QUESTION

Should CGM vs. SMBG be used for people with Type 1 diabetes receiving multiple daily injections?	
POPULATION:	people with Type 1 diabetes receiving multiple daily injections
INTERVENTION:	CGM
COMPARISON:	SMBG
MAIN OUTCOMES:	Patients with hypoglycemia (<54 mg/dL) - nonpregnant population; Episodes of hypoglycemia (<54 mg/dL) - nonpregnant population; Episodes of severe hypoglycemia - nonpregnant population; Patients with seizures - nonpregnant population; Time below range (<70 mg/dL) - nonpregnant population; Time below range (<54 mg/dL) - nonpregnant population; Time in range (70-180 mg/dL) - nonpregnant population; Hemoglobin A1c - nonpregnant population; Episodes of severe hypoglycemia - pregnant women; Time below range (<70 mg/dL) - pregnant women; Time below range (<54 mg/dL) - pregnant women; Time in range (70-180 mg/dL) - pregnant women; Episodes of severe hypoglycemia - women planning pregnancy; Time below range (<54 mg/dL) - women planning pregnancy; Time below range (<70 mg/dL) - women planning pregnancy; Time in range (70-180 mg/dL) - women planning pregnancy; Death; Myocardial Infarction; Hypoglycemia ≤70 mg/dl; Stroke;
SETTING:	Outpatient
PERSPECTIVE:	Clinical recommendation - Population perspective
BACKGROUND:	The majority of individuals with type 1 diabetes do not meet recommended glycemic targets. Previous clinical trials showing the benefit of continuous glucose monitoring (CGM) in the management of type 1 diabetes predominantly have included adults using insulin pumps despite the fact that the majority of adults with type 1 diabetes administer insulin by injection. Compared to pump users, a smaller proportion of individuals who inject insulin use CGM. Randomized clinical trials in children have not consistently shown improvement in glycemic control (as measured by HbA1c levels) and reduced hypoglycemia.
CONFLICT OF INTERESTS:	Endocrine Society conflict of interest management policies were applied and the following panel members were recused as a result of risk of conflicts of interest: Grazia Aleppo

ASSESSMENT

Problem
Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	**The problem addressed in this question is a key priority and is highly relevant to clinical practice. The goal of treatment of type 1 diabetes is to maintain blood glucose levels within the normal range as much as possible while minimizing exposure to hypoglycemia (28). Iatrogenic hypoglycemia is the limiting factor in the glycemic management of diabetes** (1, 2)**.** • Only approximately 30% of individuals with type 1 diabetes meet the American Diabetes Association (ADA) goal of HbA1c ≤7% (53 mmol/mol), indicating the need for better approaches to diabetes management) (3). • **Continuous glucose monitoring (CGM) with glucose measurements as often as every 1-5 minutes, together with individually determined low and high glucose level alerts, glucose trend and rate of change information, can better inform diabetes management decisions than moments in time capillary blood glucose measurement with a meter (SMBG) performed several times per day.** • **Randomized clinical trials have demonstrated the benefit of CGM in adults with type 1 diabetes, but have not consistently shown improved glycemic control as measured by HbA1c level and reduction in hypoglycemia in children and adolescents** (4, 5, 6, 7, 8, 9, 10) • These clinical trials have either entirely or predominantly included subjects who use insulin pumps (4, 6, 7). • Most adults with type 1 diabetes deliver insulin with injections (11, 12) (11, 12). • Only a minority of people with type 1 diabetes who inject insulin use CGM; nonetheless, the limited available observational data suggest that glycemic benefit may be comparable to that for pump users. For example, in the T1D Exchange registry (participants with T1D duration >1 year who had a clinic visit between June 2014 and October 2015), mean HbA1c level in the 410 adults who injected insulin and used CGM was similar to that of the 2,316 participants who used both a pump and CGM (7.6% vs. 7.7%, respectively and lower than mean HbA1c level in the 6,222 injection users who did not use CGM (7.6% vs. 8.8%) (13). • Reaching current targets for time in hypoglycemia (<4% of time per day below 70 mg/dL (3.9 mmol/L) or <1% per day <54 mg/dL (3 mmol/L) while reaching HbA1c targets is challenging for people with diabetes treated with MDI both with CGM and SMBG (14).	

