

Patients With Type 2 Diabetes Are Willing to Do More to Overcome Therapeutic Inertia: Results From a Double-Blind Survey

Steven V. Edelman, 1 Richard Wood, 2 Michelle Roberts, 3 and Jay H. Shubrook 4

We performed a survey of 305 patients with type 2 diabetes receiving basal insulin and 240 physicians to measure key contrasts and similarities in patients' preferences and providers' beliefs and perceptions regarding insulin use. Many patients reported being more frustrated with their lack of treatment progress than physicians were aware of. Patients were also more likely to say they would do more than their physicians believed they would to better manage their diabetes. Identifying priorities and setting clear goals and timelines for achieving glycemic control could provide an opportunity to address these differences and reduce patients' frustration.

In patients with type 2 diabetes, timely and effective glycemic management reduces the risk for microvascular and macrovascular complications (1,2). Treatment guidelines suggest a combination of lifestyle changes and antihyperglycemic medication to maintain the recommended A1C goal of <7.0% (3,4). However, despite availability of a wide variety of antihyperglycemic agents, 53–64% of patients fail to achieve this goal (5,6). Studies indicate that both insulin-experienced and insulin-naive patients in routine clinical care often have blood glucose levels that exceed their targets. This situation has remained generally unchanged throughout the past decade (6–8).

Failure to reach glycemic targets may be the result of therapeutic or clinical inertia, whereby a patient's therapy may not be intensified in a timely manner (9,10). Delays in treatment intensification such as insulin dose titration have been reported in several studies (9–11). A report by Khunti et al. (9) found that only 31% of eligible patients received intensified treatment, and the median time from

initiation of basal insulin to treatment intensification was 4.3 years.

Diabetes management is often complex, and a number of factors related to physicians, patients, and health systems can result in therapeutic inertia (12-14). A disconnect may exist between patients and their physicians about the importance of glycemic control and perceived barriers to treatment escalation, including patient adherence, impact on daily life, and side effects (13,14). Increasing awareness of this disconnect is necessary to overcome these barriers and improve the care of patients with type 2 diabetes. To this end, we performed a survey of U.S. physicians and patients with type 2 diabetes who had not reached their A1C goal while receiving basal insulin therapy. The aim of the survey was to measure key similarities and contrasts between the perceptions of patients and physicians regarding diabetes management. Here, we present results of this survey evaluating treatment priorities, goal-setting, and timing expectations; therapy changes; and patients' frustration and emotional responses.

Design and Methods

The study consisted of two qualitative surveys for instrument design (results not reported), followed by quantitative surveys. The two qualitative studies (involving 20 patients and their spouses/partners, 9 endocrinologists, and 8 primary care physicians [PCPs]) were performed to refine the survey design and language and test for risk of social desirability bias in patient responses, particularly around willingness to try new medications. Social desirability bias describes the

¹University of California San Diego Veterans Affairs Medical Center, San Diego, CA; ²dQ&A, San Francisco, CA; ³Sanofi US, Bridgewater, NJ; ⁴College of Osteopathic Medicine, Touro University California, Vallejo, CA

Corresponding author: Steven V. Edelman, svedelman@vapop.ucsd.edu https://doi.org/10.2337/cd19-0067

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tendency of respondents to answer questions in a manner that might be viewed favorably by others.

Participants

Quantitative surveys of attitudes toward the addition of insulin for type 2 diabetes treatment were sent to patients and physicians in the United States. Eligible patients were ≥ 18 years of age, diagnosed with type 2 diabetes for ≥ 12 months, and on basal insulin for ≥ 12 months (with or without oral antidiabetic drugs [OADs]). Patients were excluded if they were currently taking prandial insulin, other injectable antidiabetic medications, or had an A1C <7.4%. Patients were recruited from the dQ&A Patient Panel (an opted-in panel of 12,000 people with diabetes; San Francisco, CA) and from a large national consumer research panel.

