This article includes updates in the form of annotations as of June 2020.
See page S83.

7. Diabetes Technology: *Standards of Medical Care in Diabetes—2020*

American Diabetes Association

Diabetes Care 2020;43(Suppl. 1):S77–S88 | https://doi.org/10.2337/dc20-S007

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/dc20-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/dc20-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, and blood glucose monitoring as assessed by meter or continuous glucose monitor. 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.

OVERALL STATEMENT

Recommendation

7.1 Use of technology should be individualized based on a patient's needs, desires, skill level, and availability of devices. Nonprofit websites can offer advice for providers and patients to determine the suitability of various options. **E**

Technology is rapidly changing, but there is no "one-size-fits-all" approach to technology use in people with diabetes. Insurance coverage can lag behind device availability, 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 such as DiabetesWise.org (1) and others 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.

SELF-MONITORING OF BLOOD GLUCOSE

Recommendations

7.2 Most patients using intensive insulin regimens (multiple daily injections or insulin pump therapy) should be encouraged to assess glucose levels using

Suggested citation: American Diabetes Association. 7. Diabetes Technology: Standards of Medical Care in Diabetes—2020. *Diabetes Care 2020;43(Suppl. 1):S77–S88*

self-monitoring of blood glucose (and/or continuous glucose monitoring) prior to meals and snacks, at bedtime, 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. **B**

7.3 When prescribed as part of a diabetes self-management education and support program, self-monitoring of blood glucose may help to guide treatment decisions and/or self-management for patients taking less-frequent insulin injections. **B**

7.4 Although self-monitoring of blood glucose in patients on noninsulin therapies has not 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**

7.5 When prescribing self-monitoring of blood glucose, ensure that patients receive ongoing instruction and regular evaluation of technique, results, and their ability to use data from self-monitoring of blood glucose to adjust therapy. **E**

7.6 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**

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

Major clinical trials of insulin-treated patients have included self-monitoring of blood glucose (SMBG) as part of multifactorial interventions to demonstrate the benefit of intensive glycemic control on diabetes complications (2). SMBG is thus an integral component of effective therapy of patients taking insulin. In recent years, continuous glucose monitoring (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, and adjusting medications (particularly prandial insulin doses). The patient's specific needs and goals should dictate SMBG frequency and timing or the consideration of CGM use.

Optimizing SMBG Monitor Use

SMBG accuracy is dependent on the instrument and user, so it is important to evaluate each patient's monitoring technique, both initially and at regular intervals thereafter. Optimal use of SMBG requires proper review and interpretation of the 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 SMBG frequency and lower A1C (3). Among patients who check their blood glucose at least once daily, many report taking no action when results are high or low (4). Patients should be taught how to use SMBG data to adjust food intake, exercise, or pharmacologic therapy to achieve specific goals. The ongoing need for and frequency of SMBG should be reevaluated at each routine visit to avoid overuse, particularly if SMBG is not being used effectively for self-management (4–6).

Patients on Intensive Insulin Regimens

SMBG is especially important for insulin-treated patients to monitor for and prevent hypoglycemia and hyperglycemia. Most patients using intensive insulin regimens (multiple daily injections or insulin pump therapy) should be encouraged to assess glucose levels using SMBG (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 SMBG, this will require testing 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 SMBG was significantly associated with lower A1C (–0.2% per additional test per day) and with fewer acute complications (7).

Patients Using Basal Insulin and/or Oral Agents

The evidence is insufficient regarding when to prescribe SMBG and how often testing 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 SMBG to inform dose adjustments to achieve blood glucose targets results in lower A1C (8,9).

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 (10–13). 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 SMBG (a paper tool was used at least quarterly to collect and interpret seven-point SMBG profiles taken on 3 consecutive days) reduced their A1C by 0.3% more than the control group (14). A trial of once-daily SMBG that included enhanced patient feedback through messaging found no clinically or statistically significant change in A1C at 1 year (13). Meta-analyses have suggested that SMBG can reduce A1C by 0.25–0.3% at 6 months (15–17), but the effect was attenuated at 12 months in one analysis (15). Reductions in A1C were greater (−0.3%) in trials where structured SMBG data were used to adjust medications, but A1C was not changed significantly without such

structured diabetes therapy adjustment (17). A key consideration is that performing SMBG alone does not lower blood glucose levels. To be useful, the information must be integrated into clinical and self-management plans.

Glucose Meter Accuracy

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 (18).

Oxygen. Currently available glucose monitors utilize an enzymatic reaction linked to an electrochemical reaction, either glucose oxidase or glucose dehydrogenase (19). 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 monitors are not sensitive to oxygen.

Temperature. Because the reaction is sensitive to temperature, all monitors have an acceptable temperature range (19). 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 (19). They are listed in **Table 7.1**.

