



Rethinking Diabetes Care In The Digital Age

Findings from the 2021 Digital Quality Summit



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Executive Summary

As of 2018, there were an estimated 34.2 million people with diabetes mellitus in the United States, representing 10.5% of the population. This includes approximately 7.3 million adults 18 years and older who met laboratory criteria for diabetes but were not aware of having diabetes (undiagnosed diabetes) or did not report it.¹ Approximately 88 million adults have prediabetes, a condition where blood glucose levels are higher than normal but not high enough to be diagnosed as type 2 diabetes. 84% of people with prediabetes do not know they have it.²

More people are developing type 1 and type 2 diabetes at earlier ages, and racial and ethnic minorities continue to develop type 2 diabetes at higher rates.¹ According to the Centers for Disease Control and Prevention (CDC), the incidence of type 1 diabetes continues to increase in U.S. youths, with steeper increases observed in Black and Hispanic youths. Since 2011, the incidence of type 1 diabetes has also significantly increased among the Asian and Pacific Islander populations.³ Diabetes and prediabetes present a significant burden on the U.S. health care system and on patients with the disease.

During the 2021 Digital Quality Summit, a collaboration between NCQA and HL7, NCQA, in partnership with The Leona M. and Harry B. Helmsley Charitable Trust and the International Diabetes Center, HealthPartners Institute (IDC), hosted a unique 5-session track—“Rethinking Diabetes Care in the Digital Age”—that explored emerging concepts in diabetes care. Experts in the fields of diabetes and behavioral health, as well as professionals focused on quality measurement, explored measure concepts with the potential to promote optimal care for persons diagnosed with type 1 or type 2 diabetes. These experts also offered recommendations for the redesign of NCQA’s Diabetes Recognition Program. Although screening for diabetes and aspects of diabetes prevention are important population health topics, they were not the focus of discussion.

The experts focused on emerging medical technologies (e.g., continuous glucose monitors) and encouraging attention on behavioral health issues; specifically:

- Use of continuous glucose monitoring (CGM) indicators in diabetes care.
 - Screening, assessment and care for comorbid behavioral health issues, including diabetes distress.
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The experts and track participants agreed on steps to advance quality measurement and potentially bridge gaps in care management for persons with diabetes (including types 1 and 2):

1. Integrate CGM metrics, which are available in digital data format, into the NCQA diabetes measure portfolio.
2. Address psychosocial needs to improve emotional and physical outcomes for individuals living with diabetes.
3. Promote precision in clinical responses to diabetes distress—screening, assessing and intervening.
4. Leverage technology to attain the right data, at the right time, for the right patient across clinical settings.



Introduction: Emerging Opportunities and the Importance of Measurement in Diabetes Care Beyond HbA1c and Depression

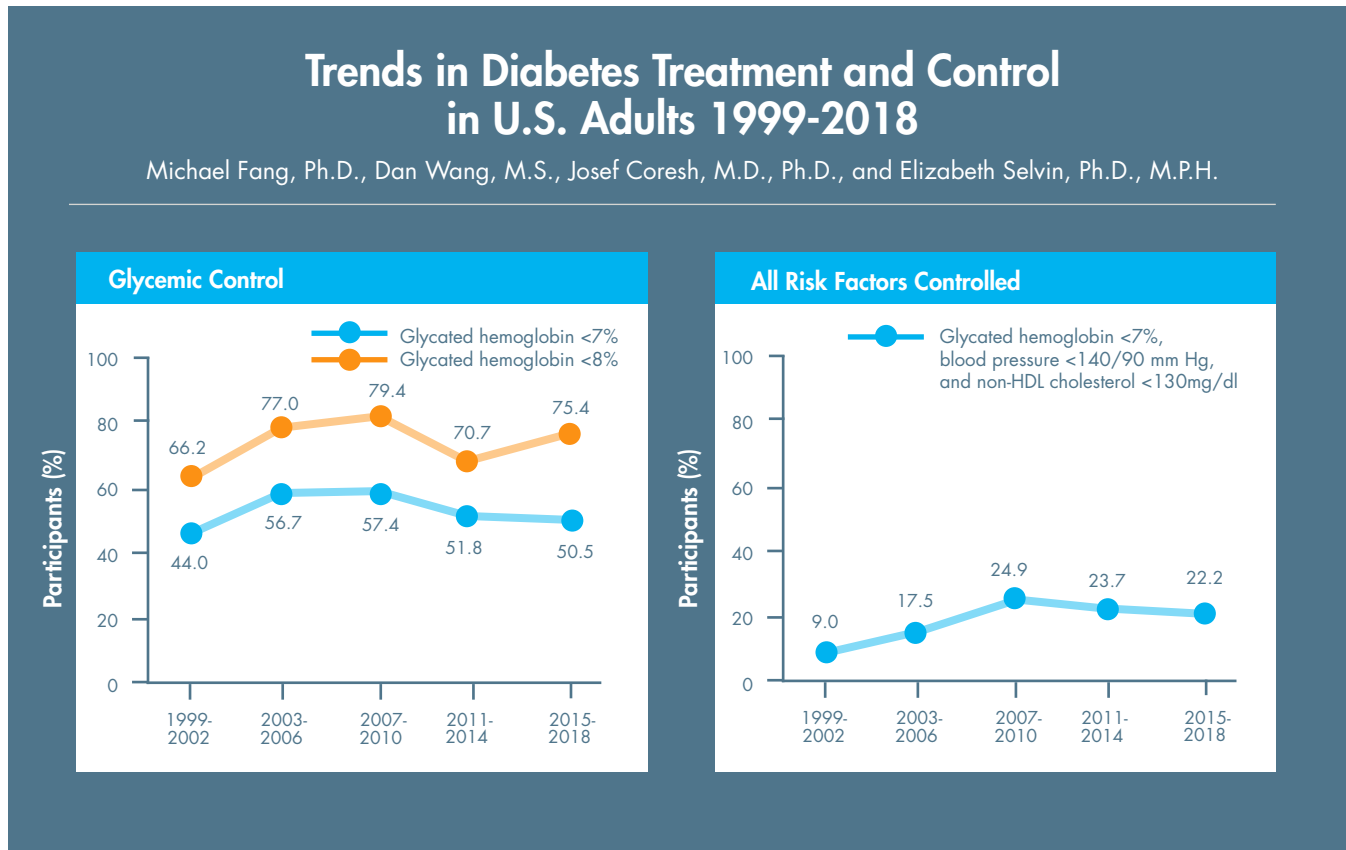
Key Diabetes Indicator Trends

Diabetes is common in the U.S. population; as of 2018, approximately 34.2 million people had diagnosed diabetes (includes type 1 and type 2).¹ According to the Centers for Diabetes Control and Prevention, approximately 88 million American adults have prediabetes.² Diabetes has a significant impact on the U.S. population, but despite its prevalence and the known relationship between glucose levels and both short- and long-term health, outcomes remain suboptimal. Unfortunately, a substantial majority (97.5%) of people with diagnosed type 2 diabetes also have at least one comorbid condition, and 88.5% have at least two. The comorbidity burden tends to increase in older age groups and is higher in men than women. The most common conditions in patients with type 2 diabetes include hypertension (82.1%), overweight/obesity (78.2%), hyperlipidemia (77.2%), chronic kidney disease (4.1%) and cardiovascular disease (21.6%).

By addressing diabetes through the promotion of evidence-based quality care, many other related health problems can be prevented or delayed. According to the American Diabetes Association's (ADA) Standards of Medical Care for Diabetes—2021, the proportion of patients with diabetes who achieve recommended hemoglobin A1c (HbA1c or A1c), blood pressure and low-density lipoprotein (LDL) cholesterol levels has fluctuated in recent years and there remains considerable room for improvement. Glycemic and cholesterol control through dietary intake are key aspects of diabetes management that remain challenging.⁴

To further demonstrate the need for improvement, data from the National Health and Nutrition Examination Survey (NHANES) indicate that after more than a decade of progress from 1999 to the early 2010s, glycemic and blood pressure control declined in adults with diabetes and lipid control leveled. From the 2007–2010 reporting period to 2015–2018, the percentage of adult NHANES participants with diabetes in whom glycemic control (glycated hemoglobin level <7%) was achieved declined from 57.4% (95% confidence interval [CI], 52.9–61.8) to 50.5% (95% CI, 45.8–55.3).⁵ (Figure 1: Trends in Diabetes Treatment and Control in U.S. Adults, 1999–2018.) An additional study, using NHANES data, indicates even fewer patients with type 2 diabetes and using insulin are at goal. For example, only 62% of patients with type 2 diabetes and using insulin were estimated to have achieved a glycated hemoglobin <8% and only 31% achieved <7%. This study suggests improvements are needed in patient and professional education on insulin use, new insulin formulations, delivery technology and/or systems of care to improve glycemic control in patients receiving insulin.⁶

