Specialist-Led Diabetes Registries and Prevalence of Poor Glycemic Control in Type 2 Diabetes: The Diabetes Registry Outcomes Project for A1C Reduction (DROP A1C)

Ronnie Aronson,[1] Naomi Orzech,[1] Chenglin Ye,[2] Ruth E. Brown,[1] Ronald Goldenberg,[1] and Vivien Brown[3]

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OBJECTIVE

To highlight the utility of a large patient registry to identify functionally refractory patients (persistent HbA_{1c} ≥75 mmol/mol [9.0%]) with type 2 diabetes, identify their barriers to glycemic control, and implement barrier-specific care path strategies to improve glycemic control.

RESEARCH DESIGN AND METHODS

A working group developed a structured tool to optimize the collection of information on barriers to glycemic control and designed structured care paths to address each barrier. Participants were identified from a large Canadian registry and were assigned to a certified diabetes educator (CDE) as their case manager for a 12-month period to coordinate assessment of their barriers and to implement appropriate care path strategies. The primary outcome measure was the mean change in HbA_{1c} from baseline at 12 months.

RESULTS

Overall, 3,662 refractory patients were initially identified of whom 1,379 were eligible for inclusion and 155 enrolled. The most common barrier categories participants identified were psychological/support (93%), socioeconomic (87%), and accessibility (82%), with high concordance (75–94%) between participant and CDE. No specific barriers were predictive of hyperglycemia. After implementation of barrier-specific care paths, the mean reduction in HbA_{1c} at 12 months was 17 mmol/mol (1.5%; $P < 0.01$ vs. baseline) versus only 5 mmol/mol (0.5%) in the source cohort ($n = 966$) who continued with standard care. The incidence of severe hypoglycemia did not change significantly during the study.

CONCLUSIONS

In registry-identified hyperglycemic patients with type 2 diabetes, the use of barrier-specific care paths significantly improved glycemic control in otherwise refractory patients with persistently elevated HbA_{1c}. Further studies using this strategy in other practice settings are warranted.

[1]LMC Diabetes & Endocrinology, Toronto, Ontario, Canada
[2]Oncology Biostatistics, Genentech, San Francisco, CA
[3]University of Toronto, Toronto, Ontario, Canada

Corresponding author: Ronnie Aronson, ronnie.aronson@lmc.ca.

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Optimal self-care of diabetes requires a number of skills and self-management behaviors. Despite continual improvements in treatment options, population audits in Canada (1), the U.S. (2), and Europe (3) have consistently found low treatment goal achievement rates.

Treatment in specialist practices has been shown to improve 3–5-year cardiovascular outcomes (4) and to offer more timely health surveillance (5) but may see patients with longer disease duration, more complex therapy, and more severe complications. A recent review of specialist-led practice registries found a higher mean glycated hemoglobin (HbA_{1c}) with 22–55% of patients uncontrolled (6). In the largest specialist-led registry (n = 10,590), 16.1% had an HbA_{1c} level $\geq$75 mmol/mol (9.0%), despite active participation in comprehensive diabetes care programs (6). This poorly studied group may have a higher mortality risk than the general diabetes population (7).

The Diabetes Registry Outcomes Project for A1C Reduction (DROP A1C) began in January 2011 and was designed to examine functionally refractory patients within specialist practices. A representative working group of Canadian health care professionals (HCPs) experienced in the care of refractory patients met monthly to *1*) identify their clinical characteristics, *2*) identify features predictive of potential improvement, *3*) develop tools for HCPs to assess their potential barriers, and *4*) develop structured care paths aligned to these barriers. The working group included physician specialists in primary care, endocrinology, psychiatry, and psychoanalysis and HCPs in the disciplines of social work, nursing, and nutrition, each experienced in the care of diabetes and related comorbidities. The working group developed the Barriers to Care Questionnaire (Supplementary Appendix 1) to identify the particular barriers among this refractory cohort. Care paths specific to each strategy underwent a trial study between July and November 2011 (Supplementary Appendices 2*A*–*E*).