Table 7.1—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)

Meter Standards

Glucose meters meeting U.S. Food and Drug Administration (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 7.2**. 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 blood glucose monitoring systems (20). The Diabetes Technology Society Blood Glucose Monitoring System Surveillance Program provides information on the performance of devices used for SMBG (diabetestechnology.org/surveillance). In a recent analysis, the program found that only 6 of the top 18 glucose meters met the accuracy standard (21).

Counterfeit Strips. Patients should be advised against purchasing or reselling preowned or second-hand test strips, as these may give incorrect results. Only unopened vials of glucose test strips should be used to ensure SMBG accuracy.

CONTINUOUS GLUCOSE MONITORING DEVICES

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

Recommendations

7.8 When prescribing continuous glucose monitoring (CGM) devices, robust diabetes education, training, and support are required for optimal CGM device implementation and ongoing use. People using CGM devices need to have the ability to perform self-monitoring of blood glucose in order to calibrate their monitor and/or verify readings if discordant from their symptoms. **E**

7.9 When used properly, real-time continuous glucose monitors in conjunction with insulin therapy are a useful tool to lower A1C levels and/or reduce hypoglycemia in adults with type 1 diabetes who are not meeting glycemic targets, have hypoglycemia unawareness, and/or have episodes of hypoglycemia. **A**

7.10 When used properly, intermittently scanned continuous glucose monitors in conjunction with insulin therapy are useful tools to lower A1C levels and/or reduce hypoglycemia in adults with type 1 diabetes who are not meeting glycemic targets, have hypoglycemia unawareness, and/or have episodes of hypoglycemia. **C**

7.11 When used properly, real-time and intermittently scanned continuous glucose monitors in conjunction with insulin therapy are useful tools to lower A1C and/or reduce hypoglycemia in adults with type 2 diabetes who are not meeting glycemic targets. **B**

7.12 Continuous glucose monitoring (CGM) should be considered in all children and adolescents with type 1 diabetes, whether using injections or continuous subcutaneous insulin infusion, as an additional tool to help improve glucose control. Benefits of CGM correlate with adherence to ongoing use of the device. **B**

7.13 Real-time continuous glucose monitoring (CGM) devices should be used as close to daily as possible for maximal benefit. Intermittently scanned CGM devices should be scanned frequently, at a minimum once every 8 h. **A**

7.14 Real-time continuous glucose monitors may be used effectively to improve A1C levels, time in range, and neonatal outcomes in pregnant women with type 1 diabetes. **B**

7.15 Blinded continuous glucose monitor data, when coupled with diabetes self-management education and medication dose adjustment, can be helpful in identifying and correcting patterns of hyper- and hypoglycemia in people with type 1 diabetes and type 2 diabetes. **E**

Table 7.2—Comparison of ISO 15197:2013 and FDA blood glucose meter accuracy standards

Setting	FDA (154,155)	ISO 15197:2013 (156)
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 (157).

7.16 People who have been using continuous glucose monitors should have continued access across third-party payers. **E**

CGM measures interstitial glucose (which correlates well with plasma glucose). There are two basic types of CGM devices: those that provide unblinded data to the user and those that are blinded with data available to the patient and their health care provider for retrospective analysis. **Table 7.3** provides the definitions for the types of CGM devices. For devices that provide patients unblinded data, most of the published randomized controlled trials (RCTs) have been performed using real-time CGM devices that have alarms and alerts. It is difficult to determine how much impact having these notices makes in terms of reacting to glucose levels. There is one small study in patients at risk for hypoglycemia that compares real-time CGM with intermittently scanned CGM (isCGM) (22). The study showed improvement in time spent in hypoglycemia with real-time CGM compared with isCGM.

Some real-time systems require calibration by the user, which varies in frequency depending on the device. Additionally, for some CGM systems, the FDA suggests SMBG for making treatment decisions. Devices that require SMBG confirmation are called "adjunctive," while those that do not are called "nonadjunctive." An RCT of 226 adults suggested that a CGM device could be used safely and effectively without regular confirmatory SMBG in patients with well-controlled type 1 diabetes at low risk of severe hypoglycemia (23). Two CGM devices are approved by the FDA for making treatment decisions without SMBG calibration or confirmation (24,25).

The abundance of data provided by CGM offers opportunities to analyze patient data more granularly than was previously possible, providing additional information to aid in achieving glycemic targets. A variety of metrics have been proposed (26) and are discussed in Section 6, "Glycemic Targets" (https://doi.org/10.21337/dc20-S006). CGM is essential for creating the ambulatory glucose profile (AGP) and providing data on time in range, percentage of time spent above and below range, and variability (27).