Other important indicators of diabetes management have also declined or stagnated. After major improvements in lipid control (non-high-density lipoprotein cholesterol level <130 mg per deciliter) in the early 2000s, minimal improvement was seen from 2007–2010 (52.3%; 95% CI, 49.2–55.3) to 2015–2018 (55.7%; 95% CI, 50.8–60.5). From 2011–2014 and 2015–2018, the percentage of participants in whom blood pressure control (<140/90 mm Hg) was achieved decreased from 74.2% (95% CI, 70.7–77.4) to 70.4% (95% CI, 66.7–73.8). Figure 1: Trends in Diabetes Treatment and Control shows that even during peak performance (2007–2010), the proportion meeting all three targets was only 24.9%, indicating significant room for improvement.⁵

Figure 1: Trends in Diabetes Treatment and Control⁵

The national declines in glycemic and blood pressure control and the plateauing of lipid control after 2010 have major public health implications. Uncontrolled risk factors confer significant risk of microvascular disease, cardiovascular events and death among adults with diabetes. Findings from the NHANES data may indicate a possible population-level increase in diabetes-related illness in the future; recent evidence suggests that a “resurgence” in diabetes-related complications may already be underway.⁵ These data suggest that better management of diabetes is needed, and there is the potential that focused quality measures, aligned with evidence and current best practices, could drive improvements in care. However, with HbA1c being the sole glycemic control metric in the current diabetes care measure portfolio, an ongoing ability to accurately assess quality diabetes care may be hindered during a disruption in patients’ ability to make regular visits to a clinician’s office or medical laboratory for an HbA1c blood test. This was well documented in the U.S. in 2020, when the COVID-19 pandemic dramatically disrupted collection of HbA1c samples.⁷

Overview of NCQA Diabetes and Behavioral Health Quality Measurement

NCQA promotes improvement of diabetes care through several methods. The Healthcare Effectiveness Data and Information Set (HEDIS[®]) is one of the health care industry’s most widely used performance improvement tools. HEDIS includes measures of performance in health care, driven by opportunities to make meaningful differences in people’s lives.

Since 1999, variations of the HEDIS Comprehensive Diabetes Care measure assessed care for adults 18–75 years of age with diabetes (type 1 and type 2) and were collected and reported by health plans and clinicians. As standards for diabetes care have evolved over time and the evidence supporting measure indicators has changed, NCQA updated the suite of diabetes care measures to include the following indicators as of measurement year 2022:

- Hemoglobin A1c Control for Patients With Diabetes.
- Blood Pressure Control for Patients With Diabetes.
- Eye Exam for Patients With Diabetes.
- Kidney Health Evaluation for Patients With Diabetes.
- Statin Therapy for Patients With Diabetes.

In addition to measuring health plan performance on diabetes care through HEDIS, NCQA, in partnership with the ADA, developed and launched the Diabetes Recognition Program in 1997 and updated it in 2015. The program recognizes clinicians who provide high-quality care to their patients with diabetes. The current program tracks performance on HEDIS measures in the following clinical areas:

- HbA1c control.
- Blood pressure control.
- Eye examinations.
- Nephropathy assessment.
- Foot examination.
- Smoking and tobacco use cessation assistance.

NCQA's portfolio of diabetes measures in HEDIS and in the Diabetes Recognition Program do not include a measure focused on depression or diabetes distress (psychological stress due to managing diabetes), but HEDIS includes behavioral health-focused measures that may lend themselves to stratification or revision to focus on persons with diabetes.

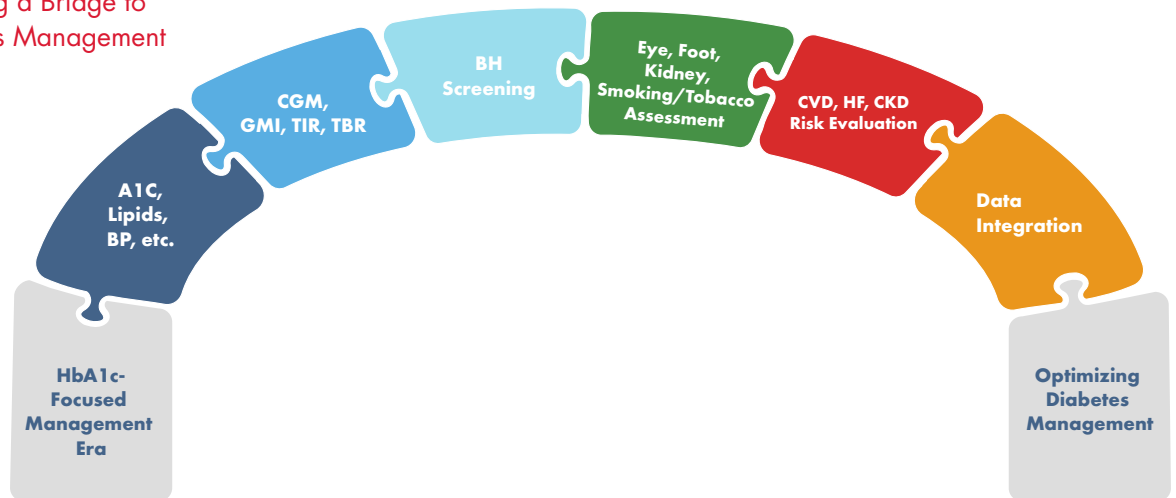
The suite of HEDIS depression measures provides a potential template to explore diabetes distress quality measurement concepts. For example, the HEDIS measure Depression Screening and Follow-Up for Adolescents and Adults assesses the percentage of members 12 years of age and older who were screened for clinical depression using a standardized instrument and, if screened positive, received follow-up care. The HEDIS measure Depression Remission and Response for Adolescents and Adults assesses the percentage of members 12 years of age and older with a diagnosis of depression and an elevated PHQ-9 score, who had evidence of response or remission within 4–8 months of the elevated score.

Advances in use and interpretation of continuous glucose monitoring (CGM), and in understanding the impact of behavioral health on long-term diabetes management, introduce important considerations for expanding quality measurement approaches into the digital realm for diabetes care. NCQA, the Helmsley Charitable Trust and the International Diabetes Center, HealthPartners Institute (IDC) recognize this important opportunity to promote optimal care for persons with diabetes, including incorporating CGM metrics into the quality measurement spectrum and recognizing the critical effects of behavioral health on self-management of diabetes.



Building a Bridge Toward Optimal Diabetes Management

Figure 2: Building a Bridge to Optimal Diabetes Management



*Adapted from R. Bergenstal presentation materials - Digital Quality Summit, July 2021

The 2022 ADA Standards of Medical Care in Diabetes call for an organized, systematic approach to optimal diabetes management:

Optimal diabetes management requires an organized, systematic approach and the involvement of a coordinated team of dedicated health care professionals working in an environment where patient-centered, high-quality care is a priority. While many diabetes processes of care have improved nationally in the past decade, the overall quality of care for patients with diabetes remains suboptimal. Additional efforts that could be deployed and subsequently impact the quality of diabetes care include:

- **Providing care that is concordant with evidence-based guidelines.**
- Expanding the role of teams to implement more intensive disease management strategies.
- Tracking medication-taking behavior at a systems level; redesigning the organization of the care process.
- Implementing electronic health record tools.
- Empowering and educating patients.
- Removing financial barriers and reducing patient out-of-pocket costs for diabetes education, eye exams, **diabetes technology**, and necessary medications.
- **Assessing and addressing psychosocial issues**
- Identifying, developing, and engaging community resources and public policies that support healthy lifestyles.⁸

Experts acknowledge the need to advance the quality of diabetes care through meaningful measures applied systematically and equitably. This white paper explores the role of quality measures in bridging the gap between current practice and optimal diabetes care through technology (CGM) and behavioral health assessments (e.g., diabetes distress).

Methods

Increasing recognition of advances in glycemic monitoring beyond HbA1c and evolving contributions of electronic data to advance quality measurement have introduced opportunities for NCGA to explore updates to the HEDIS diabetes measurement set and the Diabetes Recognition Program. In addition, the ADA's updated Standards of Medical Care in Diabetes reflect new strategies for diabetes management that may be conducive to measurement. In collaboration with The Leona M. and Harry B. Helmsley Charitable Trust and the International Diabetes Center, HealthPartners Institute (IDC), NCGA developed a focused track of presentations and discussions—"Rethinking Diabetes Care in the Digital Age"—as part of the 2021 Digital Quality Summit.

This track was a virtual event over 3 days (July 13–15, 2021) and had more than 80 registered participants who brought perspectives from specialists, primary care, behavioral health and a broad variety of health disciplines. Its goal was to advance patient-centered outcomes by forging consensus for digital diabetes quality measurement and diabetes care. Track participants self-selected either advancements in diabetes management through diabetes technology (CGM, specifically) or a behavioral health break-out group that convened separately three times and twice as a combined group. Track facilitators and participants provided foundational knowledge on glycemia and how CGM metrics offer the potential for more precise glucose management than current measures. In addition, behavioral health screening, with a focus on diabetes distress, and potential approaches for diabetes care integration were discussed as opportunities for measurement beyond those currently used in HEDIS.

