7. Diabetes Technology: *Standards of Medical Care in Diabetes—2022*

*American Diabetes Association Professional Practice Committee**

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The American Diabetes Association (ADA) "Standards of Medical 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, a multidisciplinary expert committee (https://doi.org/10.2337/dc22-SPPC), 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, please refer to the Standards of Care Introduction (https://doi.org/10.2337/dc22-SINT). 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 help manage their condition, from lifestyle to blood glucose levels. Historically, diabetes technology has been divided into two main categories: insulin administered by syringe, pen, or pump (also called continuous subcutaneous insulin infusion [CSII]), and blood glucose as assessed by blood glucose monitoring (BGM) or continuous glucose monitoring (CGM). More recently, diabetes technology has expanded to include hybrid devices that both monitor glucose and deliver insulin, some automatically, as well as software that serves as a medical device, providing diabetes self-management support. Diabetes technology, when coupled with education and follow-up, can improve the lives and health of people with diabetes; however, the complexity and rapid change of the diabetes technology landscape can also be a barrier to patient and provider implementation.

GENERAL DEVICE PRINCIPLES

Recommendations

7.1 The type(s) and selection of devices should be individualized based on a person's specific needs, desires, skill level, and availability of devices. 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), the caregiver's skills and desires are integral to the decision-making process. **E**

7.2 When prescribing a device, ensure that people with diabetes/caregivers receive initial and ongoing education and training, either in-person or remotely, and regular evaluation of technique, results, and their ability

**A complete list of members of the American Diabetes Association Professional Practice Committee can be found at https://doi.org/10.2337/dc22-SPPC.*

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to use data, including uploading/sharing data (if applicable), to adjust therapy. C

7.3 People who have been using continuous glucose monitoring, continuous subcutaneous insulin infusion, and/or automated insulin delivery for diabetes management should have continued access across third-party payers. E

7.4 Students must be supported at school in the use of diabetes technology including continuous subcutaneous insulin infusion, connected insulin pens, and automated insulin delivery systems as prescribed by their diabetes care team. E

7.5 Initiation of continuous glucose monitoring, continuous subcutaneous insulin infusion, and/or automated insulin delivery early in the treatment of diabetes can be beneficial depending on a person's/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, patient interest in devices and willingness to change can vary, and providers may have trouble keeping up with newly released technology. Not-for-profit websites can help providers and patients make decisions as to the initial choice of devices. Other sources, including health care providers and device manufacturers, can help people troubleshoot when difficulties arise.

Education and Training

In general, no device used in diabetes management works optimally without education, training, and follow-up. There are multiple resources for online tutorials and training videos as well as written material on the use of devices. Patients vary in terms of comfort level with technology, and some prefer in-person training and support. Patients with more education regarding device use have better outcomes (1); therefore, the need for additional education should be periodically assessed, particularly if outcomes are not being met.

Use in Schools

Instructions for device use should be outlined in the student's diabetes medical management plan (DMMP). A back-up plan should be included in the DMMP for potential device failure (e.g., BGM and/or injected insulin). 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 www.diabetes.org/safeatschool.

Initiation of Device Use

Use of CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management (2,3). This allows for close tracking of glucose levels with adjustments of insulin dosing and lifestyle modifications and removes the burden of frequent BGM. In appropriate individuals, early use of automated insulin delivery (AID) systems or continuous subcutaneous insulin infusion (CSII) may be considered. Interruption of access to CGM is associated with a worsening of outcomes (4); therefore, it is important for individuals on CGM to have consistent access to devices.

