionals cannot prescribe these systems but should assist in diabetes management to ensure the safety of people with diabetes. **E**

Some people with type 1 diabetes have been using do-it-yourself systems that combine an insulin pump and an rtCGM with a controller and an algorithm designed to automate insulin delivery (255–259). Data are emerging on the safety and effectiveness of specific systems (260,261). However, these systems are not approved by the FDA, although efforts are underway to obtain regulatory approval for some of them. The information on how to set up and manage these systems is freely available on the internet, and there are internet groups where people inform each other as to how to set up and use them. Although health care professionals cannot prescribe these systems, it is crucial to keep people with diabetes safe if they are using these methods for AID. Part of this entails ensuring people have a backup plan in case of pump failure. Additionally, in most do-it-yourself systems, insulin doses are adjusted based on the pump settings

for basal rates, carbohydrate ratios, correction doses, and insulin activity. Therefore, these settings can be evaluated and modified based on the individual's insulin requirements.

Digital Health Technology

Recommendation

7.32 Systems that combine technology and online coaching can be beneficial in managing prediabetes and diabetes for some individuals. **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 (262). 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) (263). 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 (264). Consumers should read the policy regarding data privacy and sharing before entering data into an application and learn how they can control 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 (265). 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 (266,267). 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 (268–273). 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 (274,275). There are limited RCT data for many of these interventions, and long-term follow-up is lacking. However, for an individual with diabetes, opting into one of these programs can be helpful in providing support and, for many, is an attractive option.

Inpatient Care

Recommendations

7.33 In people with diabetes using 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**

7.34 People with diabetes who are competent to safely use diabetes devices such as insulin pumps and CGM systems should be supported to continue using them in an inpatient setting or during outpatient procedures, whenever possible, and when proper supervision is available. **E**

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 (275–279). 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. However, this 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, changes in nutrition, and others, can impact insulin sensitivity and the insulin response (280–282).

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 (283). This approach has been used 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 (284–286). Studies have been published assessing the effectiveness of this approach, which may ultimately lead to the approved use of CGM for monitoring hospitalized individuals (278,287–296). 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 (278,297,298). 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 of 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 SM, 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. Aleppo G, Beck RW, Bailey R, et al.; MOBILE Study Group; 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
14. 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
15. King F, Ahn D, Hsiao V, Porco T, Klonoff DC. A review of blood glucose monitor accuracy. Diabetes Technol Ther 2018;20:843–856
16. 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
17. Klonoff DC, Parkes JL, Kovatchev BP, et al. Investigation of the accuracy of 18 marketed blood glucose monitors. Diabetes Care 2018;41:1681–1688
18. 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
19. 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
20. Uslan MM, Burton DM, Clements CW. Blood glucose meters that are accessible to blind and visually impaired persons. J Diabetes Sci Technol 2008;2:284–287
21. 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
22. 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
23. 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
24. 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
25. 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
26. 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
27. Endocrine Society and Choosing Wisely. Five things physicians and patients should question. Accessed 21 September 2023. Available from https://www.mainlinehealth.org/-/media/files/pdf/basic-content/physicians/mlhpp/choosing-wisely/endocrine-society–choosing-wisely.pdf
28. Ziegler R, Heidtmann B, Hilgard D, Hofer S, Rosenbauer J; 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
29. Rosenstock J, Davies M, Home PD, Larsen J, Koenen C, Schernthaner G. A randomised, 52-week, treat-to-target trial comparing insulin detemir with insulin glargine when administered as add-on to glucose-lowering drugs in insulin-naive people with type 2 diabetes. Diabetologia 2008;51:408–416
30. Garber AJ. Treat-to-target trials: uses, interpretation and review of concepts. Diabetes Obes Metab 2014;16:193–205
31. Farmer A, Wade A, Goyder E, et al. Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. BMJ 2007;335:132
32. O'Kane MJ, Bunting B, Copeland M; ESMON Study Group. Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial. BMJ 2008;336:1174–1177
33. Simon J, Gray A, Clarke P, Wade A, Neil A; Diabetes Glycaemic Education and Monitoring Trial Group. Cost effectiveness of self monitoring of blood glucose in patients with non-insulin treated type 2 diabetes: economic evaluation of data from the DiGEM trial. BMJ 2008;336:1177–1180
34. 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
35. 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
36. Malanda UL, Welschen LM, Riphagen II, Dekker JM, Nijpels G, Bot SD. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. Cochrane Database Syst Rev 2012;1:CD005060
37. 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–JC12
38. 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
39. 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