As an output of the overarching sessions on advancing measurement approaches, the track produced recommendations to implement new or revised diabetes measures and redesign the Diabetes Recognition Program. This report is based on track transcripts and recordings.

Table 1: Common Diabetes and Behavioral Health Abbreviations and Acronyms in This Report

Abbreviations

ADA	American Diabetes Association
AGP	Ambulatory Glucose Profile
BH	Behavioral Health
CGM	Continuous Glucose Monitoring or when referring to a device, Continuous Glucose Monitor
DDS	Diabetes Distress Screener / Diabetes Distress Scale
EHR	Electronic Health Record
GMI	Glucose Management Indicator (also known as "personalized A1c")
GV	Glucose Variability
HbA1c	Hemoglobin A1c (sometimes shortened to A1c)
PAID	Problem Areas in Diabetes
PHQ	Patient Health Questionnaire (includes PHQ-2, -8, -9)
SMBG	Self-monitoring of Blood Glucose
TAR	Time Above Range (glucose >180 mg/dL)
TBR	Time Below Range (glucose <70 mg/dL)
TIR	Time in Range (glucose 70–180 mg/dL)



Optimal Care for People with Diabetes: Exploring the Potential of Continuous Glucose Monitoring

The Promise of Glycemic Measurement and Monitoring Through CGM

Glycemia can be assessed by self-monitoring of blood glucose (SMBG), hemoglobin A1c (or HbA1c) measurement and continuous glucose monitoring (CGM). Patient SMBG is typically used for patient self-management and medication adjustment, particularly in individuals taking insulin. The HbA1c lab test is a common metric used in clinical trials to demonstrate the benefits of improved glycemia to reduce the micro- and macrovascular complications associated with diabetes. It measures the average glycation of hemoglobin over 3 months. Although it is the current standard for glycemic measurement in clinical practice and quality reporting, HbA1c has limitations for glycemic monitoring and guiding diabetes management decisions:

- HbA1c does not identify hypoglycemia or glucose variability.
- The accuracy of the HbA1c assay can be affected by, but not limited to:
 - » Hemoglobinopathies.
 - » Iron deficiency.
 - » Chronic kidney disease.
 - » Liver disease.
 - » Individual changes in red blood cell lifespan.
 - » Unknown genetic factors affecting glycation.
 - » Patient ethnicity.

HbA1c will remain an important measure of diabetes population health and the risk for long-term complications of diabetes, but used alone, may be insufficient to optimally guide a personalized therapy change, particularly in patients using insulin, because it cannot reveal the extent or timing of hypoglycemia or the presence of clinically important glucose variability or hyperglycemia patterns. Continuous glucose monitoring (CGM) is a powerful tool with the potential to transform management of individuals with type 1 or type 2 diabetes. In real time, CGM can show trends in hypoglycemia, hyperglycemia and glucose variability—some that warrant immediate therapeutic action.¹⁰

There are metrics that express longer-term glucose control (e.g., HbA1c); one is the glucose management indicator, or GMI (formerly “estimated A1c” or, more recently, “personalized A1c”). It is derived from the CGM-generated mean glucose value and expressed in smaller units to an A1c. For measures to be considered as standard indicators of quality glycemic control, these new metrics should be shown to positively affect outcomes of glycemia as well as or better than HbA1c.

In a 2020 meta-analysis of randomized controlled trials¹¹ comparing CGM with usual care for parameters of glycemia in both type 1 and type 2 diabetes, researchers found that CGM improves glycemia by increasing the time-in-range metric (TIR) and decreasing time below range (TBR), time above range (TAR) and glucose variability (GV). GV can be defined as the degree to which a patient’s blood glucose level fluctuates between high (peak) and low (nadir) levels.¹² Analysis of the IBM MarketScan Commercial Claims and Medicare Supplemental databases, to assess the impact of CGM on diabetes-related events and hospitalizations in a cohort of 2,463 individuals with type 2 diabetes who were on short- or rapid-acting insulin therapy, found that use of CGM reduced hypoglycemia by 43%, reduced the risk of acute diabetes events (inpatient or outpatient emergency) by 61% and reduced all-cause inpatient hospitalizations by 32%.¹³

Flash CGM is among the most recent CGM technologies; it provides immediate information about an individual’s current and projected glucose level, allowing users to respond promptly to mitigate or prevent pending hypoglycemia or hyperglycemia. In 2017, the Advanced Technologies & Treatments for Diabetes released International Consensus on Use of Continuous Glucose Monitoring with the following recommendation: CGM should be considered in conjunction with HbA1c for glycemic status assessment and therapy adjustment in all patients with type 1 diabetes and in patients with type 2 diabetes who are treated with intensive insulin therapy but are not achieving glucose targets, especially for patients experiencing problematic hypoglycemia.¹⁴

CGM serves an important role in assessing the effectiveness and safety of treatment in many patients with type 1 diabetes, including prevention of hypoglycemia, and in selected patients with type 2 diabetes, such as in those on intensive insulin regimens and on regimens associated with hypoglycemia.¹⁵ For patients prone to GV, especially patients with type 1 or type 2 diabetes with severe insulin deficiency, glycemia is best evaluated by the combination of results from frequent SMBG or CGM and HbA1c.

To streamline data interpretation, the International Consensus panel (noted above) identified “time in range” as a metric of glycemic control that provides more actionable information than A1c alone. The metric includes three key CGM measurements: percentage of readings and TIR, TBR and TAR (**Figure 3**). The primary goal for effective and safe glucose control is to increase TIR while reducing TBR. The consensus group agreed that expressing time in ranges can be done as the percentage of CGM readings, average hours and minutes spent in each range per day, or both, depending on the circumstances. **Figure 3** provides CGM-based targets for persons with type 1 or type 2 diabetes.¹⁶

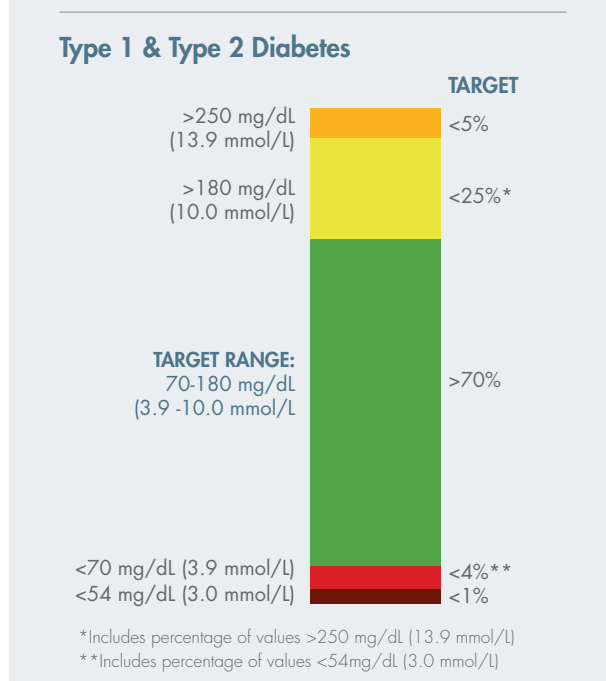
The 2022 ADA Recommendations for Glucose Assessment by Continuous Glucose Monitoring are:¹⁷

Standardized, single-page glucose reports from continuous glucose monitoring (CGM) devices with visual cues, such as the ambulatory glucose profile, should be considered as a standard summary for all CGM devices. (Section 6. Recommendation 3)

Time in range is associated with the risk of microvascular complications and can be used for assessment of glycemic control. Additionally, time below target and time above target are useful parameters for the evaluation of the treatment regimen. (Section 6. Recommendation 4)

The ADA Standards of Care also recognize that diabetes technology is used to help people with diabetes manage their condition, from lifestyle to blood glucose levels. The ADA notes that CGM has emerged as a method for assessing glucose levels and allows patients to evaluate their response to therapy and assess whether glycemic targets are being safely achieved. Integrating results into diabetes management can be a useful tool for guiding medical nutrition therapy and physical activity, preventing hypoglycemia, or adjusting medications (particularly prandial insulin doses).

Figure 3: CGM-Based Targets for Persons With Type 1 or Type 2 Diabetes¹⁶



The ADA Standards note that CGM is rapidly improving diabetes management in type 1 diabetes, and evidence is building for its effectiveness in type 2 diabetes. In recent years, it has emerged as a complementary method (to SMBG) for assessing glucose levels. Both approaches to glucose monitoring allow patients to evaluate individual response to therapy and assess whether glycemic targets are being safely achieved. Recommendations from the ADA relevant to promoting optimal care through use of technology include:¹⁸

Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring 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. (Section 7. Recommendation 11)

Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring 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. (Section 7. Recommendation 12)

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 hours. (Section 7. Recommendation 15)

Although CGM has not yet shown value in people with type 2 diabetes who are not using insulin, many feel it can provide insight into the impact on glucose levels of diet, physical activity and medication management. Glucose monitoring may also be useful in assessing hypoglycemia, glucose levels during intercurrent illness or discrepancies between measured A1c and glucose levels when there is concern an A1c result may not be reliable. This must be confirmed in clinical trials and rigorous real-world studies, however, before it is incorporated into standards of care, if indicated.