Eligible physicians (PCPs and endocrinologists) had been in post-residency practice for 2-35 years, were board-certified, and were not based at a hospital or Kaiser Permanente practice per market research restrictions with pharmaceutical companies. PCPs treated ≥50 patients with type 2 diabetes per month, of whom ≥10 received insulin therapy. Endocrinologists treated ≥80 patients with type 2 diabetes per month, of whom ≥30 received insulin therapy. Physicians were excluded if they had completed another survey on longacting insulin in the past month, participated as a clinical investigator, or practiced in Maine, Minnesota, or Vermont per state laws restricting physician honoraria for market research. Samples were sourced independently (i.e., patients were not necessarily assigned to the included physicians).

Data Collection

Online quantitative surveys containing 67 questions were conducted for patients during 5–11 June 2018 (median completion time 13 minutes); physicians completed surveys containing 61 questions during 2–17 July 2018 (median completion time 17 minutes). Question types included multiple choice, short answers using free text, yes/no, and 4-point and 10-point response scales. Responses were anonymous, and respondents were not made aware of the origin or sponsor of the surveys.

Data Analysis

Responses were analyzed descriptively with percentages of patients and physicians providing each response using the MarketSight data analytics tool (MarketSight, Newton, MA). Descriptive comparisons were made between responses of patients and physicians to the same

TABLE 1 Patient and Physician Demographic Characteristics

| Characteristics | |
|------------------------------------|--------------------------------|
| Characteristic | Patients, $\%$ ($n = 305$) |
| Age, years | |
| <40 | 22 |
| 40-49 | 17 |
| 50-59 | 22 |
| ≥60 | 39 |
| Sex | |
| Male | 43 |
| Female | 57 |
| Race/ethnicity | |
| White | 77 |
| Black | 8 |
| Hispanic Asian | 14 1 |
| | 1 |
| Metro type | 24 |
| Urban Suburban | 34 41 |
| Rural | 25 |
| | 23 |
| U.S. geographic region | 16 |
| Northeast Midwest | 23 |
| South | 23 44 |
| West | 17 |
| Insurance (multi-response) | |
| Private/employer | 41 |
| Private/self-paid | 11 |
| Medicare | 41 |
| Medicaid | 16 |
| Veterans | 6 |
| No insurance | 4 |
| Other | 2 |
| Characteristic | Physicians, $\%$ ($n = 240$) |
| Specialty | |
| PCP (n = 160) | 67 |
| Endocrinologist ($n = 80$) | 33 |
| Practice years post-residency 2-10 | 28 |
| 11-20 | 28 44 |
| 21-35 | 28 |
| Practice setting | <u> </u> |
| Office-based practice or clinic | 45 |
| Private group practice | 46 |
| Private independent practice | 10 |
| | |

question as a measure of discord in perceptions. Statistical comparisons were made using z tests at the 95% CI.

Ethical Considerations

Metro type

Urban

Rural

Suburban

Respondents agreed to standard questions on adverse event reporting, data integrity, confidentiality, nonpublic information, and employer participation approval.

33

50

17

Respondents gave consent at the start of the survey and had the option to exit at that point. Institutional review board approval was not required because this was considered a market research study.

Results

Demographic Characteristics

Respondents included 305 patients and 240 physicians (160 PCPs and 80 endocrinologists). The majority of patients (57%) were female, 77% were white, and 39% were \geq 60 years (Table 1). Overall, 44% of physicians had been in practice for 11–20 years, 45% were in an office-based practice, 46% were in a private group practice, and 50% were located in a suburban area (Table 1).

Diabetes Management Priorities

Physicians and patients were asked to choose their top three diabetes management priorities from a list (up to three responses; Table 2). "Maintaining your A1C goal over the long term" was a key priority for both patients and physicians. However, physicians were more likely to choose "making sure you can afford your medication" and "avoiding side effects (hypoglycemia)" as key goals (P < 0.0001 for both). Endocrinologists selected "achieving goal quickly" more often than PCPs (36 vs. 22%), and PCPs selected "taking your medications as prescribed" as a key goal more often than endocrinologists (30 vs. 18%).

Setting Targets and Expectations for A1C Goals

A large percentage of both physicians and patients reported giving/receiving a specific A1C goal when

initiating basal insulin (Figure 1). Patients were less likely than physicians to recall a time frame provided for reaching this goal.

