



WHITE PAPER

Collaboration Between Stability Health and Penn Medicine

to Improve the Care and Outcomes of
High Need, Complex Patients with Diabetes

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Introduction

Despite advances in therapeutics, outcomes for patients with diabetes in the United States have not changed in the last two decades. Recent evidence suggests that in the last decade, trends in diabetes control have in fact worsened.¹

Diabetes is a complex cascade of metabolic derangements that can affect multiple organ systems; hence, ideal treatment of this condition does not rest solely on a single specialty. Often, patients with diabetes have comorbidities that require care from cardiologists, nephrologists, neurologists, ophthalmologists, vascular specialists, and gastroenterologists. While endocrinologists are often the “on point” specialists for patients with diabetes, there is a shortage of endocrinologists in the U.S. and endocrinologists do not exclusively treat diabetes.² Therefore, 85% of patients with diabetes receive care from primary care physicians (PCPs). Most PCPs struggle to stay current with the number of therapeutic options that are now available to treat diabetes, including new medications, monitoring tools, and insulin delivery devices. However, ideal treatment of diabetes does not rest solely on prescribing the right regimen of medications. Patients must be empowered to make significant lifestyle changes: how they eat, whether they engage in regular exercise, and how they manage stress. Unfortunately, the current practice environment for many PCPs leaves little time for robust discussions with patients about how to self-manage diabetes. W. Edward Deming, the father of quality improvement, famously said “every system is designed to get the results it gets.” In order to improve outcomes for patients with diabetes, we need to consider a change in our systems of care for these individuals.

Ideal Care for Patients with Diabetes

Edward H. Wagner, MD and his colleagues, who recognized the need to improve the care of patients with chronic conditions such as diabetes, first proposed a Chronic Care Model in the 1990s using a systems approach. This framework advocates for a care delivery system that:

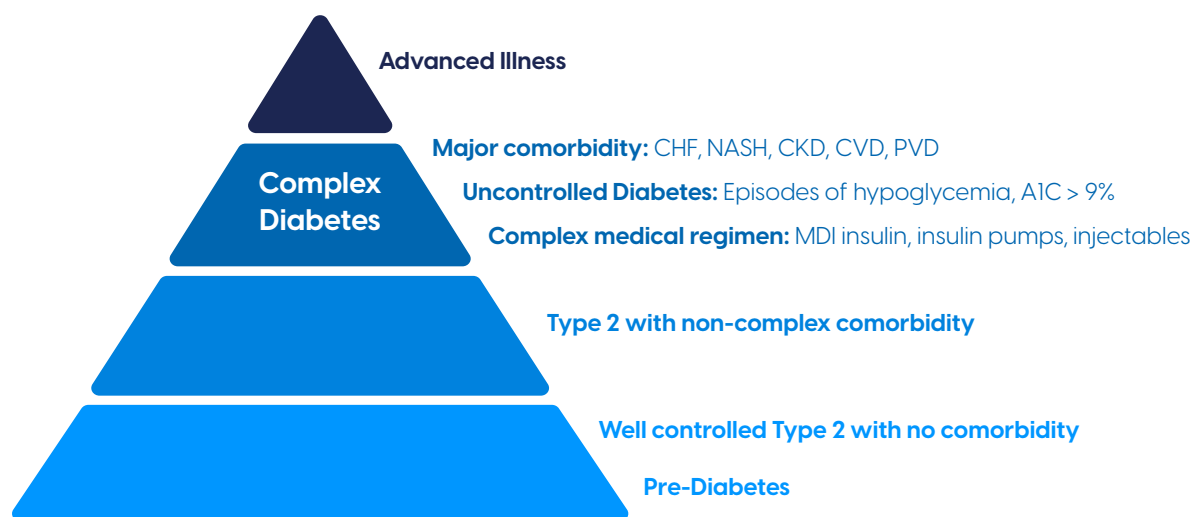
- Uses registries to proactively identify patients
- Uses decision support to enable clinicians to do the “right thing”
- Leverages community resources to assist patients holistically
- Is not dependent on one clinician but leverages a care team working together

The result of such a system is an empowered, engaged patient who interacts with a prepared and proactive care team.³

Leif I. Solberg, MD and colleagues conducted a qualitative study in Minnesota comparing high performing practices in diabetes care with lower performing practices. They found that higher performing practices were more likely to have proactive care processes and expanded care teams beyond the physician-patient dyad, while still supporting that key partnership. Higher performing practices had implemented many components of the Chronic Care Model, but they realized that redesigned workflows were insufficient to achieve outcomes. Rather, they recognized the need to build trusting relationships between care team members and between care teams and patients.⁴ Sir William Osler aptly worded this concept 100 years ago with the statement, “Every patient you see is a lesson in much more than the malady from which he suffers.”