40. Ginsberg BH. Factors affecting blood glucose monitoring: sources of errors in measurement. J Diabetes Sci Technol 2009;3:903–913
41. 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
42. 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
43. Hansen KW, Bibby BM. The frequency of intermittently scanned glucose and diurnal variation of glycemic metrics. J Diabetes Sci Technol 2022;16:1461–1465
44. 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
45. 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
46. 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
47. 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
48. U.S. Food and Drug Administration. FDA news release: FDA expands indication for continuous glucose monitoring system, first to replace fingerstick testing for diabetes treatment decisions, 2016. Accessed 21 September 2023. Available from https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm534056.htm
49. U.S. Food and Drug Administration. FDA news release: FDA approves first continuous glucose monitoring system for adults not requiring blood sample calibration, 2017. Accessed 19 September 2023. Available from https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577890.htm
50. U.S. Food and Drug Administration. Product classification [database]. Accessed 21 September 2023. Available from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm
51. Beck RW, Riddlesworth T, Ruedy K, et al.; DIAMOND Study Group. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: the DIAMOND randomized clinical trial. JAMA 2017;317:371–378
52. Lind M, Polonsky W, Hirsch IB, et al. Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: the GOLD randomized clinical trial. JAMA 2017;317:379–387
53. Riddlesworth T, Price D, Cohen N, Beck RW. Hypoglycemic event frequency and the effect of continuous glucose monitoring in adults with type 1 diabetes using multiple daily insulin injections. Diabetes Ther 2017;8:947–951
54. 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
55. 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
56. Hermanns N, Schumann B, Kulzer B, Haak T. The impact of continuous glucose monitoring on low interstitial glucose values and low blood glucose values assessed by point-of-care blood glucose meters: results of a crossover trial. J Diabetes Sci Technol 2014;8:516–522
57. van Beers CA, DeVries JH, Kleijer SJ, et al. Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial. Lancet Diabetes Endocrinol 2016;4:893–902
58. Battelino T, Conget I, Olsen B, et al.; SWITCH Study Group. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: a randomised controlled trial. Diabetologia 2012;55:3155–3162
59. 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
60. Deiss D, Bolinder J, Riveline JP, et al. Improved glycemic control in poorly controlled patients with type 1 diabetes using real-time continuous glucose monitoring. Diabetes Care 2006;29:2730–2732
61. O'Connell MA, Donath S, O'Neal DN, et al. Glycaemic impact of patient-led use of sensor-guided pump therapy in type 1 diabetes: a randomised controlled trial. Diabetologia 2009;52:1250–1257
62. Battelino T, Phillip M, Bratina N, Nimri R, Oskarsson P, Bolinder J. Effect of continuous glucose monitoring on hypoglycemia in type 1 diabetes. Diabetes Care 2011;34:795–800
63. Heinemann L, Freckmann G, Ehrmann D, et al. Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. Lancet 2018;391:1367–1377
64. Beck RW, Hirsch IB, Laffel L, et al.; Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. The effect of continuous glucose monitoring in well-controlled type 1 diabetes. Diabetes Care 2009;32:1378–1383
65. Laffel LM, Kanapka LG, Beck RW, et al.; CGM Intervention in Teens and Young Adults with T1D (CITY) Study Group; 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
66. 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
67. Garg S, Zisser H, Schwartz S, et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. Diabetes Care 2006;29:44–50
68. New JP, Ajjan R, Pfeiffer AF, 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
69. 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
70. 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
71. Yoo HJ, An HG, Park SY, et al. Use of a real time continuous glucose monitoring system as a motivational device for poorly controlled type 2 diabetes. Diabetes Res Clin Pract 2008;82:73–79
72. 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
73. 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
74. 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
75. Garg SK, Liljenquist D, Bode B, et al. Evaluation of accuracy and safety of the next-generation up to 180-day long-term implantable eversense continuous glucose monitoring system: the PROMISE study. Diabetes Technol Ther 2022;24:84–92
76. Garg SK, Kipnes M, Castorino K, et al. Accuracy and safety of Dexcom G7 continuous glucose monitoring in adults with diabetes. Diabetes Technol Ther 2022;24:373–380
77. Laffel LM, Bailey TS, Christiansen MP, Reid JL, Beck SE. Accuracy of a seventh-generation continuous glucose monitoring system in children and adolescents with type 1 diabetes. J Diabetes Sci Technol 2023;17:962–967
78. 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

