# Roadmaps to Continuous Glucose Monitoring's Role in Transforming Diabetes Management

## Preface

Richard M. Bergenstal, Guest Editor

We are experiencing a global pandemic of diabetes and its associated complications, costs, and effects on quality of life, challenging us to innovate and disrupt our current approaches to diabetes management (1–3). Over the past decade, there have been a series of innovations in diabetes research followed by positive clinical trial data leading to new drugs (e.g., glucagon-like peptide 1 [GLP-1] receptor agonists, dual GLP-1/GIP receptor agonists, possibly triple agonists, and sodium–glucose cotransporter 2 inhibitors) and a new approach to glucose monitoring (i.e., continuous glucose monitoring [CGM]), offering hope for a more comprehensive and personalized approach to diabetes care. If one adds the promise of advances in precision diabetes care (i.e., the "-omics"), digital health, and the recognition of the need to also address the social determinants of health, the elements are in place for a transformation in diabetes care within the next decade (4,5).

Transforming diabetes care is a step-by-step process from innovation to investigation to implementation (6). We need roadmaps for each component of diabetes care (i.e., drugs, devices, data, and equity) to keep the diabetes community, including people with diabetes and their families, clinicians, researchers, diabetes care and education specialists (DCESs), payers, industry stakeholders, regulators, funders, quality measurement organizations, psychologists, social workers, pharmacists, and others, focused on effectively translating research into practice (7). I would like to thank the American Diabetes Association and *Diabetes Spectrum* for giving us the opportunity to focus this From Research to Practice section on how CGM can address many of the unmet needs in diabetes management.

My partner in pulling this series together has been *Diabetes Spectrum* Associate Editor Anastasia Albanese-O'Neill, who exemplifies what it means to be both a leader and a collaborator dedicated to finding a way to help people live well with diabetes. We debated whether the communication vehicle for these insights should be roadmaps or toolkits because both embrace systematic approaches and are action-oriented. Roadmaps prevailed because this concept would allow each contributing author to map out recent advances in the use of CGM in their areas of expertise, discuss barriers remaining to be overcome, and highlight their expectations for the next frontiers in CGM innovation, investigation, and implementation.

The diabetes community is very broad and diverse, and while we did not have space in this article collection to learn from representatives of each group, we did ask respected leaders in five key diabetes care disciplines to create roadmaps outlining the opportunities and challenges for the effective use of CGM to transform diabetes care in their domain of expertise. These experts have been leaders in either innovation or landmark clinical trials moving diabetes care forward, but most important to this collection was each authors' ability to outline practical implementation strategies to translate these advances into new models of more effective clinical care. I am excited to introduce the authors, whom readers will immediately recognize as leaders in the diabetes community. I am grateful for their willingness to educate, inspire, and guide us toward transforming diabetes care with their wisdom and their roadmaps to the effective use of CGM in diabetes self-management education and support, endocrinology, primary care, and pregnancy care for people with diabetes, as well as in our efforts to achieve care equity for all people with diabetes.

Our series starts by highlighting the crucial work of DCESs, the key technology champions on most diabetes care teams (p. 288) (8). These professionals serve as an essential communication link across all disciplines providing diabetes care, as they both educate and support people with diabetes and also

facilitate professional education and skills-building for the clinical implementation of diabetes technology. There was no better person to ask to write this article than Dr. Albanese-O'Neill. She highlights how effective CGM can be in optimizing diabetes care and quality of life, and this message seems to be resonating, as evidenced by a steady uptake in CGM use in both endocrinology and primary care practices. Despite unanimous recognition among all of the major diabetes organizations that diabetes education and support services delivered by DCESs are an essential and effective component of comprehensive diabetes care, these services are still significantly underutilized. In her article for our collection, Dr. Albanese-O'Neill delivers a valuable real-world example of how to implement an effective diabetes care, education, and support service for the use of diabetes technology, outlining all of the strategies, materials, and workflow steps her team at the University of Florida's Division of Pediatric Endocrinology has implemented. Their approach can serve as a model for other institutions.

Next, we turn to CGM use in diabetes specialty care—in this case, pediatric endocrinology, as represented by Priya Prahalad and David M. Maahs, two leaders who are doing groundbreaking diabetes technology research to determine the value of early intervention with advanced technology such as CGM in children and adolescents with type 1 diabetes (p. 299) (9). They review lessons from their influential and often-cited 4T (Teamwork, Targets, Technology, and Tight Control) study. We are fortunate that Drs. Prahalad and Maahs were willing to share not only their research but many key pearls of implementation, including their work to ensure care equity, the importance of having easy access to CGM data, and the value of developing a technology data dashboard, all of which make the Stanford Pediatric Endocrinology Clinic such a valuable model clinic for other endocrinologists who are seeking to transform diabetes care.

Most care for diabetes, particularly type 2 diabetes, is delivered in the primary care setting. Thus, if CGM is going to live up to its full potential in helping to transform diabetes care, we will need many primary care provider champions who are skilled in analyzing and acting on CGM data. Primary care clinics will need to figure out how best to implement CGM into their remarkably busy workflows and determine how and when to comanage people with diabetes with DCESs and endocrinologists. This topic is addressed in our series in an article by Thomas W. Martens (p. 306) (10). It has been my pleasure to work closely with Dr. Martens, who has an active internal medicine practice at Park Nicollet/HealthPartners and is also a medical director at the International Diabetes Center (IDC). He helped to lead the MOBILE study, which showed the value of CGM in optimizing the care of individuals with type 2 diabetes on basal insulin therapy (11). This work was incorporated into the American Diabetes Association's (ADA's) *Standards of Medical Care in Diabetes* (12), and basal insulin therapy was added to the growing list of indications for the use of CGM. This is a prime example of the first step in translating research to practice. Dr. Martens' article in our series also takes us on an insightful exploration of additional opportunities and barriers encountered in implementing CGM in the real-world primary care setting.

All would agree that optimal glycemic management is essential and yet complicated when dealing with diabetes in pregnancy. We are fortunate that Helen R. Murphy, one of the world's leading experts on the management of diabetes in pregnancy, was willing to share her insights on the value of CGM and other advanced technology systems in her article for our research section (p. 315) (13). Few people have spent as much time as Dr. Murphy thinking and writing about CGM metrics, profiles, target ranges, and management strategies to help ensure the well-being of both pregnant women with diabetes and their babies. Just reading Dr. Murphy's closing paragraph on directions for future research will make you feel that it was worthwhile to open this issue of *Diabetes Spectrum*.

The preceding four articles all mention the particularly challenging goal of providing CGM-guided diabetes care in an equitable and affordable manner in each of the settings addressed. Our fifth article, by the inspiring chief medical officer of the T1D Exchange, Osagie Ebekozien, expands on this theme (p. 320) (14). Across the diabetes scientific literature, in the lay press today, and in Dr. Ebekozien's article, you can find facts and references that elucidate the current state of inequity in the prescribing and use of CGM and other advanced technology systems in diabetes management. However, Dr. Ebekozien's article is one of the few sources that focuses on the actual steps needed to move toward tangible solutions to this vexing and persistent problem. These suggestions for action are based on the findings from the CGM equity project of the dynamic and influential T1D Exchange Quality Improvement Collaborative, which Dr. Ebekozien so masterfully leads. No matter what discipline within the diabetes community you represent, you will fine recommendations that pertain to you in this comprehensive call to action toward the realization of CGM equity.

To close our From Research to Practice section, I was given the opportunity to reflect on the evolution, current impact, and future promise of CGM (p. 327) (15). I incorporated concepts from the other five articles and from what I have learned from my colleagues at the IDC throughout the past

40 years, including Don Etzwiler, Roger Mazze (who introduced us all to the concept of the ambulatory glucose profile), David Kendall, Bob Cuddihy, Mary Johnson, Gregg Simonson, Amy Criego, Anders Carlson, Dr. Martens, and others. I also drew on the knowledge I have gained from colleagues at other institutions, who I routinely call to ask, "What do you think of this idea?" or "How can I help with the amazing technology work you are doing?" These world-renowned diabetes technology experts include Roy Beck, Irl Hirsch, Anne Peters, Satish Garg, Bruce Buckingham, Grazia Aleppo, Davida Kruger, David Klonoff, Tadej Battelino, and Moshe Phillip, to name just a few.

My closing roadmap to CGM innovation, investigation, and implementation was formulated with Aaron J. Kowalski's classic artificial pancreas roadmap in mind (16). I tried to summarize the 25-year history of CGM, outlining what the diabetes community has achieved, what we are still working on, and what we need to tackle next, including innovations we all hope will materialize before much longer. Others in this field may have laid out this roadmap in a different manner, but I imagine the destination for all such CGM roadmaps will be a place and time when all who can benefit from the use of CGM or other life-changing approaches to diabetes management have equal access to these transformative therapies.

Dr. Albanese-O'Neill and I thank our coauthors and the ADA Journals production team, including our skilled Managing Editor, Debbie Kendall. We hope you enjoy this insightful collection and welcome your comments.

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Editor's note: The roadmap figures featured in each article of this From Research to Practice section are also available on a special resources page on the journal's website and can be accessed at https://diabetesjournals.org/spectrum/pages/cgm_roadmaps.

# Guest Editor

RICHARD M. BERGENSTAL, MD, is an endocrinologist and the executive director of the International Diabetes Center (IDC) of HealthPartners Institute, as well as an adjunct clinical professor of medicine at the University of Minnesota in Minneapolis, MN. Before joining the IDC in 1983, he was an assistant professor at the University of Chicago in Illinois.

Dr. Bergenstal was a site principal investigator in several landmark National Institutes of Health–funded trials, including the DCCT (Diabetes Control and Complications Trial), ACCORD (Action to Control Cardiovascular Risk in Diabetes), and GRADE (Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study). These trials demonstrated the necessity of maintaining good glycemic control. Today, Dr. Bergenstal continues to study the most effective tools and teamwork approaches needed to accomplish this goal.

He has worked toward international standardization of continuous glucose monitoring (CGM) metrics such as time in range and of the display of CGM data in the ambulatory glucose profile report. Integrating CGM data in electronic health records and organizing the data to effectively guide diabetes management are his areas of current focus.

Dr. Bergenstal was named the American Diabetes Association's Outstanding Physician Clinician in 2007 and served as the Association's President, Medicine & Science, in 2010. He has authored more than 300 peer-reviewed publications and has been included in *Best Doctors in America* since the listing began in 1992.

*Diabetes Spectrum* associate editor Anastasia Albanese-O'Neill, PhD, APRN, CDCES, coordinated this From Research to Practice section.

# Roadmap to the Effective Use of Continuous Glucose Monitoring by Diabetes Care and Education Specialists as Technology Champions

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This article describes the implementation of a diabetes technology educational program targeting continuous glucose monitoring (CGM) adoption that significantly increased utilization of CGM in the Division of Pediatric Endocrinology at the University of Florida. The author proposes that diabetes care and education specialists (DCESs) are uniquely positioned in the health care ecosystem to serve as diabetes technology champions. The article provides a step-by-step roadmap that DCESs and clinicians can use as they lead efforts to expand CGM adoption and durable use.

It has been nearly 25 years since continuous glucose monitoring (CGM) systems first became available for use by individuals with diabetes. Early models were cumbersome and inaccurate, and clinical uptake was limited to the few hardy souls who saw potential in the technology, were willing to learn how to insert, tape, and calibrate the devices, and could endure significant usability challenges in their commitment to realize the benefits of access to real-time continuous glucose data (1). Over the past decade, the accuracy and usability of CGM devices has improved significantly, leading the U.S. Food and Drug Administration (FDA) to approve most CGM systems for nonadjunctive use (2). The devices were first recommended by the American Diabetes Association (ADA) in its *Standards of Medical Care in Diabetes—2016* (3), and, since then, significant improvements in usability, connectivity to mobile devices, data-sharing with care partners, and passive data transfer to the diabetes care team via mobile technology and online data platforms have resulted in strong demand for CGM among people with diabetes.

Consistent CGM use has been associated with improved glycemic outcomes, reduced hypoglycemia, and improved quality of life, and CGM should be an essential tool in the diabetes care regimen for individuals on insulin therapy (2). However, barriers to CGM access and use have created inequities and disparities in care, which have disproportionately affected individuals in racial/ethnic minority groups, those who are publicly insured, and those whose diabetes is managed in primary care (4–6). Some state Medicaid programs still do not cover CGM for pediatric patients, and many continue to exclude adults with type 1 diabetes or those with type 2 diabetes who use insulin or other agents known to increase the risk of hypoglycemia (7).

Diabetes care and education specialists (DCESs) are uniquely positioned in the health care ecosystem to serve as diabetes technology champions, particularly with respect to CGM adoption and support (8). In this role, DCESs can improve access to CGM through advocacy to increase access at the state level, the creation of improved clinical workflows, and the provision of effective patient and professional education and support around CGM use. Such education can ensure that CGM systems are prescribed and worn and that the data they provide are used in daily decisions by people with diabetes and by diabetes care teams to improve diabetes outcomes.

## Exploring Barriers to Building a Technology-Enabled Clinical Practice

In December 2016, the FDA for the first time approved a CGM system for nonadjunctive use, allowing management decisions, including insulin dose calculations, to be determined based on CGM values and without confirmatory fingerstick blood glucose monitoring (BGM) readings. Earlier that year, the ADA had recommended that CGM be considered as adjunctive therapy to BGM in selected patients (3). In 2017, the ADA expanded its recommendation, advising that all adults with type 1 diabetes who are not meeting glycemic targets should be considered for

real-time or intermittent scanned, or "flash," CGM devices (9). In a 2018 position statement on type 1 diabetes in youth, the ADA endorsed CGM for children and adolescents using either a multiple daily injection (MDI) insulin regimen or insulin pump therapy "as an additional tool to help improve glycemic control" (10). By 2023, CGM was recommended for children and adults with type 1 or type 2 diabetes who use an MDI regimen or pump therapy, as well as for those with type 2 diabetes on basal-only insulin therapy, with the ADA noting the relationship between CGM use and improved glycemic outcomes, improved quality of life, and reduced hypoglycemia (2). As with all types of diabetes technology, robust education, training, and support are strongly endorsed in the clinical guidance (2).

Although CGM adoption has improved through the years, its uptake and durable use remain variable, and disparities in access persist. DeSalvo et al. (4), writing on behalf of the T1D Exchange Quality Improvement Collaborative (T1DX-QI), analyzed CGM data available from the group's 54 member clinics in an observational study and found that 48% of people with type 1 diabetes in these high-performing centers were using CGM ($n$ = 11,469). Of particular note, they found significant disparities in CGM adoption based on race/ethnicity, with higher usage rates among non-Hispanic White individuals (50%), lower usage among Hispanic individuals (38%), and the lowest usage rates among non-Hispanic Black individuals (18%). CGM usage was also higher among individuals with private insurance (57.2%) compared with those with public insurance (33.3%). Consistent with other data, individuals using CGM had a lower median A1C (7.7%) compared with those not using CGM (8.4%), and rates of diabetic ketoacidosis and severe hypoglycemia were significantly higher among individuals who were not using CGM (4).

Given the risk of widening care inequities and outcomes disparities between technology haves and have nots, it is important to explore barriers to CGM access beyond cost and insurance coverage. The first of these is implicit bias, which may cause clinicians to unevenly offer diabetes technology to some people with diabetes over others. Implicit bias can be based on patients' race/ethnicity (11,12), insurance type (11), and diagnosis type (13), with increased bias associated with diagnoses that are perceived to be linked to lifestyle choices. In addition to continuing education to mitigate the effects of implicit bias, carefully designed clinic workflows should also be considered, and resources are available to this end (14). Provider readiness is another potential barrier to technology integration. Tanenbaum et al. (15) surveyed 209 physicians and certified diabetes care and education specialists (CDCESs)

who worked in specialty care to ascertain their readiness to support CGM adoption. Whereas 20% of the specialty professionals surveyed were eager and ready to support CGM in their clinical practice, 40% remained cautious, and 39% indicated that they were not yet ready to integrate CGM into the clinical paradigm, citing significant barriers that were both personal and structural. Finally, although many such barriers have been eliminated, including previous requirements that people perform at least four daily BGM checks or have a specific A1C before starting insulin pump therapy, technology gatekeeping still exists in many clinical settings. Acknowledging that this practice persists, clinical guidelines have been explicit in discouraging the practice of making children and adults "earn" the right to use beneficial technology (16–18). Whether related to health care professionals' readiness, implicit biases, or outdated gatekeeping practices, the inability or unwillingness of health care professionals to offer evidence-based diabetes technology to all people with diabetes and to provide appropriate education, training, and support will continue to exacerbate inequities in care and disparities in outcomes.

## DCESs as Technology Champions

DCESs can play a unique and pivotal role as champions of technology adoption in various clinical settings (Figure 1) (8). The American Association of Clinical Endocrinologists specifically identifies DCESs as being central to developing CGM workflows in the adult specialty care setting (17). Access to and partnership with a DCES, whether remotely or as a member of the team embedded in a primary care setting, has also been associated with successful CGM adoption (19–21).

DCESs as technology champions can and should lead efforts to integrate technology into the clinical paradigm to improve outcomes and quality of care. These professionals come from a variety of disciplines, including nursing, pharmacy, dietetics, social work, psychology, and medicine. Diabetes technology champions can design systems that motivate stakeholders to work together to achieve shared goals, ultimately resulting in achievement of the Diabetes Quintuple Aim of reducing patient and clinician burden, reducing costs, improving health outcomes, and ensuring equity in access and care delivery (22).

In settings in which no workflow currently exists for the use of professional (practice-owned) and/or personal (patient-owned) CGM systems, diabetes technology champions may face barriers. These may include personal barriers such as the champion's status on the care team or within the health care system; lack of training or expertise

## Roadmap of DCESs as CGM Champions
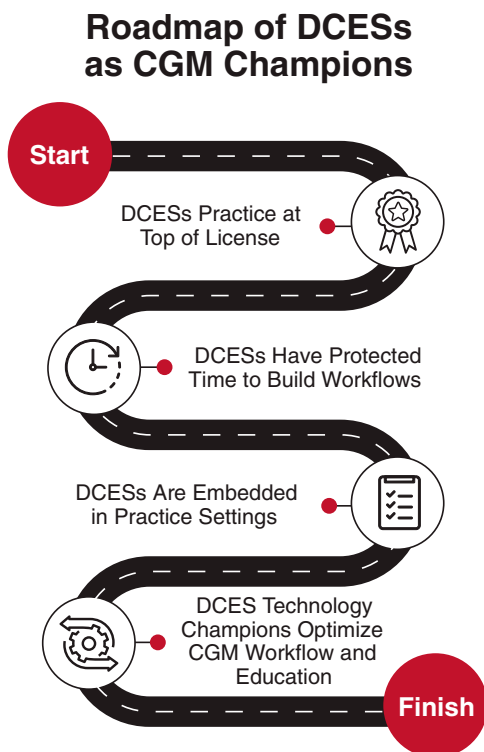


**FIGURE 1** A roadmap of the role of DCESs in championing CGM use. DCESs are well-positioned to serve as diabetes technology champions when they practice at the top of their license, have dedicated time available to build workflows, and are embedded in or accessible to clinical practices.

in CGM technology; unfunded time needed to build and implement a clinical process while carrying out other job responsibilities; inability to communicate the evidence to

support CGM adoption; and lack of confidence or fear of failing.