BLOOD GLUCOSE MONITORING

Recommendations

7.6 People with diabetes should be provided with blood glucose monitoring devices as indicated by their circumstances, preferences, and treatment. People using continuous glucose monitoring devices must have access to blood glucose monitoring at all times. A

7.7 People who are on insulin using blood glucose monitoring should be encouraged to check when appropriate based on their insulin regimen. This may include checking when fasting, prior to meals and snacks, at bedtime, prior to exercise, when low blood glucose is suspected, after treating low blood glucose levels until they are normoglycemic, and prior to and while performing critical tasks such as driving. B

7.8 Providers should be aware of the differences in accuracy among blood glucose meters—only U.S. Food and Drug Administration–approved meters with proven accuracy should be used, with unexpired strips purchased from a pharmacy or licensed distributor. E

7.9 Although blood glucose monitoring in individuals on noninsulin therapies has not consistently shown clinically significant reductions in A1C, it may be helpful when altering diet, physical activity, and/or medications (particularly medications that can cause hypoglycemia) in conjunction with a treatment adjustment program. E

7.10 Health care providers should be aware of medications and other factors, such as high-dose vitamin C and hypoxemia, that can interfere with glucose meter accuracy and provide clinical management as indicated. E

Major clinical trials of insulin-treated patients have included BGM as part of multifactorial interventions to demonstrate the benefit of intensive glycemic control on diabetes complications (5). BGM is thus an integral component of effective therapy of patients taking insulin. In recent years, CGM has emerged as a method for the assessment of glucose levels (discussed below). Glucose monitoring allows patients to evaluate their individual response to therapy and assess whether glycemic targets 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). The patient's specific needs and goals 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), patients using CGM must have access to BGM testing for multiple reasons, including whenever there is suspicion that the CGM is inaccurate, while waiting for warm-up, for calibration (some sensors) or if a warning message appears, 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.

Meter Standards

Glucose meters meeting FDA guidance for meter accuracy provide the most reliable data for diabetes management. There are several current standards for accuracy of blood glucose monitors, 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 monitors must meet current ISO standards. In the U.S., currently marketed monitors must meet the standard under which they were approved, which may not be the current standard. Moreover, the monitoring of current accuracy is left to the manufacturer and not routinely checked by an independent source.

Patients assume their glucose monitor is accurate because it is FDA cleared, but often that is not the case. There is substantial variation in the accuracy of widely used BGM systems (6,7). The Diabetes Technology Society Blood Glucose Monitoring System Surveillance Program provides information on the performance of devices used for BGM (www.diabetestechnology.org/surveillance/). In one analysis, only 6 of the top 18 glucose meters met the accuracy standard (8). There are single-meter studies in which benefits have been found with individual meter systems, but few studies have compared meters in a head-to-head manner. Certain meter system characteristics, such as the use of lancing devices that are less painful (9) and the ability to reapply blood to a strip with an insufficient initial sample, may also be beneficial to patients (10) and may make BGM less burdensome for patients to perform.

Counterfeit Strips

Patients 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 patient and the provider, to ensure that data are used in an effective and timely manner. In patients with type 1 diabetes, there is a correlation between greater BGM frequency and lower A1C (11). Among patients who check their blood glucose at least once daily, many report taking no action when results are high or low (12). Some meters now provide advice to the user in real time when monitoring glucose levels (13), whereas others can be used as a part of integrated health platforms (14). Patients should be taught how to use BGM data to adjust food intake, exercise, 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 (12,15,16).

Patients on Intensive Insulin Regimens

BGM is especially important for insulin-treated patients to monitor for and prevent hypoglycemia and hyperglycemia. Most patients using intensive insulin regimens (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 exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to and while performing critical tasks such as driving. For many patients 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 adjustment for multiple confounders, increased daily frequency of BGM was significantly associated with lower A1C (−0.2% per additional check per day) and with fewer acute complications (17).

Patients Using Basal Insulin and/or Oral Agents

The evidence is insufficient regarding when to prescribe BGM and how often monitoring is needed for insulin-treated patients who do not use intensive insulin regimens, such as those with type 2 diabetes using basal insulin with or without oral agents. However, for patients using basal insulin, assessing fasting glucose with BGM to inform dose adjustments to achieve blood glucose targets results in lower A1C (18,19).