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT

- ○ Trivial
- ○ Small
- ● Moderate
- ○ Large
- ○ Varies
- ○ Don't know

RESEARCH EVIDENCE

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with SMBG	Risk difference with real time CGM
Patients with hypoglycemia (<54 mg/dL) - nonpregnant population follow up: 6 months	149 (1 RCT)	⨁⨁◯◯ LOW [a,b]	**OR 0.15** (0.05 to 0.41)	Study population	
				932 per 1,000	**258 fewer per 1,000** (524 fewer to 83 fewer)
Episodes of hypoglycemia (<54 mg/dL) - nonpregnant population follow up: 6 months	0 (1 RCT)	⨁◯◯◯ VERY LOW [c,d]	-	We did not find a significant difference between the intervention and control (n=158; IRR = 1.40; 95% CI: 0.65 to 3.00; I2= N/A).	
Episodes of severe hypoglycemia - nonpregnant population follow up: 6 months	0 (4 RCTs)	⨁⨁⨁◯ MODERATE [e]	-	There was a significant difference in episodes of severe hypoglycemia that favored the intervention (n=794; IRR = 0.39; 95% CI: 0.18 to 0.85; I2 = 25.00%).	
Patients with seizures - nonpregnant population	203 (1 RCT)	⨁◯◯◯ VERY LOW [c,d]	**RR 0.08** (0.01 to 1.58)	Study population	
				50 per 1,000	**46 fewer per 1,000** (50 fewer to 29 more)
Time below range (<70 mg/dL) - nonpregnant population follow up: 6 months	2771 (5 RCTs)	⨁⨁◯◯ LOW [d,e]	-	The mean time below range (<70 mg/dL) - nonpregnant population was **0** percentage of time spent in range	MD **2.05 percentage of time spent in range lower** (4.71 lower to 0.6 higher)
Time below range (<54 mg/dL) - nonpregnant population follow up: 6 months	2225 (5 RCTs)	⨁⨁◯◯ LOW [d,e]	-	The mean time below range (<54 mg/dL) - nonpregnant population was **0** percentage of time spent in range	MD **0.89 percentage of time spent in range lower** (1.94 lower to 0.17 higher)

ADDITIONAL CONSIDERATIONS

Real time CGM/intermittently scanned is the intervention of interest.

Studies included patients >18 years. The panel noted that published studies that included children and adolescents, were ineligible for inclusion because subjects included in these studies used pumps. A recent example is the article in by Laffel et al (10). This RCT examined the effect of continuous glucose monitoring on glycemic control in adolescents and young adults (ages 14 to 24 years) with type 1 diabetes. Participants were randomized 1:1 to CGM or usual care using a blood glucose meter for glucose monitoring. CGM use resulted in a small but significant improvement in glycemic control over 26 weeks. However, 49% of participants randomized to CGM used a pump and 59% randomized to SMBG used a pump.

