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Changes in quality of care and costs induced by implementation of a diabetes program in a social security entity of Argentina

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Purpose: To measure the impact of a diabetes and cardiovascular risk factors program implemented in a social security institution upon short- and long-term clinical/metabolic outcomes and costs of care.

Methods: Observational longitudinal cohort analysis of clinical/metabolic data and resource use of 300 adult male and female program participants with diabetes before (baseline) and 1 and 3 years after implementation of the program. Data were obtained from clinical records (Qualidiab) and the administration's database.

Results: The implementation of the program in "real world" conditions resulted in an immediate and sustainable improvement of the quality of care provided to people with diabetes incorporated therein. We also recorded a more appropriate oral therapy prescription for hyperglycemia and cardiovascular risk factors (CVRFs), as well as a decrease of events related to chronic complications. This improvement was associated with an increased use of diagnostic and therapeutic resources, particularly those related to pharmacy prescriptions, not specifically used for the control of hyperglycemia and other CVRFs.

Conclusion: The implementation of a diabetes program in real-world conditions results in a significant short- and long-term improvement of the quality of care provided to people with diabetes and other CVRFs, but simultaneously increased the use of resources and the cost of diagnostic and therapeutic practices. Since controlled studies have shown improvement in quality of care without increasing costs, our results suggest the need to include management-control strategies in these programs for appropriate medical and administrative feedback to ensure the simultaneous improvement of clinical outcomes and optimization of the use of resources.

Keywords: management, program evaluation, chronic diseases, diabetes

Introduction

Diabetes is a costly and ever-increasing health problem frequently associated with the development of chronic complications that result in a heavy socioeconomic burden for the health system and society overall.[1–3] Cardiovascular complications represent the major cause of diabetes morbidity, mortality, and costs, and they can be significantly reduced by appropriate control of blood glucose and associated cardiovascular risk factors (CVRFs).[1,4–10] However, prevention strategies have not been widely incorporated into daily clinical practice,[11] and the care provided to people with diabetes is frequently far from optimal.[5,12–16] Consequently, the care of these people usually consumes 5%–10% of health budgets.[17]

This situation could be improved by the integration and coordination of interdisciplinary teams in a structured diabetes program capable of optimizing both effectiveness

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and resource use. Such an assertion is supported by the significant improvement in several clinical and metabolic indicators of quality of care of people with type 2 diabetes and the decrease in direct medical costs observed after the implementation of Program for the Prevention, Care and Treatment of People with Diabetes (PROPAT) in Argentina[18,19] and similar initiatives in other countries. PROPAT was a controlled study, but there is no evidence of the efficacy of this type of program in "real world" conditions. Therefore, we considered it would be important to test the effectiveness of a similar program but implemented in a social security health institution of Argentina.

The Argentine health-care system includes three independent sectors: public, social security, and private (prepaid).[20] OSPERYH (Obra Social del Personal de Edificios de Renta y Horizontal) is a health-management organization that belongs to the social security sector. It is organized at national level and provides health coverage to nearly 100,000 people in the city of Buenos Aires.

In order to obtain the information mentioned previously, in June 2005 we implemented a diabetes program in OSPERYH (DPO) that modified the traditional care system of the organization. At that time, general practitioners were responsible for the control and treatment of people with diabetes and the prescription of periodic controls by specialists. The organization had neither specific procedure manuals, medical processes, nor standardized administrative procedures. Furthermore, data from clinical practices, laboratory tests, drug prescriptions, and hospitalization events were partially recorded at different areas and used for economic and legal purposes rather than as a suitable tool to control the quality of care provided to patients. Equity of health coverage was poor, since it was determined by a national law that guarantees the provision of "baseline" care instead of care plans meeting real individual needs. Additionally, there were no diabetes-education programs for physicians or patients, with a negligible participation of the latter in control and treatment of their disease.

