Continuous glucose monitoring in primary care – are we there?

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Purpose of review
In this review, we examine the expanding role of continuous glucose monitoring in glycaemic management in primary care.

Recent findings
Improving technology and decreasing cost have increased the uptake of use of continuous glucose monitoring (CGM) for glycaemic management in primary care, wherein most diabetes is managed. Optimized use of this technology, however, will require a convergence of several factors. Availability of devices for people with diabetes, availability of data at the time of clinical interactions, and expertise in interpretation of CGM and ambulatory glucose profile (AGP) data, as well as optimization of therapies, will be required. Significant progress has been made in all three areas in recent years, yet creating systems of support for widespread use of CGM in primary care remains an area of active investigation.

Summary
There has been significant uptake in the use of CGM in the management of diabetes in primary care. Optimized use, however, requires both access to CGM data and the expertise to use the data. Although promising strategies have emerged, the task of generalizing these strategies to the broad population of primary care in America is ongoing. CGM technology holds significant potential for improving glycaemic management in primary care, yet important work remains to leverage the full potential of this promising technology.

Keywords
continuous glucose monitor, diabetes technology, glycaemic data, primary care, type 2 diabetes

INTRODUCTION

As of 2020, nearly 34.2 individuals in America have diabetes (10.5% of the population), with 90–95% of those individuals having type 2 diabetes [1]. As this number continues to grow it imposes significant challenges upon the American healthcare system, which is already strained by financial pressures and a shortage of cognitive subspecialists. To manage the care needs of individuals with diabetes, America has roughly 8000 board-certified endocrinologists as of 2021 [2]. It is clear that the vast majority of individuals with diabetes in America will need to be managed in primary care, where a much larger number of clinicians in Family Medicine, Internal Medicine, and a growing cohort of advanced care practitioners manage and coordinate the broader scope of healthcare in America.

It is also clear that despite these resources, and despite the availability of many new and promising therapies for diabetes, the American healthcare system has failed to improve the quality of the care we deliver in the management of diabetes between 1999 and 2018 [3▪]. Optimization of the quality of diabetes care has plateaued, stagnated, and in some instances, worsened over these years based on National Health and Nutrition Examination Survey (NHANES) data. Moreover, some populations have been especially challenged in meeting glycaemic and diabetes quality goals. Individuals treated with insulin, which comprise roughly 25% of the population with diabetes [3▪], struggle more in achieving glycaemic goals [4] and individuals with significant barriers to care, especially ethnic and racial minorities, disadvantaged groups, and the underinsured or

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Curr Opin Endocrinol Diabetes Obes 2022, 29:10–16
DOI:10.1097/MED.0000000000000689

KEY POINTS

- Use of CGM has expanded to populations typically managed in primary care settings, creating an urgent need for creation of systems to optimize the use of this technology in primary care.
- Access to CGM devices for broader populations will require improved coverage of devices for individuals for whom CGM technology has been shown to be of benefit.
- Availability of CGM data both in real-time and at the time of clinical interactions is critical to optimizing benefit to individuals with diabetes.
- Expertise amongst primary care clinicians in interpreting CGM and AGP data, and in the titrating medications, will be required to improve glycaemic management for the broader population of individuals with diabetes managed in primary care.
- Optimized availability of CGM technology, and support of primary care clinicians in using this technology has the potential to improve glycaemic management for broad populations of individuals with diabetes who currently are not meeting glycaemic goals.

uninsured, are much less likely to meet diabetes quality of care goals [3▪,5▪,6].

EVOLUTION IN CONTINUOUS GLUCOSE MONITORING TECHNOLOGY

Diabetes technology has made very significant advances in the past 5 years, and this evolution of technology has especially impacted continuous glucose monitoring (CGM) technology. Availability of CGM devices not requiring calibration, approved for nonadjunctive use, less affected by interference by therapeutic substances such as acetaminophen, and with greater ease of use and availability have allowed the diffusion of this technology more broadly in managing diabetes, beyond the well established indication for use in managing type 1 diabetes (T1D) on multiple daily dose insulin [7▪]. As CGM technology becomes more available for use in type 2 diabetes (T2D) and individuals managed in primary care, and as the database for use of this technology in individuals not on multiple daily dose insulin solidifies [8,9▪], the emergent question is whether America's primary care clinicians are ready and able to use CGM technology to optimize the care of the growing population with diabetes. Is the time right to use CGM technology to move the quality of the diabetes care in America beyond its current plateau?

