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PRODIACOR: A patient-centered treatment program for type 2 diabetes and associated cardiovascular risk factors in the city of Corrientes, Argentina
Study design and baseline data

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Abstract

Objective: To implement a controlled clinical trial (PRODIACOR) in a primary care setting designed 1) to improve type 2 diabetes care and 2) to collect cost data in order to be able to measure cost-effectiveness of three system interventions (checkbook of indicated procedures, patient/provider feedback and complete coverage of medications and supplies) and physician and/or patient education to improve psychological, clinical, metabolic and therapeutic indicators. All three Argentinean health subsectors (public health, social security and the private, prepaid system) are participants in the study. Patients of participating physicians were randomly selected and assigned to one of four groups: control, provider education, patient education, and provider/patient education; the system interventions were provided to all four groups.

Baseline results: Mean BMI was 29.8 kg/m^2; most subjects had blood pressure, fasting glucose and total cholesterol above targets recommended by international standards. Only 1% had had microalbuminuria measured, 57% performed glucose self-monitoring, 37% had had an eye examination and 31% a foot examination in the preceding year. Ten percent, 26% and 73% of people with hyperglycemia, hypertension and dyslipidemia, respectively, were not on medications. Most patients treated with either insulin or oral antidiabetic agents were on monotherapy as were those treated for hypertension and dyslipidemia. WHO-5 questionnaire scores indicated that 13% of the subjects needed psychological intervention.

Conclusions: Baseline data show multiple deficiencies in the process and outcomes of care that could be targeted and improved by PRODIACOR intervention.

Keywords: Type 2 diabetes management; Patient and healthcare provider education; Quality of care; Patient satisfaction; Psychological impact

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1. Introduction

Diabetes is a common, costly and ever-increasing health problem with chronic complications that result in a heavy socioeconomic burden [1–4]. The most rapid increases in incidence are in type 2 diabetes in the fourth decade of life with an increasing incidence in children and adolescents [5–7].

Chronic cardiovascular complications, the major cause of morbidity, mortality and costs of diabetes can be significantly reduced by appropriate control of blood glucose and associated cardiovascular risk factors (CVRFs) [2,8–13]. The cost of these treatments is within the range of currently accepted preventative interventions [12,14]. Despite the available evidence, prevention strategies have not been widely implemented into clinical practice [15] and the care received by people with diabetes is frequently far from optimal [16–21].

Several factors contribute to these disappointing outcomes, including a health system unable to cope with the care of chronic diseases and unwilling to pay for preventative interventions [22–24]. Inadequate knowledge and experience of the health care providers [19] and inappropriate providers' attitude towards application of guidelines are practitioner factors widely cited [25,26]. Limited patient access to care, poor patient compliance to self-care and treatment, scant attention paid to patient education and to the psychological impact of the disease are among patient factors cited [15,26]. Lack of a tradition of continuous evaluation of medical outcomes with concomitant treatment adjustments within the health care system also contributes to these disappointing outcomes [16,18,27].

Effective models of diabetes care have implemented system changes and patient and/or physician education. Among the system changes most widely implemented (included in this trial) are: the provision of specific care guidelines and reminders, improved access to care by reduction of the financial and administrative barriers to care, and patient/provider feedback to monitor the results of care. A review of reported educational interventions in disease management programs of chronic diseases, including diabetes, concluded that most of the programs directed at providers and patients are associated with improvements in care; however, little is known about the relative effectiveness and costs associated with different combinations of system changes and educational interventions [28]. A recent report of empirical findings on the cost-effectiveness of two guidelines strategies implemented at the secondary care level in the Netherlands concluded that both strategies were cost-effective compared to usual care [29]. Further research is needed to evaluate, at different care levels, the relative cost-effectiveness of different combinations of system and educational interventions in order to determine the value of their inclusion in disease management programs [30]. Such information is important to optimize allocation of healthcare dollars, particularly in developing countries with limited economic resources.

