

International Society for Pediatric and Adolescent Diabetes Clinical Practice Consensus Guidelines 2024 Diabetes Technologies: Glucose Monitoring

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Summary of What is New or Different

Since the 2022 ISPAD Guidelines, there have been advancements in continuous glucose monitoring (CGM) devices and the evidence supporting their use. Research on CGM effectiveness has proliferated, encompassing long-term observational studies, data from registries, and clinical trials. Changes to previous recommendations include the following:

1. A stronger emphasis on the pivotal role of CGM in managing diabetes among children and adolescents with type 1 diabetes (T1D), especially from diabetes diagnosis, as well as potential benefits in youth with type 2 diabetes.
2. A greater recognition of the importance of ongoing education and training for both health professionals and families in CGM use, including data interpretation, to ensure successful adoption and to optimize outcomes.
3. Updated information on CGM systems, technical aspects, and key features to guide device suitability and inform individual choices.
4. Increased evidence concerning CGM benefits for decreasing diabetic ketoacidosis and severe hypoglycemic events; and improving quality of life in children and adolescents with T1D.
5. Recent developments concerning practical considerations associated with CGM utilization, encompassing topics such as exercise, skin concerns and use in telemedicine.

Keywords

Glucose monitoring · Sensor · Children · Diabetes

Abstract

The International Society for Pediatric and Adolescent Diabetes (ISPAD) guidelines represent a rich repository that serves as the only comprehensive set of clinical recommendations for children, adolescents, and young adults living with diabetes worldwide. This chapter builds on the 2022 ISPAD guidelines, and summarizes recent advances in the technology behind glucose monitoring, and its role in glucose-responsive integrated technology that is feasible with the use of automated insulin delivery (AID) systems in children and adolescents.

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List of Abbreviations

AID:	automated insulin delivery
AGP:	ambulatory glucose profile
BG:	blood glucose
BGM:	blood glucose monitoring
CGM:	continuous glucose monitoring
DKA:	diabetic ketoacidosis
FDA:	Food and Drug Administration
HbA1c:	hemoglobin A1c (or glycated hemoglobin)
DPV:	Diabetes-Patienten-Verlaufsdokumentation (German/Austrian T1D registry)
GMI:	glucose management indicator
GO:	glucose oxidase
HCP:	healthcare professionals
ISO:	International Organization for Standardization
ISPAD:	International Society for Pediatric and Adolescent Diabetes
isCGM:	intermittently scanned continuous glucose monitoring
JDRF:	Juvenile Diabetes Research Foundation
MARD:	mean absolute relative difference
MDI:	multiple daily injections
OGTT:	oral glucose tolerance test
RCTs:	randomized controlled trials
rtCGM:	real-time continuous glucose monitoring
TAR:	time above range
TBR:	time below range
TIR:	time in range
T1D:	type 1 diabetes
T1DX:	type 1 diabetes exchange (US-based clinical registry)
T2D:	type 2 diabetes

Introduction

- Regular monitoring of glucose (using accurate fingerstick blood glucose [BG] measurements, real-time continuous glucose monitoring [rtCGM] or intermittently scanned CGM [isCGM]) is essential for diabetes management for all children and adolescents with diabetes [A].
- Each child with diabetes should have access to sufficient supplies for monitoring of glucose measurements to optimize diabetes care [B].
- Regular review of glucose values should be performed by health professionals and families with adjustments to medication and nutritional therapies to optimize control [B].
- Diabetes center personnel should advocate to ensure that all children and adolescents with diabetes have continuing access to all glucose monitoring equipment [E].

Monitoring of glucose plays a crucial role in the management of children and adolescents with diabetes: it permits tracking of both immediate and daily fluctuations in glucose levels, including hypoglycemic and hyperglycemic episodes. Tracking of glucose levels assists in medication adjustments and lifestyle modifications and enables evaluation of responses to therapy to achieve optimal glycemic targets.

Over the last 20 years, glucose monitoring has progressed from the predominant use of handheld portable meters to the implementation of newer systems for continuous glucose monitoring (CGM) based on subcutaneously placed glucose sensors for interstitial fluid. These CGM systems have advanced and become the standard of care for type 1 diabetes (T1D) in many countries, particularly for children, adolescents, and young adults [1].

Recently, CGM has been successfully employed for people with type 2 diabetes (T2D) on any treatment regimen, not just those on insulin therapy [2, 3]. CGM is now also being utilized to track glucose patterns in individuals with early-stage diabetes [4–6].

The evidence for CGM technology applications is continuing to evolve in terms of the efficacy across different populations and practical advice and approaches on its use. The following recommendations are based on currently available evidence and are intended to be a general guide to glucose monitoring. Clinical judgment should be used to determine optimal management for the individual child.

Capillary Blood Glucose Monitoring

- Individuals with diabetes should receive capillary blood glucose monitoring (BGM) devices tailored to their specific needs. Those using CGM devices also require access to BGM devices [A].
- Providers should be aware of the differences in accuracy among BG meters – only meters that achieve international accuracy standards (ISO 15197:2013 or FDA-approved) should be used [E].
- Healthcare professionals should stay informed about medications and other factors that can impact the accuracy of glucose meters [E].
- In persons not using CGM, BG testing may need to be performed 6 to 10 times per day to optimize glycemic control [B].
- Individuals who are taking insulin and using BGM should be prompted to check their blood glucose levels: before meals and snacks, after meals, at bedtime and during the night, before, during, and after exercise, when hypoglycemia or hyperglycemia is suspected, during and after drinking alcohol, and before critical tasks such as driving [B].
- Frequency of BG testing correlates with improved HbA1c levels and reduced acute complications [B].
- In limited resource settings, if the idea of 6–10 BG tests per day is not possible, at least pre-meals and bedtime BG testing is suggested for determining appropriate insulin dosing and reducing nocturnal hypoglycemia. Testing 3–4 times on the same day, several days a week, may provide more information than a single daily measurement at different times [E].

Capillary measurement of blood glucose continues to be a cornerstone of intensive management of T1D in children and adolescents, despite the increasing global acceptance of CGM. The reasons for this are twofold. The cost of CGM can be prohibitive: in many countries, availability and insurance coverage are limited [7–9]. Consequently, many individuals with diabetes continue to rely on BGM.