All of these barriers can be overcome through training, mentorship, and support. Table 1 lists numerous resources that diabetes technology champions can use to build internal capacity, including webinars, checklists, and accredited education programs. Diabetes technology champions may also face organizational barriers to implementing CGM in the care setting, including lack of support from leadership, conflicting priorities, staffing limitations, and lack of enthusiasm from colleagues. These barriers are more difficult to overcome but are not insurmountable. The best place to start may be to initiate a pilot project, particularly in a clinical environment in which the DCES lacks institutional support for a new workflow to support CGM implementation.

### Changing the Clinical Paradigm to Support CGM Utilization: A Case Study

In 2016, as evidence was mounting that CGM contributed to improved glycemic outcomes, the Division of Pediatric Endocrinology at the University of Florida embarked on a CGM implementation project led by the author. At the time, CGM training was almost exclusively provided in conjunction with insulin pump starts to support sensor-augmented pump therapy. A professional CGM process using the Medtronic iPro had been attempted but abandoned. A review of clinical records showed that 7% of patients with type 1 diabetes were using CGM in 2016. By completion of the project in 2019, 75% of the patient panel was using CGM. Although

**TABLE 1** Practical Guidance to Integrate CGM Into Clinical Practice

| Title of Education Program or Resource | Organization | Available Online From: |
|---|---|---|
| Continuous Glucose Monitoring (CGM) | American Academy of Family Physicians | https://www.aafp.org/family-physician/patient-care/care-resources/continuous-glucose-monitoring.html |
| AACE Guide to Continuous Glucose Monitoring (CGM) | American Association of Clinical Endocrinologists | https://pro.aace.com/cgm/toolkit/aace-guide-continuous-glucose-monitoring-cgm |
| Making Diabetes Technology Work | American Diabetes Association | https://professional.diabetes.org/content-page/making-diabetes-technology-work |
| Time in Range: Workflow | American Diabetes Association | https://professionaleducation.diabetes.org/Public/Catalog/StackHome.aspx?Search=Time+in+Range |
| Danatech | Association of Diabetes Care & Education Specialists | https://www.diabeteseducator.org/danatech/home |
| CGM Implementation Playbooks (Personal and Professional CGM) | Association of Diabetes Care & Education Specialists, American Pharmacists Association, APhA Foundation, and American Association of Nurse Practitioners | https://www.diabeteseducator.org/practice/practice-tools/app-resources/professional-cgm-playbook |
| DiabetesWise | DiabetesWise | https://diabeteswise.org |
| DiabetesWisePro | DiabetesWisePro | https://pro.diabeteswise.org |
| Panther Program | Barbara Davis Center for Diabetes | https://www.pantherprogram.org |
| About AGP – the Single Page Report for Everyone | International Diabetes Center | http://www.agpreport.org/agp/about |
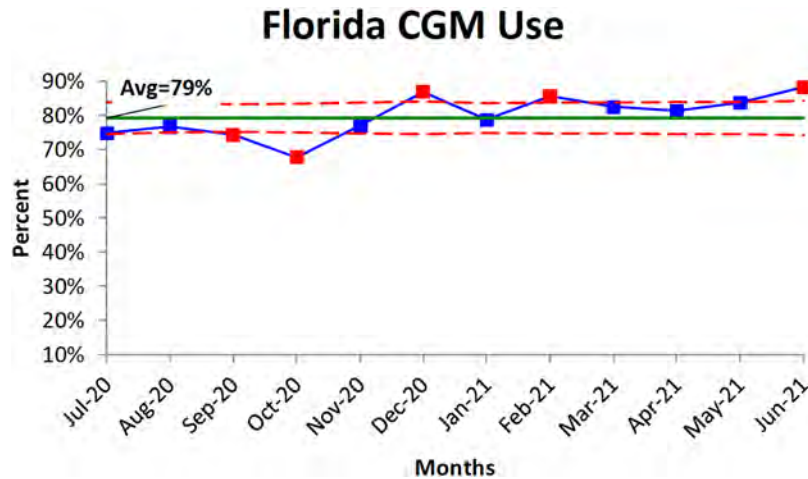
FIGURE 2 CGM use rates at the University of Florida Division of Pediatric Endocrinology from July 2020 to June 2021. Data were extracted directly from the EHR. CGM use by children and adolescents decreased during the COVID-19 pandemic but then quickly recovered and increased, demonstrating the strength of the clinical processes developed to integrate CGM into the clinical workflow. Avg, average.

CGM utilization dipped slightly in 2020 at the height of the coronavirus disease 2019 (COVID-19) pandemic, it quickly rebounded, and, by June 2021, CGM utilization was approaching 90% (Figure 2). The project also demonstrated financial sustainability, with net collection rates in 2019 for Current Procedural Terminology codes 95249 (personal CGM, start-up, training), 95250 (professional CGM), and 95251 (CGM interpretation) all exceeding 80% across insurance types, including private insurance, federal/military coverage, and public insurance (Medicaid).

The implementation team included a pediatric nurse practitioner CDCES (project lead), a registered nurse CDCES, a registered dietitian CDCES, two certified medical assistants, and an administrative staff member. Once the curriculum was developed, the process involved the following steps: identifying the need, building the team, designing the workflow, training the staff, implementing the plan, and ongoing evaluation.

### Identifying the Need

Based on the growing evidence for improved outcomes related to diabetes technology adoption, the practice decided to develop an educational program to support technology onboarding and durable use. This effort included the CGM project, which is described here. The overall program was designed to include all FDA-approved technology devices, including CGM systems, connected insulin pens, insulin pumps, and automated insulin delivery (AID) systems. To ensure readiness and support patient choice, the clinic designed and implemented the

following educational opportunities for patients and their parent caregivers:

- Group technology decision-support class. This class was initially offered in person, then was offered virtually during the pandemic, and continues to be offered both in person and virtually. Led by a DCES, the class provides a didactic overview of available diabetes technology. Children, parents/guardians, and other caregivers are encouraged to attend. After the didactic portion of the class, attendees complete the Knowledge Assessment in Type 1 Diabetes (KAT-1) Scale 10: Diabetes Technology as a patient-facing questionnaire in the Epic electronic health record (EHR) (23). Individuals/families who score <70% on the KAT-1 Scale 10 are referred for individualized follow-up education. After this portion of the class, attendees have the option of meeting with device company representatives to explore the devices and ask device-specific questions.
- Personal CGM placement. This clinic visit includes CGM sensor placement and initiation; comprehensive education on device use, data-sharing, and data review; connection to the clinic portal; and scheduling of a follow-up telehealth visit in 7–10 days to evaluate data.
- Professional CGM placement. A process was developed for professional CGM placement but eventually was discontinued because of the high uptake of personal CGM.
- CGM data-sharing education class. This education visit is available to individuals who required additional

support after their CGM sensor placement. The curriculum is individualized based on patient/family needs.

- Insulin pump/AID system training. The Division of Pediatric Endocrinology negotiated center contracts with device manufacturers to provide in-house training on insulin pumps and AID systems. This arrangement allowed the clinic to individualize training and improve staff competence, and created a revenue stream.

The sections below focus on the remaining steps needed to integrate CGM into the clinical workflow.

## Building the Team

Internal meetings were scheduled to build consensus around and support for the project by key stakeholders, including information technology (IT) staff, billing and coding staff, administrative staff, clinicians, clinic staff, an EHR builder, and clinic leadership.

IT staff were consulted to mitigate possible security risks and create a plan for privacy compliance. Multiple software platforms were evaluated, including manufacturers' software (i.e., Medtronic's CareLink, Dexcom's Dexcom Clarity, and, later, Abbott Diabetes Care's LibreView) as well as data aggregators (i.e., Glooko and Tidepool). The IT department evaluated all of these data platforms, and ultimately all were used in some capacity by the clinic team. A standard operating procedure (SOP) was developed to govern how the software would be loaded on computers and updated when new versions were released. This effort required IT staff from both the university and the hospital to collaborate so CGM data could be accessed at workstations in all areas (e.g., patient rooms, clinic workrooms, and faculty and staff offices). The IT staff also recommended best practices, including appointing a clinic administrator for each account to create individual staff accounts, manage password access, discontinue accounts when staff resigned or retired, and schedule software updates.

The project lead also met with staff from the billing and coding department for guidance. After an initial meeting, the billing and coding staff requested that an in-service training be offered on CGM so involved staff could become conversant in the technology nomenclature and related coding. After the in-service training, the clinic team created standardized EHR templates for professional CGM placement, personal CGM placement, and CGM data interpretation that were reviewed by the billing and coding department to ensure that they included essential elements to meet billing requirements. As the program grew, one significant benefit afforded by these standardized templates was a reduction in

time spent documenting CGM placements, CGM education, and data interpretation by members of the care team, which contributed to improved care team satisfaction.

The division chief advocated for support from the department's EHR builder, who operationalized the workflow in the EHR. The clinic administrator and administrative staff were also essential stakeholders. The administrative staff partnered with the project lead and EHR builder to create EHR referrals for CGM placement and education visits (Figure 3), a matrix for scheduling visits, and EHR flowsheets to capture discrete CGM metrics. The project lead developed a protocol and script for call center staff, and scheduled an in-service training session to familiarize call center staff with CGM terminology.

The DCES team built CGM placement templates that were integrated with flowsheet data to standardize documentation and reduce charting burden. The team also developed standardized patient-facing CGM education materials in the EHR and a school order set.

## Designing the Workflow

Designing the workflow included 1) defining the metrics for the implementation project; 2) optimizing EHR workflow and developing standardized flowsheets and templates to be used in all clinic visits related to CGM training, education, and interpretation; 3) creating SOPs for each visit type; 4) training the team; 5) streamlining administrative paperwork, including prior authorizations; 6) implementing the plan; and 7) evaluating the program's success.

### Defining metrics

The primary outcome metric was CGM adoption and durable use. The program also tracked the following key performance indicators: decision-support class attendance, numbers of professional and personal CGM placements, number of CGM education sessions, percentage of CGM wear time over 14 days, percentage of time in range (TIR), and A1C.

### Optimizing EHR workflow

Flowsheets were created by the EHR builder to collect information as discrete variables in the EHR. Discrete data are easy to extract from the EHR for analysis, compared with data that are entered in narrative form as a "smartphrase" or clinic note. The flowsheet design also facilitated the division's participation in quality improvement (QI) benchmarking collaboratives, including the T1DX-QI in the United States and the international SWEET Registry. Discrete CGM data collected at each clinic visit include CGM start date, CGM brand and model, supply details (making the current durable

**A**



**B**



**FIGURE 3** EHR technology referrals, including CGM placement referral (*A*) and technology education referral (*B*). Referral examples are from University of Florida Epic build.

medical equipment [DME] company or pharmacy easy to track to facilitate refills), percentage of CGM wear time over 14 days, and percentage of TIR over 14 days.

There are two key benefits of entering data into flowsheets in the EHR. First, important variables (e.g., TIR, wear time, and DME company) can easily be located, reviewed, or extracted for benchmarking or patient care. Second, the information can be integrated into standardized visit templates, which are coded to automatically pull data from the flowsheet into the visit note (Figure 4). This process reduces the documentation burden for clinicians and the clinic team.

As part of the EHR build, standardized visit templates for the decision-support class, KAT-1 Scale 10: Diabetes Technology, and CGM placement visits were included. In addition, the

DCES team created standardized patient education templates and letters of medical necessity.

The flowsheets were populated in advance of the visit by a team of two medical assistants with expertise in diabetes technology data platforms. Automating these processes has allowed clinicians and DCESs to spend significantly more time reviewing CGM data in partnership with people with diabetes and their caregivers during visits.

### Creating SOPs

SOPs were developed for each visit type (i.e., technical decision support, CGM placement, and CGM follow-up education), retrieval of data from devices and use of data platforms (if data do not automatically flow into the data

**FIGURE 4** Sample CGM flowsheets and template integration. *A*: CGM flowsheet. A medical assistant enters data into the EHR before an in-person or virtual visit. *B*: CGM interpretation template. Data are entered into the flowsheets and then auto-populate this template. The note can be started by the medical assistant and later opened by the clinician or DCES. *C*: CGM interpretation template with data auto-populated from the flowsheet and AGP copied from the data platform and pasted into the note by the medical assistant. The clinician or DCES can then add individualized interpretation related to safety, glycemic trends, and recommendations for changes in treatment.

platform), and workflow (e.g., referrals, billing and coding, and using flowsheets and templates).

The single-page SOP for CGM placement visits provides a full overview of the process, including how to prescribe a device (via DME company or pharmacy); how to complete related paperwork, including letters of medical necessity; how to place an EHR referral for CGM placement; and how to complete flowsheets during visit intake (performed by medical assistants), a list of templates to be used by clinicians and DCESs for CGM placement, CGM interpretation, patient instructions, and school order documentation; and how to connect patients to the clinic data platform before visits end.

The EHR technology referrals (Figure 3) were created to expedite and streamline scheduling for CGM placement and education, as well as general diabetes technology education and insulin pump/AID system training. A referral is made for CGM sensor placement after CGM is prescribed. The medical assistants contact patients/caregivers to confirm that they have received the CGM system, verify that all components have been received, and establish that patients have a compatible reader or smartphone app. The call center staff also worked under a protocol when scheduling visits and reminded patients/caregivers to bring all necessary items to visits, including their reader or compatible smartphone app. This protocol has significantly reduced the need to cancel or reschedule appointments because a compatible reader or app is not available.

The technology education referral is also used to facilitate scheduling for the group diabetes technology decision-support class and follow-up CGM education. This referral can be made at diabetes onset (for the decision-support class), after a CGM placement appointment when a clinician or DCES notes a need for additional follow-up, or during routine clinic visits when a need for further education is identified. CGM education visits take place in person or virtually and cover individualized topics, including skin care, placing and removing CGM sensors, connecting to the clinic account (via the reader), sharing data with care partners and when at school, reviewing the ambulatory glucose profile (AGP) data report, using trend arrows effectively in day-to-day glycemic management, and other individualized topics.

### Training the team

During division meetings, new CGM-related SOPs and changes to workflow, documentation, and coding are introduced and reviewed. In addition, the project lead provides an annual, continuing education–accredited review

of updated clinical guidelines for CGM during division rounds. Ongoing virtual and in-person training is available for clinicians and staff and provided by representatives from the device companies and data platforms. All members of the care team are invited to attend all educational opportunities. The core team also provides semiannual or periodic "wear and share" opportunities for the clinic team and staff. Working with device samples from device companies, the program provides this opportunity for the clinicians and staff to wear different technology devices, including CGM and insulin pumps (with saline). Office staff, call center staff, and partners throughout the organization are also invited to participate, as well as fellows and residents.

### Streamlining administrative paperwork

A recent study found that, in 2019, one in eight prior authorization requests sent to Medicaid managed care organizations were denied, and, of the 115 entities analyzed, 12 had prior authorization denial rates higher than 25% (24). A process to streamline the prior authorization process and reduce the risk of denials was implemented with an aim to reduce staff burden and ensure that patients received supplies in a timely manner. An EHR queue was created for incoming prior authorizations, which were routed initially to an inbox managed by the division's medical assistants. Clinic administrators evaluated software options for reducing staff burden (CoverMyMeds) and needed software was obtained (Adobe Acrobat Pro). Multiple staff members were trained to complete prior authorizations so they would not be the responsibility of a single individual who might be away from the office for vacation or illness when an authorization was needed. As the program grew, additional staff were trained to manage prior authorizations, including call center and office staff. Although the nurses, dietitians, and DCES staff knew how to process prior authorizations and could assist emergently, this task was not a core job responsibility because it limited their ability to practice at the top of their license.

### Implementing the plan

At the beginning of the project, all CGM starts were provided during designated CGM start clinics on 2 half-days/month by one nurse practitioner, with education provided by the nurse practitioner or in partnership with another CDCES. As demand increased, additional clinics were added and provided by other nurse practitioners in the practice. Now, CGM is often initiated at or soon after diagnosis as part of the initial diabetes education process. The

emphasis on providing an excellent CGM start for patients is based on evidence that suggests that the first month of CGM use is predictive of future adherence (25). Thus, ensuring patient satisfaction, reducing implementation burden, mitigating start-up distress caused by alarms/alerts, and setting realistic expectations were the focus of these visits (25,26). As the program grew, and as CGM models were discontinued and new ones introduced, the workflow was continuously evaluated and improved.

### Evaluating the program

During the implementation of the project, the core team and clinic staff met weekly to review feedback on clinical workflow. A QI approach (using Plan, Do, Study, Act [PDSA] cycles) was used to further standardize processes, improve infrastructure, modify SOPs, and guide staff trainings. Outcome data (e.g., CGM adoption rates and related clinical outcomes) were reviewed on a monthly basis and shared with all staff by the division chief. Billing and reimbursement data were reviewed, and processes were optimized. Patient satisfaction data were collected and reviewed, and feedback was incorporated into patient education. Because the division is a member of the T1DX-QI, its CGM metrics can now be reviewed in the T1D Exchange portal and benchmarked against peer clinics.

## Conclusion

Although the process described in this article is specific to CGM, it can be applied to any diabetes technology that best meets the needs of people with diabetes in a given practice setting. Clinical implementation of CGM can be initiated and led by a DCES or clinician. Clinics that do not have a DCES as a member of the care team should consider changes in staffing models or forming a partnership with a local education program.

Strategies for success include designating a diabetes technology champion to lead the effort and forming a core team. Next, the technology champion should share evidence and clinical guidelines that support or endorse CGM use and related clinical benefits for people with diabetes. This evidence can be presented at weekly division or staff meetings, and champions might consider bringing in an expert virtually to present evidence about the benefits of CGM or other diabetes technology devices. To get buy-in from staff members who may be cautious or otherwise not ready yet, consider partnering with a local device representative to provide on-body technology experiences, not only for the diabetes care team, but also for administrative staff, administrators, and other interested parties. At the outset, determine which

metrics you will track and how you will measure them. Work with billing and coding staff, administrators, and EHR experts (if available) to create a pilot workflow. Use this pilot to demonstrate program feasibility, acceptability among patients and care team members, and efficacy in terms of clinical outcomes and reimbursement. Efficacy can be measured in different ways, such as assessing glycemic outcomes and patient and staff satisfaction. If you are starting a brand-new program, consider applying for internal or external grant funding to support your pilot program.

Do not work alone, and do not reinvent the wheel. CGM processes have been implemented in a variety of settings nationwide. Reach out to colleagues across the country who will be eager to contribute to your success. Join a working group in your professional specialty for additional support. Free online resources are available to sharpen your expertise (Table 1). Build simple processes that improve efficiency and reduce documentation burdens for clinicians and other members of the clinical care team. Encourage and reward consistent use of the processes you develop (i.e., SOPs, EHR templates, and standardized referrals); consistent use of these tools will assist you in quantifying your annual outcomes. Use QI processes, with routine input from the clinical team to evaluate the program. Do not wait until the end of the pilot project to improve processes; instead, use PDSA cycles to make real-time improvements as the pilot progresses. Make sure that you have a strong working relationship with IT staff and that the CGM data platforms and software used in clinic work well; once the team becomes experienced with data-based clinic visits, conducting a diabetes visit without glycemic data will feel wasteful. Make sure all members of the team are practicing to their full professional potential; work with management to create protocols that allow licensed and certified staff (e.g., registered nurses and dietitians and CDCESs) to practice at the top of their license. Finally, find ways to thank the team and share their success, and remember that leaders can be found at all levels of an organization.

