The impact of continuous glucose monitoring on HbA1c control in primary care patients with type 2 diabetes

December 14, 2022

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The impact of continuous glucose monitoring on HbA1c control in primary care patients with type 2 diabetes

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December 14, 2022

Acknowledgements

- AMGA thanks Dexcom for funding this research.
- All AMGA research is “above brand,” focusing on care process design and implementation science — how medical groups and health systems improve population health.
- AMGA also thanks Piedmont Health for their partnership and participation in this study.

Presentation Agenda

- Study Overview
- Preliminary Results
- Workflow and Implementation Strategies
- Patient Experience: Barriers and Facilitators
- Success Stories
- Future Directions

Study Overview

Background

- Many patients with type 2 diabetes (T2DM) are not meeting their glycemic targets in order to prevent micro- and macro-vascular complications resulting from their diabetes
- Use of continuous glucose monitoring (CGM) devices has increased for patients with T2DM
- However, the effects of real-time CGM on glycemia in primary care patients with T2DM, particularly in those not on intensive insulin therapy, has not been studied in real world settings

Study Objective

- To implement CGMs in T2DM patients, prior to initiation of insulin therapy, in a primary care setting and to evaluate the impact on HBA1c control.

Dexcom’s CGM: G6

Dexcom G6 Continuous Glucose Monitoring (CGM) System

The only provider of CGM systems **indicated for children aged 2 years and older.**

- Up to **288 readings per day**
- **Exceptional accuracy**[1]
- **Zero** fingersticks required*

Smart devices sold separately.

- Customizable alerts and a fixed Urgent Low alarm
- **Predictive Urgent Low Soon Alert**

- Automatically communicates with connected devices†
- Data share features with up to **10 followers**‡

- Offers **Dexcom CLARITY** cloud-based diabetes management software

*If your glucose alerts and readings from Dexcom G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions.
†Includes compatible automated insulin dosing systems and smart devices. For a list of compatible devices, visit dexcom.com/compatibility and dexcom.com/g6-icgm.
‡Separate Dexcom Follow app required.

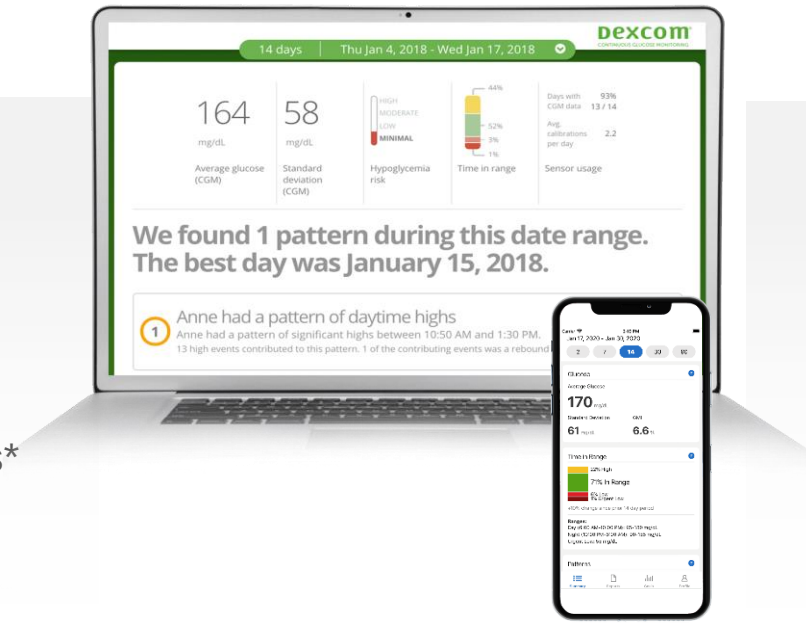
Reference: 1. Shah V LL, Wadwa P, et al. Performance of a Factory-Calibrated Real-Time Continuous Glucose Monitoring System Utilizing an Automated Sensor Applicator. Diabetes Technology and Therapeutics. 2018;20(6)

DEXCOM G6 APP FOR MOBILE DEVICES

Dexcom CLARITY and the Mobile App Increase Patient Engagement and Supports Telemedicine

Patient:

- View glucose patterns, trends, and statistics with the Dexcom CLARITY app
- Regular push notifications* facilitate coaching and decision support