In this manuscript we describe the design and implementation of a program in primary care settings developed to improve the care of people with diabetes by providing the structure and resources to deliver quality diabetes care in a manner that allows us to analyze the relative effectiveness and direct medical costs of these interventions that have been previously shown to improve the quality of care, i.e. system interventions (*evidence-based guidelines* via patient checkbooks, *improved access to care* by the provision of free medications and supplies, and *patient and provider feedback*) and physician and patient education. We also implemented routine monitoring of psychological, clinical, metabolic and therapeutic indicators. The program incorporated healthcare organizations (HCOs) from the three Argentinean health subsectors (public health, the social security system and the private, prepaid system) in order to enhance its generalizability.

2. Research design and methods

Primary care physicians were recruited from participating HCOs. These organizations signed a consortium agreement committing them to share responsibilities, to promote the implementation of the program, and to finance the activities not covered by the sponsoring grant; together they represent the public, the social security and the private health care sectors of Argentina. The public health care system of Argentina is similar to the United States public health care system for those without health insurance including Medicaid. The Social Security system is a publicly-financed health care system for governmental and non governmental employees and their families, and the private system is financed by private employers as in the United States with defined benefits provided to employees of private enterprises and their dependents.

During the recruitment phase of PRODIACOR, we implemented several promotional activities. These included meetings with investigators, local coordinators and authorities from the participating organizations. We also met with

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physicians who were considering volunteering to participate in the study to explain the rationale, importance, aims, activities, timetable and the methodology selected for the study. Posters were placed in patient care areas and leaflets for physicians and patients enrolled in the study were also used to explain the goals and activities of the program. A short bulletin describing the progress of the study and its results is periodically distributed among all PRODIACOR participants – both physicians and patients – to keep them informed about the progress of the program.

3. Statistical power and sample size

For sample size determination in each of the four groups, we considered the change in A1C from baseline to the end of the study as the primary outcome variable. A minor problem with power estimation is that we do not know how correlations of patients from the same physician are likely to be. However, we assume the correlation will be very small, from 0.20 to 0.30.

To estimate sample sizes, we have taken a two-step approach. First, we have estimated sample sizes required for the detection of effects assuming independence. This was done using a two-sided test at the 5% level of significance and 80% power using a paired *t*-test.

The second step was to inflate the sample size to account for non-independence. We have chosen to increase the sample size at the first step by 25%. We assumed that there will be a 20% dropout or failure to follow up. Hence, we increased the sample size chosen at the second step by 20%.

Assuming 1.5 to be the standard deviation of the change in A1C, we require 73 patients in each group at the first step to detect a decrease of 0.5. This gives 111 patients for each group after adjusting for correlation and dropout or failure to follow up. We enrolled 36 physicians and 13 patients per physician. Thus, to accomplish this purpose we randomly selected and enrolled 36 physicians in a 2×2 design from the list of volunteering primary care physicians provided by each participating HCO (Fig. 1); thereafter, each participating physician selected 13 patients with type 2 diabetes meeting the entry criteria (total: 468 subjects). Assignment of patients to one of the four groups was nested by physician so that all patients of an individual physician had the same group assignment.

Following a covariate balance with respect to outcome measurements, we applied a covariate adaptative randomization method using allocation concealment, that is, neither participating physicians and patients nor the investigators knew in advance to which group they would be assigned. The data considered in the covariate balance were sex, age, BMI, blood pressure, lipid profile and presence or absence of macro- and/or microvascular complications.

Differences among groups were analyzed using ANOVA and Bonferroni tests for quantitative variables and chi square for percentage values. When other tests were used, they have been mentioned in the text.