Optimal use of CGM to improve diabetes care quality involves more than simply having the availability of on-demand glucose values; to really leverage this technology will require progress in three key domains. First, people with diabetes, and clinicians managing them, will need availability and access to CGM devices, that is availability at the level of formularies and national level. Second, people with diabetes and clinicians will need rapid and easy access to both real-time and retrospective data, which is often a key failing in the use of fingerstick blood glucose monitoring (BGM) to optimize care in primary care settings. Finally, primary care clinicians must know how to use the data from CGM technology, and must pursue an appropriate pace of titration, to improve care (Fig. 1). This will involve education in interpretation of CGM data, as well as education in the titration of insulin and other noninsulin therapies. Alternatively, team-based models to manage this aspect of diabetes care could be either built into the primary care team or outsourced to third parties. In this regard, it should be noted that the promise of fingerstick BGM, a technology widely available since the 1980 s, has never met expectations, and it is suspected that this largely relates to data not being available, and not being used [10]. The opportunity for care delivery innovation and improvement is significant.

AVAILABILITY AND ACCESS

Availability and access to CGM technology, while improving, can be a significant limitation in using CGM technology to optimize diabetes care. Medicare limitations on CGM coverage, which historically have included the use of multiple daily dose insulin and documentation of four-time per day or more glucose testing, were liberalized as a result of the COVID-19 pandemic in 2020, and more recently, the requirement for frequent blood glucose testing has been dropped [11]. This has allowed improved access to individuals with either type 1 or type 2 diabetes using multiple daily dose insulin, yet barriers remain [12▪]. Onerous prior authorizations and paperwork in prescribing CGM technology persist. Public funders beyond Medicare, typically state Medicaid, vary significantly in coverage of CGM technology, and commercial insurers also vary widely [13▪]. Finally, there is a significant lack of transparency in the provision of CGM technology with commercial insurance plans, with coverage varying widely based on employer, plan election and limitations of high deductible plans.

The COVID-19 pandemic caused significant disruption in the American medical system at all levels, but especially in primary care, where clinicians were tasked with frontline management of the pandemic,

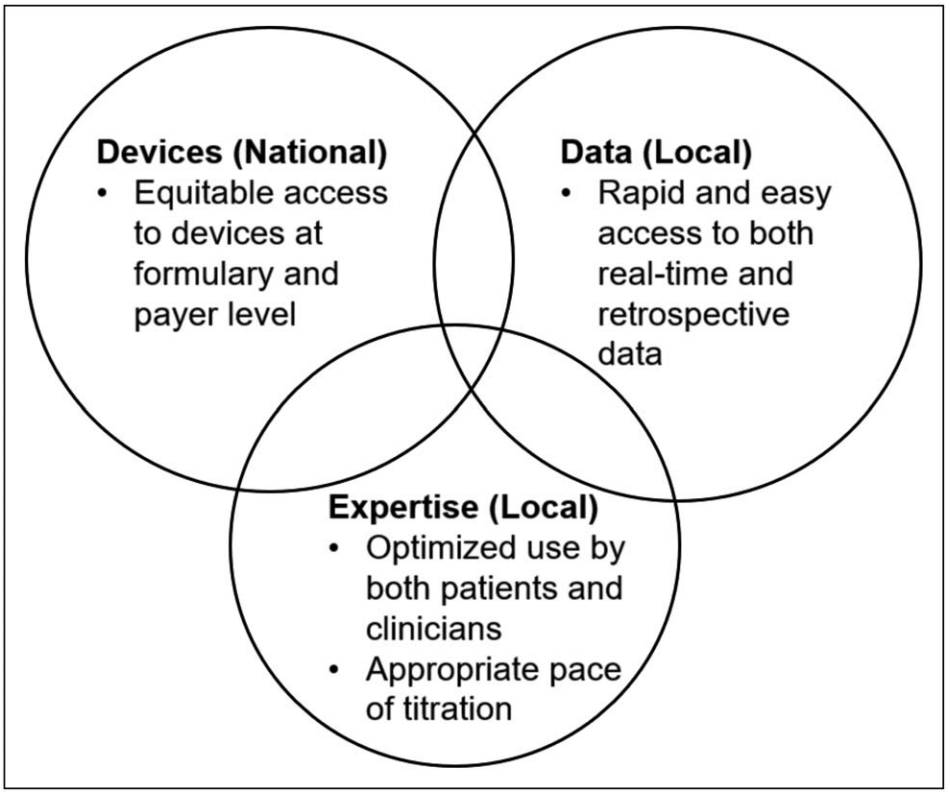

FIGURE 1. Factors impacting optimization of real-world continuous glucose monitoring use in primary care.

and access to clinic-based care for individuals managing chronic illness was limited because of infection risk. The ability to access CGM data remotely allowed an appealing option, and often in fact the only option, for management of individuals not able to attend clinic visits. At the same time, haemoglobin A1c-based management, a mainstay of management in primary care settings, became largely unavailable because of limited patient access to laboratory facilities; for individuals with access to CGM-based metrics, TIR became a default target for glycaemic optimization [14▪]. In this regard, the pandemic has provided a 'natural experiment', with numerous groups reporting maintenance or even improvement in glycaemic care in individuals using remote CGM-based management [15▪,16▪]. For the duration of the pandemic, many insurers have liberalized provision of CGM technology for a broader population of people with diabetes, and it is hoped both lessons learned through remote management during the pandemic, and the liberalized provision of CGM technology, will allow further improvement through innovative care models involving technology and remote care [17▪].