The DPO introduced the systematization of processes and procedures of care, from the enrollment of participants into the program up to drug supply. In this context, the DPO implemented standards of care, control and treatment, a yearly schedule of visits to the physician's office, and the performance of special practices (electrocardiogram, endoscopy, ergometry, spirometry, fluxometry, holter monitor, radiography, tomography), and laboratory tests based on international guidelines for good clinical practice. It also incorporated a periodic record of clinical, metabolic, and therapeutic data and the provision of a personalized check-book to facilitate patient access to clinical care, laboratory tests and different special practices, drugs, and devices. This record system also served to identify the type and amount of resource consumption. All these practices and procedures, as well as the prescription of drugs and supplies for self-control, had 100% coverage. Additionally, the DPO provided diabetes education to physicians and people with diabetes, promoting the active participation of the latter in the control and treatment of their disease. Finally, the DPO implemented a system for the continuous monitoring of diabetes care, clinical, metabolic, therapeutic, and economic indicators, and program performance.

In this study, we report the immediate and long-term clinical, metabolic, and budget impact of the DPO implemented in noncontrolled conditions in OSPERYH.

Materials and methods

Design

The study represents an observational and longitudinal prospective cohort analysis of people with diabetes. We analyzed the performance of procedures, many clinical, metabolic, and therapeutic indicators of quality of care, the rate of resource utilization and associated costs before (baseline) and at 1 and 3 years after implementation of the DPO. For every study period, data were recorded for 12 months. We simultaneously evaluated several OSPERYH indicators of the health-care management process.

The study design and its procedures were approved by the Central Advisory Committee on Bioethics of the National University of La Plata.

Population

People with diabetes were invited to participate in the study by their doctors during their periodic controls, and were incorporated into the DPO after signing the pertinent informed consent. Through this procedure, 1366 affiliates were incorporated into the DPO in the year 2006; three years later, 300 affiliates remained in the program. No significant differences were recorded between completers and dropouts from the point of view of their demographic, clinical, or metabolic characteristics (Table 1). Consequently, we only included and compared data from the 300 patients at baseline and 1 and 3 years after DPO implementation.

Diabetes diagnosis was made using the Latin American Diabetes Association criteria,[21] while obesity, hypertension, and dyslipidemia were diagnosed using the American Diabetes Association,[22,23] the Joint National Committee on

Table 1 Clinical characteristics and use of resources of the selected sample versus patients who dropped out of the diabetes program in OSPERYH

	Baseline		*P*-value	
	Study sample n = 300	Dropouts n = 1,066	Mean	Proportions
	Mean ± SD (n)	Mean ± SD (n)		
Clinical/metabolic indicators				
BMI (kg/m^2)	30.5 ± 5.6 (287)	30.3 ± 5.5 (990)	0.587	–
SBP (mmHg)	131 ± 16 (272)	133 ± 17 (941)	0.087	–
DBP (mmHg)	81 ± 11 (271)	81 ± 11 (938)	0.890	–
FBG (mg/dL)	126 ± 45 (96)	139 ± 57 (405)	<0.05	–
HbA_{1c} (%)	7.9 ± 2.1 (133)	8.2 ± 2.2 (498)	0.159	–
Creatinine (mg/dL)	0.9 ± 0.2 (176)	0.9 ± 0.3 (572)	0.271	–
Proteinuria (mg/dL)	6 ± 3 (40)	6 ± 4 (132)	0.782	–
Total cholesterol (mg/dL)	205 ± 44 (233)	209 ± 45 (821)	0.231	–
HDL-chol (mg/dL)				
Women	54 ± 35 (74)	53 ± 19 (106)	0.734	–
Men	50 ± 31 (107)	49 ± 15 (142)	0.657	–
LDL-chol (mg/dL)	119 ± 38 (162)	125 ± 37 (572)	0.073	–
Triglycerides (mg/dL)	182 ± 99 (212)	181 ± 104 (733)	0.901	–
Average consumption, percentage of performance*				
Hospitalizations	11.7 ± 9.7 [5.7, 3–9]	10.2 ± 9.8 [7.04, 6–9]	0.595	0.670
Visits to the doctor's office	9.3 ± 6.6 [98, 96–99]	9.3 ± 7.4 [98, 97–99]	0.966	0.973
Practices	1.9 ± 2.1 [32, 27–37]	1.7 ± 1.7 [28, 26–31]	0.342	0.171
Laboratory tests	15.5 ± 10.0 [90, 87–94]	16.4 ± 10.5 [89, 87–91]	0.189	0.324
Pharmacy	12.8 ± 15.6 [51, 45–57]	15.8 ± 20.5 [43, 42–48]	0.098	0.013