Time in range (70-180 mg/dL) - nonpregnant population follow up: 6 months	1156 (6 RCTs)	⨁⨁⨁◯ MODERATE [e]	-	The mean time in range (70-180 mg/dL) - nonpregnant population was **0** percentage of time spent in range	MD **5.2 percentage of time spent in range higher** (3.1 higher to 7.29 higher)
Hemoglobin A1c - nonpregnant population follow up: 6 months	1050 (5 RCTs)	⨁◯◯◯ VERY LOW [d,e,f]	-	The mean hemoglobin A1c - nonpregnant population was **0** %	MD **0.19 % lower** (0.39 lower to 0.02 higher)
Episodes of severe hypoglycemia - pregnant women follow up: 8 months	0 (1 RCT)	⨁◯◯◯ VERY LOW [d,g]	-	We found no difference between the intervention and control groups (n=207; IRR = 0.87; 95% CI: 0.46 to 1.62; I2 = N/A)	
Time below range (<70 mg/dL) - pregnant women follow up: 6 months	154 (1 RCT)	⨁⨁◯◯ LOW [d,g]	-	The mean time below range (<70 mg/dL) - pregnant women was **0** percentage of time spent in range	MD **1 percentage of time spent in range lower** (2.28 lower to 0.28 higher)
Time below range (<54 mg/dL) - pregnant women follow up: 6 months	154 (1 RCT)	⨁⨁◯◯ LOW [b,g]	-	The mean time below range (<54 mg/dL) - pregnant women was **0** percentage of time spent in range	MD **1 percentage of time spent in range lower** (1.6 lower to 0.41 lower)
Time in range (70-180 mg/dL) - pregnant women follow up: 6 months	154 (1 RCT)	⨁⨁◯◯ LOW [b,g]	-	The mean time in range (70-180 mg/dL) - pregnant women was **0** percentage of time spent in range	MD **7 percentage of time spent in range higher** (2.57 higher to 11.43 higher)
Episodes of severe hypoglycemia - women planning pregnancy follow up: 6 months	0 (1 RCT)	⨁◯◯◯ VERY LOW [d,g]	-	We found no difference between the intervention and control groups (n=109; IRR = 2.19; 95% CI: 0.82 to 5.84; I2 = N/A).	
Time below range (<54 mg/dL) - women planning pregnancy follow up: 6 months	91 (1 RCT)	⨁⨁◯◯ LOW [b,g]	-	The mean time below range (<54 mg/dL) - women planning pregnancy was **0** percentage of time spent in range	MD **1 percentage of time spent in range higher** (0.2 higher to 1.8 higher)
Time below range (<70 mg/dL) - women planning pregnancy follow up: 6 months	91 (1 RCT)	⨁◯◯◯ VERY LOW [d,g]	-	The mean time below range (<70 mg/dL) - women planning pregnancy was **0** percentage of time spent in range	MD **1 percentage of time spent in range higher** (0.92 lower to 2.92 higher)

Time in range (70-180 mg/dL) - women planning pregnancy follow up: 6 months	91 (1 RCT)	⨁◯◯◯ VERY LOW [d,g]	-	The mean time in range (70-180 mg/dL) - women planning pregnancy was **0** percentage of time spent in range	MD **5 percentage of time spent in range higher** (0.96 lower to 10.96 higher)
Death - not reported	-	-	-	**-**	**-**
Myocardial Infarction - not reported	-	-	-	**-**	**-**
Hypoglycemia ≤70 mg/dl - not reported	-	-	-	**-**	**-**
Stroke - not reported	-	-	-	**-**	**-**

a. Serious concerns about risk of bias due to risk of deviations from intented interventions, inadequate measurement of the outcome, and selective reporting.
b. Small sample size.
c. Very serious concerns about the process of random sequence generation.
d. Very serious concerns about imprecision due to very wide CI that has appreciable benefits and harms.
e. Serious concerns about risk of bias due to overall high risk of bias in all trials.
f. Serious concerns about inconsistency due to high heterogeneity in the results (confidence intervals do not overlap and I2 estimate is substantially large).
g. Serious concerns about risk of bias due to risk of deviations from intented interventions, inadequate measurement of the outcome, and selective reporting.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT

- ○ Large
- ○ Moderate
- ○ Small
- ● Trivial
- ○ Varies
- ○ Don't know

RESEARCH EVIDENCE

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
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Episodes of hypoglycemia (<54 mg/dL) - nonpregnant population follow up: 6 months	0 (1 RCT)	⨁◯◯◯ VERY LOW [c,d]	-	We did not find a significant difference between the intervention and control (n=158; IRR = 1.40; 95% CI: 0.65 to 3.00; I2= N/A).	

