Original Research

Advancing Diabetes Quality Measurement in the Era of Continuous Glucose Monitoring

The Science of Diabetes Self-Management and Care
1–14

DOI: 10.1177/26350106231163518
journals.sagepub.com/home/tde

Maliha Khan, BSPH, Naila Wahid, MS, Taylor Musser, MPH, Richard M. Bergenstal, MD, Osagie Ebekozien, MD, MPH, CPHQ, Kenneth Snow, MD, MBA, Kate Thomas, MA, and Christel Aprigliano, MSc

Abstract

Purpose: The purpose of this research is to develop a set of continuous glucose monitoring (CGM)-related measure concepts to be tested in a health care system. Existing measures assessing the quality of diabetes care do not include modern approaches to diabetes management, such as CGM. Continuous glucose monitors rival traditional methods of measuring diabetes management by providing real-time, longitudinal data and demonstrating glucose variability over time. The Improving Diabetes Quality Initiative seeks to address this gap in diabetes quality measurement.

Methods: A Technical Expert Panel (TEP) was convened to curate a diabetes quality measures portfolio and conceptualize three new CGM-related quality measures within the portfolio. From the additional measure concepts identified in the portfolio, the TEP prioritized three for conceptualization. High-level measure concept specifications were made available during a public comment period.

Results: The measure concepts prioritized by the TEP included a shared decision-making measure to assess the value of initiating CGM for disease management, a utilization measure to address disparities in access and use of CGM, and a patient-provider review of CGM data to promote routine consideration of these assessments in treatment and ongoing management. Clinical literature, public comments, and TEP feedback informed full measure specifications.

Conclusions: The evolution of diabetes technology reflects the need to shift diabetes quality of care. The measure concepts will be tested in a flexible pilot setting to understand the future of diabetes care and communicate the value of CGM to people with diabetes, providers, and payers.

Existing measures assessing the quality of diabetes care are well established in national performance programs. They commonly evaluate specific processes (eg, retinal exam, kidney health screening) or provide a discrete assessment of outcomes and risks (eg, A1C control, hospitalization). While these measures are evidence-based and demonstrate an opportunity to improve, they have yet to incorporate modern approaches to diabetes management, such as continuous glucose monitoring (CGM).

Traditional methods of measuring diabetes management—blood glucose monitoring (BGM) and A1C—have limitations that CGM can address. BGM may be performed irregularly due to financial restrictions or personal preferences and represents point-in-time rather than longitudinal data. These constraints may mask potential trends and limit utility for real-time decision-making.[1] A1C is a 3-month average measurement and does not reflect short-term glycemic variability or hypoglycemic events.[2] Unlike the static singular point that an A1C provides, CGM data are longitudinal and can depict glucose variability and several metrics, including percentage of time spent in, above, and below target ranges. Evidence suggests that wearing a CGM device that assesses real-time blood sugar results may improve glycemic control, understanding variability, and promote lifestyle changes.[3] The 2022 American Diabetes Association (ADA) Standards of Medical Care in Diabetes (SOC; Table 1) highlighted

Avalere Health, Washington, DC (Ms Khan, Ms Wahid); National Committee for Quality Assurance, Washington, DC (Ms Musser); International Diabetes Center, HealthPartners Institute, Minneapolis, Minnesota (Dr Bergenstal); T1D Exchange, Boston, Massachusetts (Dr Ebekozien); Insulet, Acton, Massachusetts (Dr Snow); Association of Diabetes Care & Education Specialists, Chicago, Illinois (Ms Thomas); and Beyond Type 1, San Carlos, California (Ms Aprigliano).

*Thomas is also affiliated to Eli Lilly and Company, Indianapolis, IN

Corresponding Author:
Naila Wahid, Avalere Health, 1201 New York Avenue NW, Suite 1000, Washington, DC 20005, USA.
Email: nwahid@avalere.com

Table 1. American Diabetes Association Continuous Glucose Monitoring-Related Recommendations

Recommendation	Grade
When prescribing a device, ensure that people with diabetes/caregivers receive initial and ongoing education and training, either in person or remotely, and regular evaluation of technique, results, and their ability to use data, including uploading/sharing data (if applicable), to adjust therapy	C
Real-time continuous glucose monitoring **(A)** or intermittently scanned continuous glucose monitoring **(B)** should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs.	A B
Real-time continuous glucose monitoring **(A)** or intermittently scanned continuous glucose monitoring **(C)** can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs.	A C
In patients on multiple daily injections and continuous subcutaneous insulin infusion, real-time continuous glucose monitoring devices should be used as close to daily as possible for maximal benefit. Intermittently scanned continuous glucose monitoring devices should be scanned frequently, at a minimum once every 8 h.	A A
When used as an adjunct to pre- and postprandial self-monitoring of blood glucose, continuous glucose monitoring can help to achieve A1C targets in diabetes and pregnancy.	B
Periodic use of real-time or intermittently scanned continuous glucose monitoring or use of professional continuous glucose monitoring can be helpful for diabetes management in circumstances where continuous use of continuous glucose monitoring is not appropriate, desired, or available.	C
Skin reactions, either due to irritation or allergy, should be assessed and addressed to aid in successful use of devices.	E
People who have been using continuous glucose monitors should have continued access across third-party payers.	E

the need for CGM access from the outset of a diabetes diagnosis requiring insulin management to promote detailed tracking and to allow for appropriate lifestyle modifications.[4]

Although there are more than 20 individual performance measures targeting diabetes care endorsed by the National Quality Forum, the use of these measures in quality reporting programs is typically limited to a select few.[5,6] As of February 2022, there are limited CGM-specific quality measures to track optimal care for people with diabetes (PWD) despite consensus-based clinical targets for CGM glucose data.[7] There is a need to evolve diabetes quality measurement to account for emerging technologies and innovations in care delivery and to provide transparency on health inequities for diabetes care and education. This measurement gap limits the ability of stakeholders to perform quality improvement, assign accountability, or generate new evidence to support clinical research to continuously advance the quality of care.