The population chosen was a clinic group within the Canadian public health care system, which provides ongoing care and education to patients referred by primary care physicians based on Canadian clinical practice guidelines (LMC Diabetes & Endocrinology [LMC]). The LMC registry (n = 10,590) (Supplementary Appendix 3) has been described in detail, including a refractory component of 16.1% (6), which served as the analysis and intervention cohort for the DROP A1C study series.

RESEARCH DESIGN AND METHODS

Study Design and Participants

Consecutive eligible patients were enrolled during routinely scheduled visits (or by telephone if there was no immediate scheduled visit) at seven LMC sites in Ontario between November 2011 and December 2012. The LMC database was screened for men and women between 18 and 80 years of age with type 2 diabetes receiving two or more glucose-lowering therapies, having an HbA_{1c} $\geq$75 mmol/mol (9.0%) at baseline, and receiving care from LMC for $>$6 months.

At their baseline visit, participants were assigned a certified diabetes educator (CDE) who functioned as their case manager throughout the study period. All study CDE staff were specifically trained and experienced in motivational interviewing and in the elements of cognitive behavioral counseling. They were also trained in the five categories of the study assessment tools: comorbidity, accessibility, culture, socioeconomic, and psychological/support. Staff also received workshop training in the care paths, organization, counseling, and patient-focused counseling supplemented by weekly case rounds and monthly training in counseling skills.

Measures

Participants and CDEs both completed the LMC Barriers to Care Questionnaire (Supplementary Appendix 1), which includes 31 questions and is organized in traditional patient-centered categories. CDEs conducted further interviews to obtain more insight into the participants and to screen for additional barriers. Participants also completed the Stanford Diabetes Self-Efficacy Scale (8), Stanford Health Distress Scale (9,10), and the EQ-5D Health Perception Questionnaire (11,12). Data collected from all questionnaires were used to guide individual care path selection.

Interventions

Structured care paths (Supplementary Appendices 2*A*–*E*) developed by the working team to address participant barriers were applied based on the barriers identified. Individualized office and telephone visit plans spanned the 12-month intervention period; there was no preset number or frequency or location of visits. Specialist and primary physician care continued independently on the basis of the participant's prior care pattern. At each study visit, the plan was reassessed based on active barriers, hypoglycemia, and therapy changes. Counseling was individualized within each care path for each barrier identified. For example, the psychological/support care path (Supplementary Appendix 2*A*) included interventions such as referral to mental health care programs link to self-management programs and/or additional physician visits.

Socioeconomic barriers included level of education, prior diabetes education, workplace obstacles, and financial limitations. The care path (Supplementary Appendix 2*B*) included personalized teaching, workplace support, cost-effective meal planning, and access to social support services.

Examples of accessibility barriers were transportation, outstanding administrative fees, and poor communication. The care path (Supplementary Appendix 2*C*) used any of the following: home visits, remote consultations (telephone/e-mail), visit flexibility, alternate CDE involvement, organizing transportation, forgiveness of prior invoices, and life coaching.

Comorbidity barriers included difficulty managing multiple disorders and appointments, and feeling overwhelmed. Common solutions (Supplementary Appendix 2*D*) included scheduling, organizing support from family and community, and identifying internal motivators.

Cultural barriers often centered on language or ethnic beliefs. Care path examples (Supplementary Appendix 2*E*) were live translation, resource translation, and regional language–based programs.