CGM incorporates a small, accurate monitoring system that can be used at home to provide patients and clinicians with the glucose management information needed to better manage risk and improve outcomes. CGM systems provide a continuous stream of glucose data, indicating the current interstitial glucose level and the direction and velocity of changing glucose. This information allows users to quickly intervene to prevent or reduce acute hypoglycemia or hyperglycemia. In early diabetes management, patients and clinicians focused on glucose monitoring through multiple fingersticks (using SMBG) to support the notion that everyone with diabetes should know their glucose level, but for over 40 years, the use of fingerstick glucose in primary care has not captured a complete picture of glycemic management. As diabetes management progressed, attention shifted to HbA1c, which was found to be a strong mechanism to reduce morbidity and mortality. Yet, over time, improvements in glycemic management have plateaued.⁴

With the advent of CGM in the early 2000s, patients and clinicians were introduced to a personal and professional pathway to transform diabetes management. In the initial days of CGM reporting, shared data could result in 20–30-page reports, which are still produced today. To reduce the burden of interpretation and as a mechanism to promote understanding of CGM metrics, experts streamlined 14 days of data produced by CGM into a standardized, 1-page format: the Ambulatory Glucose Profile (AGP) Report.^{20,21}

Adoption of CGM metrics and AGP or device-specific summary reports represents a significant change for patients and health care professionals who are familiar with HbA1c as an indicator of diabetes management. Patients react favorably to the graphical representation of data, which associates the “flat curve” with TIR and glycemia, and due to the availability of digital data, clinicians can interact effectively and efficiently with patients about AGP/device-specific summary reports in a virtual visit. Reports often engage people beyond periodic HbA1c. It is also possible to use CGM metrics presented in non-AGP formats. In addition to evidence for AGP, there is also evidence for CGM effectiveness (with and without AGP). Refer to **Appendix 1** for an example of AGP and descriptions of each section and their contribution to improved glycemic monitoring.

Challenges and Limitations in CGM Data Use for Analysis and Action

Although widespread use of CGM offers opportunities for optimizing care, there are challenges to effective use of CGM data to inform diabetes management decisions, performance measurement development and implementation. Some include standardization of and access to sufficient data at the point of care, integration of CGM core metrics into personal and clinical diabetes management, cost and coverage, and the need for data to show benefits in patients with type 2 diabetes who are not on insulin (i.e., treated with lifestyle and noninsulin therapies). CGM use has substantially increased in recent years and, as noted, is associated with lower HbA1c levels, but racial disparities remain in use of technology and in glycemic control²² and can be exacerbated by lack of widespread adoption by the medical community.

Independent technology vendors and data aggregation companies are moving to pull CGM reports into EHRs. There are also recent reports of development of a process to incorporate discrete CGM data points in EHR follow-sheets, along with PDFs of standardized CGM reports. Continued efforts are needed to foster collaboration between CGM device manufacturers and the largest EHR vendors before wide adoption and use of CGM metrics as diabetes quality measures.

There is variation between physician specialties in promotion of CGM use, as well. Endocrinologists are more likely to refer patients for CGM; however, approximately 50% of adults with type 1 diabetes and 90% of adults with type 2 diabetes are treated in primary care practices, and only one-third of primary care clinicians have prescribed CGM. Clinician education and training can accelerate use of CGM metrics (e.g., GMI, TIR) and implementation in practice as supporting CGM use evolves.

CGM Measure Concepts: Bridging the Gap to Optimal Diabetes Care Through Use of GMI and TIR in Quality Measurement

The most common metrics used by NCQA for health plan and health care professional accountability and in state and federal programs are based on assessing and monitoring HbA1c as part of a comprehensive diabetes panel. HbA1c is recognized as an imperfect indicator of glycemia and may be inappropriate in certain clinical situations (e.g., hemoglobinopathy, chronic kidney disease).²⁴ Emerging evidence supports use of CGM devices to drive improvements in glycemia. Participants in the CGM break-out session of “Rethinking Diabetes Care in the Digital Age” suggested measurement concepts that use CGM for NCQA to explore in the near term:

1. Modify the current NCQA diabetes control measures to allow the use of GMI as an indication of numerator compliance.

- No change to the structure of the current measure would be necessary, except for allowing the most recent lab HbA1c or the most recent GMI value, as reported by CGM, in the numerator.
 - » The existing diabetes measure eligible population (denominator) would not need modification.
- The measure would not specify a required number of GMI values, the percentage of data acquired over the period or the type of device.
- The measure specification would only include codes (e.g., CPT, ICD-10) to allow recognition of CGM use and calculation of glycemic metrics.

2. Explore development of a process measure, such as percentage of eligible patients using CGM to track glycemia.

- Eligible population inclusion criteria would need to be supported by evidence, including strong indications that CGM use correlates with improved diabetes outcomes.
- Benefit coverage and current evidence suggest the eligible population include all patients with type 1 diabetes and patients with type 2 diabetes treated with insulin (including multiple daily dose insulin and single daily dose or background insulin).

Often, innovative approaches to improving quality start with process measures that can nudge changes in practice. After these measures are widely adopted and show trends in improvement, outcome measures to expand the field can be introduced. For example, the use of a process measure to incentivize HbA1c testing of patients with diabetes made way for the current HbA1c control measures. CGM break-out session participants suggested an initial staged approach to introducing CGM based-metrics in conjunction with existing measures based on HbA1c.

3. Explore integration of an improvement measure, such as the number of patients who achieve an improvement of 5% TIR.

- The numerator would reflect the number of patients with diabetes and CGM who achieve an improvement of 5% TIR. (The periodicity of measurement was not discussed.)
- The denominator (eligible population) would include all patients (types 1 and 2) who monitor glucose with CGM.

4. Explore a measure that assesses the percentage of patients with diabetes who meet specified thresholds for attaining core CGM metrics.

- This numerator would assess the number of patients who achieved at least 70% TIR and no more than either 4% TBR <70 mg/dL or 1% TBR <54 mg/dL for a specified period, to encourage maximizing optimal glycemia.
- The denominator would include all patients with diabetes (type 1 or type 2) who monitor glucose with CGM.

CGM track participants concurred that revising an existing measure or exploring new measures to utilize CGM data will be important for the future of diabetes quality measurement. They noted that a 5% improvement in TIR is a significant indicator and studies show a relationship with reducing risk of developing microvascular complications. They also noted that this is a tangible goal for patients to understand and incorporate into self-management. Experts indicated the 2-week time frame (14 days of continuous monitoring) is more meaningful to inform patient choices for activity, diet and other behaviors than the 90-day average reported in HbA1c. A recent quality improvement project shows that using professional CGM in primary care, within a comprehensive care model, is effective at lowering A1c, increasing TIR and reducing time in hyperglycemia without necessarily requiring additional medications. Professional CGM, also known as P-CGM, allows people living with diabetes to wear a CGM for a brief period (usually 1–2 weeks). The wearer is usually blind to the data until it is downloaded and analyzed at the clinician’s office. This differs from regular CGM, where the patient has primary access to data captured by the device.

Track participants also support exploring diabetes measure sets that can be designed for specific purposes (e.g., accountability, public reporting, HEDIS, quality improvement), use common definitions and permit data from multiple sources (e.g., EHRs, registries, claims). Measures in such a set could also be used at different levels of the health system.



Recognizing Behavioral Aspects in Management and Optimization of Diabetes Care: Screening, Assessment and Intervention for Diabetes Distress

Achieving optimal outcomes in diabetes management can be difficult for patients with comorbidities; for example, many people with diabetes have elevated rates of depressive and distress symptoms. Elevated depressive symptoms affect one in four adults with type 1 or type 2 diabetes, and clinical depression affects one in eight people with diabetes.²⁶ In addition, as illustrated in **Figure 4**, the psychosocial landscape of diabetes is a dynamic interplay between an individual's characteristics and the progression of the disease throughout their life. Evidence indicates a continuum of experiences ranging from adaptive responses to living with diabetes, to experiences considered clinically impactful or contributing to functional impairment. Clinicians and the health care team have important roles to play in screening, evaluating and supporting adaptive emotional and behavioral responses to each person's course of diabetes. When impairment or interference in diabetes self-management is evident, referral to behavioral health clinicians for evaluation and treatment is indicated; these professionals can work interactively with patients, families and members of the health care team.²⁷

Figure 4: Continuum of Psychosocial Issues and Behavioral Health Disorders in People With Diabetes²⁸



