



Personal Continuous Glucose Monitoring Use Among Adults with Type 2 Diabetes: Clinical Efficacy and Economic Impacts

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Abstract

Purpose of Review This article reviews recent clinical efficacy research and economic analysis of the use of personal continuous glucose monitoring (CGM) in type 2 diabetes (T2D).

Recent Findings Studies from the past 5 years include a variety of randomized controlled trials, meta-analyses, and other studies which generally favor CGM over self-monitoring of blood glucose (SMBG) in T2D, especially among people with T2D treated with insulin. Concurrently, some studies show no significant difference, but there is no evidence of worse outcomes with CGM. CGM is frequently associated with greater reduction in HbA1c than is SMBG. HbA1c reductions tend to be greater when baseline HbA1c is higher. Reductions in hypoglycemia and hyperglycemia have also been demonstrated with CGM in people with T2D, as have comfort with, preference for, and psychosocial benefits of CGM compared to SMBG. There is a small but growing evidence base on the economics and cost-effectiveness of CGM in T2D.

Summary CGM has been clearly demonstrated to have clinical benefits in people with T2D, especially among those treated with insulin. Economic and cost-effectiveness data are more scant but are generally favorable. CGM should be an important consideration in the management of T2D, and its use is likely to increase as efficacy data accumulate further and as costs associated with CGM gradually decrease.

Keywords Continuous glucose monitor · Type 2 diabetes · Economics · CGM · Diabetes technology

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Introduction

The American Diabetes Association (ADA) significantly updated its thoroughly evidence-based Standards of Medical Care in Diabetes in 2021 around use of continuous glucose monitoring (CGM) [1••]. ADA had already noted that CGM could be useful with multiple daily injections (MDI) or continuous subcutaneous insulin infusion [2], but they added “other forms of insulin therapy,” which was absent previously. No longer excluding any particular insulin regimen, ADA noted that CGM can be helpful in reducing and/or maintaining HbA1c, reducing hypoglycemia, and reducing or even replacing self-monitoring of blood glucose (SMBG). Previous recommendations were restricted to those not achieving glycemic targets, with hypoglycemia unawareness, and/or experiencing hypoglycemia. With the updated standards, there is broader support even for people who are achieving glycemic targets to help them maintain this achievement. Recommendations from the American Association of Clinical Endocrinology and American College of Endocrinology are similar and even further-reaching, clearly stating their preferred recommendation of CGM over SMBG, and with one of their 11 principles of comprehensive management of T2D being that “CGM is highly recommended, as available, to assist patients in reaching goals safely” [3••]. They cite the clarity with which CGM can reveal glycemic patterns, more easily and more quickly than SMBG, noting also that this enables more rapid titration of therapy to achieve glycemic targets. They further note CGM’s utility in reducing the risk and frequency of hypoglycemia.

Despite growing evidence of CGM’s clinically efficacy among many people with T2D, CGM has seen limited expansion into clinical care. The goal of this article is to review research published within the past 5 years specific to personal CGM (where the patient can view their glucose data) among adults with T2D and to provide an overview of current knowledge of the economic impacts of CGM use in T2D.

Overview of Evidence in Type 2 Diabetes

This brief summary discusses evolution of the evidence, study types reviewed, outcomes measured, and findings. Detailed review of individual studies follows in the next section.

As CGM systems have evolved, data have accumulated about CGM use and associations with outcomes. Most earlier work focused on type 1 diabetes (T1D), and T2D-focused CGM research has emerged over the past

few years. While some early work remains relevant, the technology has changed dramatically, with improvements in accuracy such that some may now be used for therapeutic and dosing decisions, rather than their prior status as purely adjunctive to SMBG. Because of this rapid evolution, we restrict this review to new evidence within the past 5 years, focusing on personal (where the patient can view their glucose data on their own device, any time they want) rather than professional CGM (where the glucose data are blinded to the patient and reviewed retrospectively by a diabetes care professional).

In most randomized controlled trials (RCTs) and meta-analyses, CGM use was evaluated on HbA1c change from baseline to after some period of CGM use. Most RCTs compared CGM to SMBG, usually employing blinded CGM readings among participants using SMBG to allow direct comparisons of glycemia. Most studies found greater HbA1c reductions with CGM than SMBG, though the magnitude varied among studies and populations. Some differences are likely due to varying average baseline HbA1c between studies; in general, greater HbA1c reductions were seen in studies with higher baseline HbA1c, with smaller reductions seen with lower baseline HbA1c. Some differences are also likely due to treatment regimen among participants. Most recent studies involved intensive insulin therapy (IIT) among participants with T2D, but the variety of diabetes treatment regimens has broadened, with more studies now including people using basal-only or even non-insulin regimens. Not surprisingly, higher baseline HbA1c correlated with greater HbA1c reduction with CGM use. Some studies found no significant difference, but none found a greater HbA1c reduction with SMBG than with CGM. Various quality of life and treatment satisfaction measures also generally favored CGM over SMBG. When evaluated, time in range (TIR), time above range (TAR), and average sensor glucose correlated well with HbA1c and change in HbA1c, again generally favoring CGM over SMBG. Hypoglycemia results were mixed, with some studies finding less hypoglycemia with CGM use and some finding no difference. One meta-analysis looked specifically at the correlations of HbA1c with various CGM metrics, and therefore how CGM can be used to reflect not only HbA1c-like measures of glycemia, but also how CGM can be used to evaluate aspects of glycemia not reflected by HbA1c (notably, hypoglycemia). One study found more frequent hypoglycemia with CGM, though the method of measuring hypoglycemia with CGM was quite different than with SMBG. Another study found a difference in its primary outcome of change in treatment satisfaction, while others included such satisfaction and quality of life measures as secondary outcomes and were therefore not powered to find such differences. Nearly all studies that evaluated such domains, including treatment or monitoring satisfaction, ease of management, likelihood

to recommend, and various quality of life measures, found CGM to be superior. On most clinical and behavioral/psychosocial outcomes, and with only rare exceptions, CGM has consistently been demonstrated to be as beneficial as or superior to SMBG. Likewise, CGM was usually found to be beneficial for TIR, TAR, and time below range (TBR). The studies reviewed include several RCTs, several meta-analyses, and several observational studies, which are reviewed in turn below and summarized in Table 1.

Recent Studies

Randomized Controlled Trials Most studies found a greater decrease in HbA1c among participants using CGM compared to SMBG, with some exceptions where no difference was found. For example, the 24-week adjusted difference in HbA1c was -0.4% (-0.9% for CGM, -0.5% for SMBG; $p < 0.001$) in a 2017 RCT of 116 adults aged 60 or older and using MDI (82 with T2D and 34 with T1D) randomized to real-time CGM (rtCGM) or SMBG [6]. There were also significant benefits in the CGM group at 24 weeks in mean glucose, TIR, and TAR. There were too few episodes of hypoglycemia to allow for meaningful comparisons, with both groups already experiencing fewer episodes of hypoglycemia than recommended as acceptable limits even at baseline.

