



Evaluation of public drug provision policies for type 2 diabetes mellitus in Argentina: a case study

Evaluación de políticas públicas de provisión de fármacos para diabetes mellitus tipo 2 en Argentina: estudio de caso

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ABSTRACT In Argentina, the provision of drugs for patients suffering from type 2 diabetes mellitus who lack health insurance is carried out through public programs. In the Province of Buenos Aires, the national program Remediador and the provincial program PRODIABA (from the Spanish *Programa de Prevención, Diagnóstico y Tratamiento del Paciente Diabético*) coexist. This study estimates the percentage of adults in the municipality of Bahía Blanca (Province of Buenos Aires) who suffer from type 2 diabetes mellitus and lack health insurance, thus satisfying their need for oral antidiabetic treatments within the public sector. It is a quantitative study that assesses the need and demand for public provision. The results indicate that: 1) the greatest percentage of demand is satisfied at the primary health care level; 2) the province of Buenos Aires funds the largest share of the pills, followed by the municipal and the national levels; 3) the local government intervenes to satisfy the demand and 4) the total public provision covers approximately 25% of the overall need in relation to the average consumption. This shows that despite the presence of these public programs, the provision is insufficient and thus requires the intervention of the local government even though economic theory does not recommend the decentralization of drug purchases.

KEY WORDS Diabetes Mellitus; Public Policies; Decentralization; Health Services Needs and Demand; Argentina.

RESUMEN En Argentina, la provisión de fármacos para pacientes con diabetes mellitus tipo 2 (DM2) sin cobertura de salud se efectúa mediante programas públicos. En la provincia de Buenos Aires coexisten el programa Remediador, de nivel nacional, y el Programa de Prevención, Diagnóstico y Tratamiento del Paciente Diabético (PRODIABA), de nivel provincial. El presente trabajo estima el porcentaje de población adulta con DM2 sin cobertura del municipio de Bahía Blanca (provincia de Buenos Aires) con necesidad de tratamientos de antidiabéticos orales, que satisface su demanda en el sector público. Es un estudio cuantitativo que evalúa la demanda y la necesidad de provisión pública. Los resultados indican que: 1) el mayor porcentaje de la demanda se satisface en el primer nivel de atención; 2) la provincia de Buenos Aires financia el mayor porcentaje de comprimidos, seguida por el nivel municipal y el nacional; 3) el nivel local también interviene para satisfacer la demanda y 4) la provisión pública total solo daría cobertura a aproximadamente el 25% de las necesidades en el escenario correspondiente al consumo medio. Esto muestra que, incluso con diferentes programas públicos, la provisión no es suficiente y se requiere de la intervención local aun cuando la descentralización en la adquisición de fármacos no es recomendada por la teoría económica.

PALABRAS CLAVE Diabetes Mellitus; Políticas Públicas; Descentralización; Necesidades y Demanda de Servicios de Salud; Argentina.

INTRODUCTION

The Argentine health care system is organized into three sectors: the social security sector, the private sector and the public sector. The latter provides services at the three levels of government (national, provincial and municipal) through hospitals and primary health care centers. The following are some of its duties: 1) to ensure medical and health coverage to low-income people without health insurance and/or with geographical limitations to access, and 2) to implement programs to prevent and/or control certain pathologies, such as non-communicable chronic diseases, which are the leading causes of morbidity and mortality worldwide (1).

Particularly, type 2 diabetes mellitus (T2DM) is a common pathology which accounts for 80% to 90% of diabetes cases (2). Although genetic predisposition is a determining factor (3), type 2 diabetes is usually triggered by risk factors such as obesity, sedentarism and smoking (4,5). It can be controlled by changes in lifestyle (6-8) and with pharmacological treatments, which frequently involve oral antidiabetic drugs (OAD) (9) such as glibenclamide and metformin (10).

The relevance of this disease lies in its high and growing prevalence (11,12) as well as to the substantial number of premature deaths it causes (13). It imposes a considerable socioeconomic burden on health systems because, in addition to the sizeable direct cost of treatment (14), there are high indirect costs due to the loss of work capacity (15) as well as intangible costs associated with pain, stress and employment discrimination. At the same time, the costs of all medical services are greater in diabetic patients than in non-diabetic patients (16).