Defining High Need, Complex Diabetes Patients

The American Diabetes Association (ADA) estimates that in the U.S., the direct cost of medical care for patients with diabetes is \$237 billion.⁵ In most populations, a high percentage of medical costs is attributed to a smaller group of patients with complex medical and psychosocial needs. The National Academy of Medicine (NAM) convened a series of workshops to create a definition of high need patients and published its recommendations in 2017.⁶ One group of patients defined as high need are medically complex patients. These patients have major chronic conditions, including diabetes, and a number of comorbidities and psychosocial factors. Using the NAM framework for medically complex patients, we propose a population stratification of patients with diabetes and define a segment of medically complex diabetes:



In addition to diabetes, patients in the medically complex segment have comorbidities defined by the NAM as major complex comorbidities. Patients with these co-existing complications have greater potential for organ failure and death. Included in this segment of complex diabetes are also those patients whose diabetes is not under control and those who have complex medical regimens; both of these factors signal the possibility that there are underlying psychosocial or health related social needs factors. Defining high need patients is important because it is this group of patients that especially needs different models of care to achieve desired outcomes.

The Penn Rodebaugh Diabetes Center

Named a "Center of Excellence" by Philadelphia Magazine, the Penn Rodebaugh Diabetes Center is a world-class clinic providing comprehensive care for 5,000 patients with diabetes and related conditions. Seventy percent of these patients have complex Type 2 diabetes and 30% have Type 1 diabetes. In addition to patient care, the Center provides training in diabetes management for endocrinology and diabetes fellows, nurses, nurse practitioner students, dietitians, medical students, and internal medicine house officers. The Rodebaugh care team includes endocrinologists, nurse specialists, nurse educators, and nutritionists. In addition to providing patient care, the Center participates in research and clinical trials to advance the treatment of diabetes and ultimately find a cure. Since its inception in 2003 the Penn Rodebaugh Diabetes Center has been under the direction of Mark H. Schutta, MD, the G. Clayton Kyle Professor in Diabetes.

Despite the resources available at the Penn Rodebaugh Diabetes Center, Dr. Schutta is all too aware that most patients with diabetes do not receive care in such a Center. He has been an outspoken advocate of the need for new scalable care delivery models and was eager to test the Stability Health model with the most complex patients cared for by his team at the Penn Rodebaugh Center.

Penn Rodebaugh Diabetes Center and Stability Health: A New Care Model

Stability Health is a tech-enabled care model for patients with complex diabetes that combines digital technology with human connection. Its founders recognized the failures of the U.S. healthcare system and the continued gaps in diabetes care. In the Stability Health model, patients have a designated health coach who provides support and education that empowers patients to engage in self-management, modify unhealthy living habits, and adhere to treatment. Coaching includes access to Certified Diabetes Care and Education Specialists (CDCES) for intensive diabetes education individualized to the patient. A technology platform monitors for care gaps and adherence to ADA Standards of Care. Stability Health endocrinologists review coaching plans and intervene to make recommendations when exceptions to standards of care arise, or are too vague or insufficient for that particular patient's needs. All care plans are shared with patients' clinical care teams to coincide with appointments so that recommendations can be acted on at the point of care.

Stability Health partnered with three physicians and their care teams from the Penn Rodebaugh Diabetes Center, enrolled 28 of their most complex patients into the Stability Health program, and followed the patients over a 6-month period.

Results

A total of 34 patients were initially referred to Stability Health and 30 patients completed the initial assessment and enrolled in the program at an enrollment rate of 88%. After enrollment, two patients dropped out, leaving a cohort of 28 patients with baseline characteristics shown below:

Gender	Male (10)	36%
	Female (18)	64%
Age Range	43-80 yrs. old	
Race	Caucasian (16)	57%
	African American (11)	39%
	Asian (1)	4%
Highest Level Education	High School (5)	18%
	Associates Degree (3)	11%
	Bachelor's (10)	36%
	Advanced Degree (8)	29%
Employment	Currently Employed (11)	39%
Type of Diabetes	Type 1 (8)	28.6%
	Type 2 (20)	71.4%
Comorbidities	Chronic Kidney Disease (10)	36%
	Cardiovascular Disease (4)	14%
	Liver Disease (2)	7%

Weight Reduction and Improvement in A1C

After 6 months in the Stability Health program, 46.4% of patients experienced weight reduction with an average reduction of 3.18%. About a third of patients improved their BMI by at least 1 kg/m² though none of the patients whose initial BMI met criteria for obesity had reductions of BMI below 30 kg/m². Initially, there were 13 patients whose HbA1C was greater than 9% and five of these patients were able to reduce A1C below 9%. In total, at 6 months, 53% of patients had lowered their A1C and 25% of patients achieved an A1C below 8%.