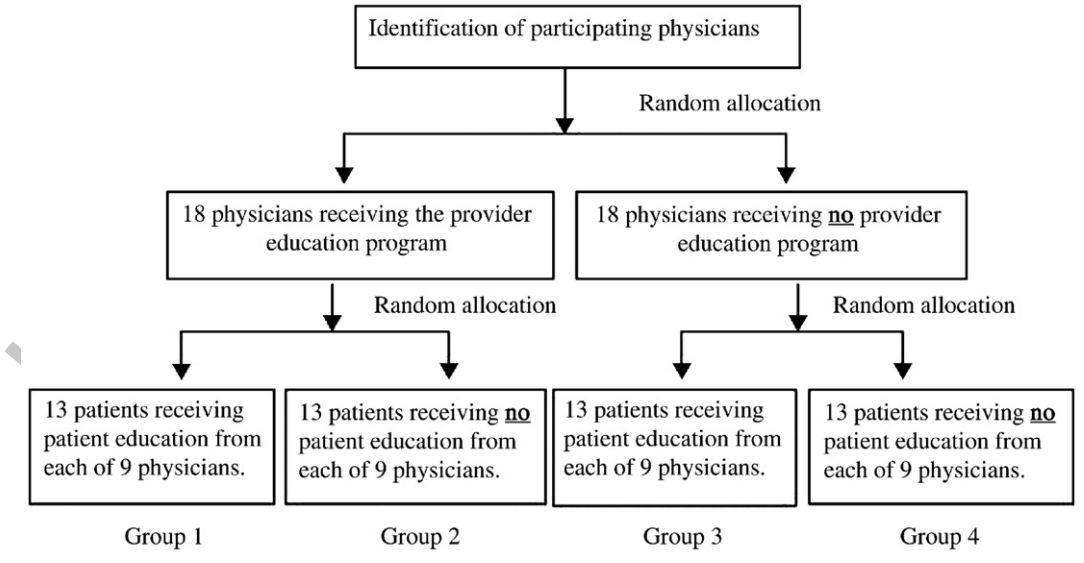

Fig. 1. Randomization plan for the 2×2 design.

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We developed a registry to collect patients' clinical, psychological, biochemical, therapeutic and economic data before and after PRODIACOR implementation. The registry included the following elements:

3.1. Physician data form

This is a summary of demographic and practice characteristics of the participating physicians. All participating physicians are primary care practitioners.

3.2. Annual and bi-annual clinical record form

We used the Qualidiab Data Sheet [17] and a shortened version for the six-month assessment, recording only the indicators to be used to determine clinical, metabolic and associated CVRFs outcomes. Both sheets are completed by the physician.

Prior to initiation of the program and initial data collection, physicians were instructed on the processes of initial and follow up data collection in sessions specifically designed for this purpose. As mentioned below, a physician monitor was assigned to each participating physician who completed a 100% chart review of all patients participating in to program to assure data completeness and to resolve any data discrepancies.

For the initial data collection, participating physicians were instructed to enter any clinical or biochemical data collected within one year, but they were specifically instructed not to perform any additional clinical evaluations or biochemical tests just to make the record more complete. Accordingly, absence of recorded results of any parameter means that it was absent from the clinical record in the preceding twelve months.

3.3. Patient questionnaire

This is based on that previously used in the Diabetes Advantage Program (DAP); it includes questions about the disease, well-being (WHO-5 [31], PAID [32], personal assessment of current health status [33], and satisfaction with the diabetes care received [34]. The questionnaires are completed in interviews conducted by trained data managers once a year. In addition to serving as a data collection tool *per se*, this data form also serves a data quality purpose. If there are any data discrepancies between those reported on the patient questionnaire and the data recorded by the physician (for example a patient reporting the performance of a cholesterol test, not recorded by the physician), the physician monitor is charged with resolving this discrepancy prior to data entry into the CENEXA data system for analysis.

3.4. Personalized checkbook

Following the initial data collection, the primary data collection instrument during this program is the personalized checkbook developed for the PROPAT study [35]. It has proved to be an efficient tool for reminding the patients and their physicians about the need for specific aspects of care, for data collection and for payment. It is the integration of these three aspects that is unique and makes the checkbook so reliable. In PROPAT, data collection using the checkbook coupons proved to be nearly 100% complete [35]. Briefly, the checkbook serves first as a reminder system (its individualized "checks" recommend medical visits, laboratory tests, consultations and drugs and supplies at intervals determined by medical guidelines); second as a data collection system (results are written directly on these "checks", be they laboratory tests, consultations, or prescriptions for drugs or devices); and third as a payment voucher (all payments are made via the documentation provided by the checkbook "checks"). The "checks" are thus integral to the data system for the HCOs; they serve to order procedures, consultations, laboratory tests, prescriptions, to record and communicate results, and as payment vouchers. They are integrated in our programs in a manner similar to what a computerized medical record system might be in developed countries.