Assessments

The primary outcome was the mean change in HbA_{1c} from baseline in the intervention cohort. Additionally, refractory patients from the original source cohort who did not receive the intervention and who had an evaluable HbA_{1c} at baseline and 12 months (n = 966) comprised a comparison group. Secondary outcomes were the proportion of participants whose HbA_{1c} decreased by $>$11 mmol/mol (1%); the proportion achieving HbA_{1c} $<$53 mmol/mol (7.0%), 53 to $<$64 mmol/mol (7.0% to $<$8.0), and 64–75 mmol/mol (8.0–9.0%); and

changes in mean BMI, waist circumference, blood pressure, lipid parameters, and urinary albumin excretion from baseline. Weekly hypoglycemia incidence was captured at baseline and 6 and 12 months. Hypoglycemia was considered mild/moderate if blood glucose was <4.0 mmol/L and severe if it was <2.8 mmol/L; severe hypoglycemia was also defined as requiring the assistance of another person.

The study was conducted in accordance with Good Clinical Practice, the International Conference on Harmonization, and the Declaration of Helsinki. An independent review board approved the protocol. Each patient gave written informed consent.

Statistical Analysis

Analyses were based on an intention-to-treat cohort (all patients signed the informed consent form, regardless of whether they completed the intervention). All outcome analyses include patients with evaluable baseline and outcome data. Paired *t* tests were used to compare changes in continuous variables from baseline to 6 or 12 months; McNemar test was used to compare corresponding changes in categorical variables. As an exploratory analysis, changes in the incidence of hypoglycemia from baseline to 6 or 12 months were compared by nonparametric Wilcoxon signed rank tests. The proportions of participants reporting health problems on the EQ-5D Health Perception Questionnaire were analyzed by means of McNemar test.

Correlations between the reported barriers and HbA_{1c} outcomes were investigated mainly with descriptive statistics only; however, clinically important correlations were quantified by linear regression analysis and Pearson correlation coefficients. All statistical analyses were performed using SAS 9.2 software (SAS Institute, Cary, NC), and the significance level was set at 5%.

Table 1—Baseline demographics

	Intervention cohort (*n* = 155)	Source cohort (*n* = 1,363)
Age (years)	56.3 (10.0)	55.3 (9.7)
Men (%)	80 (52)	701 (51)
Duration of diabetes (years)	17.4 (7.0)*	12.2 (7.7)
Duration with LMC (years)	3.6 (2.3)	3.4 (2.5)
HbA_{1c} (mmol/mol)	96 (15.3)*	91 (15.3)
HbA_{1c} (%)	10.9 (1.4)	10.5 (1.4)
Weight (kg)	91.0 (25.0)	88.7 (22.7)
BMI (kg/m^2)	32.2 (7.9)	
Waist (cm)	106.0 (17.0)	104.4 (15.7)
Systolic blood pressure (mmHg)	129.5 (14.0)	
Diastolic blood pressure (mmHg)	74.1 (10.5)	
LDL cholesterol (mmol/L)	2.2 (1.0)	
HDL cholesterol (mmol/L)	1.2 (0.3)	
Triglycerides (mmol/L)	2.0 (2.1)	
Chronic kidney disease		
Stage 3 (eGFR 30–59 mL/min/1.73 m^2)	21 (13.6)	120 (8.9)
Stage 4 (eGFR <30 mL/min/1.73 m^2)	1 (0.7)	23 (1.7)
Race/ethnicity		
Caucasian	74 (47)	
Southeast Asian	25 (16)	
Black	25 (16)	
Other	32 (21)	
Postsecondary education	85 (55)	
Income		
High (>$100,000 per annum)	17 (11)	
Moderate ($30–$100,000 per annum)	67 (43)	
Low (<$30,000 per annum)	51 (33)	
No	21 (14)	
Insulin use	141 (90)	
Mean number of injections per day	3	
Renin-angiotensin system blocker use	99 (63)	
Statin use	124 (79)	
Associated conditions		
Hypertension	125 (80)	
Dyslipidemia	137 (87)	
Coronary artery disease	20 (13)	
Neuropathy	37 (24)	
Nephropathy	22 (14)	
Retinopathy	42 (27)	
Depression	50 (32)	

Data are mean (SD) or *n* (%). *Significantly different compared with the source cohort ($P < 0.05$). eGFR, estimated glomerular filtration rate.