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

Setting	FDA (224,225)	ISO 15197:2013 (226)
Home use	95% within 15% for all BG in the usable BG range† 99% within 20% for all BG in the usable BG range†	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‡
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	

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 (228).

In people with type 2 diabetes not using insulin, routine glucose monitoring may be of limited additional clinical benefit. By itself, even when combined with education, it has showed limited improvement in outcomes (20–23). However, for some individuals, glucose monitoring can provide insight into the impact of diet, 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. It may be useful when coupled with a treatment adjustment program. In a year-long study of insulin-naive patients with suboptimal initial glycemic stability, a group trained in structured BGM (a paper tool was used at least quarterly to collect and interpret seven-point BGM profiles taken on 3 consecutive days) reduced their A1C by 0.3% more than the control group (24). A trial of once-daily BGM that included enhanced patient feedback through messaging found no clinically or statistically significant change in A1C at 1 year (23). Meta-analyses have suggested that BGM can reduce A1C by 0.25–0.3% at 6 months (25–27), but the effect was attenuated at 12 months in one analysis (25). Reductions in A1C were greater (−0.3%) in trials where structured BGM data were used to adjust medications, but A1C was not changed significantly without such structured diabetes therapy adjustment (27). 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 plans.

Glucose Meter Inaccuracy

Although many meters function well under a variety of circumstances, providers and people with diabetes need to be aware of factors that can impair meter accuracy. A meter reading that seems discordant with clinical reality needs to be retested or tested in a laboratory. Providers in intensive care unit settings need to be particularly aware of the potential for abnormal meter readings, 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 (28).

Oxygen. Currently available glucose monitors utilize an enzymatic reaction linked to an electrochemical reaction, either glucose oxidase or glucose dehydrogenase (29). Glucose oxidase monitors are sensitive to the oxygen available and should only be used with capillary blood in patients 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 false high glucose readings. Glucose dehydrogenase–based monitors are not sensitive to oxygen.

Temperature. Because the reaction is sensitive to temperature, all monitors have an acceptable temperature range (29). 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.

Interfering Substances. There are a few physiologic and pharmacologic factors that interfere with glucose readings. Most interfere only with glucose oxidase systems (29). They are listed in **Table 7.2**.

CONTINUOUS GLUCOSE MONITORING DEVICES

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

Recommendations

7.11 Real-time continuous glucose monitoring **A** or intermittently scanned continuous glucose monitoring **B** should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs.

7.12 Real-time continuous glucose monitoring **A** or intermittently scanned continuous glucose monitoring **C** can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs.

7.13 Real-time continuous glucose monitoring **B** or intermittently scanned continuous glucose monitoring **E** should be offered for diabetes management in youth with type 1 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs.

7.14 Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in youth with type 2 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs. **E**

7.15 In patients on multiple daily injections and continuous subcutaneous insulin infusion, real-time continuous glucose monitoring devices should be used as close to daily as possible for maximal benefit. **A** Intermittently scanned continuous glucose monitoring devices should be scanned frequently, at a minimum once every 8 h. **A**

7.16 When used as an adjunct to pre- and postprandial blood glucose monitoring, continuous glucose monitoring can help to achieve A1C targets in diabetes and pregnancy. **B**

7.17 Periodic use of real-time or intermittently scanned continuous glucose monitoring

or use of professional continuous glucose monitoring can be helpful for diabetes management in circumstances where continuous use of continuous glucose monitoring is not appropriate, desired, or available. **C**

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

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: those that are owned by the user, unblinded, and intended for frequent/continuous use, including real-time CGM (rtCGM) and intermittently scanned CGM (isCGM); and professional CGM devices that are owned and applied in the clinic, which provide data that are blinded or unblinded for a discrete period of time. **Table 7.3** provides the definitions for the types of CGM devices. For people with type 1 diabetes using CGM, frequency of sensor use was an important predictor of A1C lowering for all age-groups (30,31). Frequency of swiping with isCGM devices was also correlated with improved outcomes (32–35).