Phase of living with diabetes		Nonclinical (normative) symptoms/behaviors	Clinical symptoms/diagnosis
	Behavioral health disorder prior to diabetes diagnosis	None	<ul style="list-style-type: none"> • Mood and anxiety disorders • Psychotic disorders • Intellectual disabilities
	Diabetes diagnosis	Normal course of adjustment reactions, including distress, fear, grief, anger, initial changes in activities, conduct or personality	<ul style="list-style-type: none"> • Adjustment disorders*
	Learning diabetes self-management	Issues of autonomy, independence, and empowerment. Initial challenges with self-management demonstrate improvement with further training and support	<ul style="list-style-type: none"> • Adjustment disorders* • Psychological factors affecting medical condition**
	Maintenance of self-management and coping skills	Periods of waning self-management behaviors, responsive to booster educational or supportive interventions	<ul style="list-style-type: none"> • Maladaptive eating behaviors • Psychological factors** affecting medical condition
	Life transitions impacting disease self-management	Distress and/or changes in self-management during times of life transition***	<ul style="list-style-type: none"> • Adjustment disorders* • Psychological factors** affecting medical condition
	Disease progression and onset of complications	Distress, coping difficulties with progression of diabetes/onset of diabetes complications impacting function, quality of life, sense of self, roles, interpersonal relationships	<ul style="list-style-type: none"> • Adjustment disorders* • Psychological factors** affecting medical condition
	Ageing and its impact on disease and self-management	Normal, age-related forgetfulness, slowed information processing and physical skills potentially impacting diabetes self-management and coping	<ul style="list-style-type: none"> • Mild cognitive impairment • Alzheimer's or vascular dementia
			
		All health care team members (e.g., physicians, nurses, diabetes educators, dieticians) as well as behavioral providers	Behavioral or mental health providers (e.g., psychologists, psychiatrists, clinical social workers, certified counselors or therapists)
Providers for psychosocial and behavioral health intervention			

Figure 4 contains multiple references to the term “distress.” Diabetes distress is distinct from a psychological disorder (depression)^{29,30,31,32} and is an often overlooked but consequential comorbidity. It refers to unique, often hidden emotional burdens and worries that are part of the spectrum of patient experience when managing a severe, demanding, chronic disease like diabetes.³³ Diabetes distress is associated with anxiety, depression and reduced health-related quality of life.

The constant behavioral demands of diabetes self-management (medication dosing, frequency, titration; monitoring blood glucose, food intake and eating patterns and physical activity) and the potential or actuality of disease progression are directly associated with reports of diabetes distress.³⁰ Its point prevalence is reported to be 18%–45%, with an incidence of 38%–48% over 18 months.³⁴ High levels of diabetes distress adversely affect medication-taking behaviors and are linked to higher HbA1c, lower self-efficacy and poorer dietary and exercise behaviors.³⁵

About one-third of adolescents with diabetes develop diabetes distress, which may be associated with decline in self-management behaviors and suboptimal blood glucose levels.³⁶

SCREENING & ASSESSMENT OF DEPRESSION AND DIABETES DISTRESS

Validated screening measures:

- Depression—PHQ-2, PHQ-9—adults and adolescents
- Diabetes Distress Screener (DDS2) and Diabetes Distress Scale (DDS17 type 2; T1DDS)
- Problem Areas in Diabetes (PAID-5)—children, adolescents, adults



More information at
Diabetesdistress.org

Comorbid diabetes and depression are linked with worse diabetes outcomes, including:

- Higher glycemia (HbA1c), values above target.
- Diabetes complications, including severe hyperglycemic and hypoglycemic events.
- Increased risk for mortality.
- Increased health care utilization and costs.

Diabetes distress is also common and evident in people with type 1 or type 2 diabetes. The condition does not resolve without intervention and has significant clinical impact. High diabetes distress is associated with:

- Higher glycemia (HbA1c), not achieving target.
- Missed medications and health care appointments.
- Less healthy physical activity and diet behaviors.
- Less interest in changing treatment and trying new devices.
- Lower quality of life.³⁷

According to the ADA, psychological well-being is foundational to reaching treatment goals for people with diabetes. Complex environmental, social, behavioral and emotional factors (psychosocial factors) influence living with both types of diabetes and achieving satisfactory medical outcomes and psychological well-being. The ADA Standards of Medical Care for Diabetes include the following recommendations for psychosocial issues:³⁸

- Psychosocial care should be integrated with a collaborative, patient-centered approach and provided to all people with diabetes, with the goals of optimizing health outcomes and health-related quality of life. (Section 5. Recommendation 36)
- Psychosocial screening and follow-up may include, but are not limited to, attitudes about diabetes, expectations for medical management and outcomes, affect or mood, general and diabetes-related quality of life, available resources (financial, social, and emotional), and psychiatric history. (Section 5. Recommendation 37)
- Providers should consider assessment for symptoms of **diabetes distress**, depression, anxiety, disordered eating, and cognitive capacities using appropriate standardized and validated tools at the initial visit, at periodic intervals, and when there is a change in disease, treatment, or life circumstance. Including caregivers and family members in this assessment is recommended. (Section 5. Recommendation 38)
- Consider screening older adults (age ≥ 65) with diabetes for cognitive impairment and depression. Monitoring of cognitive capacity, i.e., the ability to actively engage in decision-making regarding regimen behaviors, is advised. (Section 5. Recommendation 39)

The 2022 Standards of Medical Care for Diabetes expanded the discussion and added a recommendation specific to diabetes distress:

Routinely monitor people with diabetes for diabetes distress, particularly when treatment targets are not met and/or at the onset of diabetes complications. (Section 5. Recommendation 40)

The ADA expanded the discussion, noting that diabetes distress is common and distinct from other psychological disorders and should be routinely monitored using person-based, diabetes-specific validated measures. If diabetes distress is identified, the patient should be referred for specific diabetes education to address areas causing distress and affecting clinical management. People whose self-care remains impaired after tailored diabetes education should be referred by their care team to a behavioral health provider for evaluation and treatment.³⁹

Although psychosocial issues may challenge improvements in diabetes management, there is also good news about diabetes distress:

- It is malleable.
- It is highly responsive to intervention.
- Dramatic reductions can occur quickly.
- Interventions targeting the emotional side of diabetes directly, rather than focusing exclusively on behavior, produce the strongest effects.⁴⁰

More than 20 years of evidence supports improvement in outcomes when depression and diabetes distress are identified and treated:

- Screening can uncover a previously unknown emotional status affecting self-management of diabetes.
- Assessment provides the opportunity for linking with interventions to improve emotional health and diabetes outcomes.
- Depression symptoms and diabetes distress are highly responsive to intervention—but they must first be identified.

Figure 5 describes real-world clinical practice examples of how enhanced screening and integration into practice workflow enable improvements in patient-reported outcomes in diabetes, diabetes distress and depression symptoms. Diabetes distress screening and assessment is a unique opportunity to improve the lives of people with diabetes.

Figure 5: Impact of Real-World Clinical Practice-Based Interventions

IMPACT OF REAL-WORLD CLINICAL PRACTICE-BASED INTERVENTIONS

Enhanced screening enables impactful change in patient-reported outcomes

	INTERVENTION	DIABETES DISTRESS	DEPRESSION SYMPTOMS
Spencer et al., 2018	Community Health Worker ± peer-led diabetes self-management program	↓	↓
Hessler et al., in press	Primary care based behavioral health screening and self-management support	↓	↓
Wagner et al., 2016	Community Health Worker led stress management intervention vs. diabetes education	↓	↓

There are two main reasons why people get referred to behavioral health:

(1) identification of some level of management difficulty and the provider can't figure out exactly why that's going on, and (2) concern with depression or distress in impacting management.

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Challenges and Limitations in Identification and Treatment of Diabetes Distress

Despite recognition of psychosocial considerations as essential to improving self-management and outcomes in diabetes, the health care system does not routinely assess psychological well-being. In the Diabetes Attitudes, Wishes and Needs (DAWN2) study, researchers found that psychological well-being was evaluated in only one-third of individuals with diabetes. Most respondents reported having no access to person-centered chronic illness care and only 23.7% reported that their health care team asked them how diabetes impacted their life.

Although ADA Standards of Medical Care for Diabetes recommend psychosocial screening, screening rates could indicate lack of recognition of the importance of depression and diabetes distress in diabetes management.

To influence improvements in diabetes care, psychosocial screening (depression and diabetes distress) should be more frequent than annually and should reflect each patient's situation; for example, disease complications, significant life changes or stressful events should prompt screening.

Determining screening frequency and indicators for screening are supported by the ADA Position Statement on Psychosocial Care for People with Diabetes:

Providers should consider an assessment of symptoms of diabetes distress, depression, anxiety, and disordered eating and of cognitive capacities using patient-appropriate standardized/validated tools at the initial visit, at periodic intervals, and when there is a change in disease, treatment, or life circumstance. Including caregivers and family members in this assessment is recommended.⁴²

Health system capacity is an essential consideration when promoting screening and timeliness of follow-up in primary care and broader settings. Diabetes Distress break-out group participants indicated that the likelihood of a positive screen, full assessment and follow-up care within 30 days is unrealistic. Limitations in the number of mental/ behavioral health providers, insurance coverage and other health system challenges may result in access issues. Having a variety of pathways for intervention can alleviate health system burden; not all follow-up must be an in-person appointment with a psychologist.