RESULTS

Analysis of the patient registry identified 3,662 potential participants. Of these, 1,379 were eligible for inclusion, and 155 were enrolled. Their baseline characteristics, along with those of the larger eligible cohort (*n* = 1,379) are shown in Table 1. Generally, the enrolled cohort was representative of the larger eligible population, other than small, but statistically significant differences in greater duration of diabetes and higher baseline HbA_{1c} in the intervention cohort.

One hundred forty-six participants with evaluable HbA_{1c} were included in the HbA_{1c} analysis. Twenty patients did not complete the entire 12-month program, of whom 13 had an evaluable HbA_{1c} outcome at 12 months and were included in the analysis. Two participants died during the study, one as a result of sepsis related to a diabetic foot infection discovered at enrollment and the other as a result of myocardial infarction complicated by heart failure; hypoglycemia was not a factor in either death.

Barriers

The most common barriers identified by participants were psychological/support (93%), socioeconomic (87%), and accessibility (82%). Although there was high participant–CDE concordance (75–94%), some areas of prominent discordance were lack of diabetes education (66% of CDEs, 27% of participants) and

anxiety (54% of participants, only 4% of CDEs). Of note, participants with a briefer duration of diabetes were more likely to find that time and clinic access were significant barriers to their self-care. No other individual barriers were found to be related to duration of diabetes, and no specific barriers were associated with weight or BMI. Participants who used insulin were 3.5-fold more likely to describe lack of diabetes education as a barrier, but no other barriers were linked to insulin use. In CDE assessments, the most commonly reported specific barriers were lack of diabetes education (66%), lack of motivation (45%), financial limitations (33%), mental health issues (24%), fear (22%), compliance (18%), lack of time (17%), and lack of support from health care providers (16%).

Outcomes

An evaluable HbA_{1c} outcome was available for 146 patients. The mean (SD) baseline HbA_{1c} was 96 (15) mmol/mol (10.9% [1.4%]), which improved to 78 (21) mmol/mol (9.4% [1.9%]) at 12 months, representing a mean reduction of 18 mmol/mol (1.5%, $P < 0.01$ vs. baseline) (Fig. 1*A*). A decrease in HbA_{1c} of >11 mmol/mol (>1.0%) was seen in 60% of patients. At 12 months, 6.8% of patients had achieved an HbA_{1c} <53 mmol/mol (<7.0%), 18.5% had achieved a level between 53 and 64 mmol/mol (7.0–8.0%), and 24.7% had achieved a level between 64 and 75 mmol/mol (8.0–9.0%) (Fig. 1*B*). No significant changes were found in other secondary outcomes, such as weight, blood pressure, or lipid parameters.

The original source cohort of eligible patients who had continued with standard care through their LMC-based physician within the same time period was examined as a point of comparison. Those with a recorded HbA_{1c} after a further 12 months of care (n = 966) showed a much smaller HbA_{1c} reduction of only 6 (18) mmol/mol (0.5% [1.6%], n = 966, $P < 0.0001$) (Fig. 1*A*). Furthermore, we used multivariate analysis incorporating all patients in both the intervention cohort and the source cohort and adjusted for age and HbA_{1c} at baseline and found an adjusted least squares mean change of 9 (17) mmol/mol (0.8% [1.5%]) difference ($P < 0.0001$). Finally, an analysis of only those patients who completed the full 12 months of the intervention (n = 133) revealed a nearly identical HbA_{1c} improvement of 18 (19) mmol/mol (1.6% [1.7%], $P < 0.001$).