79. 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
80. 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
81. 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
82. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, 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
83. 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
84. 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
85. 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
86. 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
87. 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
88. 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
89. Nathanson D, Svensson AM, 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
90. Roussel R, Riveline JP, 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
91. Riveline JP, 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
92. Wright EE Jr, 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
93. 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
94. Elliott T, Beca S, Beharry R, Tsoukas MA, Zarruk A, Abitbol A. The impact of flash glucose monitoring on glycated hemoglobin in type 2 diabetes managed with basal insulin in Canada: a retrospective real-world chart review study. Diab Vasc Dis Res 2021;18:14791641211021374
95. Tyndall V, Stimson RH, Zammitt NN, et al. Marked improvement in HbA_{1c} following commencement of flash glucose monitoring in people with type 1 diabetes. Diabetologia 2019;62:1349–1356
96. 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
97. 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
98. 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
99. 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
100. 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
101. 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
102. Danne T, Nimri R, Battelino T, et al. International consensus on use of continuous glucose monitoring. Diabetes Care 2017;40:1631–1640
103. 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
104. Szmuilowicz ED, Aleppo G. Stepwise approach to continuous glucose monitoring interpretation for internists and family physicians. Postgrad Med 2022;134:743–751
105. 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
106. Rosenfeld C, Blevins T, Aleppo G, et al. Expert roundtable on continuous glucose monitoring. Endocr Pract 2022;28:622–627
107. Lee GS, Lupsa BC. Continuous glucose monitoring for the internist. Med Clin North Am 2021;105:967–982
108. 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(S2):S217–S225
109. Abbott. U.S. FDA clears Abbott's Freestyle Libre 2 and Freestyle Libre 3 sensors for integration with automated insulin delivery systems. Accessed 19 September 2023. Available from https://abbott.mediaroom.com/2023-03-06-U-S-FDA-Clears-Abbotts-FreeStyle-Libre-R-2-and-FreeStyle-Libre-R-3-Sensors-for-Integration-with-Automated-Insulin-Delivery-Systems
110. Dexcom, Inc. Dexcom G7 Continuous Glucose Monitoring System. Integrated Continuous Glucose Monitoring System, Factory Calibrated. Accessed 21 September 2023. Available from https://fda.report/PMN/K213919
111. 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
112. 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
113. Law GR, Gilthorpe MS, Secher AL, et al. Translating HbA_{1c} measurements into estimated average glucose values in pregnant women with diabetes. Diabetologia 2017;60:618–624
114. 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
115. 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
116. 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
117. Wyckoff JA, Brown FM. Time in range in pregnancy: is there a role? Diabetes Spectr 2021;34:119–132
118. 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
119. Ribeiro RT, Andrade R, Nascimento do ÓD, 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
120. 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
121. Fantasia KL, Stockman MC, 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
122. 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
123. 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
124. 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 Dermat 2020;83:25–30
125. 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
126. 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
127. Aerts O, Herman A, Bruze M, Goossens A, Mowitz M. FreeStyle Libre: contact irritation versus contact allergy. Lancet 2017;390:1644
128. Herman A, Aerts O, Baeck M, et al. Allergic contact dermatitis caused by isobornyl acrylate in Freestyle Libre, a newly introduced glucose sensor. Contact Dermat 2017;77:367–373
129. Hyry HSI, Liippo JP, Virtanen HM. Allergic contact dermatitis caused by glucose sensors in type 1 diabetes patients. Contact Dermat 2019;81:161–166
130. 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
131. 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
132. Oppel E, Kamann S, Heinemann L, Reichl FX, Högg C. The implanted glucose monitoring system Eversense: an alternative for diabetes patients with isobornyl acrylate allergy. Contact Dermat 2020;82:101–104
133. 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
134. 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
135. 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
136. Heinemann L. Interferences with CGM systems: practical relevance? J Diabetes Sci Technol 2022;16:271–274
137. Tellez SE, Hornung LN, Courter JD, et al. Inaccurate glucose sensor values after hydroxyurea administration. Diabetes Technol Ther 2021;23:443–451
138. Szmuilowicz ED, Aleppo G. Interferent effect of hydroxyurea on continuous glucose monitoring. Diabetes Care 2021;44:e89–e90
139. 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. 13 May 2022 (Epub ahead of print]. DOI: 10.1177/19322968221095573
140. 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
141. 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
142. U.S. Food and Drug Administration. Summary of safety and effectiveness data (SSED). Continuous glucose monitor (CGM), implanted, adjunctive use, 2018. Accessed 21 September 2023. Available from https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048B.pdf
143. 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
144. 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
145. Korytkowski M, Bell D, Jacobsen C; 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
146. 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
