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Multistrategic approach to improve quality of care of people with diabetes at the primary care level: Study design and baseline data

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ABSTRACT

Aim: To test the one year-post effect of an integrated diabetes care program that includes system changes, education, registry (clinical, metabolic and therapeutic indicators) and disease management (DIAPREM), implemented at primary care level, on care outcomes and costs.

Methods: We randomly selected 15 physicians and 15 nurses from primary care units of La Matanza County to be trained (Intervention-IG) and another 15 physicians/nurses to use as controls (Control-CG). Each physician-nurse team controlled and followed up 10 patients with type 2 diabetes for one year; both groups use structured medical data registry. Patients in IG had quarterly clinical appointments whereas those in CG received traditional care. DIAPREM includes system changes (use of guidelines, programmed quarterly controls and yearly visits to the specialist) and education (physicians' and nurses' training courses). Statistical data analysis included parametric/nonparametric tests according to data distribution profile and Chi-squared test for proportions.

Results: Baseline data from both groups showed comparable values and 20–30% of them did not perform HbA1c and lipid profile measurements. Majority were obese, 59% had HbA1C $\geq 7\%$, 86% fasting blood glucose ≥ 100 mg/dL, 45%, total cholesterol ≥ 200 mg/dL, and 92% abnormal HDL- and LDL-cholesterol values. Similarly, micro and macroangiopathic complications had not been detected in the previous year. Most patients received oral antidiabetic agents (monotherapy), and one third was on insulin (mostly a single dose of an intermediate/long-acting formulation). Most people with hypertension received specific drug treatment but only half of them reached target values; dyslipidemia treatment showed similar data.

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Conclusions: Baseline data demonstrated the need of implementing an intervention to improve diabetes care and treatment outcomes.

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1. Introduction

Diabetes complications, the major cause of morbidity, mortality and costs of diabetes, are significantly reduced by appropriate control of blood glucose and associated cardiovascular risk factors (CVRFs) [1–7]. Cost of these treatments is within the range of currently accepted preventive interventions [6,8].

Despite available evidence supporting these benefits, prevention strategies have not been widely incorporated into clinical practice [9], and care received by people with diabetes is frequently far from optimal [10–15].

Several factors contribute to this disappointing situation, namely: (a) an inefficient health system unable to cope with the care of chronic diseases and unwilling to pay for preventive interventions [16–18]; (b) inadequate knowledge and experience of health care providers [13], (c) inappropriate providers' attitude toward application of guidelines [19,20], (d) limited patient access to care, (e) poor compliance with self-care and treatment and (f) scant attention paid to the psychological impact of the disease and to patient education [9,20]. Lack of continuous evaluation and systematic registry of medical outcomes with concomitant treatment adjustments close the vicious circle that leads to poor care outcomes [10,12,21]. In this context, late diabetes diagnosis and inappropriate control/treatment are the final common path leading to the high morbimortality of the disease. In this regard, early detection and treatment of type 2 diabetes reduces cardiovascular morbimortality, and intensity of glucose and other CVRF treatment after diagnosis is less important than the timeliness of its initiation [22].

Effective models of diabetes care which include system changes and patient and/or physician education help to overcome most of the above mentioned problems. System changes most widely implemented included provision of specific care guidelines and reminders, improved access to care by reduction of financial/administrative barriers to care, and patient/provider feedback to monitor care outcomes. Indeed, a review of educational interventions in disease management programs of chronic diseases, including diabetes, concluded that most programs directed at providers and patients improved care outcomes; however, little is known about the relative effectiveness and costs associated with different combinations of system changes and educational interventions [23]. A recent report on cost-effectiveness of two guideline strategies implemented at secondary care level in the Netherlands, concluded that both strategies were cost-effective compared to usual care [24]. However, further research is needed to evaluate, at different care levels, the relative cost-effectiveness of different combinations of system and educational interventions to determine the value of their inclusion in disease management programs [25]. This

information is important to optimize allocation of healthcare funds, particularly in developing countries with limited economic resources.