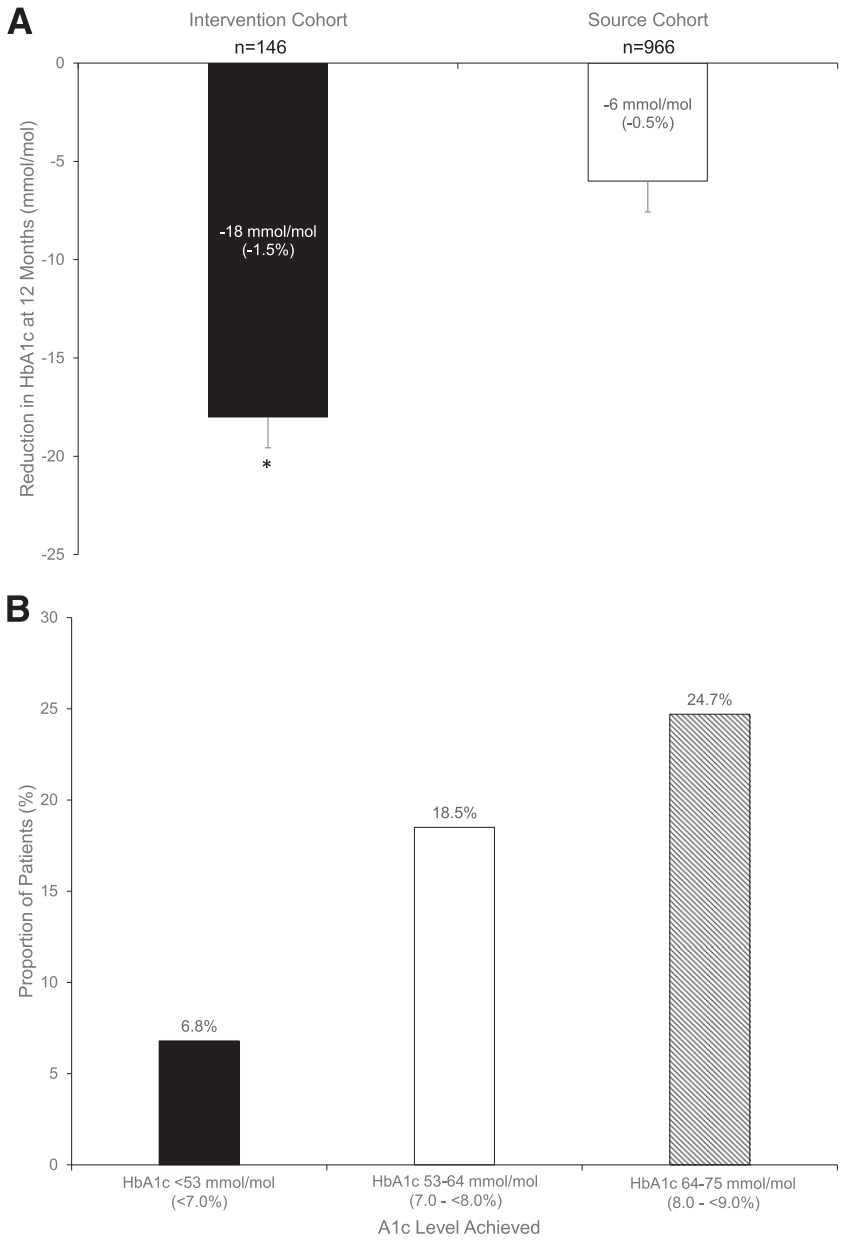

Figure 1—*A*: Reduction in HbA_{1c} after 12 months in the intervention cohort and source cohort. Data are mean ± SE. *Significant reduction in HbA_{1c} compared with the source cohort ($P < 0.05$). *B*: Proportion of patients in the intervention cohort who achieved an HbA_{1c} of <53 mmol/mol (<7.0%), 53 to <64 mmol/mol (7.0 to <8.0%), and 64–75 mmol/mol (8.0 to <9.0%) after 12 months.

The mean number of oral antidiabetic (OAD) therapies at baseline was 1.2 (1.0) and did not change throughout the study. For insulin users, the number of daily injections increased from 2.9 (1.4) to 3.3 (1.4) injections/day by 12 months ($P < 0.01$). The total daily dose increased by 28.7% from 82.7 (65.4) to 106.8 (82.6) units/day by 12 months ($P < 0.01$).