147. 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
148. Frid AH, Kreugel G, Grassi G, et al. New insulin delivery recommendations. Mayo Clin Proc 2016;91:1231–1255
149. 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
150. 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
151. 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
152. Pawaskar MD, Camacho FT, Anderson RT, Cobden D, Joshi AV, Balkrishnan R. Health care costs and medication adherence associated with initiation of insulin pen therapy in Medicaid-enrolled patients with type 2 diabetes: a retrospective database analysis. Clin Ther 2007;29:1294–1305
153. Seggelke SA, Hawkins RM, Gibbs J, Rasouli N, Wang CC, Draznin B. Effect of glargine insulin delivery method (pen device versus vial/syringe) on glycemic control and patient preferences in patients with type 1 and type 2 diabetes. Endocr Pract 2014;20:536–539
154. 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
155. 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
156. Eby EL, Boye KS, Lage MJ. The association between use of mealtime insulin pens versus vials and healthcare charges and resource utilization in patients with type 2 diabetes: a retrospective cohort study. J Med Econ 2013;16:1231–1237
157. Anderson BJ, Redondo MJ. What can we learn from patient-reported outcomes of insulin pen devices? J Diabetes Sci Technol 2011;5:1563–1571
158. Luijf YM, DeVries JH. Dosing accuracy of insulin pens versus conventional syringes and vials. Diabetes Technol Ther 2010;12(Suppl. 1):S73–S77
159. Ignaut DA, Schwartz SL, Sarwat S, Murphy HL. Comparative device assessments: Humalog KwikPen compared with vial and syringe and FlexPen. Diabetes Educ 2009;35:789–798
160. 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
161. 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
162. Reinauer KM, Joksch G, Renn W, Eggstein M. Insulin pens in elderly diabetic patients. Diabetes Care 1990;13:1136–1137
163. 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
164. 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
165. 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
166. Eiland L, McLarney M, Thangavelu T, Drincic A. App-based insulin calculators: current and future state. Curr Diab Rep 2018;18:123
167. 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
168. 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
169. 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
170. Huckvale K, Adomaviciute S, Prieto JT, Leow MK, Car J. Smartphone apps for calculating insulin dose: a systematic assessment. BMC Med 2015;13:106
171. Yeh HC, 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
172. 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
173. 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
174. 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
175. 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
176. Ramchandani N, Ten S, Anhalt H, et al. Insulin pump therapy from the time of diagnosis of type 1 diabetes. Diabetes Technol Ther 2006;8:663–670
177. Berghaeuser MA, Kapellen T, Heidtmann B, Haberland H, Klinkert C; 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
178. 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
179. 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
180. 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
181. 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
182. Kordonouri O, Lauterborn R, Deiss D. Lipohypertrophy in young patients with type 1 diabetes. Diabetes Care 2002;25:634
183. Kordonouri O, Hartmann R, Remus K, Bläsig S, Sadeghian E, Danne T. Benefit of supplementary fat plus protein counting as compared with conventional carbohydrate counting for insulin bolus calculation in children with pump therapy. Pediatr Diabetes 2012;13:540–544
184. Guinn TS, Bailey GJ, Mecklenburg RS. Factors related to discontinuation of continuous subcutaneous insulin-infusion therapy. Diabetes Care 1988;11:46–51
185. 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
186. 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
187. 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
188. 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
189. Doyle EA, Weinzimer SA, Steffen AT, Ahern JA, 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
190. 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
191. 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
192. 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
193. 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
194. 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
195. 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
196. 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
197. 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
198. Weintrob N, Benzaquen H, Galatzer A, et al. Comparison of continuous subcutaneous insulin infusion and multiple daily injection regimens in children with type 1 diabetes: a randomized open crossover trial. Pediatrics 2003;112:559–564
199. 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
200. Sundberg F, Barnard K, Cato A, et al. ISPAD guidelines. Managing diabetes in preschool children. Pediatr Diabetes 2017;18:499–517
201. 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
202. 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
203. 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
204. 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
205. 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
206. 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
207. 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
208. 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
209. 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
210. 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
211. 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
212. 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
213. 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
214. 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
215. 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
216. 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
217. 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
218. 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
219. 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
220. 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
221. 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
222. 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