Some factors that are beyond the control of the clinic leadership and staff include insufficient CGM coverage by private and public insurance plans. Many practices have successfully advocated to achieve policy change (27). This was also true in Florida. In 2016, the state Medicaid plan did not cover CGM placement for children and adolescents. In 2017, through a series of letters and meetings, members of the University of Florida Division of Pediatric Endocrinology care team provided evidence supporting CGM use in this population and were able to achieve expanded coverage for CGM placement and supplies. In 2023, based on evidence

provided by members of the health care team and others, the state legislature (in Florida Senate Bill 988) expanded Medicaid coverage for CGM to adults with insulin-requiring diabetes. Increased access sometimes requires advocacy in addition to a strong clinical workflow, and if we hope to eliminate inequities and reduce disparities, we must be willing to get off the sidelines and advocate for improved technology access for people with diabetes.

## DUALITY OF INTEREST

A.A.-O. is a full-time staff member at JDRF International and the volunteer founder and board chair of Diabetes Toolkit, a Florida-based diabetes education nonprofit (501c3) organization. Until November 2021, she was a contracted certified product trainer for Insulet, Medtronic, and Tandem Diabetes Care. No other potential conflicts of interest relevant to this article were reported.

## AUTHOR CONTRIBUTION

As the sole author of this article, A.A.-O. researched the data and wrote and revised the manuscript and is the guarantor of this work.

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# Roadmap to Continuous Glucose Monitoring Adoption and Improved Outcomes in Endocrinology: The 4T (Teamwork, Targets, Technology, and Tight Control) Program

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Glucose monitoring is essential for the management of type 1 diabetes and has evolved from urine glucose monitoring in the early 1900s to home blood glucose monitoring in the 1980s to continuous glucose monitoring (CGM) today. Youth with type 1 diabetes struggle to meet A1C goals; however, CGM is associated with improved A1C in these youth and is recommended as a standard of care by diabetes professional organizations. Despite their utility, expanding uptake of CGM systems has been challenging, especially in minoritized communities. The 4T (Teamwork, Targets, Technology, and Tight Control) program was developed using a team-based approach to set consistent glycemic targets and equitably initiate CGM and remote patient monitoring in all youth with new-onset type 1 diabetes. In the pilot 4T study, youth in the 4T cohort had a 0.5% improvement in A1C 12 months after diabetes diagnosis compared with those in the historical cohort. The 4T program can serve as a roadmap for other multidisciplinary pediatric type 1 diabetes clinics to increase CGM adoption and improve glycemic outcomes.

Glucose monitoring is a key component of diabetes care (Figure 1). The first attempt at glucose monitoring was the introduction of urine glucose monitoring in 1908 (1). Urine testing remained the standard of care until the introduction of home blood glucose monitoring (BGM) in the 1980s. The ability to closely monitor glycemia using BGM helped to revolutionize the care of diabetes to more precisely dose insulin. We are now undergoing another paradigm shift in glucose monitoring. The U.S. Food and Drug Administration (FDA) approved the first continuous glucose monitoring (CGM) system in 1999. Early-generation CGM systems were blinded devices from which data were downloaded in health care providers' clinics.

CGM systems now have evolved to obtain interstitial glucose values every 1–15 minutes, display these readings on a receiver, and sound alarms to alert users to hypoglycemia and hyperglycemia. Early CGM systems required calibration with glycemic levels obtained through BGM. In 2016, the first factory-calibrated CGM system was introduced. Modern CGM devices can passively share users' glycemic data to other individuals and to their diabetes clinic through the use of smartphone apps and Cloud-based data platforms. Because CGM has been shown to improve A1C and quality-of-life measures in people with type 1 diabetes (2–9), the

American Diabetes Association (ADA) now recommends CGM for all individuals with type 1 diabetes, and the International Society for Pediatric and Adolescent Diabetes (ISPAD) recommends CGM use for youth with type 1 diabetes (10–12).

As glucose monitoring technology has evolved, so too has insulin delivery technology (13). Insulin was first administered by injection in 1922. The first commercial insulin pump was introduced in 1979, and insulin pens were introduced in the 1980s. At that time, conventional insulin therapy consisted of one to two injections per day of mixed intermediate- or rapid-acting insulin, with glucose levels monitored through urine testing or BGM. In 1993, the Diabetes Control and Complications Trial (DCCT) reported its findings that intensive insulin therapy, consisting of four or more insulin injections per day or insulin pump therapy to provide both basal and bolus insulin, decreased microvascular complications of diabetes, and intensive insulin therapy became the new standard of care for type 1 diabetes (14,15). With the goal of intensive glycemic management, diabetes technology rapidly advanced to today's state-of-the-art automated insulin delivery (AID) systems, which combine CGM with an insulin pump and a control algorithm to deliver insulin automatically based on real-time glucose levels and trends. Currently, there are several FDA-approved hybrid closed-loop
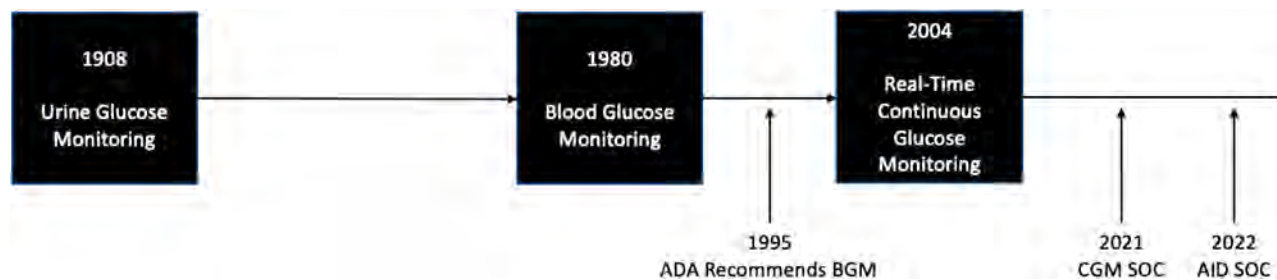
**FIGURE 1** Evolution of glucose monitoring and recommendations as standards of care (SOCs).

AID systems (automating basal insulin but requiring user input to deliver bolus doses) on the U.S. market. Because AID has been shown to improve glycemia and quality of life (16–24), the ADA and ISPAD as of 2022 now recommend the use of AID systems (with a level A evidence grade, indicating clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered) for people with type 1 diabetes (25–27).

Despite the findings from the landmark DCCT and subsequent advances in diabetes technology, people with diabetes, especially those in the pediatric age-group, continue to struggle to meet A1C targets (28–30). A1C typically exceeds glycemic targets soon after diabetes diagnosis (31,32), and this can have long-term implications; data suggest that hyperglycemia early in the course of diabetes is strongly associated with long-term glycemic control (33). In the DCCT, tight glycemic control was achieved in people with type 1 diabetes in part as a result of frequent insulin dose adjustments made for study participants by their care team. Unfortunately, this aspect of the DCCT intervention still has not been implemented broadly even more than 30 years later.

In post-DCCT clinical practice, accessing BGM data outside of clinical visits has been limited, and insulin dose adjustments have tended to occur only at quarterly clinic visits. With the advent of modern CGM technology, glucose data can be shared passively via Cloud-based platforms. The availability of these platforms decreases the data-sharing barrier to expanding remote patient monitoring (RPM); however, having sufficient staff to perform RPM remains a challenge. Without a way to identify individuals who would most benefit from data review, RPM would be difficult to scale without expanding clinic resources.

In the 4T (Teamwork, Targets, Technology, and Tight Control) study, we adapted established methods to better manage glycemia in the first year after type 1 diabetes diagnosis to improve long-term outcomes (34–43; J.C. Leverenz, B. Leverenz, P.P., et al., unpublished observations). Initiating CGM in the first month after diagnosis was a cornerstone of this program. The 4T study used findings from the Hviodere study and others, which showed that teamwork and consistent setting of tight glycemic targets can improve clinical outcomes (44). We intensified education in the new-onset period based on the rationale that this period is when people are most open to and in need of education and that this early time investment would result in better long-term outcomes. We also aimed to implement the DCCT intervention of making frequent dose adjustments by developing a sustainable, asynchronous RPM program (41–43). This effort encompassed the principle of equitable access independent of insurance or language status (35) because, historically, the introduction of new technology has increased disparities in glycemia as a result of inequitable access (45).

## Roadmap to Early CGM Initiation: The 4T Study

Before the start of the 4T study, youth with newly diagnosed diabetes had a 4- to 6-hour outpatient new-onset education visit with the clinical team to learn about diabetes care (Figure 2A). That visit was followed up by a 1-month recent-onset visit and routine quarterly diabetes visits during which dose adjustments occurred. There was no standardized approach to discussing or initiating diabetes technology (e.g., CGM or an insulin pump).

The 4T study introduced a team-based approach to diabetes care to intensify new-onset education, standardize early technology access and glucose targets, and increase touchpoints via RPM. The protocol for the 4T study has been previously described (11,37). Briefly, after routine new-onset education, youth are offered the opportunity to start on CGM within the first 30 days of diabetes diagnosis (Figure 2B). An initial month of supplies is provided by the 4T study, and subsequent CGM supplies are submitted for coverage through the youth's insurance plan. Many diabetes programs have access to starter CGM materials, which could be used to initiate CGM early and support individuals while they await insurance approval
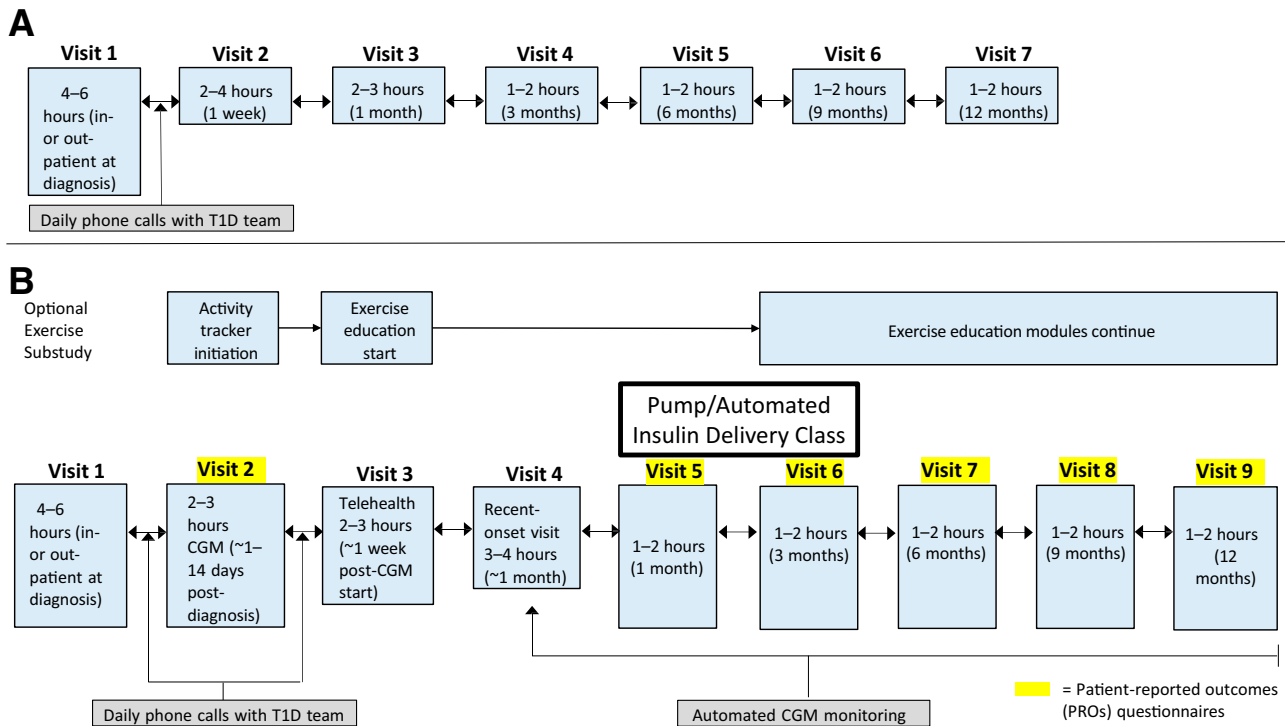
**FIGURE 2** New-onset type 1 diabetes management program with standard care (*A*) and in the 4T study protocol (*B*). T1D, type 1 diabetes.

for CGM. Those who elect to start on CGM have a follow-up visit with a certified diabetes care and education specialist (CDCES) to start CGM, with an additional CGM follow-up visit 1 week later. Youth return for a 1-month recent-onset visit, followed by quarterly clinic visits. Between clinic visits, CGM data are reviewed weekly, and insulin dose adjustments are communicated to families through electronic health record (EHR) system–based secure portal messaging (Figure 3). During the pilot 4T study, we used an A1C target of <7.5%, which was the ADA's recommended target in 2018 (46). Youth in the pilot 4T cohort, who were diagnosed from July 2018 to June 2020 (*n* = 135), had an improvement of 0.5% in A1C compared with our clinic's historical cohort, who had been diagnosed from June 2014 to December 2016 (*n* = 272) (36).

The 4T program has continued to evolve since the pilot phase. In 4T study 1, which has completed enrollment, the A1C target was lowered to <7%, and patient reported outcomes (PROs) and exercise education were incorporated (47). Participants in 4T study 1 were diagnosed from June 2020 to March 2022 (*n* = 133). In the currently enrolling 4T study 2, we are encouraging early AID adoption by standardizing a pump/AID class within the first 3 months of diabetes diagnosis and further tightening targets by lowering the A1C goal to <6.5% with associated glucose targets.

## Implementation of the 4T Program

Teamwork is the foundation of the 4T program. Before rolling out the program, the clinical diabetes team, including physicians, nurse practitioners, CDCESs, registered dietitians, and social workers, participated in planning sessions to map out the program (J.C. Leverenz, B. Leverenz, P.P., et al., unpublished observations). Once the group had agreed on a rollout that would include early CGM initiation, RPM, and consistent glucose targets in the new-onset period, youth were enrolled. Since implementing the 4T program in July 2018, the diabetes team has held routine team meetings to share findings and fine-tune the program through an iterative process. The 4T program added RPM time to the CDCES team, but this was offset by hiring a pharmacy technician to whom to offload appropriate tasks (e.g., prior authorizations) to allow CDCESs to perform CGM data reviews, make insulin adjustments, and work at the top of their professional scope (48).

## Development of the RPM Program

Starting in March 2019, youth enrolled in the 4T study were offered the opportunity to receive RPM. Initially, CGM tracings were reviewed from the manufacturer's website for every patient, and a CDCES would contact families by secure portal messaging for insulin dose adjustments or additional

# Roadmap of CGM in Endocrinology
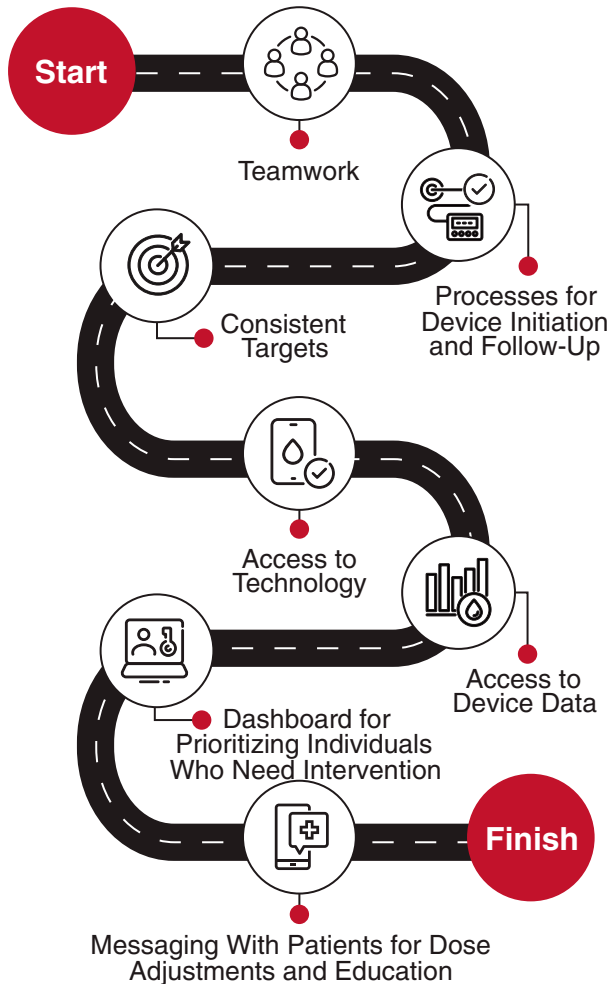


**FIGURE 3** The 4T approach as a roadmap to CGM use in pediatric endocrinology clinics.

education. This procedure quickly became unsustainable, so we collaborated with engineers in the Systems Utilization Research Force Stanford Medicine team to develop a system for prioritizing youth who would benefit from closer data

review and dose adjustments. Our first iteration was an *R*-based tool that would run on a clinician's laptop and use CGM consensus guidelines (5) to flag youth who would benefit from closer review (43). The 4T investigators and CDCES team made iterative changes to flags and have now developed a dashboard on Tableau, a software for data visualization. This dashboard, called Timely Interventions for Diabetes Excellence (TIDE), prioritizes youth for closer review and allows for review of CGM data within the dashboard (Figure 4). As the program has grown from one to five CDCESs, >400 youth have now participated in RPM. Compared with reviewing each CGM tracing individually, use of the TIDE dashboard decreased review time by 60% (42). The programming code for TIDE is open source and can be deployed at other clinics.

## Roadmap: Promoting Equity in the 4T Study

Individuals on public insurance and those from minoritized groups have higher A1C levels and higher rates of diabetes-related complications than non-Hispanic White individuals and those from higher income groups (29,49–51). Although many socioeconomic and racial factors contribute to this disparity (52), technology access is one key component if it is preferentially available to individuals of higher socioeconomic status. Insulin pumps are typically covered by public insurance, but there is variability in CGM coverage in the United States. Youth from underserved groups have lower use of diabetes technology (45,50,53,54). Although CGM access is universal in other countries (e.g., Australia [55]), the gap has widened in the United States (45). We reported that individuals from minoritized groups have persistent CGM use when CGM is accessible (56) and improvements in A1C when CGM coverage is uninterrupted (2). We observed similar findings in the pilot 4T study. We found similar A1C reductions in 4T participants by insurance status and race/ethnicity, although the program did not eliminate A1C disparities (35), likely because of additional social determinants of health that the 4T program was unable to address. Still, the 4T program offers a roadmap that can be used to achieve equitable



**FIGURE 4** Population health view of the TIDE dashboard.

introduction of diabetes technology to avoid increasing disparities. An article by Ebekozien (57) in this From Research to Practice section provides insights on improving CGM equity from the T1D Exchange Quality Improvement Initiative.

In 2018, when we started the 4T program, CGM coverage was unpredictable for youth on public insurance. We were able to obtain first philanthropic and then research funding to provide ongoing equal access to CGM and a safety net for individuals with insurance disruptions. We used the data from the pilot 4T study and other studies to work with California Children's Services leadership to advocate for CGM coverage for all youth with public insurance. CGM coverage is now available for all youth with type 1 diabetes in California.

The 4T program also depends on having access to a smart device from which to share CGM data and access RPM messages through the secure patient portal. To address disparities in access to such a smart device, we provided iPod Touch devices to participants who needed them. Although we could not supply the Internet access our participants needed, we were able to collaborate with schools to allow children access to the school's Internet service for data-sharing during the school day.