Table 7.3—Continuous glucose monitoring (CGM) devices

Real-time CGM	CGM systems that measure glucose levels continuously and provide the user automated alarms and alerts at specific glucose levels and/or for changing glucose levels.
Intermittently scanned CGM	CGM systems that measure glucose levels continuously but only display glucose values when swiped by a reader or a smart phone that reveals the glucose levels.
Blinded (professional) CGM	CGM devices that measure glucose levels that are not displayed to the patient in real time. These devices are generally initiated in a clinic, using a reader that is owned by the clinic. They are removed after a period of time (generally 10–14 days) and analyzed by the patient and provider to assess glycemic patterns and trends.
Unblinded CGM	CGM devices that measure glucose levels that are displayed to the patient.

Real-time CGM Device Use in Adults With Type 1 Diabetes

Data exist to support the use of real-time CGM in adults, both those on multiple daily injections (MDI) and continuous subcutaneons insulin infusion (CSII). In terms of RCTs in people with type 1 diabetes, there are four studies in adults with A1C as the primary outcome (28–32), three studies in adults with hypoglycemia as the primary outcome (33–35), four studies in adults and children with A1C as the primary outcome (36–39), and three studies in adults and children with hypoglycemia as a primary outcome (40–42).

Primary Outcome: A1C Reduction

In general, A1C reduction was shown in studies where the baseline A1C was higher. In two larger studies in adults with type 1 diabetes that assessed the benefit of real-time CGM in patients on MDI, there were significant reductions in A1C: –0.6% in one (28,29) and –0.43% in the other (30). No reduction in A1C was seen in a small study performed in underserved, less well-educated adults with type 1 diabetes (31). In the adult subset of the JDRF CGM study, there was a significant reduction in A1C of –0.53% (43) in patients who were primarily treated with insulin pump therapy. Better adherence in wearing the real-time CGM device resulted in a greater likelihood of an improvement in glycemic control (32,36).

Primary Outcome: Hypoglycemia

In studies in adults where reduction in episodes of hypoglycemia was the primary end point, significant reductions were seen in individuals with type 1 diabetes on MDI or CSII (33–35). In one study in patients who were at higher risk for episodes of hypoglycemia (35), there was a reduction in rates of all levels of hypoglycemia (see Section 6 "Glycemic

Targets," https://doi.org/10.2337/dc20-S006, for hypoglycemia definitions). Real-time CGM may be particularly useful in insulin-treated patients with hypoglycemia unawareness and/or frequent hypoglycemic episodes, although studies have not been powered to show consistent reductions in severe (level 3) hypoglycemia (36–38).

Intermittently Scanned CGM Device Use in Adults With Type 1 Diabetes

isCGM does not currently provide alarms and alerts but is an option used by many patients. There is relatively little RCT data proving benefit in people with type 1 diabetes. One study, designed to show a reduction in episodes of hypoglycemia in patients at higher risk for hypoglycemia, showed a significant benefit in terms of time spent in a hypoglycemic range ($P < 0.0001$) (33). Additional observational studies have shown benefit in terms of A1C reduction (44).

There are several published reviews of data available on isCGM (45–47). The Norwegian Institute of Public Health conducted an assessment of isCGM clinical effectiveness, cost-effectiveness, and safety for individuals with type 1 and type 2 diabetes, based on data available until January 2017 (45). The authors concluded that, although there were few quality data available at the time of the report, isCGM may increase treatment satisfaction, increase time in range, and reduce frequency of nocturnal hypoglycemia, without differences in A1C or quality of life or serious adverse events. The Canadian Agency for Drugs and Technologies in Health reviewed existing data on isCGM performance and accuracy, hypoglycemia, effect on A1C, and patient satisfaction and quality of life and concluded that the system could replace SMBG, particularly in patients who require frequent testing (46). A final review (47) also supported the use of isCGM as a more affordable alternative to real-time CGM systems for individuals with diabetes who are on intensive insulin therapy.

Real-time and Intermittently Scanned CGM Device Use in Adults With Type 2 Diabetes

Studies in people with type 2 diabetes are heterogeneous in design—in two, participants were using basal insulin with oral agents or oral agents alone (48,49); in one, individuals were on MDI alone (50); and in another, participants were on CSII or MDI (42). The findings in studies with MDI alone (50) and in two studies in people using oral agents with or without insulin (48,49) showed significant reductions in A1C levels. The Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes (DIAMOND) study in people with type 2 diabetes on MDI did not show a reduction in hypoglycemia (50), although it did show a reduction in A1C. Studies in individuals with type 2 diabetes on oral agents with or without insulin did not show reductions in rates of hypoglycemia (48,49).

In one study of isCGM in people with type 2 diabetes on a variety of insulin regimens and an initial A1C of ~8.8%, no reduction in A1C was seen; however, the time spent in a hypoglycemic range was reduced by 43% (51). In a study of isCGM in individuals with type 2 diabetes on MDI, the A1C was reduced by 0.82% in the intervention group and 0.33% in the control group ($P = 0.005$) with no change in rates of hypoglycemia (52).

