

How Does Diabetes Affect Daily Life? A Beyond-A1C Perspective on Unmet Needs

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■ IN BRIEF To better understand the unmet needs of people with diabetes, dQ&A Market Research of San Francisco, Calif., fielded an online survey of more than 7,000 patients/caregivers. In addition to not reaching A1C targets recommended by the American Diabetes Association and the American Association of Clinical Endocrinologists, participants reported stress, time demands, costs as a large barrier to self-care, and negative impacts on school, work, future planning, self-confidence, and social interactions as major issues facing people with diabetes. Moreover, the emotional and physical needs of people with type 1 diabetes often varied significantly from those of people with type 2 diabetes. These findings illuminate aspects of life with diabetes beyond glycemic control that therapies and tools should aim to address.

Despite progress in the development of therapies and devices to treat diabetes, the burden of living with the disease remains high. Patients across cultures and countries report negative experiences from diabetes, not only with regard to glycemia, but also regarding physical, emotional, social, and financial health metrics (1). Diabetes is a 24/7 unwanted job with no vacations, breaks, or set-it-and-forget-it phone apps.

In the fall of 2014, The diaTribe Foundation and dQ&A Market Research of San Francisco, Calif., surveyed a broad group of the diabetes online community to better understand the impacts of diabetes on daily life and to share these concerns with the U.S. Food & Drug Administration (FDA). Results were presented at a public workshop on 3 November 2014 that convened FDA representatives, patient advocacy organizations, and more than 1,000 people online. The purpose of the dialogue was to provide patients' perspectives on how diabetes affects daily life, desired tools (drugs and devices)

that would improve life with diabetes, challenges of current management, and the risks associated with managing diabetes. The event and survey aimed to 1) continue to open lines of communication between the FDA and the diabetes patient community; 2) give FDA leaders a better sense of what it is like to live with diabetes, what patients find difficult, and what patients want in new tools; and 3) serve as a pilot program for future FDA-patient meetings.

Research Design and Methods

The survey had 6,934 partially or fully completed responses. Of those, 66% were from people with diabetes ($n = 4,575$), and 34% were from parents/partners/caregivers of people with diabetes ($n = 2,359$). Of the people with diabetes, most self-identified as having type 1 diabetes (73%, $n = 3,350$), and the remainder identified as having type 2 diabetes (27%, $n = 1,225$). Almost all of the parents/partners/caregivers (97%) took care of someone with type 1 diabetes.

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The survey was fielded through Qualtrics, a data collection and analytics software (Qualtrics, Provo, Utah, and Seattle, Wash.), and distributed online through social media, with outreach through diabetes patient organizations including but not limited to the American Diabetes Association (ADA), JDRE, The diaTribe Foundation, and other patient-orientated groups (e.g., Six Until Me and Scott's Diabetes Blog).

The survey asked respondents to:

- Rank factors that had the greatest impact on day-to-day life with diabetes, including hypoglycemia, time commitment, weight management, and stigma
- Rank barriers to better diabetes management
- Assess the impact of diabetes on various aspects of life, including self-confidence, ability to take on life's challenges, and relationships
- Provide information on demographics, technologies and therapies used, A1C values, and the presence of complications

Participants also had the opportunity to provide open-ended comments about how diabetes affects their daily lives and how a new medication or technology could be most useful for people living with diabetes. We collected more than 4,500 open-ended comments, samples of which are provided in Supplementary Appendix A. Survey analysis was conducted through MarketSight (MarketSight, LLC, Newton, Mass.) and Excel (Microsoft, Redmond, Wash.). A detailed version of the survey questionnaire is provided in Supplementary Appendix B.

Results

In this nonrepresentative sample, only 37% of respondents with type 1 diabetes and 54% of those with type 2 diabetes reported having an A1C $\leq 7.0\%$ (Table 1; note that ADA recommends an A1C of $< 7.0\%$ for most people with diabetes), and only 19% of those with type 1 diabetes and 37% of those with type 2 diabetes met the

TABLE 1. Respondents' Self-Reported A1C Values

A1C (%)	Respondents With Type 1 Diabetes (%)	Respondents With Type 2 Diabetes (%)
≤ 6.5 (AACE goal)	19	37
≤ 7.0 (Note: ADA goal is $< 7.0\%$)	37	54
> 7.0	62	42
> 8.0	25	16
> 9.0	8	6