Notes: *Values in brackets: %, 95% CI.

Abbreviations: OSPERYH, Obra Social del Personal de Edificios de Renta y Horizontal; SD, standard deviation; BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; FBG, fasting blood glucose; HbA_{1c}, glycated hemoglobin; HDL-chol, high-density lipoprotein cholesterol; LDL-chol, low-density lipoprotein cholesterol; CI, confidence interval.

Prevention, Detection, Evaluation, and Treatment of High Blood Pressure,[24] and the National Cholesterol Education Program[25] criteria, respectively. Cardiovascular risk was assessed with the Second Joint European Task Force guidelines,[26] while the degree of metabolic control was determined using the Latin American Diabetes Association[21] and the International Diabetes Federation[27] guidelines.

Inclusion and exclusion criteria

We only incorporated adult male and female OSPERYH participants (age ≥18 years) from the city of Buenos Aires, Argentina, with diabetes, who had been controlled for their disease for at least 2 years and regularly attended the DPO. People with mental illnesses that affected behavior, alcohol or drug abuse, or who refused to sign the informed consent were excluded from the study.

Data-collection instruments

The annual and semiannual Qualidiab data-collection forms[28] and an annual personalized check-book of medical and laboratory tests and drug prescription were used to measure the following variables: demographic data, diabetes-education indicators, performance of diagnostic/control procedures, presence of acute and chronic complications (micro/macrovascular complications), hospitalization rate, and absenteeism. We also recorded clinical and therapeutic indicators of degree of control of hyperglycemia, associated CVRFs, other health conditions, and costs of care (annual consumption of diagnostic and therapeutic resources). All the data recorded were anonymously stored at CENEXA (Center of Experimental and Applied Endocrinology) in a database using SQLyog (Webyog, Santa Clara, CA, USA) software.

Data analysis

The effectiveness of the intervention was measured through changes in: (1) glycated hemoglobin (HbA_{1c}) values, showing the degree of metabolic control during the last 3 months; (2) fasting blood glucose (FBG) levels; (3) serum lipid profile (total cholesterol and triglyceride levels); and (4) average resource consumption, percentage of performance, and per capita direct medical costs (hospitalizations, medical practices, laboratory tests, visits to the doctor's office, and consumption of drugs and devices for self-monitoring blood

glucose). All indicators from the 300 selected affiliates were measured at baseline and 1 and 3 years after implementation of the DPO.

Cost-of-care analysis included (1) resource identification (units of measure and quantities), (2) choice of analysis perspective (social security subsector), inclusion of relevant resources and unit-cost identification, and (3) estimation of total and incremental costs. For the analysis we used the CostIt version 4.4 (WHO, Geneva, Switzerland) software and the WHO-CHOICE methodology proposed by WHO.[29] Budget impact was evaluated comparing the nonintervention (baseline) versus the intervention (1- and 3-year) scenarios. The unit cost of resources was obtained from values of the Nomenclador Asistencial Nacional, Nomenclador Bioquímico Único, and Nomenclador Agremiación Médica Platense. All costs are expressed in Argentine pesos (AR$) for the year 2011.

Descriptive statistics are presented as percentages with 95% confidence intervals (CIs) and means ± standard deviation. Chi-squared testing was performed for all proportions, and Student's *t*-test was used for all means. The significance level was set at $P < 0.05$. All statistical analyses were performed with the Epi-Info 6.4 (CDC, Atlanta, GA, USA) statistical package or SPSS 15.0 (IBM, Armonk, NY, USA).

