Considerations on the use of CGM within type 2 diabetes

The use of CGM within type 2 diabetes is increasing. Dexcom ONE+ is Dexcom's product for this patient group, but the IFU (Instructions For Use) for the product states only indications and functionality. Hence, evidence and additional considerations on the use of CGM, including Dexcom ONE+, for type 2 diabetes is not covered by that information. Instead, Nordic Infucare has summarized relevant evidence and perspectives.

Effects

Several studies have investigated the effects of CGM in people with type 2 diabetes (T2). The main focus of these studies has been effects on glycemic control (HbA1c, time in range (TIR)). Here we highlight a recent Nordic study but several others exist.

In the Steno2tech study, a Danish randomized controlled trial (RCT) published in 2024, people with T2 with HbA1c > 58 mmol/mol and treated with basal or basal and meal insulin were given a CGM for 12 months. Their outcomes and changes from baseline were compared with those of a control group using blood glucose meters (BGM/fingerstick). The participants were to a large extent treated with modern pharmacological approaches like GLP-1 receptor antagonist and SGLT inhibitors, in addition to insulin.[1]

Time in range (3.9-10 mmol/l) improved for the CGM group but not for the BGM group, and the effect was sustained during the 12 months of the study. The same was the case for HbA1c, as the CGM group reduced 9.4 mmol/mol more in HbA1c compared with the BGM group after 12 months.[1]

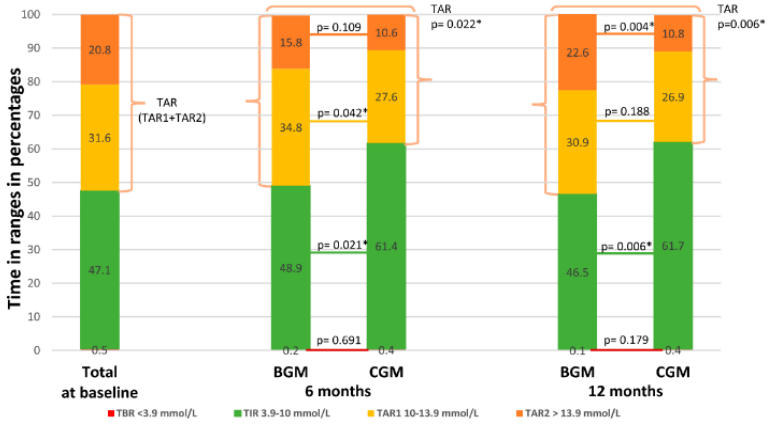


Figure 1—TIR, TAR, and TBR over the study period.

Figure from Lind et al., 2024[1]

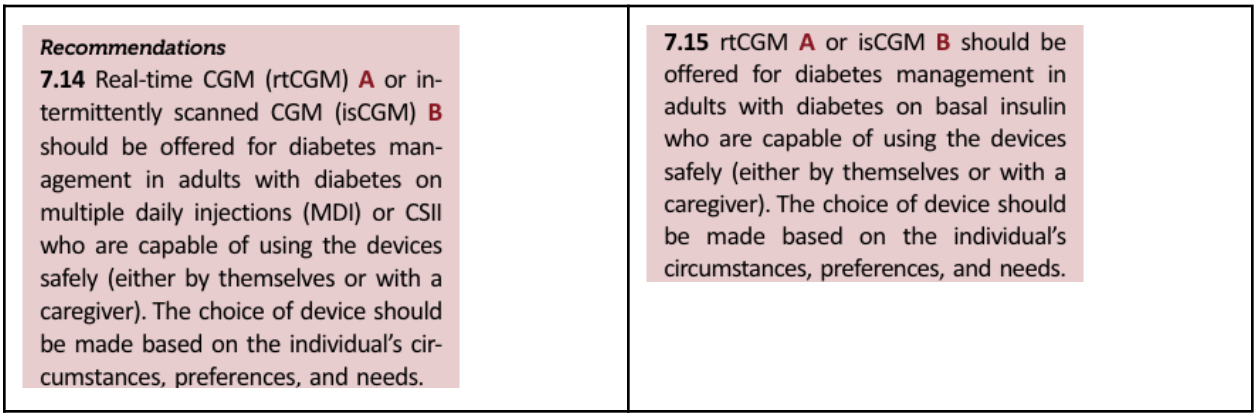
[1] *Lind et al, 2024: Comparing Continuous Glucose Monitoring and Blood Glucose Monitoring in Adults With Inadequately Controlled, Insulin-Treated Type 2 Diabetes (Steno2tech Study): A 12-Month, Single-Center, Randomized Controlled Trial.* Available on https://diabetesjournals.org/care/article-lookup/doi/10.2337/dc23-2194

Also self-reported general health, diabetes distress and treatment satisfaction were significantly improved in the CGM group compared with the BGM group.[1]

Recommendations

There are different guidelines and recommendations on the use of CGM for type 2 diabetes in different countries.

