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Using mHealth strategies in a Diabetes Management Program to improve the quality of care in Argentina: Study design and baseline data

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ABSTRACT

Aim: To evaluate the one-year post effect of the implementation of a diabetes program that includes mHealth interventions on the quality of diabetic care in public primary care centers. **Method:** It is a quasi-experimental study with outcome measurements at baseline, 6 and 12 months. The program includes primary care team training, a diabetes registry with a decision support tool in an app. and text messages for patients.

Results: At baseline, 947 patients were included in the registry, 62.3% women with a mean age of 53.6 ± 11.5 years and 92% with type 2 diabetes. Common comorbidities were hypertension (61.3%) and obesity (59%). Only 16.9% had one HbA1c and 48.9% a cholesterol lab in the last year, 61.9% were screened for diabetic peripheral neuropathy, and 29.0% had one eye exam in the previous year. With respect to blood sugar, lipid and blood pressure control: 44.4% of those with HbA1c measurements had levels $\geq 8\%$, total cholesterol was over 200 mg/dL in 40.6% and 48.2% had uncontrolled blood pressure values.

Conclusion: Patients with diabetes received a low quality of care at public primary care clinics. A diabetes registry allowed us to draw an epidemiological profile of diabetic patients and determine the quality of care provided.

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1. Introduction

Diabetes mellitus (DM) is an important cause of mortality and morbidity worldwide, through both direct metabolic complications and increased mortality from cardiovascular and kidney

diseases [1]. It is estimated that by 2040, diabetes will grow from 29.6 to 48.8 million in South and Central America [2]. According to the National Risk Factor Survey DM in Argentina increased from 8.4% to 9.8% between 2005 and 2013, reaching epidemic proportions and representing a significant public health problem [3]. In this epidemic, type 2 DM is a tracer of

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the global epidemiological transition and is over-represented among lower socioeconomic groups [4]. Health systems in low-and-middle-income countries (LMIC) are facing challenges to control the rising burden diabetes possess on these countries.

Although health systems in most Latin-American countries have undertaken adjustments and changes to incorporate the evidence-based interventions addressing chronic diseases in order to improve clinical outcomes and quality of care, these have not been widely incorporated into daily clinical practice [5].

Given the increasing prevalence of DM in LMIC, there is a need for innovative and effective ways to deliver interventions to improve diabetes care in resource constrained health care systems. In this sense, mobile health (mHealth) interventions constitute a promise for health care delivery, especially in resource-constrained settings in developing countries where mobile technology has a high penetration. In many places in Argentina, people have better access to mobile phone services than to basic services such as water, electricity, sewage, and sanitation [6]. In a systematic review, the results showed that mHealth yielded positive health outcomes in diabetes in LMIC due to improvements in the supply side of health care systems. These improvements were used as a channel to deliver education, increase patients' caregivers' knowledge, and improve health-seeking behaviors and health-related lifestyle decisions [7].

In keeping with the global context, a diabetes program (DP) is implemented in the province of Corrientes in Argentina. We will evaluate if the implementation of a diabetes program (DP) that include mHealth interventions improve the quality of care in the diabetic population that attends public primary care clinics (PCCs). In this manuscript, we are presenting the design, and baseline evaluation of the program.

2. Methods

2.1. Study design and study settings

For the evaluation of the DP we will use a quasi-experimental study (before and after without control group) with outcome measurements at baseline, six and twelve months. The interventions have been implemented in 20 PCCs from the National Public Primary Care Network (Cobertura Universal de Salud Medicamentos program) in Corrientes. Corrientes is a poor province located in the northeast of the country with an area of 88,199 km² divided into 25 departments. It has more than one million inhabitants and 48% have no health insurance. It is also one of the provinces with the highest percentage of unmet basic needs and infant mortality rates in Argentina.

The following departments participate in the study: Corrientes Capital (8 PCCs), Riachuelo (1 hospital), Paso de la Patria (1 hospital), Paso de los Libres (8 PCCs and 1 hospital), and San Luis del Palmar (1 hospital). These PCCs and hospitals provide health care services to underserved populations. These were selected based on the criteria outlined in Table 1.

Table 1 – Inclusion criteria for study PCCs and hospitals.