In addition, people with diabetes who use CGM should also have access to BGM for calibration (if required), when inaccurate CGM readings are suspected, during rapidly fluctuating glucose levels, potentially leading to a discrepancy between CGM and blood glucose readings, during the warm-up period of CGM sensors or during CGM transmission interruptions, or when warning messages are displayed.

Meter Standards and Accuracy

There are significant differences in the accuracy of blood glucose meters [10]. The most reliable information comes from meters that adhere to current international accuracy criteria, e.g., standards established by the International Organization for Standardization (ISO) (ISO 15197:2013) [11] and the US Food and Drug Adminis-

tration (FDA) [12]. ISPAD recommends only using glucose meters that meet these standards. Healthcare providers (HCPs) should recommend models that are durable, precise, reliable, and affordable.

Accuracy standards of BGM meters achieved under controlled conditions may differ considerably from actual performance in real-world situations [10]. Comprehensive details regarding the genuine performance of BGM devices are available through The Diabetes Technology Society Blood Glucose Monitoring System Surveillance Program (www.diabetestechology.org/surveillance/) or the diabetes.co.uk website (<https://www.diabetes.co.uk/blood-glucose-meters/iso-accuracy-standards.html>).

The accuracy of BGM relies on several critical factors. These include proper handwashing followed by thorough drying, correct blood application, and the use of unexpired test strips stored appropriately and obtained from reliable sources [13, 14]. Providers and individuals with diabetes should be conscious of factors that may compromise meter accuracy, which could be associated with the particular enzymatic electrochemical reaction utilized. Examples include extremes in ambient temperature, humidity, oxygen levels, and other substances (e.g., uric acid, acetaminophen, L-dopa, ascorbic acid, tolazamide) [14].

Expert Meters

Advanced blood glucose meters feature built-in bolus advisors for insulin dosage calculations. Randomized controlled trials (RCTs) have demonstrated that using a bolus calculator is associated with a significant increase in the number of individuals reaching HbA1c targets and a reduction in hypoglycemia [15–17].

Frequency and Timing of BGM

The frequency of BGM is linked to improved HbA1c levels and a decrease in acute complications [18–21]. A cross-sectional study revealed that for multiple daily injections (MDI) users, each additional daily blood glucose measurement correlated with a decrease of 0.2% (2 mmol/mol) in HbA1c, while for pump users, the decrease was 0.1% (1 mmol/mol) [21]. The frequency of blood glucose measurements obtained from meter downloads was significantly lower than the self-reported frequency by individuals with diabetes [21].

BGM should be conducted at a frequency tailored to optimize diabetes management for each child. For individuals not on CGM utilizing intensive insulin regimens, i.e., MDI, or insulin pump therapy, BGM testing should be performed:

- During the day, prior to meals and snacks.

- At intervals (for example, 2–3 h post-meal) to ascertain suitable mealtime insulin doses and to observe blood glucose levels in relation to insulin action profiles.
- To confirm hypoglycemia and, after treating, low BG to monitor recovery.
- At bedtime, as necessary overnight, and upon waking to identify and mitigate nocturnal hypoglycemia and hyperglycemia.
- Before and while performing critical tasks (e.g., driving).
- In association with vigorous exercise (before, during, and several hours after physical activity).
- During concurrent illness to mitigate the risk of hyperglycemic crisis.
- During and following alcohol consumption along with the use of other substances (cannabis or stimulants) [22] that may impact blood glucose or heighten the risk of diabetic ketoacidosis (DKA).

Effective intensive insulin management requires conducting at least six to ten checks per day, responding appropriately to the observed values, and consistently reviewing the results to recognize patterns that may warrant adjustments to the diabetes treatment regimen [19].

In settings with limited resources, the availability and affordability of glucose meters and test strips cannot be guaranteed. Despite many children being on MDI, few may be able to afford the frequent blood glucose testing necessary to optimize diabetes control. Often, testing is limited to 3–4 times a day (before breakfast, before lunch, before dinner, and at bedtime), and sometimes only twice daily monitoring is possible, typically before breakfast and before dinner.

Continuous Glucose Monitoring

CGM devices utilize enzyme-tipped electrodes or fluorescence technology to monitor interstitial glucose concentrations subcutaneously at intervals ranging from 1 to 15 min. Advancements in CGM device technology, such as improved accuracy, approval for non-adjunctive use (use without confirmation through BGM), reduced or no calibration needs, increased availability, smaller sizes, remote monitoring, compatibility with insulin delivery devices, and enhanced personal acceptance, have driven its widespread adoption in clinical practice.

In many countries, CGM has become the standard for glucose monitoring in T1D care [1]. Data from German, Austrian, and US registries show a continuing rise in CGM use in recent years, especially among children

(DPV: 40% in 2017 to 76% in 2020; T1DX: 25% in 2017 to 49% in 2020) [23, 24]. Recent statistics from Australia also indicate widespread adoption, with 79% of individuals under 21 years using CGM technology [25].

CGM technology is central to diabetes management and education (see Fig. 1) and a cornerstone of automated insulin delivery (AID) systems. Specific CGM metrics, such as “time in range” (TIR) (defined as the percentage of time with sensor readings between 70 and 180 mg/dL or 3.9 and 10 mmol/L), glucose management indicator (GMI) (estimated HbA1c value derived from CGM data over a defined duration) [26], or most recently “time in tight range” [27] (the time spent within the 70–140 mg/dL or 3.9–7.8 mmol/L range), have emerged as valuable clinical markers [28–30] with evidence for their clinical application still evolving [30, 31]. The metrics are generally viewed as complementary to HbA1C for individuals with diabetes [32].

Obstacles to adopting and using technology can arise at structural, individual, and provider levels [33, 34]. Structural barriers include availability, costs and reimbursement or insurance coverage. Individual challenges may include alarm fatigue, perceived inaccuracy, effort required, discomfort, and skin reactions [35, 36]. Healthcare professionals may lack time or expertise to educate and promote technology [34].

Data from diabetes registries reveal notable differences in CGM use based on socioeconomic status [37]. System and clinic-specific interventions are crucial to address barriers and promote CGM adoption and continued use [34].