Mental Health America's Access to Care Ranking indicates that the number of mental health providers has improved in recent years, but Health Resources and Services Administration projections predict an immense shortage of mental health and substance use treatment providers by 2030. Mental health provider shortages result in decreased access to care, high burnout rates among providers and long waits for necessary treatment.⁴³

There is maldistribution of behavioral health providers throughout the country. In 2016, more than half of U.S. counties had no psychiatrists. Although integrating primary care and behavioral healthcare is a necessary first step toward reducing the shortage's impact, primary care health professionals alone cannot fill the void created by a lack of psychiatrists. Further efforts must be made to improve access to necessary mental health care throughout the country, such as expanding the use of telepsychiatry and employing peer-support specialists and other paraprofessionals as providers of care.⁴⁴

Behavioral Health Measure Concepts: Bridging the Gap to Optimal Diabetes Care Through Screening, Assessment and Intervention for Diabetes Distress

Although there is a direct clinical association between assessing for diabetes distress and improved outcomes, the practice of screening for psychological well-being, which includes diabetes distress, is low, indicating opportunities for improvement. Measurement approaches to promote this practice should include clinician and patient/ family education resources. Stakeholders indicated that for children diagnosed with diabetes, it is also worth considering screening for diabetes distress among parents/ caregivers because these individuals are heavily involved in managing diabetes care.

Clinicians who participated in the Diabetes Distress break-out group noted that screening and assessment is insufficient without targeted intervention, when warranted. Experts emphasize that screening is essential but is not enough, and identified the following key recommendations:

- **Clinicians should identify the root cause of distress, which requires active listening and engagement with the patient:**
 - If distress stems from family conflict, family-based treatment may be indicated (e.g., psychotherapy).
 - If distress is financial, social services referrals may be indicated (e.g., psychosocial intervention).
 - If distress stems from frequency of hypoglycemic episodes, blood glucose awareness training may be appropriate.
 - If a patient is identified as depressed or distressed, a broader group of resources and practitioners is needed for follow-up and should not be limited to behavioral health practitioners.

Depression and distress have significant impact on patient outcomes in chronic conditions, including diabetes. Although existing quality measures encourage regular screening, follow-up, monitoring and assessment of outcomes for depression (e.g., Depression Screening and Follow-Up for Adolescents and Adults, Depression Remission and Response for Adolescents and Adults), gaps remain in addressing distress among people diagnosed with diabetes.

Experts from the Diabetes Distress break-out group expressed interest in leveraging existing measures and established clinical workflows to integrate diabetes distress identification and intervention into the diabetes care quality conversation. Collecting screening, assessment and follow-up data will require generating patient-reported data. Stakeholders recommended considering the perspectives of people, processes and technology on data integration to help ensure that patient-generated data can inform the care process.

Break-out group participants discussed different measurement concepts for development and implementation:

1. Explore a new measure focused on screening and follow-up for individuals who screen positive for diabetes distress, using as a model the HEDIS measure Depression Screening and Follow-Up for Adolescents and Adults.

- The age range of the eligible population would need to align with available testing and screening tools. Available diabetes distress screening tools have been validated for children 13 years and older.
- The screening component would require use of a validated diabetes distress screening tool (e.g., PAID-T, PAID, DDS, T1-DDS).
- The follow-up time frame would need to be explored. For example, response to a positive screen should happen immediately, but it may take longer to offer treatment. Thirty days was discussed as optimal, but may not be feasible due to lack of mental/behavioral health clinician access in some geographic areas.
- Follow-up should include evidence-based services with all relevant clinicians and modalities (e.g., psychiatrists; psychologists; social workers; licensed therapists; diabetes educators; health coaches; community health workers; telehealth and virtual visits; peer support; pharmacists, in some cases, for medication adherence).

2. Explore a new measure focused on assessing outcomes among individuals who screen positive for diabetes distress, using as a model the HEDIS measure Depression Remission or Response for Adolescents and Adults.

- The age range of the eligible population would need to align with testing and administration of assessment tools.
- The “remission” and “response” components of the numerator would require use of a validated diabetes distress assessment tool.

3. Consider developing a diabetes and behavioral health measurement set that integrates additional aspects of behavioral health affecting diabetes management (e.g., assessing for depression, tobacco, alcohol use).



Health Equity/Justice Considerations in Diabetes Management

The burden of diabetes, including disease prevalence and risk of complications, is greater among minority populations, particularly the African American and Latino populations. Considering this health disparity, health care professionals have an increased challenge to design culturally sensitive and targeted strategies for managing the disease and its complications, when assisting racial and ethnic minority patients with self-management. Identifying disparities is a first step to understanding what causes them and what can be done to reduce them. There must be better understanding of diabetes distress in particular and assessment of diabetes-related emotional distress (i.e., worries or concerns related to managing a chronic disease) in general.⁴⁶

Mean HbA1c levels vary with age, race, ethnicity and socioeconomic status. The ADA's 2018 target of <7.5% (<58 mmol/mol) for youths with type 1 diabetes was achieved by only a small percentage of children and adolescents <18 years old (17%); only 21% of adults achieved the goal of <7.0% (<53 mmol/mol); and 37% of adults had HbA1c values of <7.5% (<58 mmol/mol). Mean HbA1c is 0.4%–0.5% higher in the African American population than in non-Hispanic White or Hispanic White populations across all age groups, even after adjusting for differences in socioeconomic status, which supports the notion that A1c alone has limitations as the standard of measurement.⁴⁷ These disparities reinforce the need for diabetes technology to better manage the disease.

Additional studies highlight racial and ethnic disparities in insulin pump and CGM use in people with type 1 diabetes across all age groups;⁴⁸ however, drivers of disparities remain poorly understood beyond socioeconomic status. Insulin pump and CGM use were lowest in the non-Hispanic Black population, intermediate in the Hispanic population and highest in non-Hispanic White young adults with type 1 diabetes. Socioeconomic status was not the sole driver of disparities, nor did additional demographic, health care or diabetes-specific factors fully explain them. There is a continued need to examine how minority preferences, provider implicit bias, systemic racism and mistrust of medical systems help explain disparities in diabetes technology use.⁴⁹

Exposure to discrimination is associated with distress, low levels of psychological resources and health risk behaviors. In these ways, racial distress may influence diabetes distress among persons with diabetes. Diabetes distress is characterized by frustration, fatigue, low motivation for self-care and suboptimal diabetes planning, problem solving and adherence. It is associated with worse glycemia in cross-sectional and time-concordant longitudinal studies and thus could be one mechanism for discrimination to impair glycemia.⁵⁰

The Latino population is almost twice as likely to have diabetes as the White population. Whereas there is considerable variability among subethnicities, the Latino population also reports lower perceived health status than the non-Hispanic White population, which is a strong predictor of mortality across racial and ethnic groups, even after adjusting for socioeconomic status and comorbidities. The U.S. Latino population faces a host of mental stressors, including financial strain.

Addressing the psychological well-being of minorities with diabetes is paramount. Although there are effective group-based psychosocial treatments for patients with diabetes, lack of access to psychosocial services is problematic for many, especially low-income patients and patients with limited English proficiency. Thus, there is an urgent need for—and an untapped potential in—accessible treatments that address psychological well-being among Latino patients with diabetes.⁵¹

In a study assessing the role of perceived discrimination and other psychosocial factors in explaining diabetes distress among older African American and White adults, higher diabetes distress was associated with being a member of the African American population, higher levels of perceived discrimination, lower levels of physician trust and lower levels of social support. Racial differences in diabetes distress remained significant after controlling for demographics, social support and cognition, and physician trust and perceived discrimination accounted for more than half the association between race and diabetes distress. The study provides evidence suggesting that diabetes distress is related to psychosocial factors linked to health disparities. Diabetes-related stress is clearly a multifactorial construct, and interventions aimed at reducing it should address diabetes distress directly, as well as the roles of social support, perceived discrimination and trust in a physician. Findings highlight the need to address stress factors unique to racial and ethnic minorities in order to improve diabetes-related outcomes.⁵²

As noted, beyond racial and ethnic disparities in persons with diabetes, diabetes distress may also be a higher risk for older adults due to greater prevalence of comorbidities. In a study examining everyday life experiences of living with type 2 diabetes and elevated diabetes distress, the most prevalent lived experiences were strained relationships with health care providers, guilt, fear, loneliness and forgetfulness. These experiences created challenges in managing diabetes and increased diabetes-related distress. Improving knowledge about the lived experience of older adults with diabetes-related distress may help health care providers tailor treatment to this population, thus improving outcomes.⁵³



Summary: Opportunities to Drive Improvements in Diabetes Care With CGM and Screening for Diabetes Distress

Use of technologies such as CGM and screening for diabetes distress can positively affect patient-reported outcomes and glycemia, including reduction in related complications. CGM devices reduce patient burden and provide knowledge and resources to help people prevent hypoglycemic events and reduce hyperglycemia, and can potentially lead to improvement in distress. Several studies indicate a relationship between use of CGM and reduction in distress, improvement in well-being and increased confidence in catching hypoglycemia early, resulting in fewer adverse events.^{54,55}

Track participants identified the need for education about the importance of diabetes distress in diabetes management and including screening as part of an integrated approach to physical and behavioral health treatment.