Patients reporting physician-stated goal timing and all physicians were asked about physician-stated and patientexpected timing to reach their A1C goal after starting basal insulin. Similar proportions of patients and physicians reported that they expected themselves/their patients to reach this goal within 6-12 months; 37% of patients reported that this was a physician-stated expectation, and 36% reported this as a personal expectation. Similarly, 56% of physicians reported this as a physician-stated expectation, and 37% estimated this to be a personal expectation of patients. However, patients were more pessimistic than physicians about how quickly they could achieve glycemic control after basal insulin initiation, with 28% of patients personally expecting to reach their goal within 1-5 years and 10% stating that they did not expect to ever reach their goal. Only 2% of physicians estimated that their patients did not expect to achieve their goal.

Actual Time to Reach A1C Goal and Perceived Diabetes Control

Nearly half of patients (49%) reported not having reached goal. In patients who did reach their goal, 3–6 months was most frequently mentioned by both patients (16%) and physicians (27%) as the actual amount of time to reach goal. The proportion of patients who achieved targets within 12 months, as measured by their predetermined goal, was reported to be far higher by physicians than by patients (85 vs. 44%).

| TABLE 2 Diabetes Management Priorities of Patients and Physicians for Patients on Basal Insulin | | | |
|---|-------------|---------------|--|
| Priorities (up to three responses) | Patients, % | Physicians, % | |
| Maintaining your A1C goal over the long term | 62 | 45 | |
| Staying healthy for your family | 44 | 28 | |
| Not gaining weight | 43 | 35 | |
| Taking your medications as prescribed | 36 | 26 | |
| Making sure you can afford your medication | 29 | 53 | |
| Avoiding side effects (hypoglycemia) | 27 | 55 | |
| Achieving your A1C goal quickly | 23 | 27 | |
| Being able to keep working | 13 | 16 | |
| Maintaining an active social life | 13 | 14 | |
| Other | 1 | 1 | |

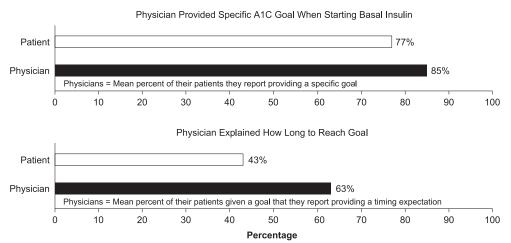


FIGURE 1 Patients and physicians reporting discussing A1C goalsetting and timing expectations at basal insulin initiation.

When asked about their patients' overall diabetes control, physicians reported that 4 in 10 patients believed their diabetes was controlled when it was not; this number was higher among PCPs than endocrinologists (44 vs. 36%). Physicians estimated that almost half of patients were actually in control (PCPs: 53%; endocrinologists: 42%). Among patients on basal insulin for more than 12 months with an A1C >7.4%, >60% thought their diabetes was either well controlled or somewhat controlled. About one-third of these patients thought they had achieved their goal, which was skewed toward those with a baseline A1C <8%.

Patient Willingness to Make Changes to Reach Goals Faster

More than 60% of patients wanted to reach their A1C goal faster, which matched physicians' perceptions of patients' preference; PCPs were more likely than endocrinologists to select "patient wanted to achieve A1C goal at the speed described" (35 vs. 15%). Ninety-three percent of patients identified as "very willing" or "somewhat willing" to do more to achieve better control, almost twice as many as physicians believed would be willing to do more (56%, P < 0.0001) (Figure 2); there were no significant differences between PCPs and endocrinologists in this regard. Similar results were reported for specific questions about increasing physician visits, making medication changes, and trying a different injectable medication (P < 0.01 for all).

Titration and Change in Therapy

Patients who had not yet reached their A1C goal after 12 months on basal insulin were asked how much longer dosage adjustments could be made before additional medications were needed to reach their goal. Physicians

were asked how much longer basal insulin could be effectively titrated without adding other medications while patients were trying to reach their A1C goal. Sixty percent of physicians believed that patients who had already gone for 1 year without reaching goal could attain their target in another 6 months; about 40% said they could continue titrating for ≥1 year to achieve the goal. Fewer than 30% of patients selected another 6 months, but >40% selected "don't know."