- Affiliated with the Cobertura Universal de Salud Medicamentos Program [8].
- Located in poor urban areas, as stated the 2010 census data.
- 800 or more outpatient visits each month (to facilitate effective recruitment).
- Physician visits and essential medications are free of charge to diabetic patients.
- Employs community health workers.
- Possesses Internet connectivity.

Table 2 – Eligibility criteria for study participants.

Inclusion criteria	Exclusion criteria
Age \geq 18 years.	Plans to move from the neighborhood in the next year.
No health insurance.	Pregnant at the time of screening.
Access to a mobile phone for personal use.	Bed-bound
Family home located within 10 km from the clinic.	Persons who does not consent.
Has a diagnosis of diabetes	

2.2. Participants

Participants were recruited from community settings. Eligibility and exclusion criteria are shown in Table 2. Each clinic had the goal of recruiting between 50 and 100 participants, since the intervention is planned to reach 1000 people with diabetes. All included patients agreed to participate in the study after signing an informed consent.

2.3. Interventions

The program includes a multi-component intervention to improve diabetes management and control at a system, provider and patient level. (Fig. 1)

Interventions included in the Diabetes Program are:

2.3.1. Primary care team training to implement Diabetes Clinical Practice Guidelines (CPG) and provide diabetes education

In conjunction with the Diabetes Province Program and the Redes program, a public program to strength chronic care in the primary care level, we will implement an on-site two-day intensive workshops for primary care physicians, nurses and community health workers (CHWs) [8]. These workshops are focused on diabetes diagnosis, stepped-care management of diabetes and cardiovascular risk factors based on national CPG, promotion of lifestyle changes; diabetes self-management education, chronic follow-up and diabetes prevention [9]. Primary care physicians and nurses will be trained in diabetes prevention, patient care management and self-management education and CHWs will be trained in providing outreach education and support to diabetes patients and their families as well as liaising patients with the primary care team at the clinics.

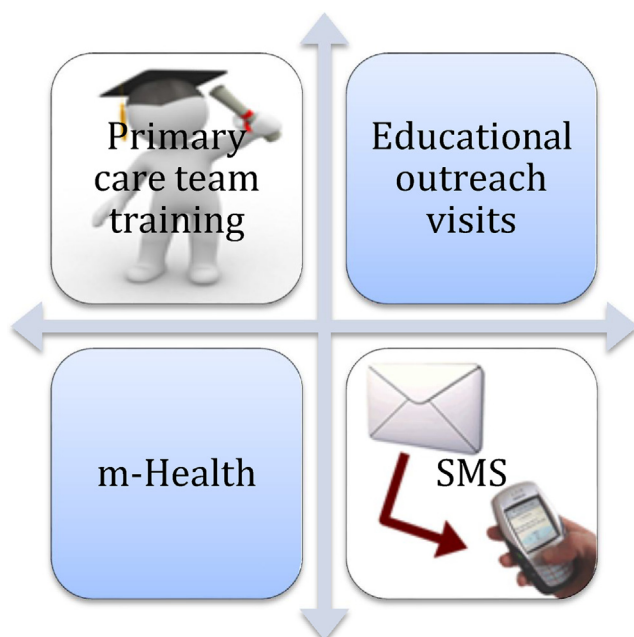


Fig. 1 – Multi-component intervention.

2.3.2. Educational outreach visits

In addition, educational outreach visits (EOVs) will be conducted to audit the clinical practice, address barriers to the implementation of CPG and provide feedback to health care professionals about their performance in order to overcome barriers in the management of diabetic patients and improve care. These face to face interactions will be tailored to the needs of the healthcare personnel at the PCCs and will focus on the barriers to implementing the Diabetes CPG and in the use of a diabetes registry.

2.4. mHealth interventions

These interventions are integrated in an information and communication system that includes a diabetes registry in an app. and a web-based platform to deliver text messages. The system has the following functionalities: (1) collect data during clinical encounters, (2) provide a decision support tool based on CPG to guide diabetes treatment and management, (3) monitor the diabetic population through surveillance lists that will be sent to healthcare providers at the clinics, and (4) provide diabetes education through SMS text messages.