Categories of Sensors

Multiple CGM systems are presently available and undergoing development, employing varied technologies for measuring glucose levels and providing data to users [38, 39]. Most commercially available sensors measure interstitial glucose utilizing electrochemical methods, particularly glucose oxidase (GO)-based technology. Minimally invasive CGM sensors, designed for transdermal self-application and with a wearing duration of 6–15 days, are currently the available options for pediatric age groups.

CGM devices can be categorized into rtCGM, intermittently scanned CGM (isCGM), and masked (or blinded) CGM, with the third usually only used for research purposes (Table 1). Detailed specifications of major CGM systems are shown in Table 2. rtCGM systems automatically transfer glucose data from the sensor to the display device(s), which may include an insulin pump, a smartphone, and/or dedicated receiver. This allows for continuous glucose tracking and timely alerts. Sensor data can be transmitted to a cloud-based

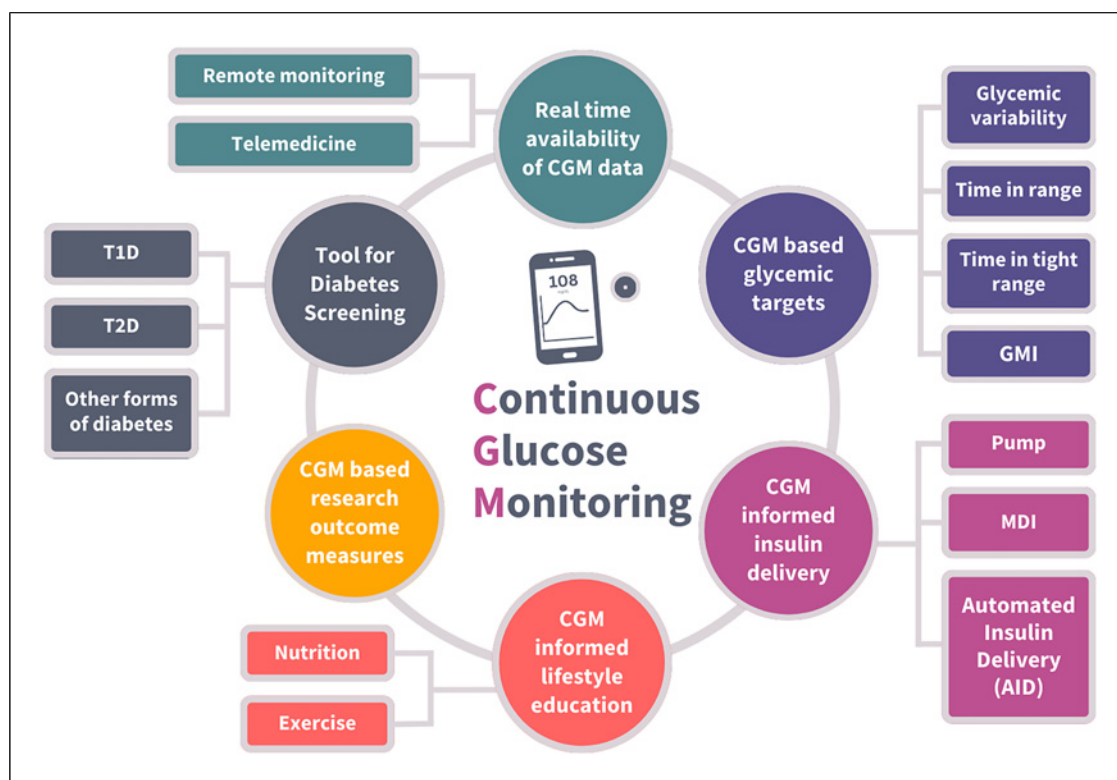


Fig. 1. CGM technology plays a pivotal role in diabetes management.

Table 1. Currently available glycemic monitoring tools

Real-time CGM (rtCGM)	Intermittently scanned CGM (isCGM)	Retrospective CGM
		
CGM systems that measure and display glucose levels continuously, programmable glucose alarms	Sensor needs to be “scanned” with reader/smartphone to acquire readings, with and without alarms	Retrospective nature of glucose data collection – glucose readings blinded to user, primarily used in research settings

server in real time, making it accessible for remote monitoring by relatives and caregivers.

isCGM, also known as flash CGM, does not automatically make glucose levels available to the user but is easily and instantly accessed by scanning the arm-worn sensor with a handheld reader or a smartphone. First-generation devices lacked alarms (e.g., Abbott FreeStyle

Libre), whereas second-generation devices (e.g., Abbott FreeStyle Libre 2) offer optional alarms to notify individuals when their glucose levels are outside the target range. Notably, although labeled as an isCGM, Abbott's FreeStyle Libre 2 operates as a streaming device when used with the LibreLink App on a mobile device, providing continuous real-time glucose measurements. The

Table 2. Comparison of widely available CGM systems

	Approved ages	Factory calibrated	Non-adjunctive use*	Sensor wear time	Sensor warm-up time	Accuracy (MARD)	
						adult data	pediatric data
FreeStyle Libre 1	≥4 years	Yes	Yes	14 days	1 h	11.4% [40]	13.9% [41]
FreeStyle Libre 2	4+ (2+ ^a) years	Yes	Yes	14 (15 ^a) days	1 h	9.2% [42, 43]	9.7% [42]
FreeStyle Libre 3	4+ (2+ ^b) years	Yes	Yes	14 (15 ^b) days	1 h	7.5% [44]	8.6% [44]
Dexcom G6/ Dexcom One	2+ years	Yes	Yes	10 days	2 h	9.8–9.9% [45, 46]	7.7–10.1% [45, 46]
Dexcom G7/ Dexcom One+	2+ years	Yes	Yes	10 days	30 min	8.2–9.1% [47]	8.1–9.0% [48]
Guardian Sensor 3	7+ years	No	No	7 days	2 h	8.7–9.6% [49] ^c	10.9–11.1% [50]
Guardian Sensor 4	7+ years	Yes	Yes	7 days	2 h	10.6% [51]	11.6% [51]
Medtronic Simpler/ Sync	2+ years	Yes	Yes	7 days	2 h	10.8% [52]	
GlucRx AiDEX	14+ years	Yes	No	14 days	1 h	9.1 ^c –21.9% [43, 53]	
GlucMen Day	6+ years	No	Yes	14 days	55 min	9.7% [54] ^d	
Medtrum TouchCare	2+ years	No	Yes	7 days	2 h	9.1% [55]	