Real-time CGM Device Use in Children and Adolescents With Type 1 Diabetes

Data regarding use of real-time CGM in youth consist of findings from RCTs and small observational studies as well as analysis of data collected by registries. Seven RCTs have included both adult and pediatric participants (36–42), while others have only included pediatric participants (53) or limited the analysis of larger studies to just the pediatric participants (36). Given the feasibility problems of performing RCTs in very young children, small observational studies have also provided data on real-time CGM use in the youngest age-groups (54–56). Finally, while limited by the observational nature, registry data provide some evidence of real-world use of the technologies (43,57).

Impact on Glycemic Control

When data from adult and pediatric participants are analyzed together, real-time CGM use in RCTs has been associated with reduction in A1C levels (37–39). Yet in the JDRF CGM trial, when youth were analyzed by age-group (8- to 14-year-olds and 15- to 24-year-olds), no change in A1C was seen, likely due to poor real-time CGM adherence (36). Indeed, in a secondary analysis of that RCT's data in both pediatric cohorts, those who used the sensor ≥6 days/week had an improvement in their glycemic control (58). One critical component to success with CGM is near-daily wearing of the device (37,59–61).

Though data from small observational studies demonstrate that real-time CGM can be worn by patients <8 years old and the use of real-time CGM provides insight to glycemic patterns (54,55), an RCT in children aged 4–9 years did not demonstrate improvements in glycemic control following 6 months of real-time CGM use (53). However, observational feasibility studies of toddlers demonstrated a high degree of parental satisfaction and sustained use of the devices despite the inability to change the degree of glycemic control attained (56).

Registry data has also shown an association between real-time CGM use and lower A1C levels (43,57), even when limiting assessment of real-time CGM use to participants on injection therapy (57).

Impact on Hypoglycemia

There are no studies solely including pediatric patients that assess rates of hypoglycemia as the primary outcome. Some of the studies where pediatric and adult patients were combined together did show potential reductions in hypoglycemia (10,62,63).

Intermittently Scanned CGM Device Use in Children and Adolescents With Type 1 Diabetes

Data on use of isCGM in children come from observational studies. In these reports, isCGM is favorably adopted and is associated with improvements in outcomes (64–67).

Impact of Frequency of CGM Device Use (All Age-groups)

For patients with type 1 diabetes using real-time CGM, an important predictor of A1C lowering for all age-groups was frequency of sensor use (36). In this study, overall use was highest in those aged ≥25 years (who had the most improvement in A1C) and lower in younger age-groups.

Real-time CGM 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 (68). Neonatal outcomes were better when the mother used CGM during pregnancy (28). Two studies employing intermittent use of real-time CGM showed no difference in neonatal outcomes in women with type 1 diabetes (69) or gestational diabetes mellitus (70).

Use of Blinded (Professional) CGM Devices

Blinded CGM devices, which provide retrospective data for analysis, can be used to identify patterns of hypo- and hyperglycemia. While minimal RCT data exist to support their use, in some settings, blinded CGM can be helpful to evaluate patients when either real-time or isCGM is not available to the patient or the patient prefers a blinded analysis. It can be particularly useful to evaluate periods of hypoglycemia in patients on agents that can cause hypoglycemia for making medication dose adjustments. It can also be useful to evaluate for periods of hyperglycemia. Use of blinded CGM should always be coupled with analysis and interpretation for the patient, along with education as needed to adjust medication and change lifestyle behaviors.

Side Effects of CGM Devices

Contact dermatitis has been reported with all devices that attach to the skin (71). 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 (72–74). Patch testing can be done to identify the cause of the contact dermatitis (75).

INSULIN DELIVERY

Insulin Syringes and Pens

Recommendations

7.17 For people with diabetes who require insulin, insulin syringes or insulin pens may be used for insulin delivery with consideration of patient preference, insulin type and dosing regimen, cost, and self-management capabilities. **B**

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

7.19 Patients using insulin should have an examination of insulin injection/infusion sites on a routine basis—at least annually and if there are clinical issues related to insulin delivery. **E**

7.20 Smart pens may be useful for some patients to help with dose capture and dosing recommendations. **E**

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

7.22 Competent patients using diabetes devices should be allowed to use them in an inpatient setting when proper supervision is available. **E**

Injecting insulin with a syringe or pen is the insulin delivery method used by most people with diabetes (76,77), although inhaled insulin is also available. Others use insulin pumps or automated insulin delivery devices (see sections 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. 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 9.3** 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 (78–80), 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 giving injections.

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 (81).