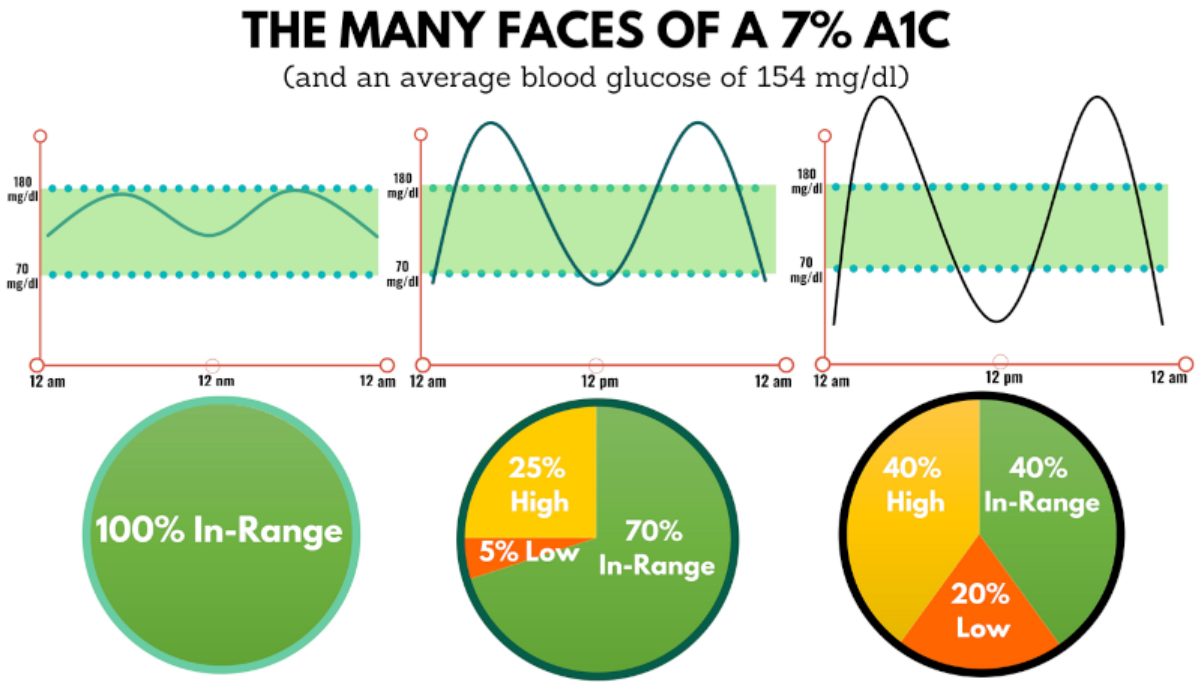


HCP:

- Data can be shared with HCPs on an ongoing basis to make appointments more efficient
- Allows providers to prioritize problems and find diabetes management solutions

*Users must opt in to receive notifications in the app settings.

Limitations of HbA1c



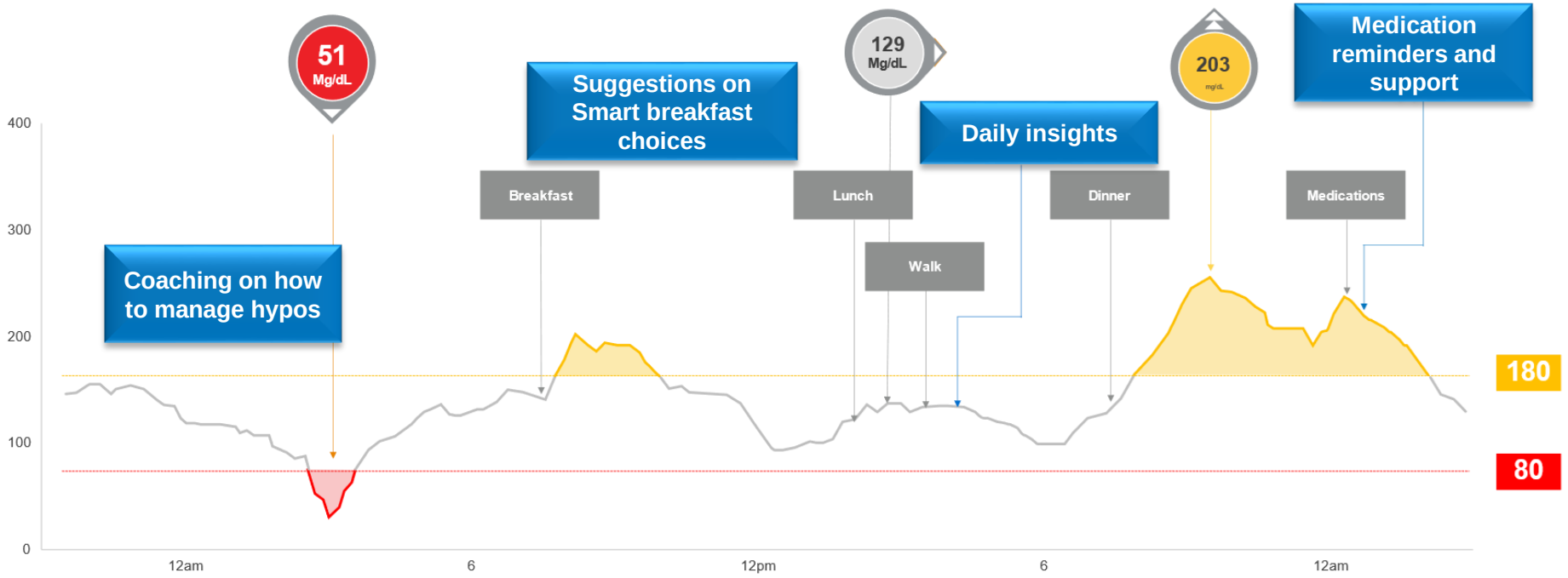
Metrics that only CGM can provide:

- Time in target Range (TIR)
- Time Above Range (TAR)
- Time Below Range (TBR)
- Glycemic Variability (GV)
- Glycemic Management Indicator (GMI)

diaTribe

CGM to Unlock Diabetes Management Insights

288 passively collected, daily glucose points from CGM inform effects of Rx, exercise and diet and symptoms



Source: Dexcom T2D pilot study. Similar observations using Dexcom CGM have been published in Vigersky et al., "Short- and Long-Term Effects of Real-Time Continuous Glucose Monitoring in Patients With Type 2 Diabetes," *Diabetes Care* 2012, 35(1): 32-38; Ehrhardt et al., "The Effect of Real-Time Continuous Glucose Monitoring on Glycemic Control in Patients with Type 2 Diabetes Mellitus," *J Diabetes Sci Technol* 2011, 5(3): 668-75; Cox et al., "Continuous Glucose Monitoring in the Self-Management of Type 2 Diabetes," *Diabetes Care* 2016, 39(5): 71-73.