223. 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
224. 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
225. 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
226. 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
227. 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
228. 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
229. 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
230. 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
231. 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
232. 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
233. 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
234. 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
235. 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
236. 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
237. 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
238. 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
239. Benhamou PY, 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
240. Benhamou PY, 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
241. 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
242. 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
243. 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
244. 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
245. 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
246. 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
247. 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
248. 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. 5 July 2019 (Epub ahead of print). DOI: 10.18553/jmcp.2019.18438
249. 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
250. 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
251. 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
252. 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
253. 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
254. 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
255. Lewis D. History and perspective on DIY closed looping. J Diabetes Sci Technol 2019;13:790–793
256. Hng TM, Burren D. Appearance of do-it-yourself closed-loop systems to manage type 1 diabetes. Intern Med J 2018;48:1400–1404
257. Petruzelkova L, Soupal J, Plasova V, et al. Excellent glycemic control maintained by open-source hybrid closed-loop AndroidAPS during and after sustained physical activity. Diabetes Technol Ther 2018;20:744–750
258. Kesavadev J, Srinivasan S, Saboo B, Krishna B M, Krishnan G. The do-it-yourself artificial pancreas: a comprehensive review. Diabetes Ther 2020;11:1217–1235
259. 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
260. 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
261. Burnside MJ, Lewis DM, Crocket HR, et al. Extended use of an open-source automated insulin delivery system in children and adults with type 1 diabetes: the 24-week continuation phase following the CREATE randomized controlled trial. Diabetes Technol Ther 2023;25:250–259
262. 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
263. 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
264. 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
265. Chao DY, Lin TM, Ma WY. Enhanced self-efficacy and behavioral changes among patients with diabetes: cloud-based mobile health platform and mobile app service. JMIR Diabetes 2019;4:e11017
266. 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
267. Kaufman N, Ferrin C, Sugrue D. Using digital health technology to prevent and treat diabetes. Diabetes Technol Ther 2019;21(S1):S79–S94
268. 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
269. 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
270. 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
271. 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
272. Yang Y, Lee EY, Kim HS, Lee SH, Yoon KH, Cho JH. 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
273. 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
274. McGill DE, Volkening LK, Butler DA, Wasserman RM, Anderson BJ, Laffel LM. Text-message responsiveness to blood glucose monitoring reminders is associated with HbA_{1c} benefit in teenagers with type 1 diabetes. Diabet Med 2019;36:600–605
275. 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
276. Umpierrez GE, Klonoff DC. Diabetes technology update: use of insulin pumps and continuous glucose monitoring in the hospital. Diabetes Care 2018;41:1579–1589
277. 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
278. 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
279. Houlden RL, Moore S. In-hospital management of adults using insulin pump therapy. Can J Diabetes 2014;38:126–133
280. 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
281. 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
282. 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
283. 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 21 September 2023. Available from https://www.fda.gov/media/136290/download
284. 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
285. 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
286. 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
287. 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

288. 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
289. 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
290. 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
291. 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
292. 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
293. Wright JJ, Williams AJ, Friedman SB, et al. Accuracy of continuous glucose monitors for inpatient diabetes management. J Diabetes Sci Technol 2022;17:19322968221076562
294. 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
295. 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
296. 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
297. 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
298. 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
299. 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 21 September 2023. Available from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoring-blood-glucose-test-systems-over-counter-use
300. 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 21 September 2023. Available from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/blood-glucose-monitoring-test-systems-prescription-point-care-use
301. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. Diabetes Care 2000;23:1143–1148