Medication Adherence and Medication Optimization

A Stability Health coach's assessment of medication adherence found 10 patients whose self-report indicated they were not taking medications as prescribed. Information about medication adherence and the care plan to improve this was included in reports to the Penn Rodebaugh Diabetes Center care team. The Stability Health coaches worked with patients to assess barriers to adherence, understand reasons for medications, and gain strategies for adherence. After 6 months enrolled in Stability Health, only one patient remained non-adherent to prescribed medications.

The endocrinologist oversight embedded in the Stability Health operating system drove suggestions for significant medication changes: Seven patients were started on a GLP-1 RA and an additional nine patients had other medication changes recommended as shown below. In the end, 54% of patients' non-insulin medication regimens were optimized to ADA Standards of Care.

Drug Class	# of the 28 Subjects
GLP1R agonists (Trulicity, Ozempic)	7
SGLT2i (Jardiance)	1
Glucagon (Baqsimi)	3
Anti-hypertensive (atenolol, amlodipine, HCTZ, lisinopril, Norvasc)	3
ACE inhibitor (for renal protection - lisinopril)	1* (counted above)
Sulfonylurea	1

At enrollment, 25 of the 28 patients were prescribed insulin as part of their diabetes regimen. Of the patients using insulin, 15 patients needed modification of their insulin regimen: Four patients needed increases in their insulin and 11 patients needed insulin decreases due to significant Time Below Range or significant hypoglycemic episodes. Overall, 23 patients were using continuous glucose monitoring devices that enabled calculation of time in specified ranges. Of these 23 patients, all using insulin, 10 patients were not meeting ADA Standards of Care for Time Below Range (i.e., having significant hypoglycemia). Decreasing insulin regimen and optimizing non-insulin medications with use of GLP-1 RA or SGLT2i agents for these patients brought six of these 10 patients into standards for Time Below Range.

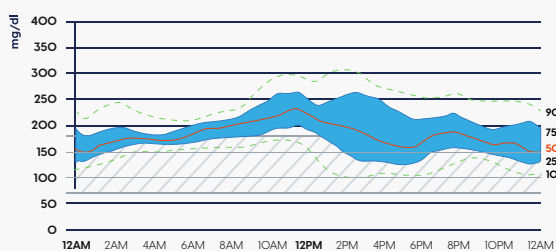
Case Example

LA is a 61-y.o. South Asian woman with a 15-year history of Type 2 diabetes complicated by microalbuminuria. Her diabetes control has worsened, and in the past two years, her A1C ranged from 7.7% to 9.2% despite additional medications including multiple doses of insulin. Her medication regimen includes metformin ER 2 grams daily, sitagliptin 100 mg daily, Levemir 36 units daily and Novolog 13-16 units with meals plus correction insulin. She was unable to tolerate a GLP-1RA or SGLT2i. Her BMI at the time of enrollment with Stability Health was 29 kg/m².

After 4 months of engagement with Stability Health, her A1C decreased from 7.7% to 6.8% and was associated with 2 lbs. weight loss and ~10 % reduction in her insulin dose. Her Time In Range reflected by Dexcom CGM improved from 45.9% to 82.9%. Her diet improved dramatically, now consuming three balanced meals with more vegetables and salads.

4

Pre-Stability Health: November 2020



Glucose Statistics

AVG. Glucose
mg/dL
191
Glucose
Ranges

Very Low	Low	In Target Range	High	Very High
< 54 mg/dL	< 70 mg/dL	< 70 - 180 mg/dL	> 180 mg/dL	> 250 mg/dL
0.0%	0.2%	46.9%	52.9%	14.3%

Glucose Ranges

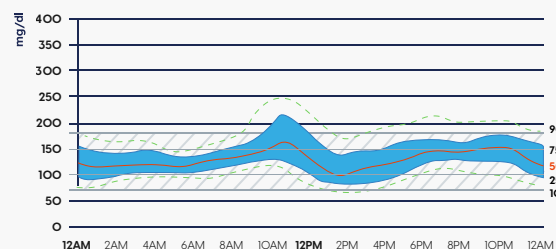
Coefficient
of Variation
28.6%

SD
mg/dL
54

% Time CGM
Active
85.1%
Data
Sufficiency

Stability Health Intervention Diet much improved. Lost 2 lbs. Continues Metformin and Januvia
Has reduced insulin
Eating salad for lunch
Levemir 30
Aspart 12/10/10