ADDITIONAL CONSIDERATIONS

While not a prioritized outcome, the panel discussed contact dermatitis from the adhesive which affects a minority of patients using CGM. There are a variety of useful strategies for managing contact dermatitis that may ameliorate the problem. There are some individuals (especially adolescents) who do not want a medical device attached to their bodies.

Episodes of severe hypoglycemia - nonpregnant population follow up: 6 months	0 (4 RCTs)	⨁⨁⨁◯ MODERATE [e]	-	There was a significant difference in episodes of severe hypoglycemia that favored the intervention (n=794; IRR = 0.39; 95% CI: 0.18 to 0.85; I2 = 25.00%).	
Patients with seizures - nonpregnant population	203 (1 RCT)	⨁◯◯◯ VERY LOW [c,d]	**RR 0.08** (0.01 to 1.58)	Study population	
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Death - not reported	-	-	-	**-**	**-**
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Stroke - not reported	-	-	-	**-**	**-**

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g. Serious concerns about risk of bias due to risk of deviations from intented interventions, inadequate measurement of the outcome, and selective reporting.

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies		Studies conducted with older CGM systems that are outdated, but we did not downgrade further for indirectness. All the studies were conducted using CGM devices that are now obsolete. Accuracy, usability, duration of wear time, no requirement to calibrate the device have all enhanced the attractiveness of current CGM devices to PWD and, in the case of children, their caregivers. This is reflected in an exponential increase in their use.

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	**There is little evidence of variability in the outcome of avoiding hypoglycemia, which is a condition that is feared widely by all with type 1 diabetes, as it risks increased instability of glucose control, increases the chances of repeated and more serious hypoglycemia (loss of consciousness or seizures), and is associated with poor QOL, diabetes distress and potential injury when driving or operating hazardous machinery and, rarely, death. Damage to the brain and heart can occur.** Hypoglycemia is a major concern for patients and their family members. Iatrogenic hypoglycemia is the limiting factor in the glycemic management of diabetes (1, 2). • The Diamond study (15) showed that use of CGM compared to SMBG led to greater increases in hypoglycemic confidence (i.e., staying safe from serious hypoglycemia problems while sleeping and while driving; participants' partners also had increased overall hypoglycemic confidence) and greater decrease in diabetes distress. There were no significant differences in well-being, health status or fear of hypoglycemia. The Clarke Hypoglycemia Unawareness score was not different. • CGM contributed to significant improvement in diabetes-specific QOL (diabetes distress, hypoglycemia confidence), but not with QOL measures not specific to diabetes (well-being, health status). CGM satisfaction was associated with most of the QOL outcomes but not with glycemic outcomes. Effect sizes for between group differences in diabetes-specific QOL were in the low/moderate range (16). • In the GOLD study, an open label crossover RCT in adults treated with MDI with inadequate control (mean HbA1c 8.6%), CGM was compared with conventional SMBG for 26 weeks. There was less fear of hypoglycemia (3.4 vs 3.27, P <.01) on the Hypoglycemia Confidence Questionnaire. During CGM use both overall well-being (WHO-5 questionnaire) (96.1 vs 62.7, P=.02) and satisfaction with diabetes treatment improved during use of CGM (Diabetes Treatment Satisfaction Questionnaire; 30.2 vs 26.6, P <.001) (17). CGM use improved hypoglycemia-related confidence in social situations (P=.016) and confidence in more broadly avoiding serious problems due to hypoglycemia (P=.002). Subjects reported greater confidence in detecting and responding to decreased blood glucose levels (thereby avoiding hypoglycemia during CGM use (P=.0033) and indicated greater conviction that they could more freely live their lives despite risk of hypoglycemia (P=.022) (18). • In adults with T1D and a history of impaired hypoglycemia awareness or severe hypoglycemia during the previous year (i.e., individuals at high-risk of hypoglycemia), Heinemann et al. showed that use of rtCGM improved hypoglycemia unawareness scores in both groups by approximately 40% with no between group differences. Fear of hypoglycemia decreased in both groups (between-group difference P=.067). Diabetes distress total score decreased in both groups; however, the hypoglycemia distress subscale was significantly different between groups. The CGM group was more satisfied with the method of glucose monitoring. Self-reported health status (EQ-5D questionnaire) showed no significant different between groups (19). • In a prespecified subgroup analysis of the IMPACT RCT (20), flash glucose testing significantly reduced the time adults with well controlled T1D using MDI therapy spent in hypoglycemia without a change in A1c. There were no differences in hypoglycemia fear behavior, worry scores or diabetes distress; however, patient satisfaction with treatment significantly improved and perception of hypo- and hyperglycemia improved with CGM (21).	