Physicians were asked the maximum daily units of basal insulin they would set for titration using a free text field. Twenty-five percent of all physicians considered a maximum daily basal insulin dose to be 100 units (mean and median). Endocrinologists considered slightly higher doses compared with PCPs (110 vs. 95 units). Twenty-six percent of physicians considered maximum basal insulin doses of >100 units, with 12% considering a maximum of \ge 200 units.

Patient Frustration and Discontinuation

More than 60% of patients reported frustration about not reaching their A1C goal, whereas physicians estimated this to occur in only 36% of patients. Patients reported high frustration at first diagnosis, which decreased through the first 3 months of treatment and then increased over time to peak at 12 months as goals were not reached (Figure 3). At 12 months, physicians estimated their patients' frustration to be at higher levels than those reported by patients themselves.

About two-thirds of patients strongly or somewhat agreed that not achieving their goal had a negative effect on their emotional well-being and happiness; ~40% agreed that not achieving their goal had a negative effect on their social and family life. Overall, 22% of patients stated that

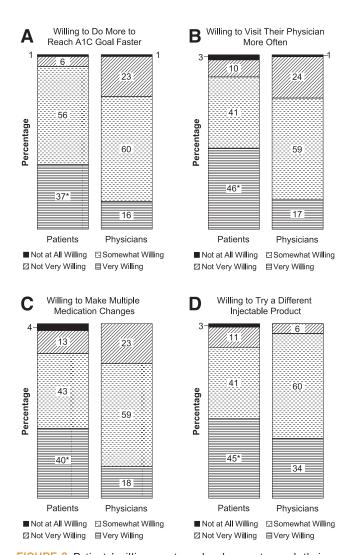


FIGURE 2 Patients' willingness to make changes to reach their A1C goal. *P <0.01. Not all percentages sum to 100 because of rounding.

they discontinued basal insulin without consulting their physician, whereas physicians estimated that 16% of patients discontinued without notice; cost was the main reason patients cited for discontinuation (54%), followed by side effects (37%) and not making progress or reaching goal fast enough (18%). Fourteen percent of patients reported that they discontinued basal insulin after consulting their physician, whereas physicians reported that 30% of patients discontinued after consultation.

Discussion

To our knowledge, the results of this study are the first to present perspectives from both patients with type 2 diabetes and physicians; these findings highlight key differences in patients' and

physicians' beliefs and perceptions and differing expectations regarding priorities and timelines.

Communication between patients and their physicians is a key component of patient engagement, empowering them to manage their diabetes effectively (15–17). Communication also allows physicians to consider a more multifaceted approach to each patient's management given that guidelines from the American Diabetes Association (ADA), the American Association of Clinical Endocrinologists, and the European Association for the Study of Diabetes all recommend tailoring therapy to individual patients, with the opportunity to re-evaluate at regular intervals (4,18,19).

Patients included in this survey prioritized achieving their A1C goal quickly, which was aligned with physicians' treatment goals. However, patients were willing to do more than physicians estimated to achieve this goal, with a high percentage of patients willing to make multiple changes to their treatment regimen and to try a different injectable product versus physicians' perceptions of what patients were willing to do. This finding is important given the minimal improvement during the past decade in the number of patients who reach goal (6), as well as the risks for complications associated with lack of glycemic control (1).

Overbasalization, or detrimental up-titration of basal insulin without attaining A1C targets, is a serious concern when managing type 2 diabetes and may require changes in medication and other resources to avoid adverse events (20). Even if patients had not reached their control target after 1 year, the majority of physicians believed that the target could be reached within an additional 6 months of continued up-titration of basal insulin. However, it was common among this group to wait 18 months to make changes. Most physicians reported setting a maximum basal insulin dose of 100 units, and 12% of physicians reported ≥200 units, despite the high percentage of patients reporting a willingness to try a different injectable and make multiple changes to their treatment to reach their A1C goals faster.