The Association of Diabetes Care & Education Specialists (ADCES) and Beyond Type 1 (BT1) worked with Avalere Health (Avalere) to launch the Improving Diabetes Quality Initiative (iDQI) in late 2021 to improve the quality of diabetes care and change standards of care in an era of new and emerging diabetes technology. iDQI envisions a multistakeholder diabetes community united in advancing evidence-based, high-quality, person-centered, and equitable access to care, technology, and services. These aims were initiated through the thought leadership of a Technical Expert Panel (TEP). The TEP focused on building 2 foundational outputs: (1) a portfolio of quality measures and concepts that reflect modern-day advances in technology, patient preferences, and care delivery for diabetes based upon a bedrock of health equity and (2) conceptualization of three CGM-related quality measures within the quality measure portfolio.

Methods

The iDQI TEP was convened to represent a diversity of perspective, opinion, and expertise. The panel included endocrinologists, Advanced Practice Providers, diabetes care and education specialists (DCESs), psychologists,

Table 2. Technical Expert Panel

Name	Organization
Richard Bergenstal, MD	Executive Director, International Diabetes Center and Health Partners Institute
Kathleen Shoemaker, PharmD, MBA	Senior Director for Strategic Alliances, Premier Inc.
Osagie Ebekozien, MD, MPH, CPHQ	Vice President, Population Health and Quality Improvement, T1D Exchange
Daniel Ruck, DNP, FNP, BC-ADM, CDCES	Diabetes Nurse Practitioner/Certified Diabetes Care and Education Specialist at Florence Endocrine Clinic
Ken Snow, MD	Medical Director, Chronic Condition Team at CVS Health
Alicia H. McAuliffe-Fogarty, PhD	Principal, Health Psych Strategists

pharmacists, payers, measurement experts, quality improvement experts, and patient advocates (Table 2). The methodology used by the TEP in developing a diabetes quality measures portfolio and new CGM-related quality measure concepts was informed by the Centers for Medicare & Medicaid Services (CMS) Measures Management Blueprint and is detailed in the following. The following efforts were conducted between September 2021 and February 2022.

A targeted environmental scan was conducted to identify the existing quality priorities for diabetes, how CGM is accounted for in the current standards of care, and existing evidence gaps on integrating CGM for diabetes management. The environmental scan built on a national dialogue session hosted by Avalere and BT1 in November 2020 to consider gaps in diabetes quality of care and identify actionable steps to address them.[8] The scan included a targeted review of clinical guidelines, peer-reviewed evidence, quality reporting programs, and quality measure inventories.[9]

The TEP used findings from the environmental scan to outline guiding principles for construction of a diabetes measure portfolio through iterative consensus-based discussion and then applied these to map existing quality measures to construct a draft measure portfolio. This was reviewed by the iDQI measure stewards and TEP for potential gaps and new measure concepts were identified to expand the portfolio. New measure concepts were identified by the TEP to account for evolving disease management approaches and goals, including several CGM-related measure concepts. The draft measure portfolio was finalized through 2 rounds of TEP discussion and measure steward review.

The TEP reviewed CGM-related measure concepts generated during the national dialogue session hosted by Avalere and BT1 in November 2020. Members discussed the continued value of these concepts and provided input on additional concepts for consideration. To select candidate concepts for further measure development, the TEP performed a prioritization activity, which included iterative rounds of voting and discussion, to narrow the concept list to 3 target candidates. The prioritization activity accounted for concept importance, feasibility, improvement opportunity, and related measure development efforts by other organizations.

High-level measure concept specifications were made available during a public comment period hosted by ADCES from December 17, 2021, to January 10, 2022. The public comment responses (N = 33) were analyzed for themes and implications for measure specification for the three CGM-related measures.

The TEP reviewed public comment themes and available clinical evidence to refine further measure concept specifications inclusive of the eligible population, numerator definitions, potential data sources, and data elements to evaluate during measure testing.

Results

Diabetes Quality Measures Portfolio

The guiding principles for the diabetes quality measure portfolio discussed by the TEP were identified to capture aspects of quality beyond clinical efficacy and to serve as a roadmap for future quality measure development efforts. The TEP identified 5 measurement domains to structure the portfolio: health equity, patient values, access

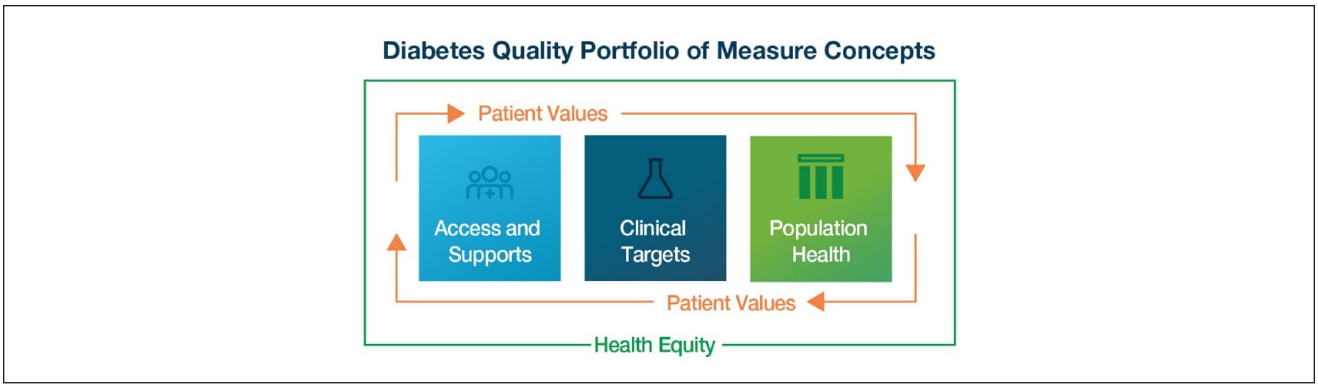

Figure 1. Diabetes quality portfolio of measure concepts.

and supports, clinical targets, and population health (Figure 1). The TEP also specified that measure selection for the portfolio should not be constrained to singular use cases, data availability, or calculation burden. These guiding principles established parameters to identify individual existing measures or new concepts for inclusion.