Although a number of barriers had been identified, no individual barrier was associated with baseline HbA_{1c} nor with the reduction in HbA_{1c} at 12 months. Participants who did not identify compliance as a barrier showed a baseline HbA_{1c} of 98 (15) mmol/mol (10.8% [1.4%]) and a significantly improved reduction of 19 (20) mmol/mol (1.7% [1.8%], $P < 0.001$). The baseline HbA_{1c} in participants identifying medication compliance as a barrier was 95 (15) mmol/mol (11.1% [1.5%]), and the decrease at 12 months was smaller, but still significant at 12 (19) mmol/mol (1.1% [1.7%], $P < 0.0001$). The difference in HbA_{1c} improvement

between the two groups was not significant ($P = 0.1$).

HbA_{1c} outcome was not affected by sex or ethnicity. However, patients >65 years of age achieved a greater HbA_{1c} reduction at 12 months ($n = 25$, HbA_{1c} reduction of 24 [33] mmol/mol [2.2% (3.0%)]) than those <65 years of age ($n = 121$, reduction of 16 [19] mmol/mol [1.4% (1.7%)]).

The most commonly used care paths were the socioeconomic (87.1%), psychological/support (60.7%), and comorbidity (36.1%) (Table 2). Although a wide range of intervention steps were used within each care path, the most common included remote visits (58.1%), diabetes education (79.4%), highlighting individual motivators (54.2%), and reinforcing compliance (45.2%). Overall, patients were treated with 3.0 (1.6) care paths per person. The HbA_{1c} reduction associated with each care path was consistent, ranging from 14 to 20 mmol/mol (1.4–1.8%). A linear regression analysis to adjust for other care paths confirmed that no single care path resulted in greater HbA_{1c} lowering. A trend toward a particular prominent effect was seen in the socioeconomic care path in which the adjusted HbA_{1c} reduction was 19 mmol/mol (1.7%) versus 10 mmol/mol (0.9%) in patients not assigned to that care path; the difference, however, was not statistically significant ($P = 0.08$).

All enrolled patients ($n = 155$) had at least one clinic visit with a CDE. The number of CDE encounters varied widely among individual patients, with 11.2 (7.1) visits per patient. Physician visits generally continued with a quarterly pattern (3.4 [1.8] physician visits per patient). Visit frequency with either HCP was not correlated with outcome HbA_{1c} ($P = 0.49$ and 0.15, respectively). Visit pattern was similar across all care paths, with an overall 5.2 (3.1) clinic visits, 15.3 (8.0) total visits, and 8.6 (5.2) h spent with an HCP throughout the 12-month intervention (Table 3). The 11 patients who required an emergency department visit during the study period showed a numerical trend to a greater HbA_{1c} reduction of 27 mmol/mol (2.5%) [2.4%] compared with the rest of the intervention cohort of 18 mmol/mol (1.5% [1.6%]), which did not reach statistical significance.

At baseline, 11.5% of participants had experienced daytime hypoglycemia, 4.5% experienced nocturnal hypoglycemia, and 1.3% experienced severe hypoglycemia. Each figure had increased at 6 months (46.5%, 18.1%, and 9.7%, respectively; $P < 0.01$), but by 12 months, only the incidence of daytime hypoglycemia was significantly higher than at baseline (45.1% vs. 11.5%, $P < 0.01$).

Nocturnal hypoglycemia and severe hypoglycemia increased from 4.5% to 11% and from 1.3% to 6.7%, respectively, but because of the low incidence of such events in this population with type 2 diabetes, the change was not statistically significant.