Methods: Study Design

- A prospective observational matched cohort study design in one health system
- Implementation period: 3 months with potential for 3-month extension
- Patients were recruited from 8 primary care clinics using following inclusion criteria:
  - Age 18 – 75 at baseline
  - Diagnosis of type 2 diabetes at least 90 days prior
  - Two documented records of HbA1c ≥7.5 (separated by ≥3 months) within the past year
  - Access to compatible smart device or willingness to use provided device
- Exclusion criteria (past 12 months):
  - Dx of gestational or chemically induced T2DM, or ESRD
  - Hospice of palliative care
  - Bolus insulin Rx in past 12 months (if ≥2 weeks)
  - History of personal CGM use
  - Currently pregnant
  - Current alcohol/drug dependence/abuse

Methods: Primary Outcomes

- All outcomes measured at 4 time periods:
  - Pre: last available measure in past year prior to enrollment
  - During: 3-month implementation period (excludes 10d baseline)
  - Post: 3 months post enrollment
  - Post2: 6 months post enrollment (if patient chose to extend)
- Outcomes:
  - HbA1c
  - Percent of patients with HbA1c<7, HbA1c<8, HbA1c<9
  - Rates per 1,000 patient-days of documented: hypoglycemic events, CV events, DM-related events, all-cause events
  - Clinical indicators: BMI, BP, lipids,
  - CGM readings: time-in-range, time-below-range, time-above-range
  - Feasibility
  - Provider and care team satisfaction
  - Patient satisfaction

Methods: Surveys

- Patients (first at Baseline, then at 3 months):
  1. Work Productivity and Activity Impairment (WPAI) questionnaire
  2. Diabetes Empowerment Scale-Short Form (DES-SF)
  3. Ease of, and satisfaction with, use of technology (baseline [current method], post [CGM])

- Providers (post-enrollment)
  1. Feasibility, acceptance, usability, net promoter score

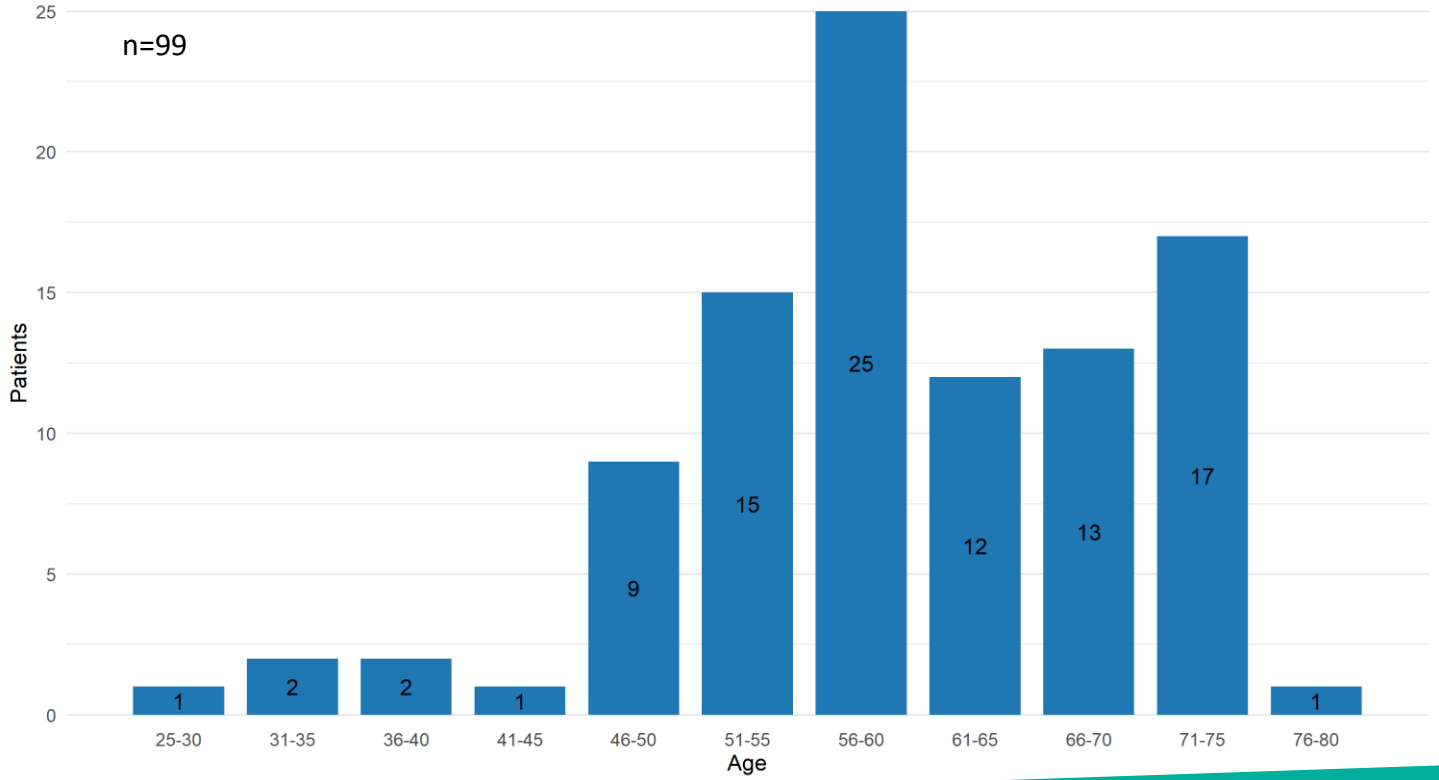
Results

Preliminary Results: Patient Demographics

n = 99			
Sex (Female)	40%	**Insurance Type**	
Race		Commercial	55%
White	75%	Medicare Adv	30%
Black or African American	13%	Medicare	11%
Unknown	7%	Medicaid	2%
Asian	4%	Self Pay	2%
American Indian or Alaska Native	1%		