Similar findings regarding HbA1c change were seen among participants with T2D treated with MDI, where adjusted mean HbA1c was changed 0.3% greater at 12 and 24 weeks with rtCGM than with SMBG ($p = 0.005$ and $p = 0.02$, respectively) [4•]. In this study, baseline HbA1c decreased from 8.5 to 7.5% with rtCGM and to 7.9% with SMBG at 12 weeks and to 7.7% with rtCGM and 8.0% with SMBG at 24 weeks among 158 adults with T2D treated with MDI randomized to rtCGM or four daily SMBG checks. Participants' CGM usage was quite high, with 6.9 days of use per week in month 1 and sustained at 6.7 days/week in months 3 and 6. No meaningful differences were seen in secondary outcomes of measured hypoglycemia or quality of life.

A 2017 RCT found no difference in HbA1c change at 6 months for the whole study population of 224 adults with T2D treated with IIT, but among participants < 65 years old, participants randomized to intermittently scanned CGM (isCGM) experienced more substantial change in HbA1c (-0.53%) than those randomized to SMBG (-0.20%), $p = 0.03$ [5•]. There was also a significant decrease in hypoglycemia, for both time below 70 mg/dL and time below 55 mg/dL, which decreased by 43% and 53% more with CGM, respectively, compared to SMBG. This corresponds to 0.47 h per day less (or -1.9% time below 70 mg/dL), which is noteworthy especially in light of the consensus

target of $< 4\%$ time below 70 mg/dL. Likewise, time below 55 mg/dL decreased by 0.9% , again noteworthy with a consensus target of $< 1\%$ time below 55 mg/dL.

A 2021 RCT conducted among primary care centers demonstrated greater HbA1c reduction at 8 months (adjusted difference -0.4% , $p = 0.02$) among 116 adults with T2D treated with basal insulin and randomized to CGM compared to 59 randomized to SMBG [8]. TIR was greater in the CGM group (59% vs. 43% , adjusted difference 15% , $p < 0.001$), time above 250 mg/dL was less (11% vs. 27% , adjusted difference -16% , $p < 0.001$), and mean glucose was lower (179 mg/dL vs. 206 mg/dL, adjusted difference -26 mg/dL, $p < 0.001$).

A shorter-term RCT also found greater HbA1c change at 10 weeks (-0.53% , $p < 0.0001$) with isCGM than with SMBG among 101 adults with T2D treated with MDI [9]. This study also assessed treatment satisfaction, and participants expressed greater preference for CGM than SMBG regarding flexibility and likelihood to recommend. While no difference in *measured* hypoglycemia was found (perhaps because participants randomized to SMBG were not followed by blinded CGM, while CGM users had much greater opportunity for detection of hypoglycemia by the CGM), CGM users reported a greater decrease in *perceived* hypoglycemia.

In 2020, RCTs of CGM in T2D moved further beyond CGM alone as the intervention. For example, one study showed greater HbA1c reduction for a medication management intervention combining a lifestyle education intervention to minimize glycemic excursion with rtCGM, compared to conventional medication management [11]. There was 1.2% greater HbA1c reduction in the intervention group than the control group (-1.3% vs. -0.1% , $p = 0.03$) among 30 adults with T2D not treated with insulin and with HbA1c $> 7.0\%$. Intervention participants also experienced significant benefits compared to controls in secondary measures including quality of life, diabetes empowerment, diabetes distress, and glucose monitoring satisfaction.

Another 2020 RCT specifically focused on hypoglycemia using isCGM or SMBG, with severe hypoglycemia as the primary outcome and any hypoglycemia as a secondary outcome [10]. It found no difference in severe hypoglycemia between the isCGM and SMBG groups but also had relatively low power to detect such a difference, with 30 participants—predominantly people with T1D, with less than $1/3$ of participants with T2D—in each group and low baseline estimates of severe hypoglycemia events. However, for the secondary outcome of any reported hypoglycemia, the CGM group demonstrated twice as many events (205 per person-year) than the SMBG group (96 per person-year), $p < 0.001$. The authors offer potential explanations for this, including the lower accuracy of the isCGM system in lower blood glucose ranges, in which it has a tendency to measure

Table 1 Studies of CGM use in T2D, 2016–2021

Author/year	Aim(s)	Sample	Main outcomes	Results
Beck, 2017 [4•]	Determine effectiveness of rtCGM vs. usual care (SMBG at least 4 times a day) Intervention group received general guidelines about using CGM and their clinicians individualized recommendations about incorporating CGM trend information into their diabetes management	253 participants Age ≥ 25 (mean age 60) Median diabetes duration = 17 years T2D treated with MDI for ≥ 1 year Baseline A1c 7.5–10.0 (mean = 8.5) Stable diabetes medications and weight over prior 3 months	Clinical: Change in A1c, baseline to 24 weeks Other A1c and CGM outcomes, weight Psychosocial: General QoL, hypoglycemia unawareness, fear of hypoglycemia, diabetes distress, hypoglycemia confidence	Clinical: CGM use sustained at 6.7 days/week in month 6 Adjusted difference in mean change in A1c = -0.3% ($p = .005$) at 12 weeks and -0.3% ($p = .002$) at 24 weeks Median CGM TIR increased from 802 to 882 min/day in CGM group and 794 to 836 min/day in control group, reflecting a greater reduction in time above range in the CGM group and a reduction in time below range in the CGM group with no change in time below range in control group Weight: CGM group experienced a 1.3 kg weight gain and a 0.2 kg weight loss in control group Psychosocial: No difference in QoL, fear of hypoglycemia, diabetes distress, hypoglycemia confidence, or hypoglycemia unawareness
Haak, 2017 [5•]	Assess safety and efficacy of isCGM to replace SMBG	224 participants with type 2 diabetes on intensive insulin therapy randomized 2:1 to isCGM or SMBG Intervention participants entered additional 6-month follow-on phase after initial 6-month RCT	Primary: change in A1c from baseline to 6 months Secondary: time in hypoglycemia, effect of age, patient satisfaction, at 6 months At 12 months: time in range, time in hypoglycemia, nocturnal hypoglycemia, frequency of SMBG checks	Change in A1c: No difference in full sample between CGM (-0.29%) and SMBG (-0.31%), $p = 0.82$ Significant difference for participants ages < 65 years between CGM (-0.53) and SMBG (-0.20), $p = .03$ Time in hypoglycemia: Time below 70 mg/dL: reduced for CGM compared to SMBG (reduced 43% from baseline or -0.47 h/day, $p = .0006$) Time below 55 mg/dL: reduced for CGM compared to SMBG (reduced 53% from baseline or -0.22 h/day, $p = .0014$) Treatment satisfaction was higher for CGM than for SMBG ($p < .0001$) In the 6-month follow-on, at 12 months, there was no change in TIR; time below 70 mg/dL was reduced by 50% or -0.70 h/day over baseline, $p = .0002$; nocturnal hypoglycemia was reduced by 52%, $p = .0002$; SMBG decreased from 3.9 to 0.2 checks per day HbA1c decreased more in CGM group (-0.9%) than in SMBG group (-0.5%) at 24 weeks; adjusted difference in mean change in HbA1c -0.4%, $p < .001$ There were significantly greater improvements in mean glucose, time in range, and time in hypoglycemia in the CGM group compared to the SMBG group at 24 weeks No differences were seen between groups in time in hypoglycemia, but there was very little time in hypoglycemia at baseline, limiting ability to detect a significant difference
Ruedy, 2017 [6]	Determine the effectiveness of rtCGM in adults ≥ 60 years old with T1D or T2D using insulin via MDI	116 participants ≥ 60 years old (mean 67 years) with T1D (34) or T2D (82) using MDI therapy for at least 1 year and with baseline HbA1c 7.5–10.0% randomized to rtCGM or SMBG (4+checks/day) for 24 weeks. Baseline HbA1c 8.5	Primary: change in HbA1c at 24 weeks Secondary: time < 60 mg/dL, time > 250 mg/dL, time 70–180 mg/dL, CV at 12 and 24 weeks	