No significant changes in EQ-5D Health Perception Questionnaire, Stanford Health

Table 2—Care path usage

Care path	*n* (%)
Accessibility	
Transportation	
Offer remote visits (home, e-mail, or phone)	90 (58.1)
Refer to a closer Diabetes Education Program	2 (1.3)
Coordinate community transportation	1 (0.6)
Lack of time for appointment	
Provide after hours appointments	4 (2.6)
Remove outstanding invoice	3 (1.9)
Slow/nonadvancement of therapy	
Therapy modification	41 (26.4)
Culture	
Language	
Bring an English-speaking family member	3 (1.9)
Use a translator	1 (0.6)
Provide translated resources	7 (4.5)
Cultural	
Refer to a culturally specific program	1 (0.6)
Refer to a culturally specific educator	3 (1.9)
Comorbidity	
Multiple medical appointments	
Prioritize health problems	13 (8.3)
Multiple health problems/overwhelmed	
Assist in time management	9 (5.7)
Educate about diabetes complications	43 (27.4)
Socioeconomic	
Education level	
Educate patient to their education level	20 (12.9)
Provide appropriate learning tools	55 (35.5)
Lack of diabetes education	
Provide diabetes education	123 (79.4)
Financial	
Coordinate financial program through patient association	14 (9.0)
Coordinate financial program through industry	28 (18.1)
Coordinate financial program through other	11 (7.1)
Displeasure with current diabetes care	
Refer internally to another HCP	25 (15.9)
Workplace	
Discuss patient needs with the workplace	2 (1.3)
Lack of compliance	
Reinforce compliance	70 (45.2)
Educate about poor outcomes	43 (27.7)
Psychological	
Therapy anxiety	
Refer to a psychiatrist	9 (5.8)
Refer to a support group	0 (0)
Coordinate an accompanying support person	9 (5.8)
Difficulty coping/support	
Involve family/friend in self-care	21 (13.6)
Activate a mental health program	0 (0)
Link to a self-management program	3 (1.9)
Motivational level	
Find patient's motivators	84 (54.2)
Mental health issues	
Refer to structured community support program	0 (0)

Table 3—Visits by care path

Visit type	Time (min)	Accessibility (*n* = 107)	Culture (*n* = 9)	Comorbidity (*n* = 56)	Socioeconomic (*n* = 135)	Psychological/ support (*n* = 94)	Total cohort (*n* = 155)
Endocrinologist	15	3.5 (1.6)	3.3 (1.4)	3.3 (1.3)	3.4 (1.7)	3.7 (1.7)	3.4 (1.8)
Educator		12.8 (7.4)	10.2 (9.0)	13.0 (7.6)	12.0 (7.2)	13.3 (7.1)	11.8 (7.1)
Clinic	60	5.6 (3.2)	3.7 (2.8)	5.8 (3.2)	5.3 (3.2)	6.1 (3.3)	5.2 (3.1)
Phone	22	5.7 (6.1)	3.2 (2.9)	5.5 (6.3)	5.4 (5.8)	5.6 (6.1)	5.4 (5.7)
E-mail	10	1.2 (2.4)	0.4 (1.3)	1.1 (2.4)	1.0 (2.2)	1.2 (2.5)	1.0 (2.2)
Home	90	0.3 (2.6)	2.9 (8.7)	0.7 (3.6)	0.3 (2.3)	0.4 (2.8)	0.3 (2.2)
Total visits		16.3 (8.0)	13.6 (9.6)	16.4 (8.1)	15.5 (8.0)	17.1 (7.7)	15.3 (8.0)
Estimated total visit time (h)		9.2 (5.6)	10.1 (13.3)	9.8 (6.5)	8.8 (5.4)	9.9 (5.6)	8.6 (5.2)

Data are mean (SD).

Distress Scale, or Stanford Diabetes Self-Efficacy Scale scores were seen over the course of the study. No correlations were found between these scores and the primary outcome.

CONCLUSIONS

The DROP A1C study has shown that a patient registry can be used to identify participants who appear to be refractory to prior efforts to improve HbA_{1c}, that a structured assessment and strategic diabetes care programming can result in a significant improvement in mean HbA_{1c} of 18 mmol/mol (1.5%), and that 60% of participants can improve their HbA_{1c} by at least 11 mmol/mol (1.0%). Improvements were achieved with no increase in mean number of OAD therapies and only a 28.7% increase in insulin total daily dose for insulin users. Hypoglycemia increased numerically over the course of the study but only the increase in daytime hypoglycemia was statistically significant. The hyperglycemia of this refractory population may explain the lower hypoglycemia than sometimes is seen in therapy intensification.