Results

Population characteristics

Fifty-eight percent of the patients included in the analysis were men, with an average age of 55 years; 8% and 92% of them had type 1 and type 2 diabetes, respectively. Except for FBG, no differences were recorded at any of the parameters tested between completers and dropouts (Table 1).

Clinical and metabolic impact

Procedure performance increased significantly 1 year after DPO implementation and continued on an upward trend thereafter, except for body mass index (BMI) and blood pressure control, which declined to baseline values. It is worth noting that the performance of these two procedures was already high at baseline (90% and 91%, respectively; Table 2).

Habits

At baseline, 19% of the sample population consumed tobacco, 21% consumed alcohol, 67% followed a meal plan, and 35% were physically active. These figures did not change significantly 1 and 3 years after DPO implementation, except for a slight increase in physical activity (38%).

Table 2 Changes in the performance of control procedures

Parameter	Baseline n = 300	1 year n = 300	3 years n = 300
	% (95% CI)	% (95% CI)	% (95% CI)
Foot examination*	51 (44–78)	92 (85–96)[a]	96 (90–98)[a]
Eye examination†	46 (38–54)	72 (64–79)[a]	74 (65–81)[a]
BMI	90 (86–93)	99 (97–100)[a]	92 (88–95)[b]
Blood pressure	91 (87–94)	96 (93–98)[a]	92 (88–95)[b]
FBG	32 (27–38)	65 (59–70)[a]	91 (87–94)[a,b]
HbA_{1c}	44 (38–50)	77 (72–81)[a]	81 (76–85)[a]
Creatinine	59 (53–64)	79 (74–83)[a]	79 (74–83)[a]
Total cholesterol	78 (73–82)	77 (72–81)	85 (80–89)[a,b]
HDL-chol	60 (54–66)	76 (71–80)[a]	83 (78–87)[a]
LDL-chol	54 (48–60)	71 (66–76)[a]	81 (76–85)[a,b]
Triglycerides	71 (65–76)	83 (79–87)[a]	83 (78–87)[a]
Microalbuminuria	3 (1–6)	4 (2–7)	12 (9–16)[a,b]

Notes: *Baseline n = 210, 1 year n = 98, 3 years n = 117; †baseline n = 170, 1 year n = 144, 3 years n = 118; [a]compared to baseline, $P < 0.05$; [b]compared to 1 year, $P < 0.05$.
Abbreviations: CI, confidence interval; BMI, body mass index; FBG, fasting blood glucose; HbA_{1c}, glycated hemoglobin; HDL-chol, high-density lipoprotein cholesterol; LDL-chol, low-density lipoprotein cholesterol.

Clinical and metabolic parameters

Most of the clinical and metabolic parameters improved significantly 1 year after implementation of the DPO, with significant decreases of systolic and diastolic blood pressure, HbA_{1c}, and serum triglyceride levels (Table 3). These improvements were still present 3 years after DPO implementation, except those related to glucose metabolism (FBG and HbA_{1c}), whose values returned almost to those recorded at baseline. In the case of triglyceride levels, the improvement recorded 1 year after was sustained and became even larger 3 years after program implementation.

Related to these changes, we also observed a significant beneficial effect of the DPO on the percentage of people attaining target treatment values in several parameters (Table 4). One year after implementation, there was a significant increase in the percentage of people at target blood pressure, serum total cholesterol, and triglyceride levels; these effects were still evident 3 years later. Conversely, no significant changes were observed in BMI, FBG, or HbA_{1c} values.

Treatment characteristics

At baseline, 94% of patients were on oral antidiabetic drugs (56% of them were treated with only one drug), while 14% received insulin (Table 5). One year after implementation, we detected a significant increase only in the percentage of people treated for dyslipidemia. Conversely, 3 years after DPO implementation, a significant treatment increment was observed in every condition tested, with the only exception being insulin administration, which showed an increasing but not statistically significant trend.