Insulin pens offer added convenience by combining the vial and syringe into a single device. Insulin pens, allowing pushbutton injections, come as disposable pens with prefilled cartridges or reusable insulin pens with replaceable insulin cartridges. Some reusable pens include a memory function, which can recall dose amounts and timing. "Smart" pens that can be programmed to calculate insulin doses and provide downloadable data reports are also available. Pens also vary with respect to dosing increment and minimal dose, which can range from half-unit doses to 2-unit dose increments.

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 technique is a requisite to obtain the full benefits of insulin injection therapy, and concerns with technique and using the proper technique are outlined in Section 9 "Pharmacologic Approaches to Glycemic Treatment" (https://doi.org/10.2337/dc20-S009).

Another insulin delivery option is a disposable patch-like 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 (82).

Bolus calculators have been developed to aid in dosing decisions (83–87). These 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

Recommendations

7.23 Insulin pump therapy may be considered as an option for all adults, children, and adolescents with type 1 diabetes who are able to safely manage the device. **A**

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

CSII or insulin pumps have been available in the U.S. for 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.

Most studies comparing MDI with CSII have been relatively small and of short duration. However, a recent 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 (88). 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 (89). 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 him or her. Newer systems, such as sensor-augmented pumps and automatic insulin delivery systems, are discussed elsewhere in this section.

Adoption of pump therapy in the U.S. shows geographical variations, which may be related to provider preference or center characteristics (90,91) 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 (91,92). Given the additional barriers to optimal diabetes care observed in disadvantaged groups (93), 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 (94,95). Practical aspects of pump therapy initiation include assessment of patient and family readiness (although there is no consensus on which factors to consider in adults [96] or pediatric patients), selection of pump type and initial pump settings, patient/family education of potential pump complications (e.g., diabetic ketoacidosis [DKA] with infusion set failure), transition from MDI, and introduction of advanced pump settings (e.g., temporary basal rates, extended/square/dual wave bolus).

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 (97); lipohypertrophy or, less frequently, lipoatrophy (98,99); and pump site infection (100). Discontinuation of pump therapy is relatively uncommon today; the frequency has decreased over the past few decades, and its causes have changed (100,101). Current reasons for attrition are problems with cost, wearability, disliking the pump, suboptimal glycemic control, or mood disorders (e.g., anxiety or depression) (102).

Insulin Pumps in Pediatric Patients

The safety of insulin pumps in youth has been established for over 15 years (103). 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 (104) 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 (105,106). Observational studies, registry data, and meta-analysis have also suggested an improvement of glycemic control in participants on CSII (107–109). Although hypoglycemia was a major adverse effect of intensified insulin regimen in the Diabetes Control and Complications Trial (DCCT) (110), data suggest that CSII may reduce the rates of severe hypoglycemia compared with MDI (109,111–113).

There is also evidence that CSII may reduce DKA risk (109,114) and diabetes complications, in particular, retinopathy and peripheral neuropathy in youth, compared with MDI (62). Finally, treatment satisfaction and quality-of-life measures improved on CSII compared with MDI (115,116). 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. In particular, pump therapy may be the preferred mode of insulin delivery for children under 7 years of age (63). 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 idea of having a device on the body, therapeutic effectiveness, and financial burden (107,117).

Insulin Pumps in Patients With Type 2 and Other Types of Diabetes

Certain patients with insulin deficiency, for instance those with long standing type 2 diabetes, those who have had a pancreatectomy, and/or individuals with cystic fibrosis may benefit from insulin pump therapy. This is an individual decision and must be tailored to fit patient needs and preferences.

Insulin Pumps in Older Adults

Older individuals with type 1 diabetes benefit from ongoing insulin pump therapy. There is no data to suggest that measurement of C-peptide levels or antibodies predicts success with insulin pump therapy (118,119). Additionally, frequency of follow-up does not influence outcomes. Access to insulin pump therapy should be allowed/continued in older adults as it is for younger people.

Combined Insulin Pump and Sensor Systems

Recommendations

7.25 Sensor-augmented pump therapy with automatic low glucose suspend may be considered for adults and children with type 1 diabetes to prevent/mitigate episodes of hypoglycemia. **B**

7.26 ~~Automated insulin delivery systems may be considered in children **B** and adults with type 1 diabetes to improve glycemic control. **A**~~

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 can provide safety information/troubleshooting/backup advice for the individual devices to enhance patient safety. **E**

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 (39). 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 (120). 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 (121,122).

Automated insulin delivery systems increase and decrease insulin delivery based on sensor derived glucose level to begin 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. With these systems, insulin delivery can not only be suspended but also increased or decreased based on sensor glucose values. Emerging evidence suggests such systems may lower the risk of exercise-related hypoglycemia (123) and may have psychosocial benefits (124–127).