Table 1 (continued)

Author/year	Aim(s)	Sample	Main outcomes	Results
Wada, 2020 [7•]	Evaluate isCGM compared to SMBG in patients with T2D not treated with insulin	100 adults with T2D not treated with insulin and not using CGM or SMBG randomized to receive isCGM or SMBG Devices (CGM or SMBG) were available to participants for 12 weeks	Primary: change in HbA1c at 12 and 24 weeks Secondary: changes in other clinical measures (e.g., BMI, BP, FPG, HDL, CGM metrics including time < 70 mg/dL, time < 55 mg/dL, TIR, time > 180 mg/dL, time > 240 mg/dL, time > 300 mg/dL, mean glucose, glucose variability (SD, CV, MAGE, BGRI, CONGA, MODD) Non-biologic: change in treatment satisfaction	A1c reduced from baseline to 12 weeks for CGM (-0.43, <i>p</i> < .001) and for SMBG (-0.30, <i>p</i> = .001), with the between-group difference of -0.13% not significant, <i>p</i> = .241; the reduction was sustained for the CGM group at 24 weeks (-0.46, <i>p</i> < .001) but not for SMBG (-0.17, <i>p</i> = .124), for a significant between-group difference of -0.29, <i>p</i> = .022 Significant differences were seen between CGM and SMBG for decreases in mean glucose (-15 mg/dL, <i>p</i> < .001), SD (-5, <i>p</i> < .001), time > 180 mg/dL (-2.66 h/day), time > 240 mg/dL (-1.23 h/day), and time > 300 mg/dL (-0.39 h/day), all <i>p</i> < .001 Significant difference between CGM and SMBG for increase in time in range (2.36 h/day, <i>p</i> < .001) Time below range and CV did not change significantly Treatment satisfaction increased significantly for CGM compared to SMBG, with a difference increase of 3.4, <i>p</i> < .001
Martens, 2021 [8]	Determine effectiveness of CGM in adults with T2D treated with basal insulin in primary care practices	175 adults with T2D on basal-only insulin therapy, receiving diabetes care from a primary care physician, randomized 2:1 to CGM (<i>n</i> = 116) or SMBG (<i>n</i> = 59)	Primary: HbA1c at 8 months Secondary: CGM-measured TIR, time > 250 mg/dL, mean glucose level at 8 months	Mean HbA1c decreased from 9.1 to 8.0% at 8 months in the CGM group, compared to 9.0% to 8.4% in the SMBG group (adjusted difference -0.4%, <i>p</i> = .02) TIR was 59% in the CGM group compared to 43% in the SMBG group (adjusted difference 15%, <i>p</i> < .001) Time > 250 mg/dL was 11% in the CGM group compared to 27% in the SMBG group (adjusted difference -16%, <i>p</i> < .001) Mean glucose was 179 mg/dL in the CGM group compared to 206 mg/dL in the SMBG group (adjusted difference -26 mg/dL, <i>p</i> < .001)
Yaron, 2019 [9]	Assess treatment satisfaction and effectiveness of isCGM in T2D patients using basal-bolus insulin	101 participants with T2D on MDI insulin therapy randomized to isCGM or SMBG (4+checks/day) for 10 weeks	Primary: treatment satisfaction Secondary: change in HbA1c, change in quality of life, percentage of participants reaching physician recommended personal A1c target, changes in hypoglycemia events (< 70 mg/dL and < 54 mg/dL)	Treatment satisfaction was high in both groups, with the observed difference not significant (<i>p</i> = .053) for mean DTSQ score, and likewise for most DTSQ individual items. However, flexibility was rated as higher for CGM than for SMBG (2.28 vs. 1.61, <i>p</i> = .019), and CGM participants were more willing to recommend CGM than SMBG participants were to recommend SMBG (2.61 vs. 2.19, <i>p</i> = .023) HbA1c reduced from baseline to 10 weeks more for CGM (-0.82%) than for SMBG (-0.33%); unadjusted mean change -0.49%, <i>p</i> = .005, mean change adjusted for baseline HbA1c -0.53%, <i>p</i> < .001 69% of CGM group vs. 30% of SMBG group experienced HbA1c decrease of ≥ 0.5% 39% of CGM group vs. 19% of SMBG group experienced HbA1c decrease of ≥ 1.0% No difference seen in hypoglycemia, but CGM group hypoglycemia was based on CGM readings and self-report, while SMBG group hypoglycemia was based on SMBG readings and self-report

Table 1 (continued)