TABLE 2. Respondents' Self-Reported Diabetes-Related Complications

Diabetes-Related Complications	Respondents With Type 1 Diabetes (%)	Respondents With Type 2 Diabetes (%)
High blood pressure	29	67
Cholesterol	32	58
Depression	45	31
Eye problems	25	19
Nerve damage	21	26
Foot problems	17	25
Kidney problems	12	12
Cardiovascular problems	11	20
Arthritis	16	30

TABLE 3. Respondents' Self-Reported Use of Diabetes Devices

Diabetes Devices	Respondents With Type 1 Diabetes (%)	Respondents With Type 2 Diabetes (%)
Blood glucose meter	95	98
Insulin pump	71	8
CGM device	46	4
Diabetes-specific phone apps	33	17
Pen for injecting insulin or another diabetes medication	35	36

more stringent American Association of Clinical Endocrinologists (AACE) A1C goal of an $\leq 6.5\%$. In addition, as shown in Table 2, respondents reported having high rates of diabetes-related complications. Almost half of those with type 1 diabetes and almost one-third of those with type 2 diabetes reported undergoing treatment or taking medications for depression. Two-thirds of those with type 2 diabetes reported having high blood pressure, 58% reported having high cholesterol, 26% reported having nerve damage, and 25% reported having feet problems. These results were reported despite the reported extensive use of

diabetes technology in respondents with type 1 diabetes (71% using insulin pumps and 46% using continuous glucose monitoring [CGM] devices) and high reported use of insulin (48%) and pills (73%) in respondents with type 2 diabetes (Tables 3 and 4).

A majority of respondents with type 1 or type 2 diabetes reported that diabetes had a negative impact on their life when planning for the future (72 and 54%, respectively) (Table 5). Most patients with type 1 diabetes also reported negative effects on their ability to take on life's challenges (67%), their self-confidence (66%), and their success at work

TABLE 4. Respondents' Self-Reported Use of Diabetes Therapies

Diabetes Therapies	Respondents With Type 1 Diabetes (%)	Respondents With Type 2 Diabetes (%)
Insulin	100	48
Noninsulin injections (e.g., Bydureon [exenatide extended release], Byetta [exenatide], Victoza [liraglutide], or Symlin [pramlintide])	2	13
Pills	4	73
Diet and exercise	<1	8

TABLE 5. Most Frequently Reported Impacts of Diabetes on Basic Aspects of Life

	Respondents With Type 1 Diabetes (% "negative impact"/% "serious negative impact")	Respondents With Type 2 Diabetes (% "negative impact"/% "serious negative impact")
Planning for the future	72/25	54/17
Ability to take on life's challenges	67/16	50/13
Self-confidence	66/20	48/14
Success at work or school	67/15	28/8
Family relationships	43/6	35/6
Intimacy/sexual relationships	42/12	43/19
Dating and romance	36/9	24/9
Relationships with coworkers or fellow students	39/5	17/2
Building and maintaining friendships	35/5	22/4

TABLE 6. Respondents' Rankings of the Five Biggest Barriers to Diabetes Management*

	Respondents With Type 1 Diabetes (% of 14,095 total mentions)	Respondents With Type 2 Diabetes (% of 3,366 total mentions)
First most frequently mentioned barrier	Cost of medications and devices and care (24)	Difficulty sticking to diet and exercise (23)
Second most frequently mentioned barrier	Stress involved in managing diabetes (23)	Cost of medications and devices and care (18)
Third most frequently mentioned barrier	Side effects from diabetes medications, such as hypoglycemia and weight gain (14)	Stress involved in managing diabetes (15)
Fourth most frequently mentioned barrier	Difficulty sticking to diet and exercise (8)	Side effects from diabetes medications, such as hypoglycemia and weight gain (13)
Fifth most frequently mentioned barrier	Managing the numbers of pills/insulin doses you have to take each day (7)	Managing the numbers of pills/insulin doses you have to take each day (6)

*Choices included managing the number of pills and/or insulin doses you have to take each day, side effects from diabetes medications (for example, hypoglycemia, weight gain, etc.), lack of adequate training on taking medications and using devices, drug and medication device labeling that is not clear or easy to understand, not being able to find a combination of medications that works for you personally, stress involved in managing diabetes, difficulty sticking to diet and exercise, lack of support from those around you (friends, family, work), stigma associated with diabetes, and fear surrounding diabetes.

or school (67%). Respondents with type 2 diabetes reported being only slightly less affected by diabetes; 50% reported a negative impact on their ability to take on life's challenges, and 48% reported a negative impact

on self-confidence. The only category in which respondents with type 2 diabetes reported feeling more negatively affected than those with type 1 diabetes was in intimacy/sexual relationships (42 vs. 43% reporting

a negative impact). Diabetes had a negative impact on family relationships for 43% of those with type 1 diabetes and 35% of those with type 2 respondents. In several categories, diabetes had a "serious" negative