Table 2 describes the key points generated by the experts to support broad adoption of CGM and related metrics and screening, assessment and follow-up for diabetes distress.

Table 2: Encouraging Broad Adoption of CGM and Screening for Diabetes Distress

→	Although insurance coverage for CGM is improving, it needs to keep up with evidence-based standards of diabetes care. Advocacy efforts are underway and more can be done; part of driving coverage inclusion is an accountability framework. Quality measures are an important component of accountability.
→	Data accessibility is critical to measure success. Existing codes (e.g., procedure, device) may need to be tweaked for use in measurement and to enable standardized comparison. Larger EHR vendors are starting to embrace integration of CGM data, but there must be more alignment between CGM companies and EHR vendors regarding CGM data accessibility and data flow between systems.
→	The science and evidence behind the use of core CGM metrics is sufficient and the ADA Standards of Care include recommendations for CGM use in type 1 and type 2 diabetes.
→	CGM data can easily produce a proxy (GMI) of the well-known HbA1c metrics understood by many patients and physicians and can provide other, more clinically relevant information to guide interventions. This is the most immediately actionable way to begin to incorporate a CGM metric into practice and reporting, but more robust and meaningful assessment of glycemia can be accomplished by moving beyond HbA1c and GMI to other core CGM metrics (especially TIR and TBR, considered concurrently).
→	EHR integration. Larger EHR vendors and device (CGM) companies are engaged. Easy access to data at the point of care is important; lack of integration of core CGM metrics and of the AGP into EHRs limits decision support for diabetes management. Integration is also considered a lever to help move primary care toward widespread use of CGM data and is important in behavioral health. With digital behavioral health screening and assessment tools, score interpretation can be built into decision support tools in the EHR and linked to resources or to follow-up and referral.
→	Encouraging and increasing the use and core metrics of CGM (GMI, TIR and TBR in particular) require educating and training health care professionals, patients and caregivers. Using CGM results (e.g., in AGP reports or device summary reports) promotes opportunities for feedback and dialogue between patients and health care professionals, specifically where alignment of data and feedback opportunities are present. Data can be integrated into patient apps and used by all members of the care team between appointments and at the point of care.
→	Integrate medical and psychosocial care into holistic care standards. This emerging concept uses a holistic pathway, rather than a medical and psychosocial standard, to screen all people with diabetes for depression and diabetes distress. Incorporating a holistic view into a standard for clinical practice would also help reduce workflow barriers and care disruptions.
→	Engage patients and families in workflow design. Clinics can consider patients and families as essential stakeholders and partner with them during a visit to do what makes sense to clinicians, patients and families. This is important for integrating patient-reported data, including data on diabetes distress, depression, quality of life, other patient reported outcomes and social determinants of health. Patients are starting to embrace and understand that CGM and AGP or device summary reports offer better tools for clinical management. Health care professionals see CGM as empowering patients to understand their glucose levels, understand fluctuations over time and use the data to change behavior and actions that can influence diabetes management.
→	ADA Standards of Medical Care support screening and assessment of diabetes distress, along with other psychological issues facing people with diabetes. More financial and operational support for screening is necessary, along with increasing the number of providers who can treat these psychological issues.



Co-/Redesigning the Diabetes Recognition Program: The Journey to Optimizing Outcomes for Individuals With Types 1 or 2 Diabetes, and Future Perspectives

NCQA Recognition programs (Patient-Centered Medical Home, Patient-Centered Specialty Practice, Heart-Stroke Recognition, Diabetes Recognition) assess structure, process and outcomes of care. These programs are often developed in partnership with leading national health organizations and collaborators and are sometimes linked to incentives through health plans, employer coalitions and/or medical boards (i.e., credit for Maintenance of Certification).

The Diabetes Recognition Program was developed in 1997 in partnership with the ADA. It is a voluntary program, eligible for physician Maintenance of Certification credit. Approximately 4,400 Recognized clinicians represent all eligible clinician types across 34 states. In addition to physicians (MD, DO), eligible clinicians include APRNs, PAs and practice groups.

The program was updated in 2015 and represents an opportunity for NCQA to refresh based on current science and evidence to promote optimal diabetes care.

NCQA presented questions for session participants about program redesign concepts:

1. **Participation:** How do we make the Diabetes Recognition Program more valuable for primary care and specialists (e.g., nephrologists, cardiologists and other specialists focused on diabetes care)?
2. **Measures:** Which measures should be retired? Are there measures that can be added? Should concepts beyond diabetes distress and incorporation of CGM metrics be considered? Additional patient-centric measure concepts suggested include:
 - Patient activation and engagement.
 - Person-driven outcomes and patient-reported outcomes.
3. **Beyond measurement:** What expectations should be required beyond reporting of measures? The track participants suggested avenues for NCQA to explore:
 - Access, adherence to guidelines, care coordination, population health and screening, action on social determinants of health.
 - Integration and coordination of behavioral health services.
4. **Scoring:** Should NCQA consider a sampling method vs. a report on the total population eligible for a particular measure?

Participants offered ideas for updates:

- Reevaluate eligibility requirements and add certified diabetes care and education specialists.
- Redefine “visits” as encounters and include both virtual and face-to-face contact.
- Encourage integration of behavioral health and primary and specialty care through program requirements and scoring.
- Review the [Know Diabetes by Heart](#) Initiative requirements and consider collaboration with the ADA and the American Heart Association, particularly around appropriate inclusion of the use of GLP-1 receptor agonists and/or SGLT2 inhibitors due to demonstrated cardiovascular and renal benefits.
- Stratify the program by levels (platinum, gold, silver) to differentiate practices and support incentive payments based on quality performance.
- Create a HbA1c-to-CGM crosswalk that includes HbA1c rates of 7, 8 and 9 and the equivalent measures from CGM (GMI, TIR, TBR) using digital data. Consider the potential to award bonus points to those practices moving in the right direction.
- Include the new HEDIS Kidney Health Evaluation measure, which follows the ADA Standards of Care for Diabetes recommendations more closely. It includes an annual eGFR and urinary albumin to creatinine ratio assessment for all people with diabetes and will be evaluated for inclusion in the DRP.
- Integrate race, ethnicity and equity considerations.
- Consider both thresholds and improvement over time when revising measure scoring thresholds.
- Consider measurement and quality improvement opportunities related to preventing or delaying progression to chronic kidney disease and cardiovascular risk in patients with diabetes. Potential areas to explore include:
 - » Use of SGLT-2 inhibitors to prevent or delay progression to chronic kidney disease.
 - » Assessment for cardiovascular disease, heart failure and chronic kidney disease, and if present or if at high risk, consider prescribing or discussing use of medications shown to reduce these risks (e.g., GLP-1 and SGLT-2 inhibitors).



Conclusions

Participants in the “Rethinking Diabetes Care in the Digital Age” track of the 2021 Digital Quality Summit acknowledged that outcomes for people with diabetes can be significantly improved if clinicians and diabetes care teams follow the evidence, use available technology and apply available knowledge about how to optimize care. Experts pointed to clinical value and patient engagement opportunities associated with use of CGM, associated metrics and standardized data and management reports. Experts also agreed that research supports addressing psychosocial needs in an effort to improve emotional and physical outcomes for people living with diabetes, recognizing an imperative to integrate behavioral health and primary care for people with chronic conditions such as diabetes.

Track participants also encouraged NCQA to update and refine the Diabetes Recognition Program, to encourage adoption of best practices such as incorporating patient-generated data (e.g., diabetes distress screening data, CGM data, social determinants of health, depression screening) into clinician workflows and measurement reporting.

A key to successfully integrating data from across the health care system and patient journey is to gain a better understanding of existing clinical practice workflows and opportunities to encourage efficiencies through use of digital technologies. As the use of digital data increases and quality measures reflect the availability and interoperability of data, Diabetes Recognition and other accountability programs can be refreshed to better align with current practices. For example, as practices learn how to leverage technology (e.g., wearables, CGM) and other data sources to support patient engagement, remote monitoring and condition management, integration of patient-generated data will become part of clinical workflows and will ultimately result in better care. Adoption and use of CGM metrics and collection of diabetes distress data are two excellent ways for practices to begin.

When considering measurement and system changes, the patient perspective and engagement in the change process is paramount to success. In efforts to optimize diabetes care, it is important to consider how the clinical/patient dynamic is approached, how care and disease management are explained to patients and families and how to gain input and engagement throughout the patient’s journey.