Author/year	Aim(s)	Sample	Main outcomes	Results
Davis, 2020 [10]	Assess efficacy of isCGM compared with SMBG in reducing incidence of hypoglycemia among insulin-treated adults with a recently confirmed episode of clinically significant hypoglycemia	59 adult participants with T2D (17), T1D (40), or LADA (2) treated with insulin and with event of symptomatic hypoglycemia with glucose < 72 mg/dL or of glucose < 54 mg/dL within 2 weeks prior to recruitment, randomized to isCGM or SMBG for 6 months	Primary: hypoglycemia requiring second-party assistance Secondary: self-reported hypoglycemia, blood/interstitial glucose < 54 mg/dL, blood/interstitial glucose 54–70 mg/dL, blood/interstitial glucose < 72 mg/dL, change in HbA1c	No difference in severe hypoglycemia between CGM and SMBG groups Higher incidence in CGM than SMBG of any self-reported hypoglycemia (114 vs. 78 events/person-year, $p < .001$), blood/interstitial glucose < 54 mg/dL (67 vs. 33 events/person-year, $p < .001$), blood/interstitial glucose 54–70 mg/dL (137 vs. 64 events/person-year, $p < .001$), blood/interstitial glucose < 72 mg/dL (205 vs. 96 events/person-year, $p < .001$) No difference in change in HbA1c between CGM and SMBG groups (-0.21 vs. -0.06 , $p = .40$)
Cox, 2020 [11]	Compare conventional medication management of T2D to medication management plus GEM lifestyle intervention plus rCGM	RCT of 30 adults with T2D not treated with insulin, with HbA1c > 7.0	Primary: change in HbA1c from baseline to 6 months WHO QoL, diabetes empowerment, DDS, glucose monitoring satisfaction survey	Intervention participants experienced a greater decrease in HbA1c than controls (mean difference -1.2% , $p = .03$), which decreased from 8.9 to 7.6% and 8.8 to 8.7%, respectively Intervention participants experienced significant benefits compared to controls on secondary outcome measures including WHO QoL (psychological subscale), diabetes empowerment, diabetes distress (emotional and regimen subscales), and glucose monitoring satisfaction
Meta-analyses evaluating change in glycaemia				
Park, 2018 [12]	Synthesize evidence of effectiveness of CGM in adults with T2D	7 RCTs and 3 cohort studies; 8 studies involving 1384 participants for rCGM and proCGM, and 2 studies involving 4902 subjects for isCGM	Difference in HbA1c change between CGM and controls	rCGM and proCGM were associated with a greater reduction in HbA1c compared to controls; standard mean difference -0.20 (95% CI -0.09 to -0.31) among all 8 rCGM/proCGM studies (7 RCTs and 1 cohort study), and -0.33 (95% CI -0.13 to -0.52) among the 7 RCTs Pooled analysis of 2 studies of isCGM (1 RCT, 1 case control) showed no difference between the CGM and control; standard mean difference $[-0.02\%$ (95% CI -0.07 to 0.04)]
Ida, 2019 [13]	Investigate the effects of CGM on blood glucose levels, body weight, BP, and hypoglycemia in patients with T2D	7 RCTs involving 669 participants; 3 involving rCGM and 4 involving proCGM	Differences between CGM and controls in HbA1c change, body weight, BP, time in hypoglycemia < 70 mg/dL, and time in hyperglycemia > 180 mg/dL	CGM groups experienced lower HbA1c levels than controls; standard mean difference -0.35 , $p = .006$ for all studies pooled; -0.45 , $p < .001$ for rCGM studies; -0.43 , $p = 0.13$ for proCGM studies. Baseline HbA1c and age were not associated with the effect of CGM on HbA1c change Time in hypoglycemia < 70 mg/dL was lower in CGM than controls; standard mean difference -0.35 h/day, $p = .006$ No differences were seen between CGM and controls in time in hyperglycemia > 180 mg/dL, BP, or body weight change

Table 1 (continued)

Author/year	Aim(s)	Sample	Main outcomes	Results
Janapala, 2019 [14]	Evaluate the evidence of efficacy of CGM compared to SMBG in patients with T2D	5 RCTs involving 374 participants	Differences between CGM and controls in HbA1c change	CGM groups experienced greater HbA1c reductions than controls; standard mean difference -0.25% , $p = .01$; 4 of the 5 studies favored greater HbA1c reduction in CGM than in controls, while 1 found no difference
Evans, 2020 [15]	Establish whether use of isCGM favors a reduction in HbA1c among people with T1D or T2D as a replacement for SMBG; identify whether change in HbA1c with isCGM is associated with baseline HbA1c; and determine whether HbA1c change with isCGM differs by length of study or by type of diabetes (T1D vs. T2D)	21 studies (RCTs and real-world observational studies) involving 1496 participants with T1D and 227 participants with T2D	Differences between CGM and controls in HbA1c at 2, 3, or 4 months, and up to 12 months of follow-up	Mean HbA1c change for all subjects at 2–4 months was -0.55% (95% CI -0.39 to -0.70) and for adult subjects was -0.56% (95% CI -0.36 to -0.76) Mean HbA1c change was associated with baseline HbA1c; for each 1% higher in mean baseline HbA1c, mean HbA1c change at follow-up changed by -0.31% (95% CI -0.19 to -0.43) No significant differences in mean HbA1c change were found between adults with T1D vs. adults with T2D Where longer follow-up could be evaluated, HbA1c was found to decrease within the first 2 months, with the change sustained at 12 months
Other studies				
Ish-Shalom, 2016 [16]	Evaluate use of isCGM with T2D, HbA1c $\geq 7.5\%$, and other factors making their diabetes “difficult-to-control”	Cross-sectional study of 31 patients using MDI therapy (25 with T2D) followed for 12 weeks with isCGM	Change in HbA1c at 8, 12, and 24 weeks	HbA1c decreased for all subjects (T1D and T2D) at 8 weeks by -1.33% ($p < .0001$), and this decrease was sustained at 12 weeks in all subjects (data not reported) and at 24 weeks for those who chose to continue the device (27 of 31) by -1.21% ($p = .009$) All participants reported high satisfaction, desire to continue isCGM use, that isCGM was easy to use, and that it was painless
Cox, 2016 [17]	Assess feasibility and efficacy of replacing SMBG with CGM to increase qualitative and quantitative feedback in the GEM lifestyle modification program	Pilot study of 4 adults with T2D for whom GEM was augmented with isCGM	Change in HbA1c, QoL (PAID-5)	Mean change in HbA1c was -1.1% (from 7.8 to 6.7%), with a decrease in each participant. Despite a lower baseline mean HbA1c in this pilot, the mean HbA1c decrease was greater than in a prior pilot without CGM (-1.0% , from 8.4 to 7.4%) Participants also experienced fewer diabetes-associated problems at follow-up, with a lower PAID-5 score post-intervention (3.3 for CGM/GEM vs. 5.8 for SMBG/GEM) and a greater decrease in PAID-5 score from baseline to post-intervention (-3.2 for CGM/GEM vs. -2.1 for SMBG/GEM)
Weiss, 2018 [18]	Evaluate use of isCGM and effect on HbA1c in Australia	Cross-sectional study (clinical chart audit) of 22 patients (18 with T1D and 4 with T2D) using isCGM for ≥ 2 weeks	Change in HbA1c	The overall sample experienced HbA1c change of -1.0% , from 8.7 to 7.7% ($p = .001$) The T2D subset ($n = 4$) experienced HbA1c change of -3.4% , from 11.9 to 8.5% (p not reported)
Hirsch, 2019 [19]	Evaluate correlations of HbA1c with CGM metrics	Meta-analysis of 4 RCTs	Correlation of HbA1c with mean glucose, GMI, TIR, time > 250 mg/dL, time < 70 mg/dL, time < 54 mg/dL	HbA1c correlated strongly with mean glucose and GMI ($r = 0.80$), with TIR ($r = 0.75$), and with time > 250 mg/dL ($r = 0.72$) HbA1c correlated only weakly with time < 70 mg/dL ($r = 0.39$) and time < 54 mg/dL ($r = 0.21$)