While eventually insulin delivery in closed-loop systems may be truly automated, currently meals must be announced. A so-called hybrid approach, hybrid closed-loop, has been adopted in first-generation closed-loop systems and requires users to bolus for meals and snacks. Multiple studies, utilizing a variety of systems with varying algorithms, pump, and sensors have been performed in adults and children (128–138). Use of these systems depends on patient preference and selection of patients (and/or caregivers) who are capable of safely and effectively using the devices.

Some people with type 1 diabetes have been using "do-it-yourself" (DIY) systems that combine a pump and a real-time CGM with a controller and an algorithm designed to automate insulin delivery (139–141). 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 not prescribed by providers, it is important to keep patients who are using these methods for automated insulin delivery safe. 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

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. 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" (142). 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 HIPAA (U.S. Health Insurance Portability and Accountability Act of 1996) compliant. These programs can be useful for monitoring patients, both by the patients themselves as well as their health care team (143). Consumers should read the policy regarding data privacy and sharing before providing data into an application and learn how they can control how 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 (144). 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 (145,146). 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 (147–149). 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 (150,151). For many of these interventions, there are limited RCT data and long-term follow-up is lacking. But for an individual patient, opting into one of these programs can be helpful and, for many, is an attractive option.

Inpatient Care

Patients who are comfortable using their diabetes devices, such as insulin pumps and sensors, should be given the chance to use them in an inpatient setting if they are competent to do so (152,153). 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.

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 provider 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.