Table 3 Clinical/metabolic indicators

Parameter	Baseline	1 year	3 years
	Mean ± SD (n)	Mean ± SD (n)	Mean ± SD (n)
BMI (kg/m^2)	30.5 ± 5.6 (287)	30.4 ± 5.5 (264)	30.4 ± 5.4 (275)
SBP (mmHg)	131 ± 16 (272)	127 ± 13.3 (257)[a]	128 ± 14 (276)[a]
DBP (mmHg)	81 ± 11 (271)	77,9 ± 10 (256)[a]	79 ± 9 (277)[a]
FBG (mg/dL)	126 ± 45 (96)	118 ± 38 (187)	132 ± 40 (277)[b]
HbA_{1c} (%)	7.9 ± 2.1 (133)	7.3 ± 1.6 (212)[a]	7.7 ± 1.7 (244)
Creatinine (mg/dL)	0.9 ± 0.2 (176)	0.9 ± 0.2 (219)	0.8 ± 0.4 (236)[b]
Proteinuria (mg/dL)	6 ± 3 (40)	3 ± 4 (40)	1 ± 6 (152)[a,b]
Total cholesterol (mg/dL)	205 ± 44 (233)	201 ± 40,8 (233)	197 ± 42 (256)[a]
HDL-chol (mg/dL)			
Women	54 ± 35 (107)	54 ± 15 (85)	52 ± 58 (106)
Men	50 ± 31 (74)	48 ± 11 (121)	46 ± 17 (142)
LDL-chol (mg/dL)	119 ± 38 (162)	119 ± 36 (194)	121 ± 37 (243)
Triglycerides (mg/dL)	182 ± 99 (212)	159 ± 92 (226)[a]	140 ± 74 (250)[a,b]

Notes: [a]Compared to baseline, $P < 0.05$; [b]compared to 1 year, $P < 0.05$.
Abbreviations: SD, standard deviation; BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; FBG, fasting blood glucose; HbA_{1c}, glycated hemoglobin; HDL-chol, high-density lipoprotein cholesterol; LDL-chol, low-density lipoprotein cholesterol.

Related to this, we observed a marked tendency to use combined therapy rather than monotherapy, particularly in the cases of hyperglycemia and high blood pressure.

Complication-related events

The number of people with at least one event related to chronic complications showed a nonsignificant decrease from 45% to 42% 3 years after DPO implementation. These complication-related events included microangiopathic (blindness, chronic renal failure with replacement therapy, peripheral neuropathy, nephropathy, orthostatic hypotension, and erectile dysfunction) and macroangiopathic (acute myocardial infarction, stroke, angor, lower-limb claudication, and revascularization) complications.

Economic impact

The percentage of people who had at least one hospitalization event increased significantly 1 year after implementation of the DPO, but it was no longer observed 3 years after implementation (Table 6). The same trend was recorded in people who performed at least one special practice, but in this case the change was still evident 3 years later. Laboratory test performance did not change significantly 1 year after implementation, but it increased significantly 3 years after implementation.

The average number of visits to the doctor's office (either clinicians or specialists) increased significantly 1 year after implementation and remained high 3 years later; this increase was associated with a significant increase in costs in both study periods. However, visits specifically related to diabetes and CVRFs (medical clinic, nutrition, cardiology, and diabetology) increased less than those due to unrelated causes (43% and 71%, respectively).