Table 7.2—Interfering substances for glucose readings

Glucose oxidase monitors
Uric acid
Galactose
Xylose
Acetaminophen
L-DOPA
Ascorbic acid
Glucose dehydrogenase monitors
Icodextrin (used in peritoneal dialysis)

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. Devices that do not have this requirement, outside of certain clinical situations (see BLOOD GLUCOSE MONITORING above), are called "nonadjunctive" (36–38).

One specific isCGM device (FreeStyle Libre 2 [no generic form available]) and one specific rtCGM device (Dexcom G6 [no generic form available]) have been designated as integrated CGM (iCGM) devices (39). This is a higher standard, set by the FDA, so these devices can be reliably integrated with other digitally connected devices, including automated insulin-dosing systems.

The first version of isCGM did not provide alerts or alarms. Currently published literature does not include studies that used isCGM with alarms, which became available in June 2020 in the U.S. Therefore, the discussion that follows is based on the use of the earlier devices.

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 (30,31,40–61). The initial studies were primarily done in adults and youth with type 1 diabetes on CSII and/or MDI (30,31,40–43,46–57). The primary outcome was met and showed benefit in adults of all ages (30,40,41,46,47, 49,51,52) including seniors (48). Data in children are less consistent (30,54,55). RCT data on rtCGM use in individuals with type 2 diabetes on MDI (58), mixed therapies (59,60), and basal insulin (61,62) have consistently shown reductions in A1C 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.

RCT data for isCGM is more limited. One study was performed in adults with type 1 diabetes and met its primary outcome of a reduction in rates of hypoglycemia (44). In adults with type 2 diabetes on insulin, two studies were done; one study did not meet its primary end point of A1C reduction (63) but achieved a secondary end point of a reduction in hypoglycemia, and the other study met its primary end point of an improvement in Diabetes Treatment Satisfaction Questionnaire score as well as a secondary end point of A1C reduction (64). 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 (65). One study in youth with type 1 diabetes did not show a reduction in A1C (66); however, the device was well received and was associated with an increased frequency of testing and improved diabetes treatment satisfaction (66).

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 patients. In adults with diabetes, these data include results from observational studies, retrospective studies, and

Table 7.3—Continuous glucose monitoring devices

Type of CGM	Description
rtCGM	CGM systems that measure and store glucose levels continuously and without prompting
isCGM with and without alarms	CGM systems that measure glucose levels continuously but require scanning for storage of glucose values
Professional CGM	CGM devices that are placed on the patient in the provider's office (or with remote instruction) 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. These devices are not fully owned by the patient—they are clinic-based devices, as opposed to the patient-owned rtCGM/isCGM devices.

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

analyses of registry and population data (67,68). In individuals with type 1 diabetes using isCGM, most (35,67,69), but not all (70), studies have shown improvement in A1C levels. Reductions in acute diabetes complications, such as diabetic ketoacidosis (DKA) and episodes of severe hypoglycemia, have been seen (35,70). Some retrospective/observational data are available on adults with type 2 diabetes on MDI (71), basal insulin (72), and basal insulin or noninsulin therapies (73) showing improvement in A1C levels. 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 (74). Results of patient-reported outcomes varied, but where measured, patients had an increase in treatment satisfaction when comparing isCGM with BGM.

In an observational study in youth with type 1 diabetes, a slight increase in A1C and weight was seen, but the device was associated with a high rate of user satisfaction (68).

Retrospective data from rtCGM use in a Veterans Affairs population (75) with type 1 and type 2 diabetes treated with insulin show that use of real-time rtCGM significantly lowered A1C 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 done comparing isCGM and rtCGM (76–78). In two of the studies, the primary outcome was a reduction in time spent in hypoglycemia, and rtCGM showed benefit compared with isCGM (76,77). In the other study, the primary outcome was improved time in range (TIR), and rtCGM also showed benefit compared with isCGM (78). A retrospective analysis also showed improvement in TIR comparing rtCGM with isCGM (79).