TABLE 7. Respondents’ Rankings of the Ways in Which Diabetes Has the Greatest Impact on Day-to-Day Life*

	Respondents With Type 1 Diabetes (% of 15,966 total mentions)	Respondents With Type 2 Diabetes (% of 3,720 total mentions)
First greatest impact	The time commitment and burden good diabetes management takes (23%)	Managing your diet (19%)
Second greatest impact	Difficulty managing blood glucose (23%)	Managing your weight (18%)
Third greatest impact	Hypoglycemia (14%)	Getting exercise (14%)
Fourth greatest impact	Other people’s perceptions and opinions about diabetes (8%)	Difficulty managing your blood glucose (14%)
Fifth greatest impact	Focusing on work or school (7%)	The time commitment and burden good diabetes management takes (13%)

*Choices included difficulty managing your blood glucose, hypoglycemia (low blood glucose), the time commitment and burden good diabetes management takes, managing your diet, focusing on work or school, getting exercise, sticking to the diabetes medication routine your doctor recommends, managing your weight (losing weight or keeping weight off), other people’s perceptions and opinions about diabetes, getting enough sleep or sleep problems, and other.

impact on life in more than 10% of respondents, including planning for the future, ability to take on life’s challenges, self-confidence, and intimacy/sexual relationships.

To identify areas for improvement for the FDA and other stakeholders, the survey then asked patients to rank barriers to diabetes management (Table 6) and the ways in which diabetes has the greatest impact on day-to-day life (Table 7). Cost emerged as a key barrier to optimal diabetes care; nearly one in four respondents with type 1 diabetes and one in five of those with type 2 diabetes endorsed it as an obstacle. For individuals with type 1 diabetes, cost was the most frequently cited barrier (24% of all mentions), and stress and side effects from medications (e.g., hypoglycemia and weight gain) were the next two most frequently mentioned barriers (23 and 14% of all mentions, respectively). For type 2 respondents, the number one most frequently mentioned barrier was difficulty sticking to diet and exercise (23%), followed by cost (18%), stress (15%), and side effects of medications (13%).

Factors having the greatest impact on day-to-day life differed by respondents’ type of diabetes. Among those with type 1 diabetes, difficulty managing blood glucose and the time commitment/burden of good diabetes management rose to the top (both

with 23% of all mentions). Among those with type 2 diabetes, managing diet and weight were the most frequently ranked factors that affected daily life (19 and 18% of all mentions, respectively). Rounding out the top five for people with type 1 diabetes were hypoglycemia (14%), perceptions and opinions of others about diabetes (8%), and focusing on work or school (7%). For respondents with type 2 diabetes the third, fourth, and fifth most cited factors were getting exercise (14%), difficulty managing blood glucose (14%), and the time commitment/burden of good diabetes management (13%), respectively.

In the more than 4,500 open-ended comments, patients pointed to very high levels of stress, therapy burden, and time commitment associated with diabetes management. Many individuals advocated for the development of simpler therapies that require less thought, medications (such as insulins) that had less associated weight gain and hypoglycemic side effects, and simpler and more effective CGM devices and automated insulin delivery systems. Many respondents expressed concerns about the costs of available therapies and technologies (Supplementary Appendix A).

Discussion

This online survey demonstrates that diabetes has a wide-ranging nega-

tive impact on many patients’ lives, extending far beyond the effects on glycemic control and diabetes-related health. Patients experience added stress and vulnerability to stressful life events, time demands, and effects on work or school, future planning, self-confidence, and social interactions. Although diabetes therapies and management technologies have improved dramatically, they are still falling short of addressing the wide-ranging impact of diabetes on quality of life.

It will be crucial for new therapies and technologies to measure and strive to reduce these real-life, day-to-day negative factors, which are arguably just as important as A1C. For example, a therapy that reduces A1C but causes significant hypoglycemia or one that boosts time-in-range blood glucose but is expensive or cumbersome to use would not be ideal. Diabetes invades all aspects of life and therefore should be treated as a holistic condition rather than as merely a disease of poorly regulated glycemia.

Our results also suggest that in an aware and engaged population, the cost of medications, devices, and care remains a major barrier to successful diabetes management. Cost was among the top two most frequently cited barriers for all respondents regardless of the type of diabetes they had (Table 6). Improvements in available treatments and devices

will be meaningless unless they are made accessible and affordable. Our data are in line with those found in the work of Tanenbaum et al. (2). Even among the highly engaged T1D Exchange registry participants whom they surveyed, most respondents (57–61%) endorsed cost/insurance coverage as a barrier to device use, far above other barriers.