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know		The panel commented that if studies were to be done today, with apps that allow customizing alert settings for example, the data would likely be different. Alerts and alarms are annoying, embarrassing and disruptive; glucose values every 5 minutes (288 values per day) may be overwhelming. These issues can be mitigated by proper training/education. Also, alarm thresholds can be customized to minimize their impact; e.g., a patient with poor glucose control can have the high threshold set at 300 mg/dL or higher, whereas, the person with well controlled diabetes may choose a high threshold of 200 mg/dL.

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ● Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	**Cost of continuous glucose monitoring systems as well as fingerstick blood glucose monitoring (SMBG) varies considerably depending on the specific device used and, for SMBG, the daily frequency of blood glucose measurements.**	Cost is moderate with insurance coverage, and much larger without coverage.

	Commercial Insurance	Medicare	Medicaid	No Insurance Self pay
FreeStyle Libre*	$0-75**	80% coverage†	Varies by state§	$65 + tax; reader $85
Dexcom G6	$0-79**	80% coverage†	Varies by state§	~$360; ~$85 per transmitter***
Medtronic Guardian¶				

*one month supply; **depends on insurance plan coverage, cost to the patient (copay) depends on the contracted arrangement between the insurance company and Abbott. For Dexcom these represent copay amounts for patients obtaining product through the pharmacy channel. One-third of patients pay $0 per month out of pocket and ~70% pay less than $60 per month. Patients covered via Durable Medical Equipment benefit have out of pocket costs that vary according to their respective plans and deductible progress.
†For FreeStyle Libre, if government criteria are met for CGM (diagnosis of T1D or T2D, ≥3 injections of insulin per day or insulin pump, fingersticks 4x per day, meeting with healthcare provider a minimum of every 6 months. If patient has a secondary plan, this may cover the remaining 20%. For Dexcom, if government criteria are met for CGM (diagnosis of T1D or T2D, ≥3 injections of insulin per day or insulin pump, fingersticks 4x per day, meeting with healthcare provider a minimum of every 6 months. If patient has a secondary plan, this may cover the remaining 20%. Monthly supplies of Dexcom G6 sensors are covered as a subscription for eligible Medicare customers, according to the DME schedule assigned for Class II real-time CGMs. The 20% copay is approximately $45 per month for the patient.
§In Massachusetts, MassHealth (Medicaid) covers FreeStyle Libre and Dexcom G6 with the same criteria as Medicare; copay is <$10 per month for 2 FreeStyle Libre sensors or 3 Dexcom Sensors (one-month supply)

***Represents the approximate average monthly cost of a 90-day transmitter.
¶ Personal communication with Robert A. Vigersky, MD, Chief Medical Officer, Global Medical and Clinical Affairs, Medtronic: “a range of typical cost of sensors - $2,500-$3,000 per year ... the actual cost will differ according to the insurance plan that a

patient has."
The Medtronic Guardian™ Sensor 3 can be worn for up to 7 days. The price listed on the Medtronic website is $608.30 for a box of 5 sensors.
Although CGM can replace BG monitoring (22) for making insulin dosing decisions, it is recommended that when sensor glucose values are not consistent with the patient's symptoms (or do not make sense), the value should be confirmed with a fingerprick blood glucose measurement. Accordingly, people with diabetes who manage their diabetes with CGM should have a glucose meter and blood glucose test strips available for backup.