Table 1 (continued)

Author/year	Aim(s)	Sample	Main outcomes	Results
Kröger, 2020 [20]	Evaluate the impact of iCGM on HbA1c in real-world use in each of 3 European countries among patients with T2D on basal-bolus insulin therapy	Analysis of 3 cross-sectional (chart review) studies involving 363 adults (92 in Austria, 88 in France, 183 in Germany) with T2D treated with basal-bolus insulin therapy for ≥ 1 year, with iCGM use for ≥ 3 months, and with HbA1c 8.0–12.0% at baseline	Change in HbA1c from baseline (≤ 3 months before starting CGM) to 3–6 months after starting CGM use	HbA1c decreased for the pooled participants from the 3 countries, from 8.9 to 8.0% (mean change -0.9%, <i>p</i> < .0001) and for each country (Austria -0.9%, <i>p</i> < .0001; France -0.8%, <i>p</i> < .0001; Germany -0.9%, <i>p</i> < .0001). HbA1c decreased across age, sex, duration of insulin use, and BMI. Higher baseline HbA1c was associated with greater HbA1c decreases. There was no difference in HbA1c change between females vs. males, higher vs. lower BMI, or higher vs. lower age
Majithia, 2020 [21]	Evaluate glyceemic outcomes associated with participation in a virtual diabetes clinic for 4 months	Prospective single-arm analysis of 55 adults with T2D and HbA1c 8.0–12.0% and not using an insulin pump, enrolled from two primary care centers into a virtual diabetes clinic including telehealth endocrinologist consultation, a proprietary app for data management, virtual engagement with an education program, diabetes education and care specialists, coaches, and rCGM worn intermittently for 60 days of the 4-month study period	Primary: change in HbA1c from baseline Secondary: changes from baseline in TIR, time 180–250 mg/dL, time > 250 mg/dL, time < 70 mg/dL, weight	Mean change in HbA1c was -1.6%, <i>p</i> < .001. Greater reductions were seen for the 19 participants with baseline HbA1c > 9.0% (-2.4%, <i>p</i> < .001) than for the 36 participants with baseline HbA1c 8.0–9.0% (-1.2, <i>p</i> < .001) TIR increased 10.2% (<i>p</i> = .002), from 65.4 to 75.5% and therefore from not meeting to meeting the TIR target of > 70% Time 180–250 mg/dL decreased 7.2% (<i>p</i> = .005) Time > 250 mg/dL decreased 3.0% (<i>p</i> = .01) There was no difference in time < 70 mg/dL Weight decreased by 9.0 pounds (<i>p</i> < .001)
Bergental, 2021 [22]	Evaluate a virtual diabetes clinic's participants' attitudes toward remotely prescribed rCGM and the relationship between rCGM use and change in HbA1c	Observational study of 594 adult participants with T2D who participated in virtual diabetes clinic for CGM education and startup, used at least one provided rCGM sensor, and with baseline HbA1c 7.7%, with mean follow-up of 10.2 months. 36.5% of respondents were treated with insulin, 25.8% were treated with sulfonlylurea	CGM satisfaction and change in HbA1c from baseline	Mean CGM satisfaction score was 4.5 of 5. 94.7% of respondents agreed or strongly agreed that they were comfortable with remote CGM insertion, 97.0% agreed or strongly agreed that rCGM use improved their understanding of the impact of eating, 95.7% agreed or strongly agreed that rCGM use increased their knowledge, and 79.4% agreed or strongly agreed that rCGM use helped improve their diabetes treatment even when not wearing a sensor Mean change in HbA1c was -0.6% (from 7.7% at baseline to 7.1% after a mean 10.2 months of follow-up), <i>p</i> < .001
Gilbert, 2021 [23]	Quantify short-term changes in glycemia and quality of life in the first few months of CGM use	Observational study of 248 adults (182 with T1D, 66 with T2D) on basal-bolus insulin therapy who had not previously used CGM	Change in HbA1c and QoL indicators (diabetes distress evaluated by DDS, hypoglycemia concerns evaluated by HABS score)	Among only the participants with T2D: HbA1c decreased by 1.4% (from 8.5 to 7.1, <i>p</i> < .001) Diabetes distress decreased overall and in the emotional burden, regimen distress, and interpersonal domains (all <i>p</i> < .001) Hypoglycemia concerns decreased overall and in the avoidance and anxiety domains (all <i>p</i> < .001)

Table 1 (continued)

Author/year	Aim(s)	Sample	Main outcomes	Results
Karter, 2021 [24]	Estimate clinical outcomes of initiating rCGM	Retrospective cohort study of 41,753 people with insulin-treated diabetes (36,080 T2D, 5,673 T1D) engaging in SMBG and without prior CGM use, including 3,806 who began rCGM and 37,947 who did not	Change in HbA1c, hypoglycemia resulting in ED visit or hospital admission; hyperglycemia resulting in ED visit or hospital admission; HbA1c < 7%; HbA1c < 8%; HbA1c > 9%; ED visit for any reason; hospital admission for any reason; number of outpatient visits; number of telephone visits	rCGM initiators experienced greater HbA1c reduction than noninitiators (mean difference -0.40%, $p < .001$). They also experienced a reduction in hypoglycemia ED visits or hospital admissions compared to an increase in noninitiators (mean difference -2.7%, $p = .001$). The rCGM cohort experienced a greater increase in proportion achieving HbA1c < 7% (mean difference 9.6%, $p < .001$), a greater increase in proportion achieving HbA1c < 8% (mean difference 13.1%, $p < .001$), a greater decrease in proportion achieving HbA1c > 9% (mean difference -7.1%, $p < .001$), a greater decrease in office visits (mean difference -0.4, $p < .001$), and a greater increase in telephone visits (mean difference 1.1, $p < .001$). There was no association found between initiating rCGM and hyperglycemia-related ED visits or hospital admissions, ED visits for any reason, or hospital admissions for any reason

