

Continuous glucose monitoring for the routine care of type 2 diabetes mellitus

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Abstract

Although continuous glucose monitoring (CGM) devices are now considered the standard of care for people with type 1 diabetes mellitus, the uptake among people with type 2 diabetes mellitus (T2DM) has been slower and is focused on those receiving intensive insulin therapy. However, increasing evidence now supports the inclusion of CGM in the routine care of people with T2DM who are on basal insulin-only regimens or are managed with other medications. Expanding CGM to these groups could minimize hypoglycaemia while allowing efficient adaptation and escalation of therapies. Increasing evidence from randomized controlled trials and observational studies indicates that CGM is of clinical value in people with T2DM on non-intensive treatment regimens. If further studies confirm this finding, CGM could soon become a part of routine care for T2DM. In this Perspective we explore the potential benefits of widening the application of CGM in T2DM, along with the challenges that must be overcome for the evidence-based benefits of this technology to be delivered for all people with T2DM.

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Introduction

The most-recent guidelines for treating adults with type 2 diabetes mellitus (T2DM)¹, published in 2022, emphasize the importance of diabetes mellitus self-management education and support (DSMES) to promote healthy behaviours regarding weight management, tobacco and substance use, adequate physical activity and appropriate management of mental health conditions². These healthy behaviours can lead to improved glycaemic and psychosocial outcomes in people with T2DM^{3–5} but DSMES goals are also important for optimization of pharmacological treatment strategies in T2DM⁶. Pharmacotherapy in T2DM typically starts with non-insulin medications, primarily as oral therapeutics, such as metformin, sodium–glucose cotransporter 2 inhibitors (SGLT2i), dipeptidyl peptidase 4 inhibitors and injectable glucagon-like peptide 1 receptor agonists (GLP1RAs). These medications are initially utilized as monotherapy then combination therapies, before moving to basal insulin for daily glucose control and subsequently progressing to multiple daily injections (MDI) if necessary. MDI involves adding rapid-acting bolus insulin at mealtimes to control postprandial glucose (PPG) excursions after eating, or using pre-mixed insulins, as well as daily basal insulin injections¹. This latter MDI stage is termed intensive insulin therapy, which can also be managed in T2DM using a continuous subcutaneous insulin infusion (CSII) pump¹. Each treatment intensification step can lead to improved glycaemia, as measured by a decrease in HbA_{1c} and other benefits, such as weight loss, which contribute to reducing the risk of microvascular complications and long-term macrovascular disease^{7–9}. Therefore, DSMES is important at every step of diabetes mellitus management and not just during the early stages of T2DM.

Despite these evidence-based treatment strategies, the majority of people with T2DM throughout the world do not achieve the recommended HbA_{1c} glycaemic targets^{10,11}. The landmark UK Prospective Diabetes Study (UKPDS) has shown that early intensive glycaemic control that starts at the time of diagnosis of T2DM, is associated with sustained reductions in risk of myocardial infarction and death from any cause, compared to a comparator group on conventional treatment, in addition to reductions in the risk of microvascular disease^{8,12}. A retrospective cohort analysis of 105,477 people with newly diagnosed T2DM in the UK concluded that a 1-year delay in treatment intensification in people with HbA_{1c} >7.5% was associated with a 67% increase in the risk of myocardial infarction, a 51% increase in the risk of stroke and a 64% increase in the risk of heart failure, compared to those who received timely treatment intensification¹³. Early glycaemic control is therefore critical for long-term prevention of complications in people with T2DM.

The inadequate achievement of glycaemic goals in T2DM, particularly in the early stages of pharmacotherapy, are known to be related to non-adherence with treatment by individuals with T2DM¹⁴ and to therapeutic inertia, defined as failure to initiate or intensify therapy in a timely manner^{15–18}. Although guidelines for T2DM recommend a change of therapy if HbA_{1c} targets are not met or if HbA_{1c} is not stable after 3–6 months^{19,20}, the observed times to treatment intensification reported across international studies are measured in years rather than months²¹. From a health outcomes standpoint, such delayed treatment intensification is linked to a high incidence both of microvascular and macrovascular disease in T2DM^{13,22}, as well as substantially increased direct and indirect costs of diabetes mellitus complications^{23,24}. Therefore, early intensification of glycaemic therapies must be a priority in the treatment of people with T2DM.

To date, self-monitoring of blood glucose (SMBG) using fingerstick testing is still recommended to help most people with T2DM to make

daily decisions on self-management and medication adjustment¹. SMBG testing is safe and accurate, it can be performed reasonably quickly and has a relatively low cost per test. However, many people with T2DM experience difficulty integrating SMBG into their daily life with T2DM, for reasons related to the physical and psychological burden of SMBG testing^{25,26}. Moreover, SMBG testing can be particularly cumbersome for people with comorbidities, such as severe arthritis or Parkinson disease. In addition, lack of appropriate understanding how SMBG readings can be used to interpret the effect of diet and lifestyle activities and the limited glucose information provided (that is, it does not indicate whether blood levels of glucose are rising or falling), coupled with patient fear of hypoglycaemia and inadequate access to health-care support, can make therapy escalations that are intended to improve glycaemic control hard to accomplish. Continuous glucose monitoring (CGM) can overcome most of these barriers to treatment intensification and are therefore likely to be a more effective tool than SMBG during therapy escalations.

Given the success of CGM in optimizing glycaemia in T1DM, the role of this technology in the management of T2DM should be fully explored. It has been known since 2007 that using CGM in people with T2DM reveals critical abnormalities in glycaemic homeostasis, including the early-morning hormone-induced spikes in blood levels of glucose known as the dawn phenomenon, high postprandial glycaemic excursions and extensive short-term glycaemic variability^{27–32}. The available evidence now indicates that each of these can be proactively monitored and mitigated using CGM. However, it is unlikely that a prospective randomized controlled trial (RCT) on the scale, duration and cost of the UKPDS will be implemented to fully explore the effect of using CGM compared with a SMBG control arm in T2DM. Therefore, we review here the glycaemic effects of CGM in T2DM in smaller RCTs and larger real-world studies, both prospective and retrospective, and also assess the effect of CGM on quality of life (QoL), treatment satisfaction and behavioural changes, in order to provide an expert perspective on the use of CGM in the heterogeneous population of individuals with T2DM, wherever they are treated.

Glucose dysregulation in T2DM

It is clear that T2DM exhibits substantial heterogeneity. Nonetheless, there exist common characteristics that outline the typical natural history of individuals with T2DM and the glycaemic difficulties they encounter, which are outlined below.

The dawn phenomenon

The dawn phenomenon is a consequence of hepatic glucose production overnight that reaches a peak towards the end of an overnight fast²⁸. It can result in high early-morning fasting plasma levels of glucose and abnormally high and delayed PPG excursions after eating breakfast (the ‘extended dawn phenomenon’)²⁷. In people with T2DM, the dawn phenomenon is estimated to contribute 0.4% to HbA_{1c} levels³¹ and is an early manifestation of dysglycaemia in T2DM, even when HbA_{1c} and PPG levels are within normal ranges³³. Use of CGM in people with T2DM can help to profile the dawn phenomenon to minimize its effect on PPG excursions at breakfast and on daily glucose levels.