Cost of a representative sample of blood glucose meters and test strips

	Cost of meter $	Cost per strip $**	Annual cost of strips†
Accu-Chek Guide Care Kit*	28.74	0.48-0.60	876-1,095
Contour Next meter system	18	1.32	2,409
Freestyle Lite meter	18	1.68-1.74	3,066-3,176
One Touch Verio Flex meter system	21.60	0.82	1,497
Prodigy Autocode Talking glucose meter	9.94	0.45	821

* Includes blood glucose meter, Accu-Chek Fastclix Lancing Device with 6 lancets; **cost per strip varies according to number of strips per package (lower cost per strip for larger package); †based on the assumption of blood glucose measurements 5 times daily
Source: AmerisourceBergen Corporation. (n.d.). *Drug Catalog*. ABC Order. Retrieved March 25, 2021, from https://abcorder.amerisourcebergen.com/

Resources required may depend on the particular CGM system used, as well as patient-specific factors.

- Cost estimates vary considerably depending on the specific details of the individual's insurance coverage.
- Some CGM systems require calibration via fingerprick capillary blood glucose measurement every 12 hours which leads to increased costs (for blood glucose testing supplies).
- Although CGM can replace BG monitoring (22) for making insulin dosing decisions (non-adjunctive dosing), it is recommended that when sensor glucose values are not consistent with the patient's symptoms (or do not make sense), the value should be confirmed with a fingerprick blood glucose measurement. Accordingly, people with diabetes who manage their diabetes with CGM must have a glucose meter and blood glucose test strips available for backup.
- This part would fit best under feasibility, and perhaps acceptability if the intermittent replacement is an issue that would impact how acceptable patients find the devices.

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies		People with diabetes who use CGM must have a blood glucose meter and use it to measure BG in certain circumstances; i.e., CGM does not completely replace the need for SMBG.

Cost effectiveness

Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ No included studies	**There is limited data regarding cost-effectiveness regarding current CGM systems, though what is available suggests that these systems are cost-effective** • A **cost-effectiveness analysis** of data from the DIAMOND study of adults with T1D using MDI with suboptimal glycemic control showed that CGM was cost-effective at the willingness-to-pay threshold of $100,000 per quality adjusted life year (QALY), with improved glucose control and reductions in non-severe hypoglycemia. In a lifetime analysis, CGM was projected to reduce risk of diabetic complications and increase QALY by 0.54. The incremental cost-effectiveness ratio (ICER) was $98,108 per QALY for the overall population. By extending sensor use from 7 to 10 days, the ICER was reduced to $33,459 per QALY (23). • In a cost-effectiveness study funded by Dexcom (manufacturer of the Dexcom CGM system), Chaugule and Graham used treatment effects and baseline characteristics of adult patients in the DIAMOND RCT; all other assumptions and costs were obtained from published research. The lifetime analysis showed that the Dexcom G5 mobile was cost-effective in adults with T1D using MDI assuming a Canadian willingness to pay threshold of $50,000 CAD per QALY. The incremental cost-effectiveness ratio for the base case G5 Mobile CGM vs SMBG was $33,789 CAD per quality-adjusted life year (QALY). Sensitivity analyses showed that base case results were most sensitive to changes in percent reduction in hypoglycemia events and disabilities associated with hypoglycemia events. Base case results were only minimally impacted by changes in baseline HbA1c, incorporation of indirect costs, changes in discount rate and baseline utility of patients. Base-case Dexcom G5 was associated with an improvement of 3.35 QALYs compared to SMBG alone in adults with T1D receiving MDI (24). • It must be noted that the cost-effective analyses cited above were based on the use of earlier versions of the Dexcom CGM system that was less accurate than current sensors, required calibration, and had a duration of use of only 7 days. No cost-effectiveness data are available for other CGM systems.	The panel noted that the available data do not reflect newer versions of CGM. It is relatively easy to compare direct costs of CGM vs SMBG for a year. It is much more challenging to measure long-term cost-effectiveness, which would include: 1. Reduction of episodes of severe hypoglycemia and attendant costs (ambulance, evaluation and treatment in an Emergency Room, hospitalization); impact on improved glycemic control and resulting reduction of long-term complications, improved long-term health and productivity, etc.