References

1. DiabetesWise.org. Accessed 24 September 2019. Available from https://www.diabeteswise.org
2. 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
3. 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 A_{1c} levels in T1D Exchange clinic registry participants. Diabetes Care 2013;36:2009–2014
4. 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
5. 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
6. Endocrine Society and Choosing Wisely. Five things physicians and patients should question. Accessed 1 November 2019. Available from http://www.choosingwisely.org/societies/endocrine-society/
7. Ziegler R, Heidtmann B, Hilgard D, Hofer S, Rosenbauer J, Holl R; DPV-Wiss-Initiative. Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes. Pediatr Diabetes 2011;12:11–17
8. 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
9. Garber AJ. Treat-to-target trials: uses, interpretation and review of concepts. Diabetes Obes Metab 2014;16:193–205
10. 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
11. O'Kane MJ, Bunting B, Copeland M, Coates VE; 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
12. Simon J, Gray A, Clarke P, Wade A, Neil A, Farmer 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
13. 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
14. 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
15. Malanda UL, Welschen LMC, Riphagen II, Dekker JM, Nijpels G, Bot SDM. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. Cochrane Database Syst Rev 2012;1:CD005060
16. 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
17. 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
18. 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
19. Ginsberg BH. Factors affecting blood glucose monitoring: sources of errors in measurement. J Diabetes Sci Technol 2009;3:903–913
20. King F, Ahn D, Hsiao V, Porco T, Klonoff DC. A review of blood glucose monitor accuracy. Diabetes Technol Ther 2018;20:843–856
21. Klonoff DC, Parkes JL, Kovatchev BP, et al. Investigation of the accuracy of 18 marketed blood glucose monitors. Diabetes Care 2018;41:1681–1688
22. 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
23. 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
24. 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 1 November 2019. Available from https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm534056.htm
25. 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 1 November 2019. Available from https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577890.htm
26. Danne T, Nimri R, Battelino T, et al. International consensus on use of continuous glucose monitoring. Diabetes Care 2017;40:1631–1640
27. 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
28. 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
29. 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
30. 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 [published correction appears in JAMA 2017;317:1912]. JAMA 2017;317:379–387
31. 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
32. 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
33. 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
34. 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
35. van Beers CAJ, 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
36. 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
37. 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
38. Deiss D, Bolinder J, Riveline J-P, 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
39. 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
40. 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
41. 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
42. 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
43. Wong JC, Foster NC, Maahs DM, et al.; T1D Exchange Clinic Network. Real-time continuous glucose monitoring among participants in the T1D Exchange clinic registry. Diabetes Care 2014;37:2702–2709
44. Paris I, Henry C, Pirard F, Gérard A-C, Colin IM. The new FreeStyle libre flash glucose monitoring system improves the glycaemic control in a cohort of people with type 1 diabetes followed in real-life conditions over a period of one year. Endocrinol Diabetes Metab 2018;1:e00023
45. Norwegian Institute of Public Health. FreeStyle Libre flash glucose self-monitoring system: a single-technology assessment, 2017. Accessed 1 November 2019. Available from http://www.fhi.no/en/publ/2017/freestyle-libre-systemet-for-egenmaling-av-blodsukker-en-hurtigmetodevurder/
46. Palylyk-Colwell E, Ford C. Flash glucose monitoring system for diabetes. In *CADTH Issues in Emerging Health Technologies*. Ottawa, ON, Canadian Agency for Drugs and Technologies in Health, 2016. Accessed 1 November 2019. Available from http://www.ncbi.nlm.nih.gov/books/NBK476439/
47. Leelarathna L, Wilmot EG. Flash forward: a review of flash glucose monitoring. Diabet Med 2018;35:472–482
48. 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
49. 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
50. 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
51. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline J-P, Rayman G. Flash glucose-sensing technology as a replacement for blood glucose monitoring for the management of insulin-treated type 2 diabetes: a multicenter, open-label randomized controlled trial. Diabetes Ther 2017;8:55–73
52. 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
53. Mauras N, Beck R, Xing D, et al.; Diabetes Research in Children Network (DirecNet) Study Group. A randomized clinical trial to assess the efficacy and safety of real-time continuous glucose monitoring in the management of type 1 diabetes in young children aged 4 to <10 years. Diabetes Care 2012;35:204–210
54. Jeha GS, Karaviti LP, Anderson B, et al. Continuous glucose monitoring and the reality of metabolic control in preschool children with type 1 diabetes. Diabetes Care 2004;27:2881–2886
55. Gandrud LM, Xing D, Kollman C, et al. The Medtronic Minimed Gold continuous glucose monitoring system: an effective means to discover hypo- and hyperglycemia in children under 7 years of age. Diabetes Technol Ther 2007;9:307–316
56. Tsalikian E, Fox L, Weinzimer S, et al.; Diabetes Research in Children Network Study Group. Feasibility of prolonged continuous glucose monitoring in toddlers with type 1 diabetes. Pediatr Diabetes 2012;13:301–307
57. Foster NC, Miller KM, Tamborlane WV, Bergenstal RM, Beck RW; T1D Exchange Clinic Network. Continuous glucose monitoring in patients with type 1 diabetes using insulin injections. Diabetes Care 2016;39:e81–e82
58. Beck RW, Buckingham B, Miller K, et al.; Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Factors predictive of use and of benefit from continuous glucose monitoring in type 1 diabetes. Diabetes Care 2009;32:1947–1953
59. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Effectiveness of continuous glucose monitoring in a clinical care environment: evidence from the Juvenile Diabetes Research Foundation continuous glucose monitoring (JDRF-CGM) trial. Diabetes Care 2010;33:17–22
60. Chase HP, Beck RW, Xing D, et al. Continuous glucose monitoring in youth with type 1 diabetes: 12-month follow-up of the Juvenile Diabetes Research Foundation continuous glucose monitoring randomized trial. Diabetes Technol Ther 2010;12:507–515
61. Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. BMJ 2011;343:d3805
62. Zabeen B, Craig ME, Virk SA, et al. Insulin pump therapy is associated with lower rates of retinopathy and peripheral nerve abnormality. PLoS One 2016;11:e0153033
63. Sundberg F, Barnard K, Cato A, et al. ISPAD Guidelines. Managing diabetes in preschool children. Pediatr Diabetes 2017;18:499–517
64. Pintus D, Ng SM. FreeStyle Libre flash glucose monitoring improves patient quality of life measures in children with type 1 diabetes mellitus (T1DM) with appropriate provision of education and support by healthcare professionals. Diabetes Metab Syndr 2019;13:2923–2926
65. Vergier J, Samper M, Dalla-Vale F, et al. Evaluation of flash glucose monitoring after long-term use: a pediatric survey. Prim Care Diabetes 2019;13:63–70
66. Landau Z, Abiri S, Gruber N, et al. Use of flash glucose-sensing technology (FreeStyle Libre) in youth with type 1 diabetes: AWeSoMe study group real-life observational experience. Acta Diabetol 2018;55:1303–1310
67. Deja G, Kłeczek M, Chumięcki M, Strzała-Kłeczek A, Deja R, Jarosz-Chobot P. The usefulness of the FlashStyle Libre system in glycemic control in children with type 1 diabetes during summer camp. Pediatr Endocrinol Diabetes Metab 2018;24:11–19
68. 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
69. 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
70. 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
71. 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
72. 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
73. Aerts O, Herman A, Bruze M, Goossens A, Mowitz M. FreeStyle Libre: contact irritation versus contact allergy. Lancet 2017;390:1644
74. 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
75. Hyry HSI, Liippo JP, Virtanen HM. Allergic contact dermatitis caused by glucose sensors in type 1 diabetes patients. Contact Dermat 2019;81:161–166
76. 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
77. 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
78. 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
79. Williams AS, Schnarrenberger PA. A comparison of dosing accuracy: visually impaired and sighted people using insulin pens. J Diabetes Sci Technol 2010;4:514–521