Data Analysis

The abundance of data provided by CGM offers opportunities to analyze patient data more granularly than previously possible, providing additional information to aid in achieving glycemic targets. A variety of metrics have been proposed (80) and are discussed in Section 6, "Glycemic Targets" (https://doi.org/10.2337/dc22-S006). CGM is essential for creating an ambulatory glucose profile and providing data on TIR, percentage of time spent above and below range, and variability (81).

Real-time Continuous Glucose Monitoring Device Use in Pregnancy

One well-designed RCT showed a reduction in A1C levels in adult women with type 1 diabetes on MDI or CSII who were pregnant and using rtCGM in addition to standard care, including optimization of pre- and postprandial glucose targets (82). This study demonstrated the value of rtCGM in pregnancy complicated by type 1 diabetes by showing a mild improvement in A1C without an increase in hypoglycemia as well as reductions in large-for-gestational-age births, length of stay, and neonatal hypoglycemia (82). An observational cohort study that evaluated the glycemic variables reported using rtCGM found that lower mean glucose, lower standard deviation, and a higher percentage of time in target range were associated with lower risk of large-for-gestational-age births and other adverse neonatal outcomes (83). Use of the rtCGM-reported mean glucose is superior to use of estimated A1C, glucose management indicator, and other calculations to estimate A1C given the changes to A1C that occur in pregnancy (84). Two studies employing intermittent use of rtCGM showed no difference in neonatal outcomes in women with type 1 diabetes (85) or gestational diabetes mellitus (86).

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 hypo- and hyperglycemia (87,88). Professional CGM can be helpful to evaluate patients when either rtCGM or isCGM is not available to the patient or the patient prefers a blinded analysis or a shorter experience with unblinded data. It can be particularly useful to evaluate periods of hypoglycemia in patients on agents that can cause hypoglycemia in order to make medication dose adjustments. It can also be useful to evaluate patients for periods of hyperglycemia.

There are some data showing benefit of intermittent use of CGM (rtCGM or isCGM) in individuals with type 2 diabetes on noninsulin and/or basal insulin therapies (59,89). In these RCTs, patients with type 2 diabetes not on intensive insulin regimens used CGM intermittently compared with patients randomized to BGM. Both early (59) and late improvements in A1C were found (59,89).

Use of professional or intermittent CGM should always be coupled with analysis and interpretation for the patient, along with education as needed to adjust medication and change lifestyle behaviors (90–92).

Side Effects of CGM Devices

Contact dermatitis (both irritant and allergic) has been reported with all devices that attach to the skin (93–95). In some cases this has been linked to the presence of isobornyl acrylate, which is a skin sensitizer and can cause an additional spreading allergic reaction (96–98). Patch testing can be done to identify the cause of the contact dermatitis in some cases (99). Identifying and eliminating tape allergens is important to ensure comfortable use of devices and enhance patient adherence (100–103). In some instances, use of an implanted sensor can help avoid skin reactions in those who are sensitive to tape (104,105).

INSULIN DELIVERY

Insulin Syringes and Pens

Recommendations

7.19 For people with diabetes who require insulin, insulin pens are preferred in most cases, but insulin syringes may be used for insulin delivery with consideration of patient/caregiver preference, insulin type and dosing regimen, cost, and self-management capabilities. **C**

7.20 Insulin pens or insulin injection aids should be considered for people with dexterity issues or vision impairment to facilitate the administration of accurate insulin doses. **C**

7.21 Connected insulin pens can be helpful for diabetes

management and may be used in patients using injectable therapy. E

7.22 U.S. Food and Drug Administration–approved insulin dose calculators/decision support systems may be helpful for titrating insulin doses. E