Postprandial glucose excursions

PPG excursions contribute 70% to overall hyperglycaemia in individuals with T2DM³⁴ and 50% of all glycaemic variability. In people with T2DM and low HbA_{1c} levels (<7.3%), about 70% of their elevated glycaemic exposure above normal levels is due to PPG, with this contribution

decreasing as HbA_{1c} levels rise, such that in people with the highest HbA_{1c} levels (>10.2%), PPG contributes around 30% of the elevated glycaemic exposure, with PPG making up about 70%³⁵. PPG contributes approximately 1% of the overall hyperglycaemia measured by an HbA_{1c} test result in people with T2DM, regardless of their total HbA_{1c} level³⁶. The application of CGM in T2DM can help to visualize and mitigate PPG fluctuations in ways that are not possible using SMBG testing.

Risk of hypoglycaemia

In individuals with T2DM, the risk of hypoglycaemia depends on both their daily mean blood glucose concentration³⁷ and their short-term glycaemic variability within each day^{37–39}. To minimize the risk of hypoglycaemia in T2DM and achieve a time below range in hypoglycaemia of <3.0 mmol/l (54 mg/dl) target of <1% of readings each day⁴⁰, it is important that glycaemic variability, as measured by coefficient of variation over the observation period, remains <30% of the mean glucose concentration^{39,41}. Use of CGM can enable people with T2DM to maintain mean glucose levels at a level that minimizes the risk of low blood levels of glucose and to mitigate glycaemic variability across the day.

Glycaemic variability

Short-term glycaemic variability, as defined by CGM-derived metrics, has been linked as an independent risk factor to the development of cardiovascular disease over a 10-year period in people with T2DM⁴² and with major adverse cardiac events in people with T2DM⁴³, particularly in high-risk populations with acute coronary syndrome⁴⁴. In cross-sectional studies in the context of microvascular disease in T2DM, CGM-defined glycaemic variability has been linked with deterioration in renal function⁴⁵, diabetic retinopathy⁴⁶ and neuropathy^{47–50}. Using CGM can help to identify patterns of glycaemic variability, allowing people with T2DM and health-care professionals (HCPs) to take action to reduce them.

CGM in adults with T2DM: a proposal

CGM offers the opportunity to transform health outcomes and QoL in people with T2DM, a view that is supported by a growing body of evidence. However, this opportunity is accompanied by substantial challenges that highlight the need for a paradigm shift in the health care of people with T2DM. Such a shift should better support the empowerment of people with T2DM and enable them to take full responsibility for their own long-term health, within the scope of what is feasible as part of daily self-management. This paradigm shift will emphasize the available digital health tools and the role of telemedicine in diabetes mellitus care, which began on a large scale during the COVID-19 pandemic^{51,52}.

Given the undisputed benefits of early glycaemic control and the progressive nature of T2DM, we believe that health-care services must be driven by dual guiding principles: to optimize glycaemia early and to act immediately if deterioration occurs. The application of CGM technology makes this combined goal realistic, allowing people with T2DM to engage better with their condition and take responsibility for day-to-day diabetes mellitus decisions, and for HCPs to take timely steps to escalate or de-escalate therapy to optimize glycaemic management.

To date, CGM systems have been designated as either real-time CGM (rtCGM) or intermittently scanned CGM (isCGM). The key difference is that rtCGM systems automatically transmit glucose values from the glucose sensor to a receiver or smartphone, whereas isCGM systems require users to scan their glucose sensor with the receiver or smartphone to get their up-to-date glucose readings and the associated

trend arrows that show the direction and rate of glucose change at any point⁵³. For isCGM systems, users are required to scan at least once every 8 h to ensure complete glycaemia data capture. In contrast to rtCGM systems, first-generation isCGM systems do not have an alarm function to alert users to high or low glucose levels, whereas second-generation isCGM systems do include optional alarms. The accuracy and efficacy of both types of sensors in T2DM has been proven (Table 1). Given the evolving nature of CGM technology and the adaptation in 2023 of the FreeStyle Libre 2 isCGM device to allow constant streaming, we will use the term 'CGM' to refer to both types of system, unless it is necessary to differentiate between them.

A number of RCTs and real-world studies have shown that the use of CGM in people with T2DM on intensive insulin therapy with MDI is associated with lower HbA_{1c} coupled with reductions in hypoglycaemia, compared with the use of SMBG^{54–57}. Other RCTs and real-world studies have demonstrated that CGM is associated with reductions in HbA_{1c} in people with inadequately controlled T2DM treated with basal insulin only^{58–61} or with non-insulin therapies, compared with the use of SMBG^{61–63}. These reductions are achieved early, within 3–6 months of starting CGM, with the benefits reversed if CGM is discontinued⁶⁴. Notably, the use of CGM in people with T2DM on basal insulin therapy or non-insulin therapies is also associated with statistically significant reductions in clinical outcomes such as hospitalization for diabetic ketoacidosis or severe hypoglycaemia^{65,66}. A retrospective analysis of large health-care claims datasets indicated that CGM in T2DM is associated with more timely treatment intensification compared with SMBG⁶⁷. It is not possible from these data to know whether CGM is associated with reduced reluctance of people with T2DM to intensify therapy and start insulin or whether the use of CGM gives the physician confidence to make more timely decisions on treatment escalation. Although therapeutic inertia is a consequence of multiple factors^{21,68–70}, fear of hypoglycaemia is known to slow therapy escalations^{71,72}. This finding is not surprising given the association between hypoglycaemia and adverse outcomes, such as hospitalization or ambulance attendance^{73,74}, which is likely to be modifiable with the use of CGM to improve awareness of impending low blood levels of glucose⁷⁵. A reduced frequency of hypoglycaemia and hypoglycaemia-related acute events with CGM can help clinicians and people with T2DM to engage with therapy escalation to achieve the desired glycaemic targets⁴⁰.

In addition to glycaemia, the efficacy of CGM has been assessed against patient-reported outcomes (PROs) that measure aspects of QoL. In small-scale studies, early CGM systems in people with T1DM were found to have neither beneficial nor adverse effects on QoL outcomes compared with SMBG⁷⁶, although it has been argued that dissatisfaction with early CGM systems was related to technical issues, including suboptimal accuracy, skin reactions and intrusive alarms⁷⁷. With increased use of CGM systems and increased accuracy in study situations over time, QoL was assessed as improving with CGM systems compared with SMBG in both people with T1DM and those with T2DM on intensive insulin therapy^{57,78}. Psychosocial benefits, including in people with T2DM not on insulin therapy, include: increased hypoglycaemic confidence, reduced diabetes mellitus distress and better overall wellbeing^{79,80}, as well as improved psychological function, diabetes mellitus empowerment and greater diabetes mellitus treatment satisfaction^{62,63}.