80. Reinauer KM, Joksch G, Renn W, Eggstein M. Insulin pens in elderly diabetic patients. Diabetes Care 1990;13:1136–1137
81. 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
82. 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
83. 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
84. Eiland L, McLarney M, Thangavelu T, Drincic A. App-based insulin calculators: current and future state. Curr Diab Rep 2018;18:123
85. Huckvale K, Adomaviciute S, Prieto JT, Leow MK-S, Car J. Smartphone apps for calculating insulin dose: a systematic assessment. BMC Med 2015;13:106
86. 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
87. 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
88. Yeh H-C, Brown TT, Maruthur N, et al. Comparative effectiveness and safety of methods of insulin delivery and glucose monitoring for diabetes mellitus: a systematic review and meta-analysis. Ann Intern Med 2012;157:336–347
89. Pickup JC. The evidence base for diabetes technology: appropriate and inappropriate meta-analysis. J Diabetes Sci Technol 2013;7: 1567–1574
90. Blackman SM, Raghinaru D, Adi S, et al. Insulin pump use in young children in the T1D Exchange clinic registry is associated with lower hemoglobin A1c levels than injection therapy. Pediatr Diabetes 2014;15:564–572
91. 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
92. 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
93. 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
94. 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
95. Berghaeuser MA, Kapellen T, Heidtmann B, Haberland H, Klinkert C, Holl RW; German working group for insulin pump treatment in paediatric patients. Continuous subcutaneous insulin infusion in toddlers starting at diagnosis of type 1 diabetes mellitus. A multicenter analysis of 104 patients from 63 centres in Germany and Austria. Pediatr Diabetes 2008;9:590–595
96. 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
97. 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
98. Kordonouri O, Lauterborn R, Deiss D. Lipohypertrophy in young patients with type 1 diabetes. Diabetes Care 2002;25:634–634
99. 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
100. Guinn TS, Bailey GJ, Mecklenburg RS. Factors related to discontinuation of continuous subcutaneous insulin-infusion therapy. Diabetes Care 1988;11:46–51
101. 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
102. 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
103. 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
104. 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
105. Doyle EA, Weinzimer SA, Steffen AT, Ahern JAH, Vincent M, Tamborlane WVA. 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
106. 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
107. 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
108. 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
109. 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
110. The DCCT Research Group. Epidemiology of severe hypoglycemia in the Diabetes Control and Complications Trial. Am J Med 1991;90:450–459
111. Haynes A, Hermann JM, Miller KM, et al. 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
112. 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
113. 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
114. 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
115. 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
116. 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
117. 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
118. 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
119. 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
120. 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
121. 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
122. 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
123. 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
124. 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
125. 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
126. Barnard KD, Wysocki T, Thabit H, et al.; Angela Consortium. Psychosocial aspects of closed- and open-loop insulin delivery: closing the loop in adults with type 1 diabetes in the home setting. Diabet Med 2015;32:601–608
127. 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
128. 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
129. 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
130. 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
131. 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
132. 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
133. 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
134. 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
135. 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
136. 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
137. 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
138. Brown S, Raghinaru D, Emory E, Kovatchev B. First look at Control-IQ: a new-generation automated insulin delivery system. Diabetes Care 2018;41:2634–2636
139. Lewis D. History and perspective on DIY closed looping. J Diabetes Sci Technol 2019;13:790–793
140. Hng T-M, Burren D. Appearance of do-it-yourself closed-loop systems to manage type 1 diabetes. Intern Med J 2018;48:1400–1404
141. 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
142. 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 5 December 2019 [Epub ahead of print]. DOI: 10.2337/dci19-0062
143. 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
144. Chao DY, Lin TM, Ma W-Y. Enhanced self-efficacy and behavioral changes among patients with diabetes: cloud-based mobile health platform and mobile app service. JMIR Diabetes 2019;4:e11017
145. 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
146. Kaufman N, Ferrin C, Sugrue D. Using digital health technology to prevent and treat diabetes. Diabetes Technol Ther 2019;21(S1):S79–S94
147. 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
148. 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
149. 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
150. 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
151. 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
152. Stone MP, Agrawal P, Chen X, et al. Retrospective analysis of 3-month real-world glucose data after the MiniMed 670G system commercial launch. Diabetes Technol Ther 2018;20:689–692
153. Umpierrez GE, Klonoff DC. Diabetes technology update: use of insulin pumps and continuous glucose monitoring in the hospital. Diabetes Care 2018;41:1579–1589
154. U.S. Food and Drug Administration. Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use [Internet], 2016. Accessed 1 November 2019. Available from: http://www.fda.gov/regulatory-information/searchfda-guidance-documents/self-monitoring-bloodglucose-test-systems-over-counter-use-0
155. 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 [Internet], 2016. Accessed 1 November 2019. Available from http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm380325.pdf
156. International Standards Organization. ISO 15197:2013. In vitro diagnostic test systems – requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. Accessed 24 September 2019. Available from http://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/05/49/54976.html
157. 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