The consensus from the American Diabetes Association in their latest (2024) Standards of Care publication is, that CGM should be considered as part of the treatment for all insulin treated T2, independently on HbA1c levels and insulin regimen[2]. They grade the evidence for this recommendation as level A (best possible evidence) for real-time CGM. The recommendation is *not* specific to certain HbA1c levels.



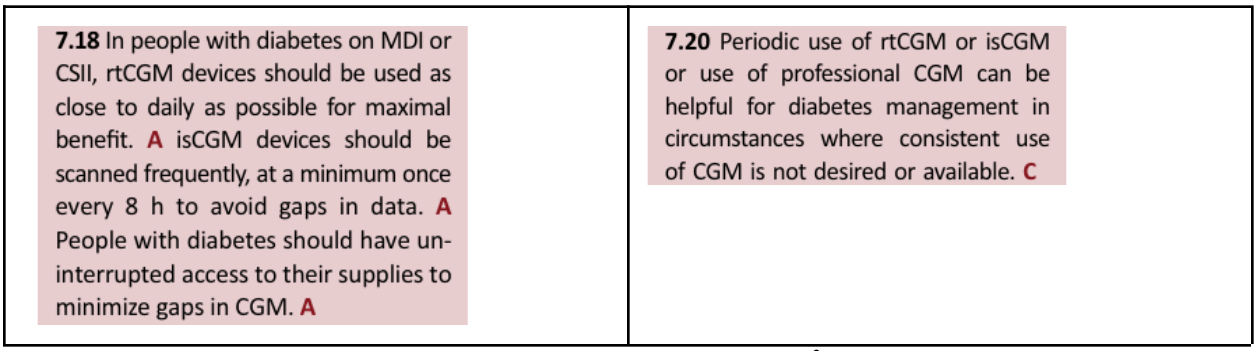
Recommendations

7.14 Real-time CGM (rtCGM) **A** or intermittently scanned CGM (isCGM) **B** should be offered for diabetes management in adults with diabetes on multiple daily injections (MDI) or CSII who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.

7.15 rtCGM **A** or isCGM **B** should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.

Screendumps from American Diabetes Association Standards Of Care 2024[2]

In the consensus, CGM is recommended for consistent/full time use, and the evidence is graded to level A. Periodic CGM use for those on MDI is recommended only if consistent/full-time CGM use is not possible, and the evidence is graded lower than for consistent/full-time use.



7.18 In people with diabetes on MDI or CSII, rtCGM devices should be used as close to daily as possible for maximal benefit. **A** isCGM devices should be scanned frequently, at a minimum once every 8 h to avoid gaps in data. **A** People with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM. **A**

7.20 Periodic use of rtCGM or isCGM or use of professional CGM can be helpful for diabetes management in circumstances where consistent use of CGM is not desired or available. **C**

Screendumps from American Diabetes Association Standards Of Care 2024[2]

[2] *American Diabetes Association Professional Practice Committee, 2024: 7. Diabetes Technology: Standards of Care in Diabetes—2024.* Available on https://diabetesjournals.org/care/article/47/Supplement_1/S126/153939/7-Diabetes-Technology-Standards-of-Care-in

Health economics

Some treatments save more money than they cost, and are thus *cost-saving*. That is, however, rarely the case in healthcare, so instead, the cost versus the value is assessed, i.e. whether they are *cost-effective*. The two terms cost-saving and cost-effective must thus not be confused or used interchangeably.