TECHNOLOGY AND SUPPORT

Populations with diabetes managed in primary care, especially those with T2D, tend to be older, less technologically savvy and more challenged by social determinants of health and demographics than populations with T1D intensively managed in endocrinology practices. Indeed, 'diffusion of innovations theory' fully predicts that early adopters of technology tend to be those with higher levels of education and financial means to access the technology [18]. Yet, the potential benefit of CGM to broader populations cuts across demographic lines. Anderson *et al*. [19▪] demonstrated the potential of remote monitoring and coaching in reducing (but not eliminating) racial disparities in A1c improvement, using fingerstick BGM technology. The MOBILE study, which evaluated CGM vs. BGM in individuals with T2D not on prandial insulin, recruited from a population facing numerous challenges in optimizing medical care – 53% were other than white, 55% lacked a college degree and only 42% were privately insured – and clearly demonstrated that this population, using real-time CGM technology, improved glycaemic metrics far beyond those using BGM-based technology [9▪,20]. With availability comes benefit. As Drs. Monica Peek and Celeste Thomas point out so well in their 2021 *JAMA* editorial [21▪], data from the MOBILE study and observational data support the value of CGM in broader populations: 'important policy changes in Medicare eligibility to CGM for type 2 diabetes and institutional changes that promote its use in primary care will go a long

way to improving diabetes control and reducing complications, particularly among populations most in need. The time has come to broaden access to CGM for patients with type 2 diabetes'.

Beyond issues of access to CGM devices, issues of access to CGM data often limit optimized use in primary care settings. Currently, there are a number of mechanisms to access CGM data, but ideally, access to smartphone-based real-time or near real-time data is needed for optimized clinical interaction and shared decision-making. The reality of practical experience suggests that if the data are difficult to obtain in a primary care setting, it is not obtained, and it does not get used [10].

Currently, the gold standard of access to CGM data is via industry-based websites (Libreview, Dexcom Clarity, others), but other mechanisms of data acquisition, including direct uploading of data from readers/receivers either at home or in clinic, can provide access. A key limitation in primary care settings continues to be the time required to access this data, as care teams often balance multiple priorities at the time of visits, and time and labour-intensive processes tend to be lost along the way. This has been the experience in accessing BGM-based data, wherein a multitude of devices require proprietary cords, cables and cloud-based data sites for data upload. In this regard, the ideal state would be direct importation of data from industry-based cloud sources into electronic medical record systems (EMRs), allowing 'one-click' access to data via native EMR resources, for ease of access. Espinoza *et al.* [22] published a 'proof of concept' validation of direct importation of CGM data into EMR. Dr Amy Criego at the International Diabetes Center in Minnesota provided a real-world demonstration of the next step at the 2021 ADA Scientific Meeting: importation of both ambulatory glucose profile (AGP) and glycaemic metrics directly into the native EMR environment, allowing trending and availability of metrics for clinical and registry purposes. This process is currently being utilized throughout the very large HealthPartners Care System in Minnesota and Wisconsin (A. Criego, personal communication). It is anticipated that expansion of EMR-based access will move to clinical reality in the near future.

OPTIMIZATION OF THERAPY: LOCAL LEVEL

Beyond data availability, the cadence of medication titration has historically been a limitation to optimizing glycaemic therapy [23,24▪,25▪]. Current primary care practice typically centres around 3-month follow-up for individuals with suboptimal glycaemic management, predicated on the significant lag before changes in medication are evident based on A1c values. CGM-based management using standardized data presentations such as AGP reports and CGM-derived glycaemic metrics [26▪▪,27,28] allows the opportunity of a much quicker 'cadence of titration'. Glycaemic targets based on CGM metrics such as 'TIR 70–180' (time spent in an optimal glucose range of 70–180 mg/dl) have now been validated in numerous studies as a marker for risk of diabetes complications [29▪,30–35]. As CGM-based metrics are much less time-limited than haemoglobin A1c, a titration cadence of every 2 weeks, or even more rapidly, becomes very feasible.

Another limitation to optimizing glycaemic therapy in primary care is clinician discomfort with titration of medications, which is especially the case with insulin-based therapy. Clinician training in interpretation of CGM and AGP data, and in optimization of noninsulin therapies and insulin titration will be critical in this regard. [36▪,37–42].