Injecting insulin with a syringe or pen (106–122) is the insulin delivery method used by most people with diabetes (113,123), although inhaled insulin is also available. Others use insulin pumps or AID devices (see section on those topics below). For patients with diabetes who use insulin, insulin syringes and pens are both able to deliver insulin safely and effectively for the achievement of glycemic targets. When choosing among delivery systems, patient preferences, cost, insulin type and dosing regimen, and self-management capabilities should be considered. Trials with insulin pens generally show equivalence or small improvements in glycemic outcomes when compared with use of a vial and syringe. Many individuals with diabetes prefer using a pen due to 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 only be available in 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 (124–126), while insulin injection aids are also available to help with these issues. (For a helpful list of injection aids, see main.diabetes.org/dforg/pdfs/2018/2018-cg-injection-aids.pdf). 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 of U-100 insulin, respectively. 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 (126).

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, which can range from half-unit doses to 2-unit dose increments. 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 (CIPs) are insulin pens with the capacity to record and/or transmit insulin dose data. They were previously known as "smart pens." Some CIPs can be programmed to calculate insulin doses and provide downloadable data reports. These pens are useful to assist patient insulin dosing in real time as well as for allowing clinicians to retrospectively review the insulin doses that were given and make insulin dose adjustments (127).

Needle thickness (gauge) and length is another consideration. Needle gauges range from 22 to 33, with 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 shorter needles may lower the risk of intramuscular injection. When reused, needles may be duller and thus injection more painful. Proper insulin injection technique is a requisite for obtaining the full benefits of insulin therapy. Concerns with technique and use of the proper technique are outlined in Section 9, "Pharmacologic Approaches to Glycemic Treatment" (https://doi.org/10.2337/dc22-S009).

Bolus calculators have been developed to aid in dosing decisions (128–132). These systems are subject to FDA approval to ensure safety in terms of dosing recommendations. People who are interested in using these systems should be encouraged to use those that are FDA approved. Provider 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

7.23 Automated insulin delivery systems should be offered or 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 patient circumstances, desires, and needs.

7.24 Insulin pump therapy alone with or without sensor-augmented low glucose suspend should be offered for diabetes management to youth and adults on multiple daily injections 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/interested in an automated insulin delivery system. The choice of device should be made based on patient circumstances, desires, and needs. A

7.25 Insulin pump therapy can be offered for diabetes management to youth and adults on multiple daily injections 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 patient circumstances, desires, and needs. A

7.26 Individuals with diabetes who have been successfully using continuous subcutaneous insulin infusion should have continued access across third-party payers. E

Insulin Pumps

CSII, or 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 blood 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, discussed below, are preferred over nonautomated pumps and MDI in people with type 1 diabetes.

Most studies comparing MDI with CSII 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 (−0.30% [95% CI −0.58 to −0.02]) and for reducing severe hypoglycemia rates in children and adults (133). There is no consensus to guide choosing which form of insulin administration is best for a given patient, and research to guide this decision-making is needed (134). Thus, the choice of MDI or an insulin pump is often based upon the individual characteristics of the patient and which is most likely to benefit them. 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 provider preference or center characteristics (135,136) and socioeconomic status, as pump therapy is more common in individuals of higher socioeconomic status as reflected by race/ethnicity, private health insurance, family income, and education (135,136). Given the additional barriers to optimal diabetes care observed in disadvantaged groups (137), addressing the differences in access to insulin pumps and other diabetes technology may contribute to fewer health disparities.

Pump therapy can be successfully started at the time of diagnosis (138,139). Practical aspects of pump therapy initiation include assessment of patient and family readiness, if applicable (although there is no consensus on which factors to consider in adults [140] or pediatric patients), selection of pump type and initial pump settings, patient/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, 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 (141,142). Additionally, frequency of follow-up does not influence outcomes. Access to insulin pump therapy 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, occlusion), which place patients at risk for ketosis and DKA and thus must be recognized and managed early (143). Other pump skin issues included lipohypertrophy or, less frequently, lipoatrophy (144,145), and pump site infection (146). Discontinuation of pump therapy is relatively uncommon today; the frequency has decreased over the past few decades, and its causes have changed (146,147). Current reasons for attrition are problems with cost or wearability, dislike for the pump, suboptimal glycemic control, or mood disorders (e.g., anxiety or depression) (148).