At baseline, the annual per capita cost was AR$4,657 and had the following distribution: hospitalization events, 59%; visits to the doctor's office, 18%; pharmacy, 16%; laboratory test, 12%; medical practices, 3% (Table 6). This cost increased at the other two study points (AR$7,139 and AR$8,437 1 year and 3 years later, respectively), having an uneven distribution: hospitalizations, 9.5%; visits to the doctor's office, 48%; pharmacy, 432%. Interestingly, the high-

Table 4 Percentage of people who achieved treatment target values of clinical and metabolic parameters

Parameter	Baseline	1 year	3 years
	% [95% CI] (n)	% [95% CI] (n)	% [95% CI] (n)
BMI < 25 kg/m^2	15 [11–20] (287)	15 [11–19] (299)	13 [9–17] (275)
SBP < 130 and DBP < 85 mmHg	38 [33–44] (272)	48 [42–54] (287)[a]	49 [43–55] (277)[a]
FBG < 100 mg/dL	39 [29–49] (96)	31 [25–38] (194)	30 [25–36] (273)
HbA_{1c} < 7%	40 [32–49] (133)	46 [40–53] (231)	41 [35–47] (244)
Total cholesterol <200 mg/dL	48 [42–55] (233)	48 [42–54] (262)	56 [50–62] (255)[a]
Triglycerides <150 mg/dL	46 [39–53] (212)	57 [51–63] (250)[a]	64 [58–70] (250)[a]

Notes: [a]Compared to baseline, $P < 0.05$; compared to 1 year, $P < 0.05$.
Abbreviations: CI, confidence interval; BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; FBG, fasting blood glucose; HbA_{1c}, glycated hemoglobin.

Table 5 Type of diabetes and CVRF treatment

Parameter	Baseline	1 year	3 years
	% [95% CI] (n)	% [95% CI] (n)	% [95% CI] (n)
OADs	94 [90–97] (237)	93 [90–96] (265)	97 [94–99] (238)[b]
Monotherapy	56 [49–62]	49 [42–55]	40 [34–47][a,b]
Combined therapy (≥2 drugs)	44 [38–51]	51 [45–58]	60 [53–66][a,b]
Insulin	14 [11–19] (300)	16 [12–20] (300)	18 [14–23] (300)
Hypertension	68 [62–74] (242)	75 [69–80] (256)	75 [70–80] (277)
Monotherapy	65 [58–73]	63 [56–70]	52 [46–60][a,b]
Combined therapy (≥2 drugs)	35 [27–42]	37 [30–44]	48 [41–54][a,b]
Dyslipidemia	39 [33–46] (224)	48 [42–55] (231)[a]	54 [48–61] (261)[a]
Monotherapy	92 [84–96]	97 [93–99]	91 [85–95][b]
Combined therapy (≥2 drugs)	8 [4–16]	3 [1–7]	9 [5–15][b]

Notes: [a]Compared to baseline, $P < 0.05$; [b]compared to 1 year, $P < 0.05$.
Abbreviations: CVRF, cardiovascular risk factor; CI, confidence interval; OADs, oral antidiabetic drugs.

est increase in visits to the doctor's office corresponded with unrelated causes (68%) rather than those related to diabetes and CVRFs (41%).

The pharmacy per capita cost increased significantly (almost fivefold) from baseline to the other two observational periods (drug and supply group distribution: diabetes, 21%; dyslipidemia, 37%; hypertension, 13%; other pathologies, 61%). Such distribution changed at the two other post-DPO implementation periods, the largest being that related to other pathologies (56%), followed by diabetes (29%), hypertension (10%), and dyslipidemia (6%).

Discussion

Reported evidence shows that implementation of controlled diabetes prevention and treatment programs can simultaneously improve quality of care and decrease direct medical costs. In our country, the implementation of PROPAT, an example of this type of controlled program, also showed such a dual beneficial impact.[18,19]

Implementation of the DPO under real-world conditions clearly demonstrated a significant improvement in the performance of most medical procedures and laboratory tests 1 year later; in most cases, the effect was sustained 3 years

Table 6 Average consumption, percentage of performance, and per capita cost in local currency (AR$)