*Indications may vary depending on local approval. ^aFreeStyle Libre 2 plus, limited availability in specific countries. ^bFreeStyle Libre 3 plus, limited availability in specific countries. ^c≥14 years. ^dMARD calculated only for glucose levels ≥100 mg/dL (5.6 mmol/L).

latest generations of rtCGM systems (i.e., Dexcom G6, Dexcom G7, Medtronic Guardian 4, Medtronic Simpler, Abbott FreeStyle Libre 3) and all available isCGM (i.e., FreeStyle Libre, FreeStyle Libre 2) are factory-calibrated, meaning that unlike with previous sensor generations, user calibrations using capillary BG measurements are not required. However, manual calibration is still an option for some rtCGM systems if CGM readings and capillary BG readings do not align well over an extended period.

Newer generations or updated versions of sensors have been developed (e.g., Medtronic Simpler Sync with the Medtronic 780G System, or FreeStyle Libre 2 Plus and FreeStyle Libre 3 Plus, which feature revised age limits for use starting at 2 years old and an extended wear time of 15 days). However, since these sensors are not yet widely available at the time this manuscript was completed, they were not included in Table 2.

Benefits of CGM

- Continual use of CGM is strongly recommended in all children, adolescents, and young adults with T1D [A].
- Initiation of CGM use as soon as possible after diagnosis of T1D may benefit HbA1c through the first year and beyond [B].
- Real-time continuous glucose monitors (rtCGM) can be used to lower HbA1c, reach target HbA1c, reduce glucose variability across all types of insulin therapy, increase TIR, improve quality of life, reduce mild to moderate hypoglycemia and shorten the time spent in hypoglycemia in children and adolescents with T1D [A].
- The effectiveness of rtCGM in children and adolescents with T1D is related to the amount of sensor wear [A].
- Use of rtCGM systems is associated with fewer episodes of DKA and fewer severe hypoglycemic events in children and adolescents with T1D than BGM alone [B].
- Real-time CGM data can particularly benefit children who cannot articulate symptoms of hypoglycemia and those with hypoglycemia unawareness [A].

- Intermittently scanned/viewed CGM (isCGM), also known as flash glucose monitoring, is safe, may improve TIR and HbA1c levels, decrease time in hypoglycemia and lower glycemic variability [B].
- For isCGM, higher scanning frequency (11–13 scans/per day) is associated with improved glycemic markers including HbA1c and TIR [B].
- rtCGM offers greater benefits compared to first-generation isCGM systems in terms of enhancing TIR and decreasing hypoglycemia [A].
- Consider CGM for children and adolescents with T2D who are on insulin therapy [B].
- CGM can be used to detect stages of T1D and offers an alternative method to confirm normoglycemia in early-stage individuals [B].

rtCGM Systems

Early-generation rtCGM systems used by children with T1D were associated with modest benefits in glycemia when compared with capillary blood glucose monitoring [40–42]. The JDRF landmark RCT [56] in 2008 showed no overall glycemic benefit with CGM use in the younger age groups (8–14 years and 14–25 years), likely related to <50% wear adherence in these groups. A secondary analysis demonstrated benefits across all age groups when the sensor was used ≥ 6 days/week [57]. RCTs and meta-analyses conducted since 2010 utilizing newer generation rtCGM systems consistently demonstrate that use of rtCGM improves glycemia in both children and adults with T1D, and depending on the population studied, benefits are seen in terms of lower HbA1c concentrations, increased TIR, reduced hypoglycemia (including severe hypoglycemia), and reduced glucose variability [2, 45–49].

RCTs using the latest generation of rtCGM systems have shown positive effects on both HbA1c and TIR [58, 59] in adolescents and young adults. The MILLENIAL Study, that assessed the use of a factory-calibrated rtCGM, showed that TIR increased when compared with BGM [59] irrespective of insulin delivery modality [60]. Supporting this finding, data from single-center observational studies with a selected population aged <20 years describe a decrease in HbA1c after initiation with uninterrupted use of rtCGM [53–55].

Data from RCTs in small children have replicated the results of studies from adolescents and young adults. Though data from small observational studies report that CGM can be used successfully in children <8 years [61–63], a more recent trial of non-adjunctive rtCGM in 143 young children (mean age 5.7 years) did not show a statistically significant improvement in TIR. However, there was a substantial

reduction in the rate of hypoglycemia with rtCGM versus traditional capillary measures over 6 months [64]. Data from a 12-month RCT with newer CGM technology coupled with a family behavioral intervention showed sustained reductions in hypoglycemia with no differences in TIR or HbA1c [65]. Notwithstanding, data from national and multinational-based real-world cohorts have reported that the use of the CGM system seems to be well tolerated by preschool children and has a positive effect on glucose variability [66].

Contemporary large registry-based studies have also shown that rtCGM use is associated with lower HbA1c, higher achievement of HbA1c targets, and fewer episodes of DKA in children and adolescents compared to BGM [1, 7, 23, 67–70]. This positive effect on HbA1c has also been seen in studies that described a progressive decrease of HbA1c in very young children, in parallel with the increasing use of pumps and CGM [71, 72]. Following the implementation of rtCGM/isCGM reimbursement programs, improvement of glycemic outcomes at the population level in children, adolescents, and adults with T1D has also been reported [25, 60, 73, 74].

In contrast, while older studies were not initially able to show a decrease in the number of severe hypoglycemic events in people using rtCGM/isCGM [1, 7, 75, 76], contemporary analyses from registries have reported a decrease in severe hypoglycemic episodes in those using CGM. This reduction in severe hypoglycemic events can be seen from the first year of CGM use after diagnosis [77, 78, 79].