Improved QoL is also evident at extremes of age: in small-scale studies, adolescents and young adults with T2DM on insulin therapy have reported improvement in diabetes mellitus-related QoL with

Table 1 | Key outcome studies related to using CGM technology in people with T2DM

Author (year)	Type of study	Number of participants	Treatment	Participant age (years) at study start	Glycaemic status (HbA _{1c} (%)) at study start	CGM sensor	Intervention period	Key outcomes associated with CGM use
Allen et al. (2008) ¹²⁴	RCT	52	Non-insulin	≥18	Mean 8.6	Not specified; CGMs used for 3 days in week 1	8 weeks	1.16% mean reduction in HbA _{1c} compared with 0.32% with SMBG ($P < 0.05$) 0.53 kg/m ² reduction in BMI compared with 0.12 kg/m ² in control group ($P < 0.05$)
Yoo et al. (2008) ¹⁹⁴	RCT	65	Any	20–80	8–10	Guardian RT	12 weeks	1.1% reduction in HbA _{1c} compared with 0.4% with SMBG ($P = 0.004$) CGM group reported a significant reduction in total daily calorie intake ($P = 0.002$) and body weight ($P = 0.014$), with increased exercise time ($P = 0.02$), compared with SMBG group
Vigersky et al. (2012) ¹²¹	RCT	100	Basal insulin	≥18	7–12	Dexcom SEVEN	52 weeks	0.8% mean reduction in HbA _{1c} with intermittent CGM compared with 0.2% with SMBG ($P < 0.04$)
Beck et al. (2017) ⁵⁴	RCT	158	MDI	37–79	7.5–9.9	Dexcom G4 Platinum	24 weeks	0.3% mean reduction in HbA _{1c} ($P = 0.022$) compared with SMBG ($P = 0.022$) 20% more participants in the CGM group achieved an HbA _{1c} reduction of ≥1.0% at study end compared with SMBG group
Yaron et al. (2019) ⁵⁵	RCT	101	MDI	30–80	7.5–10	FreeStyle Libre	10 weeks	0.85% mean reduction in HbA _{1c} with isCGM compared with 0.32% with SMBG ($P < 0.0001$)
Haak et al. (2017) ⁵⁷	RCT	224	MDI or CSII	≥18	7.5–11.5	FreeStyle Libre	6 months	43% reduction in hypoglycaemia <70 mg/dl (3.9 mmol/l) compared with SMBG 54% reduction in nocturnal hypoglycaemia <70 mg/dl (3.9 mmol/l) compared with SMBG 64% reduction in hypoglycaemia <45 mg/dl (2.5 mmol/l) compared with SMBG
Martens et al. (2021) ⁵⁸	RCT	176	Basal insulin	≥30	7.5–11.5	Dexcom G6	8 months	0.4% mean reduction in HbA _{1c} compared with SMBG ($P = 0.022$) 27% increase in TIR compared with SMBG ($P < 0.001$)
Wada et al. (2020) ⁵²	RCT	93	Non-insulin	<70 (adults)	≥7.5–8.4	FreeStyle Libre	12 weeks	0.29% (3.2 mmol/mol) mean reduction in HbA _{1c} compared with SMBG ($P = 0.022$) Metrics of glycaemic variability were significantly reduced compared with SMBG ($P < 0.001$)
Cox et al. (2020) ⁵³	RCT	30	Non-insulin	30–80	≥7.0	Dexcom G4 or G5	5 months	1.11% mean reduction in HbA _{1c} compared with SMBG ($P = 0.03$)
Karter et al. (2021) ¹⁹⁵	Retrospective cohort study	36,080	Insulin	Mean 59.3 (adults)	Mean 8.2	Various, HMO-dependent	12 months	0.56% reduction in HbA _{1c} compared with SMBG ($P < 0.001$) 4.0% reduction in hospital admission for severe hypoglycaemia compared with SMBG group ($P = 0.04$)
Roussel et al. (2021) ¹³³	Retrospective	40,846	Any	18–99	–	FreeStyle Libre	1 year	39.4% reduction in hospital admissions for acute diabetes mellitus events compared with the 12 months prior to CGM 52.1% reduction in admissions for DKA compared with the 12 months prior to CGM 10.8% reduction in admissions for hypoglycaemia compared with the 12 months prior to CGM

Table 1 (continued) | Key outcome studies related to using CGM technology in people with T2DM

Author (year)	Type of study	Number of participants	Treatment	Participant age (years) at study start	Glycaemic status (HbA _{1c} (%)) at study start	CGM sensor	Intervention period	Key outcomes associated with CGM use
Riveline et al. (2022) ¹³⁵	Retrospective	41,027	Any	18–99	–	FreeStyle Libre	2 years	48% reduction in hospital admissions for acute diabetes mellitus events compared with the 12 months prior to CGM 47% reduction in admissions for DKA compared with the 12 months prior to CGM 43% reduction in admissions for hypoglycaemia compared with the 12 months prior to CGM
Guerci et al. (2023) ¹³⁶	Retrospective	5,933	Basal insulin	18–99	–	FreeStyle Libre	2 years	63% reduction in hospital admissions for acute diabetes mellitus events compared with the 12 months prior to CGM 68% reduction in admissions for DKA compared with the 12 months prior to CGM 58% reduction in admissions for hypoglycaemia compared to the 12 months prior to CGM
Ajjan et al. (2023) ¹³⁶	RCT	141	Insulin or sulfonylurea	Adults with AMI		FreeStyle Libre	90 days	Increased TIR compared with SMBG Reduced hypoglycaemia compared with SMBG
Chesser et al. (2022) ⁹¹	Single-arm interventional	9	Any	13–21	Mean 11.9	Dexcom G6	12 weeks	Significantly improved PedsQL score compared with prior SMBG ($P=0.026$) Change in HbA _{1c} not reported
Aronson et al. (2023) ¹⁰	RCT	116	Non-insulin	≥18	Mean 8.6	FreeStyle Libre	16 weeks	9.9% (2.4 h) increase in TIR compared with SMBG ($P<0.01$) 0.3% baseline adjusted reduction in HbA _{1c} compared with SMBG ($P=0.048$)
Manfredo et al. (2023) ¹³⁵	Prospective interventional	41	Insulin	Median 16.2 (youth)	Mean 10.3	Dexcom G6	10 days	Participant-reported changes in behaviour, including improved insulin adherence, reduced meal portion sizes, less snacking and increased physical activity
Chang et al. (2023) ¹³⁶	Crossover RCT	9	Insulin	15–19	Mean 11.5	Dexcom G6	3 months	2.8% mean reduction in HbA _{1c} compared with SMBG ($P=0.003$) 3.8% mean reduction in HbA _{1c} for users with >85% CGM wear time compared with SMBG ($P=0.001$)

AMI, acute myocardial infarction; CGM, continuous glucose monitor; CSII, continuous subcutaneous insulin infusion; DKA, diabetic ketoacidosis; HMO, health maintenance organization; isCGM, intermittently scanned CGM; MDI, multiple daily injections; PedsQL, paediatric quality of life inventory; RCT, randomized controlled trial; SMBG, self-managed blood glucose; T2DM, type 2 diabetes mellitus; TIR, time in range.

CGM, compared with standard care⁸¹, and individuals >65 years old on insulin therapy have reported improved sleep quality and a sense of security after starting CGM compared with SMBG⁸², as well as improved wellbeing and reduced diabetes mellitus distress compared with standard care⁸³. It is important to acknowledge that PROs using CGM in T2DM are often part of studies that include elements of diabetes mellitus education and coaching, which can also influence outcomes. Also, PROs are rarely the focus of CGM studies as these measures are typically used as an ‘add-on’ to glycaemic outcomes, and are thus relegated to secondary or exploratory outcomes, although exceptions exist⁵⁵. Therefore, there is a continued need for work that centres on the application of CGM as a driver of improved PROs in T2DM and for studies in which PROs form the primary end point.