2.4.1. Diabetes registry

This registry lists all individuals with an identified diagnosis of diabetes. It was created using the SANA framework (<http://sana.mit.edu/>), a highly customizable, open-source, android-based mHealth information system to collect, store, manage and analyze healthcare data [10]. The mobile application (app.) collects information regarding demographic and diabetes information of participants, cardiovascular risk factors, diabetic complications and treatment and contains a decision support tool that provides prompts to guide diabetes management (Supplemental material). In addition, the software allows the surveillance of high-risk patients to re-

establish care, generate reports and for further statistical analysis.

Data collected can be either transmitted online via 3G/4G or stored offline in a tablet or mobile phone and synchronize later via Wi-Fi. All the information that is collected pertaining to patients will be kept confidential and identifiable information encrypted.

The app. was installed on tablets that were given to primary care teams to collect information regarding baseline and follow-up visits. An operating procedure manual was generated and provided to primary care teams to guide data collection. One-day training workshop and practice audit with feedback to health care providers was implemented.

2.4.2. Text messaging intervention

Short text messages (SMS) to provide diabetes education and promote medication adherence will be used in this study and were previously developed and validated [11]. Information collected in the registry during the baseline visit is going to be assembled using specific algorithms based on the Trans Theoretical Model and characteristics collected at baseline to customize SMS [12]. A web-based platform used to deliver customized weekly SMS containing reminders for medical appointments and educational messages to the patients included in the registry. One-way weekly SMS will be sent to diabetic patients.

Interventions will be rolled out in the following phases: (1) preparation for implementation of the intervention and training (2) baseline assessment training and (3) intervention implementation

2.4.3. Phase 1: preparation and training

Before the implementation of the intervention, the geographic area was mapped for internet connectivity. The app. was installed in the tablets devices and tested to ensure functionality of the app. and Wi-Fi connectivity. Individual user profiles were created on the tablets and each user was granted access to the app. Primary care teams received the tablets and were trained during a one-day interactive workshop. Training session will be followed by field observation and feedback in educational outreach visits during the implementation of the study. A quality monitoring subcommittee was conformed in this phase and will review during the study implementation the data regularly, the completeness of the registry, protocol adherence and data quality.

2.4.4. Phase 2: baseline assessments of diabetic patients

During the baseline visit at the clinics, healthcare professionals conducted medical interviews to diabetic patients who provided informed consent. They registered socio demographic and clinical information such as: age, gender, cardiovascular risk factors, history of diabetes, lifestyle habits (consumption of fruits and vegetables and physical activity) and treatment in a case report form contained in the diabetes registry app. The primary care team (physicians, nurses and community health workers) had access to the registry and data could be either collected in the household (e.g. in those patients with limited mobility) or in the clinics.

Collected information was regularly transferred via internet to a central server and to the data management unit

at Institute for Clinical Effectiveness and Health Policy (Supplemental material). Blood pressure (BP) measurements and anthropometric measurements were obtained according to a standard protocol at the baseline clinical visit by trained staff [13]. Primary care teams received manuals of operations describing the procedures for the recruitment and inclusion of diabetic patients as well as how to perform measurements and other operational aspects of the study.

2.4.5. Phase 3: intervention implementation

This stage includes the implementation of the training activities, educational outreach visits, diabetes education through text messages and monitoring activities to promote follow-up with healthcare providers at the clinics.

2.5. Statistical analysis

For this baseline analysis we used descriptive statistics. Continuous variables are presented as mean \pm standard deviation and median (interquartile range), and categorical variables as absolute (number of cases) and relative frequency (percentage). Calculations and graphics were performed with Excel for Window software. Data analysis was conducted using the statistical program SAS (Version 9.3, SAS Institute, Cary NC).

3. Results

3.1. Baseline characteristics

Socio-demographic and clinical characteristics of the participants are depicted in Table 3. Out of the 947 patients included, most had type 2 diabetes (92.9%). More than half of the population were women (62.3%), 47.6% did not have health coverage and 77.6% had low educational attainment (less than 12 years of formal education). Patients mean age was 53.6 ± 11.5 years, and the median diabetes duration was 4 years (IQR 1-10).