Parameter	Cost per capita					
	Baseline		1 year		3 years	
	Mean ± SD (%)	(AR$)	Mean ± SD (%)	(AR$)	Mean ± SD (%)	(AR$)
Hospitalizations*	11.7 ± 9.7 (5.7) [3–9]	2,528	9 ± 10.6 (11.4) [4–9][a]	1,944	12.8 ± 11.2 (7.3) [5–11]	2,768
Practices*	1.9 ± 2.1 (32) [27–37]	116	1.9 ± 1.6 (49) [44–55][a]	128	1.8 ± 1.9 (37) [32–43][b]	110
Laboratory tests*	15.5 ± 10.0 (91) [87–94]	567	15.5 ± 8.1 (94) [90–96]	542	18.8 ± 10.3[a,b] (96) [9–98][a]	759
Visits to the doctor's office*	9.3 ± 6.6 (98) [96–99]	752	13.5 ± 7.9[a] (96) [94–98]	1,095	13.7 ± 7.9[a] (100) [98–100][a,b]	1,110
Diabetes and CVRF	7.0 ± 4.7	577	10.6 ± 4.9	248	10.0 ± 4.8[a]	815
Other	2.1 ± 3.3	175	4.6 ± 4.4	847	3.6 ± 5.0[a]	295
Pharmacy*	12.8 ± 15.6 (51) [45–57]	694	55.6 ± 31.6[a] (93) [89–95][a]	3,430	54.1 ± 29[a] (97) [95–98][a,b]	3,690
Dyslipidemia	1.8 ± 1.4	37	4.3 ± 3.4	223	3.6 ± 2.8[a]	207
Diabetes	4.1 ± 4.7	149	13.6 ± 8.8	874	12.0 ± 7.6[a]	1,078
Hypertension	3.2 ± 3.9	88	9.0 ± 6.9	320	9.5 ± 7.3[a]	356
Other drugs and supplies	7.1 ± 8.0	421	26.5 ± 15.2	2,012	25.9 ± 14.9[a]	2,049
Total		4,657		7,139		8,437

Notes: *Between parentheses percentage of people who had at least one: hospitalization; specialized practice; laboratory practice; visit to the doctors' office; drug to treat diabetes, hypertension or dyslipidemia between brackets, 95% CI; n = 300; [a]compared to baseline, $P < 0.05$; [b]compared to 1 year, $P < 0.05$.
Abbreviations: CVRF, cardiovascular risk factor; CI, confidence interval; AR$, Argentine pesos.

later (Table 2). These data represent indirect evidence of quality-of-care improvement.[30] Interestingly, despite the significant increase in procedure performance, none of the values reached 100% either 1 or 3 years after DPO implementation, even when costs were fully covered by the DPO. Similar data were recorded with PROPAT,[18,19] thus showing how difficult it is to remove long-established inappropriate routines.

The DPO data also showed a significant improvement in most of the clinical/metabolic parameters evaluated 1 year after its implementation; though of a lower magnitude, these changes were comparable to those recorded in PROPAT.[18,19] It can be argued that the small magnitude of improvement in some parameters could not have clinical significance, but they were however associated with a significant decrease in the number of events related to both micro- and macroangiopathic complications. Such association does not mean that chronic complications were reversed; rather, that the intervention was sufficient to prevent the development of complication-related events. The facts that every 10% decrease in HbA_{1c} reduces the risk of developing microalbuminuria (20%), retinopathy (56%), and its progression (64%),[31] and that a 10 mmHg decrease in blood pressure also reduces the development of such complication-related events,[32] would account for our current data. It should be noted that the beneficial impact of the DPO remained constant after the 3-year implementation, except for FBG and HbA_{1c} levels. Moreover, further improvement was observed in creatinine, total cholesterol, and triglyceride levels during the last study period.

Since the aforementioned favorable changes were not accompanied by similar changes in the percentage of people with overweight/obesity, we could assume that improvements in care quality were more related to increases in drug prescription/consumption than to the adoption of healthy habits. The fact that implementation of the DPO induced a significant and sustained increase in overall drug consumption and a shift from monotherapy towards combined therapy for the control of hyperglycemia, blood pressure, and dyslipidemia lends support to this assumption.