Several research studies have estimated the importance of the direct costs of this disease. It was noted that in developed countries the expenses incurred for insulin and OAD are low in comparison with hospitalization expenses (17-20). However, according to Oliva *et al.*, if the expenditures for insulin and OAD are added to the expenditures for other drugs, overall drug expenses exceed hospitalization expenses (21). According to Barceló *et al.*, in Latin America, pharmacological treatments account for 44% of the direct costs of diabetes (22).

Given that in medium and low income countries between 50% and 90% of the population

must pay for their medicines (23), free provision of pharmacological treatments for this type of diseases represents a key aspect of public policies (24). According to a study by the International Diabetes Federation, 61% of a wide sample of countries including Argentina had implemented some type of national diabetes program, usually including free provision of drugs (25).

Various authors have identified problems in accessing T2DM drugs. According to Mendis *et al.*, availability of insulin and some OAD is scarce in medium and low-income countries where free provision exists (26). Reséndez *et al.* note that inefficiency in drug provision management affects OAD availability in some cities in Mexico (27). Viera Paniz *et al.* observe shortages of medications for diabetics in some cities in Brazil, although there are public policies at the different levels of government (28).

Although many research studies analyze the public policies of drug provision to T2DM patients, it is important to evaluate these policies from a need-demand-supply approach, as the estimated needs of a population do not always match the real demand for the drugs under study (29).

In order to estimate the need for health goods or services, the epidemiological information on that medical condition, the perceptions of individuals, or certain objective clinical measurements can be used (30). The demand will be strictly related to the behavior patterns of the consumption of the goods and services under analysis (31). There are several factors which make it so that the demand may not be equal to the need; for instance, the presence of unreported morbidity or of silent disease (32).

From the perspective of economic theory, the public provision of drugs should be analyzed as a private good distributed publicly, whose acquisition justifies policies with a certain degree of centralization due to the presence of economies of scale (33). However, preventive policies must be regarded as public goods whose provision may be analyzed from the perspective of the theory of fiscal federalism (34). Within this focus, decentralization in the allocation of public goods to lower levels of government is justified by the gains in welfare obtained through adapting the supply to local preferences (35,36).

In Latin America there are numerous local initiatives in social policy funded, in many cases, by

local resources (37). According to Guillen, these initiatives involve a special process of decentralization in which local governments decide to intervene in certain issues although they are not obliged to do so by the institutional framework (38). Some research studies indicate that local levels are crucial in the provision of a wide range of health services (39) because they achieve reductions in the child mortality rate (40).

However, regardless of the level of government providing the healthcare good or service, coordination among all levels is essential in order to ensure the impact, efficacy and efficiency of public policies (41). In this respect, Peters suggests that coordination problems may justify centralized policies, even if this means losing the benefits of local policies (42). In the case of Latin American drug provision policies, although there were huge monetary benefits to centralized purchases (43), there were also extensive losses due to waste, theft and/or expiration when the central level was in charge of the distribution (44). In this region evidence suggests that there are scarce mechanisms of coordination among levels of government (45). This generates dispersion in the effects of social public policies that pursue the same goals (a) (37).

In Argentina, Act 23753 of 1989 establishes that the national level must coordinate the policies that ensure drug access, while the provinces must ensure free pharmacological treatments to patients who lack health insurance and economic resources (46).

In particular, in the province of Buenos Aires, Act 11620 of 1994 seeks to improve the quality of life of diabetic patients (47). Based on this law, in 1996 the Provincial Program for the Prevention, Diagnosis and Treatment of Diabetic Patients (PRODIABA, from the Spanish *Programa Provincial de Prevención, Diagnóstico y Tratamiento del Paciente Diabético*) was implemented. It includes free provision of drugs to patients who lack health insurance and/or economic resources.

Additionally, in the context of the 2001 socioeconomic crisis, the National Ministry of Health, supported by international credit institutions, implemented the national public drug provision program *Remediar*, which includes essential drugs such as those used to treat T2DM.