Intermittently Scanned CGM Systems

Limited RCTs have been conducted using isCGM [80, 81], with only one in children [82] and another including adolescents [81]. The IMPACT multicenter RCT in young adults with HbA1c <7.5% (58 mmol/mol) at study entry, demonstrated that isCGM use reduced time spent in hypoglycemia, reduced glucose variability, and improved TIR when compared to BGM [80]. Use of this technology with those not achieving glycemic targets remains less certain. In a 6-month RCT in youth aged 13–20 years with elevated HbA1c (HbA1c $\geq 9\%$, >75 mmol/mol), differences in HbA1c levels were not reported when using isCGM compared to BGM [81]. Nevertheless, this youth population increased testing frequency 2.5 fold and reported a higher satisfaction with treatment [83]. A recent randomized clinical trial with a second-generation isCGM system including customizable alarms did

not show differences between this system and BGM in terms of HbA1c or TIR, although the percentage time below range (TBR) decreased [82].

Data from observational clinical studies in children aged 4–18 years at isCGM initiation have shown greater TIR [84] and lower HbA1c [84, 85] compared to BGM use prior to isCGM start [84, 85], similar to what is described in adults [78, 79, 86]. Interestingly, when comparing isCGM users across different age groups [71, 72, 87], benefits were more pronounced in children under 12 years [88] and preschool children [89] compared to adolescents [88, 89] and adults [88]. Scanning frequency (11–13 scans/per day) is clearly associated with favorable glycemic markers (HbA1c and TIR), though not with reduction of TBR [84, 85, 88, 90, 91]. These studies were all performed using first-generation systems without alarms for impending hypo- and hyperglycemia. Studies using newer systems with optional real-time alarms and improved accuracy are needed.

Real-world data studies have shown increased scanning frequency decreases time in hypoglycemia [92–94]. An observational study in children and adults using data from 12,256 individuals in the Scotland national diabetes registry found that isCGM initiation was associated with significant reductions in HbA1c, with the greatest reductions in those with the highest starting HbA1c values and children aged below 13 years; DKA episodes were also decreased except in adolescents and among those at higher risk for severe hypoglycemia requiring hospitalization (SHH), a marked reduction in SHH event rates was also observed [95]. A prospective real-world cohort study including individuals after 1 year of nationwide reimbursement of isCGM in Belgium reported a lower number of severe hypoglycemia and DKA events with the use of isCGM [87].

Comparing rtCGM and isCGM

To date, there have been six studies directly comparing rtCGM and first-generation isCGM systems, including 414 adults and 92 children and adolescents [81–85, 96]. Two of these studies were focused on individuals <20 years of age [97, 98]. A recent systematic review and meta-analysis including the 2 studies involving children, concluded that rtCGM confers benefits over first-generation isCGM, with a 7% (95% CI: 5.8–8.3%, $p < 0.01$) improvement in TIR, and favorable reductions in time spent <70 mg/dL (3.9 mmol/L) of 1.7% (95% CI: –3.0% to –0.4%; $p = 0.03$) [99]. No differences were reported in HbA1c [99]. Observational data have reported similar findings [100, 101]. A large study with more than 5,000 participants showed that the proportion of individuals achieving recommended TIR, time above range (TAR) and TBR targets was higher when using

rtCGM (either with injections or pump) than when isCGM was used [102]. It is important to note that no studies have directly compared second-generation isCGM to rtCGM so this question remains unanswered. Going forward, this question may become less relevant given subsequent isCGM generations are now offering rtCGM functionality. Additional details of suggestions for the use of rtCGM and isCGM in low-resource countries are further delineated in the ISPAD Clinical Practice Consensus Guidelines 2022: Management of the child, adolescent, and young adult with diabetes in limited resource settings [103].

CGM Use from Diabetes Onset

There are benefits to using CGM early in the course of T1D [104]. Achieving target glycemia from diabetes onset has been shown to benefit long-term glycemic trajectories in individuals with T1D [105]. Early introduction of CGM in children with new-onset diabetes has been associated with a 0.7% (7.5 mmol/mol) lower HbA1c at 12 months after diagnosis compared to those who did not start CGM [73]. Long-term improvement in HbA1c over a 7-year follow-up period was seen when CGM was initiated in the first year of T1D, compared to no CGM use or when CGM was initiated after the first year [106].

Similarly, observational data describe that early initiation of isCGM is associated with lower HbA1c compared with no initiation during the first year after diagnosis [107]. Introduction of CGM at the time of diagnosis seems to be associated with a higher uptake of the device [108]. Additional studies in children and adolescents have reported that irrespective of the insulin delivery system, early initiation of CGM within 1 year following T1D diagnosis is associated with fewer severe hypoglycemic events and more favorable glucose outcomes [73, 109].

Residual beta-cell preservation, often assessed by residual c-peptide secretion, has long been a goal of interventions for persons with new onset T1D to decrease risk of long-term diabetes-related complications [110–112]. As the role of CGM and CGM-derived metrics in clinical trials as outcome parameters is being established [113, 114], CGM will be used to monitor glycemic trajectories in pharmaceutical intervention studies on diabetes onset or prevention [115].

CGM Use for Screening, Pre-Symptomatic Stages, and Classification of Diabetes

As screening initiatives for diabetes expand, there is increasing discourse surrounding the utilization of CGM and CGM-derived metrics for diabetes screening and pre-symptomatic T1D classification. CGM holds promise in identifying individuals at risk of rapid progression to

stage 3 T1D, even among those with normal oral glucose tolerance test (OGTT) results. Progressors to clinical diabetes have higher sensor glucose levels and greater variability [6]. Spending ≥ 5 –10% time above 140 mg/dL (7.8 mmol/L) was associated with progression to stage 3 diabetes in autoantibody-positive youth [5, 6]. Combining CGM with home-OGTT could help identify T1D stages [116]. New technologies such as machine learning combined with CGM could help T1D risk detection without hospital visits or laboratory tests [117]. While CGM measures are predictive of subsequent T1D, they are less robust than OGTT-derived variables, and despite their practical benefits, there is currently insufficient evidence to entirely substitute OGTT measures in clinical trial settings [118].