In Argentina, the health care system includes three independent sectors: the public, the social security and the private sectors [26]. The public sector is mainly financed through taxes and provides universal access to free health care to 42% of the population (mostly unemployed and low-income population that are not insured by social security or private sector), through primary care units (PCU) and hospitals. PCU includes different kinds of disease management programs for the ambulatory treatment of chronic diseases with free supply of drugs through public entities; however, not all chronic diseases are fully covered. People with diabetes have free-access to human insulin, some oral drugs and a limited number of strips for self-monitoring blood glucose (SMBG), as part of public health system coverage. The social insurance sector includes more than 300 institutions organized at national and subnational levels by provincial government or labor unions, covering around 48% of the population. Degree of health coverage is determined by law in the Mandatory Medical Program (PMO), being financed by compulsory contributions made by employees (3%) and employers (6%). The private sector is financed through organized prepaid medical plans, and covers about 10% of the population; it operates like the social insurance system, using PMO as a reference standard of minimum level of coverage.

Attempting to answer some of the open questions, we are planning to implement at primary care level, an integrated diabetes care program that includes system changes, education, registry (clinical, metabolic and therapeutic indicators), education (physicians and nurses) and disease management (DIAPREM: DIAbetes Primary care, Registry, Education and Management). DIAPREM will evaluate clinical and metabolic outcomes as well as economic cost during a one-year follow up. We are currently presenting its design and baseline data.

2. Research design and methods

2.1. Background

Argentina has 40,117,096 inhabitants (2010 National Census). Thirty-nine percent of this population lives in the province of Buenos Aires (15,645,667 inhabitants) of which 18% lives in the city suburbs of this province (7,221,077 inhabitants). Of these, 1,775,816 people live in the county of La Matanza. According to the prevalence defined by the 2013 National Risk Factors Survey, our diabetes population is around 2,892,000 people; only about half of them know they have the disease (1,445,973), 70% of those diagnosed is on regular treatment (1,012,181) and less than 50% attain preventive treatment goals (455,481). Half of this population receives free care from the public health sys-

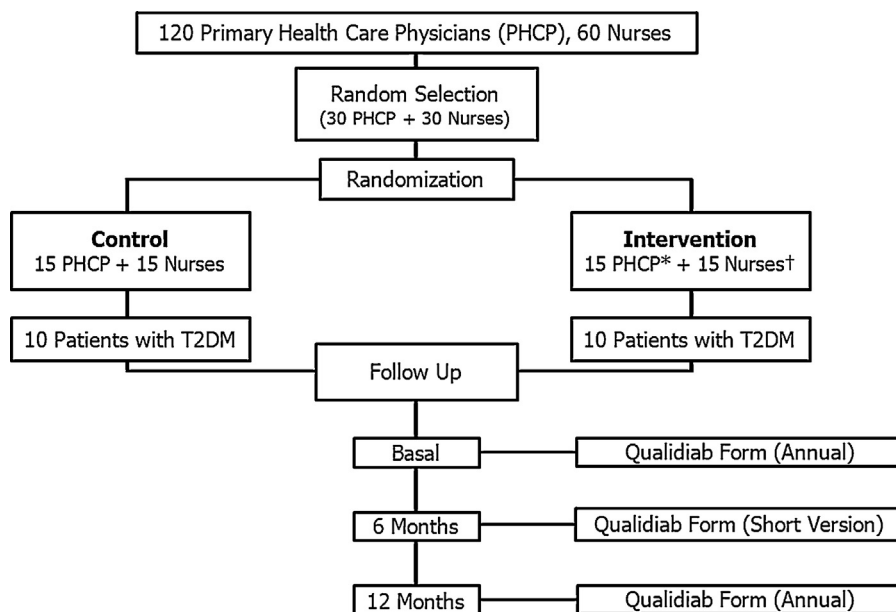


Fig. 1 – Study design. *PHCP received e-learning courses. †Nurses received face to face courses.

tem (506,091 people). Of this diabetes population, 4.43% lives in one area (La Matanza) of the city suburbs in the province of Buenos Aires (22,420 people), a low-income population with 34% unsatisfied basic needs and only 40% of the people has completed a primary school education.

2.2. Design

In this area, the La Matanza Health Secretariat has 40 Primary Health Care Units (PHCU) with 120 physicians and 60 nurses. From these PHCUs, we randomly selected 15 and from each one a physician (15) and a nurse (15) to be trained while another group of 15 physicians and nurses from other PHCUs were selected to use as controls.