Preliminary Results: Patient Demographics

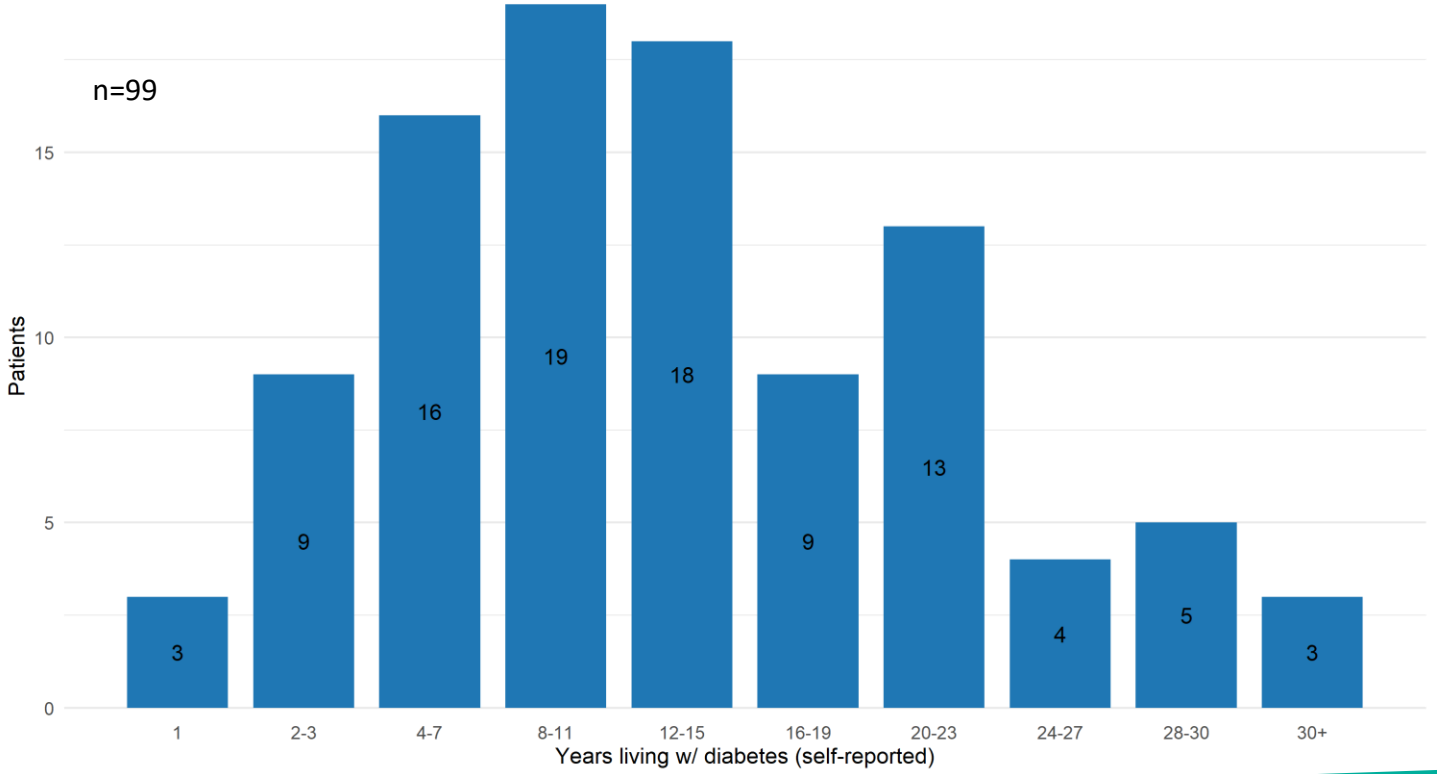
Most patients were age 51 to 70. Some were age 71+, and a small handful were <45



Preliminary Results: Patient Demographics

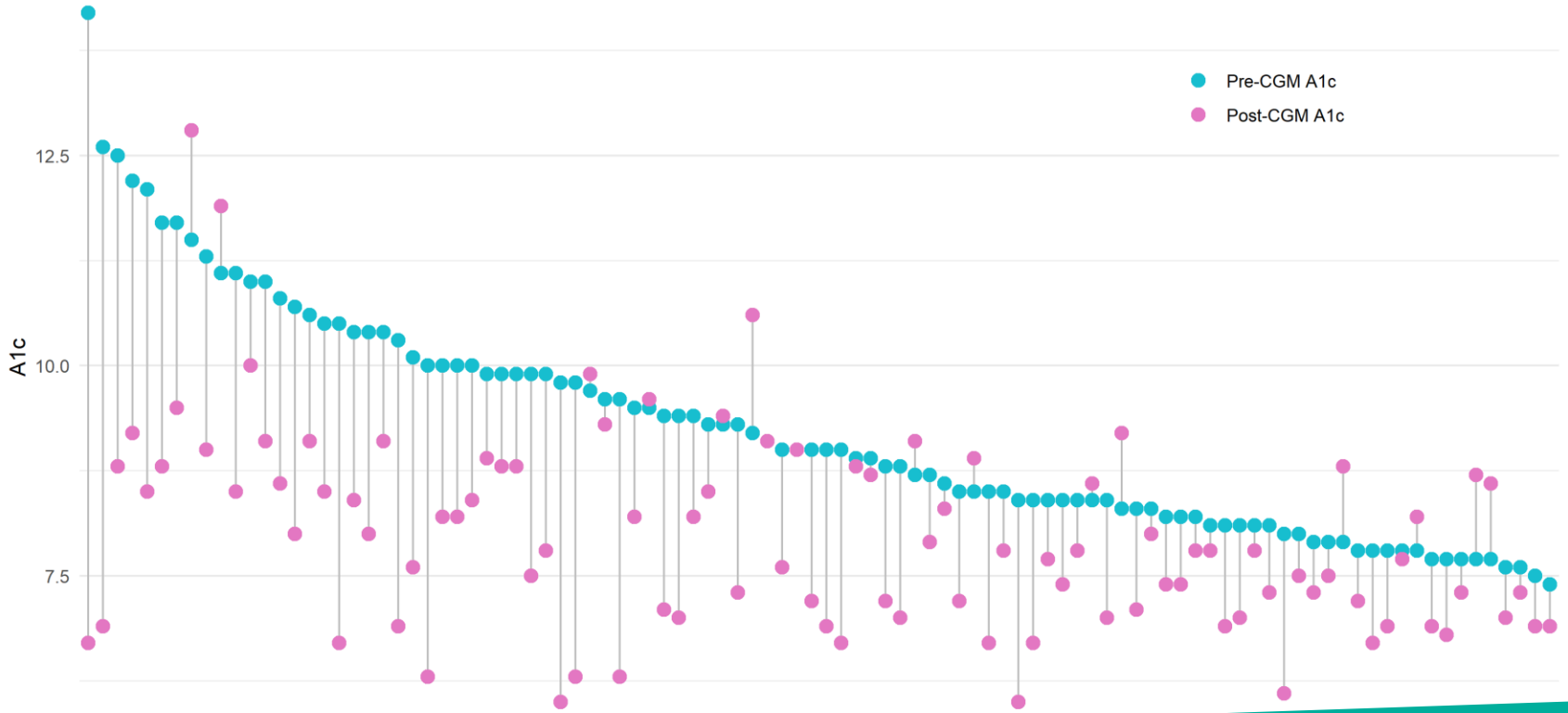
Years living with diabetes varied widely, from a just a few years to 20+ years.