## Conclusion

The DCCT demonstrated the benefits of intensive glucose management combined with frequent insulin dose adjustments. Thirty years later, technology has advanced to allow for more frequent glucose measurements via CGM, automated insulin delivery, and now RPM to provide precision medicine approaches on a population level. Clinical implementation of recommendations for diabetes technology as a standard of care should be initiated widely. The 4T program has shown that a team-based approach to early technology initiation and RPM can improve outcomes in youth with newly diagnosed type 1 diabetes (34–40, J.C. Leverenz, B. Leverenz, P.P., et al., unpublished observations).

Care should be taken to ensure that implementation of technology does not increase disparities. Health care providers and patient groups should engage in advocacy efforts to ensure equitable access to diabetes technology. In addition, there should be advocacy efforts to allow for free basic Internet service to facilitate the sharing of medical data. Until that goal is achieved, health care teams can collaborate with local schools to facilitate data-sharing via school-based wireless Internet service. Integrating wifi or cellular functionality directly into diabetes devices would eliminate the need for users to have another smart device for data-sharing. Finally, attention should be taken to ensure that copayments for

RPM services are not overly burdensome, resulting in disparities in the use of RPM-based interventions.

An RPM program also needs to be flexible enough to adapt to changing technology and clinical needs. Developing these programs requires a team-based approach, leadership support, and infrastructure to enable clinical teams to provide this service (38). Currently, one of the barriers to streamlining RPM workflows is inaccessibility of data from diabetes devices. Although some device manufacturers have application programming interfaces to retrieve data, many others have made data access difficult. People with diabetes and their caregivers should have the primary voice in data accessibility and data-sharing. In addition, not all devices passively upload data, which can increase the burden on families and may introduce disparities. Clinical teams would like for CGM data to be integrated in the EHR to further streamline data-sharing and reviewing processes. However, such integration to date has only been achieved through custom work for individual institutions (58–60). Interdisciplinary groups such as iCode have developed standards to help guide these efforts (61,62), but a more sustainable solution should be developed. Finally, dashboards that facilitate RPM (e.g., Tidepool+ and Glooko) should have flags that are customizable to an institution's capacity and to new technology such as AID systems and exercise trackers (47). While RPM can add to the workload of existing teams, developing a sustainable reimbursement model is key to gaining hospital support. Although we do not currently charge for RPM, financial modeling of patients receiving RPM at our institution shows that current RPM billing codes are potential revenue-positive solutions (41).

In summary, we have developed a roadmap to implement CGM and RPM in a pediatric population with new-onset type 1 diabetes with the use of existing technology. Growing this program will require partnerships among clinics, payers, hospital leadership, and industry to improve health equity and care for all people with type 1 diabetes.

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FROM RESEARCH TO PRACTICE

# Roadmap to the Effective Use of Continuous Glucose Monitoring in Primary Care

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Diabetes technology has undergone a remarkable evolution in the past decade, with dramatic improvements in accuracy and ease of use. Continuous glucose monitor (CGM) technology, in particular, has evolved, and coevolved with widely available consumer smartphone technology, to provide a unique opportunity to both improve management and decrease the burden of management for populations across nearly the entire spectrum of people living with diabetes. Capitalizing on that opportunity, however, will require both adoption of and adaptations to the use of CGM technology in the broader world of primary care. This article focuses on mechanisms to expand pathways to optimized glycemic management, thereby creating a robust roadway capable of improving care across broad populations managed in primary care settings. Recent expansions in access to devices combined with improved mechanisms for data access at the time of primary care visits and improved training and evolving systems of support within primary care, hold potential to improve glycemic management in diabetes across the health care spectrum.

## Primary Care: Key Infrastructure on the Road to Optimizing Glycemic Management

Diabetes has become the great epidemic of the 21st century and is arguably one of the greatest epidemics in human history (1,2). With an estimated prevalence of 37.3 million, or 11.3% of the population (3), diabetes and its complications consume one of every four health care dollars spent in the United States (4).

Yet, the specialty resources available to help battle this epidemic remain severely limited. Endocrinology as a subspecialty is significantly under-resourced to manage the diabetes epidemic; an estimated 8,000–9,000 board-certified endocrinologists currently practice in the United States (5). Even with a larger cohort of specialty-focused advanced practice clinicians to augment MD-credentialed endocrinologists, the capacity to guide over 10% of the American population in managing diabetes is inadequate.

Primary care providers are the obvious group to address the diabetes epidemic. With both established connectedness with people with diabetes and the capacity to see and help manage these individuals (6), primary care not only *can* be the pathway to optimized glycemic management, but also *needs* to be. The task, then, is to provide primary care providers with both the tools they need to optimize glycemic management and the systems of support they need to use those tools adequately.

Primary care, by its nature, is tasked with the holistic management of a wide spectrum of health conditions extending far beyond diabetes. For this reason, "bandwidth" can be a major limitation to attempts to optimize diabetes management in primary care settings. Primary care simply lacks the singular focus that specialty care can bring to diabetes management. Additionally, a lack of provider expertise, especially with regard to insulin therapy, is often another significant barrier. Finally, primary care clinics and clinicians often lack the systems of support that are typically available within endocrinology practices. Structured support for obtaining glycemic data for use during clinical interactions is typically available as part of standard workflows in endocrinology practices. However, in primary care settings, where workflows often involve capturing data from across the broader spectrum of human health, this level of support typically is not available.

These factors, combined with relatively infrequent clinic visits, lead to suboptimal glycemic management through the widely recognized phenomenon of clinical inertia in primary care settings (7). Optimizing the support of people with diabetes, and especially individuals with type 2 diabetes, must therefore, of necessity, require empowering primary care clinicians to improve how they manage diabetes. Empowering primary care providers in this regard requires providing them with the tools and data they need to optimize care and,

beyond that, with the knowledge and support systems necessary to move diabetes care forward.

## Tools to Manage Glycemia: A Better Engine to Get Us Further Down the Road

A1C is the standard diabetes quality measure in primary care and beyond, for compelling reasons. It was the primary outcome measure in the major outcomes trials conducted from the 1980s through the first decade of the 21st century (8–10). Correlations between A1C and the development and progression of diabetes complications have been established beyond doubt. Based on these studies, A1C targets for quality assessment on a population basis, and with some limitations (11–13) on an individual basis, are established, widely known, and widely used. Yet, this measure can only paint a broad picture of glycemic management. It is less useful for day-to-day management because it is insensitive to the daily excursions into hyperglycemia and sometimes hypoglycemia that are the target of glycemic management.

The established standard for day-to-day glycemic management, especially in primary care settings, has been fingerstick blood glucose monitoring (BGM). The value of BGM has been well proven in type 1 diabetes and insulin-treated type 2 diabetes (14,15). It is widely available and widely prescribed. Yet, BGM has been less effective in typical realworld settings than in clinical trials. Its limitations involve the burden of its use: the inconvenience of testing, discomfort, and payer-imposed limitations on the number of tests performed per day. These barriers limit BGM's ability to reveal a person's full glycemic picture throughout the day. Additionally, a lack of availability of glycemic data at the time of clinical interactions, especially in primary care settings, further limits the effectiveness of BGM. The promise of BGM has never been fulfilled, and today, many clinical practice guidelines recommend against its routine use in non–insulin-treated individuals with diabetes (16–18).

Continuous glucose monitoring (CGM) has been available since the early 2000s, but use has dramatically increased in just the past 5 years, driven by the availability of newer systems with improved ease of use (i.e., no calibration requirement, greater accuracy, and longer sensor wear times), increased availability at lower costs, and evolving data reporting and sharing to support their use in broad populations, including those with type 2 diabetes (19). Driven by randomized controlled trials (RCTs) showing the superiority of CGM versus BGM in improving A1C or reducing hypoglycemia in individuals with type 2 diabetes using a multiple daily injection (MDI) or basal-only insulin regimen (20–22), and further supported by observational data suggesting benefit in type 2

diabetes more broadly (23–29), practice recommendations have now evolved to include larger populations for whom CGM offers potential benefits (30).

Additional benefits of CGM include a decreased burden in obtaining robust glycemic data both day and night; the ability to access glycemic data through smartphone-linked, Cloud-based data repositories; and the availability of a standardized and remarkably intuitive data presentation format. That format, known as the ambulatory glucose profile (AGP) report (31), allows the rapid review of glycemic data in a structured and predictable manner by specialists, nonspecialist medical professionals, and people with diabetes (Figure 1).

The convergence of conclusive evidence from research, improved availability and ease of use of CGM systems, and availability of robust CGM-driven glycemic data in an intuitive and accessible format (the AGP report) all suggest that we now really do have a better vehicle to take us further down the road toward optimized glycemic management. Through the broader resource of primary care, we have the opportunity to reach the vast population of people with diabetes in the United States. Thus, we have a vehicle, and we have a driver for the vehicle. So, how do we create a roadmap to success? How do we avoid the same types of pitfalls that left BGM technology with its potential unfulfilled?

Our objective in creating a roadmap is to minimize barriers and maximize benefit. Minimizing barriers means making the best path also the easiest and most direct path, and making the roadmap clear and easy to follow for both primary care clinicians and people with diabetes. Maximizing benefit means using CGM and the data it provides to its fullest extent. We need to optimally use both point-in-time data to optimize the impact of lifestyle behaviors, nutrition, and pharmacotherapies, and retrospective data to pursue pattern-based glycemic management and improve shared decision-making via visualization of CGM data at the time of visits and clinical interactions (Figure 2).

## You Can't Make the Journey If You Don't Have Access to a Vehicle

A fundamental reality in creating a roadmap for the optimized use of CGM in primary care settings is that nobody benefits if CGM systems are unavailable to the people they might help. The journey starts with access, and access to technology typically starts with compelling trial data and, beyond that, real-world data to identify populations that might benefit from it.

RCT data are available to support the use of CGM for individuals with type 2 diabetes who are on insulin therapy

## AGP Report

July 28 - August 10 (14 Days)

### GLUCOSE STATISTICS AND TARGETS

| July 28 - August 10 | 14 Days |
|---|---|
| **Time CGM Active:** | **100%** |

| Ranges And Targets For | Type 1 or Type 2 Diabetes |
|---|---|
| **Glucose Ranges** | **Targets** % of Readings (Time/Day) |
| Target Range 70-180 mg/dL | Greater than 70% (16h 48min) |
| Below 70 mg/dL | Less than 4% (58min) |
| Below 54 mg/dL | Less than 1% (14min) |
| Above 180 mg/dL | Less than 25% (6h) |
| Above 250 mg/dL | Less than 5% (1h 12min) |
| Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial. | |

| | |
|---|---|
| **Average Glucose** | **211** mg/dL |
| **Glucose Management Indicator (GMI)** | **8.4%** |
| **Glucose Variability** | **37.2%** |

Defined as percent coefficient of variation (%CV)

### TIME IN RANGES

| | | |
|---|---|---|
| **Very High** >250 mg/dL | **34%** | (8h 10min) |
| **High** 181 - 250 mg/dL | **28%** | (6h 43min) |
| **Target Range** 70 - 180 mg/dL | **38%** | (9h 7min) |
| **Low** 54 - 69 mg/dL | **0%** | (0min) |
| **Very Low** <54 mg/dL | **0%** | (0min) |

### AMBULATORY GLUCOSE PROFILE (AGP)

*AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.*
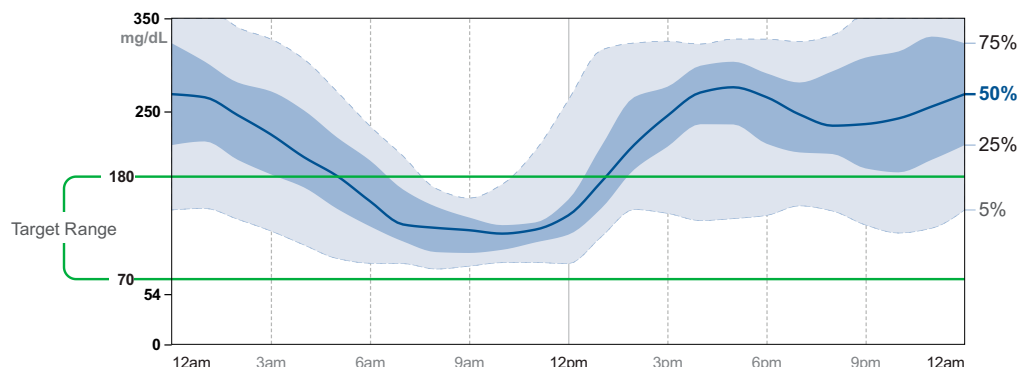


### DAILY GLUCOSE PROFILES

*Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner.*
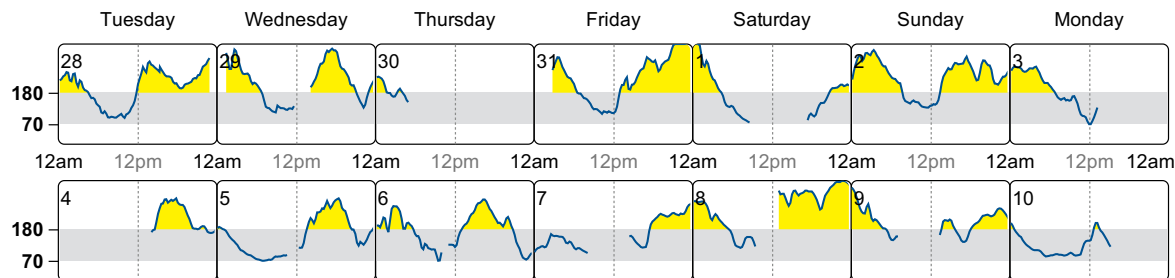


Source: Battelino, Tadej, et al. "Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range." Diabetes Care, American Diabetes Association, 7 June 2019, https://doi.org/10.2337/dci19-0028.

**FIGURE 1** The AGP report is a standardized viewing format for retrospective CGM data. By presenting thousands of data points obtained over multiple days in an intuitive format, it allows for rapid identification of glycemic patterns and problem areas, facilitating shared decision-making between providers and patients regarding lifestyle modifications and pharmacotherapy. This sample AGP report is from an elderly patient who was prescribed a basal-bolus insulin regimen after not responding to a previous treatment plan that included a glucagon-like peptide 1 receptor agonist plus basal insulin. Review of the AGP report allowed the clinician to rebalance the patient's insulin therapy and explain to the patient the rationale for basal-bolus therapy, with subsequent improvement in that patient's glycemia.

# Roadmap of CGM in Primary Care
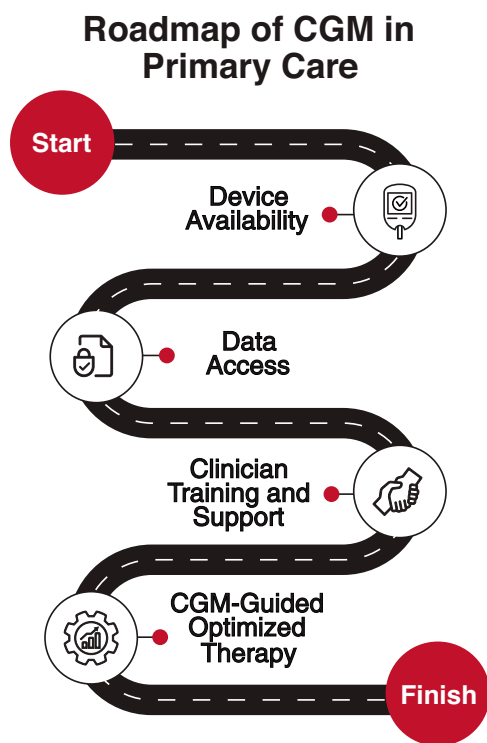


**FIGURE 2** A roadmap to the effective use of CGM in primary care.

regardless of regimen (20–22). These studies typically involved insulin titration by researchers and diabetes experts, with both BGM and CGM arms titrated using best-practice care. Whether the benefits of CGM over BGM exist to a greater or lesser extent in real-world settings and specifically in populations managed in primary care has not yet been shown definitively. However, compelling observational data are available (23–29), and real-world, fundamentally pragmatic studies are currently underway (32). Early studies and compelling observational data suggest a potential benefit of CGM use for individuals with type 2 diabetes who do not take insulin (33,34), but, again, definitive data are not yet available.

Beyond compelling evidence of efficacy, a long-range perspective on costs versus benefits and on the impact of improved glycemic status on total costs of care over time helps to support CGM use across broad populations and earlier in the course of illness, when optimized glycemic status has been shown to decrease long-term risks of complications (35). The vast majority of the $237 billion spent on direct medical costs of diabetes in 2017 went to inpatient hospitalizations and emergency department visits, nursing home care, and medications for diabetes complications. Shifting even a fraction of that cost to the 2% of the total spent on diabetes supplies (4) has the potential to dramatically decrease the total cost of care by improving care upstream (i.e., optimizing glycemic

status earlier in the course of illness and for a greater portion of the overall population with diabetes).

If data support benefits, we need to make CGM systems available with minimal hassles and barriers to acquisition. For commercially insured individuals, availability and access, although variable, has improved in the past 5 years. A key component of availability for individuals managed in primary care settings is to minimize prior authorization hoops and hassles, which can be a fundamental barrier limiting access (36,37). In primary care clinics, which often have less developed processes for paperwork completion and less sophistication with regard to knowing the steps necessary to obtain coverage approvals, prior authorization requirements can be a common cause of abandonment of attempts to provide CGM for patients. Short-term workarounds in primary care settings may include process management for prior authorizations, but a far more cost-effective route would be to decrease the burden by decreasing prior authorization requirements.

For individuals covered by Medicare and Medicaid, the purchase of a CGM system is typically handled as a durable medical equipment (DME) acquisition. There have been significant improvements in Medicare-based DME access to CGM. Even with the sunsetting of short-term improved access during the coronavirus disease 19 (COVID-19) pandemic (38), requirements for onerous documentation of BGM-based testing for approval of CGM were dropped in 2021 (39), and the requirement of an MDI insulin regimen are currently under review and likely will be dropped in 2023 (40).

Despite these changes, DME-based acquisition of CGM can be problematic because of the paperwork requirements of individual DME suppliers. For individuals with Medicaid coverage, access is even more variable and remains extremely limited in many states. The fact remains that CGM technology can only benefit the broader population of people with type 2 diabetes if they have access to the technology. This is especially true for populations with the highest burden of diabetes complications, who often, because of demographic, social, and financial barriers related to social determinants of health, have the most limited access to newer technology and pharmacotherapies (41–43). The role of health equity advocacy in reaching these often-marginalized populations cannot be overstated. You simply cannot make the journey if you don't have a vehicle.

## Data Are the Fuel Driving Glycemic Improvement

Access to CGM technology is necessary but not sufficient to improve care in primary care settings through the use of CGM. The CGM system itself ultimately is not the agent

of glycemic optimization; rather, it is the data produced by the CGM system that drive favorable change.

In this regard, it should be noted that CGM produces two types of data: point-in-time data and retrospective data. Point-in-time data include the current glucose value, a trend arrow, and a trend line, allowing people with diabetes to see the impact of dietary, exercise, and medication factors on an immediate basis and thereby take steps to significantly improve glycemic management on a purely heuristic basis. Aggregated retrospective data, presented as glycemic metrics and visualized via the AGP report, allows for rapid review and interpretation of the percentage of time spent in various glycemic ranges, other key glycemic metrics, as well as a composite "modal day" graph and individual daily view graphs (31,44,45). Glycemic metrics summarized from retrospective CGM data allow for the rapid identification of problematic glycemic patterns and enhancing discussion of therapeutic options using shared decision-making.