BGR1 blood glucose risk index; *BMI* body mass index; *BP* blood pressure; *CGM* continuous glucose monitoring; *CI* confidence interval; *CONGA* continuous overall net glycemic action; *CV* coefficient of variation; *DDS* Diabetes Distress Scale; *DTSQ* Diabetes Treatment Satisfaction Questionnaire; *ED* emergency department; *FPG* fasting plasma glucose; *GEM* glycemic load, exercise, and monitoring glucose lifestyle modification program; *GMI* glucose management indicator; *HABS* Hypoglycemia Attitudes and Behavior Scale; *HDL* high density lipoprotein; *isCGM* intermittently scanned continuous glucose monitor; *LADA* latent autoimmune diabetes in adults; *MAGE* mean amplitude of glycemic excursion; *MDI* multiple daily injections; *MODD* mean of daily differences; *PAID-5* Problem Areas in Diabetes 5-item short form; *proCGM* professional/blinded continuous glucose monitor; *QoL* quality of life; *rCGM* retrospective continuous glucose monitor; *RCT* randomized controlled trial; *rCGM* real-time continuous glucose monitor; *SD* standard deviation; *SMBG* self-monitoring of blood glucose; *T1D* type 1 diabetes; *T2D* type 2 diabetes; *TIR* time in range; *WHO* World Health Organization

falsely lower interstitial glucose concentration than simultaneous venous measurement. It is also notable that hypoglycemia was measured by self-reported symptoms, SMBG value, and/or CGM value. Therefore, another plausible explanation is that isCGM provides many more data points (96 per day with the system in the study) than SMBG (4 per day in this study) and therefore roughly 24-fold as many opportunities to detect hypoglycemia. Much asymptomatic hypoglycemia, which accounts for a significant proportion of all hypoglycemia [25–27], could therefore be captured by isCGM but missed by SMBG. This is supported by the lack of blinded CGM for any period of the follow-up in the SMBG group, whereas most studies comparing hypoglycemia between CGM and control groups use blinded CGM in the controls for some period to enable direct comparison during that time. Further, the analysis was conducted on the entire study population without sub-analysis by diabetes type, making it difficult to draw significant conclusions about this use of CGM for T2D specifically.

Finally, another 2020 RCT found that when stopping glucose monitoring by either CGM or SMBG after a 12-week period of monitoring, participants who had been using CGM sustained their 12-week HbA1c decrease at 24 weeks, while those who had been using SMBG did not [7•]. In this study, 100 adults with T2D not treated with insulin and not previously monitoring glucose via either CGM or SMBG were randomized to receive either isCGM or SMBG for 12 weeks, after which the devices were made unavailable to participants. Benefits extended beyond sustained HbA1c decreases; both groups experienced increases in TIR, but participants using CGM experienced 9.8% TIR more than those using SMBG, or 2.35 h per day, $p < 0.001$. CGM users' mean TIR increased from 59.8%, below the consensus target for TIR of $> 70\%$, to 78.0%. SMBG users' TIR increased from 65.1 to 69.4%, a more modest rise not quite reaching target. There was no significant change in hypoglycemia, but baseline rates were very low, quite possibly because all participants were non-users of insulin and therefore at lower risk of hypoglycemia than other populations.

This group of RCTs illustrates the recent demonstration and replication of HbA1c benefits of using CGM in the treatment of T2D, as well as the movement toward investigating outcomes beyond HbA1c and interventions incorporating CGM without consisting solely of CGM.

Meta-analyses Rather than relying only on RCTs, it is also instructive to review meta-analyses of other studies. Several recent meta-analyses have been reported, often involving overlapping groups of studies, including data pooled from some of the RCTs mentioned above. One meta-analysis pooled data from 7 RCTs and 3 cohort studies [12]. Among the studies' 1384 patients using rtCGM or professional CGM (they did not separate these CGM types for

analysis), they found a greater decrease in HbA1c with CGM compared to controls (mean difference -0.20% , 95% confidence interval -0.09 to -0.31). Among 4902 patients using isCGM, they found no difference compared to controls. With newer meta-analyses conducted since then, and when restricted to RCTs only, the evidence becomes clearer. A meta-analysis of RCTs of isCGM involving 1023 adults with T1D and T2D found a mean HbA1c change of -0.56% in the pooled CGM groups, with the HbA1c decrease occurring within the first 2 months and sustained at 12 months [15]. Sub-analysis showed no difference between T1D and T2D, concluding that there was significant and sustained HbA1c decrease among adults with T2D using isCGM. A meta-analysis of RCTs restricted to T2D concluded that CGM reduced HbA1c by 0.25% more than SMBG did ($p = 0.01$), with 4/5 included studies favoring CGM [14]. Another meta-analysis of RCTs of CGM restricted to T2D demonstrated a significantly greater change in HbA1c with any personal CGM (rtCGM or isCGM) than with SMBG (mean difference -0.42% , $p = 0.004$) [13]. Sub-analysis by CGM type showed similar benefits for rtCGM compared to SMBG (mean difference -0.45% , $p < 0.001$), with a non-significant trend of similar magnitude also favoring isCGM (-0.43% , $p = 0.13$). The CGM groups also spent less time in hypoglycemia than the SMBG groups (-0.35 h/day, $p = 0.006$), corresponding to a decrease in time below range (TBR) of 1.46%.

Other Studies Beyond RCTs and meta-analyses, some recent pilot and observational studies bear review. A 2016 pilot studied 4 subjects with T2D using CGM in addition to a lifestyle education intervention designed to minimize postprandial glycemic excursion [17]. Participants' baseline HbA1c was higher than a group in a prior pilot of the intervention without CGM, yet their HbA1c decrease was slightly greater, demonstrating that CGM might augment the effect of the lifestyle education program. HbA1c decreases of 1.33% by 2 months and 1.21% at 6 months ($p < 0.001$, $p = 0.009$, respectively) were seen in a 2016 cross-sectional study of isCGM use among 31 patients (25 with T2D, 6 with T1D) using MDI with deliberately higher mean baseline HbA1c (8.9%) [16]. All participants reported high satisfaction with and desire to continue using isCGM, and they reported that it was painless and easy to use. Physicians in the study found the data reporting (using the standardized ambulatory glucose profile report generated by the isCGM system) to be excellent and to enable better and easier glucose management. In Australia, isCGM for at least 2 weeks demonstrated reduction in HbA1c from a mean of 11.9 to 8.5% (a decrease of 3.4%) in a cross-sectional study involving chart review of 22 patients with T2D [18]. While this change is more pronounced than seen in most other studies, baseline HbA1c was also higher, and other