CGM Use in Youth with T2D

Growing evidence supports the use of CGM in adults with T2D, irrespective of treatment modality. In recent meta-analyses, significant benefits of CGM over capillary blood glucose measurement for HbA1c [3, 119] and across multiple glycemic measures [119] were demonstrated, with the effects being more pronounced in people using rtCGM and insulin therapy, and during short-term interventions [119], while the impact of CGM devices on body composition, blood pressure, and lipid levels remains unclear [2].

However, evidence regarding the clinical advantages for adolescents with T2D is limited. A pilot RCT with a cross-over design comparing CGM versus BGM demonstrated the feasibility of CGM use in youth with T2D using insulin therapy over a 3-month period and showed an improvement in HbA1c levels in this vulnerable demographic [120]. In a non-randomized, prospective study, the utilization of CGM for 10 days in insulin-treated adolescents living with T2D did not result in significant alterations in short or long-term glycemic control; however, many participants reported behavioral changes and expressed a desire to continue using CGM [121]. Although adolescents with T2D generally view CGM as convenient, concerns have arisen regarding its potential to exacerbate stigma and create conflicts with parents [122]. For more information, refer to the Type 2 Guidelines 2024 [123].

Accuracy of CGM Devices

From the first generations of sensors, the accuracy of CGM has greatly improved. Improved accuracy allows non-adjunctive use of CGM for clinical decision-making.

Differences between BG levels and CGM readings occur regularly, especially during hypoglycemia or rapid glucose changes. These discrepancies stem from physiological delays in glucose transfer, sensor responsiveness, signal smoothing techniques, and biomechanical factors like motion and pressure [108, 109, 124]. CGM accuracy is evaluated using metrics like mean absolute relative difference (MARD), error grid analysis or agreement rates. It should be noted that in the home-use setting, CGM systems may be less accurate than during in-clinic studies [125]. Further, measurements of MARD may differ across pediatric and adult data (see Table 2) and according to the study design used, with studies minimizing glucose variability showing lower MARD compared to those reflecting real-life glucose fluctuations [126].

One of the major unfilled gaps regarding CGM devices regulation is the lack of international standards in CGM requirements [19, 23]. For CGM devices, there are no published regulatory standards with minimum accuracy requirements, except the FDA's classification of integrated CGM systems (iCGM) [127]. Recent initiatives by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the Clinical and Laboratory Standards Institute (CLSI) are working to address this issue [128, 129].

Sensor Interference

- Individuals utilizing CGM devices should receive education regarding potential substances and other factors that could impact accuracy [E].

CGM sensors can be affected by various substances, including commonly used medications, which can impact sensor accuracy. However, there is limited research addressing how medications and other substances interfere with sensor performance.

Hydroxyurea at therapeutic doses can lead to marked elevation of sensor glucose readings compared with BG values (e.g., for Dexcom G6/G7, Medtronic Guardian sensors) [130], and the same applies to acetaminophen/paracetamol at standard doses (e.g., for Medtronic Guardian) or doses higher than 1,000 mg every 6 h (for Dexcom G6/G7) [117–120]. Salicylic acid may mildly reduce glucose readings. Ascorbic acid (vitamin C) at supra-therapeutic doses may cause falsely higher readings (e.g., for FreeStyle Libre) [131]. There is also evidence of CGM interference with ingestion of lisinopril, albuterol and atenolol [132]. Alcohol consumption can also impact sensor

accuracy, probably due to the ethanol-induced changes in pH, but the effect is not clinically relevant [133, 132].

Common medications like salicylic acid, acetaminophen/paracetamol, and vitamin C, available over the counter, may be unknowingly consumed by individuals with diabetes, possibly affecting CGM accuracy. Of note, the interference of substances with sensor readings varies by sensor brand, depending on the specific sensor technology and coatings used. CGM users should be cautious and verify with traditional glucose meters when symptoms do not match CGM readings. Further research is needed to explore sensor interference, especially with combined substances [134].

Practical Considerations Education

- HCPs should promote the use of CGM devices as an important tool in diabetes management and provide device informational materials to youth and families as part of a shared decision-making process [E].
- Structured initial and ongoing education and training, including data review, are paramount to successful CGM adoption and continued use [E].

Initial and ongoing team-based education and training in CGM use remains key to optimize CGM uptake and continued use. Glycemic benefit can only be realized if the device is worn consistently (>75% of time) [135, 136]. Structured training of youth and parents/caregivers about CGM device components, insertion, skincare, and data interpretation are critical to ensure safe and effective use and can be provided both face to face and virtually [135, 137]. Realistic expectations of the device are an important part of education to help avoid discontinued use [135]. An RCT for caregivers of young children demonstrated CGM-focused education may help reduce parental burden and fear of hypoglycemia [138]. Ongoing education is essential to overcome barriers to consistent CGM use as technologies are continuously updated [135, 139]. Follow-up training is also recommended for retrospective glucose data use and analysis [135, 140].

Structured educational material and written healthcare plans to support the successful use of CGM should be provided to all caregivers involved in the care of children with diabetes, including daycare providers, school nurses, teachers, babysitters, and after-school programs [135, 141, 142]. HCPs also need ongoing CGM device education [143]. Table 3 provides an overview of education aspects at CGM initiation.

Exercise

- CGM can reduce glycemic excursions with physical activity in youth with diabetes [C].
- The glucose rate of change and trend arrows can be helpful in predicting hypoglycemia before, during, and after activity [E].

CGM systems can be helpful in reducing glycemic excursions associated with exercise [144]. CGM has proven to be effective in both the prevention and early detection of exercise-induced hypoglycemia [145].

The use of predictive hypoglycemia thresholds and rate-of-change-in-glucose alerts in CGM devices allows prompt action to avoid glycemic fluctuations during and after exercise. The use of thresholds for lower glucose values along with trend arrows allows consideration of carbohydrate consumption to mitigate hypoglycemia [146, 147]. CGM remote monitoring tools offer the possibility for parents and caregivers to facilitate supportive action in case of glycemic excursions associated with exercise or to avoid post-exercise nocturnal hypoglycemia in children [146].

CGM and Skin Issues

- To support the use of CGM, clinicians should assess and address skin reactions due to irritation or allergy [E].
- Strategies to preserve skin integrity include correct device placement, prophylactic skincare, the use of barrier agents, and appropriate removal techniques [E].
- In case of suspected allergy to materials in CGM, collaboration with dermatologists to perform allergy testing should be considered [E].