February 2021



Glucose Statistics

AVG. Glucose
mg/dL
136
Glucose
Exposure

Very Low	Low	In Target Range	High	Very High
< 54 mg/dL	< 70 mg/dL	< 70 - 180 mg/dL	> 180 mg/dL	> 250 mg/dL
0.6%	3.0%	83.0%	14.0%	17%

Glucose Ranges

Coefficient
of Variation
31.7%

SD
mg/dL
43

% Time CGM
Active
98.2%
Data
Sufficiency

Conclusion

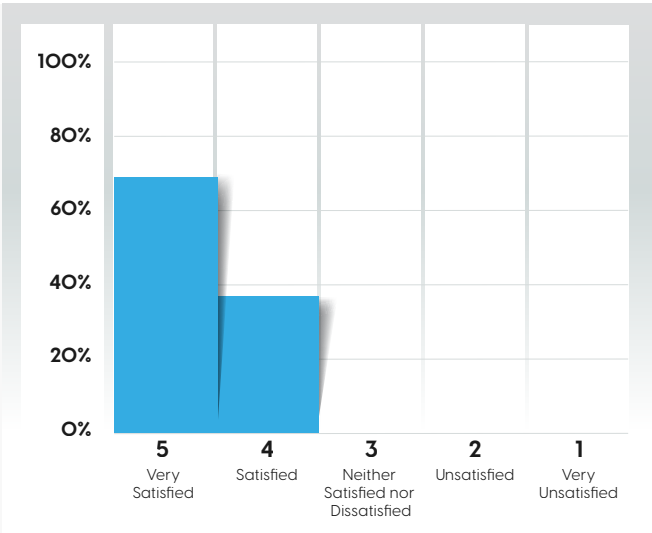
The cohort described above meets the criteria for medically complex diabetes:

- Over half had a comorbidity that would meet criteria for a major complex comorbidity defined by the NAM⁶
- Initial clinical parameters included 46.4% of patients whose A1C was greater than 9% indicating poor control
- About a third of the patients had Type 1 diabetes
- The majority of patients were using insulin regimens and 43% were not meeting ADA Standards of Care for Time Below Range

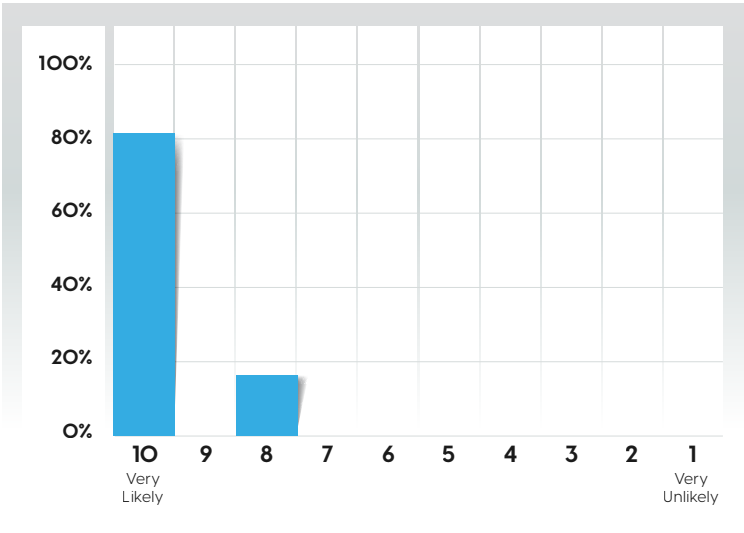
Once enrolled in the Stability Health program, patients engaged with health coaches and CDCES and in 6 months, 53% improved diabetes control and 46% lost weight. Additionally, the proprietary operating system identified where there were gaps to the ADA Standards of Care and enabled an efficient exchange of information to the treating clinical team to optimize insulin and non-insulin medication regimens.

Overall, patients were very satisfied with the program and rated it very highly:

On a scale from 1 to 5: How would you rate your overall satisfaction with the Stability Health program?



On a scale from 1 to 10: How likely are you to recommend the Stability Health program to a friend?