An optimized approach to CGM involves both helping people with diabetes to use point-in-time data optimally and reviewing retrospective data consistently at the time of clinical interactions to drive care improvement. Typically, point-in-time data are available to CGM users via a handheld reader or smartphone app without further logistical requirements. Reviewing retrospective data requires access to the data, which can be a key challenge and barrier in primary care settings.

Aggregate retrospective CGM data can be obtained in several ways. Reader devices can be downloaded during clinic visits if they are available. People with diabetes can upload data from their reader at home, allowing access via industry Cloud-based repositories. Finally, CGM data can be linked to industry Cloud-based repositories by smartphone, allowing web-based visualization by clinicians in real time. Although all three of these mechanisms can be used and are helpful for clinical interactions, they all have limitations that can present barriers to use in primary care settings. Downloading readers during clinic visits can be limited by organizational firewalls or a lack of access to drivers, preventing linking with Cloud-based repositories. Additionally, this mechanism requires that the CGM reader be physically present at the time of clinical encounters, which limits its usefulness during telehealth encounters, and relies on device users to remember to bring their reader to appointments.

Uploading device data to a Cloud-based repository via a home computer is also feasible for people with diabetes, but operating system and driver incompatibility, lack of appropriate cables, or simply the need to remember to upload the data can all limit access through this mechanism. Home uploading of data requires levels of computer sophistication, Internet access, and engagement that can pose a significant limitation.

Ultimately, access via industry Cloud-based resources allows the broadest access to primary care teams, whether for clinic visits, telehealth encounters, or quick clinical touchpoints to optimize insulin titration. For individuals with compatible smartphones, app-based Cloud access can allow for the most consistent and smoothest data delivery to clinicians. Once smartphones have been connected to receive sensor data and to communicate the data to a Cloud-based platform, users simply accept a sharing invitation via e-mail to allow their care team to access their CGM data. Lack of access to a smartphone can be a limitation to this mechanism of data acquisition in resource-poor environments, although the technology gap does show signs of narrowing, at least with regard to smartphones (46). Gaining Web-based access to data are currently the option that has become the best-practice alternative to obtaining retrospective CGM data by other means.

Even with Web-based access, barriers remain to obtaining data when they are needed during clinic visits. Computer systems used in clinical practice are typically highly protected by firewalls to prevent intrusion. Institutional and organizational firewalls can limit access to industry data, either by directly blocking that access or by blocking access to drivers necessary to upload the data. Engagement of the clinic or health system Information Technology team can be critical when working toward organizational solutions to gain broader access to CGM data; whereas smaller endocrinology departments can often use "one-off" solutions for data access, the much larger world of primary care will require more global access.

Health Insurance Portability and Accountability Act regulations have significant implications for accessing health information via the Web. Safe password practices and steps to avoid storing data on personal devices are crucial. Two-factor authentication is becoming the industry standard in accessing Cloud-based data repositories. Although necessary and appropriate, the work involved to maintain and ensure the connectivity of passwords and password protection while accessing multiple sites in the course of busy clinical practice can be a significant limitation to accessing data.

Although it is possible for individual clinicians to personally access CGM data via the Web at the time of clinical interactions, time constraints can be a significant barrier. Primary care clinicians are typically tasked with managing the broad spectrum of health in a 15- to 30-minute time slot. Diabetes visits comingle with visits for medical urgencies and emergencies, health maintenance activities, phone and other messaging, and various other health needs of the broader population. A key element of support, and therefore a key element of the roadmap

to successful use of CGM in primary care, is the creation of a workflow, which typically involves office personnel and sets the protocol for a smooth, uniform process for obtaining glycemic data in advance or at the time of clinical interactions. A team-based, uniform, and consistent approach to managing chronic disease can be a key component of quality optimization in primary care settings (47–49) and is likewise a key component of optimized CGM use in primary care. Workflow and consistent processes facilitate the availability of key glycemic data during clinical interactions, enabling clinicians to focus on the patient interaction and shared decision-making, rather than on data acquisition, during visits.

Beyond workflow, optimized use of CGM in primary care starts with optimized set-up of devices at the time of CGM initiation. Designating a clinic diabetes champion who has expertise in setting up and troubleshooting CGM systems can be extremely helpful in ensuring success at the time of start-up and also in helping people with diabetes understand and use their CGM data. Populations with type 2 diabetes tend to be older and less technologically savvy than populations with type 1 diabetes; ensuring that steps as seemingly simple as having the correct language set on the device and having the date and time correctly set can prevent significant issues down the road when trying to access patients' glycemic data. Diabetes educators, when available, can often be the optimal resource in this champion role, but other diabetes care team members can also assist with these tasks.

## Electronic Medical Record–Based Access: Moving From City Streets to the Information Superhighway

Clinicians at all levels typically work and live in an electronic medical record (EMR) system. These systems offer significant benefits with regard to data availability and data integration, and, with an additional push from American governmental incentives (50), have been widely adopted throughout the U.S. medical system. The near-universal use of EMR systems presents a unique opportunity for glycemic data integration: direct importation of CGM-based glycemic data and AGP reports into patients' EMRs. For people with diabetes who are able to link smartphone CGM data to industry Cloud-based platforms, an opportunity exists for collaboration among industry, device manufacturers, and health care organizations to create processes to pull CGM data directly into the EMR system, removing significant barriers to data access.

Direct importation of CGM data into EMRs likely represents the single best solution for data accessibility during clinical visits. In this regard, significant progress has been made in creating this critical on-ramp to the information superhighway. Proof-of-concept trials of direct EMR-based access have been conducted at several institutions, including the International Diabetes Center in Minneapolis, MN; Northwestern University in Chicago, IL; and the Children's Hospital of Los Angeles/University of Southern California (51–56). We await more formal publications on these integration projects. Although this mechanism of data access is not yet widely available, it is clear that it is both feasible and critical in facilitating the broader use of CGM glycemic data in primary care settings. Direct EMR-based access to glycemic data is a key element on the roadmap to using CGM successfully in primary care.

## Driver Education: Building the Knowledge Base

Just as access to devices is necessary but not sufficient to provide glycemic data at the time of clinical interactions, having data at the time of clinical interactions is necessary but not sufficient to optimize glycemic management. The final key aspects of improving care include improving primary care expertise in managing glucose-lowering therapies (especially insulin) and improving the cadence of titration to reduce clinical inertia.

Improving the cadence of titration becomes much easier in a CGM-based world, given that access to glycemic data are much easier using Cloud-based mechanisms. Glycemic data becomes available for multiple touchpoints and interactions beyond traditional clinic visits. The explosion of telehealth, or "virtual" care, driven by the COVID-19 pandemic (57–59) has provided new and unique opportunities. With the availability of Cloud-based CGM data, the opportunity for multiple and frequent diabetes titration touchpoints offers significant promise for reducing clinical inertia.

Data acquisition, interpretation, and utilization all take time. The viability of using CGM to optimize care rests on the viability of reimbursement for time spent using CGM to optimize care. Fortunately, reimbursement for cognitive resources in managing CGM is growing. Currently, reimbursement is available for the start-up and application of CGM devices as well as the interpretation of data (60). Current trials of Medicare-based remote patient monitoring codes (61,62) open additional possibilities for care model innovation, making optimizing glycemic management more viable within a wider clinical practice spectrum.

Building expertise within primary care to use CGM to optimize glycemic management is the final stop on the roadmap to successful CGM use in primary care. Access to devices and data only helps if people with diabetes and the clinicians who help them manage their diabetes know how to use CGM data appropriately. The fingerstick BGM experience suggests that technology without training or

appropriate use does not improve care (16). The question is not only "*Can* we do better with CGM-based monitoring?" but also "*Will* we do better with CGM-based monitoring?" CGM data are robust relative to BGM data, and standard data presentation formats like the AGP report make data interpretation straightforward. Concepts such as time in range (TIR; the percentage of time a person spends with glucose levels within a target range) are both intuitive and actionable at the individual level and create a framework for understanding in primary care.

Clinical programs offering training on the TIR and the related concepts of time above range and time below range, as well as the use of other CGM-based glycemic metrics to optimize therapy have emerged online through professional organizations and advocacy groups such as the American Diabetes Association, American College of Physicians, and American Academy of Family Physicians and at clinical conferences. Literature on using CGM and CGM-based metrics targeting primary care audiences is available and expanding (44,63,64). At its heart, this literature emphasizes a systematic approach to using CGM glycemic data. The knowledge base for using CGM and AGP data reports in primary care settings is improving, but work remains to be done. The diffusion of these approaches into training programs is ongoing and needs to continue. The potential payoff of this final stop on the roadmap to optimized use is huge.

An additional component of successful diabetes management in primary care settings is the concept of team-based care. Diabetes management using CGM integrates nicely into team-based models of care. The spectrum of diabetes management ranges from relatively straightforward noninsulin glycemic management to complex issues of polypharmacy and MDI insulin regimens. Primary care clinicians are in the truest sense "jacks of all trades, but masters of none." That fact, combined with typically brief clinical visits and very busy schedules, makes team-based management of complex chronic medical conditions not a luxury, but rather a necessity.

Resources for team-based management vary. In some practices, a clinician acting as a diabetologist or an endocrinologist able to do outreach using a Project ECHO–type (or similar) model (65–67) can help to optimize complex care. Pharmacists who can perform medication management and registered nurses who can coordinate care can be tremendous assets in team-based management. Diabetes educators perhaps hold the most promise for teaming with primary care providers to optimize glycemic management. Having access to diabetes educators with expertise, patient focus, and more time to address the complexities of diabetes management has been shown to improve metabolic parameters (68), and

the addition of CGM-based management to this role likely provides additive benefits. What remains to be developed is a reimbursement model to allow the expansion of this critical resource in managing 13% of the U.S. population.

## Creating a Roadway to Success

The rapidly expanding availability of CGM in primary care settings has already increased awareness of pattern-based glycemic management, including the identification of problem areas and pitfalls rarely appreciated using only BGM data. The robust nature of CGM data allows for more nuanced glycemic insights with the potential to dramatically improve the efficacy and safety of glycemic management, especially for individuals using insulin. A primary care colleague made this analogy: "BGM is like looking at a room through a keyhole; CGM is like looking at the room with the door wide open." The impact of CGM in primary care has been large, but the potential impact remains much larger.

The path forward involves building systems of support to allow the optimized use of CGM in the much larger world of primary care. By removing barriers to the availability of CGM technology, optimizing data-sharing so that CGM data and AGP reports are universally available, and giving primary care clinicians both the knowledge and data they need to advance care forward at an appropriate cadence, we have the opportunity to improve the care of broad populations of people with diabetes. It is time to move beyond the roadmap and create the roadway. It's time to make the future of diabetes management a reality for primary care.

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# Roadmap to the Effective Use of Continuous Glucose Monitoring in Pregnancy

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The landscape for managing type 1 diabetes during pregnancy has been transformed by increasing use of continuous glucose monitoring (CGM). Women are aiming for pregnancy-specific glucose targets or 70% time in range for pregnancy (TIRp; 63–140 mg/dL) as soon as possible, knowing that every extra 5% TIRp has benefits for reducing the risks of complications in their babies. Ongoing monitoring of maternal A1C (at pregnancy confirmation and at 20, 28, and 36 weeks' gestation) remains useful. Intensification of glycemic management and instruction in using CGM (if not already used) is recommended for individuals with an A1C >6.0% after 20 weeks. A better understanding of CGM-documented glycemic changes throughout pregnancy is needed to inform future management of gestational diabetes and pregnancy in people with type 2 diabetes. Research regarding overcoming barriers to CGM use and optimal TIRp targets for pregnant individuals with type 2 diabetes from diverse racial/ethnic groups is urgently needed.

Continuous glucose monitoring (CGM) empowers individuals to manage their daily glucose levels, alerting them if their glucose is too high or too low and providing unprecedented options for data-sharing with partners, parents, and clinicians. This article provides an overview and roadmap of the effective use of CGM in pregnancy (Figure 1).

The landscape for managing type 1 diabetes outside of pregnancy has been transformed by increasing use of CGM in the past 5 years. Likewise, use of CGM in type 1 diabetes pregnancy is now widespread based on randomized controlled trial data showing that CGM use improves maternal glucose levels and reduces the frequency and duration of neonatal care unit admissions, meaning that it is both clinically and cost-effective during pregnancy in people with type 1 diabetes (1–3). Based on data from the CONCEPTT (Continuous Glucose Monitoring in Pregnant Women With Type 1 Diabetes) trial (1) and changes in remote care during the coronavirus disease 2019 pandemic (4), CGM use is widely established as a standard of care in type 1 diabetes pregnancy. Listening to women's voices has become increasingly pertinent, in society at large and especially in maternity health care settings (5).

CGM gives women more information, empowering them to make informed diabetes treatment decisions. Unlike laboratory A1C measurements, which assess average glucose over the preceding 8–12 weeks and are announced to patients by clinicians, patients hold their own daily CGM glucose information (e.g., mean glucose and time spent in, above, and below the target glycemic range) on their smartphones. Patients find CGM time in range (TIR) information engaging because it provides immediate feedback on changes they make to their dietary intake, physical activity, and diabetes treatment. The patient-centeredness of CGM TIR data are strongly endorsed by people with diabetes, who ranked TIR as the factor that, only after their food choices, has the biggest impact on their daily lives (6). This sentiment was summarized by a pregnant study participant with type 1 diabetes, who said, "I really feel it's a game-changer in helping me understand where I am. It determines if I'm on track, and, when I'm not, I know things need to be done" (7).

Pregnant women are uniquely motivated to achieve tight glucose targets for their babies to have the best possible health outcomes. They are aiming for glucose levels between 63 and 140 mg/dL for at least 16 hours, 48 minutes, per day or 70% time in pregnancy range (TIRp) throughout the type 1 diabetes pregnancy (8). The challenge of achieving and maintaining 70% TIRp in the face of early pregnancy nausea, changing eating patterns, and gestational changes in insulin sensitivity should not be underestimated. Achieving 70% TIRp is broadly similar to achieving 90% standard TIR (70–180 mg/dL) outside of pregnancy. Furthermore, pregnant women have to balance the consequences of above-target glucose increasing their babies' risk of preterm birth, large birth weight, and neonatal hypoglycemia with their
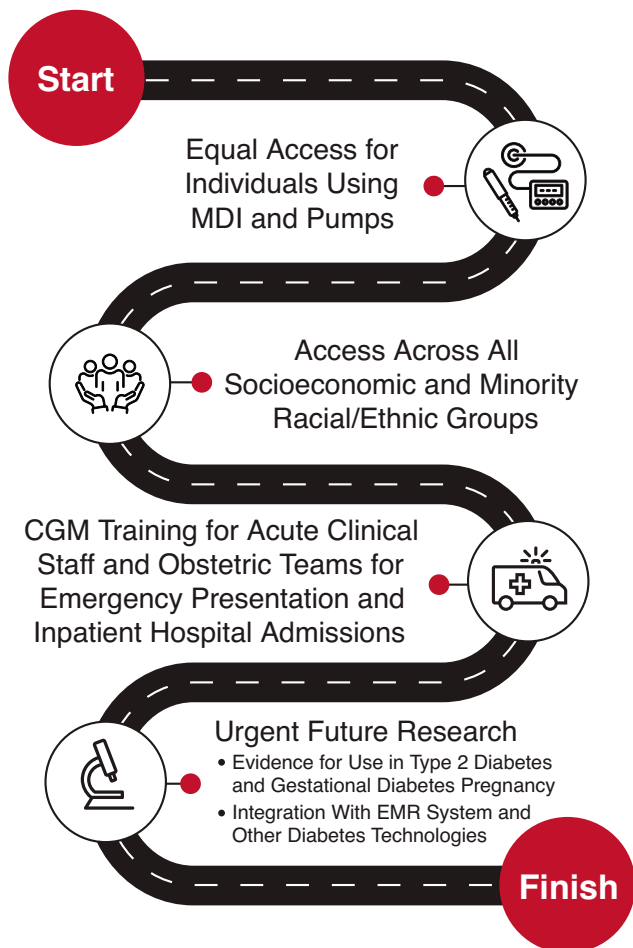
# Roadmap of CGM in Pregnancy Care



**FIGURE 1** A roadmap to the effective use of CGM in pregnancy. EMR, electronic medical record; MDI, multiple daily injection insulin therapy.

own immediate risk of hypoglycemic events (9). Pregnant CGM users often share their glucose alerts (particularly low glucose alerts) with a partner or CGM follower. Participants in type 1 diabetes pregnancy trials reiterate that being able to share CGM alerts when glucose levels are dangerously low provides crucial reassurance, especially during early pregnancy, when the risk of severe hypoglycemia is particularly pertinent. As one said, "I had an overwhelming fear that I would go to bed and not wake up, so having someone like [partner] check in was so important. I always had a follower, so that I didn't die" (7).

Studies of type 1 diabetes pregnancy have demonstrated that very small changes in maternal glucose levels are associated with large effects on neonatal health outcomes (10). Knowing that every extra 5% TIRp has benefits for

reducing their babies' risks of complications is crucially important information for pregnant women who are struggling to achieve the recommended 70% TIRp (11).

Although the target of 70% TIRp was based on consensus opinion, there are increasing data relating CGM TIRp metrics to A1C and clinical outcomes for mothers and babies in type 1 diabetes pregnancy (1,12). We used data from the CONCEPTT trial to compare how useful A1C and key CGM metrics (TIRp and time above range for pregnancy [TARp]) were at 12–13, 24–25, and 34–35 weeks' gestation for predicting common complications of type 1 diabetes pregnancy (i.e., preeclampsia, preterm delivery, large for gestational age [LGA], neonatal hypoglycemia, and admission to the neonatal intensive care unit). Even though CGM metrics were only available for 1 week, they were still important predictors of obstetric and neonatal complications (13).

Most CGM metrics (e.g., mean sensor glucose, TIRp, and TARp) are closely correlated with A1C. In clinical practice, just a few key CGM metrics (i.e., mean sensor glucose, TIRp, TARp, and time below range for pregnancy [TBRp]) are used routinely to assess maternal glycemia and guide treatment decisions. Although its associations with pregnancy outcomes are unclear, maintaining a TBRp (time <63 mg/dL) ≤4% (1 hour/day) is crucially important for maternal safety. This is even lower than the standard TBR (time <70 mg/dL) outside of pregnancy. Modern glucose sensors may allow women to achieve lower TBRp targets.

Ongoing monitoring of maternal A1C (at pregnancy confirmation and at approximately 20, 28, and 34–36 weeks' gestation) remains useful because of the established association of A1C with pregnancy outcomes and discrepancies between A1C and the glucose management indicator (a CGM-derived estimate of A1C). Based on data from the National Pregnancy in Diabetes (NPID) audit (Figure 2), an urgent action plan and multidisciplinary team review advising CGM use is implemented for individuals with an A1C >6.5% after 20–24 weeks' gestation. Those with an A1C between 6.0 and 6.5% are reviewed for intensification of glycemic management and CGM use (if not already initiated), and those with an A1C <6.0% are supported to continue their current management plan (9).