Each physician–nurse team, has to take care of and follow up 10 patients with type 2 diabetes (T2DM) for one year; each patient is to have clinical appointments at least every 3 months (150 people with T2DM in the control and 150 people in the intervention group; see Fig. 1). Patients of both groups resemble the general characteristics of the daily practice attendants, excluding people with expected short survival (cancer or terminal conditions), with different kind of addictions or psychiatric disorders.

The study was approved by the La Plata University Ethical Committee and before their incorporation into the study cohort, each participating patient must provide signed informed consent. At the end of the study, the 15 physicians and 15 nurses who were initially part of the control group will receive the same education courses previously received by the intervention group.

Primary care physicians were recruited from participating PHCUs. These organizations signed a consortium agreement committing them to share responsibilities for implementing the program.

During the recruitment phase, we implemented several promotional activities. They included meetings with investi-

gators, local coordinators and authorities from participating organizations to explain the rationale, importance, aims, activities, timetable and methodology selected for the study.

2.3. Early diagnosis of T2DM

The program also includes identification of people at risk of developing T2DM. For this purpose, we apply the FINDRISC questionnaire that can be self-completed by patients while waiting for the physician's interview [27]. We currently have 4504 completed questionnaires, loaded into a database and analyzed; meanwhile we actively continue to collect this data.

People with a score over 15 are considered people with high risk and are recommended to adopt healthy life style changes (healthy meals and regular physical activity). We have developed educational material to provide these people with information on how to adopt these beneficial changes.

2.4. Statistical power and sample size

Changes in HbA1C from baseline to the end of the study were considered the primary outcome variable for determination of sample size in each group of the study. For this purpose, we chose a two-step approach. First, we estimated sample sizes required for detection of effects assuming independence. This was done using a two-sided test with 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. Consequently, we chose to increase the sample size at the first step by 25%. We assumed that there would be a 20% rate of dropout or failure to follow up. Hence, we increased the sample size for the second step by 20%.

As mentioned above, we included 15 physicians and nurses and 10 patients per physician–nurse team. Each participating team selected 10 patients with T2DM who met entry criteria. The control group included 157 patients and the interven-

tion group 154 patients, after adjustment for correlation and dropout or failure to follow up (total: 311 people with T2DM). Following a covariate balance with respect to outcome measurements, we applied a covariate adaptive randomization method using allocation concealment: that is, neither participating physicians and patients nor investigators knew in advance to which group they would be assigned. Data considered in the covariate balance were gender, age, BMI, blood pressure, lipid profile and presence or absence of macro- and/or microvascular complications.

2.5. Data registry

We developed a structured registry form to collect patients' clinical, biochemical, educational and therapeutic data before, during and after implementation of the project. The registry included the following items:

- i. Physician data form: It summarized demographic and practice characteristics of the participating physicians. All participating physicians were primary care practitioners.
- ii. Annual and bi-annual clinical record form: We used the Qualidiab Data form [11] and a shorter version for the six-month assessment, recording only the indicators to be used to determine clinical, metabolic and associated CVRF outcomes. These forms were completed by the physician and nurses.
- iii. Feedback form: Physicians–nurses received a form from each patient comparing treatment target values and current values from different clinical and metabolic indicators (HbA1c and the other CVRF); in case the patient did not achieve target values, the form suggests the issues the care team must pay special attention.

Prior to initiating the program's collection process, physicians and nurses were trained how to proceed in group sessions specifically designed for this purpose. They were also instructed how to perform registry at baseline, 6 and 12 months of the follow up period. Therefore, absence of recorded results of any parameter means that it was absent from the clinical record in the preceding twelve months.

2.6. Educational interventions

2.6.1. Diabetes training course for physicians

It consists of online course (National University of La Plata web frame) with 14 compulsory and 12 optional modules, plus 8 h of practical activities at a national reference center. This course is released through the Postgraduate Departments of the National University of La Plata (UNLP) School of Medicine (Argentina) and Indiana University (USA).

Each participant receives a manual with all the algorithms for diagnosis, control and treatment of T2DM included in these modules. Physicians in the control groups did not receive this intensive education [28].

2.6.2. Course for nurses

Five-day full-time intensive theoretical and practical course given at the Bernardo A. Houssay Center (La Plata) as part

of the Human Development Department of the School of Medicine UNLP.

During the course, nurses had the opportunity to live as a person with diabetes, in order to enhance empathy for and provide better understanding of the complexity of the needs of people with diabetes. They also had practical activities at the hospital of the School of Medicine of UNLP.