Thus, the checkbook includes "checks" for annual visits to the primary care and specialist physicians as appropriate, prescriptions (oral agents, insulin, antihypertensive and lipid lowering agents, strips for glucose self-monitoring), laboratory tests and studies (CBC, ESR, urea, creatinine, total cholesterol, HDL- and LDL-cholesterol, triglycerides, proteinuria, microalbuminuria, creatinine clearance, glycemia, and A1C). It is customized for each patient according to the presence of associated CVRFs and chronic complications, it facilitates the standardization of medical care, and represents a source of information about results and use of resources (economic assessment).

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The data collected from these sources are then incorporated into our CENEXA database that includes software to prepare a biannual feedback report for physicians and their patients containing the values recorded for certain parameters (glycemia, cholesterol, blood pressure) and the goal proposed for each parameter according to international standards. It also includes recommendations about appropriate treatment to achieve therapeutic goals. The Feedback Report has been previously used in the Las Vegas study [36].

4. Educational interventions

4.1. Diabetes training course for physicians

This consists of four intensive theoretical-practical modules with frequent interaction between lecturers and physician participants. Each participant receives a Manual with all the algorithms for diagnosis, control and treatment of type 2 diabetes included in these modules. Physicians in the control groups not receiving this intensive education only receive the Manual [37].

4.2. Diabetes structured education courses for people with type 2 diabetes

The methodology and the results obtained with this type of courses have been previously published [38]; their primary focus is to improve health behavior. The courses are given in an ambulatory group setting of up to 10 patients; interaction between the educator and attendees is a key component of the program. There are 4 weekly teaching units of 90 to 120 min each with a reinforcement session scheduled for month six. Family members and spouses are encouraged to attend. The educational material used includes multiple pedagogic tools, questionnaire cards to verify the knowledge acquired in previous sessions, an individual log-book to record all the self-monitored data (glucosuria, blood glucose and body weight) and a patient book including the main contents of the program. Patients not included in the intensive diabetes education courses only receive this book.

4.3. Data monitoring

Every physician included in the study is periodically (at least twice a year) visited by a physician monitor who assesses the quality of the data recorded by the physician and the concordance between physician-collected data and