## Underserved Population: Individuals With Early-Onset Type 2 Diabetes

There are stark differences in the characteristics of pregnant women in the United Kingdom. Those with type 1 diabetes are predominantly of White European race/ethnicity, have lower BMIs, and are less socioeconomically disadvantaged,
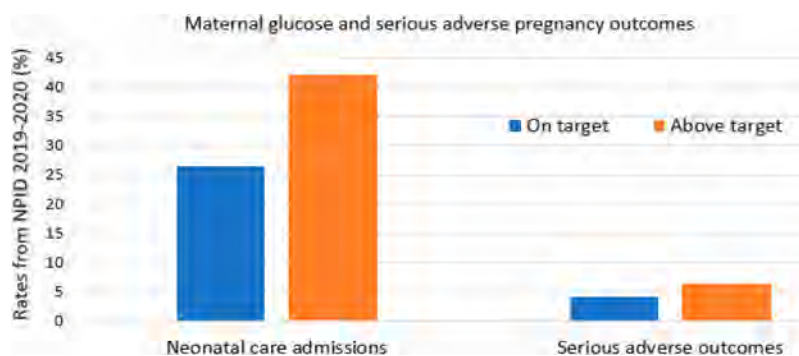
**FIGURE 2** Maternal glucose and serious adverse pregnancy outcomes in individuals with early-onset type 2 diabetes.

whereas those with early-onset type 2 diabetes (defined as onset at <39 years of age) are from more diverse racial/ethnic backgrounds, have higher BMIs, and live in more socioeconomically deprived communities. Therefore, we cannot necessarily extrapolate the benefits of CGM use in type 1 diabetes pregnancy to type 2 diabetes pregnancy (9). Furthermore, women with type 1 diabetes receive extensive diabetes support and specialist multidisciplinary team care from the time of diagnosis. By contrast, those with early-onset type 2 diabetes are usually managed in primary care settings and get very little specialist diabetes support. The U.K. NPID audit data showed that only 18% of pregnant women with early-onset type 2 diabetes were treated with insulin and routinely monitored their capillary glucose levels before pregnancy (9). As one such patient noted, "I was told to take pills or lose weight. I know one or two [high glucose levels] might not have been the end of the world, but people really don't see how important it is to get it right for the safety of the babies and indeed the mother" (personal communication). This disparity in care in part stems from the fact that health care services for individuals with type 2 diabetes traditionally have been targeted to older age-groups and also from the considerable stigma and negative emotions associated with maternal overweight, obesity, and early-onset type 2 diabetes; fewer than 5% of research participants with type 2 diabetes are 18–39 years of age, with women who are pregnant or planning pregnancy often excluded from type 2 diabetes trials (14). Furthermore, anxiety and depression are particularly common in this patient population, with a recent Danish study suggesting that 36% experienced anxiety and 14% had depressive symptoms during pregnancy (15).

Data regarding CGM use in type 2 diabetes pregnancy are extremely limited (16). A 2019 systematic review (17) found only three trials that included small numbers of pregnant women with type 2 diabetes ($n$ = 25 from the United Kingdom, $n$ = 31 from Denmark, and $n$ = 82 from the Netherlands). All three of these studies were focused

primarily on pregnant women with type 1 diabetes and used older-generation, less user-friendly CGM systems intermittently rather than continuously (18–20).

Recent data from the U.K. NPID audit suggest that, for optimal obstetric and neonatal outcomes, pregnant women with type 2 diabetes may need even tighter pregnancy glucose targets than pregnant women with type 1 diabetes (9). However, there are no consensus or evidence-based CGM targets to guide glycemic management in type 2 diabetes pregnancy. This information is urgently needed, as pregnancies in women with early-onset type 2 diabetes are rapidly increasing. In the United Kingdom, pregnancies in those with early-onset type 2 diabetes have doubled in the past 2 decades (9).

In the United States, the TODAY (Treatment Options for Type 2 Diabetes in Adolescents and Youth) study highlighted alarming pregnancy outcomes for mothers and babies in youth-onset type 2 diabetes pregnancy (21). Only 15% of young sexually active women and girls used any form of contraception, so most of these pregnancies were unplanned. This patient group entered pregnancy with above-target glycemia (mean A1C 8.7%) and consequently had high rates of major congenital anomaly (10%). Congenital anomaly rates were <5% in those with an early pregnancy A1C of <8% and almost 20% in those who entered pregnancy with an A1C >8%, suggesting that many congenital anomalies could have been prevented by supporting women and girls to use contraception until safe A1C levels are achieved. Individuals in this group also experienced high rates of pregnancy loss and pregnancy complications, including hypertension and preeclampsia. Only 43% of pregnancies resulted in a live term birth, with approximately one-fourth of babies delivered before 37 weeks. Similar to the TODAY participants, individuals with early-onset type 2 diabetes who took part in our research said they didn't just want to hear about all the pregnancy risks; they also wanted, as one put it, "more focus on the positivity of managing glucose levels and the results for my pregnancy/birth, for example, being

able to deliver naturally—proper support to manage diabetes without compromising my mental health and unborn baby" (H.R.M., personal communication with focus group participant). Research regarding the role of CGM use, overcoming barriers, and optimal TIRp targets for pregnant individuals with early-onset type 2 diabetes is urgently needed.

## Role of CGM in Gestational Diabetes

Glucose levels are dynamic, with glucose tolerance and insulin sensitivity varying across the 24-hour day with a circadian rhythm. Insulin sensitivity also varies across pregnancy, with insulin resistance increasing with advancing gestation. Because the oral glucose tolerance test (OGTT), which is the traditional screening method for detecting gestational diabetes mellitus (GDM), relies on just two glucose readings taken 2 hours apart on 1 day, it cannot detect all of the nuances of daily glycemic variations or changes across pregnancy.

CGM provides the most objective method of assessing fetal exposure to maternal glucose in daily life. Although there have been small, short-term studies of glucose metabolism in healthy pregnant women and those with risk factors for hyperglycemia, comprehensive, longitudinal description of gestational changes in CGM profiles in both healthy and GDM-complicated pregnancy is lacking (22,23). It is also unknown how CGM metrics relate to traditional screening for GDM by OGTT and whether CGM metrics (e.g., mean sensor glucose, TIRp, and TARp) are correlated with fetal growth parameters and neonatal health outcomes in GDM pregnancy. CGM could potentially also be used to detect glucose dysregulation earlier in pregnancy, allowing earlier initiation of dietary changes and pharmacotherapy; however, data from adequately powered, high-quality randomized trials examining the use of CGM as a diagnostic or therapeutic tool in GDM pregnancy are lacking. A small study comparing CGM compared with capillary glucose monitoring found no differences, but this study was not powered to detect differences in TIRp or pregnancy outcomes (24).

The optimal timing for diagnosing GDM (in the first trimester vs. the traditional 24–28 weeks' gestation) is also unclear. The TOBOGM (Treatment of Gestational Diabetes Mellitus Diagnosed Early in Pregnancy) trial detected minimal differences in maternal and neonatal outcomes between those with GDM detected during a first trimester and those with GDM diagnosed with the traditional OGTT at 24–28 weeks (25). However, we have previously shown that excess fetal growth assessed by ultrasound scan is detectable from 20 weeks' gestation, pre-dating biochemical diagnosis of GDM (26). We also know that performing a conventional OGTT at 24–28 weeks' gestation is often too late to prevent abnormal fetal growth, particularly in individuals with a higher BMI, but there are no validated screening and/or diagnostic criteria for earlier diagnosis of GDM.

Indeed, despite the use of the OGTT, the majority of LGA babies are born to mothers without a GDM diagnosis. This fact suggests that pregnant women who could benefit from earlier diagnosis and earlier treatment of GDM potentially are not being identified correctly. The OGTT is an outdated test for diagnosis of type 2 diabetes and is no longer widely used outside of pregnancy. It is poorly reproducible during pregnancy; 40% of pregnant women who had a second OGTT immediately after an abnormal OGTT had normal results (27). OGTT reproducibility was pertinent in the TOBOGM trial, with discrepancies between early and late OGTTs among one-third of TOBOGM trial participants (25). Among the milder glycemic cohort, discrepancies between the early and late OGTTs were noted in 50% of TOBOGM participants (25). Whether this finding relates to gestational variations in maternal glycemia or to poor reproducibility of OGTT results remains unclear.

Gaining a better understanding of glycemic changes by using CGM throughout pregnancy is urgently needed to inform both the diagnostic criteria for and management of GDM. Data from the United Kingdom suggest that women from higher-risk racial/ethnic groups, with higher BMIs, and from more resource-challenged communities are least likely to attend visits for an OGTT. Thus, broadening inclusion in future research is imperative (28).

## Directions for Future Research

In clinical practice, women with type 1 diabetes are increasingly entering pregnancy using a range of commercially available hybrid closed-loop automated insulin delivery systems, so more information regarding the safety and efficacy of these systems throughout pregnancy is needed. Future research should also evaluate whether the use of new technology is associated with more positive pregnancy experiences. It is imperative that patients, clinicians, and researchers acknowledge the crucial role of maternal glucose management in reducing adverse pregnancy outcomes in individuals with early-onset type 2 diabetes as well as type 1 diabetes. A better understanding of CGM-documented glycemic changes throughout pregnancy is needed to inform future GDM and type 2 diabetes pregnancy management. Prioritizing these patient groups is essential to address health care inequalities in research and access to technology for pregnant women with diabetes.

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# Roadmap to Achieving Continuous Glucose Monitoring Equity: Insights From the T1D Exchange Quality Improvement Collaborative

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This article describes successful interventions from the T1D Exchange Quality Improvement Collaborative (T1DX-QI) to reduce inequities in access to and use of continuous glucose monitoring (CGM). The author proposes a roadmap with recommendations for different stakeholders to achieve CGM equity using insights from the T1DX-QI experience.

The American Diabetes Association recommends continuous glucose monitoring (CGM) as the standard of care for people with type 1 diabetes or type 2 diabetes who are on intensive insulin therapy (1). Many professional societies, including the International Society for Pediatric and Adolescent Diabetes, European Association for the Study of Diabetes, Endocrine Society, and American Association for Clinical Endocrinology, have recommended the use of CGM to optimize diabetes care (2,3).

Effective use of CGM can improve glycemic management and reduce acute and chronic complications of diabetes (4–6). CGM is a cost-effective solution that can reduce burnout and increase quality of life for people with diabetes (7,8). The coronavirus disease 2019 (COVID-19) pandemic amplified the importance of CGM; access to CGM was associated with reduced risk of hospitalization for people with type 1 diabetes and COVID-19 (9,10).

Recent studies have demonstrated the value of CGM for people with diabetes irrespective of insulin dependency (11,12), as well as for people with prediabetes (13).

Sadly, there are significant racial and ethnic inequities in CGM usage and outcomes (5,14,15). Minoritized groups such as low-income earners, residents of rural communities, non-native English speakers, and individuals who identify as non-White by race and Hispanic by ethnicity are all less likely to use CGM.

These inequities exist even among people who have adequate insurance coverage (16). A cross-sectional T1D Exchange Quality Improvement Collaborative (T1DX-QI) observational study reported that people with type 1 diabetes who had private insurance were more likely to use CGM than those with public insurance (57 vs. 33%). Unfortunately, in this cohort, non-Hispanic Black individuals with private insurance had lower CGM use than non-Hispanic White individuals with public insurance (24 vs. 41%) (5).

CGM usage inequities are significantly more profound in the United States than in other developed countries (17). These inequities are unfair, unjust, and unacceptable. They can and must be addressed (Figure 1).

## T1DX-QI CGM Equity Journey

The T1D Exchange established the T1DX-QI in 2016 as a learning health network to share real-world data and improve outcomes for people with diabetes. Today, more than 50 diabetes centers across 22 states participate in the collaborative (18). The T1DX-QI is accelerating the implementation of evidence-based guidelines in clinical improvement, contributing to population health research, and promoting best practices through benchmarking and quality improvement (QI) (19–21).

T1DX–QI approach to addressing inequities has been previously described (22). This article highlights T1DX-QI activities specifically designed to reduce racial inequities in CGM. The timeline of T1DX-QI CGM health equity activities is shown in Figure 2.
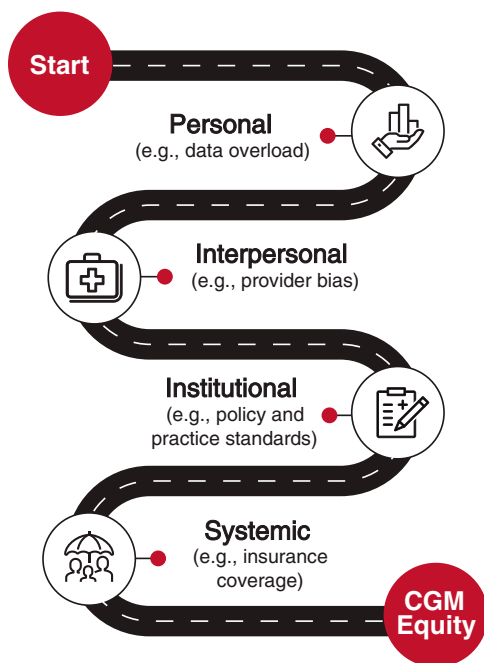
In 2018, the T1DX-QI Collaborative identified improving CGM uptake as a quality goal. T1DX-QI centers used QI principles to successfully increase the adoption of CGM in pediatric and adult centers (23). Insights from this QI project led to comprehensive data analysis stratified by race, ethnicity,

## Roadmap of CGM Equity



**FIGURE 1** Roadmap to overcoming barriers to CGM equity.

and insurance (14). Since 2019, the T1DX-QI has extensively published real-world data showing inequities in CGM adoption and elucidating the role of insurance, contribution of provider bias, association with adverse outcomes, and impact of CGM on glycemic management (4,10,14,24–26).

In 2020, the T1DX-QI published a framework incorporating QI and health equity principles through a practical 10-step process using CGM equity as a case study (27). This effort

was expanded to include CGM equity in diabetes research (28).

T1DX-QI centers share de-identified electronic medical record (EMR) data for center-to-center benchmarking and population health research (29). In 2021, the T1DX-QI expanded its center-to-center benchmarking tool, the QI Portal. This tool allows centers to review their CGM access data with an equity lens. In addition to comparing the performance of participating centers, providers can sort the data by race, ethnicity, and insurance, which allows them to prioritize equity interventions.

Diabetes centers are supported by T1DX-QI coaches to use QI methods for operational efficiency, clinical process effectiveness, and reduction of inequities (20,30,31). In 2020, seven teams embarked on a pilot QI project to reduce inequities in CGM prescription and adoption, and this initiative was expanded in 2022. These efforts have resulted in significant reductions in CGM inequities among T1DX-QI centers (32–35). One of the participating centers increased its CGM prescription rate for non-Hispanic Black people with type 1 diabetes from a baseline of 12% to 72% and for Hispanic people with type 1 diabetes from 15% to 74% in 36 months. Additional successful examples from the T1DX-QI are summarized in Table 1.

In 2021, the T1D Exchange established its Health Equity Advancement Lab (HEAL). HEAL is an innovative laboratory to incorporate the voice of patients of color in strategic research decisions and create a platform to discuss equity best practices from nondiabetes sectors. Ideas from HEAL have been tested in new CGM equity QI and research projects (36).

The T1DX-QI also actively collaborates with pharmaceutical companies and device manufacturers on different CGM



**FIGURE 2** T1DX-QI CGM equity timeline.

| TABLE 1 Examples of CGM Equity QI Projects From T1DX-QI Centers (32–35) | | | | |
|---|---|---|---|---|
| Practice Type | Patients With Type 1 Diabetes, n | Intervention Period, months | Intervention Examples | Outcomes |
| Pediatric | 613 | 12 | • Patient education folders for families<br>• Establishment of relationship between CGM champion and durable medical equipment company | • 6% increase in non-Hispanic Black CGM use<br>• 10% increase in overall center CGM use |
| Pediatric | 1,886 | 22 | • Multidisciplinary team approach<br>• Targeted patient education<br>• Onboarding assistance for non-Hispanic Black individuals | • 50% reduction in equity gaps between non-Hispanic White and non-Hispanic Black individuals |
| Pediatric | 2,784 | 12 | • CGM submission process for high-risk patients<br>• CGM evidence-based practice summary submitted to state Medicaid office | • >50% increase in CGM use for publicly insured patients |
| Pediatric | 1,500 | 6 | • Efforts to improve provider understanding of requirements for CGM coverage<br>• Documentation assistance for patients | • Reduction in CGM disparity between publicly and privately insured patients from 36 to 12% |
| Adult | 1,357 | 36 | • Single provider streamlining paperwork to one location<br>• Inclusion of social worker to streamline process<br>• Social needs assessments and management<br>• Training of support staff to place trial CGM sensors at the point of care<br>• Optimization of prescription workflows<br>• Provider education about CGM | • Increase in CGM prescription from 12 to 72% in non-Hispanic Black and from 15 to 74% in Hispanic people with type 1 diabetes |
| Adult | 285 | 23 | • Single provider streamlining paperwork to one location<br>• Inclusion of social worker to streamline process<br>• Provider education about CGM | • Increase in CGM use from 12 to 57% in non-Hispanic Black people with type 1 diabetes |

research, real-world data, implementation, and QI initiatives to promote equity (36). Furthermore, recognizing that achieving CGM equity is a team sport, the T1DX-QI has partnered with diabetes centers and philanthropic, advocacy, and charitable organizations to support Medicaid and Medicare advocacy for CGM with an equity lens.

## Roadmap to CGM Equity

The diabetes community can join the pursuit for CGM equity by adopting some of the equity principles outlined below, which are derived from the ongoing journal of the T1DX-QI.

1. Designate a health equity champion/leader who will motivate the team, make critical decisions, and navigate the road ahead.

2. Understand and articulate your "why." This clarity of purpose is crucial to building trust and influence. For example, the leader can use the disturbing data on CGM inequities or personal stories of people affected by CGM inequities as part of the articulated reason to address this problem.

3. Establish an equitable team. To ensure the credibility of the mission to achieve CGM equity, it is crucial that people with lived experiences be given a voice at the table and potentially decision-making power.

4. Recognize your "lane" and sphere of influence; there is a role for all stakeholders, clearly identifying where their biggest influence would be most pivotal for CGM equity. Are you an advocate? Funder? Innovator? Researcher? Based on your identified lane, how can you maximize your contributions to the CGM roadmap?

5. Implement SMARTER goals. SMARTER is an acronym for Specific, Measurable, Actionable, Realistic, Time-bound, and including Equity Revision (27). Equity revision denotes being intentional about which marginalized community the proposed goal will directly affect. Equity goals need to be crystal clear and communicated intentionally.

6. Select an applicable framework, evaluate, and implement practices. There are myriad QI and implementation science frameworks available (27,28,37,38), as well as actionable steps and tested ideas that can be adopted to advance CGM equity within diabetes centers (Table 1), research laboratories, manufacturing units, and legislative chambers.

7. Publicly share results, including both successful and unsuccessful interventions. It is important to learn from all activities, including those that did not achieve desired outcomes.

8. Embrace persistence. Achieving health equity takes time. There will be many bumps in the road. Stakeholders must accept the importance of grit, persistence, and perseverance as virtues in the CGM health equity journey.

## Recommendations for Achieving CGM Health Equity for Diabetes Stakeholders

CGM inequities are worsened by different levels of injustice at the individual, provider, institution, and population health levels. The following practical recommendations for different diabetes stakeholders can help to address some of the barriers on the road to achieving equity in CGM. These recommendations are based on insights from the ongoing work of the T1DX-QI and other allied CGM equity efforts across the United States.