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ● Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	**The impact on health equity would be significantly influenced by access, insurance coverage and out of pocket cost for CGM.** If health insurance coverage for CGM for all people with type1 diabetes who desire to use this method of glucose monitoring were not available, healthy inequity would be exacerbated. Moreover, only partial coverage will result in significant out of pocket cost to the user such that persons with diabetes without adequate personal resources will not be able to afford the out of pocket expense. • It should be noted that participants in the DIAMOND Study conducted in the USA were racially homogenous; the majority were non-Hispanic white with high levels of education (15, 16). • The GOLD study was performed in Sweden, which has a national health service that provides CGM and glucose test strips. • Use of CGM in increasing 10 fold, however, racial disparities were present in CGM use across all age groups (including in children) (25).	The panel noted that lack of access is the main issue. The cost of CGM, not the intervention itself, would limit access to the technology and probably lead to reduced equity. Internet access is not, per se, a requirement for CGM use, but is required to upload and share CGM data with diabetes care providers.

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	**This intervention is likely acceptable to key stakeholders.** • Earlier versions of CGM were difficult to use, required multiple daily calibrations, and management decisions could not be based on glucose values obtained from CGM (i.e., a confirmatory fingerstick blood glucose measurement was required). • Improvements in CGM technology over the last decade, as well as evidence for clinical efficacy and increased usability led to FDA approval for nonadjunctive use of CGM. • The tremendous increase in use of CGM, both real-time and intermittently scanned, has been well documented in countries where the technology is available and insurance coverage makes it affordable, suggesting that the newest, improved CGM devices are acceptable to large numbers of people with diabetes. The increased use of CGM has been observed across all ages and most especially in young children (26, 27). • In the DIAMOND study (performed using Dexcom G4 that required twice daily calibration and was not approved for nonadjunctive use), satisfaction with CGM was high with perceived benefits common and perceived hassles relatively rare. CGM satisfaction was not significantly associated with glycemic changes but was associated with reductions in diabetes distress and fear of hypoglycemia, and increases in hypoglycemia confidence and well-being (16). • In a small study of CGM (Dexcom G4) use in elderly people with well-controlled diabetes, investigators found a high degree of satisfaction without imposing additional diabetes distress and subjects reported improved sleep quality (28). • In the GOLD study (performed using Dexcom G4 Platinum that required twice daily calibration and was not approved for nonadjunctive use), time of CGM use averaged 87.8%; and mean frequency of daily BG checks decreased to 2.75 during CGM compared to 3.66 during conventional therapy (17). • Satisfaction with CGM use was high; mean score 4.2 on CGM Satisfaction Survey; mean score 4.2 on benefits subscale and 4.3 on subscale for lack of hassles. The CGM group reported significantly higher glucose monitoring satisfaction (Glucose Monitoring Satisfaction Survey score); at 26-weeks, 0.27 (95%CI: 0.06-0.54). CGM satisfaction was not significantly associated with glycemic changes but was associated with reductions in diabetes distress and hypoglycemia fear and increases in hypoglycemia confidence and well-being. • The REPLACE-BG study (Dexcom G4 Platinum CGM System with an enhanced algorithm (Software 505) showed that use of CGM without regular use of confirmatory BGM is as safe and effective as using CGM with BGM in adults with well controlled T1D using an insulin pump at low risk for severe hypoglycemia (22). Despite the demonstrated benefits of CGM, there are individuals with diabetes who do not want a medical device attached to their bodies.	Acceptability with newer systems has improved: greater accuracy, longer duration of use, and either no calibration or less frequent calibration required than earlier CGM systems that are now obsolete. The panel considered that a minority of patients may not want to be attached to a device (e.g. adolescents considering body image with device use.) There is also the cost of environmental impact to consider, in that CGM would have less detrimental impact.