Inflammatory skin reactions elicited by skin irritation or allergy to adhesive or device materials remain a barrier to consistent long-term CGM use, especially in young children and in children with a history of atopy [148, 149]. Reports on skin issues related to CGM use are becoming more frequent with the long-time use of sensors and the availability of devices with longer wear time [132, 135–141]. Skin conditions associated with CGM use include localized eczematous reactions under the device or the fixation plasters, post-inflammatory hyperpigmentation at CGM sensor insertion sites, and device-associated pruritus at the application site [148, 150, 151].

Increasing evidence identifies sensitizing components of sensors and adhesives as factors possibly responsible for skin reactions, including allergic contact dermatitis [152, 153]. The exact composition of adhesives is rarely made available by manufacturers, but most devices contain

Table 3. Practical and educational considerations at CGM initiation

Before initiation 1	<ul style="list-style-type: none"> • Review device components and features • Advocate or confirm insurance coverage/reimbursement • Support consistent options for CGM supplies • Ensure access to CGM data platforms • Provide access to customer service contact for technological support • Assess family expectations and challenges for using the system
Device insertion and adherence 2	<ul style="list-style-type: none"> • Review: <ul style="list-style-type: none"> – Sensor site selection, site rotation, signs and symptoms of cutaneous/subcutaneous issues – Insertion techniques • Offer supplementary adhesive products: <ul style="list-style-type: none"> – Wipes: Skin Tac IV Prep, Skin Prep – Dressings and barriers: Tegaderm, IV-3000, Hypafix – External Wraps: Coban, Pre-Wrap • Offer adjunctive adhesive removers <ul style="list-style-type: none"> – Unisolve or Detachol – Products one may have at home (e.g., baby oil) • Review signs and symptoms of skin irritation or contact dermatitis
Calibration 3	<ul style="list-style-type: none"> • For sensors requiring calibrations, discuss frequency of calibrations and ideal times to calibrate • Consider a pre-emptive calibration schedule. If calibrations are required every 12 h, encourage persons to calibrate three times a day (for example, prior to breakfast, dinner, and bedtime) • Discuss calibrating when glucose is relatively stable (no arrows present, no rapid change on sensor glucose graph)
Alerts and alarms 4	<ul style="list-style-type: none"> • Rate-of-change alerts or predictive alerts might be turned on in situations where rapid changes in glucose levels are more likely than under normal everyday conditions (e.g., more physical activity) • In the beginning, do not employ rate-of-change or predictive alerts. Consider how these additional alerts may be actionable moments prior to incorporating them. This will help prevent alarm fatigue • Consider leaving alerts off initially to help prevent alarm fatigue • When incorporating alerts, personalize them and use wide thresholds at first (i.e., 70–250 mg/dL [3.9–13.9 mmol/L]). These can be adjusted over time
Retrospective Review 5	<ul style="list-style-type: none"> • Encourage downloading, if required to review data • Encourage retrospective review of data to help inform insulin dose titrations • As appropriate discuss non-adjunctive use of sensor data • Review significance of <ul style="list-style-type: none"> – Sensor lag – Trend arrow • Consider recommendations on adjustments of insulin doses based on sensor glucose values and trend arrows • Create a plan with the family and child for remotely monitoring glucose levels

acrylate which is known to cause contact dermatitis [152]. Initiatives for full and accurate labeling of the chemical composition of devices have been presented [154].

Strategies to preserve skin integrity include correct device placement, prophylactic skincare, appropriate removal techniques and promotion of skin healing. Barrier agents to minimize the risk of hypersensitivity reactions may reduce the risk of skin irritation due to frequent sensor use. In the case of suspected allergy to materials in CGM, collaboration with dermatologists to perform patch testing should be considered [155].

CGM Information/Data Sharing and Remote Monitoring

- Parents and caregivers of youth with diabetes should be educated on the benefits of remotely monitoring the youth's CGM data, including improved psychosocial outcomes [E].
- Careful planning and clear communication regarding diabetes management is essential to successful implementation of remote monitoring of CGM data in the home and school settings [E].

Mobile phone-based CGM systems allow for digital remote monitoring, through which parents and other caregivers can view the child's CGM tracing and receive alerts on their own devices, including smartphones, tablets, and smartwatches. Remote monitoring of CGM improves psychosocial outcomes in parents of children with diabetes, including quality of life, reduced family stress, and improved parental sleep [144–146, 149]. Remote monitoring of CGM data has been shown to prevent prolonged nocturnal hypoglycemia in youth with diabetes [156]. Parents may have increased comfort in leaving their children with other caregivers (e.g., daycare, school, sitters) [149]. Remote monitoring of CGM data in the school setting may enable a collaborative approach to diabetes management between the student with diabetes, parents, and school personnel [142].

However, conflicts can arise because of remote monitoring of CGM data [149]. For example, youth with diabetes may have the feeling of being monitored by their loved one, resulting in feelings of frustration. There is a need for constructive communication around diabetes management with clear expectations regarding when and how caregivers should intervene based on remote monitoring of glucose data and alerts received. This is particularly important for adolescents who may desire increasing autonomy in diabetes management, but still benefit from the support of their parents and other caregivers.

CGM and Telemedicine

- CGM is an essential tool for enabling remote glucose data review by HCPs via telemedicine [E].

CGM has become fundamental to the delivery of effective remote diabetes care. The HCP can review and interpret glucose data to make therapy adjustments during telemedicine consultations. Observational data indicate improvements in CGM glucose metrics (e.g., GMI) with telemedicine in youth with diabetes using CGM [157, 158]. Caregivers of young children have reported quality of life benefits with remote monitoring support by health professionals [159].

CGM Interpretation and Analysis

- The ambulatory glucose profile (AGP) should include at least 14 days of CGM data with >70% CGM wear time to indicate data patterns reliably [C].
- HCPs need to be skilled at interpreting CGM data to optimize diabetes treatment regimens and clinical outcomes in youth with diabetes [E].