Several existing measures were included in the measure portfolio given their strong evidence base and opportunity for improvement. A majority of these measures assess clinical targets and population health goals. The TEP noted missing, yet essential, elements to advance quality of care and education for PWD. These essential elements included addressing structural supports (eg, centralization of patient-reported and clinical data in electronic medical records), accounting for patient values (e.g., utilizing shared decision-making [SDM] tools for diabetes management), identifying social risk factors that add barriers and burden to care, and measures that account for blood glucose information derived from emerging technologies, such as CGM (eg, assessing percentage of time in target blood glucose ranges).

Recognizing existing measures are not comprehensive, additional concepts were discussed, particularly those that may support increased access and uptake of CGM. Seven CGM-related measure concepts were identified and added to the diabetes quality measure portfolio (Table 3).

CGM-Related Quality Measures

The TEP discussed the 7 CGM-related measure concepts in the diabetes measure portfolio, prioritizing 3 for further development. Selected measure concepts included an SDM measure to assess the value of initiating CGM for disease management, a utilization measure to address disparities in access and use of CGM, and a patient-provider review of CGM data to promote routine consideration of these assessments in treatment and ongoing management. The proposed measures aim to account for advancements in technology and consumer preferences while potentially providing signals of high-quality care that encourage person-centeredness, equitable care, and improved clinical outcomes. Although the TEP agreed that quality measures directly assessing outcomes are important, initial development efforts for CGM-related quality measures can focus on process measures; the TEP agreed that outcome measures can be deprioritized for the initial measure set due to feasibility concerns.

Results summarizing the 3 CGM-related measure concepts are described in the following sections, including where public comment and TEP feedback shaped decisions. All 3 measures focus on the adult population (ages 18 or older) given varied clinical workflows and approaches in treating the pediatric population. The measures target individuals with a diagnosis of type 1 diabetes (T1D) or type 2 diabetes (T2D), excluding those with evidence during the measurement period of use of hospice services and/or palliative care. Existing guidelines broadly supported CGM for maintaining glycemic control in people with T1D, but recent literature also associated CGM with reduced A1C and increased time in range without increasing the risk of hypoglycemia or medication burden in people with T2D.[10-14]

A few public commenters (N = 2) noted the importance of including a pediatric population. Although data have confirmed the benefit of CGM for people with T1D, the denominator for all measures in this study are limited to individuals 18 and older to ensure targeted measure use and to align with other publicly available measures

Table 3. Diabetes Quality Measures Portfolio

Health Equity		
Stratification of quality measures can reveal preventable disparities in access to care, delivery of services, and diabetes outcomes • CGM utilization • Screening and follow-up for social risk and determinants of health • Data collection on race, ethnicity, insurance status, preferred language, socioeconomic status		
Access and Supports	**Clinical Targets**	**Population Health**
Existing Measures • Educational intervention for patients at greater risk of hypoglycemia measure concepts • Provider review of CGM results • CGM education for patients • CGM education for providers • Integration of CGM results into EHR • Adequate diabetes provider network • Coordinated referrals (including education) for diabetes care • Routine and follow-up (including education) for diabetes care • Coordinated communication among diabetes care team	Existing Measures • Hemoglobin A1C control for patients with diabetes • Eye exam for patients with diabetes • Blood pressure control for patients with diabetes • Diabetic foot and ankle care: peripheral neuropathy[a] • Kidney health evaluation • Statin use in patients with diabetes • Adherence for diabetes medications • Medications to prevent major cardiovascular events • Measure concepts • Advancement of therapy • CGM time below range (TBR), time in range (TIR), and time above range (TAR) • Glycemic variability • SGLT1 inhibitors consumption • SGLT2 inhibitors consumption • GLP1 consumption	Existing Measures • Optimal diabetes care (MN Community Measurement D5 Composite) • Hospitalization for potentially preventable complications composite • Patients assessed to be at greater risk for hypoglycemia • Patient-reported Level 3 hypoglycemic event "requiring assistance" • Measure concepts • ED visit for hypoglycemia • Diabetes readmission rates • Patient absenteeism due to diabetes • Change in hypoglycemia frequency • Cardiac events incidence • Onset of complications (vision loss, dialysis, amputation) • Screening and diagnosis of prediabetes • Cost (eg, from absenteeism) • Summary statistics (eg, mean, median, variance, <7% reaching target) for A1C across populations
Patient Values & Engagement		
Measure Concepts • SDM regarding CGM initiation • Goal setting for self-management • Patient engagement	• Health-related quality of life • Psychological well-being (anxiety/depression) • Diabetes distress; fear of hypoglycemia • Patient empowerment	• Lifestyle impact • Burden of navigating complex health system[b] • Burden of managing diabetes on daily life[b]

Abbreviations: CGM, continuous glucose monitoring; ED, emergency department; EHR, electronic health records; GLP1, glucagon-like peptide 1; SDM, shared decision-making; SGLT1, sodium/glucose cotransporter 1; SGLT2, sodium/glucose cotransporter 2.
[a]Diabetic Foot and Ankle Care measures represent footwear and neurological evaluation.
[b]The Technical Expert Panel members suggested developing into patient-reported outcome measures (PROMs) for greatest value.

focusing on the 18 and older population.[15] Although this initiative does not address the pediatric population, there are significant opportunities to expand CGM measure development in separate, future efforts.

When asked what type of individual would benefit from SDM on CGM initiation with a provider, the overwhelming majority said "all" or "anyone." Some commenters emphasized including those with prediabetes (N = 3), and others designated newly diagnosed PWD (N = 2) or individuals with T1D (N = 2) as a high priority. From internal discussion and TEP feedback, it was determined that prediabetes should not be included in the measure target populations due to data feasibility limitations for the identification of persons with prediabetes. In conclusion, the responses confirmed that both individuals with existing T1D and T2D should be included in all denominators.

Literature suggested that including clinical conditions like end-stage renal disease (ESRD) or pregnancy could have unintended consequences for measurement. However, TEP members expressed that exclusions for individuals providing a personal or clinical rationale for not using CGM, experiencing pregnancy, or being diagnosed with ESRD were potentially unnecessary for initial measure testing. Information on exclusion size and impact on measure performance can be evaluated during measure testing. Applicable additional exclusions are specified under the respective measure descriptions in the following.

Public commenters responded to questions about the measure specifications (Table 4); additional notable responses are described in the following.