Microvascular chronic complications were reported with the following frequencies: neuropathy 3.3%, nephropathy 2.1%, and retinopathy 11.0%. As regards macrovascular complications, 9.4% referred having either chronic ischemic heart disease or stroke. Acute complications like hypoglycemia were reported in 10.2% of the cases. Only 38% performed self-monitoring of blood glucose

As regards to lifestyle behavior, only 1.3% of subjects reported consuming five or more fruits or vegetables per day and 31.7% achieved the recommended levels of physical activity. The majority of the diabetic patients (89.5%) were either obese or had overweight.

As for antidiabetic treatment, few patients (5.9%) received neither oral antidiabetic agents nor insulin; 62.0% of those treated were on monotherapy and only 5.8% were on insulin therapy. The most frequent antidiabetic medication used was metformin (89.8%) followed by glibenclamide (31.5%).

In relation to clinical and metabolic profile (Table 4), the mean fasting blood glucose was 178 mg/dL (SD 71.9) and for HbA1c was 8.6 ± 2.3 in those who had an HbA1c at baseline. Mean blood pressure values were compatible with prehypertension.

Table 3 – Characteristic of study participants.

Socio-demographic and clinical characteristics	Diabetic patients (N = 947)
Socio-demographic	
Age in years, mean (SD)	53.6 (11.5)
Women, %	62.3
Less than 12 years formal education, %	77.6
No health coverage, %	47.6
Diabetes	
Duration of diagnosed diabetes in years ^a , median (SD)	4 (1–10)
Type of diabetes, %	
Type 1	4.6
Type 2	92.9
Gestational	1.6
Other	0.8
Treatment ^a	
No treatment, %	5.9
Only oral antidiabetic drugs (OADs), %	79.4
Only Insulin, %	5.8
Insulin + oral drug, %	8.9
Number of drugs	
One, %	62
Two, %	33.4
Lifestyle	
Physical activity ^a , %	31.7
Five or more fruits or vegetables per day ^a , %	1.3
Comorbidities	
Hypertension ^a , %	61.3
Dyslipidemia ^a , %	32.4
Overweight (BMI 25–30), %	30.5
Obesity (BMI \geq 30), %	59
Alcohol consumption ^a , %	20.1
Smoking ^a , %	10.7

^a Self-reported.

Table 4 – Clinical and metabolic profile in diabetic patients.

Clinical and metabolic parameters	Diabetic patients (N = 947)
HbA1c %, mean (SD)	8.6 (2.3)
Systolic BP (mmHg), mean (SD)	135 (19.8)
Diastolic BP (mmHg), mean (SD)	81.6 (10.9)
Fasting blood glucose (mg/dL), mean (SD)	178 (71.9)
Total cholesterol (mg/dL), mean (SD)	200 (54.7)
LDL-c (mg/dL), mean (SD)	116 (40.7)
HDL (mg/dL), mean (SD)	46.8 (13.6)
Creatinine (mg/dL), mean (SD)	1.1 (1)

As shown in Table 5, process of care outcomes show a low access to lab and to specialist care. In terms of health outcomes, poor metabolic control (HbA1C levels \geq 8%) was found in 44.4% of the patients with HbA1c measurements and total cholesterol was over 200 mg/dL in 40.6% of participants. Moreover, 48.2% of diabetic patients had uncontrolled blood pressure values (SBP \geq 140/DBP \geq 90 mmHg) at baseline.

Table 5 – Cross-sectional outcomes indicators for diabetic patients included.

Quality of care indicators	Diabetic patients (N = 947)
Process of care	
At least one HbA1c lab in the last year, % (n)	16.9 (160)
At least a foot exam in the last year, % (n)	61.9 (586)
An eye exam in the last year, % (n)	29.0 (275)
At least one cholesterol lab in the last year, % (n)	48.9 (463)
Health outcomes	
HbA1c \geq 8% among those who had HbA1c lab, % (n)	44.4 (71/160)
With uncontrolled blood pressure values (SBP \geq 140 mmHg and/or DBP \geq 90 mmHg), % (n)	48.2 (453/939)

4. Discussion

In this study we found a socio-demographic profile consistent with other studies conducted in Latin America regarding the average age expected for this disease, the lack of health coverage among users who attend the public clinics, a low educational level and a predominance of the female sex. This latter point could also respond to a higher rate of utilization of outpatient services by women and eventually to their greater acceptance to participate in the program in accordance to what was found by others studies conducted in Latin America [14,15].