Question: Approximately how many years have you had diabetes?



Preliminary Results: Pre/Post CGM HbA1c

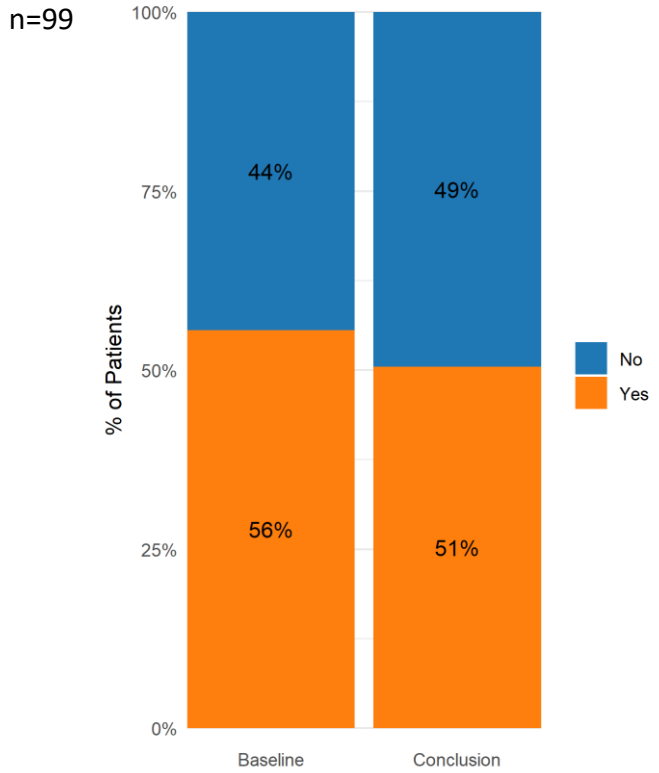
After 3 months of CGM use, ~86% of patients had a decrease in A1c, while ~14% had an increase.



Preliminary Results: Patient Surveys *(Work Productivity)*

About half of patients were employed. Slightly more were employed at Baseline.

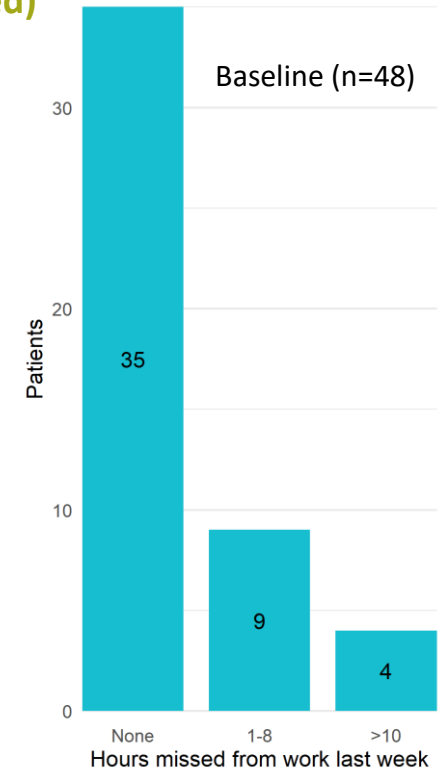
Question: Are you currently employed (working for pay)?

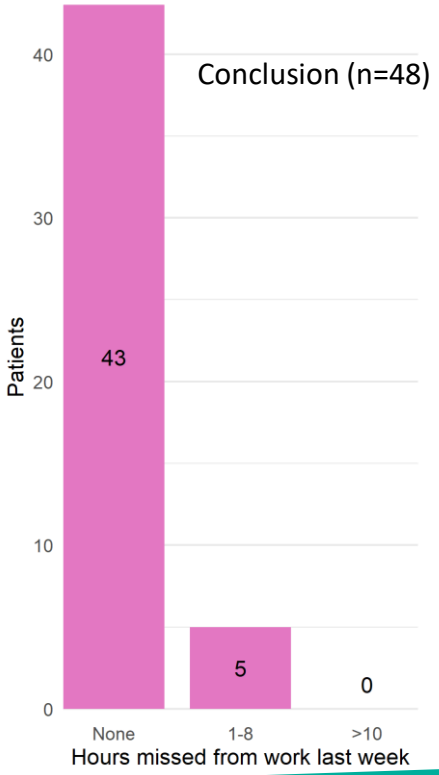


Preliminary Results: Patient Surveys *(Work Productivity)*

At Conclusion, fewer patients reported work hours missed due to health problems (among those who were employed)

Question: During the past seven days, how many hours did you miss from work because of your health problems?