Measure 1: SDM Regarding CGM Initiation

For PWD, SDM is a process that occurs throughout the treatment journey (ie, decision to start treatment, diabetes device initiation, data review for CGM maintenance). For the purposes of this measure, SDM is applied to a specific point in time when an individual without previous CGM utilization is considering initiating CGM.

The SDM regarding CGM initiation measure assesses the percentage of people with T1D and T2D without previous CGM utilization who engaged in SDM to initiate personal or professional CGM during the measurement period. This measure aims to incentivize increased exposure and consideration of CGM for diabetes management among "CGM-naïve" individuals.

Clinical guidelines support the use of robust diabetes education, support, and training for optimal CGM implementation. However, the TEP emphasized that SDM is more than education alone; SDM requires a bidirectional discussion and should account for available data on diabetes management.

Preliminary data indicated that, especially in people who are newly diagnosed, CGM usage combined with regular review of the data and SDM with a clinician was associated with improvements in clinical results due to lifestyle modifications such as improved physical activity regimes as opposed to medication additions.[16,17]

The TEP noted a lack of standardized and validated SDM tools for CGM initiation. Although validated, standardized tools lend themselves to measure testing, providers may prefer to use homegrown tools or protocols (eg, CGM training) customized to their patient populations. Thus, the intervention design for the measure-testing pilot should seek to produce an inventory of examples that may help health care professionals identify what works best for their workflow and patients (Figure 2).

Measure 2: CGM Utilization

The CGM utilization measure assesses the percentage of people with T1D or T2D who had evidence of personal or professional CGM use during the measurement period. This measure is constructed as a utilization measure and may support the identification of disparities in access and uptake of CGM. These signals can be useful for internal benchmarking and trending, and throughout measure testing, further insight can be gleaned about its use for indicating measure performance.

Interrupted CGM access may lead to worse outcomes, highlighting the importance of consistent access to those using a CGM device.[4] See Table 1 for a full list of the ADA SOC CGM-related recommendations. Despite the documented benefit of CGM access, studies show that CGM use differs by race/ethnicity and type of insurance, with uptake higher among White patients and those with private insurance compared to non-White patients and those with public insurance.[4] The TEP underscored these disparities as a key driver behind specifying a utilization measure that has the potential to identify gaps in CGM access and promote more equitable diabetes care. To understand how to address variable uptake in CGM, it is also important to understand the general barriers that affect all PWD. Public commenters specified health plans as a stakeholder to influence easier access to CGM, suggesting a health-plan level of attribution (Figure 3).

Measure 3: Collaborative CGM Data Review

The final measure assesses the percentage of people utilizing a continuous glucose monitor who had evidence of standardized CGM data review with a provider during the measurement period. Clinical guidelines like the American Academy of Clinical Endocrinology and the 2022 ADA SOC recommend that CGM device data be reviewed in standardized reports, such as the ambulatory glucose profile (AGP), to promote understanding and

Table 4. Specification of CGM-Related Quality Measures

Related CGM Measure	Question	Key Results
SDM regarding CGM initiation Numerator	What providers can be involved in CGM decision counseling and review of CGM data for diabetes management (eg, diabetes care and education specialists, pharmacists, physicians)	Public commenters supported the role of most provider types (eg, DCESs, physicians, nurses, PAs, pharmacists, registered dietitians) to conduct SDM with patients, assuming these professionals are well informed, trained, and motivated to discuss CGM.
	What standardized tools could be used or adapted to facilitate decision counseling regarding CGM initiation?	Public comment did not reach consensus on available SDM tools for CGM initiation. The clinical evidence does not point to a specific tool but instead highlights several tools that could be adapted or homegrown: • ADCES Identify-Configure-Collaborate Technology Framework • ADCES Technology Decision Aid • Mayo Clinic online SDM tool, Diabetes Medication Choice Decision Conversation Aid • Online portals (eg, Glooko, Tidepool)
CGM utilization	What initiatives to increase exposure, uptake, and value of CGM are you aware of, and how do these proposed measures potentially intersect with those efforts?	One-third (N = 9) of public commenters are not aware of or see limited efforts to increase exposure, uptake, and value of continuous glucose monitors. Of the 23 who responded, a majority said CGM exposure came from continuous glucose monitor manufacturers (ie, commercials, sales team interactions). Other responses included: • ADA standards of care (N = 2) • Education including ADCES materials or recommendations (N = 5) • Samples or free kits (N = 4) • TIR Coalition or language related to TIR (N = 3) • Work done in clinic to increase awareness (N = 4)

	What are the barriers to obtaining access to CGM, and what stakeholders can influence easier access to these technologies (eg, health plans, providers)?	• Difficulty gaining insurance coverage and cost (N = 24)
		• Ambiguous coverage requirements for CGM (ie, DME benefit; N = 4)
		• Provider-related barriers (N = 14)
		  ○ Treatment inertia (N = 4)
		  ○ Lack of knowledge or resources (N = 7)
		• System-level barriers
		  ○ Administrative burden (N = 5)
		  ○ Burdensome IT and ordering processes (N = 5)
		• Reimbursement variation across different provider types (N = 2)

Review of CGM data	What providers can be involved in CGM decision counseling and review of CGM data for diabetes management (eg, DCESs, pharmacists, physicians)?	A wide range of professionals can conduct CGM data review: • Majority said DCESs and clinicians (eg, nurse practitioners, physician assistants, endocrinologists) • Anyone involved in the care team with understanding of the CGM data (N = 9)

(continued)

Table 4. *(continued)*

Related CGM Measure	Question	Key Results
		• Pharmacists (N = 9) ○ Some (N = 2) said pharmacists do not or should not review CGM data • Dietitians (N = 5)
	How often should CGM data be jointly reviewed between providers and patients (eg, quarterly, biannually, patient-dependent)?	• Depends on the PWD and should be individualized • Importance of CGM data review among certain high-risk groups and people who are newly diagnosed or who newly initiated CGM • Recommended data review or changes to frequency of this review after therapy, lifestyle, or medication changes
	How much CGM data are needed for review to be meaningful (eg, 14 d)?	• Majority said 14 d, or between 7 and 14 d, of CGM data should be reviewed with a provider for actionable data, • Some said the number of days depends on the PWD and their goals/therapy plans (N = 5). • Review on a biannual or quarterly basis, dependent on disease progression
	Where can collaborative review occur (eg, patient encounter, virtual visits, via patient portal)?	The majority of respondents expressed CGM data review can occur at any encounter (ie, virtual or in person). While some specified use of a portal, there was no consensus among providers around familiarity with this type of review or a sense of comfort sharing data virtually if a patient does not have visual access.
	Does the use of a standardized tool, like the ambulatory glucose profile, support shared SDM on ongoing management?	Evidence suggests a lack of provider training regarding CGM data review. Based on public comments, facilitators for collaborative review of CGM data may include use of the AGP, data-sharing apps (eg, Clarity, LibreView, Glooko, Tidepool), unbranded handouts, readiness to change tools, and provider education on data assessment.