Various authors have assessed the access to pharmacological treatments provided by these programs in the province of Buenos Aires. Marín *et al.*, through an epidemiologic research study, estimated that the program *Remediar* in 2004 provided uninterrupted annual treatment to only 0.65% of potential patients with T2DM (48). However, according to Doménech, in the same year PRODIABA provided coverage to 43% of the target population (49).

In addition to the programs mentioned above, in the municipality of Bahía Blanca (province of Buenos Aires) there is another, local initiative, the Municipal Program of Drugs for Prevalent Chronic Diseases (*Programa Municipal de Medicamentos para Patologías Crónicas Prevalentes*) – hereinafter called the Municipal Program – which involves the free provision of OAD to patients suffering from T2DM who lack health insurance. Therefore, this article seeks to analyze in that municipality the percentage of the adult population suffering from T2DM that lacks health insurance and is in need of free OAD treatments that has satisfied their demand for medication during the period October 2008-September 2009.

MATERIAL AND METHODS

Using a quantitative and descriptive study, the OAD treatments effectively demanded in the public sector were estimated. As the treatments demanded are not always equal the treatments needed, the percentage of the population needing public provision that actually received treatment was estimated. This is a retrospective research study comprising the period between October 2008 and September 2009. The treatments considered in the control of T2DM are metformin (500 mg) and glibenclamide (5 mg).

The methodology implemented to estimate the adult population suffering from T2DM without health insurance in the municipality of Bahía Blanca was made up of the following steps:

1. The adult population (between 15 and 65 years old) in Bahía Blanca in 2008 was obtained via the statistical projection of the 2001 National Population Census conducted by the National Institute of Statistics and Censuses

- (INDEC, from the Spanish *Instituto Nacional de Estadísticas y Censos*) (50).
- The adult population in Bahía Blanca in need of drugs for T2DM was estimated using the rate of regional diabetes prevalence in the central region of Argentina, estimated at 7% (51), and the frequency of cases of T2DM within the total diabetes cases, estimated at 85% (2).
 - It was calculated that 28% of the population estimated above depends on the public provision of treatments. This estimation comes from the percentage of the population without health insurance estimated for the Pampean Region in 2005 according to the National Survey of Risk Factors (52).

In order to estimate the effective demand for free treatments of glibenclamide and metformin in the municipality the following steps were carried out:

- The free provision of tablets of glibenclamide and metformin to the adult population affected by T2DM in Bahía Blanca was determined. This information was obtained through data provided by institutions at the different levels of government: the Planning Management Office of Remediar+Redes (a project of the National Ministry of Health in order to promote Primary Health Care, at the national level); representatives of the program PRODIABA in Sanitary Region I (at the provincial level); the Diabetes Unit of the Endocrinology Department at the Dr. José Penna General Interregional Acute Care Hospital (*Hospital Interzonal General de Agudos "Dr. José Penna,"* at the provincial level); and the Sub-directorate of Management and Programs of the Department of Health of the Municipality of Bahía Blanca (at the municipal level).
- The number of treatments provided by the public sector (in monodrug therapy), according to the type of drug and prescription dose, was estimated. Two dose types were considered, which represent minimum and maximum prescription scenarios:
 - Mean daily dose: as proposed for the region by the Latin American Association of Diabetes (53), this dose is 10 mg for glibenclamide and 1,700 mg for metformin. In order to convert the

number of tablets into treatments the following formula was applied for each drug: number of mean daily doses = available units per year (in mg) / mean daily dose (in mg).

- Maximum daily dose: according to the theory suggested by Goodman and Gilman (54), this is 15 mg for glibenclamide and 2,550 mg for metformin. In this case, in order to convert tablets into treatments the following formula was applied for each drug: number of maximum daily doses = available units per year (in mg) / maximum daily dose (in mg).

RESULTS

In accordance with the current regulations, patients suffering from T2DM who lack insurance and reside in the municipality of Bahía Blanca should satisfy their medication needs through free provision at the provincial or national level. However, even after acknowledging that the demand for treatment is usually lower than actual need, the local level detected that in the case of metformin the treatments available were insufficient to meet the demand. For that reason, the municipality implemented a Municipal Program consisting of free provision through the first level of health care to patients suffering from chronic diseases, including T2DM.