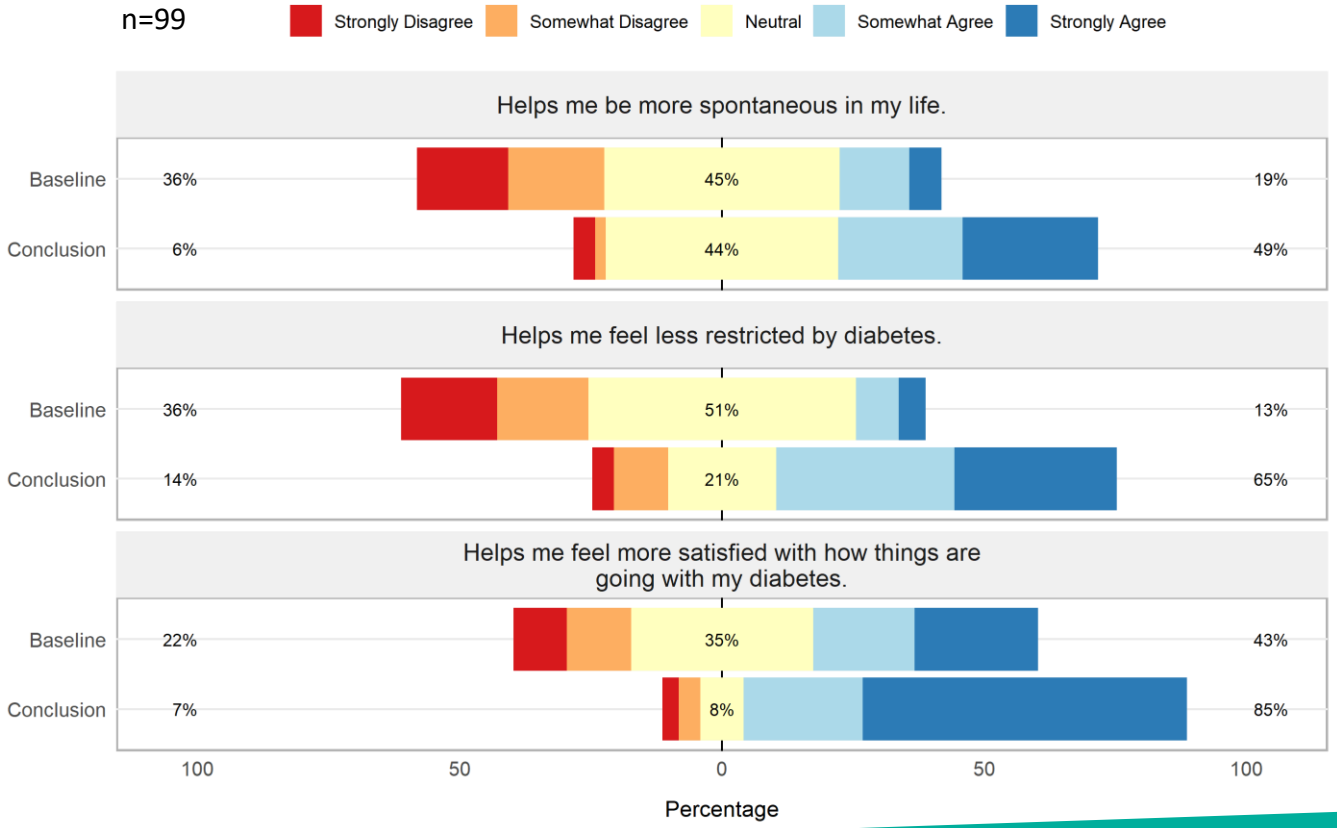




Preliminary Results: Patient Surveys *(Monitor Satisfaction)*

Question: How much you agree or disagree with each statement as it pertains to your current monitor.

My current monitor:



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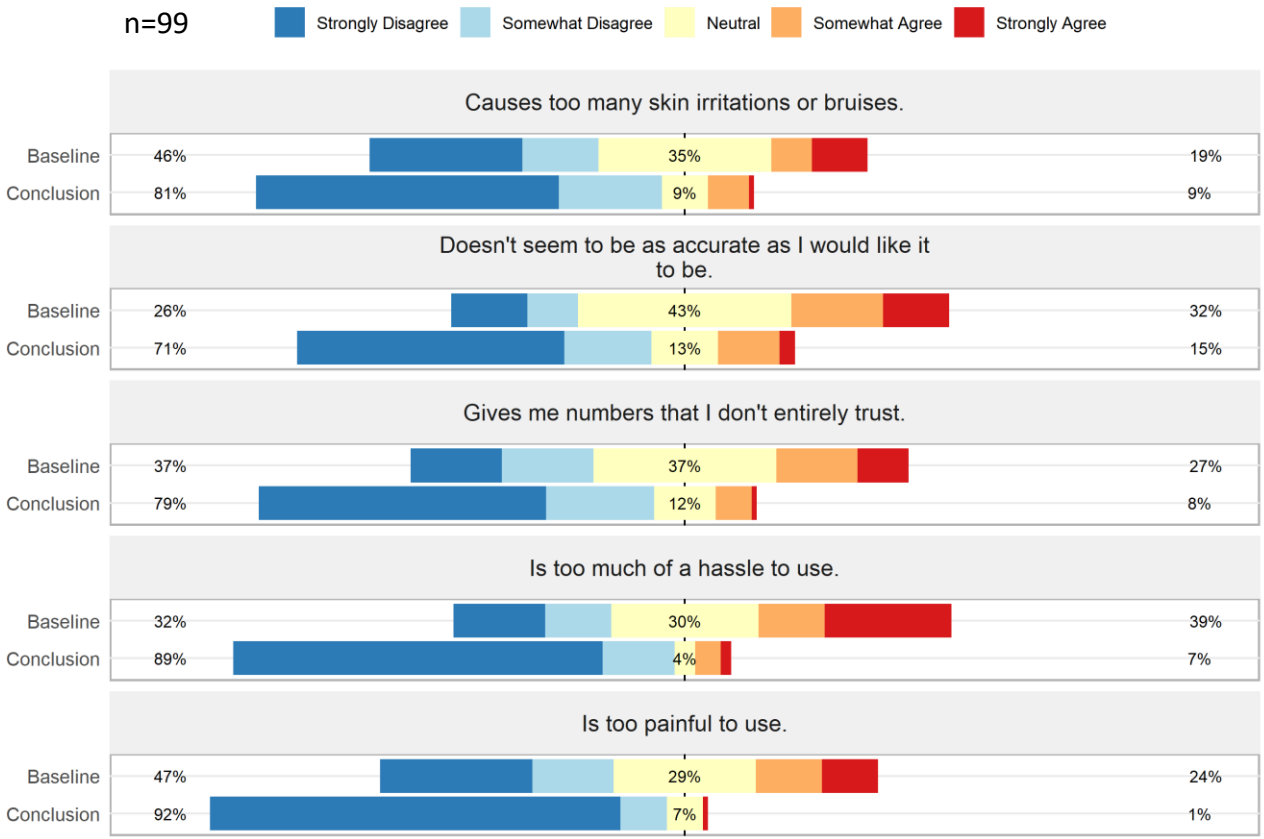
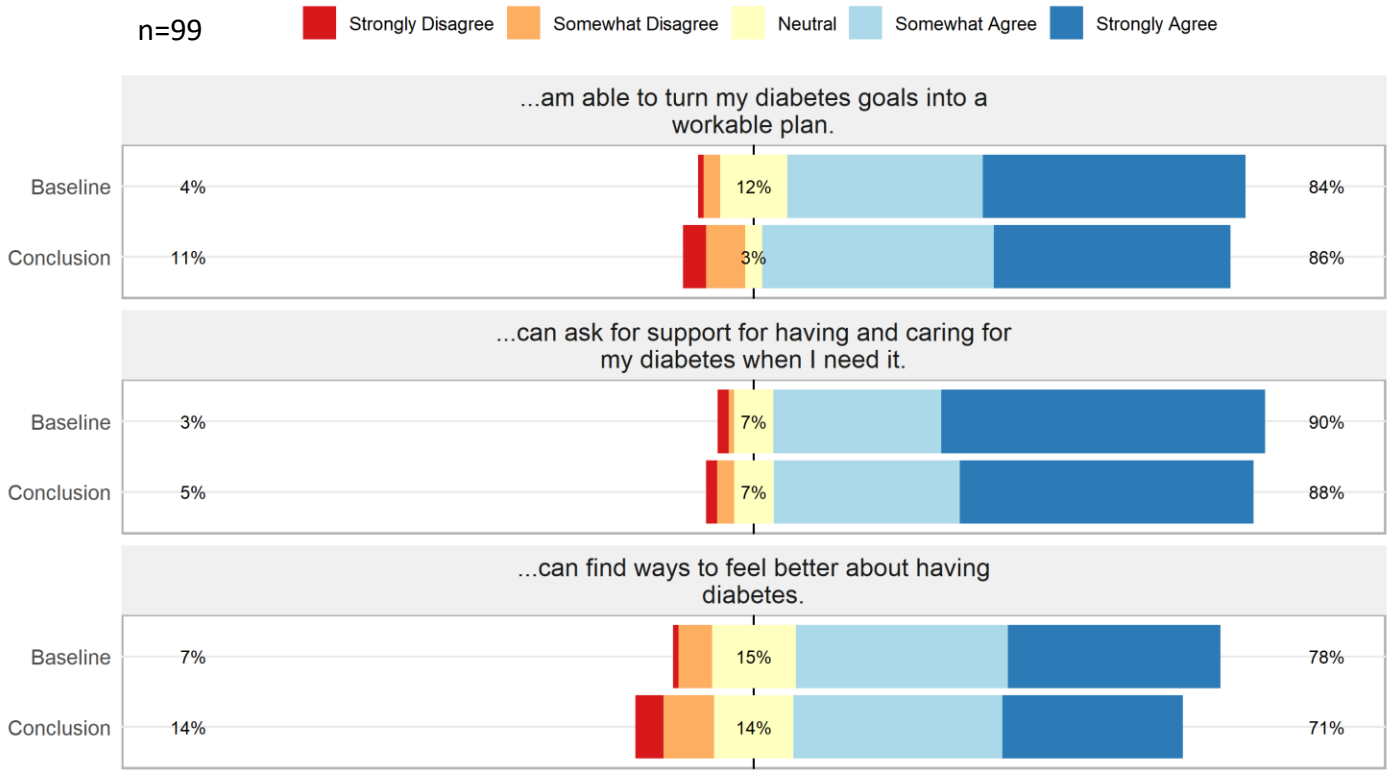


Preliminary Results: Patient Surveys *(Attitudes towards DM)*

Question: The following statements finish the sentence,

"In general, I believe that I…"



Preliminary Results: Provider Surveys (n=9)

- 2 MDs, 1 PA, 3 MOAs, 1 CCMA, 1 Office Manager, 1 front office staff member completed survey
- On a 5-point Likert scale:

Overall Experience	
CGMs made my patient's management of T2DM easier	4.3
CGMs improve the quality of T2DM care	4.3
CGMs take more time and work than it is worth	2.7
CMGs can benefit all patients with T2DM	3.8
Satisfaction	
Ease of use	3.7
Usefulness for patients	4.1
Data format	3.4
Ability to improve glycemic control	4.1
Modifying treatment patterns such as visit frequency and medical changes	3.7

Preliminary Results: Provider Surveys (n=9)

- Main reasons patients declined to participate:
  - Not interested
  - Not motivated
  - Technology issues: phones, app
  - Too busy, e.g., work schedule
- Contributed to success:
  - Provider referral
  - Free device, hopes for improving A1c
  - Checking on them during study
  - Patients seeing value in how device helped them improve health
  - Motivated patients
  - Desire to avoid finger sticks
  - Training

Preliminary Results: Provider Survey Comments (n=9)

"Majority of patients loved their device, felt more educated and aware of effect of diet on sugars."

"With the help of CGMs, a patient can actively make lifestyle changes that will reduce the need for expensive medications."