2.6.3. Patient follow-up

Participants in the Intervention group are seen every three months. For that purpose, immediately after each control visit the patient is given an appointment for the next control, and the date is sent to a Call Center. Additionally, once a year the patient is given an appointment for cardiovascular and ophthalmological controls performed at the hospital on the same morning. In this way we try to facilitate attendance to these controls and decrease the number of days off work.

2.6.4. Call-center

Its activity consists of calling each participant of the intervention group one week ahead of the quarterly control to ensure the patient's attendance to such these controls and decrease the desertion rate.

2.6.5. Data monitoring

To verify the impact of the diabetes education intervention, we used the Qualidiab data system (see Section 2.5) [11]. Additionally, the feedback form already described is a simple educational tool for the health care team. Data collected is also useful both to evaluate impact of the intervention and also to allocate resources (human and financial) considering real demand.

2.7. Current statistical data analysis

We used the Statistical Package for Social Sciences version 15 (SPSS Inc., Chicago, IL, USA). Descriptive statistics are presented as percentages and mean \pm standard deviation (SD). Group comparisons for continuous variables were performed by parametric or nonparametric test depending on the data distribution profile. The Chi-squared test was used to estimate differences between proportions. The level of significance was established at $P \leq 0.05$.

3. Baseline results

As shown in Table 1, the randomization procedure implemented resulted in reasonable well-balanced control and intervention groups with respect to gender, age, BMI, blood pressure, lipid profile and presence or absence of macro- and/or microvascular complications. Although it was not included as a randomization criterion, diabetes duration was also well-matched.

Not all patients included in the study have regularly controlled some parameters, indicating their degree of metabolic control, such as HbA1c (81%), LDL-c (81%) and proteinuria (30%). This low values, will represent a great challenge for

Table 1 – Clinical and metabolic data.

Parameters	All	Intervention	Control	P
Age (years)	55.25 ± 10.1 (311)	54 ± 10 (154)	56 ± 10.4 (157)	0.16
Male (%)	36 (112)	38 (154)	38 (157)	0.15
Diabetes duration (years)	7 ± 6.2 (288)	7 ± 6.9 (143)	7 ± 5.4 (145)	0.93
BMI (kg/m ²)	32.8 ± 8.03 (294)	32.84 ± 6.5 (149)	32.8 ± 9.3 (145)	0.96
SBP (mmHg)	129 ± 17 (309)	127 ± 17 (153)	131 ± 17 (156)	0.04
DBP (mmHg)	80 ± 12 (309)	81 ± 11 (153)	79 ± 12 (156)	0.27
FBG (mg/dL)	162.5 ± 74.1 (297)	162.6 ± 73.3 (142)	164.5 ± 75 (155)	0.82
HbA1C (%)	7.8 ± 2.2 (253)	7.78 ± 2.2 (131)	7.9 ± 2.2 (122)	0.66
Creatinine (mg/dL)	0.81 ± 0.24 (238)	0.79 ± 0.25 (128)	0.83 ± 0.22 (110)	0.19
eGFR	84.8 ± 22.6 (236)	87 ± 24.3 (126)	82.2 ± 20.4 (109)	0.09
Proteinuria (mg/dL)	9.8 ± 34.8 (94)	7.8 ± 31.1 (57)	12.9 ± 40.1 (37)	0.48
Total cholesterol (mg/dL)	196.6 ± 44 (272)	197 ± 44.7 (137)	196.4 ± 43.3 (135)	0.9
HDL-c (mg/dL)	47.5 ± 18.7 (255)	48.3 ± 22.6 (131)	46.7 ± 13.6 (124)	0.5
LDL-c (mg/dL)	118.9 ± 38.1 (253)	117.4 ± 36.2 (132)	120.5 ± 40.2 (121)	0.5
Triglyceride (mg/dL)	180.3 ± 112 (270)	202.4 ± 136.1 (133)	158.8 ± 76.8 (137)	0.01

Number of cases in parentheses. Values are mean ± standard deviation (SD); BMI, body mass index; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; FBG, Fasting Blood Glucose; eGFR, estimated Glomerular Filtration Rate; HDL-c, HDL cholesterol; LDL-c, LDL cholesterol. P-values represent the statistical difference between intervention and control group.