Studies on health economic perspectives of CGM in T1 as well as T2 mainly consider the latter, i.e. costs/savings of CGM as a treatment and the costs/savings in use of healthcare relating to diabetes complications (acute and long-term) and compare the costs/savings with "how much health" is gained by using CGM. One very extensively used measure for "gained health" is the standardized measure of health-related quality of life (QALY - Quality Adjusted Life Years), quantifying how much different aspects of disease, disability and treatment components reduce quality of life, compared with living with perfect health, and it incorporates both life length and quality of that life. Usually, the cost of winning a quality adjusted life year with CGM is compared with an amount of money that is generally accepted as fair to pay, the so-called "willingness to pay". The TLV in Sweden has been found to generally accept costs up to 200.000 SEK to win a QALY in diseases with low severity and up to 600.000 in diseases with medium severity[3]. Diabetes is generally considered "severe", i.e. above the severity levels mentioned, and the willingness to pay is then generally higher. In the UK, CGM is found to have additional costs per QALY around 1100-9700 GBP depending on calculation assumptions (15.000-131.000 SEK)[4].

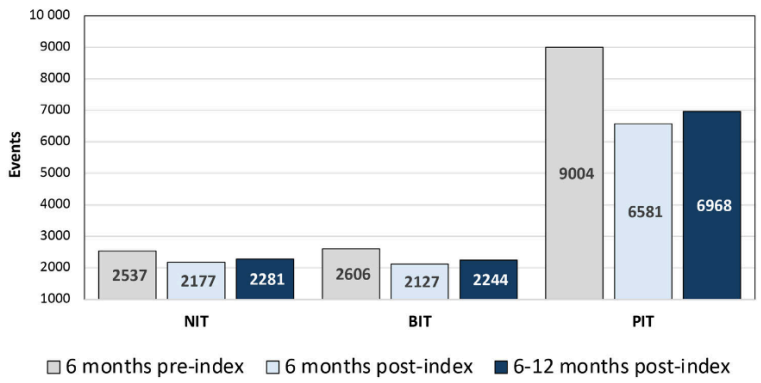
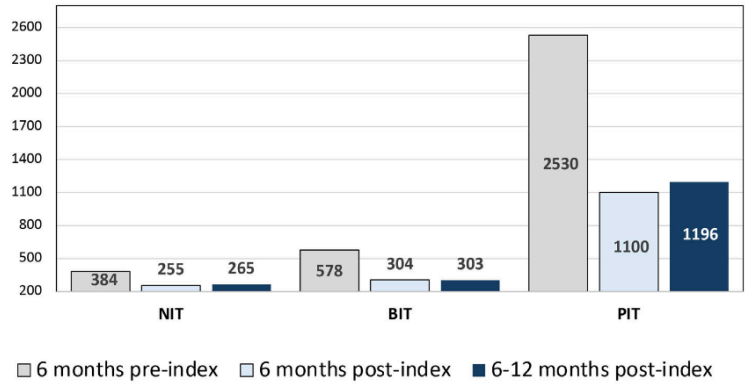
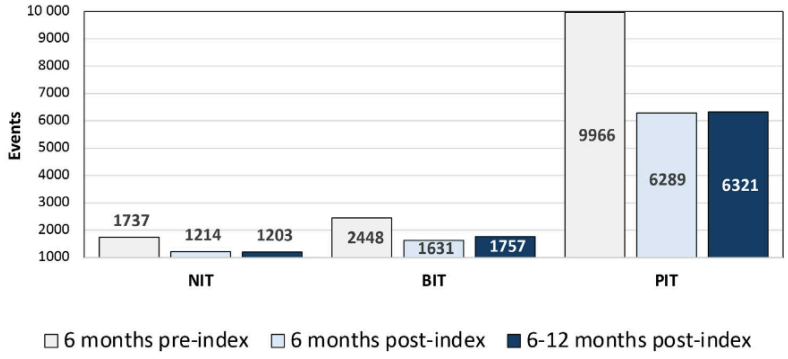
With such health economic analyses, there is a long time-perspective; usually minimum a decade but often as much as 50 years. This means that future savings, despite evident in a 20, 30 or 50 years perspective, are difficult to fund in the current situation - you can't pay for technology today, with money you will save in 20 years!