Team-based models have promise in extending the expertise of primary care clinicians [43▪]. Diabetes educators are very well positioned to facilitate insulin titration and improve outreach and titration. Unfortunately, access to diabetes education can be a limitation for many primary care practices [44,45], and current levels of reimbursement limit the feasibility of building care team models around diabetes education. It is hoped that the move towards 'remote patient management'-based billing may improve the feasibility of team-based models, which utilize diabetes educators in innovative ways in the titration of glycaemic medications in primary care, especially with the availability of CGM-based data. Further extension of the care team using endocrinology-primary care or endocrinology-primary care-diabetes education-based teaming, or integration of a clinical pharmacist, are other avenues worthy of investigation [43▪,46–48].

Glycaemic management beyond primary care, that is outsourcing of glycaemic management using BGM or CGM data, is an area of active growth in the management of T2D. Numerous groups are creating models of third-party support for glycaemic management, both for insulin managed and noninsulin managed individuals with T2D, some with impressive early results [49▪,50–53]. This approach may be especially promising in areas with limited access to endocrinology specialists. At the present time, a limitation to this approach is how to monetize third-party management in our mixed payer system; availability of these programmes is often predicated on contracting with specific insurers. It remains to be seen whether third-party outsourced management, that is having another party at the table, will gain wider acceptance as an option for management of glycemia.

Another area of active exploration is the addition of one further layer of technology beyond CGM, either by using smart-pen or hybrid closed-loop pump-based therapy to optimize glycaemic management for individuals using insulin in T2D, or by using artificial intelligence-based guidance for titrating insulin especially for individuals using multiple daily dose insulin [54–57]. As current smart pen and hybrid closed-loop technology requires significant expertise on the part of clinicians to help support individuals using the technology, availability of management expertise may be a limitation in using this technology more broadly.

What is clear is that optimized used of CGM technology will likely require further training and/or support of primary care clinicians, as well as new reimbursement models allowing more frequent titration, along with significant care model innovation to broadly improve the management of diabetes in America.

CONCLUSION: ARE WE THERE YET?

CGM technology is diffusing rapidly into the management of T2D in primary care. Already, large observational databases suggest that the broader population of people with T2D in America is benefiting from the availability of CGM technology [58,59▪,60▪]. To an increasing degree, CGM is being used in primary care, but the true opportunity is not just using CGM, but using CGM optimally to maximize benefit. Maximizing benefit will require learning how to best use this technology to titrate insulin and other therapies, and then translating that learning to help clinicians in primary care to best use this technology to maximize benefit.

Mindful of lessons learned with the successes and failures of fingerstick BGM technology [10], we need to help all individuals, including populations disenfranchised from the medical system and with significant barriers of care, to have access to this technology. We need to help primary care clinicians and clinics across America easily access patient-generated glycaemic data. We need to teach clinicians in primary care how to interpret CGM data, and how to titrate insulin and other therapies efficiently and safely. We need to create team-based support systems. Finally, we need to continue to expand our database on populations that benefit from this technology. The time to create these systems of access and support is now. CGM technology has the potential to dramatically improve our stalled progress in improving the quality of diabetes care in primary care settings. Are we there yet? No. Is the time right to make a true investment in the health of America by expanding the availability and optimizing the use of CGM in primary care? Absolutely.

Acknowledgements

The author would like to thank his colleagues at the International Diabetes Center in Minneapolis Minnesota for ongoing support.

Financial support and sponsorship

This work was supported by ongoing salary support by the International Diabetes Center in Minneapolis, Minnesota, USA. The International Diabetes Center is an affiliate of HealthPartners Institute, a non-profit dedicated to clinical research.

Conflicts of interest

T.W.M. reports that his employer, HealthPartners Institute, has received payments on his behalf for research and speaking support from Abbott Diabetes Care, Dexcom, Medtronic, Insulet, Lilly and Novo Nordisk, and for serving on an advisory board for Dexcom. His employer has also received payment from the American Diabetes Association, American College of Physicians and American Medical Group Association for speaking, and for creating CGM Education resources. He has not received personal payments from industry sources.

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- ▪ of special interest
- ▪▪ of outstanding interest

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Karter *et al.* [59■] use a retrospective cohort study to evaluate registry data from the Kaiser Permanente system in California to show that in initiators of real-time CGM with either T1D or T2D on insulin, CGM significantly improved A1c and reduced ER and hospital visits for hypoglycaemia, in a real-world population. It is encouraging to see that these real-world outcomes parallel, and in some cases exceed, findings of randomized control trials conducted in a research environment.

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This retrospective real-world study used claims and Medicare data to examine the impact of intermittently scanned CGM on acute diabetes related events and all-cause hospitalizations in the first 6 months after acquiring CGM, compared with the 6 months prior. In this study, acquisition of isCGM was associated with reduced acute diabetes related events and all-cause hospitalizations in the 6 months that follow acquisition. As with the Karter study, this work provides validation for the use of CGM in real world environments.