The key clinical studies underlining the value of CGM in T2DM are summarized in Table 1, including 12 RCTs and four retrospective cohort studies, which are discussed in the wider context of care in T2DM below (Table 1). The evidence to date includes the use of a variety of

CGM devices, both current and discontinued. Our review and opinions expressed in this Perspective do not imply a preference for any specific CGM sensor type. We must also point out that there are very few studies that have investigated the issue of T2DM in children and adolescents, as discussed below. Consequently, our discussion is focused largely on using CGM for the management of T2DM in adults.

CGM and predicting long-term complications of T2DM

The majority of studies of CGM in T2DM have shown that the use of this technology reduces HbA_{1c}, which is an accepted marker of microvascular complications and long-term macrovascular disease^{7,8,84}. However, there are an increasing number of studies that make a closer link between the use of CGM and reduced long-term complications of T2DM. Across these studies, time in range (TIR) is emerging as a relevant surrogate end point for microvascular complications, with a higher percentage of TIR being associated with decreased rates of

retinopathy⁸⁵ and painful diabetic neuropathy⁸⁶, and with preserved peripheral nerve function⁸⁷. Both intraday glycaemic variability and time in hypoglycaemia have been associated with retinal nerve fibre thinning in retinopathy and neuropathy in T2DM^{88,89}, and glycaemic variability has also been associated with cardiovascular autonomic neuropathy⁹⁰. In terms of macrovascular outcomes, a lower percentage of TIR is associated with risk markers for vascular disease^{90,91}, a high risk of all-cause and cardiovascular disease mortality⁹², as well as peripheral artery disease⁹³ and diabetic foot ulcers⁹⁴.

Overall, in T2DM there is a consistent association between a higher percentage of TIR and fewer macrovascular and microvascular complications^{87,90,95–99}. As the use of CGM is a driver for increased TIR in people with T2DM, wider application of CGM systems can contribute to the goal of reducing long-term complications in T2DM. Following on from these observations, initiatives to use CGM data in artificial intelligence algorithms to more accurately predict the risk of diabetes mellitus complications are underway¹⁰⁰. The evidence supports the value of using CGM in addition to assessment of HbA_{1c} levels as a tool for predicting complications in T2DM; however, larger studies over extended follow-up periods are needed to fully understand the link between CGM-derived glycaemic measures and vascular complications of T2DM.

Use of CGM in subgroups of people with T2DM The newly diagnosed person with T2DM

The heterogeneity of disease in people diagnosed with T2DM is considerable¹⁰¹ and can be mapped to a number of glucometric profiles, in which different measures of glycaemia identify separate clusters of T2DM disease phenotypes^{101–104}. It has been proposed that adults with newly diagnosed T2DM can be stratified into up to five subgroups with different disease progression and risk profiles for diabetes mellitus complications^{101,104}. In this context, it is helpful to establish the baseline glucometric profile at diagnosis, including intraday glycaemic variability, patterns of glucose excursions and glycaemic responses to medication, such that a T2DM management plan can be tailored to the needs of each individual. Equally, use of CGM for a short period as soon as possible following diagnosis would provide people with T2DM with daily biofeedback on their glycaemic control that could help to foster the behavioural changes that are emphasized by DSMES.

The UKPDS study, which included 5,102 people with newly diagnosed T2DM, demonstrated the importance of early and proactive glycaemic control for reducing long-term diabetes mellitus complications^{7–9}. CGM can effectively contribute to the optimization of glycaemic control during the period following diagnosis of T2DM through the establishment of baseline glycaemic profiles for each individual. Subsequent treatment decisions can be compared against these glycaemic profiles and T2DM disease progression can be monitored, thus avoiding delays in therapy intensification. This early period, when the person with newly diagnosed T2DM is likely to have considerable hyperglycaemia, is a critical opportunity to use CGM to demonstrate how glycaemia is affected by changes in diet and exercise, and to reinforce initial education on the need for behavioural change in T2DM (Table 2). Thereafter, intermittent use of CGM can be indicated for management, unless treatment is initiated using insulin or evidence of frequent hypoglycaemia is confirmed (Table 2), at which point continuous access to CGM would be indicated.

Individuals with T2DM on non-insulin therapies

Although the most recent American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) consensus

reports do not strictly specify a treatment cascade for non-insulin agents, monotherapy with metformin remains an established first step in the management of glycaemia in T2DM¹. Treatment with oral sulfonylurea drugs was previously indicated as a second-line therapy because of their efficacy¹⁰⁵ and low cost. However, sulfonylureas have a number of drawbacks including hypoglycaemia^{39,106}, weight gain and greater glycaemic variability, compared with non-sulfonylurea therapies¹⁰⁷, and have therefore been gradually replaced by newer agents for second-line therapy. Many of these newer classes of drugs, such as SGLT2i and GLP1RAs, also have non-glycaemic benefits, such as reduced risk of cardiovascular disease and heart failure, as well as improved kidney outcomes, compared with sulfonylureas, which have contributed to their increased adoption. Furthermore, although recommendations state that people with T2DM who do not meet their glycaemic goals for 3 months should be prescribed additional T2DM medications in a stepwise fashion¹⁹, this guidance is inadequately applied in clinical practice. Accordingly, support is growing for a more proactive approach, in which combinations of glucose-lowering agents are started immediately following initial diagnosis¹⁰⁸.

Four small RCTs (Table 1) and a number of real-world studies have shown that the use of CGM in non-insulin-treated T2DM can significantly reduce HbA_{1c} compared with SMBG^{61–63,109,110}, and this reduction is greater in people with higher HbA_{1c} levels⁶⁶. The RCT data involved only 291 adults with T2DM across the four trials, so the outcomes certainly need to be confirmed in larger studies. Glycaemic variability, which is associated with adverse clinical outcomes^{42,111–113}, is also reduced in people with T2DM on non-insulin therapy using CGM compared with those on SMBG⁶². Similarly, use of CGM in T2DM treated with non-insulin therapy is associated with reduced incidence of acute T2DM events requiring hospital attendance or admission in the 6 months after starting CGM compared with the 6 months prior⁶⁶. Notably, by visibly illustrating glycaemic fluctuations after eating and during exercise, as well as reducing the risk of hypoglycaemia, CGM has been shown to act as a motivational tool for helping people with inadequately controlled T2DM on non-insulin therapy to establish and adhere to lifestyle changes, and thereby reduce glycaemia^{114,115}.