As expected, type 2 diabetes was the most frequent and the time since diagnosis was almost three times less than reported in other studies [14,16,17]. This leads us to consider on whether the proactive search used as a recruitment strategy with community screening fosters this remarkable and positive difference, knowing that in low and middle income countries more than 50% of people with diabetes are not diagnosed, configuring themselves as one of the great challenges for the health system.

As regards lifestyle habits, a very low intake of fruits and vegetables and low physical activity was observed; which as a whole could partially explain the high proportions of poor metabolic control and obesity in this population.

However, the proportion of patients who received antidiabetic treatment was high and consistent with the recommendations of the national CPG for primary care. Metformin was the first-line drug, similar to that reported by other studies [18,19]. On the other hand, baseline results showed that the prescription of two or more associated drugs is not frequent, contrary to the recommendations for treatment intensification. This shows that the presence of a national public program that increased access to chronic medication in the first level of care does not guarantee an adequate treatment. In this sense, it is necessary to emphasize the intensification of pharmacological treatment since most of the patients had clinical parameters of poor metabolic control.

A high frequency of hypertension was observed in people with diabetes coinciding with other studies that report a high prevalence in this population, which also responds to common pathophysiological links. Obesity also stands out as a very important comorbidity [18,19]. The association of type 2 diabetes with hypertension and obesity is very frequent,

and is part of the so-called metabolic syndrome, denoting an important risk factor for macrovascular complications [20].

The results related to the quality of care indicators showed that the CPG recommendations for primary care in Argentina have not been properly incorporated to clinical practice, and this is manifested in the process of care and health outcomes indicators obtained at baseline. The low access to lab and to specialist care observed indicates the need to systematize comprehensive care for people with type 2 diabetes.

In this sense, the multi-component intervention proposed in this study aims at strengthening clinical practice in PCCs through two main components: the incorporation of technology and the continuous training of the health team to improve the care process. Studies on quality of care practices have reported that the basic and fundamental elements for primary care of high performance are: leadership, improvement based and driven by data, nominalization of users of the health center and teamwork [21,22].

The incorporation of mHealth technology encompasses a registry in an app that allows the empanelment of people with type 2 diabetes in the coverage area of each PCCs. This registry covers variables that correspond to both process indicators and clinical outcomes and is configured to facilitate identification and follow-up, including reminders about both delayed and upcoming queries.

A Diabetes registry goes beyond being a data repository of users of the health system and becomes an active tool in the management process within the primary care strategy.

Additionally, the second element of mHealth is text messages (SMS). These are personalized based on an algorithm guided by the individual each person's characteristics and can encourage the linkage with the health team, in addition to providing support for self-care diabetic education. Studies have shown that SMS has a positive effect on several health outcomes, including self-care of diabetes when used in behavioral change interventions [23–27].

During the baseline assessment, the diabetes registry app provided recommendations to health care professionals to individualize therapeutic goals according to the patients' needs. It also allowed public health managers to draw and know the epidemiological profile and determine the quality of care that was being provided to the people with diabetes that attended public clinics of whom they are responsible.

Expected benefits of this research is to provide understanding of how to include the use of mHealth in the clinical workflow of primary care teams in public clinics, as well as to improve understanding of how to use mobile technology to intervene patients with diabetes in order to improve clinical outcomes. A possible limitation of the study is the short 1-year intervention, which may not be long enough to observe the effect of the proposed interventions on occurrence of long term diabetes outcomes.

In summary, we are planning to implement a program at the primary care level that include mHealth strategies to improve the quality of diabetes care, outcomes of diabetes and of associated cardiovascular risk factor management. The baseline assessment was a good opportunity to prove the effectivity of the diabetes registry app. Given the above, the registry and SMS emerge as possible tools to strength diabetes

services, given that as a whole they point to the pillars of high performance primary care.

Conflict of interest

The authors state that they have no conflict of interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.pcd.2018.07.014>.

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