Our data also suggest that people with type 1 diabetes face challenges that are different from those of people with type 2 diabetes, although there is significant overlap in barriers to management and effects of diabetes on daily life. In our survey, respondents with type 2 diabetes were largely affected by lifestyle modifications such as managing diet, weight, and exercise, whereas those with type 1 diabetes reported more impact from the highs and lows of managing blood glucose, hypoglycemia, and social effects. However, both groups reported serious negative consequences on global aspects of life such as planning for the future, ability to take on life's challenges, and self-confidence. Therapies, devices, and tools need to prioritize giving patients their lives back by reducing worry, stress, and time demands and increasing energy, discretion, and the ability to live one's life. Moreover, we believe that these survey results call for more research into how family members and caregivers can remain supportive of the unmet needs of patients with diabetes.

Limitations of this survey include self-reporting of all data and a non-representative sample of people with diabetes in the United States. Caregivers of children with diabetes (<18 years of age) responded on behalf of their children, and their answers may not have accurately reflected their children's feelings.

The diaTribe Foundation helped to spearhead the patient-centered "Outcomes Beyond A1C" movement to encourage the FDA and other stakeholders to consider out-

come metrics such as time-in-range, hypoglycemia, and patient-reported quality of life in the development, assessment, and labeling of diabetes therapies and devices. The foundation hosted a landmark FDA Center for Drug Evaluation and Research (CDER) workshop titled "Diabetes Outcome Measures Beyond Hemoglobin A1C" on 29 August 2016 and a follow-up meeting on 21 July 2017 titled "Glycemic Outcomes Beyond A1C: Standardization & Implementation." Both meetings invoked the patients' perspective and dQ&A survey data to share with FDA information regarding what patients would like their diabetes treatments to achieve. Before these meetings, The diaTribe Foundation presented these data at a 3 November 2014 FDA workshop on "Unmet Needs in Diabetes" and presented on outcomes beyond A1C at a 2012 Drug Information Association gathering.

The device side of the FDA (its Center for Devices and Radiological Health [CDRH]) has recognized the need to consider patients' perspectives fully, including expanded outcomes beyond A1C (e.g., time-in-range and hypoglycemia). The CDRH review of Medtronic's MiniMed 670G hybrid closed-loop system is one example of the agency's willingness to listen to patients. Immediately after the 3-month, single-arm, 670G pivotal trial (designed for safety), more than 80 trial participants wrote to the FDA asking if they could stay on the investigational system while it was under review. The agency granted these users permission and quickly approved the product within an unprecedented timeframe of about 3 months. The CDRH also incorporated input from JDRF and other groups on artificial pancreas guidance and embraced the patients' perspective in ruling that patients could dose insulin directly from therapeutic CGM. We hope the CDRH's focus on patients and sense of urgency extends to other devices and also to the drug side of FDA (the

CDER). There is still room for drug therapies to improve on measuring outcomes beyond A1C and incorporating such findings into product labels and indications.

Duality of Interest

This dQ&A Market Research study was commissioned by The diaTribe Foundation. The authors from Close Concerns (D.G., B.L., A.B., and K.L.C.) report that multiple academic institutions, government bodies, and pharmaceutical and medical device companies in the diabetes field subscribe to the company's fee-based newsletter, *Closer Look*. The authors from The diaTribe Foundation (N.L., A.B., and K.L.C.) report that the organization receives contributions from some pharmaceutical and device companies in the diabetes field. The authors from dQ&A Market Research, Inc., (P.Y. and R.W.) report that its clients include several pharmaceutical and medical device companies in the diabetes field. No other potential conflicts of interest relevant to this article were reported.

Author Contributions

D.G. drafted the manuscript. B.L. drafted and edited the manuscript. N.L. and R.W. researched and collected data and reviewed the manuscript. P.Y. researched and collected data. A.B. and K.L.C. reviewed and edited the manuscript. K.L.C. is the guarantor of this work, and, as such, had full access to all the data in the study and takes full responsibility for the integrity of the data and the accuracy of the data analysis.

Prior Presentation

A large portion of the data in this article was presented in a poster titled "Patient Perspectives on the Daily Impact of Diabetes Management" (Abstract 1246-P) at the ADA's 76th Scientific Sessions in New Orleans, La., 10–14 June 2016. Portions of the study findings were also presented at an FDA-Patient Dialogue on Unmet Needs in Diabetes in Silver Spring, Md., 3 November 2014.

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