Given current evidence, the intermittent use of CGM can be a viable option at 3-monthly intervals (Table 2) or during treatment change in people with T2DM on non-insulin therapy, until their treatment profile mandates daily CGM use. Such treatment profiles could include sulfonylurea therapy in people with T2DM in whom a risk of hypoglycaemia is evident or has been confirmed by CGM¹⁰⁶, particularly if these people are on higher doses¹⁰⁷. Adopting CGM in this way in people with T2DM has been proposed¹¹⁶, and is also recommended in ADA guidance for technology use in diabetes mellitus¹¹⁷. A systematic review of 11 studies involving 5,542 participants, 90% not on intensive insulin therapy, found that intermittent use of CGM, compared with SMBG, was associated with reductions in HbA_{1c} and body weight, as well as improved adherence to dietary plans and physical activity¹¹⁸. Indeed, compared to SMBG, periodic use of CGM in non-insulin-treated people with T2DM has demonstrated a positive effect on glycaemic control, including reduced HbA_{1c}¹¹⁹ and improved TIR¹²⁰. A 2022 RCT demonstrated that using one CGM sensor for 1 week every 3 months achieved a significant reduction in HbA_{1c} at 3 and 6 months compared with SMBG alone or a single application of CGM at 3 or 6 months, which was effective at 3 months only¹¹⁹. In a further study, statistically significant reductions in HbA_{1c} achieved during a 12-week period of CGM use in people with T2DM not on intensive insulin therapy persisted for 52 weeks, despite a subsequent 40-week period using only

Table 2 | Proposed use of CGM throughout the natural history of T2DM

Group	At diagnosis and early disease	Management of stable disease	Long duration of disease ^a
All people with T2DM	Utilize CGM for 14 days after T2DM diagnosis Establish a baseline glucometric profile Provide education on the glycaemic response to diet and exercise in T2DM Decide on the initial treatment plan and therapy Evaluate the patient's early (14-day) response to T2DM treatment	Predict risk of microvascular complications Adjust therapy Manage glycaemic goals for time in range, time below range, time above range, glycaemic variability and glucose management indicator (CGM-defined HbA _{1c} correlate)	Facilitate T2DM therapy de-escalation in older and/or frail people with T2DM Prevent hypoglycaemia Reduce risk of cardiorenal complications (for example, chronic kidney disease) Reduce incidence and progression of microvascular disease Allow care workers to more effectively manage the care of people with T2DM
People with T2DM on: Multiple daily injections Basal insulin Premixed insulin Insulinotropic drugs ^b	Continuous access to CGM for daily use		
	Prevent hypoglycaemia Manage hyperglycaemia Support self-management	Prevention of hypoglycaemia Manage hyperglycaemia Facilitate periods of therapy escalation or de-escalation Support self-management	
People with T2DM on non-insulin therapy ^c	Intermittent use of CGM at least every 3 months, with HCP review		
	Reinforce education on glucose profiles, diet, physical activity and the effects of medication	Can be combined with a coincident HbA _{1c} test HCP can make decisions on whether to change therapy or not Predict changes in risk of microvascular complications People with T2DM can re-establish the behaviours of good self-management with support from CGM	

CGM, continuous glucose monitoring; HCP, health-care professional; T2DM, type 2 diabetes mellitus. ^aPeople with long-standing T2DM, with risk of consequent comorbid microvascular and macrovascular disease. ^bPeople with T2DM at increased risk of frequent hypoglycaemia confirmed during a CGM-led medical review. ^cCan include people on insulinotropic oral drugs with low risk of hypoglycaemia confirmed during a CGM-led medical review.

SMBG¹²¹. These outcomes are encouraging but the studies were limited in scope and size.

An additional benefit of CGM assessment in people with T2DM once every 3 months could be the inclusion of an HbA_{1c} test at the same time, in order to monitor the variability in their HbA_{1c} levels. Analysis has shown that a coefficient of variation in HbA_{1c} greater than 5% is indicative of an increased risk of microvascular and macrovascular complications of diabetes mellitus¹²². Combining intermittent use of CGM with monitoring of HbA_{1c} stability in people with suboptimally controlled T2DM (HbA_{1c} >7%) would be an effective and simple check on the need for therapeutic adjustment. Certainly, a larger RCT on the use of daily versus intermittent CGM over a longer period is needed to establish the benefits of intermittent CGM use on glycaemic metrics in people with T2DM on non-insulin therapies, as well as testing the persistence of behavioural change in the absence of continual CGM feedback (Box 1). We also point out that intermittent use of CGM could be indicated in a range of other acute conditions, including neurological and oncological diseases, that can occur in people with T2DM or T1DM, as outlined in a 2023 review¹²³.

Professional CGM, in which the CGM data are blinded to the user and available only to the HCP, has also been tested in people with T2DM not on insulin therapy. A pivotal RCT demonstrated that blinded CGM over a single 3-day period with a follow-up review and diabetes education can lead to changes in behaviour and reduced HbA_{1c} in people with T2DM on suboptimal non-insulin therapy¹²⁴. Blinded CGM has revealed that approximately 50% of people with T2DM, including those on non-insulin therapy, experience frequent instances of mild or clinically significant (defined as blood glucose concentrations of <3.0 mmol/l)

hypoglycaemia¹²⁵, which are asymptomatic. Such insights support treatment adjustment focused on reducing the risk of hypoglycaemia alongside improved overall glycaemic control using blinded CGM; however, they also support the use of intermittent unblinded CGM with current real-time sensors, to mitigate the risk of hypoglycaemia in day-to-day clinical practice and to reinforce behavioural change in support of lifestyle and dietary goals (Table 2).

Together, these studies show that intermittent use of CGM systems provides glycaemic information of value both to the person with T2DM and to the HCP, which can facilitate improved glycaemic control through changes to lifestyle and periodic medication adjustments. An important goal for this group of people with T2DM is to delay progression to insulin therapy. As obesity is a major factor in metabolic decompensation leading to insulin treatment¹²⁶, CGM could potentially be used to monitor hyperglycaemia in people with T2DM on weight-loss medications, such as GLP1RAs^{127,128}, during this period of weight change.

Based on the available evidence, we believe that CGM sensors are beneficial in people with T2DM on non-insulin therapies when applied intermittently (at least every 3 months) as standard of care (Table 2). In this way it will be possible to actively engage people with the management of their T2DM, to evaluate treatment responses and achievement of goals, to adjust therapy as needed, to more accurately evaluate risks of microvascular and cardiometabolic complications, and to reinforce education and diabetes mellitus self-management skills in people with T2DM. We acknowledge that further research is needed to evaluate the persistence of lifestyle changes and therapeutic adherence during the intervals between periods of CGM use. Equally, there are

Box 1

Evidence generation will drive the paradigm shift to using continuous glucose monitoring in type 2 diabetes mellitus

This Box summarizes the outstanding requirements for evidence from prospective and retrospective studies (as indicated) to inform clinical decisions in primary care treatment of type 2 diabetes mellitus (T2DM) using continuous glucose monitoring (CGM). These studies could be randomized controlled trials, real-world studies and studies with patient-reported outcome measures.

- The cost-effectiveness of using CGM in people with T2DM who are not on intensive insulin therapy but are treated with basal insulin only and/or non-insulin therapies (retrospective studies)
- The cost-effectiveness of using CGM in people with T2DM in primary care for each country (retrospective studies)
- Primary care study on using CGM in people with T2DM not treated with insulin; outcomes centred on changes to key measures of diabetes mellitus health, including HbA_{1c}, hypoglycaemia, incidence of macrovascular and microvascular complications (prospective and retrospective studies)
- Comparison of daily versus intermittent (periodic) use of CGM in people with T2DM and the effect of both formats on key

glycaemic metrics, such as time in range, time below range, time above range, glycaemic variability and HbA_{1c} levels (prospective studies)

- The correlation between the use of CGM and adherence with the treatment plan in people with T2DM (retrospective studies)
- Biofeedback and patient self-management behaviour with objective outcomes, such as changes to daily diet and physical activity, changes to T2DM treatment satisfaction and diabetes mellitus distress (prospective and retrospective studies)
- Correlation between using CGM in people T2DM and escalation or de-escalation of T2DM therapy (retrospective studies)
- The link between the use of CGM in people with newly diagnosed T2DM and the rate and timing of progression to antihyperglycaemic therapy (retrospective studies)
- Use of CGM in people with T2DM admitted to hospital for any reason to improve inpatient outcomes, such as length of stay, risk of admission to intensive care, acute complications (for example, nosocomial infection) or mortality (prospective studies)

no cost-effectiveness data that address the use of CGM in people with T2DM on non-insulin regimens, and this is an important unmet need.