### People With Diabetes and Their Caregivers

Every sincere effort to address CGM inequities should be inclusive of minoritized people with diabetes and their parents, siblings, partners, spouses, or other caregivers. The diabetes ecosystem should actively empower these individuals by providing appropriate education, support, and opportunities to participate in CGM research and improvement teams.

People of color and members of other minoritized communities with diabetes should be encouraged to use shared decision-making (SDM) as a tool to determine the right CGM options for them. SDM can yield simplified solutions to ensure that the voice of the person with diabetes is heard. One practical tip is to encourage people with diabetes to explain to their diabetes care providers what really matters to them,

as opposed to what is the matter, during any relevant interaction. For example, what really matters to people might be to have a CGM system that will allow them to sleep better at night or that will not interfere with their daily activities. Understanding what is important to each person with regard to CGM options can guide conversations about onboarding minoritized people with diabetes who are naive to CGM.

People with diabetes and their caregivers are also the best advocates for individual, systemic, and institutional changes. We can all learn from the experiences of marginalized people with diabetes.

The T1DX-QI has been actively working with patients of color through participation on improvement teams, in focus group discussions, within patient-parent advisory committees, and through the HEAL advisory group.

### Diabetes Providers, Primary Care Centers, and Researchers

Diabetes care providers include diabetes educators, advanced care practitioners, diabetologists, primary care providers, endocrinologists, pharmacists, and other professionals who might be responsible for discussing, recommending, or prescribing CGM.

Multiple studies have shown that there is racial or insurance-mediated bias in the process of discussing and prescribing CGM (39,40). Diabetes centers should offer customized professional education trainings on CGM bias and implement EMR clinical decision support solutions to promote CGM as a standard of care. Practices should also review practice- and provider-level CGM data stratified by race, ethnicity, insurance type, zip code, and other variables. This stratification might uncover existing disparities and provide a focus for intervention.

Centers should also critically review CGM prescription policies, procedures, and processes with an equity lens. For example, a center that has a practice of not offering CGM to patients with an A1C >9% might inadvertently contribute to more inequities, given that marginalized patients are more likely to have higher A1C levels (4,5,14).

Primary care diabetes providers, including those in federally qualified health centers, need to be equipped to prescribe, interpret, and support the use of CGM for the millions of diabetes patients receiving care outside of endocrinology centers (41). Telehealth and virtual onboarding training might be successful in expanding access to CGM in different settings (42).

Researchers should focus on practical solutions that can address CGM inequities, as opposed to only reporting on the extent of the problem. QI and implementation science

methods are viable solutions to integrate CGM practices and close equity gaps. In the T1DX-QI, centers are using an equity-focused project to reduce the inequity in CGM access between non-Hispanic White and non-Hispanic Black patients (Table 1). Diabetes centers can also identify peer centers or other members of the research coalition to develop a benchmarking routine, which can facilitate collaborative learning and sharing to accelerate the achievement of equity.

## CGM Manufacturers, Distributors, and Pharmacies

CGM manufacturers have a major role to play in addressing CGM equity gaps. CGM trials have historically excluded minoritized people with diabetes (43). Device manufacturers should have a stronger expectation to ensure that CGM research participants represent the entire diabetes population. Marketing and advertising of CGM systems should also include appropriate racial, cultural, and ethnic representation.

It will be beneficial to work with durable medical equipment suppliers and pharmacies to streamline the process of obtaining a CGM system after prescription and to remove any burdensome administrative processes that do not add value for people with diabetes.

It is also important for manufacturers in conducting post-marketing surveillance to identify equity trends in adoption of their devices based on available data. For CGM to become more readily available and equitable, the cost of the systems should be reduced, and deliberate efforts should be made to support minoritized patients.

## Funders and Advocacy Organizations

Funding and advocacy opportunities should be tailored to more sustainable and replicable initiatives that can address CGM inequities. Funders should support creative solutions that test better payment models and implementation efforts to promote equitable CGM adoption (44). For example, it will be beneficial to further support solutions that can enhance the integration of CGM data into EMR systems, making CGM data more accessible.

## Insurance Companies and Other Payers

Burdensome administrative paperwork from some insurance companies is a major barrier to the adoption of CGM. Payers should review their approval processes and remove any unnecessary roadblocks to CGM access (45,46).

There also should be substantial coverage for support services to close equity gaps in CGM access and use, including coverage for CGM training, onboarding, and the interpretation of resulting data. Payers can also implement new quality metrics, value-based models, and payment incentives to promote equitable adoption of CGM. Policy changes can lead to significant improvements in access to CGM (47).

## Conclusion

Achieving CGM equity will require the diabetes ecosystem to critically review the roadmap and remove any barriers that might contribute to unjustly limited CGM access for marginalized people with diabetes.

CGM equity can be achieved with intentionality, sincerity of purpose, partnership, and commitment to undoing systemic injustices. In the words of Martin Luther King, Jr., "It's all right to tell a man to lift himself by his own bootstraps, but it is cruel jest to say to a bootless man that he ought to lift himself by his own bootstraps."

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# Roadmap to the Effective Use of Continuous Glucose Monitoring: Innovation, Investigation, and Implementation

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For 25 years, continuous glucose monitoring (CGM) has been evolving into what it is now: a key tool to both measure individuals' glycemic status and to help guide their day-to-day management of diabetes. Through a series of engineering innovations, clinical investigations, and efforts to optimize workflow implementation, the use of CGM is helping to transform diabetes care. This article presents a roadmap to the effective use of CGM that outlines past, present, and possible future advances in harnessing the potential of CGM to improve the lives of many people with diabetes, with an emphasis on ensuring that CGM technology is available to all who could benefit from its use.

The incidence and prevalence of diabetes is increasing globally; yet, today, the overall quality of diabetes care is far from optimal (1), pushing us to explore new tools for and approaches to diabetes management. Glucose monitoring is one of the core components of diabetes management, along with personalized medication selection, insulin delivery systems, lifestyle management, and a focus on reducing diabetes distress and addressing the social determinants of health (SDOH) that significantly affect diabetes care and quality of life.

## The Evolution of Glucose Monitoring

Remarkable strides have been made in the how we monitor glycemia, progressing from urine testing to fingerstick blood glucose monitoring (BGM) to, over the 30 years since the Diabetes Control and Complications Trial, reliance in large part on A1C assessment to evaluate glycemic status and guide diabetes management. These strides represent 40 years of progress in glucose monitoring, but it was not until continuous glucose monitoring (CGM) was incorporated into the care process for type 1 diabetes between 2008 and 2015 that we had a glucose monitoring modality that was engaging, enlightening, and began to connect people with diabetes and health care professionals (HCPs).

Since the introduction of CGM, there have been so many "Ah-Ha!" moments for people with diabetes (e.g., "It changed my life!" "It opened my eyes." "It gave me peace of mind.") and for HCPs (e.g., "I never knew an A1C of 8.3% could have a CGM profile that looked so abnormal and needed immediate attention!"). There is even a CGM education–based initiative titled, The AH-HA! Project (2).

A1C, with the most robust and longitudinal data, is currently the most commonly used marker of glycemic risk for long-term, diabetes-related vascular complications. However, CGM is the best tool to assess and manage the occurrence of acute glycemic complications of diabetes (i.e., dangerous hypoglycemia or extreme hyperglycemia), and data are also steadily building that correlate CGM metrics to long-term vascular complications (3,4). To reiterate, whereas A1C is a good long-term risk measurement tool, CGM has evolved to be an important measurement tool for both acute and long-term risks and is also an effective personalized diabetes management tool (5). Today, many clinicians are setting glycemic management goals based on the glucose management indicator (GMI), a CGM-derived approximation of A1C previously referred to an "estimated A1C." Clinicians are increasingly also setting management goals based on the CGM-derived time in range (TIR) and time below range (TBR) metrics.

The U.S. Food and Drug Administration first approved CGM in 2001 (6). Since then, there have been major technical advances in interstitial glucose-sensing technology, including decreased sensor size, increased convenience and accuracy, elimination with some CGM systems of the need for calibration using BGM, approval of nonadjunctive status for some systems, and improved interoperability.

Five years ago, it seemed to me that the stage was set for CGM to transform type 1 diabetes care and also to have a significant impact on type 2 diabetes management, but that these paradigm changes were going to come about through a step-by-step process (7). Looking back at the past 25 years and also contemplating the steps still ahead that will be needed to realize

CGM's true potential, I created a roadmap for the effective use of CGM, which is presented in Figure 1 and explained in detail in the remainder of this article. This roadmap is organized in a general chronological progression starting with approval of the first CGM system in the United States in 2001 and laying out the steps or areas of CGM-focused research and development that have built on each other, allowing for the incredible progress we have seen to date and can anticipate continuing to see in the future.

## A CGM Roadmap: Cycles of Innovation, Investigation, and Implementation

After a decade of CGM data and nomenclature standardization, the roadmap illustrates a path forward to develop effective widespread clinical implementation and workflow strategies. Seeing the potential value of CGM in clinical practice, efforts over the past 5 years began to focus on finding ways to *1)* facilitate CGM-guided clinical decision-making, *2)* include CGM metrics as outcome measures in clinical trials and regulatory drug prescribing information, and *3)* elucidate how CGM metrics can be considered diabetes quality measures. These three efforts to further enhance the clinical value of CGM for diabetes assessment and management, shown as separate steps on the roadmap, when considered together, constitute the CGM Triple Aim, as shown in Figure 2.

CGM research and development did not stop with the Triple Aim, however. Innovations in diabetes technology connected CGM systems and insulin pumps with a glucose-responsive control algorithm, and thus the field of automated insulin delivery (AID) emerged. AID development successfully followed the insightful artificial pancreas roadmap championed by the JDRF's Aaron Kowalski (8), forever changing and improving the course of type 1 diabetes management. Additionally, investigations, including clinical trials, quality improvement programs, and studies analyzing real-world data, have led to new indications for the use of CGM in people with type 2 diabetes who use insulin, as well as during pregnancy in people with diabetes.

The pace of CGM uptake in clinical practice is steadily building, but there have been detours on the journey, and even some U-turns, when we needed to circle back and update CGM metrics, find ways to better integrate data into electronic health record (EHR) systems, and find more efficient ways to use the CGM data for population health management.

Every roadmap (certainly in the era of GPS) needs a destination we are trying to reach in a timely manner. The destination of the roadmap presented here is a health care system that reaches the Diabetes Quintuple Aim, which comprises equity in diabetes care, quality of diabetes care, reduced patient burden, reduced clinician burden, and reduced costs. This is a diabetes management–focused adaptation of the broader Quintuple Aim for Health Care Improvement recently proposed by Nundy et al. (9).

It is worth briefly reviewing the progress we have made on the first nine steps along the roadmap and why steps 10 and 11 (the future steps) are still important to pursue. Exploring the CGM roadmap reveals that people with diabetes, clinicians, and even entire health care systems can benefit from learning how to use CGM effectively. We need to ensure that every person with diabetes who can benefit from CGM is given the opportunity to use this transformative technology. When traversing any roadmap, it is also important to keep an eye on the rearview mirror to appreciate the ground we have already covered and also to realize that we will likely be revisiting many of these steps again for additional refinement toward further innovation, investigation, and implementation.
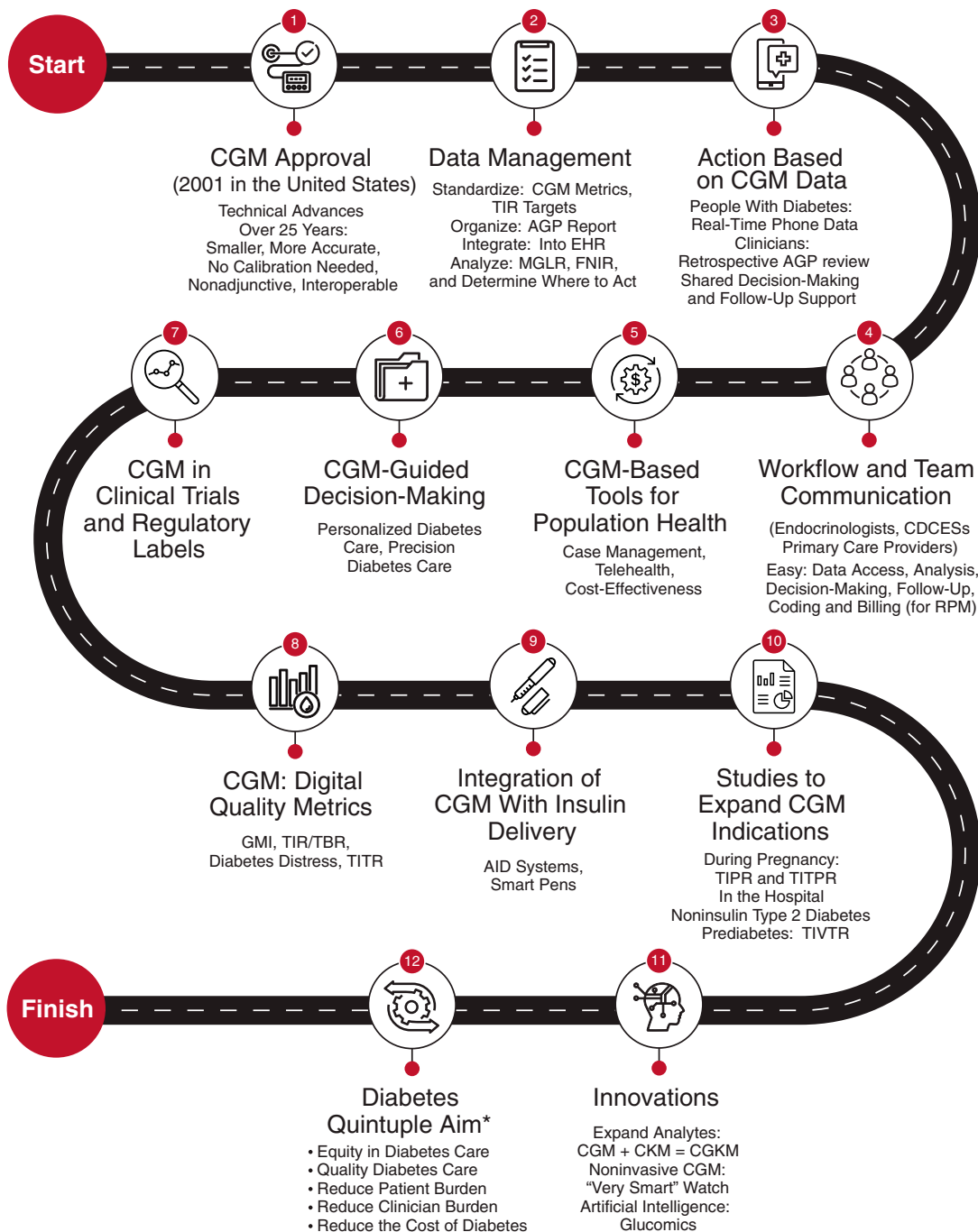
## CGM Metrics and Visualization: A Report to Help Standardize, Organize, and Analyze Data

In 2012, just over a decade after CGM was approved and early studies showed its promise for improving glycemic management (10,11), the first expert consensus development meeting (facilitated by the International Diabetes Center [IDC] and supported by the Leona M. and Harry B. Helmsley Charitable Trust) was held to begin the process of standardizing CGM metrics and CGM data reporting (12). This meeting resulted in the development of the one-page, three-panel ambulatory glucose profile (AGP) report. This effort built on the original AGP concept, which was developed by Mazze et al. (13) in 1987 using BGM data.

The CGM metrics and AGP report were refined in a series of additional consensus development meetings. Through these meetings, participating experts agreed on 10 core clinical CGM metrics in 2017 (14–16), and, in 2019, CGM targets were added for the five key "times in ranges" metrics (TIR [70–180 mg/dL], time above range [>180 and >250 mg/dL], and TBR [<70 and <54 mg/dL]) (17). The core metrics, targets, and AGP data visualization report (Figure 3) were then incorporated into the American Diabetes Association's (ADA's) *Standards of Medical Diabetes Care—2020* and have been updated in subsequent years (18).

As consensus was building for the CGM metrics and data visualization report, efforts were also underway to develop a method for systematically analyzing CGM data, starting with the IDC's nine-step guide to CGM interpretation (19–21), followed by the five-step DATAA Model (22). In response to busy clinicians who wanted to use CGM but were hoping for an even simpler or faster approach to CGM data analysis, a

# Roadmap of the Effective Use of CGM: Innovation, Investigation, and Implementation

**Start**

**1 CGM Approval**
(2001 in the United States)

Technical Advances
Over 25 Years:
Smaller, More Accurate,
No Calibration Needed,
Nonadjunctive, Interoperable

**2 Data Management**

Standardize: CGM Metrics,
TIR Targets
Organize: AGP Report
Integrate: Into EHR
Analyze: MGLR, FNIR,
and Determine Where to Act

**3 Action Based on CGM Data**

People With Diabetes:
Real-Time Phone Data
Clinicians:
Retrospective AGP review
Shared Decision-Making
and Follow-Up Support

**4 Workflow and Team Communication**

(Endocrinologists, CDCESs
Primary Care Providers)
Easy: Data Access, Analysis,
Decision-Making, Follow-Up,
Coding and Billing (for RPM)

**5 CGM-Based Tools for Population Health**

Case Management,
Telehealth,
Cost-Effectiveness

**6 CGM-Guided Decision-Making**

Personalized Diabetes
Care, Precision
Diabetes Care

**7 CGM in Clinical Trials and Regulatory Labels**

**8 CGM: Digital Quality Metrics**

GMI, TIR/TBR,
Diabetes Distress, TITR

**9 Integration of CGM With Insulin Delivery**

AID Systems,
Smart Pens

**10 Studies to Expand CGM Indications**

During Pregnancy:
TIPR and TITPR
In the Hospital
Noninsulin Type 2 Diabetes
Prediabetes: TIVTR

**11 Innovations**

Expand Analytes:
CGM + CKM = CGKM
Noninvasive CGM:
"Very Smart" Watch
Artificial Intelligence:
Glucomics

**12 Diabetes Quintuple Aim***

• Equity in Diabetes Care
• Quality Diabetes Care
• Reduce Patient Burden
• Reduce Clinician Burden
• Reduce the Cost of Diabetes

**Finish**

**FIGURE 1** Roadmap to the effective use of CGM: innovation, investigation, and implementation. For most people with diabetes, TIR is defined as time spent with glucose 70–180 mg/dL and depicted on the AGP report in green; TBR is time spent with glucose <70 mg/dL and is depicted on the AGP report in red. *Adapted from ref. 9. CDCES, certified diabetes care and education specialist; RPM, remote patient monitoring. ©2023 HealthPartners Institute, International Diabetes Center. All rights reserved. Used with permission.
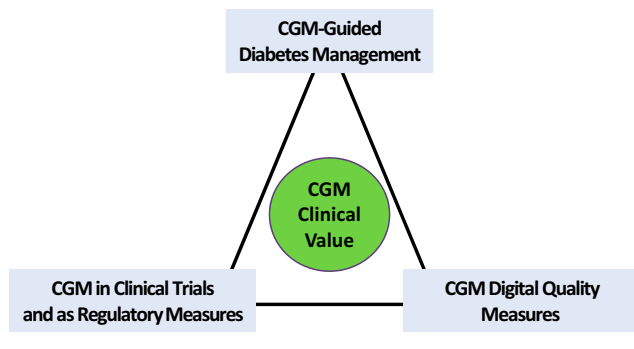
FIGURE 2 CGM Triple Aim. ©2022 HealthPartners Institute, International Diabetes Center. All rights reserved. Used with permission.
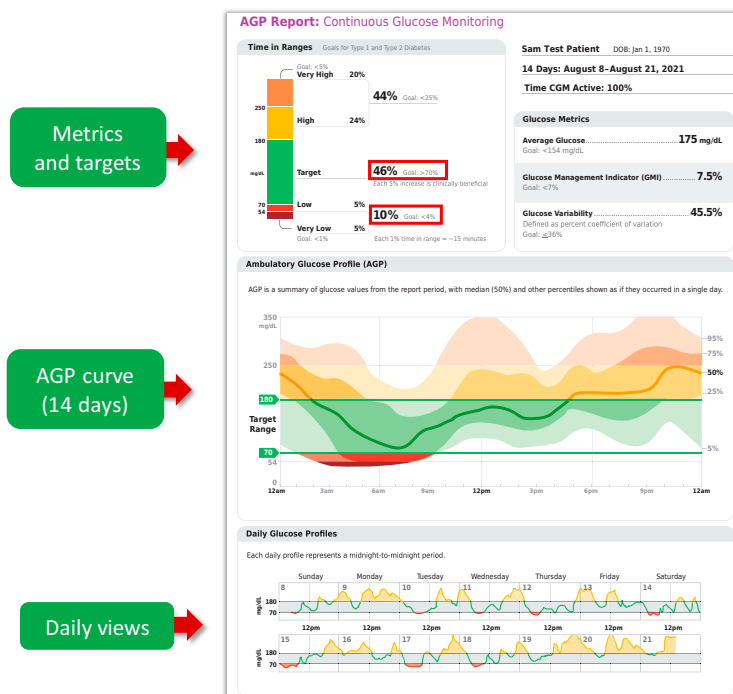
three-step AGP interpretation guide was presented (23), published (24,25), and revised (26) by the IDC between 2020 and 2022. Over the next year, other simplified CGM interpretation guides followed (27).