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	**The intervention is feasible to implement, though insurance coverage is a major determinant of its use.** • Depending on the specific CGM system being used, the life of glucose sensors varies from 7-14 days (an implantable sensor must currently be replaced after 90 days) and a transmitter that must be intermittently replaced. If the user has a smartphone, this can be used as a receiver. Without a compatible smart phone, the system also requires a receiver. • A recent report from the Type 1 Diabetes Exchange registry showed that use of CGM increased from 7% in 2010-2012 to 30% in 2016-2018, with an exponential increase in use beginning between 2013 and 2014. The use of CGM in children increased more than 10-fold. It must be noted that the Type 1 Diabetes Exchange registry is not population based. All the participants in the registry were treated at endocrinology centers that focus on the care of patients with T1D. • A major determinant of CGM use is insurance coverage. • Assuming that access to CGM is not a barrier, implementing current CGM systems is relatively simple and is not associated with great pain or discomfort. • Reimbursement for CGM continues to be a challenge and varies across countries, states, regions and insurance companies.	Alarm settings are adjustable and customizable with newer devices. Access to the devices is a key issue for implementation.

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	**Trivial**		Varies	Don't know

CERTAINTY OF EVIDENCE	Very low	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	**Moderate costs**	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	**Low**	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	No included studies
EQUITY	Reduced	**Probably reduced**	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	**Strong recommendation for the intervention**
○	○	○	○	●

CONCLUSIONS

Recommendation

We recommend CGM rather than SMBG for patients with T1D receiving multiple daily injections. (strong recommendation, low certainty of evidence) (1⊕⊕◯◯)

Remarks:

- Appropriate patient education on how to use CGM devices and interpret the data is critical.
- SMBG continues to be necessary to validate or confirm CGM values; therefore, with respect to use and insurance coverage there will be times where SMBG must be used.

Justification

The panel issued a strong recommendation based on low certainty of evidence, given the balance of effects and placing high value for reducing hypoglycemia and improving glycemic control. The considered having an episode of severe hypoglycemia to be a life-threatening situation. The panel considered that for the vast majority of patients with Type 1 diabetes receiving multiple daily injections CGM is recommended. The recommendationo will apply for anyone with Type 1 diabetes and even more strongly for patients with impaired hypoglycemia awareness or hypoglycemia unawareness, fear of hypoglycemia, or young children who have functional hypoglycemia unawareness with parents having fear of nocturnal hypoglycemia. .

Another aspect not captured in published studies, but noted by the panel, is knowing the direction and rate of change of blood glucose, which helps patients with Type 1 diabetes make more informed management decisions. Trend arrows enable the CGM user to predict glucose level in the next 30 minutes.

Subgroup considerations

None

Implementation considerations

Many CGMs require that finger sticks are still used to validate CGM, therefore with respect to use and coverage (e.g. private insurers) there will be times when SMBG will still need to be used. (e.g. during the warm up period, for calibration, as a back-up when there is loss of sensor signal)

Real-time and intermittently scanned CGM are both available. For Type 1 diabetes the panel noted that real-time CGM would be safter over intermittently scanned CGM for monitoring and detection of hypoglycemia, especially during sleep.
Education on how to use the devices and interpret the data is required for individuals to gain familiarity with the tools. Monitoring and communication with diabetes specialists are still quite important with use of CGM and algorithm driven pumps, and there is a need for diabetes educators to be up to speed on available technologies.

Monitoring and evaluation

None.

Research priorities

Studies with newer versions of the devices.

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