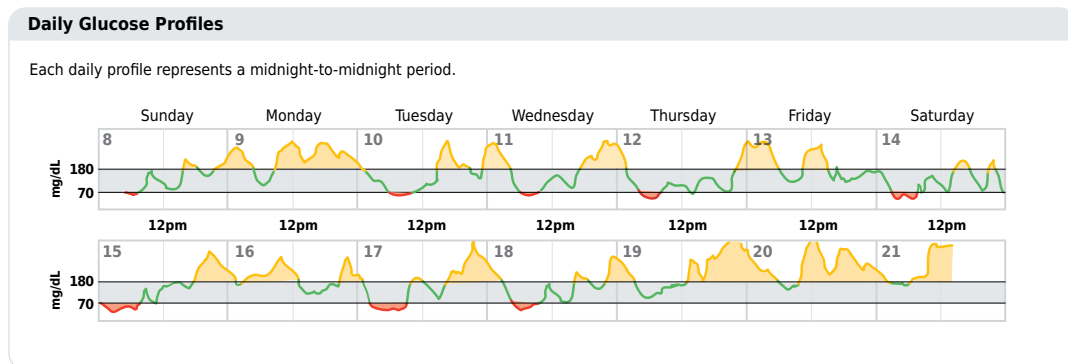
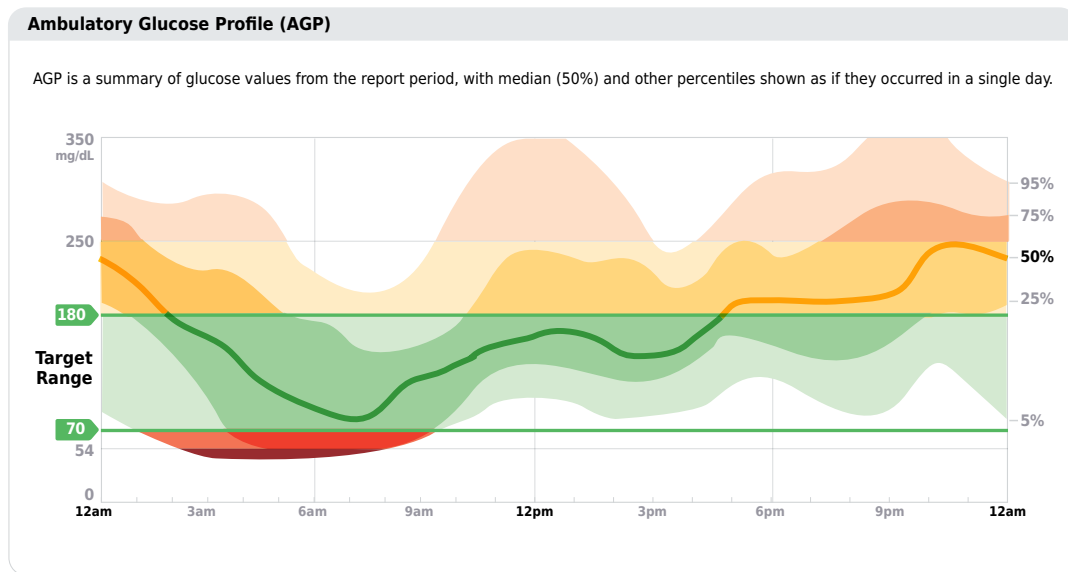
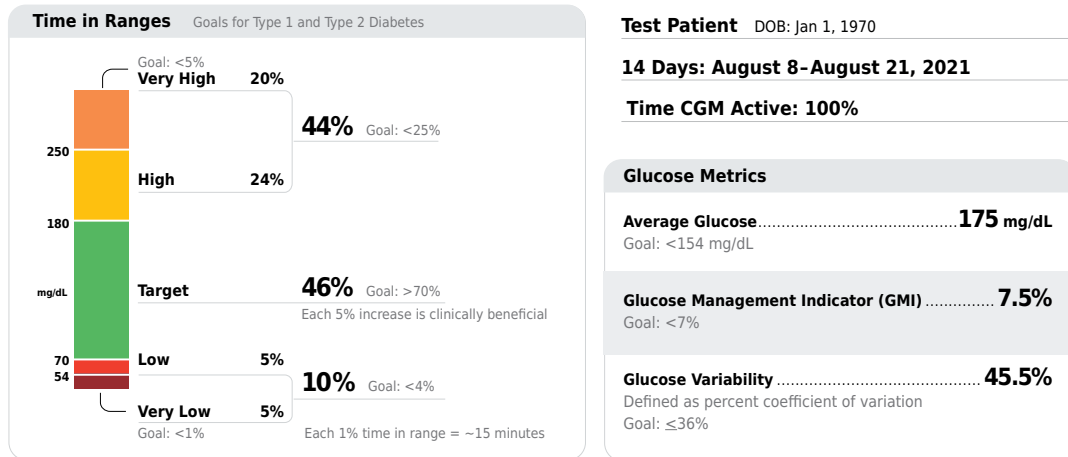
Revision, development and implementation of quality measures to improve the use of available technologies (CGM) and address important aspects of behavioral healthcare in people with diabetes combine to drive implementation and change. Although not the focus of this digital summit, NCQA could also evaluate how to incorporate measures to help reduce cardiovascular disease, heart failure and chronic kidney disease in people with diabetes. The joined forces of research, specialty organizations, health systems, payers, patient advocacy organizations and quality programs move industry and stakeholder groups—including patients—toward change and overcoming the inertia that delays implementation of best practices. Now is the time to rethink diabetes care and promote engagement of all stakeholders—health care professionals, the broader care teams, health systems, payers, technology vendors, patients and caregivers—to collaborate and coordinate to move toward an ideal state of diabetes management.

Appendix

Appendix 1: Example AGP Report

METRICS AND TARGETS →

AGP Report: Continuous Glucose Monitoring



Holt RIG, DeVries JH, Hess-Fischl A, et al The Management of Type 1 Diabetes in Adults. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2021 Nov;44(11):2589-2625.

The AGP currently contains over 4,000 values representing 2 weeks of data and includes metrics and targets at the top; a profile of 14 days in a picture of midnight to midnight, with the median line and the interquartile range in the center; and all 14 daily views at the bottom, which allows evaluation of patterns in glucose levels and differentiation between weekends and weekdays or workdays and non-workdays.

Understanding the CGM Core Metrics for Clinical Care

There are 10 core CGM metrics for clinical care (as noted above). The first 2 establish data completeness. The mean glucose is the standard measurement and the GMI is an initial indicator to cross the measurement bridge from HbA1c to CGM indicators. The GMI tells clinicians how much glucose exposure occurs over a user-definable period and is therefore analogous to the HbA1c (which is limited to approximately 3 months).

There is a measure of variability, then five measures of glucose ranges: TIR (time in the target range, 70 mg/dl–180 mg/dl), 2 ranges above target and 2 ranges below target. These are important for clinical management. GMI, TIR and time below range (TBR) are the three critical measures (Figure A.1). TIR is an important concept because it correlates well with HbA1c levels. For example, clinicians want patients to strive for TIR >70% of the time over a 2-week period; this translates to glucose levels being maintained between 70 mg/dl and 180 mg/dl; TIR of 70% correlates to an HbA1c of 7. This metric is consistent across populations with type 1 or type 2 diabetes, with the exception of pregnant women (the target for pregnant women is 63 mg/dl–140 mg/dl, to reduce complications in babies).¹⁹

Figure A.1 Core CGM Metrics for Clinical Care

KEY STANDARDIZATION OF CGM METRICS & REPORTS			
Care CGM metrics for clinical care			
1. Number of days CGM worn (minimum 10-14)			
2. Percentage of time CGM is active (minimum 70% of data from 14 days)			
3. Mean glucose			
4. GMI (Glucose Management Indicator)		 Estimated A1C or Personalized A1C 	
5. Glycemic variability (%CV target ≤36%)			
6. TAR: % of readings and time >250 mg/dL (>13.9 mmol/L)	Level 2	Very high	
7. TAR: % of readings and time >181-250 mg/dL (10.1-13.9 mmol/L)	Level 1	High	
8. TIR: % of readings and time >70-180 mg/dL (3.9-10.0 mmol/L)	In range		
9. TBR: % of readings and time 54-69 mg/dL (3.0-3.8 mmol/L)	Level 1	Low	
10. TBR: % of readings and time <54 mg/dL (<3.0 mmol/L)	Level 2	Very Low	
Use of AGP for CGM report			
CV, coefficient of variation, GMI, glucose management indicator; TAR, time above range; TBR, time below range			

CGM Device Coverage

CGM devices are typically covered through health insurance plans for people with type 1 diabetes, but coverage varies for people with type 2 diabetes and is more likely for people who are treated with insulin. Coverage often follows inclusion of a recommended treatment approach or device in clinical guidelines. The ADA’s Standards of Care—2022 support coverage of CGM for individuals with diabetes on multiple daily injections or continuous subcutaneous insulin infusion and for individuals who use basal insulin and are capable of using devices safely.

Acknowledgements

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