Another approach to health economics is therefore to assess the impact on budgets on an annual level, often for a specific clinic or entity (for instance a healthcare region) in the healthcare system. This type of analysis mainly looks at costs/savings of CGM and costs/savings for treating acute complications as well as non-diabetes related healthcare use. CGM generally reduced both hospitalizations and emergency room visits; below is an example of findings from a recent study comparing figures on hospitalizations and emergency room visits before CGM initiation with after CGM initiation[5]:

[3] *Viollet et al 2022, Willingness to Pay for Different Severity Levels in Sweden: An Analysis of TLV Decisions (2014-2022)*, available on https://quantifyresearch.com/wp-content/uploads/2024/01/WTP-for-Different-Severity-Levels-in-Sweden-TLV-Decisions-2014-to-2022_Quantify-Research.pdf

[4] *Isitt et al 2022, Cost-Effectiveness of a Real-Time Continuous Glucose Monitoring System Versus Self-Monitoring of Blood Glucose in People with Type 2 Diabetes on Insulin Therapy in the UK,* available on https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9663778/

[5] *Garg et al, 2024: Impact of continuous glucose monitoring on hospitalizations and glucose control in people with type 2 diabetes: real-world analysis,* available on https://dom-pubs.pericles-prod.literatumonline.com/doi/epdf/10.1111/dom.15866

All-cause hospitalizations (including but not limited to Acute diabetes-related hospitalizations as per figure B below)	(A) 
Acute diabetes-related hospitalizations	(B) 
Acute diabetes-related emergency room visits	(C) 

Figures from Garg et al, 2024[5]. NIT=non-insulin therapy (n=25269), BIT=basal insulin therapy (n=16264), PIT=basal+prandial insulin therapy (n=33146).

Publications also suggest that use of primary care (general practice visits) is reduced for insulin-treated T2 when using CGM, compared with fingerstick[6].

Results like these underline that there is a big risk of mismatch between the entities doing the investments and the entities that get the savings, i.e. that the entities who have to invest in CGM for T2 will not benefit from the savings, even though they are evident even in the short run.

Furthermore, health economic analyses and budget impact analyses do not in general take into account the lost work productivity for the patient and relatives, that is the consequence of complications to diabetes, and also the lost tax payments due to this lost work productivity is omitted. This is because 1) it is very difficult to quantify, and 2) generally assessing health economics with a strong focus on productivity will favor spending money on treatment of people with current and potentially future ability to work, which goes against generally accepted principles of equity and same value of all persons, independently on the ability to work or not.

Impact of CGM system on feature use

Different CGM systems work differently and offer different functionality, but little research has been done to compare the effect of switching from one system to another in people with T2. In T1, several switch studies exist. One of the latest switch studies on T1 compares switching from Freestyle Libre 2 (isCGM) to Dexcom G7 (rtCGM) in a service evaluation (real-world evidence setting) in the UK[7]. Differences between the two CGM systems include the opportunity to select your own alert signals (including “vibrate only”), the opportunity to snooze for a user-specified period of time, and for the high alert also the “delay first high” for a user-specified time.

There was a substantial increase in the proportion using the low alert, and the proportion using the high alert was more than doubled.

N=28	Freestyle Libre 2	Dexcom G7	p-value
Proportion using low alert	50.0%	93.1%	*p<0.001*
Proportion using high alert	37.0%	82.8%	*p<0.001*

Table with results from Preechasuk et al, 2024 (on people with type 1 diabetes)[7]

Summary

There is strong evidence for the beneficial effects of CGM in people with type 2 diabetes. There is also consensus in the American Diabetes Association that CGM should be considered as part of the treatment for all insulin treated T2, independently on HbA1c levels and insulin regimen.

[6] *Alsaif et al 2024: Budget impact analysis of continuous glucose monitoring in individuals with type 2 diabetes on insulin treatment in England*, available on https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11071237/).

[7] *Preechasuk et al, 2024: Switching from Intermittently Scanned Continuous Glucose Monitoring to Real-Time Continuous Glucose Monitoring with a Predictive Urgent Low Soon Alert Reduces Exposure to Hypoglycemia*, available on https://www.liebertpub.com/doi/epdf/10.1089/dia.2023.0434

CGM is associated with less healthcare use, but it is not necessarily the clinic or entity that pays for CGM that will also win in terms of healthcare use reductions, despite CGM generally being less costly than accepted for many other kinds of treatment, compared with the effects. Little is known about the results from different CGM systems, but at least in T1 there is a difference in the use of alerts and these results may also translate to T2.

Version 1.3, Sept 25, 2024.

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Dexcom ONE+ is CE-marked according to MDR (EU) 2017/745.

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