The simplified three-step approach to AGP interpretation from 2021 asked three questions of clinicians, progressing down the three panels of the AGP report: *1*) Is there a problem with glucose control? *2*) Where is the problem with glucose control? and *3*) What adjustments in medications or lifestyle are needed to reach optimal glucose control?

Because the term "glucose control" did not represent ideal patient-centered language (28) and the key message of immediate action was not prominent enough, the IDC has since reframed the three-step CGM analysis to be much more action-oriented, with the goal of overcoming therapeutic inertia (Figure 3). The current three steps that are suggested for rapid interpretation of an AGP report and intended to lead to action can be summarized by the directive phrase "Determine Where to Act," as follows:

1. **Determine** whether action is needed.
   - Review the times in ranges with a focus on TIR and TBR.
   - Action is needed if both TIR and TBR are not both at target (>70% and <4%, respectively). Goal: more green, less red (MGLR).
2. **Where** is action needed?
   - Review the AGP curve and daily views graphs.
   - Action is needed at the time of day when the glucose profile is furthest from being flat, narrow, and in range (FNIR).
   - Always start by addressing any hypoglycemia first (shown in red in the current version of the AGP report included in the ADA's 2023 Standards of Care [29]).
3. **Act** on the data.



FIGURE 3 AGP report three-step action plan. ©2022 HealthPartners Institute, International Diabetes Center. All rights reserved. Used with permission.

- Adjust lifestyle and medications and address diabetes distress and SDOH.
- Adjustments should be made right away, with timely follow-up adjustments scheduled (in clinic or virtually).
- Follow up: adjust, adjust, adjust, until MGLR targets are reached and the AGP curve is approaching FNIR.

## Acting on CGM Data: Thinking Fast and Slow

People with diabetes need to learn how to effectively act on the CGM data they see in real time, and clinicians need to determine where to act on the CGM data they review retrospectively, either in person or remotely. I refer to these actions as either "acting fast" or "acting slow," as described by the Nobel laureate Daniel Kahneman in his book, *Thinking Fast and Slow* (30).

Fast thinking or action occurs when people with diabetes look at real-time CGM data minute by minute and day by day, responding to high and low glucose values or alerts using the CGM trend arrows displayed on their smartphone app to guide their corrective actions. Fast-*ish* thinking can also include making individual changes in behavior based on postprandial and post-exercise CGM data. It is remarkable how fast CGM metrics improve in clinical trials after starting people with diabetes on real-time CGM. In an analysis by Raghinaru et al. (31) of data from eight randomized trials, TIR was found to have improved within the first week of starting CGM to the level it would remain, on average, throughout the duration of the trials. TBR usually took ~2 weeks to reach stable improved levels in these trials.

Slow thinking or action occurs with the retrospective analysis of AGP reports (via the three-step Determine Where to Act process, with the aim of achieving MGLR and FNIR and following up to adjust as needed). Such retrospective analysis is usually visualized on a computer or other larger monitor. Ideally, a shared decision-making session between the clinician and the person with diabetes would follow each AGP report analysis to reach agreement on the best therapy changes to make and a follow-up plan for further adjustments, as needed to avoid therapeutic inertia. Although some improvement in TIR and TBR occurs very quickly when starting real-time CGM (described above as fast and fast-ish thinking), to reach optimal CGM targets and A1C goals, there is added benefit to performing retrospective analysis of CGM data (i.e., slow thinking) and making adjustments as needed through shared decision-making. Additional study is needed to determine the appropriate educational strategies and management tools, including smartphone apps, and the ideal mix of face-to-face and virtual visits needed to optimize the use of real-time (fast) and retrospective (slow) CGM data.

If discrete CGM metrics and AGP reports can be automatically incorporated into the EHR with just an order placed in an individual's electronic chart (requiring a U-turn back to step 2 of the roadmap), this ability not only helps clinic workflow and communication among team members (as in roadmap step 4), but also allows for population health and case management guided by a clinician, clinic, pharmacy, or health plan. Population-level CGM data, along with EHR demographics, medication history, and laboratory results combined with health plan claims data will allow for real-world CGM cost-effectiveness studies in the future (roadmap step 5). Although this step may be considered a future component of the CGM roadmap, some important diabetes registries are already starting to develop ways to streamline the pull of CGM data, and approaches to direct EHR integration of discrete CGM metrics have already been presented by the IDC (32) and highlighted in the consensus document on comprehensive CGM EHR integration (33).

## CGM Metrics to Guide Management and Serve as Quality and Regulatory Measures

Over the past 15–20 years since the approval of CGM in the United States, as outlined in roadmap steps 1–5, clinical trials and analyses of existing diabetes datasets have shown CGM to be effective in improving glycemic management (i.e., improving A1C or GMI) and achieving more TIR and less TBR (34,35) and correlated with fewer long-term diabetes complications (3,4,36) and reduced diabetes distress (37). After showing CGM to be an effective management tool in clinical trials, the next phase of focused CGM work, happening now, is to achieve the CGM Triple Aim (roadmap steps 6–8). This effort involves developing tools to automate CGM data analysis and decision support (e.g., to suggest adjustments to diabetes medications based on CGM data), adding CGM as an end point in more clinical trials, and establishing CGM metrics as diabetes quality measures. Progress is being made on CGM-guided medication decision-support tools (for both insulin and noninsulin agents) (38), including CGM-guided nutrition selection (39). Personalizing medication and lifestyle adjustments based on CGM metrics, while also addressing diabetes distress and SDOH will start to move us toward a type of precision diabetes management (roadmap step 6). It stands to reason that, if clinicians use CGM metrics to make treatment choices, they will want CGM data to be accepted as outcome metrics in drug comparison trials and to have CGM data displayed in drug prescribing information (roadmap step 7) (40). The third part of the CGM Triple Aim (roadmap step 8) is to establish CGM metrics such as the GMI (41), TIR, TBR, and a measure of diabetes distress as digital quality metrics to be included in quality measurement sets such as HEDIS (the

Healthcare Effectiveness Data and Information Set) from organizations such as the National Committee for Quality Assurance (42) and others (43). If these sections of the roadmap are completed, health care organizations and clinicians will be more likely to implement the tools needed to optimize their CGM-derived diabetes quality metrics.

While we were all learning how to organize and analyze standalone CGM data (roadmap steps 1–8), major efforts were also underway to improve CGM sensor accuracy and develop integrated CGM sensors that could be linked to insulin pumps via control algorithms in AID systems (44). Digital diabetes ecosystems and models for effective virtual diabetes care (roadmap step 9) are now established (45,46).

## Expanding Indications, New Investigations, and Additional Applications

Many CGM studies are now underway or planned to expand the indications of who may benefit from the use of CGM (roadmap step 10). CGM use in pregnancy is increasing after positive early trials (47–49). Further investigations are needed to establish the value of CGM used early in pregnancy as a predictor of risk for developing gestational diabetes and the optimal use of AID systems during pregnancy. There is also great interest in CGM in the hospital setting, particularly after the difficulties encountered in monitoring glucose levels in the inpatient setting during the coronavirus disease 2019 pandemic. Improved CGM utilization in the inpatient setting also has the potential to mitigate dangers associated with inpatient hypoglycemia and hyperglycemia (50). The use of CGM in the hospital may be of particular importance when admission plasma glucose levels differ substantially from known previous glucose levels (i.e., the admission A1C) (51).

Step 10 of the CGM roadmap also highlights the need for studies to determine whether people with type 2 diabetes who are not using insulin and individuals with prediabetes can benefit from CGM. To date, there has been only one multicenter randomized controlled trial in people with non–insulin-treated type 2 diabetes (52), but almost all the data available from nonrandomized trials, registries, case management programs, and patient and clinician surveys suggest that this cohort is likely to benefit significantly from the personalized lifestyle insights and increased motivation to make healthy changes that CGM can yield (53).

We are just beginning to understand what CGM metrics and glucose profiles might look like for people with prediabetes. We need to know that these metrics and profiles may vary depending on which of the three main methods of diagnosing prediabetes (oral glucose tolerance testing, fasting glucose testing, or A1C) is used. Recently, there has been a call

to update the consensus guidance on how best to diagnose prediabetes and also a suggestion to even do away with the imprecise term "prediabetes" and replace it with a calculation of individuals' personal risk of developing diabetes calculated from glycemic, sociodemographic, and clinical data (54). Perhaps CGM metrics or some type of artificial intelligence (AI) analysis of a CGM profile will prove to be the most accurate assessment of individuals' true glycemic status and risk for progression.

In pregnancy and in individuals with non–insulin-treated type 2 diabetes or prediabetes, we will need to adopt some of the new nomenclature for CGM metrics currently being introduced. These terms include "time in tight range" (TITR; 70–140 mg/dL) and, for prediabetes, we may even want to evaluate what I suggest we call "time in very tight range" (TIVTR; 70–120 mg/dL). It would then be appropriate to name the currently accepted CGM pregnancy target range "time in pregnancy range" (TIPR; 63–140 mg/dL) with a possible goal of (90% TIPR) and, if tighter glycemic management in pregnancy becomes desirable, we could include "time in tight pregnancy range" (TITPR; 63–120 mg/dL). These new, more specific, metrics, if accepted, would need to be incorporated into AGP reports as a menu of target range options.

## The Future Is Now: Exploring New Analytes, Noninvasive Sensors, and AI Data Interpretation

Step 2 outlines an exciting set of planned super highways on the CGM roadmap that many in the field are hoping will be achieved, to some extent, in the not-too-distant future. Adding another metabolic analyte, such as the ketone body β-hydroxybutyrate, which could be continually measured in interstitial fluid along with glucose (and called "continuous ketone monitoring" [CKM]) is showing early promise, and we await pivotal trials (55–57). CKM on its own or combined with CGM in an accurate, affordable system for continuous glucose and ketone monitoring (CGKM) may facilitate the studies needed to demonstrate the safety of and obtain regulatory approval in the United States for the use of sodium–glucose cotransporter 2 inhibitors as adjunctive therapy for people with type 1 diabetes and known heart failure or chronic kidney disease (58) or for individuals with type 1 diabetes who are not reaching their glycemic goals on insulin therapy alone. CGKM may also prove helpful in the management of people with diabetes on very-low-carbohydrate diets, those with recurrent episodes of diabetic ketoacidosis, and those using an AID system who have more frequent insulin infusion site occlusions and failures than is typical.

A spot has also been saved on this CGM roadmap, assuming innovation prevails, for when we someday move

from minimally invasive to noninvasive CGM systems. A recent review of the past 2 decades of work on noninvasive CGM (59) concludes that there are four methodologies of noninvasive glucose detection that may have the potential to eventually progress to an "efficient, affordable, accurate, and pain-free" way of monitoring glucose and guiding diabetes management. These four methods are optical spectroscopy, photoacoustic spectroscopy, electromagnetic sensing, and nanomaterial-based sensing. Like almost every other step on the CGM roadmap, any successful innovation would be followed by investigation and then implementation.

Finally, it seems clear that we will be exploring applications of AI to better understand CGM data and how data patterns can interact with genomic, proteomic, and metabolomic data to enhance precision diabetes diagnosis and care (60). We may need to generate additional CGM data–related nomenclature, such as a glycemic subset of metabolomics that could be called "glucomics."

As these next-generation innovations evolve, we need to refine and better implement the previous 10 steps of the CGM roadmap to help more health care systems achieve the Diabetes Quintuple Aim, which is the ultimate destination for our roadmap to the effective use of CGM.

### The Roadmap Destination: Achieving the Diabetes Quintuple Aim With a Focus on Equity

The most respected guide to improving health care systems overall was established in 2008 by Berwick et al. (61). Known

as the Healthcare Triple Aim, it includes *1*) improving the patient experience, *2*) improving the quality of care, and *3*) reducing costs. Diabetes is a significant component of every health care system, particularly when we consider that 25% of adults ≥65 years of age have diabetes, that their care costs twice as much as someone without diabetes, and that the overall costs of diabetes care accounts for ~25% of all U.S. health care dollars spent per year.

Thus, it seems reasonable to establish a parallel Diabetes Triple Aim (Figure 4). The first component of this Diabetes Triple Aim is reducing the burden of people living with diabetes (diabetes distress). The second component is improving the quality of diabetes care, as defined by the CGM metrics of GMI, TIR, and TBR or A1C and including attention to the use of organ-protecting medications for people with diabetes who have known cardiovascular disease, heart failure, or chronic kidney disease. Today, high-quality diabetes care also includes addressing obesity, blood pressure, cholesterol, smoking cessation, and any SDOH that may be impeding optimal care. The third component of the Diabetes Triple Aim is reducing cost, which would best be achieved by overcoming therapeutic inertia and reducing acute and chronic diabetes complications. All three components of the Diabetes Triple Aim are affected by the effective use of CGM.

In 2014, the Healthcare Triple Aim was expanded to the Quadruple Aim, with the fourth aim of reducing clinician burden, in recognition of the need for more efficient workflows in clinical practice (62). Efficient workflows are also an essential component of sustainable CGM implementation, as shown in
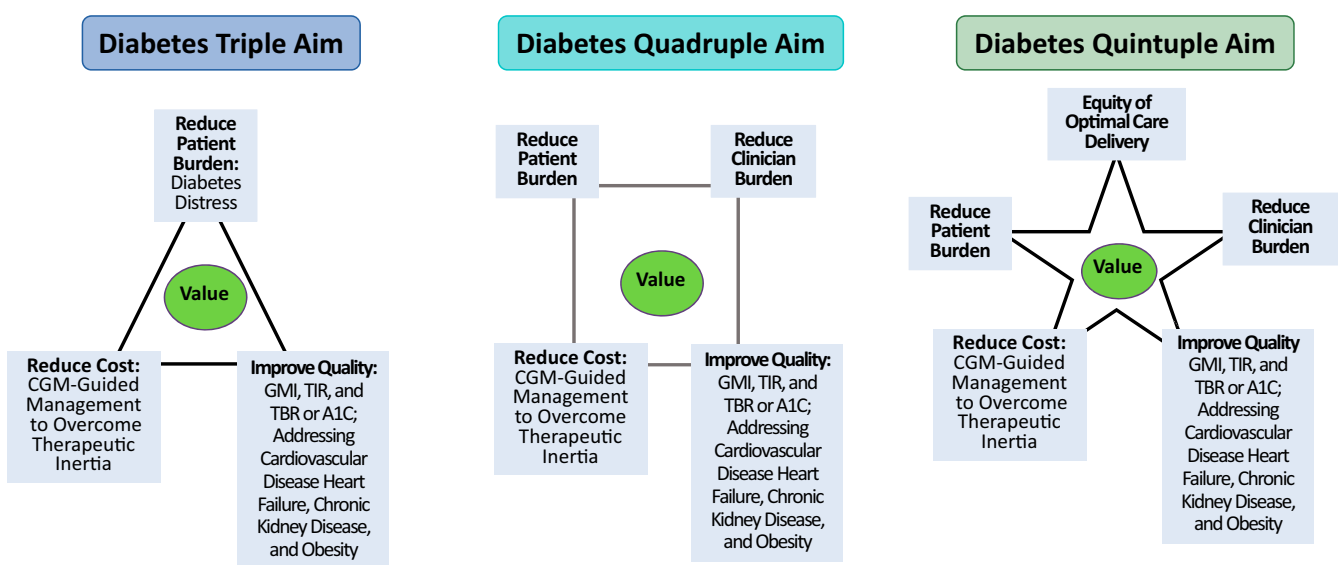


**FIGURE 4** Transforming diabetes care step by step: the Diabetes Triple Aim, Quadruple Aim, and Quintuple Aim. Adapted from refs. 9, 61, and 62.

the Diabetes Quadruple Aim (Figure 4). This fourth aim can be addressed in both specialty practice and primary care (63,64) by instituting measures such as a clear process for onboarding and supporting durable use of CGM, integration of CGM in the EHR, professional education on rapid AGP analysis such as the previously described Determine Where to Act method, implementation of CGM-guided decision-making tools, and a support team who can provide timely follow-up and who can use billing codes for remote patient monitoring (65).

Finally in 2022, in recognition of the large gap in equity of care for many medical conditions, including diabetes, a proposal was made for health care systems to move to a Quintuple Aim by adding a specific goal of establishing equity in care (66). Unfortunately, there may be no better example than diabetes to highlight the inequitable nature of care delivered and, of most relevance to this discussion, the vastly different levels of technology prescribing and implemented for people with diabetes based on race/ethnicity or income. Thus, equity is also addressed in the Diabetes Quintuple Aim (Figure 4). Studies are now showing that CGM can be started remotely and managed effectively by telehealth (67), which may broaden the adoption of this important tool to anyone with a smartphone, particularly now that Medicare and Medicaid have expanded CGM coverage. The treatment of other chronic diseases may benefit from laying out a similar roadmap for effective care, as well as defining overarching aims.

It may have taken 25 years, but with repeated cycles of innovation, investigation, and implementation, CGM is helping to transform diabetes management. Let's aim for the stars as we work together to complete this CGM roadmap and not stop until we achieve all five components of the Diabetes Quintuple Aim: equity, quality, reduced burden for people with diabetes, reduced clinician burden, and reduced cost of diabetes care.

## AUTHOR CONTRIBUTION

As the sole author of this article, R.M.B. researched the data and wrote and revised the manuscript and is the guarantor of this work.

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