Abbreviations: ADA, American Diabetes Association; ADCES, Association of Diabetes Care & Education Specialists; AGP, ambulatory glucose profile; CGM, continous glucose monitoring; DCESs, diabetes care and education specialists; DME, durable medical equipment; IT, information technology; PAs, physician assistants; PWD, person with diabetes; SDM, shared decision-making; TIR, time in range.

interpretation.[18,19] In addition to the denominator specifications outlined previously, individuals eligible for this measure must also have evidence of using a personal or professional CGM for a minimum of 10 consecutive days in the measurement period.

Literature shows that any form of personal diabetes data review improves individual empowerment in making treatment-related decisions.[20] Feedback from public commenters emphasized AGP as a tool to support data review and decision-making, dependent on how well the reviewer and individual understand the report. The TEP concurred that a reasonable definition of CGM data review could include collaborative review of a standardized glucose report with visualizations (eg, AGP), as currently recommended in clinical guidelines.

Public commenters supported a wide range of professionals to conduct CGM data review. The TEP determined pharmacists are acceptable reviewers of CGM data, concluding that expanding access to local retail pharmacies could promote broader access to CGM management as a potential option to close the gap in disparities. Public commenters affirmed the TEP's commentary that CGM review typically occurs with providers who have a background in diabetes care.

Public comment responses confirmed that individuals maintaining continuous glucose monitor use should review a minimum of 10 out of 14 days of data at least annually with a provider. Individuals newly initiating CGM

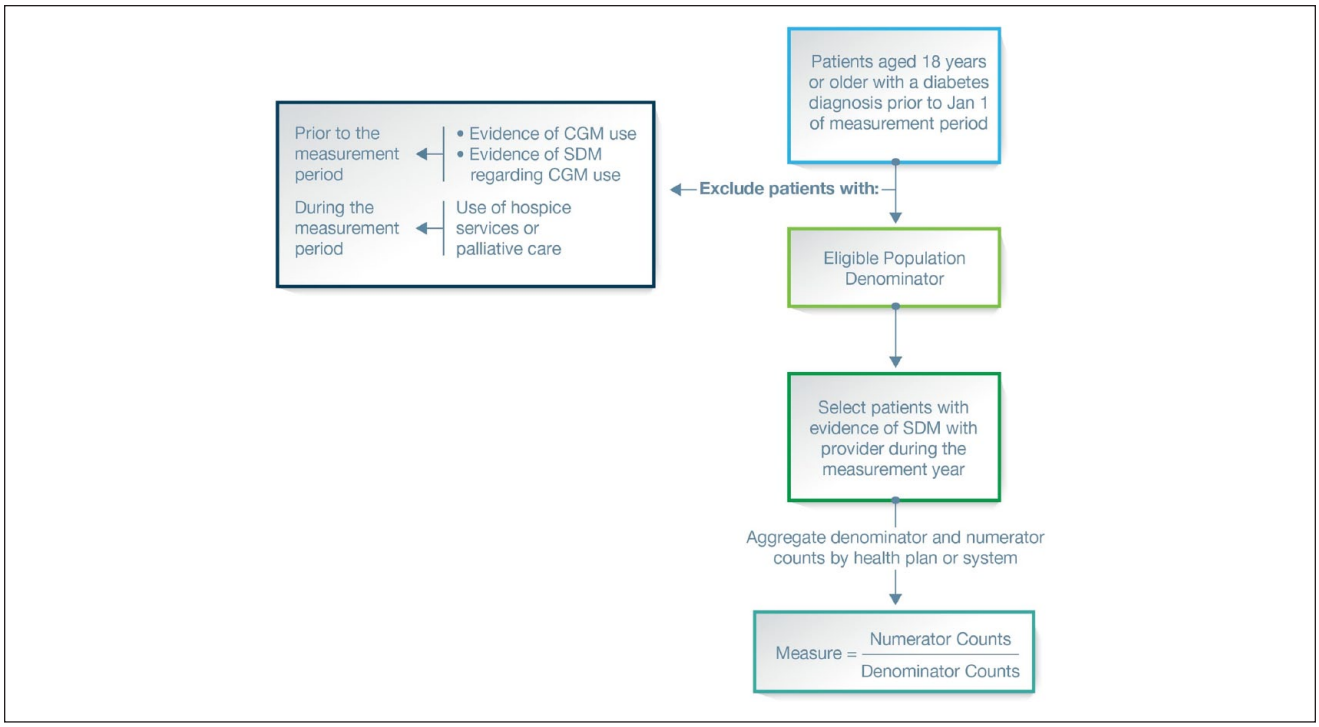

Figure 2. SDM regarding CGM initiation measure workflow.
Green: denominator; yellow: denominator exclusions; blue: eligible population; orange: numerator; gray: included patients.
Abbreviations: CGM, continuous glucose monitoring; SDM, shared decision-making.