CGM-derived glucose metrics and data visualization provide a more complete profile of glycemic patterns than HbA1c alone or blood glucose meter data, providing insight into the frequency, duration, timing, and severity of episodes of hypoglycemia and hyperglycemia. The data provided by CGM enable the creation of an AGP [160], an internationally recognized standard for interpreting glucose control for people with diabetes. The AGP requires sufficient collection of CGM data with studies indicating that 14 consecutive days of CGM use with at least 70% data capture will adequately represent glycemic patterns to make therapy adjustments [161, 162].

A variety of CGM metrics including time in range, above range, below range, and glycemic variability (i.e., coefficient of variation, standard deviation) can be reviewed in the AGP. These CGM-specific metrics are clinically useful measurements that complement HbA1c in making effective therapy adjustments and tracking glycemic outcomes. Effective interpretation of CGM data is time intensive but improves with clinical experience [163]. A practical approach to interpreting and optimizing CGM data in youth with diabetes includes (1) confirm the duration of active CGM use, (2) review informative and actionable CGM-derived glucose metrics (e.g., TIR, TBR, TAR, coefficient of variation [%CV], and GMI), (3) personalize CGM-derived glucose metric goals, and (4) discuss an achievable, stepwise action plan with personalized shared decisions [164]. When discussing CGM data, language used by HCPs should be non-judgmental, person-centered, strength-based, and foster collaboration between the young person with diabetes, caregivers and providers [165].

Quality of Life and Person with Diabetes Perspectives on Use of CGM

- Setting realistic expectations for the integration of CGM into day-to-day diabetes management is important to determine optimal management tailored for the individual child [B].
- Identify and counsel regarding potential barriers to adoption and continued use of CGM [B].
- Support youth and families in initiating CGM use, interpreting and using the CGM data to reduce diabetes burden [B].

Many users report greater overall treatment satisfaction with CGM [166, 167]. There are also reports of significant alleviation of diabetes distress and worries about hypoglycemia, and improved general well-being [168, 169]. Person-reported outcomes have become

integral parts of randomized trials on CGM, and offer a broader view of the lived experience of using devices in T1D management [58].

Ensuring a positive experience with new technologies, including CGM, involves developing an understanding of the psychosocial aspects of the youth and family. While there are significant benefits of CGM use [64], there are reports of heightened worries [170, 171] among adolescents and young adults, and many discontinue CGM for a variety of reasons including cost, too many alarms, issues with accuracy, and discomfort wearing a device [36]. Providing referrals for any psychosocial need that may serve as a barrier to optimal use are indicated. In addition, the following recommendations are made when considering CGM use:

- Encourage uptake and refrain from having youth and families “earn” the right to use devices (i.e., achieve a certain hemoglobin HbA1c before considering starting a device). If payers/insurance companies require logging or other documentation prior to device approval, convey that directly instead of as a requirement of diabetes care practice. It is important to consider how social determinants of health for the child and family impact access and sustained use of CGM.
- Conduct a brief assessment of expectations and barriers to uptake and use. Common barriers are cost [172], wearing multiple devices, the sensation of wearing a device on a changing and growing body, frequent alarms, and maintenance of the device.
- Determine a plan for remote monitoring of glucose values. This may be in the form of “rules of engagement” and note that times it is okay for parents/caregivers to monitor values remotely and times it is preferable for the teen to not be monitored. Ultimately, safety is the most important aspect, but without collaborative agreement, teens may disable sharing.
- Problem solve with the youth and their family on ways to break down barriers. This may require referral to a psychological care provider to teach problem-solving skills [173].
- If psychosocial needs are reported or identified, refer to psychological care provider [173].

More clinically translatable research, specifically conducted in the pediatric population, is needed on ways to break down barriers to CGM use and prevent discontinuation. This likely rests in setting realistic expectations, being mindful of broader influences like social determinants of health, teaching effective technology-specific problem-solving skills, and viewing digital health applications as a scaffolding for youth to internalize the salience of specific health behaviors.

Conclusions

Over the last three decades, glucose monitoring has progressed from urinary glucose testing and capillary blood glucose measurements to CGM systems employing factory-calibrated interstitial sensor technology. This evolution has significantly enhanced CGM technology, improving accuracy, device size, sensor lifespan, user-friendliness, and compatibility with AID systems. Increased availability of CGM systems, supported by better insurance coverage globally, has made CGM the standard of care for many individuals with T1D due to its demonstrated benefits over capillary point-measurements.

With factory-calibrated CGM sensors becoming licensed for non-adjunctive use, capillary measurement of blood glucose appears to be receding in importance for glucose monitoring. Nonetheless, it retains significance. Even AID system users with calibration-free CGM may still need capillary measurements for situations such as confirming hypoglycemia or calibrating inaccurate readings.

Whenever possible, CGM initiation should be prioritized for all children, adolescents, and young adults with T1D shortly after diagnosis. For those without access to CGM, BGM remains crucial. ISPAD advocates for increased CGM availability for children, adolescents, and young adults with diabetes.

Methodology

A literature search was conducted to gather updated evidence, using a combination of relevant medical subject headings (MeSH, Emtree) and free text terms specific to each chapter's focus. Studies published from 2021 to 2022 onward, related to children and young adults, were retrieved from MEDLINE. The Project Officer, in collaboration with chapter leads and co-authors, performed the literature searches. The resulting articles (with search terms summarized in the online suppl. material; for all online suppl. material, see <https://doi.org/10.1159/000543156>) were then uploaded to COVIDENCE for screening and review. Two authors/experts involved in drafting this guideline version, independently screened the articles. Any disagreements were resolved by a third reviewer. Where relevant, further literature was included.

The draft chapter was posted on the ISPAD forum to allow feedback from the greater ISPAD membership. Modifications were made with authorship consensus, with

the chapter receiving endorsement from the ISPAD editorial team. Literature search terms are summarized in online supplementary material.

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Conflict of Interest Statement

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Author Contributions

M.T. and C.E.S. co-directed the guideline development process. M.T., R.C.-H., D.J.D., K.H., D.N.L., A.L.O., B.J.W., and C.E.S. contributed equally to the content of individual chapters and participated in revising both the original manuscript and subsequent versions. M.T. synthesized these contributions to develop the original full draft of the guideline. C.E.S., as the editor of the guideline, supervised the overall development and revision process.

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