t1.1 Table 1
t1.2 Randomization results. Clinical and metabolic characteristics

t1.3		All Groups	Physicians/ patients educated	Physicians educated/ patients not educated	Physicians not educated/ patients educated	Physicians/ patients not educated	*P*
t1.4	Age (yrs)	62.2	62.0±[illegible]117)	62.4 [illegible]117)	62.2±8.4 (117)	62.2±9.0 (117)	0.992
t1.5	Gender (%)	66.7	67.5	70.1	66.7 (117)	62.4 (117)	0.656
t1.6	Diabetes duration (yrs)[a]	10.3±9.3	10.9±9.4 (117)	10.7±8.4 (117)	10.6±11.14 (117)	9.1±8 (114)	0.432
t1.7	Smoking[a]	9.4 (9.4)	6.8 (8)	11.1 (13)	12.8 (15)	6.8 (8)	0.282
t1.8	BMI	29.8±5.4 (464)	29.7±5.2 (117)	29.6±5.6 (115)	29.6±5.4 (117)	30.4±5.2 (115)	0.615
t1.9	SBP	141.9±17.8 (465)	141.5±18.5 (117)	143.6±14.9 (115)	140.8±19.3 (117)	141.7±18.2 (116)	0.668
t1.10	DBP	87.9±14.3 (465)	88.4±18.0 (117)	87.7±11.7 (115)	87.9±12.3 (115)	87.4±14.4 (116)	0.967
t1.11	FBG	145.5±47.1 (461)	147.5±48.9 (117)	142.4±43.6 (114)	146.6±43.8 (115)	145.3±51.9 (115)	0.853
t1.12	HbA1	7.5±1.6 (57)	6.4±1.4 (14)	±1.9 (20)	7.6±1.9 (8)	7.7±0.9 (15)	0.051
t1.13	HbA1C	7.8±1.4 (158)	7.4±1.7 (45)	±1.1 (29)	8.1±1.4 (24)	7.8±1.3 (60)	0.033
t1.14	Creatinine	1.2±0.7 (145)	1.2±0.6 (49)	1.2±0.4 (35)	1.4±1.0 (32)	1.2±0.3 (29)	0.319
t1.15	Proteinuria	77.2±135.8 (89)	78.8±139.0 (29)	109.1±209.7 (19)	85.6±102.2 (21)	35.7±38.2 (20)	0.397
t1.16	Cholesterol	205.5±39.3 (460)	207.0±39.1 (114)	209.7±39.4 (117)	209.3±41.9 (115)	195.7 ±35.3 (114)	0.020
t1.17	HDL-c	61.2±93.4 (129)	45.3±13.2 (45)	108.9±203.4 (24)	67.0±57.3 (25)	44.9±10.3 (35)	0.032
t1.18	LDL-c	137.6±43.2 (86)	124.9±22.4 (27)	145.6±69.4 (14)	148.8±45.9 (22)	136.9±37.3 (23)	0.235
t1.19	TG	160.9±61.2 (376)	157.2±49.9 (89)	173.3±69.9 (100)	157.9±70.6 (94)	154.3±48.3 (93)	0.126
t1.20	Microalbuminuria	47.6±26.2 (5)	40.0±14.1 (2)	–	–	52.7±34.3 (3)	0.992

t1.21 [a] Percentage; number of cases between parentheses. Values are mean±S.D. BMI, Body Mass Index; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; FBG, Fasting Blood Glucose; HDL-c, HDL cholesterol; LDL-c, LDL cholesterol; TG, triglycerides.

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those obtained by the monitor during an interview with patients. This physician monitor is responsible for assuring complete data collection and resolving any data conflicts between the charts, the patient questionnaire and the Qualidiab form submitted to CENEXA prior to data entry. All site staff that collected and recorded data were previously trained by the investigators on the processes and procedures of collection and data recording.

5. Baseline results

As can be seen in Table 1, the randomization achieved subject groups well-balanced as to sex, age, BMI, blood pressure, lipid profile and presence or absence of macro-and/or microvascular complications. While there were lower total cholesterol values in group 4, lipid fractions were well-matched; while not a randomization criterion, diabetes duration was also well-matched. Smoking and alcohol consumption were uncommon. Regarding CVRFs, overweight was present in most patients as was uncontrolled hypertension. Both A1 and A1C fractions are recorded; 84% of those measurements were above 6.5%. Almost half of the subjects did not have either value. Mean fasting blood glucose was above 100 mg/dL in 87% of the subjects. Total cholesterol was greater than 200 mg/dL in 57% of subjects. Only 28% and 18% of the patients had values for HDL-and LDL-cholesterol, respectively. Forty seven percent of patients had triglyceride values above 150 mg%. Among other risk factors, microalbuminuria was measured in only about 1% of the population.

Fifty seven per cent of the patients were prescribed self-monitoring blood glucose (SMBG) prior to the program. During the program subjects in all four groups will be prescribed SMBG and receive self-monitoring devices and strips at no cost.

Initially, the physicians recorded the presence of co-morbid conditions and chronic complications among their patients from review of their medical records. Co-morbid conditions were reported with the following frequencies: neuropathy 15%, nephropathy 1.7%, previous acute myocardial infarction 6%, angina 3%, stroke and amputations 2%. Considering that the average diabetes duration in the PRODIACOR population was 10 years, these frequencies appear low and suggest the patients may have had incomplete evaluations for the presence or absence of complications. This is supported by the fact that only 37% had had an eye examination and only 31% had had a foot examination recorded in the previous 12 months.

Acute diabetic complications and hospitalizations were uncommon in our subjects: only two had an episode of severe hypoglycemia, two had an episode of ketoacidosis and one an episode of hyperosmotic coma recorded in the past 12 months.