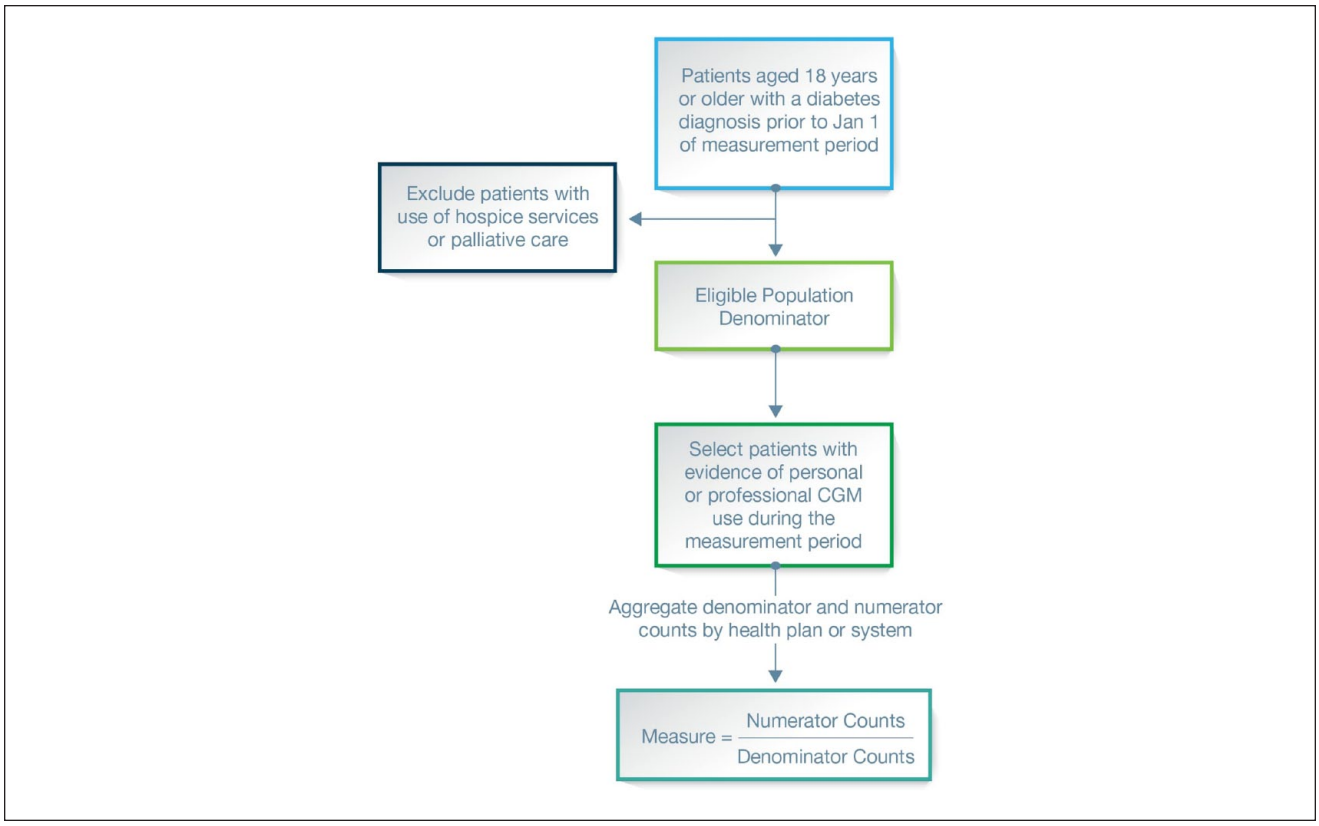

Figure 3. CGM utilization measure workflow.
Green: denominator; yellow: denominator exclusions; blue: eligible population; orange: numerator; gray: included patients.
Abbreviation: CGM, continuous glucose monitoring.

Figure 4. CGM data review measure workflow.
Green: denominator; yellow: denominator exclusions; blue: eligible population; orange: numerator; gray: included patients.
Abbreviation: CGM, continuous glucose monitoring.

should review data with a provider after 10 to 14 days of starting CGM.[21,22] The TEP encouraged more frequent data review to encourage high-quality care and suggested evaluating the frequency of review and feasibility of requiring multiple reviews per year during measure testing (Figure 4).

Limitations

Public commenters influenced changes to the measure specifications and informed many of the key narratives around diabetes quality care but did not provide input on the diabetes quality measures portfolio. Given that ADCES hosted and publicized the public comment opportunity, the majority (N = 16) of responses were from licensed or currently practicing DCESs. Although DCESs reflect an interprofessional group of clinicians from registered dietitians to MDs, this potential bias may impact the feasibility and suggested workflow implemented in pilot testing and will need to be considered when applying the findings of this study to practices.

There are also limitations on what the measures themselves can assess. Although cost is a significant barrier in continuous glucose monitor access, the measures are not intended to influence direct changes to cost or coverage. A broader conversation around cost is needed among multiple stakeholders to ensure cost does not create a "race to the bottom."

Discussion

Efforts to gather relevant information revealed a lack of awareness around or uptake of standardized diabetes care and workflows for continuous glucose monitor use. Using the previously referenced guiding principles (ie, health equity, patient values, access and supports, clinical targets, and population health) as a framework, the iDQI designed a diabetes quality measures portfolio to organize existing measures and new measure concepts for

potential inclusion in the portfolio. TEP members identified gaps in the proposed portfolio to guide a final version of the diabetes quality measures portfolio.

Note that this portfolio is not limited by what is currently feasibly measured and, instead, represents both existing measures and innovative concepts that account for new technologies, broader populations, patient experiences, and broader integration of equity into all aspects of care. This portfolio will remain dynamic and evolve as the health care system changes and innovates.

Evident from multiple sources (ie, public comment, literature, and TEP discussions) is the need for awareness and advocacy efforts to drive CGM uptake and access—in addition to specific solutions to improve access in relation to cost, coverage, and provider education.

Underscoring the conversation around continuous glucose monitor access is the importance of health equity in high-quality diabetes care. iDQI envisions these measures as tools for identifying disparities, evaluating underlying drivers, and motivating change to ensure equitable access, delivery, and outcomes of care. The specific intent and expected real-world implications of each measure concept is discussed in the following.

SDM Regarding CGM Initiation

The SDM regarding CGM initiation measure intends to increase CGM exposure and awareness among "CGM-naïve" individuals through an approach that engages the person with diabetes and accounts for individual preferences. The use of SDM provides information necessary for PWD to self-manage their diabetes. By allowing PWD to participate in their health care decisions, SDM can bridge the gap between evidence-based medicine and true person-centered care. Broadly, this measure reflects the environmental shift toward person-centered care and inclusion of individual preferences in clinical conversations.