studies have found that HbA1c decreases with CGM tend to be greater with higher baseline HbA1c. A 2019 cross-sectional European study demonstrated HbA1c decrease overall (-0.9% , $p < 0.0001$, from 8.9 to 8.0%) and in each participating country (Austria -0.9% , France -0.8% , Germany -0.9% ; all $p < 0.0001$) by chart review of 363 adult patients (92 in Austria, 88 in France, 183 in Germany) with T2D treated with IIT for at least 1 year, on CGM for at least 3 months, and with baseline HbA1c of 8.0–12.0% [20]. A recent 2021 cross-sectional study involved 248 patients on IIT (182 with T1D and 66 with T2D) and new to rtCGM, assessing change in HbA1c and quality of life [23]. Those with T2D experienced a decrease in HbA1c of 1.4% (from 8.5 to 7.1%), $p < 0.001$. Likewise, 21% had HbA1c $< 7.0\%$ before CGM use, while 50.0% achieved HbA1c $< 7.0\%$ after CGM use ($p < 0.001$). Among the T2D cohort, quality of life, as measured by diabetes distress and hypoglycemia concerns, improved significantly. A large 2021 retrospective cohort study found a greater HbA1c decrease (adjusted difference -0.40% , $p < 0.001$) among 3,806 insulin-treated patients who initiated rtCGM compared to 37,947 insulin-treated patients who did not initiate CGM [24]. The cohorts included 41,753 patients, of whom 36,080 (86.4%) had T2D and 5,673 (13.6%) had T1D. CGM initiators also experienced a decrease in hypoglycemia-related ED visits or hospital admissions from 5.1 to 3.0%, compared to an increase among noninitiators from 1.9 to 2.3% (net difference estimate -2.7% , $p = 0.001$). 9.6% more of the CGM initiators than the noninitiators achieved HbA1c $< 7\%$ ($p < 0.001$), 13.1% more achieved HbA1c $< 8\%$ ($p < 0.001$), and 7.1% fewer achieved HbA1c $> 9\%$ ($p < 0.001$).

Beyond the more traditional face-to-face care delivery of most study environments and healthcare delivery environments, at least before the upturn in telehealth seen with COVID-19, there are emerging data about diabetes care delivery, including CGM training and support, via telehealth. Mean HbA1c reduction of 1.6% ($p < 0.001$) was seen in a 2020 report of a pilot study of 55 adults with T2D treated through a virtual diabetes specialty clinic, including with rtCGM [21]. Greater reductions were seen in participants with baseline HbA1c $> 9.0\%$ (-2.4% , $p < 0.001$) than for those with baseline HbA1c of 8.0–9.0% (-1.2% , $p < 0.001$). TIR increased significantly, from 65.4 to 75.5%. Time > 180 mg/dL and time > 250 mg/dL also decreased significantly. In a recent survey of 594 adults with T2D who were remotely initiated on rtCGM via telehealth, mean HbA1c change was -0.6% (from 7.7% at baseline to 7.1% after mean follow-up of 10.2 months), $p < 0.001$ [22]. Respondents reported very high satisfaction (4.5/5), with 94.7% agreeing or strongly agreeing that they were comfortable with rtCGM insertion, 97.0% that rtCGM improved their understanding of the impact of foods, 95.7% that rtCGM use increased their knowledge, and 79.4% that

rtCGM use helped improve their treatment even when not wearing a sensor.

Finally, beyond examining efficacy or quality of life around CGM, a 2019 study evaluated associations of CGM metrics with HbA1c [19]. The investigators found that HbA1c correlated strongly with mean glucose ($r = 0.80$), with TIR ($r = 0.75$), and with TAR ($r = 0.72$), but only moderately with time below 70 mg/dL ($r = 0.39$) and weakly with time below 55 mg/dL ($r = 0.21$). These findings are consistent with the sensitivity of HbA1c to reflect euglycemia and hyperglycemia and its insensitivity to reflect hypoglycemia.

Having reviewed clinical and psychosocial studies of the past several years, we turn now to consider the economics and value of CGM in T2D.

Health Economics and the Value of CGM in T2D

A health economics perspective on value of CGM in T2D considers both clinical benefits of CGM, as discussed above, and cost of CGM. Here we explore a socioecological view of CGM costs and value to patients, provider and healthcare systems, payers, and society overall. CGM-specific cost data for individuals with T2D in the USA is limited to descriptive data on CGM materials and equipment costs and classic cost effectiveness analysis.

Patient Perspective Patient out-of-pocket costs for CGM include co-pays for materials and equipment (sensors, and in some cases, transmitters and receivers) and range from \$2500 to \$6000 annually [28]. As CGM is often not covered by health insurance for T2D, this cost can be largely borne by patients. However, Medicare recently expanded CGM coverage to include anyone using insulin pumps or multiple daily insulin injections [28]. Additionally, Medicaid covers CGM in a growing number of states [29]. CGM may be covered under durable medical equipment and/or pharmacy benefits, depending on the insurance. The value of CGM to patients may lie in less time and pain associated with checking blood glucose, managing medication (including insulin dosing), and lower rates of complications and disability, with improved quality of life and ability to work [30]. Further research on the patient perspective of the cost and value of CGM is needed. However, patient out-of-pocket cost may limit continual CGM use, in which case intermittent use may still be valuable, which has been demonstrated in two studies below.

Payer Perspective Two studies have explored the cost-effectiveness of CGM from the payer perspective and have favored their cost-effectiveness. One study examined

third-party payer data ($N=100$, not on insulin) to project lifetime clinical and economic outcomes for CGM (Dexcom SEVEN, which required SMBG calibrations) versus SMBG, by comparing cohort experiences, outcomes, and costs between the rtCGM and SMBG cohorts in a study of an RCT [31]. Two scenarios were presented: scenario 1, 8 weeks of usage (4 periods of 2 weeks on/1 week off, over 12 weeks) in year 1, and scenario 2, a repeat of similar usage in years 1 and 2. In scenario 1, life expectancy (LE) and quality-adjusted life expectancy (QALE) from CGM were 0.10 and 0.07, indicating a 1.25 month LE gain with CGM compared to SMBG. Incremental cost of CGM was \$653/patient over a lifetime (\$66,094 vs. \$65,441). Incremental cost-effectiveness ratios were \$6293 per life year (LY) gained and \$8898 per quality-adjusted life year (QALY) gained. Scenario 2 resulted in incremental LE and QALE of 0.14 and 0.10, translating to 1.69 months and 1.20 quality-adjusted life months. Incremental costs were estimated to be approximately double at \$1312 per patient over a lifetime (\$66,763 vs. \$65,423). The incremental cost-effectiveness ratios were \$9,319 per LY gained and \$13,030 per QALY gained. These estimates favor CGM as being cost-effective for those with T2D not using prandial insulin. CGM costs related to more recent CGMs that do not require calibration or standalone receivers may elicit additional cost savings.

While this article focuses on personal rather than professional CGM, we include here a study of professional CGM because there are so few economic studies of CGM. Sierra et al. sought to understand how professional CGM affects clinical and financial outcomes, examining laboratory and third-party payer data among a large US claims and lab dataset for patients with T2D who received a professional CGM compared to SMBG only [32]. There was no difference demonstrated in growth of total annual costs for people who used professional CGM compared to those who did not. However, patients using professional CGM more than once per year had a $-\$3,376$ difference in the growth of total healthcare costs ($p=0.05$). Patients who used professional CGM while changing their diabetes treatment regimen also had a difference of $-\$3,327$ in growth of total costs ($p=0.002$). Those patients who used professional CGM were described as slightly younger with more comorbid conditions compared to controls. Though limited, these studies support the cost-effectiveness of personal and professional CGM from the payer perspective.