DIAPREM, being part of the factors that might improve after its implementation.

Regarding the degree of control of glucose homeostasis and associated CVRFs, overweight was observed in most patients while HbA1C levels $\geq 7\%$ were recorded in 59% of patients and mean fasting blood glucose ≥ 100 mg/dL in 86% of cases. Total cholesterol was over 200 mg/dL in 45% of participants and 93% and 94% of the patients had abnormal HDL- and LDL-cholesterol values, respectively. Fifty-two percent of patients had triglyceride values above the recommended target of 150 mg%. Additionally, microalbuminuria was measured in only 17% of the study population.

According to serum creatinine levels, the estimated glomerular filtration rate (eGFR) was 88.26 ± 57.65 (mean \pm SD).

Microangiopathic chronic complications and cardiovascular events were reported with the following frequencies: neuropathy 19%, nephropathy 0.1%, previous acute myocardial infarction 6%, stroke and amputations 2%.

Sixty percent of subjects were on a diet and 30% performed some kind of physical activity. Few patients (1%) received neither oral antidiabetic agents nor insulin; in this case they were treated only with life style changes (LSC) (Table 2); 47% of those treated with oral antidiabetic agents were on monotherapy, while only 27% and 42% of patients in the intervention and control group, respectively, were on insulin, in most cases receiving a single dose of an intermediate or long-acting formulation.

Of the total population, 52% of patients have SBP values above treatment target ($\leq 130/80$ mmHg) and 78% were on treatment, mostly (55%) with 2 or more antihypertensive drugs (Table 2). Since our study population was relatively young and 30% of them had already proteinuria, we have considered the mentioned tight blood pressure target values as suggested by the ADA guidelines [29].

LDL-c higher than 100 mg/dL was detected in 178 of 311 patients (57%); 52% of treated patients reached target values (LDL-c ≤ 100 mg/dL). 45% of the patients were treated with statins (Table 2).

4. Discussion

Concurring with data reported in the Encuesta Nacional de Factores de Riesgo [National Risk Factors Survey], in our sample population most of the adults with T2DM have associated CVRF [30]. Further, these CVRF (particularly BMI, serum lipid profile and blood pressure) were not adequately controlled.

Considering that the average duration of diabetes in the selected population was 7 years, the frequency of chronic complications appears low, thus suggesting that patients may not have a systematic evaluation of their existence. This is supported by the fact that only 51% had had an eye examination and 78% had had a foot examination recorded in the previous 12 months.

Based on this poor management of the disease, we could predict that in the near future these people will develop more chronic complications that will increase the cost of their care and decrease their quality of life [31,32]. Therefore, the situation brings to our attention the need to urgently implement effective preventive strategies to overcome these problems. This implementation could start at the primary care level and with general practitioners (GPs), since both are in the first scenario where people with diabetes and CVRF will consult for disease management [33]. This key role was recently stressed by the American Diabetes Association, which published a special issue of their Journal to the primary care health sector [34], as well as promotion of effective guideline implementation [35].

Despite wide dissemination of these guidelines, implementation barriers exist at different levels: patients (motivation and health education), practitioner (beliefs regarding effectiveness), practice (time and infrastructure) and system (human and financial resources) [36,37]. All these barriers contribute to low rates of clinical risk assessment, lifestyle advice, controls and timely referrals [38]. Consequently, one of the main objectives of our study is to activate discussion of current guidelines during education courses and to promote their implementation.

Table 2 – Type of treatment.