Forty eight percent of the PRODIACOR subjects were on a diet and 34% participated in some form of regular exercise. As can be seen in Table 2, 10% of the subjects received neither oral antidiabetic agents nor insulin; 20.7% of those with hypertension and 64.6% of the patients with dyslipidemia were not receiving medications for these CVRFs.

t2.1 Table 2
t2.2 Pharmacological treatment

t2.3		Hyperglycemia % (*n*)	Hypertension % (*n*)	Dyslipemia % (*n*)
t2.4	Total	100 (468)	100 (386)	100 (308)
t2.5	No treatment	10.0 (47)	20.7 (80)	64.6 (199)
t2.6	Treatment	90.0 (421)	79.3 (306)	35.4 (109)
t2.7	Monotherapy	67.7 (285)[a]	65.7 (201)[b]	89.9 (98)[c]
t2.8	Combined treatment	32.3 (136)	34.3 (105)	10.1 (11)
t2.9	2 drugs	77.9 (106)	77.1 (81)	100 (11)
t2.10	3 drugs	5.1 (7)	21.0 (22)	–
t2.11	4 drugs	0.7 (1)	1.0 (1)	–
t2.12	5 drugs	–	1.0 (1)	–
t2.13	6 drugs	0.7 (1)	–	–
t2.14	Insulin+1 drug	11 (15)	–	–
t2.15	Insulin+2 drugs	4.4 (6)	–	–

t2.16 The following values were considered as normal: blood pressure, 130/85 mm Hg; total cholesterol, 200 mg%; triglycerides, 150 mg%.
t2.17 [a] Insulin, 9.8%; one drug, 90.2%; sulfonylureas, 64%; biguanides, 31%; meglitinides, 4%; thiazolidinediones, 1%.
t2.18 [b] ACE, 74%; β-blockers, 8%; Ca-blockers, 7%; ARB, 6%; diuretics, 2%; αa-blockers, 2%.
t2.19 [c] Statins, 86%; fibrates, 11%; other, 3%.

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Only 12% of the subjects were on insulin, in most cases a single dose of an intermediate or long-acting formulation; 68% of those treated with oral antidiabetic agents were on monotherapy. Monotherapy was also the most common regimen to treat hypertension (65.7%) and dyslipidemia (89.9%). Table 2 also includes other types of drug combination.

We used thresholds suggested by Lowe et al. to analyze the results of the WHO-5 questionnaire [39]: a) scores ≤ 28 suggest the need of immediate psychological support, b) scores between 29 and 50 require further assessment of their psychological status, and c) scores ≥ 51 do not require psychological support. Seventy-five per cent of the population had a score above 51, 13% between 29 and 50, and 11% below 28. None of the subjects included in the latter group had received psychological support at any time.

For this first analysis of the data recorded in the Patient Satisfaction questionnaire we considered its score as a simple summation of items; thus the highest score (55 points) represented the highest degree of patient satisfaction. When we correlated this score to the corresponding WHO-5 questionnaire score, we found that subjects with high and low WHO-5 scores had a significantly higher and lower degree of satisfaction (mean 38 ± 1.4 *vs.* 43 ± 0.5, respectively, $P < 0.02$). Further, Pearson's coefficient demonstrated a significant and positive linear correlation between WHO-5 and satisfaction scores (Pearson's coefficient $= 0.243$; $n = 334$; $P < 0.01$). These data suggest that appropriate psychological support should also result in improvements in patient satisfaction.

More than half of the population surveyed considered their current health status as excellent (3%), very good (7%) or good (44%), whereas 37% considered it fair and 7% poor; 2% did not answer the question.

6. Discussion

We have completed the selection and randomization of physicians and patients, recorded baseline data (pre-intervention period) and trained the participating personnel and HCOs on how to optimize the use of resources and time. Herein we report basal clinical, biochemical, therapeutic and psychological indicators. Although basal patient resource consumption was also obtained (ambulatory medical costs, hospitalizations, drug and supply costs, consultations and laboratory and other diagnostic procedures), these data are not included in this report.