Insulin Pumps in Youth

The safety of insulin pumps in youth has been established for over 15 years (149). Studying the effectiveness of CSII in lowering A1C has been challenging because of the potential selection bias of observational studies. Participants on CSII may have a higher socioeconomic status that may facilitate better glycemic control (150) versus MDI. In addition, the fast pace of development of new insulins and technologies quickly renders comparisons obsolete. However, RCTs comparing CSII and MDI with insulin analogs demonstrate a modest improvement in A1C in participants on CSII (151,152). Observational studies, registry data, and meta-analysis have also suggested an improvement of glycemic control in participants on CSII (153–155). Although hypoglycemia was a major adverse effect of intensified insulin regimen in the Diabetes Control and Complications Trial (DCCT) (156), data suggest that CSII may reduce the rates of severe hypoglycemia compared with MDI (155,157–159).

There is also evidence that CSII may reduce DKA risk (155,160) and diabetes complications, particularly retinopathy and peripheral neuropathy in youth, compared with MDI (161). Finally, treatment satisfaction and quality-of-life measures improved on CSII compared with MDI (162,163). Therefore, CSII can be used safely and effectively in youth with type 1 diabetes to assist with achieving targeted glycemic control while reducing the risk of hypoglycemia and DKA, improving quality of life, and preventing long-term complications. Based on patient–provider shared decision-making, insulin pumps may be considered in all pediatric patients with type 1 diabetes. In particular, pump therapy may be the preferred mode of insulin delivery for children under 7 years of age (164). 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 (153,165).

Automated Insulin Delivery Systems

AID systems increase and decrease insulin delivery based on sensor-derived glucose levels to approximate physiologic insulin delivery. These systems consist of three components: an insulin pump, a continuous glucose sensor, and an algorithm that determines insulin delivery. While insulin delivery in closed-loop systems eventually may be truly automated, currently used hybrid closed-loop systems require entry of carbohydrates consumed, and adjustments for exercise must be announced. Multiple studies, using a variety of systems with varying algorithms, pump, and sensors, have been performed in adults and children (166–175). Evidence suggests AID systems may reduce A1C levels and improve TIR (176–180). They may also lower the risk of exercise-related hypoglycemia (181) and may have psychosocial benefits (182–184). Use of AID systems depends on patient preference and selection of patients (and/or caregivers) who are capable of safely and effectively using the devices.

Sensor-Augmented Pumps

Sensor-augmented pumps that suspend insulin when glucose is low or predicted to go low within the next 30 min have been approved by the FDA. The Automation to Simulate Pancreatic Insulin

Response (ASPIRE) trial of 247 patients with type 1 diabetes and documented nocturnal hypoglycemia showed that sensor-augmented insulin pump therapy with a low glucose suspend function significantly reduced nocturnal hypoglycemia over 3 months without increasing A1C levels (50). 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 (185). 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, showing the benefits of this technology (186–188).

Insulin Pumps in Patients 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 (189–193). Similar to data on insulin pump use in people with type 1 diabetes, reductions in A1C levels are not consistently seen in individuals with type 2 diabetes when compared with MDI, although this has been seen in some studies (191,194). Use of insulin pumps in insulin-requiring patients with any type of diabetes may improve patient satisfaction and simplify therapy (142,189).

For patients judged to be clinically insulin deficient who are treated with an intensive insulin regimen, the presence or absence of measurable C-peptide levels does not correlate with response to therapy (142). Another pump option in people with type 2 diabetes is a disposable patchlike device, which provides a continuous, subcutaneous infusion of rapid-acting insulin (basal) as well as 2-unit increments of bolus insulin at the press of a button (190,192,195,196). Use of an insulin pump as a means for insulin delivery is an individual choice for people with diabetes and should be considered an option in patients who are capable of safely using the device.