CGM Utilization

The CGM utilization measure intends to develop a standardized method for within-system/health plan trending and comparison of CGM access. Measuring CGM utilization will support identification and mitigation of barriers to access, which can improve patient outcomes. Identifying which populations have access to CGM can also have larger environmental implications on health equity evaluation.

Because CGM use provides the data necessary to make behavioral changes that can reduce diabetes-related complications (eg, heart attack, stroke), it can similarly empower providers and health systems to make choices that improve health outcomes for PWD. Furthermore, a measure at the health-plan level to support the initial and continued utilization of CGM in PWD populations not only encourages individuals to take a more active approach in their care but also encourages health plans to evaluate and support cost-effective alternatives to traditional methods of diabetes management.

CGM Data Review

The CGM data review measure intends to encourage patient-provider review of CGM data that can inform treatment and lifestyle decisions for diabetes management. Collaborative review of personal diabetes data and allowing individual participation in health care decision-making may improve person-centered care, increase autonomy, and advance a better understanding in how treatment-related decisions can affect an individual's daily life and management of their diabetes.

Although appropriate data review has the potential to empower individuals to continue managing their diabetes treatment, gaps in care are likely to occur after a continuous glucose monitor is prescribed. PWD need follow-up care after starting CGM but often go months without it. The primary barriers to continuous CGM use are a lack of follow-up and suboptimal continuous glucose monitor use. Issues involving follow-up care include unavailable appointments, limited telehealth options, inability to physically access sites of care, and provider unwillingness to discuss CGM data over the phone, in addition to financial burden, out-of-pocket costs, CGM coverage at the pharmacy level, and lack of insurance coverage for CGM data review. PWD may also be unaware of CGM best practices, contributing to the "troubleshooting period" where they may not scan enough or have tools to optimize use of CGM data. Other reasons for lack of follow-up may include issues in who can download the CGM data and which providers have access or sufficient time to review. Overall, the CGM data review measure may support further identification of barriers to continuous continuous glucose monitor use and support equitable, consistent access and use of CGM among PWD.

Conclusions

The development of advanced, person-centered technology and innovative diabetes management devices underscores the evolution of the health care system and the importance of accounting and adapting for patient preferences related to treatment and management. As diabetes technology shifts and evolves, quality of care must change in parallel. This article addresses how CGM fits into a broader effort to advance diabetes care and promote person-centered care by understanding how PWD can become involved in decision-making, which populations have access to CGM and how that impacts outcomes, and what joint review of CGM data looks like. The overarching goal of this effort is to evaluate what "good" quality diabetes care involves and identify how CGM use can help providers and individuals make informed decisions to improve outcomes and quality of life.

Measures for future field testing will be flexible in terms of provider type, setting of care, and method of CGM access to gain the richest insight on what "good" quality care looks like and to demonstrate the value of CGM to PWD, providers, and payers. Measure concepts can be tested in traditional and nontraditional sites that are using time in range metrics already (eg, retail clinics, hospitals, community-based hospitals, employer health clinics, etc) in an effort to meet people where they are and collect complete information. There is ample opportunity to cast a wide net through the proposed measure concepts and thoughtfully design future pilot testing to inform future refinement and evidence generation.

Implications

Quality diabetes care and education can be delivered by diverse provider types, across different settings, in multiple sites of care, and to any person with diabetes. The ability for individuals to be advocates in their own care relies on proper education, joint decision-making, equitable access, and consistent follow-up. Improving quality of care and education in a flexible manner will aim to holistically capture the high-quality clinical care provided to PWD; promote health equity and equitable access dependent on the individual's needs, priorities, and preferences; and account for provider workflow, infrastructure, and resources. Innovations such as CGM can help optimize glycemic management as a key component of comprehensive diabetes care.

While the new CGM-related measures aim to impact diabetes care and education, this article intentionally does not encapsulate the full range of potential "measurement" efforts or include all the populations that may benefit from CGM. Additionally, there is value in addressing assessment, prevention, and management of diabetes-related complications such as eye and foot disease.

These proposed measures do not aim to address cost or coverage directly but, rather, can influence policy change that addresses health equity and access in relation to diabetes technology. Although this initial measure set applies exclusively to individuals diagnosed with T1D and T2D, the TEP recognizes the potential benefit of CGM in prediabetes and youth populations. Further research may hone in on specific populations—including the under-18 age group, high-risk individuals (eg, those with high A1C, senior population), newly diagnosed PWD, or individuals with comorbidities. Additional studies around diabetes measures may involve developing a disease registry to track progress from providing guideline-based care or revising the D5 composite measure.

The TEP encourages further measure development and testing. As a next step, Avalere will serve as a measure developer to design and implement a pilot study to conduct beta testing and exclusions analysis of the three CGM-related measures. The pilot study will help determine the feasibility of data collection and inform the scientific acceptability and usability of the measures. Field testing is an opportunity to generate evidence about the value of engaging in activities such as SDM and CGM data review. Based on the pilot testing results, the TEP will reconvene to further refine the measure specifications. The iDQI will remain engaged with other measure developers, CMS, and key stakeholders to pioneer advances in diabetes quality.

Acknowledgments

We would also like to thank Alicia McAuliffe-Fogarty, PhD, CPsychol (Health Psych Strategists, Saratoga Springs, New York); Daniel Ruck, DNP, FNP, BC-ADM, CDCES (Joslin Diabetes Center, Boston, Massachusetts); Kathleen Shoemaker PharmD, MBA, CPHIMS (Freelance, Indianapolis, IN); and Dylan Davis, PhD (Avalere Health, Washington, DC) for their thought leadership and contributions to the Technical Expert Panel and writing and editing work for the Improving Diabetes Quality Initiative manuscript and measure concepts.