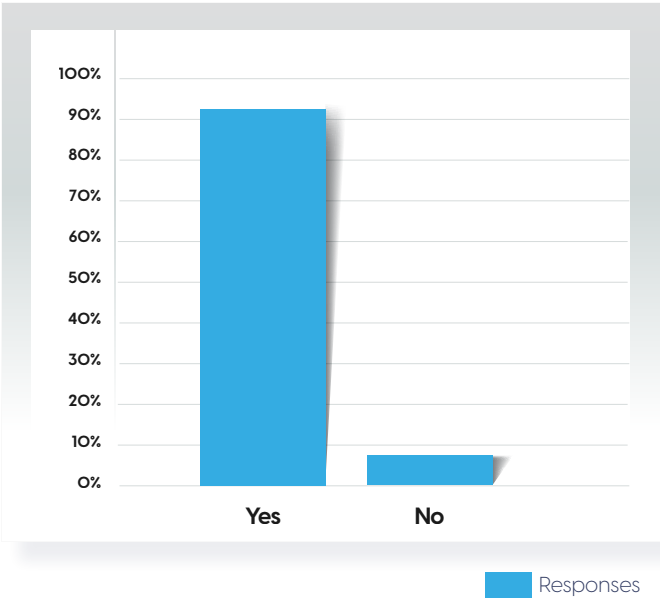
Responses

A key to managing diabetes is patient activation for self-management. Patient experience with the Stability Health program shows that the overwhelming majority of this cohort felt empowered and more confident. Having coaches help prepare patients for their appointments led patients to feel that they were more understood by their care team.

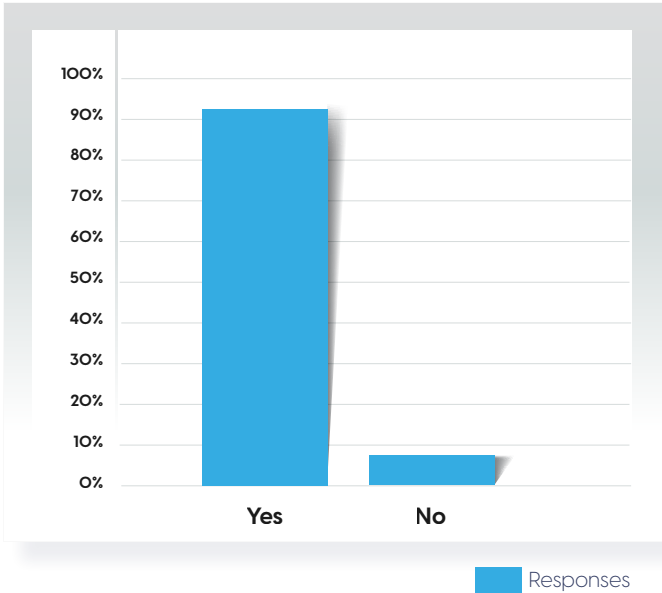
How confident are you in your diabetes self-management skills?



Has your confidence improved since starting the Stability Health Program?



Do you feel your care team has a better understanding of your diabetes and personal health needs since working with Stability Health?



Discussion

The partnership with Stability Health demonstrated that for this group of medically complex patients with diabetes, creating a new care model to support patients and clinicians produced clinically relevant outcomes. This new care model combines elements of the Chronic Care Model with newer technology to create an expanded care team with the ability to frequently connect with patients to help them adhere to treatment and self-management. The operating system enables easy identification of gaps in standards of care and feedback to clinicians to consider therapeutic changes. While technology is necessary to embed standards of care into decision support and registries, the human connection is equally important. With frequent contact from coaches, the Stability Health care model enables creation of individualized care plans and helps patients remain engaged and adherent.

Even outstanding specialty practices like the Penn Rodebaugh Diabetes Center have patients that remain unreachable by current systems. Many such patients improve with frequent “touches” from someone who knows them and their unique circumstances. Using the systems built by Stability Health helps healthcare organizations close the care continuum between the patient and their care team, improving outcomes in a cost-effective manner. Despite their advanced capabilities, practices like the Penn Rodebaugh Diabetes Center would face many barriers to creating a similar care model within their walls.

While most electronic health records have registries, the decision support for diabetes standards of care customized to a particular practice workflow would need to be built de novo. Decision support is crucial to identifying variations in practice and reducing common cause variation while allowing clinicians to use their judgement to manage appropriate exceptions to standards (“special cause variation”). Most non-procedural specialty practices operate with a very slim margin and would not have capital resources to adequately staff coaches and CDCES let alone invest in technology required to automate diabetes standards of care into care plan algorithms. Partnerships with an organization such as Stability Health enable a practice to scale these services to their population at lower cost.

The impact of improving clinical outcomes for medically complex patients with diabetes is substantial. Literature using analysis of claims databases and actuarial modeling shows that improving diabetes control, cardiometabolic parameters, and medication adherence reduces total cost of care.^{7,8,9} The complexities of the current healthcare system make it nearly impossible to align incentives around improving population total cost of care to drive innovation. Unfortunately, the inability to align incentives only perpetuates the status quo whereby patients who need the most support continue to receive sub-optimal care.

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