"Would be helpful for all T2DM patients if not too expensive and easy to obtain."

"The development of CGMs will completely revolutionize diabetes care and management and allow patients to take their health into their own hands.."

Preliminary Results: Provider Survey Comments (n=9)

"Main issue was could not use android phones. App needs to be compatible for ALL devices!"

"CGMs help insulin patients but also non-insulin patients. Insurance coverage is an issue."

"Insurance companies need to better cover this very important diabetic tool in order to save on healthcare costs due to diabetic complications later on down the road."

Clinic Workflow and Implementation Strategies

Piedmont HealthCare Overview

- **Piedmont HealthCare** is one of the largest physician-owned multi-specialty groups in North Carolina and the Southeast. We are committed to providing excellent care for the whole family. We have more than 60 convenient locations and nearly 200 physicians and providers across multiple specialties to provide the most innovative medical care for our community.

- Piedmont HealthCare is dedicated to improving health care in our community and advancing the medical field through **Clinical Research** with over 25 Physicians and teams engaged in multispecialty clinical research activities today and others looking to participate in the future.

Why did Piedmont want to participate?

- Primary care providers need data to both enable patients to achieve better glycemic control and properly treat diabetes.
- Insurance companies typically do not cover a CGM unless the patient is on insulin (4+ injections daily).
- Yet, this approach, targeting non-insulin dependent patients with diabetes, is much more cost effective and results in better outcomes for patients.
- Our goal was to advance the science, and hopefully coverage, of CGMs in the broad spectrum of patients with diabetes.

Physician and Staff Engagement and Training

All Physician and Staff Engagement was all managed remotely via E-mail and ZOOM.

- **Physician Recruitment** – physicians were informed of the opportunity via E-mail as well as in a Primary Care Department assign a clinical research assistant (clinical staff member) to the study.
- **Pilot** – Initiated with two pilot locations to facilitate getting a good process in place in advance of go-live for all 8 participating sites.
- **Clinical Research Assistant Training**
  - This was a clinical team member who either worked alongside the provider in clinic or held a management role in the clinic who were required to complete the following before starting the study:
    - GCP training
    - Study Specific Orientation
  - The clinical research assistant in each office was responsible for consenting the patient for the study, although in most locations they also provided the education, put on the device, assisted the patient with the survey, recruited patients, scheduled for follow-up visits, management of device inventory, etc.
- **Ongoing Engagement**
  - Teams received bi-weekly updates with recruitment goals/achievements and study updates.
  - Required ZOOM meetings were held as needed for Clinical Research Assistants throughout the study.
  - Practice teams had direct access to AMGA and DEXCOM teams

Challenges to Engaging in Research

- Need dedicated research coordinator
- Multiple sites across the system
- Staffing Shortage
- COVID
- Management of Device Inventory

Opportunities with Engaging in Research

- Opportunity to build research infrastructure
- Professional development for providers and staff
- Improved outcomes for patients
- Aligns with our Value Based Care focus

Patient Enrollment and Engagement

Patient Enrollment and Receptivity

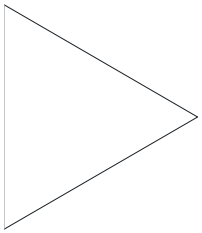
- Generated a list of eligible patients and called to determine interest → generally not receptive
- Informed all providers of study inclusion criteria who could discuss with patients at their already-scheduled visits → more receptive
- Patients were much more receptive when:
  - their provider discussed the study.
  - they were familiar with CGMs.
  - they wanted to find new ways to decrease their glucose.
- Enrollment workflow: providers → research coordinator → scheduling

Barriers to Participation

- Cell phone type
- App literacy
- Insulin usage

Success Stories

- “I had to give thought to what I was eating instead of just eating and my sugar going sky high. I got used to knowing what I could eat and couldn’t eat.”
- 58yF: 3.8 HbA1c reduction
- 67yM: 3.7 HbA1c reduction
- 53yF: 3.6 HbA1c reduction
- 51yM: 3.5 HbA1c reduction



over 3-month study period

Success Stories

"I think our biggest success story is from a longtime patient that had been struggling with his A1C since 2018. He started out with A1c levels of 12.5 in June 2018, and 11.5 in June 2021. He had managed to get his A1c down to 8.5 but was just not feeling good and couldn't get his numbers down.

He was very excited about the study and has learned how to eat better and knows what affects his sugar the most throughout the day. He said it has been a huge education tool for him to help him get down to an A1C of 6.5.

We had a lot of great success stories with our patients but this one was the best, he was here crying in the office when he started the study, at his wits end. After using the system, he was much more confident in his ability to take control of his health.

Additional Learnings

- Having a devoted employee interested in research is very helpful.
- Patients' individual needs must be taken into account. For some patients, having a CGM for only 3 months is enough to make long-term lifestyle changes. Others need the constant reminders.
- Provider involvement is very beneficial to study implementation and success.
- Being upfront with patients about potential user error when using CGMs and what to do if problems arose helped reduce unnecessary patient visits/calls.
- Patients' personal motivation played a major role in how successful they were with the CGM.

Summary and Future Directions

Summary and Future

- Patients with type 2 diabetes, but not yet on insulin, were receptive to CGM use.
- Many patients became increasingly engaged in managing their diabetes.
- Patients saw improvements in HbA1c over time.
- Patients reported improvement on many self-reported measures, however increased engagement also sometimes brought unwanted attention to their disease.
- Cost is still a significant barrier, but data from studies like this one may encourage payers to cover CGMs earlier in a patient's diabetes progression.
- A patient-level matched analysis is planned to identify the independent impact of CGM use on HbA1c control.
- Additional studies are needed to determine whether CGM use is associated with long term outcomes and potential cost savings.

Patient Testimonial

Susan’s Testimony Using Dexcom

https://www.youtube.com/watch?v=VrgjPMbTFzw

Questions and Discussion