Declaration of Conflicting Interests

Maliha Khan: funding: Abbott; employment: Fishawack Health. Naila Wahid: funding: Abbott; employment: Fishawack Health. Taylor Musser: funding: Abbott; employment: NCQA. Richard Bergenstal: Dr Richard M. Bergenstal has received research support, has acted as a consultant, or has been on the scientific advisory board for Abbott Diabetes Care, Ascensia, Bigfoot Biomedical, Inc., CeQur, DexCom, Eli Lilly, Hygieia, Insulet, Medtronic, Novo Nordisk, Onduo, Roche Diabetes Care, Sanofi, United Healthcare, Vertex Pharmaceuticals and Zealand Pharma. Dr. Bergenstals's employer, nonprofit HealthPartners Institute, contracts for his services, and he receives no personal income. Osagie Ebekozien: Dr Ebekozien is a Medtronic Diabetes Health Equity Advisory Board member. He is the principal investigator on research projects funded by Eli Lilly, Medtronic Diabetes, and Dexcom. All projects are funded through his organization T1D Exchange. Kenneth Snow: The author declares that he has no relevant or material financial interests to disclose related to the research described in this article. Christel Aprigliano: The author declares that he has no relevant or material financial interests to disclose related to the research described in this article. Kate Thomas: The author declares that he has no relevant or material financial interests to disclose related to the research described in this article.

Funding

Abbott Diabetes Care provided sole funding for this study.

Supplemental Material

Supplemental material for this article is available online.

ORCID iD

Maliha Khan https://orcid.org/0000-0003-1958-7481

References

1. Lin R, Brown F, James S, Jones J, Ekinci E. Continuous glucose monitoring: a review of the evidence in type 1 and 2 diabetes mellitus. *Diabet Med*. 2021;38(5):e14528. doi:10.1111/dme.14528
2. Chehregosha H, Khamseh ME, Malek M, Hosseinpanah F, Ismail-Beigi F. A view beyond HbA1c: role of continuous glucose monitoring. *Diabetes Ther*. 2019;10(3):853-863. doi:10.1007/s13300-019-0619-1
3. NCQA. Rethinking diabetes care in the digital age. 2022. Accessed March 30, 2022. https://www.ncqa.org/white-papers/rethinking-diabetes-care-in-the-digital-age/
4. American Diabetes Association Professional Practice Committee. 7. Diabetes technology: standards of medical care in diabetes-2022. *Diabetes Care*. 2022;45(suppl 1):S97-S112. doi:10.2337/dc22-S007
5. National Quality Forum. Quality positioning system. 2022. Accessed March 15, 2022. https://www.qualityforum.org/qps/
6. Avalere Health. Advancing diabetes care in the era of CGM. Dialogue proceedings. 2021. Accessed March 29, 2022. https://avalere.com/wp-content/uploads/2021/04/ADC-Dialogue-Sessions-Proceedings.pdf
7. Prahalad P, Ebekozien O, Alonso GT, et al. Multi-clinic quality improvement initiative increases continuous glucose monitoring use among adolescents and young adults with type 1 diabetes. *Clin Diabetes*. 2021;39(3):264-271. doi:10.2337/cd21-0026
8. Avalere Health. Advancing diabetes care in the era of CGM: dialogue proceedings. 2021. Accessed March 15, 2022. https://avalere.com/insights/advancing-diabetes-care-in-the-era-of-cgm-dialogue-proceedings
9. Centers for Disease Control and Prevention. National diabetes statistics report. 2022. Accessed March 15, 2022. https://www.cdc.gov/diabetes/data/statistics-report/index.html
10. Beck RW, Riddlesworth TD, Ruedy K, et al. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. *Ann Intern Med*. 2017;167(6):365-374. doi:10.7326/M16-2855
11. Bui A, Kim J. Continuous glucose monitoring for underserved and minority patients with type 2 diabetes in an interprofessional internal medicine clinic. *Innov Pharm*. 2020;11(4):1-5. doi:10.24926/iip.v11i4.3501
12. Ehrhardt NM, Chellappa M, Walker MS, Fonda SJ, Vigersky RA. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. *J Diabetes Sci Technol*. 2011;5(3):668-675. doi:10.1177/193229681100500320
13. Simonson GD, Bergenstal RM, Johnson ML, Davidson JL, Martens TW. Effect of professional CGM (pCGM) on glucose management in type 2 diabetes patients in primary care. *J Diabetes Sci Technol*. 2021;15(3):539-545. doi:10.1177/1932296821998724
14. Yoo HJ, An HG, Park SY, et al. Use of a real time continuous glucose monitoring system as a motivational device for poorly controlled type 2 diabetes. *Diabetes Res Clin Pract*. 2008;82(1):73-79. doi:10.1016/j.diabres.2008.06.015
15. CMS. Measures inventory tool. 2022. Accessed March 29, 2022. https://cmit.cms.gov/cmit/#/MeasureInventory

16. Allen NA, Fain JA, Braun B, Chipkin SR. Continuous glucose monitoring counseling improves physical activity behaviors of individuals with type 2 diabetes: a randomized clinical trial. *Diabetes Res Clin Pract*. 2008;80(3):371-379. doi:10.1016/j.diabres.2008.01.006
17. Maurizi AR, Pozzilli P. Do we need continuous glucose monitoring in type 2 diabetes? *Diabetes Metab Res Rev*. Published online August 24, 2013. doi:10.1002/dmrr.2450
18. American Association of Clinical Endocrinology. American association of clinical endocrinology clinical practice guideline: the use of advanced technology in the management of persons with diabetes mellitus. *Endocr Pract*. 2021;27(6):505-537. doi:10.1016/j.eprac.2021.04.008
19. American Diabetes Association Professional Practice Committee. 6. Glycemic targets: standards of medical care in diabetes-2022. *Diabetes Care*. 2022;45(suppl 1):S83-S96. doi:10.2337/dc22-S006
20. Bell AM, Fonda SJ, Walker MS, Schmidt V, Vigersky RA. Mobile phone-based video messages for diabetes self-care support. *J Diabetes Sci Technol*. 2012;6(2):310-319. doi:10.1177/193229681200600214
21. Petrie JR, Peters AL, Bergenstal RM, Holl WR, Fleming GA, Heinemann L. Improving the clinical value and utility of CGM systems: issues and recommendations. *Diabetes Care*. 2017;40(12):1614-1621. doi:10.2337/dci17-0043
22. Vigersky RA. The benefits, limitations, and cost-effectiveness of advanced technologies in the management of patients with diabetes mellitus. *J Diabetes Sci Technol*. 2015;9(2):320-330. doi:10.1177/1932296814565661