Individuals with T2DM on basal insulin therapy

Treatment with basal insulin is recommended in people with T2DM with unsatisfactory glycaemic control while on non-insulin therapies. Initiation and titration of basal insulin therapy can be associated with episodes of problematic hypoglycaemia, particularly in older people (who can be more frail)¹²⁹, which is a common reason for discontinuation of this therapy or for reluctance of HCPs to adjust the basal insulin dose upwards^{130,131}. Application of CGM can assist with predicting and avoiding episodes of hypoglycaemia following the start of basal insulin, by allowing people with T2DM to see their blood levels of glucose in real time, as well as whether these levels are falling and how fast, using the trend arrows. In discussion with their HCP, patients can address their proportion of time below range and the need to reduce their basal insulin dose to avoid episodes of hypoglycaemia. Similarly, persistent time above range can be recognized using CGM and addressed by adjusting the basal insulin dose upwards.

The MOBILE RCT, which involved 175 individuals with T2DM on basal insulin, showed that CGM can significantly reduce HbA_{1c}, time in hyperglycaemia (defined as >250 mg/dl (13.9 mmol/l)) and the rate of hypoglycaemia events over an 8-month period, compared with a control group using SMBG testing alone⁵⁸. A limitation of the study was the additional contact with clinical staff during the 8-month period of the clinical trial, making the findings hard to generalize to a real-world setting. These data are consistent with results of retrospective studies demonstrating significant reductions in HbA_{1c} in people with T2DM on basal insulin therapy^{59,60}. Therefore, we believe that the use of CGM in this group of people with T2DM should be part

of standard of care (Table 2), particularly as CGM has been shown to be cost-effective compared with routine SMBG testing (see below)¹³².

Individuals with T2DM on intensive insulin therapy

An overwhelming body of evidence shows that people with T2DM on intensive insulin therapy can benefit from CGM devices in the same way that people with T1DM can benefit. These benefits include lower HbA_{1c} levels^{54,55} and reduced hypoglycaemia^{55,57}, as well as fewer acute diabetes mellitus events leading to hospital admission in the 12 and 24 months after starting to use CGM, compared with the 12 months prior^{133–135}. Consequently, guidelines recommend CGM in people with T2DM on intensive insulin therapy^{1,20,136}, given the clinical benefits^{54,55,57} and cost-effectiveness^{137,138}.

Older individuals with T2DM

The estimated prevalence of diabetes mellitus among people aged >60 years is 22% and 19% in high-income and middle-income countries, respectively¹³⁹. However, relatively few studies have investigated CGM use in older populations with T2DM, particularly those who are frail. The REPLACE RCT that compared CGM with SMBG in people with T2DM on intensive insulin therapy found that study participants aged 65 years or older had a 56% reduction in time below range, with blood levels of glucose below 3.9 mmol/l (70 mg/dl) when using CGM, which was similar to the time below range in participants aged <65 years⁵⁷. A subgroup analysis of the DIAMOND study showed that in people aged 60 years or older with T2DM on intensive insulin therapy⁵⁴, use of CGM was associated with improved HbA_{1c} and reduced glycaemic variability, compared with SMBG, similar to the findings in the younger age group. A subgroup analysis on people with T2DM on basal-bolus insulin aged 65 years or older in the REFER study showed similar results⁵⁶. In a 2022

study, people with T2DM aged 65 years or older on basal-insulin only showed improved TIR and reduced hypoglycaemia after starting CGM, which again was similar to the results in younger adults¹⁴⁰. In the RELIEF study in people with T2DM aged 65 years and older on intensive insulin therapy, initiating CGM was associated with a statistically significant reduction in hospital admissions for diabetic ketoacidosis and severe hypoglycaemia in the 2 years after starting CGM compared with the 12 months prior¹⁴¹.

Use of blinded CGM¹⁴² and data from retrospective insurance datasets¹⁴³ have confirmed that hypoglycaemia is frequent among older people with T2DM, aged up to 77 years, including those on non-insulin therapy, and those with high mean HbA_{1c}. The risk of severe or fatal hypoglycaemia increases considerably in older individuals with diabetes mellitus treated with insulinotropic medications^{144–146}, with higher risks of falls and fractures compared with younger individuals^{147,148}. Hypoglycaemia in older people with T2DM is also associated with increased incidence of cardiovascular events, dementia and death¹⁴⁸, and therefore prioritizing hypoglycaemia avoidance over reduction in HbA_{1c} has been suggested in the treatment of older people with T2DM¹⁴⁹. These goals of therapy, in turn, raise the issue of therapy de-intensification to strike a balance between symptom control and QoL¹⁵⁰. In this context, deprescribing sulfonylureas is a clear recommendation^{148,149} in older people with T2DM, particularly in the presence of comorbidities. This revised emphasis will require careful clinical judgement, which can be facilitated by the use of CGM to maintain awareness of glycaemic changes. As the feasibility and acceptability of CGM in very old adults up to 91 years of age has also been demonstrated¹⁵¹, the case for wider CGM access in those with T2DM is clear (Table 2). Avoiding hypoglycaemia in this group of individuals can reduce hospital admissions and falls that can result in immobility. These outcomes would make CGM use in older populations cost-effective, although confirmation of this requires appropriate health economic analysis. The effect of wider medication deprescribing in older populations has been shown to be cost-effective^{152,153}, supporting the possibility of a similar strategy in older people with T2DM.

Youth and young adults with T2DM

The incidence of young-onset T2DM is growing, particularly in minority and low-income populations¹⁵⁴. A limited number of studies have investigated the use of CGM in youth and young adults with T2DM. These studies indicated that features of CGM technology, such as visible glucose readings and trend arrows, do influence changes in diabetes mellitus self-management behaviours among these groups¹⁵⁵, including improved adherence with insulin treatment and avoidance of high-sugar foods. In one small study in adolescents and young adults, use of CGM was associated with statistically significant improvements in the Paediatric Quality of Life Inventory (PedsQL) diabetes mellitus score over 12 weeks⁸¹. In a pilot randomized crossover trial in nine adolescents aged 15–19 years with a mean HbA_{1c} of 11.5%, CGM for 3 months was associated with a mean reduction in HbA_{1c} of 2.8% compared with SMBG¹⁵⁶. These small-scale studies certainly indicate that larger RCTs are needed to investigate the effect of CGM in children, adolescents and young adults with T2DM.

Changing T2DM care: essential components

The majority of people with T2DM are managed in primary care, which is not currently well equipped to move towards the wide-scale adoption of CGM that we propose. This is because application and interpretation of CGM systems and data have largely been managed in specialist clinics

to date, due to their widespread use in T1DM. Along with confronting therapeutic inertia, the clinical need is to assertively target hyperglycaemia early after diagnosis^{157,158} and to empower people with T2DM to take more control over their condition, guided by CGM-derived glucose readings, trend arrows and daily patterns. Hard-pressed primary-care teams can benefit from using CGM to stratify and triage people with T2DM, and to prioritize them for high-value care (Table 2). Ultimately, we believe that the needs of people with T2DM can be managed more effectively with CGM, as the status quo is not delivering satisfactory outcomes.