Provider and Health System Perspective The value of CGM care to health systems and providers may lie in its impact on population health and quality metrics. With slow movement towards value-based payment models in the USA, there are enhanced provider and health system incentives to improve population-level quality metrics while reducing costs, resource utilization, and burden. Several quality metrics, e.g., Healthcare Effectiveness Data and Information Set (HEDIS)

measures [33], which are used to establish reimbursement and bundled payment rates (i.e., per-member-per-month (PMPM) payments), relate to diabetes care processes and outcomes, such as achieving target HbA1c levels. Technologies like CGM may allow for more efficient use of resources while simultaneously improving diabetes quality metrics. With CGM demonstrated to lower HbA1c, one would expect CGM to improve population-level quality performance, but this hypothesis has not been explicitly tested. In their report on a virtual diabetes clinic providing CGM and diabetes to people with T2D, Bergenstal et al. presented their data not only by HbA1c change, but also by proportion before and after participation whose HbA1c was $<8\%$ —directly in the context of this core HEDIS quality measure [22]. Insulin users satisfying this HEDIS measure increased from 46.0 to 65.3%, while noninsulin users increased from 78.6 to 93.1% at 6 months.

Healthcare utilization and total cost of care may also improve with use of CGM compared to SMBG, as suggested by Isaacson et al. [34]. In a parallel randomized multi-site prospective trial, primary care patients with diabetes ($N=99$; 93 with T2D, 6 with T1D) using rtCGM significantly decreased total visits (CGM 5.6, SMBG 7.0; $p=0.009$), emergency department encounters (CGM 0.2, SMBG 0.5; $p=0.018$), and labs ordered (CGM 7.7, SMBG 11.0; $p=0.001$). In a sub-analysis of 36 people (18 CGM, 18 SMBG), CGM users had all-cost average savings of \$417 PMPM for non-Medicare and \$426 PMPM for Medicare Advantage members over 6 months. Thus, there is some evidence that CGM use may simultaneously improve quality and reduce utilization and costs in T2D. From a provider and health system perspective, these studies demonstrate that CGM use, with and without insulin use in T2D, was cost-effective and clinically effective.

Societal Perspective The cost to society of diagnosed diabetes is \$327 billion, including \$237 billion in direct healthcare expenditures and \$90 billion in reduced and lost productivity [35]. Fonda et al. additionally examined CGM in relation to societal costs, though exact dollar amounts were not reported [31]. CGM use translated into reduced cumulative rates of diabetes complications and deaths in cardiovascular disease, ulcers and amputations, and renal disease. The one exception was stroke (death and event), which, paradoxically, is predicted to be higher for patients who use CGM due to longer-term survival, or the “survival paradox.” Long-term studies are needed to better understand how CGM use relates to diabetes complications.

Gaps and Future Research

Generally, there is limited cost-analysis research on CGM in T2D, likely due to lower use in this population due to limited access and insurance coverage and only recently

Table 2 Gaps, considerations, and future directions for research

Gap	Considerations	Future directions
Gap 1. CGM influence on healthcare workforce efficiency	<p>Most limitations of CGM care will be within primary care practices, where the majority of patients with T2D are being managed. Having a workforce that understands what CGM is and how to interpret data is necessary to optimize CGM use. Clinic workflow must also consider how CGM data will be obtained (e.g., manual CGM download, download from a cloud-based system, or local viewing on patient's device), reviewed, and documented. Access to diabetes care and education specialists (including but not limited to nurses, pharmacists, dietitians) may be important for ongoing evaluation of CGM data and may increase costs. Further, integration of data into the electronic medical record may create additional work (e.g., scanning printed reports or uploading electronic reports)</p>	<p>Research on the costs of implementation of CGM within PCP settings is needed to fully appreciate uptake, sustainability, and insurance coverage</p>
Gap 2. CGM costs related to meeting quality indicators	<p>As described above, one study [24] theorized the potential role of CGM in obtaining HEDIS measures (HbA1c < 8%, HbA1c > 9%). It has been well documented that HbA1c alone does not provide the entire picture of a person's glycemia</p>	<p>In the future, time in range (% of time between 70 and 180 mg/dL) may be an additional HEDIS measure that could be examined. HEDIS measures could also be expanded to include glucose management indicator, especially for patients in whom HbA1c is unreliable (hemoglobinopathies, pregnancy, etc.), which may decrease laboratory costs</p>
Gap 3. Lack of data on healthcare utilization related to CGM use	<p>While we did identify that CGM use was cost-effective for those with T2D not using prandial insulin [29] and that healthcare utilization improved in one study [32], there is relatively little research on cost and economic implications of CGM use in T2D</p>	<p>Future research should include longitudinal analysis to examine ongoing costs, even if there are initial cost increases, due to the possibility of downstream preventative effects, such as prevention of increasing HbA1c, diabetes distress levels, and complications, in addition to worsening quality of life</p>

Note: CGM continuous glucose monitoring, T2D type 2 diabetes, PCP primary care provider, HEDIS Healthcare Effectiveness Data and Information Set

emerging clinical evidence of benefit in T2D. We identified three main gaps in the literature, related to (1) the potential influence of CGM on healthcare workforce efficiency, especially in primary care; (2) study or analysis of CGM's potential costs and benefits in achieving quality metrics, especially related to value-based payment models; and (3) lack of data on initial and downstream costs of healthcare utilization related to CGM use and its consequences. These are described in Table 2.

Another significant gap revolves around barriers to CGM use, some of which contribute to disparities in care and access. For example, most patients with T2D in the USA are managed by primary care, yet CGM remains more accessible to endocrinology practices. This also contributes to geographic disparities, given the concentration of specialists in less rural areas, balanced by the nearly universal availability of primary care clinicians across the USA [36]. There are significant efforts under way to increase awareness and use of CGM in primary care, which will help improve access to those not treated by endocrinology. Likewise, there are device language barriers, with only limited support and resources available in languages other than English. Device use can also be challenging for those with vision or hearing impairment. Insurance coverage remains a substantial barrier, with CGM among the services excluded from coverage by many states' Medicaid programs, which introduces further disparities in access between commercially insured patients and patients with fewer resources. We hope to see these barriers and disparities reduced over the coming months and years.

Conclusions

With the well-established and still growing evidence base supporting personal CGM in T1D, more recently in T2D with IIT, and most recently in T2D with any insulin therapy, CGM recommendations in professional guidelines and standards have likewise expanded. It seems increasingly clear that CGM is clinically efficacious for those on insulin. It is not yet clear what the role of CGM will be for those not on insulin, but evidence is beginning to accumulate. As CGM products evolve and as clinical and economic evidence continues to amass, we will likely see more data, more indications, more recommendations, and more standards around the rapidly changing role of personal CGM in the management of diabetes.

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Code Availability Not applicable.

Declarations

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