Our data show a wide gap between published standards and observed care; this is true for frequency of monitoring, treatment regimens for diabetes and CVRFs and outcomes. For example, A1 or A1C was measured in less than half, microalbuminuria in about 1% and HDL- and LDL-cholesterol in less than one third of the subjects. The low percentage of chronic complications recorded strongly suggests that these were not regularly assessed. While one might interpret absent values as errors in data recording rather than the test or procedures not having been performed, we have undertaken a number of steps described in the text to minimize missing data and are confident that the values are missing because the test or procedure was not performed.

A high percentage of subjects were overweight or obese and had values of blood pressure, fasting blood glucose and serum lipids above recommended targets. Additionally, none of these observed abnormalities were being aggressively treated; rather, we observed a conservative approach to prescribing agents capable of restoring them to normal levels.

These observations suggest that most of our subjects are at high risk for the development of potentially preventable vascular disease [8–10,40], with the consequent increased demand for care, increased costs and decreased quality of life [2,11–13].

The observed deficiencies in treatment and outcomes could be the consequence of a deficit in diabetes knowledge and appropriate attitudes on the part of either the subjects and/or their health providers, the failure to identify and treat those who have psychological problems, the recorded optimistic perception of current health status by the subjects, limited payments for prevention strategies (including SMBG) or a combination of these and other unidentified factors.

In PRODIACOR we hypothesize that the introduction of changes in the HCOs' system for delivering care are central to improving both the process and outcomes of care. Our interventions place emphasis on modest and inexpensive system changes to guide the HCOs and to provide increased access to needed medications and supplies. The system changes were individualized management guidelines using the checkbooks, increased access to care by providing free medications and supplies, and systematic patient and physician feedback. Our educational interventions were focused on prevention rather than treatment of complications. Thus, we will couple these system changes with the implementation of patient and physician education, including the identification of patient psychological needs. No less important from the point of view of health care organizations, we will determine the costs of each intervention implemented in our Program and perform a cost-effectiveness analysis. These results are clearly relevant to the health

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care system since it decides what activities to cover in order to improve diabetes care with the limited resources available [28,30].

PRODIACOR uses simple prevention strategies tools (mainly diabetes education and regular data recording) that do not require either great resource investments or expensive technology; this is not a minor issue in a developing country with limited resources. Since many of the participating organizations operate at national level and the public sector organization is common to each province of Argentina, a successful outcome of the PRODIACOR model could be easily and inexpensively reproduced in the remaining provinces and adapted and adopted by other developing countries.

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Appendix A

Organization and program committees: *General Coordinator*: JJ Gagliardino. *Local Coordinator* (Corrientes): S Lapertosa. *Executive Committee CENEXA:* NV Cédola (MD); C González (Statistician); JE Caporale (Economist); F Siri (Informatics); PA Oliver (Assistant management); A Sánchez (Medical Audit). *Executive Committee Corrientes:* P Torales (Private UGP); M Villagra (Private UGP); G Ojeda (SPS); A Valmagia (PROFE); A Silva (PROFE); D Dos Santos (Ministry of Public Health Corrientes); Accountant MA Yordan (Public UGP); C Segersbol (IOSCOR); F Marcopulos; J Migueles (OSPLAD). *Intersectorial Committee Corrientes:* R Cardozo (Ministry of Public Health Corrientes); R Pinchetti (Ministry of Public Health Corrientes); I Rigonatto (INSSJYP, Corrientes); B De la Vega (IOSCOR); A Karatanazopulos (IOSCOR); R Esquercia (IOSCOR); R Degregorio (IOSCOR); J Murua (Private UGP); D Mondaini (UNNE); A Silva (PROFE); M Polimeni (OSPLAD); B Benitez (Argentine Cardiology Society, Corrientes); D Dionisi (Argentine Cardiology Society, Northeast Chapter). *Advisory Committee: International*: Ch Clark Jr (Indiana University, USA). *National*: JM Domínguez (Argentina).

The different forms and questionnaires used in the study are available upon request to cenexa@speedy.com.ar.

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