The Barriers to Care Questionnaire successfully identified a broad range of barriers to glycemic control and showed high concordance between patient and CDE. No single barrier or the overall number of barriers was found to be associated with the degree of baseline hyperglycemia, indicating that for refractory patients, individualized assessment of barriers is ideally needed to improve outcomes. It may, however, still be possible that in a cohort with a broader range of HbA_{1c} values, a stronger relationship between glycemia and the number of identified barriers might be seen.

Similarly, a wide range of care path steps and interventions were used, with most patients requiring multiple care paths. No particular care path intervention, nor the number of care path steps used, were linked to improved glycemic control. Two perspectives emerged: *1*) Either refractory patients require such individualized care that no single care path dominates and therefore any individualized care would be effective. In this view, the baseline degree of refractoriness implies a prior failure of the health care system to recognize and deliver the individualized care. *2*) Alternatively, one could hypothesize that the impact was achieved through the frequency of visits and the intensity of the care provided. In this view, the particular barriers and the degree of care path individualization are less, if at all, important.

Refractory patients are consistently found within specialist practices, with up to 55% of registry populations being refractory depending on the definition used (2,6). Given the availability of both oral and injectable glucose-lowering therapies, such patients cannot be considered refractory in the usual sense. However, they have not achieved adequate glycemic control despite ongoing, comprehensive, evidence-based care, a finding that empirically defines them as functionally refractory. Understanding refractory patients is critical because they may be at higher risk of diabetes-related mortality and morbidity. Retrospective analyses of the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial suggested that persistent nonresponders to intensive treatment are at an increased risk of death (7). The current cohort was carefully selected and included only participants $<$80 years of age without significant comorbidity, coronary artery disease, or hypoglycemia unawareness to remove any post-ACCORD bias toward a looser expectation of glycemic control in refractory individuals.

Registry studies have shown that other than specialist care itself (5), factors such as the number of OAD medications, insulin treatment, younger age, younger age at diagnosis, and longer duration are predictive of refractoriness. Large population surveys have consistently found higher depression scores among refractory individuals (13) as well as patient skepticism about insulin efficacy, poor relationships with health care providers, poor perception of control, and more diabetes-related distress (14). The current findings, however, suggest that these factors are useful only as markers and are not helpful in individualization of care.

The DROP A1C study design had several important features. Participants were enrolled from a common practice group with identical resources within a public health care system. They were selected for a persistent HbA_{1c} $>$75 mmol/mol (9%) after at least 6 months of exposure to the multidisciplinary teams of the LMC clinics that used a common set of care paths and national standards. A working group comprising a broad range of HCPs experienced in this refractory population developed the Barriers to Care Questionnaire that effectively enabled a prioritization of needs. As well, the working group developed the care paths and facilitated the planning and implementation of interventions in the study cohort. Finally, the enrolled cohort was representative of the larger source population, with no known hemoglobinopathies and a negligible incidence of stage 4 chronic kidney disease, which might distort the HbA_{1c}.

This study had a number of limitations affecting the generalizability of the findings. The enrolled cohort may represent

volunteer bias and may have been more motivated or facing fewer barriers. The visit frequency as well as the staff resources and expertise may not be available in other health care environments. Finally, the study lacked a randomized control group, but the availability of the larger source cohort and their continued refractoriness over the same duration in the same time period present an interesting relative marker.

The assessment and intervention tools reported here ideally should be explored in other diabetes populations, including other specialist-led populations and general primary care diabetes practices in public, private, and mixed health care systems. We also suggest that these tools be explored through a preventive approach ideally implemented as early as possible after diagnosis.

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