Treatment	Intervention n (%)			Control n (%)			P
	Female	Male	All	Female	Male	All	
	102 (100)	52 (100)	154 (100)	97 (100)	60 (100)	157 (100)	
Hyperglycemia							
—Only LSC	1 (1)	0	1 (1)	2 (2)	–	2 (1)	
—Treated with Insulin or OAD	101 (99)	52 (100)	153 (99)	95 (98)	60 (100)	155 (99)	0.62
Monotherapy	44 (43)	28 (54)	72 (47)	36 (38)	15 (25)	51 (33)	0.01
Combined OAD (2 or more)	29 (29)	10 (19)	39 (26)	23 (24)	15 (25)	38 (25)	0.94
Insulin + OAD (1 or more)	22 (22)	9 (17)	31 (20)	29 (30)	21 (35)	50 (32)	0.016
Insulin	6 (6)	5 (10)	11 (7)	7 (8)	9 (15)	16 (10)	0.33
Hypertension							
—Only LSC	19 (19)	14 (27)	33 (21)	20 (21)	18 (30)	38 (24)	
—Treated with antihypertensive	83 (81)	38 (73)	121 (78)	77 (79)	42 (70)	119 (76)	0.65
Monotherapy	47 (56)	19 (50)	66 (55)	34 (44)	16 (38)	50 (42)	0.03
2 antihypertensives	22 (26)	15 (39)	37 (30)	32 (42)	18 (43)	50 (42)	0.04
3 or more	14 (17)	4 (11)	18 (15)	11 (14)	8 (19)	19 (16)	0.81
Dyslipidemia							
—Only LSC	58 (57)	26 (50)	84 (54)	65 (67)	34 (56)	99 (63)	0.1
—Treated with statins	44 (43)	26 (50)	70 (45)	32 (33)	26 (43)	58 (37)	0.15
Monotherapy	42 (95)	25 (96)	67 (96)	30 (98)	24 (92)	54 (93)	0.79
2 statins	2 (5)	1 (4)	3 (4)	2 (2)	2 (8)	4 (7)	0.79

LSC, life style changes; OAD, oral antidiabetic. P-values represent the statistical difference between intervention and control group.

Education of physicians and nurses is not a minor component of our program, based on the positive experience we have had with its use [39,40].

Improving management of diabetes and other chronic disease at primary care level requires a reasonable integrated approach as described in the American Chronic Care Model [41]. This model attempts to generate proactive, organized healthcare teams interacting with informed active patients. Its successful implementation is associated with improvement of healthcare processes and health outcomes in several chronic diseases such as diabetes and heart failure [42]. Shared care and inter-professional collaboration (IPC) are some of the key components of this model and of chronic care management [43]. Therefore, this approach is part of our program since physicians and nurses of the IG share patient reviews in order to optimize time usage and time devoted to each patient. Nonetheless, we are aware that development of IPC in primary care requires overcoming barriers such as health professionals' perception that they already work as a team and know (and exert), their personal roles and skills. Reported data show that this assumption is far from reality [44]. Additionally, engaging health care team members in changing negative attitudes and improving the quality of care provided is not an easy task and results in moderate outcomes [45].

Feedback was found to be an effective strategy when showing poor results of disease management, and was frequently provided by using the complete recorded health data for the entire population [46]. It enhances its power when it establishes comparisons among practices and against standards of care. COMPAS intervention implemented in Canada is an example of this effectiveness [47]. Based on all this evidence, we have planned the implementation of systematic use of the Qualidiab record and its periodic report, in which one of its

outcomes is the feedback form that gets back to physicians and nurses showing successes and failures in their personal care provision. In DIAPREM both groups share this feedback form.

In summary, we are planning to implement a program at the primary care level based on improvement of guideline implementation, regular registry of clinical, metabolic and therapeutic indicators, IPC and education to improve care outcomes of diabetes and associated CVRF. We also attempt to optimize usage of human and financial resources. The baseline clinical and metabolic data of our sample population are a good challenge to prove the effectivity of this approach.

Conflict of Interest

The authors declare that they have no competing interests.

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Appendix A.

The following names are members of DIAPREM working at the primary care units of La Matanza, responsible for the medical care of the population sample.

Alvarez G, Alvarez N, Alvez C, Andrada V, Aranda J, Bascialla R, Betiatio B, Bozani S, Bría C, Britos N, Cabaña M, Candia K, Carballo M, Castro T, Cescutti A, Chiarello C, Corbellito M, Cuellar R, Dellepiane AV, Desimone F, Ferreyra D, Fuentes V, Frank M, Gallo S, Giordano A, Godoy R, Gomez G, Iballo H, Iballo L, Jerozolimski P, Juarez S, Kulberg S, Leal E, Luche M, Marshall C, Mastrica C, Maza P, Medina C, Medina N, Meres C, Mugliaroli C, Olivera I, Orellano JF, Romam N, Romera ML, Santisteban C, Santos P, Sar JM, Scarabela C, Soria V, Speroni M, Tevez M, Tito G, Torelli N, Trentini S, Valle M, Ventrelli A, Vergara A, Villegas A.

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