Despite the number of studies that support the use of CGM in T2DM, further evidence is needed to refine the clinical implementation strategy and to evaluate the cost-effectiveness of CGM in primary care, including its use in people with newly diagnosed T2DM. Similarly, understanding the effect of using CGM on the adherence of individuals to their treatment plan is a current unmet need. Objective outcomes, using validated psychometric tools, are also needed to understand how biofeedback using CGM can contribute to constructive self-management behaviours in people with T2DM. Fixing these gaps in our understanding (Box 1) could be facilitated by recently published international consensus recommendations on the use of CGM in prospective clinical trials and studies¹⁵⁹.

The opportunity to transform care in T2DM also comes with a number of critical needs that must be met from an organizational, technological and educational standpoint, as summarized in Box 2 and Fig. 1. At its core, the first goal must be to develop the knowledge and skills among all HCPs relevant to effective interpretation of CGM data for the use of this technology across the heterogeneous populations of people with T2DM. Thus, HCPs should be enabled to focus on high-value care activities and reduce or delegate low-value tasks (tasks that can, but do not necessarily, substantially improve outcomes that matter to patients), such as investigating the glycaemic patterns that characterize each person with T2DM, potentially using artificial intelligence¹⁶⁰ or accessing the skills of allied HCPs, such as pharmacists^{161,162}. The role of peer-to-peer support programmes for people with T2DM in partnership with primary care teams is another emerging opportunity, including peer-led education or lifestyle support meetings, with phone or web-based support¹⁶³.

Cost-effectiveness of CGM in T2DM

The economic burden of T2DM is considerable and includes the direct and indirect costs of care. Direct costs include the tariffs for treatment polypharmacy, HCP-mediated care, emergency care and hospital admissions for any reason for a person with T2DM. To these are added the indirect costs associated with loss of workplace and social productivity for people with T2DM. Globally, the burden of adult diabetes mellitus is projected to cost US \$2.48 trillion annually by 2030 (ref. 164). The distribution of costs differs depending on the health-care environment. For example, in 2022, the total burden of diabetes mellitus was estimated at US \$412.9 billion, 74% of which was attributed to direct costs¹⁶⁵. The projected burden of T2DM in the UK for 2035 is £35.6 billion, 57% of which are indirect costs¹⁶⁶. These must be balanced against the costs associated with prescribing CGM systems on a continual or intermittent basis. Suboptimally controlled HbA_{1c} is known to be associated with increased costs of care in T2DM, as individuals with suboptimal glucose control use more health-care resources than those with optimized control^{167,168}. The frequency of hospital admissions for diabetes mellitus-related acute events and long-term complications is also a driver for increased costs in T2DM^{168,169}. As CGM has an effect

on these aspects of resource use, compared with standard care with SMBG (Table 1), it can be expected to have measurable cost benefits. It should also be noted that access to CGM technology is also a variable factor within health-care systems.

Intensive insulin therapy

Four studies across a range of health-care economies have found that the use of isCGM in people with T2DM on MDI or CSII therapy is considered cost-effective compared with standard care with SMBG, based on a 40-year horizon^{137,138,170,171}. Direct medical costs, including total intervention costs as well as costs for acute events, were taken into account in three of these analyses^{138,170,171}, and costs due to productivity loss were also included in the third study¹³⁷. Use of isCGM improved quality-adjusted life years (QALYs), a measure of the quality and length of life for an individual, in people with T2DM on intensive insulin therapy, leading to a favourable incremental cost-effectiveness ratio (ICER)^{137,138,170,171}.

Basal insulin therapy

One study examined the costs for people with T2DM treated with basal insulin only, without prandial insulin, with intermittent use of CGM in four cycles (2 weeks on and 1 week off) for 3 months, followed up to 52 weeks, compared with a control group using SMBG¹³². Cost inputs included the direct medical costs, including treatment for depression and for diabetes mellitus complications. Life expectancy and quality-adjusted life expectancy outcomes for the CGM cohort were improved, with gains in ICER and QALYs. This cost-effectiveness was attributed to users making informed behavioural choices without clinician guidance¹³².

Unspecified insulin therapy

Projections from a series of studies across three national health-care settings showed that using rtCGM in people with T2DM on either MDI or basal insulin therapy is associated with increased QALYs and improved ICER over a lifetime horizon compared with SMBG, based only on direct health-care costs in the UK¹⁷², Canada¹⁷³ or France¹⁷⁴. Key drivers of cost-effectiveness included HbA_{1c} reduction and reduced fingerstick testing.

Professional (blinded) CGM

People with T2DM on any medication who utilized professional CGM did not incur a statistically significant increase in total annual costs for inpatient, outpatient and pharmacy services after starting to use professional CGM compared to a control cohort using SMBG¹⁷⁵. People with T2DM using professional CGM while changing their T2DM treatment regimen saw a significant fall in their annual costs¹⁷⁵.

CGM in the primary care setting

A randomized, 6-month prospective trial in the US was conducted using CGM compared with SMBG testing in participants receiving usual care in primary care clinics. Of 99 participants, 93 had a diagnosis of T2DM but were selected without consideration of their current dietary, oral medication or injectable therapeutic regimens. After 6 months, CGM users had reduced costs overall for primary care visits, emergency department attendance and laboratory investigations, compared with SMBG users. Savings were not universal and depended on the health insurance provider¹⁷⁶.

Box 2

Unmet needs for changing care of people with type 2 diabetes mellitus

Time in range

HbA_{1c} is the gold standard marker for the risk of diabetes mellitus complications⁷¹⁹⁷ but does not provide information on the frequency of hypoglycaemia, short-term glucose variability, or daily and/or weekly glycaemia patterns. Continuous glucose monitoring (CGM) data provide accurate glycaemic metrics^{198,199} such as time in range (TIR), a central indicator of glycaemic control⁴⁰. Monitoring TIR allows rapid assessment of the efficacy of new interventions, helping to minimize delays in optimizing glycaemic control. HbA_{1c} continues to be important for predicting risks of long-term microvascular complications, but TIR is accepted as providing critical insights into short-term glucose control and has been correlated with clinically relevant reductions in HbA_{1c}²⁰⁰.

Telemonitoring and telemedicine

CGM creates the opportunity for detailed remote consultations²⁰¹, the value of which was demonstrated during the COVID 19 pandemic^{51,52,202}. A small number of health-care strategies for remote care of people with type 2 diabetes mellitus (T2DM) using CGM have been tested in real-life settings; for example the Onduo Virtual Diabetes Clinic^{188,203,204}, which is associated with a statistically significant improvement in

HbA_{1c} and with reduced diabetes mellitus distress, compared with standard care. Telemedicine programmes delivered in primary care have also demonstrated improvements in HbA_{1c}, TIR and time below range compared with standard care²⁰⁵. Telemedicine also supports precision medicine in T2DM, in which individuals can be scheduled for more-frequent or less-frequent reviews, and development of bespoke support programmes.

Electronic medical records

The opportunities of telemonitoring and telemedicine in T2DM can only be fully realized if CGM data are integrated into a unified electronic medical record (EMR) for each patient, accessible by multiple HCPs and care teams. Such EMRs would enable consistent evaluation of treatment responses, and prognostic assessment of the risks of microvascular or cardiometabolic complications in each person with T2DM.