In the Municipality of Bahía Blanca, free distribution of OAD treatments for T2DM is carried out by: a) the first level of health care through primary health care centers, b) the second level of health care through the Dr. José Penna General Interregional Acute Care Hospital and c) the Department of Health of the Municipality of Bahía Blanca.

Table 1 shows public drug distribution by institution, program and type of drug provided.

The funding of the total public provision of each OAD by each level of government shows that the provincial level, through PRODIABA, funds 87% of glibenclamide tablets and more than 70% of metformin tablets. At the national level, Remediar funds 13% of glibenclamide tablets and 6% of metformin tablets. As shown in Figure 1, between them both programs satisfy the local demand of glibenclamide, but the municipal level had to fund 22% of metformin.

Table 1. Public distribution of T2DM medications by program and institution responsible for the distribution. Bahía Blanca (Argentina). 2008-2009.

Program	Institution responsible for the distribution	Drugs
PRODIABA	Dr. José Penna General Interregional Acute Care Hospital*	Insulin, Glibenclamide, Metformin
PRODIABA	Dr. Leónidas Lucero Municipal Acute Care Hospital**	Insulin
PRODIABA	Department of Health of the Municipality of Bahía Blanca**	Glibenclamide, Metformin
Municipal Program	Department of Health of the Municipality of Bahía Blanca**	Metformin
Remediar	Primary health care centers**	Glibenclamide, Metformin

Source: Own elaboration using data provided by Health Department officers of the Municipality of Bahía Blanca

PRODIABA= Provincial Program for the Prevention, Diagnosis and Treatment of Diabetic Patients

Municipal Program = Municipal Program of Drugs for Prevalent Chronic Diseases

*Provincial jurisdiction

**Municipal jurisdiction

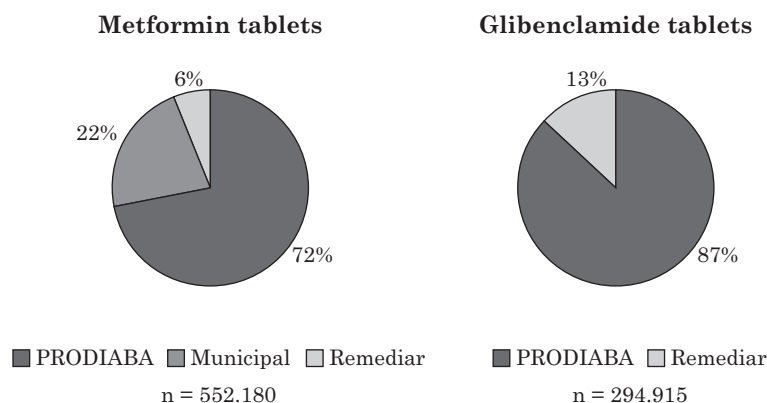
At least three significant issues may be noted regarding the funding of the tablets provided by the public sector:

1. The low percentage provided by the national level through Remediar. However, this can be explained by the fact that the program arises in a context of health emergency, with the objective of improving access to essential drugs through the first level of health care, by acting not as the

only public provider but rather as a complement to other funding sources. This panorama stems from national legislation which delegates to the provincial levels the responsibility for ensuring the largest percentage of free coverage of these treatments.

2. In aggregate terms, the provincial level funds 77.2% of the total number of tablets demanded, the municipal level 14.3% and, finally, the national level 8.4%.

Figure 1. Funding of public provision of tablets for T2DM treatment by type of drug, Bahía Blanca (Argentina). October 2008-September 2009.



Source: Own elaboration using data from the Planning Management Office of Remediar+Redes, PRODIABA (Provincial Program for the Prevention, Diagnosis and Treatment of Diabetic Patients), the Diabetes Unit of the Endocrinology Department of the Dr. José Penna General Interregional Acute Care Hospital and the Sub-directorate of Management and Programs of the Department of Health of the Municipality of Bahía Blanca.

Table 2. Annual treatments estimated for each drug and dose, by program and health care level. Bahía Blanca (Argentina). October 2008 - September 2009.