ADA guidelines recommend therapy escalation within 3 months of failure to achieve A1C targets (3). However, previous research has reported that the median delay for patients on basal insulin with blood glucose levels exceeding an A1C target of 7.5% was 3.7 years (9). Failure to set clear goals has been identified as an important factor in clinical inertia and may result in a lack of clarity around A1C targets, timelines for achieving targets, and potential medication changes (15).

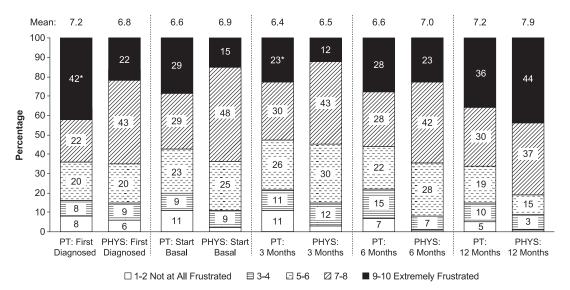


FIGURE 3 Patients' frustration levels over time. PHYS, physician; PT, patient. *P < 0.0001. Not all percentages sum to 100 because of rounding.

Physicians may be overly optimistic when estimating their patients' glycemic control. Physicians reported that 49% of their patients had reached their A1C goal; physicians also stated that ~40% of patients believed they were adequately managing their diabetes when they were not. A systematic review of 218 randomized trials reported that 39% of patients with type 2 diabetes treated with basal insulin actually achieve an A1C < 7.0% (21). A study of real-world data from a large U.S. electronic medical record database found that 38% of patients achieved an A1C target of <7% within 12 months of initiating basal insulin, and only 8% more achieved that target after 24 months (22). Similarly, a retrospective study using a European database found that 20–27% of patients reached an A1C <7.0% after 2 years of basal insulin therapy (23).

Lack of goal attainment within the expected time frame likely leads to patient frustration. In this study, patients' reported frustration was misaligned with physicians' estimation of patients' feelings and increased as time progressed. The impacts of this frustration on patients' well-being, happiness, families, and social lives are crucial because diabetes-related distress and unsatisfactory patient-physician interactions are associated with inadequate glycemic control (24). Multiple visits may be required before patients express themselves, depending on their relationship and degree of openness with their physician, their perception of being heard, and their ability to ask questions and listen to answers. Competing demands during primary care visits may also affect the decision to intensify treatment; a study of

primary care appointments for patients with type 2 diabetes with A1C >7% revealed that medication change was less likely as the number of patient concerns increased (25).

Limitations

Limitations of this study include the potential for social desirability bias; however, partner interviews were performed to address this concern as much as possible. Physicians may also not see the same types of engaged or candid patients as those who participated in this survey, but these findings still indicate an existing disconnect. Patients' frustration levels may have also been influenced by lack of titration of OADs or changes in A1C over time, for which data were not collected.

Conclusion

Although the number of glucose-lowering treatment options for type 2 diabetes has increased, the proportion of patients maintaining adequate glycemic management has not improved in the past decade (6). The results of this study reveal that a large proportion of patients are frustrated with their glycemic management and are often willing to do more to attain their A1C goal than physicians may realize. Future efforts should aim to improve communication between physicians and patients, particularly when patients are beginning therapy, to manage expectations around goals and timelines and potentially avoid disconnects between expectations and outcomes that result in overbasalization.

Further medical education should be provided to share patients' reported needs and engage providers to optimize care.

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DUALITY OF INTEREST

S.V.E. is a member of medical advisory panels for Eli Lilly, Novo Nordisk, and Sanofi. R.W. is an employee of dQ&A Market Research, Inc. M.R. is an employee of Sanofi US, Inc. J.H.S. sits on advisory panels for Bayer, Eli Lilly, Intarcia, Novo Nordisk, and Sanofi.

AUTHOR CONTRIBUTIONS

R.W. collected and analyzed the data. All authors contributed to discussion and reviewed/edited the manuscript. R.W. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

PREVIOUS PRESENTATION

Results from this study were presented as posters at the ADA's 78th Scientific Sessions, 22–26 June 2018, in Orlando, FL, and 79th Scientific Sessions, 7–11 June 2019, in San Francisco, CA.

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