The importance of digitalization and data registry is emphasized by the European Diabetes Forum²⁰⁶ and the European Commission²⁰⁷. Interoperability between CGM device data and EMRs will be a key facilitator in achieving an integrated T2DM care service, and regional health-care administrations are taking steps towards this goal²⁰⁸.

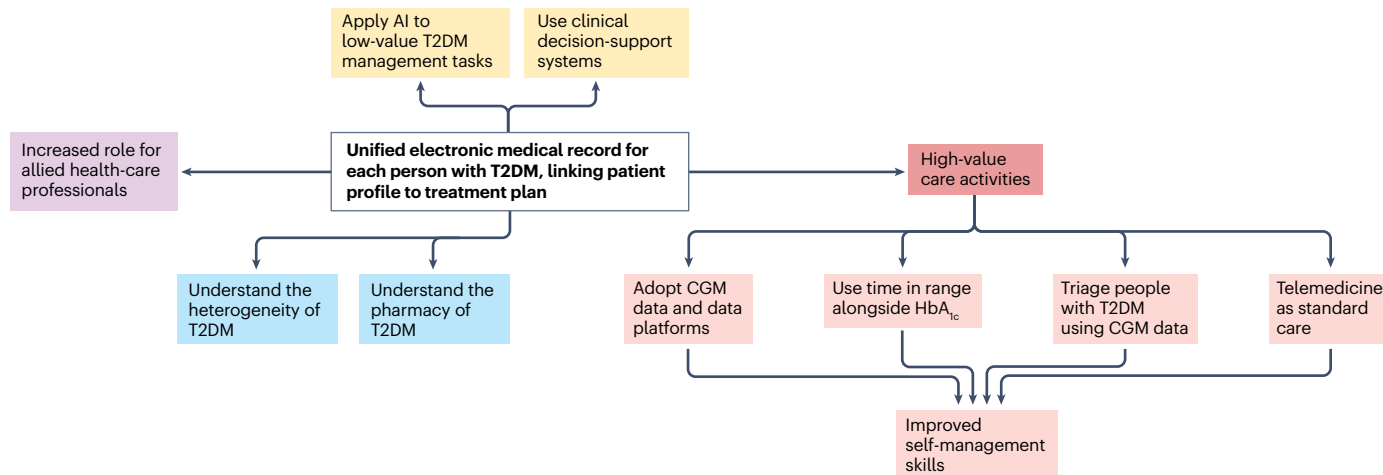


Fig. 1 | The unmet need for change in health-care services for effective management of people with type 2 diabetes mellitus. Optimized care for people with type 2 diabetes mellitus (T2DM), centred on digital electronic medical records, will require improved knowledge and interpretation (blue boxes) of CGM data across the heterogeneous populations of people with T2DM.

This increased understanding will allow health-care professionals (HCPs) to focus on high-value care activities (pink boxes) that also empower people with T2DM. Low-value tasks can be accomplished using emerging technology solutions (yellow boxes) or by accessing the skills of allied HCPs, such as pharmacists (purple box). AI, artificial intelligence; CGM, continuous glucose monitoring.

Unmet needs for HCPs, health-care services and patients

Optimizing the value of using CGM in T2DM means addressing the unmet needs for effective service delivery (Fig. 1). HCPs must understand better the heterogeneity of T2DM and the diversity of patient profiles^{101,102}, as well as the growing pharmacy of treatment options. Current ADA and EASD joint guidelines outline nine separate glycaemic drug classes that can be used as monotherapy or in combination. The multiplicity of choices can lead to ‘decision paralysis’¹⁷⁷, resulting in reluctance to prescribe medications, even if most appropriate for the patient. This decision paralysis has been suggested to be a factor in the low prescription of SGLT2i by primary care physicians¹⁷⁸, despite the high efficacy of these drugs. Similarly, the cardiometabolic benefits of injectable GLP1RAs are not well-known, and these drugs are not commonly prescribed in primary care¹⁷⁹.

Digital health literacy among HCPs is also a concern (Box 2). A 2019 survey of 302 medical schools across EU member states¹⁸⁰ concluded that less than 30% of medical schools offered eHealth courses and these were mandatory in only 19%. More concerning, a 2018 benchmarking survey found that 89% of primary care physicians across the EU did not engage with telemedicine solutions with their patients and 81% did not use it with other HCPs¹⁸¹. However, the COVID-19 pandemic has greatly changed the delivery of diabetes mellitus care to emphasize telemedicine in diabetes mellitus consultations⁵², with evidence that telemedicine is not inferior to in-clinic consultations^{52,182}. A small number of studies have also indicated that primary care teams and patients have embraced telemedicine as a consequence of the pandemic^{183,184}. Ultimately, all stakeholders in the digital ecosystem must transform their way of operating¹⁸⁵, but local implementation will require a proactive and innovative approach by multiple stakeholders.

Despite concerns among health-care providers about low health literacy of patients and poor engagement with digital health^{186,187}, practical trials have shown that people with T2DM respond well to telemedicine¹⁸⁸, with improvements in glycaemia and health-related

QoL. People with T2DM often prefer face-to-face consultations, since they perceive information to be clearer in this context^{189,190}. Thus, telemedicine works best in online consultations with joint participation by the patient and HCP, rather than e-mail or text exchanges, and the preservation of two-way communication will be a factor in developing telemedicine solutions. The use of digital health applications is also endorsed by people with T2DM^{190–192}. It improves choice and access to health care, and can reduce the costs of access (for example, through avoidance of travel costs). Certainly, use of telemedicine and digital health tools can lead to reduced diabetes distress in adults with T2DM¹⁹³. Therefore, there is not an implicit problem with digital health literacy among people with T2DM and concerns about digital health literacy are not a barrier to the wider adoption of CGM.

Conclusions

The evidence to justify the inclusion of CGM technology as the standard of care in all people with T2DM, irrespective of treatment regimen, is available and growing. Further confirmation of the value of CGM in T2DM treatment using high-quality RCTs and cost-effectiveness studies is needed but the case is becoming persuasive.

A strength of the analysis in this discussion is the consistent outcomes of the RCTs and real-world studies linking CGM with improved glycaemic outcomes in people with T2DM. Limitations include the small number of RCTs available on which to base conclusions, the diverse range of CGM systems used across the studies discussed and the lack of cost-effectiveness modelling to fully underpin the demonstrated clinical value.

We believe that a decision to include CGM as part of care at all stages in T2DM is essential to deliver an assertive clinical plan for people with T2DM. Such a plan would improve QoL, reduce hyperglycaemia and reduce the risk of diabetes mellitus-related complications, which are preventable with good glycaemic management. The use of CGM in T2DM can be through continuous use, as is accepted for the management of T1DM, or through intermittent use soon after

diagnosis and at strategic time points throughout the natural history of T2DM. The opportunity to change diabetes mellitus care in people with T2DM will require a paradigm shift in attitudes, education, technology and service design, with clear pathways to implementation of CGM in general practice. People with T2DM will also need to accept greater responsibility for making their own proactive decisions on day-to-day diabetes mellitus self-care. In doing so, they should rely less on an outmoded paternalistic approach by their health-care providers, and instead adopt a self-management approach, supported by CGM devices, that can be an important part of transforming health-care processes. The evidence indicates that this is within the capabilities of people with T2DM, irrespective of their treatment regimen.

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Author contributions

The authors contributed equally to all aspects of the article.

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