The estimation of total medical costs showed that unlike PROPAT, where the per capita cost of care decreased significantly,[18,19] it increased by 81% after implementation of the DPO. This increase was accompanied by a change in cost composition at the two other study periods: while at baseline, the highest percentage corresponded to hospitalizations, 1 and 3 years after implementation the predominant position was occupied by drug costs. The use of combined therapy rather than monotherapy to control hyperglycemia and associated CVRFs, as well as the increase in insulin prescription that demands a larger use of strips for self-monitoring blood glucose control, would explain the change in cost composition. This fact would also suggest that the DPO promoted a transfer of economic resources from rehabilitation to prevention practices.

On the other hand, the increased use of resources (number of visits to the doctor's office and pharmacy consumption; Table 5) was not caused by the control and treatment of diabetes or the associated CVRFs. One possible explanation is that the higher number of monitoring and laboratory tests performed probably facilitated the identification of other dysfunctions not perceived previously and therefore not treated (Table 4).

Altogether, our data suggest that outcomes of controlled and real-world diabetes programs are not fully the same: while national and international evidence has proved that the implementation of the former improves quality of care and simultaneously reduces costs,[18,33–36] the latter, in this case the DPO, improves quality of care but increases costs significantly. This dissociation could be ascribed to an inappropriate management and control of the program's implementation, which allowed an irrational use of resources, namely a higher number of laboratory tests and drug prescriptions and a higher doctor/specialist visit rate. Reported evidence has shown that this undesirable side effect can be avoided by implementing control mechanisms to optimize the use of resources.[16,31] These mechanisms, automatically included in controlled studies, are not necessarily present in real-world trials. One indirect piece of evidence that this was the case in this study was the high patient dropout rate observed in the DPO.

The role of program management is frequently underscored, as shown by the fact that specific indicators are not easily identified in the evaluation process. We must admit, however, that implementation of careful planning to ensure a fluid interaction among key members of the institution, program managers, and health care professionals is not an easy task. In this regard, efficient management-control strategies should include audits of the medical and administrative processes at every step of the program's implementation, ie, from participant enrollment, scheduled doctor's visits, and practice performance up to drug supply. In this context, one coordinator should take care of the program and the audit outcomes, and introduce adjustments in the core strategies to optimize medical and economic results. These adjustments should include activities to improve patient adherence, such as reminders to attend medical visits or perform laboratory tests. Additionally, the development of continuous diabetes-

education activities for physicians and patients should be closely followed up.

In brief, our data also show that in a real-world context, only a suitable combination of medical and management strategies would simultaneously improve the quality and reduce the cost of care of people with diabetes.

Limitations

Despite the novelty of the data provided by our study, some of its characteristics limit its power and force us to interpret our results with caution, namely: (1) this was not a population study, ie, it only represents a sample of people with diabetes who received care in one organization of the Argentine social security system and who volunteered to participate in the study, the latter condition certainly introducing a bias; (2) data are presented in a descriptive way after a simple statistical analysis that included the control of value distribution before applying a specific test, but without any special study, such as potential covariate influence; and (3) although several authors have shown the importance of perception of quality of life among patients with diabetes,[37] we did not evaluate the issue in our study.

Beyond these limitations, the data provide a clear example of the difficulties of reproducing a controlled study in real-world conditions, and consequently of obtaining identical outcomes; these difficulties appeared even when the study was implemented by the same research group and in a comparable health-care setting. Further, our results serve to identify barriers and constraints that need to be carefully considered to overcome their negative influence.

Conclusion

Our results show that implementation of the DPO in real-world conditions results in a significant and sustainable improvement of the quality of care provided to people with diabetes incorporated therein. This improvement was associated with an increased use of diagnostic and therapeutic resources, with a consequent negative impact upon their cost. Since controlled studies have shown that quality of care can be improved without increasing care costs, our results reinforce the need to include effective management control in real-world diabetes programs to allow appropriate medical and administrative feedback to ensure the simultaneous improvement of clinical outcomes and resource-use optimization.

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Disclosure

The authors report no conflicts of interest in this work.

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