Do-It-Yourself Closed-Loop Systems

Recommendation

7.27 Individual patients may be using systems not approved by the U.S. Food and Drug Administration, such as do-it-yourself closed-loop systems and others; providers cannot prescribe these systems but should assist in diabetes management to ensure patient safety. **E**

Some people with type 1 diabetes have been using "do-it-yourself" (DIY) systems that combine a pump and an rtCGM with a controller and an algorithm designed to automate insulin delivery (197–200). These systems are not approved by the FDA, although there are efforts underway to obtain regulatory approval for 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 these systems cannot be prescribed by providers, it is important to keep patients safe if they are using these methods for automated insulin delivery. Part of this entails making sure people have a "backup plan" in case of pump failure. Additionally, in most DIY 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 changed based on the patient's insulin requirements.

Digital Health Technology

Recommendation

7.28 Systems that combine technology and online coaching can be beneficial in treating prediabetes and diabetes for some individuals. **B**

Increasingly, people are turning to the internet for advice, coaching, connection, and health care. Diabetes, in part 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 (201). The FDA approves and monitors clinically validated, digital, usually online, health technologies intended to treat a medical or psychological condition; these are known as digital therapeutics or "digiceuticals" (202). 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 and others designed and promoted by people with relatively little skill or knowledge in the clinical treatment of diabetes.

An area of particular importance is that of online privacy and security. There are established cloud-based data collection programs, such as Tidepool, Glooko, and others, that 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 be useful for monitoring patients, both by the patients themselves as well as their health care team (203). 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).

There are many online programs that offer lifestyle counseling to aid with weight loss and increase physical activity (204). Many of these include a health coach and can create small groups of similar patients in social networks. There are programs that aim to treat prediabetes and prevent progression to diabetes, often following the model of the Diabetes Prevention Program (205,206). Others assist in improving diabetes outcomes by remotely monitoring patient clinical data (for instance, wireless monitoring of glucose levels, weight, or blood pressure) and providing feedback and coaching (207–212). 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 (213,214). For many of these interventions, there are limited RCT data and long-term follow-up is lacking. However, for an individual patient, opting into one of these programs can be helpful and, for many, is an attractive option.

Inpatient Care

Recommendation

7.29 Patients who are in a position to safely use diabetes devices should be allowed to continue using them in an inpatient setting or during outpatient procedures when proper supervision is available. **E**

Patients who are comfortable using their diabetes devices, such as insulin pumps and CGM, should be given the chance to use them in an inpatient setting if they are competent to do so (215–218). Patients who are familiar with treating their own glucose levels can often adjust insulin doses more knowledgably than inpatient staff who do not personally know the patient or their management style. However, this should occur based on the hospital's policies for diabetes management, and there should be supervision to be sure that the individual can adjust their insulin doses in a hospitalized setting where factors such as infection, certain medications, immobility, changes in diet, and other factors can impact insulin sensitivity and the response to insulin.

With the advent of the coronavirus disease 2019 pandemic, the FDA has allowed CGM use in the hospital for patient monitoring (219). This approach has been employed to reduce the use of personal protective equipment and more closely monitor patients, so that medical personnel do not have to go into a patient room solely for the purpose of measuring a glucose level (220–222). Studies are underway to assess the effectiveness of this approach, which may ultimately lead to the routine use of CGM for monitoring hospitalized patients (223,224).

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 patients in conjunction with BGM.

The Future

The pace of development in diabetes technology is extremely rapid. New approaches and tools are available each year. It is hard for research to keep up with these advances because by the time a study is completed, newer versions of the devices are already on the market. The most important component in all of these systems is the patient. 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 the patient in device/program selection and to support its 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 treating diabetes, but the tools described in this section can make it easier to manage.

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