Program	Level of health care	Annual treatments			
		Metformin		Glibenclamide	
		Mean daily dose	Maximum daily dose	Mean daily dose	Maximum daily dose
PRODIABA	First level	188	125	190	127
Municipal	First level	97	65	0	0
Remediar	First level	29	19	53	35
PRODIABA	Second level	137	92	167	111
Subtotals	First level	314	209	243	162
	Second level	137	92	167	111
Totals		451	301	410	273

Source: Own elaboration using data from the Planning Management Office of Remediar+Redes, PRODIABA, the Diabetes Unit of the Endocrinology Department of the Dr. José Penna General Interregional Acute Care Hospital and the Sub-directorate of Management and Programs of the Department of Health of the Municipality of Bahía Blanca.

PRODIABA = Provincial Program for the Prevention, Diagnosis and Treatment of Diabetic Patients
Municipal Program = Municipal Program of Drugs for Prevalent Chronic Diseases

3. In terms of the overall cost of the local provision of metformin, which was \$25,000 (USD 6,313), this intervention does not prove to be efficient technically, given that the average unit cost paid by the municipality was \$0.21 (USD 0.0530) (c), while the average unit cost paid by the national level (through the program Remediar) was \$0.11 (USD 0.0278) (d).

Finally, to focus on the aim of this work, the number of patients who satisfied their annual demand of treatments of glibenclamide or metformin at no cost was estimated.

In order to capture the variability of the treatments prescribed to patients, scenarios related to the different types of doses were considered. To this effect, Table 2 shows the result of converting the number of tablets to number of treatments by mean daily dose and maximum daily dose, using the formulas mentioned in the Material and Methods section.

Considering the different scenarios, it can be noted that the annual free treatments provided to adult patients suffering from T2DM vary from 301 to 451 for metformin and from 273 to 410 for glibenclamide.

In turn, the pharmacological treatments provided through the first level of health care account for 70% in the case of metformin and 59% in the case of glibenclamide. These results underscore

the importance that primary health care should have in the policies of prevention, treatment and control of this disease (55).

After estimating the number of patients who demanded treatments in the public sector, the adult population suffering from T2DM who may need this provision was then estimated. The importance of this analysis lies in the fact that the need for treatment is not always translated into effective demand. In our calculation, the population needing public drug provision would amount to 3,274 inhabitants. This number was arrived at by considering that in the Municipality of Bahía Blanca in 2008 there were approximately 196,505 adult inhabitants, 13,755 of whom, approximately, could have been suffering from diabetes, according to the 7% rate of prevalence estimated for the region. Specifically, 11,691 could have had T2DM. Within this population, 3,274 inhabitants suffering from T2DM would not have had health insurance, according to the data provided for the region in 2005.

However, as with any "silent" disease, a high rate of underdiagnosis (that is, people with the disease who have not yet been detected) is common in diabetes (56). Gagliardino *et al.* have estimated this rate as close to 50% in a population in the city of La Plata (Buenos Aires, Argentina) (57).

If this rate of underdiagnosis calculated by Gagliardino *et al.* is assumed for the municipality of Bahía Blanca, the population under treatment

demanding OAD from the public sector would be approximately half of the population diagnosed.

However, the results of the research study suggest that public coverage would account only for 26.3% of the treatments needed, considering a mean daily dose intake (861 treatments, 451 of which were of metformin and 410 of glibenclamide) and 17.53% of the treatments needed considering a maximum daily dose intake (574 treatments, 301 of metformin and 273 of glibenclamide). These results arise from the estimation that “the population needing public provision of drugs” is approximately 3,274 inhabitants.

It is important to clarify certain limitations of this study which could distort the results obtained. First, the doses used do not consider those who take both drugs, or who treat their disease only with diet or insulin (58).

Another weakness lies in the lack of data regarding two key aspects: 1) the percentage of the population without health insurance who get their treatments by buying them out-of-pocket, and 2) the percentage of treatments obtained in the municipality of Bahía Blanca by patients living elsewhere in the region (this could happen primarily at the provincial hospital).

The limitations mentioned above are factors that could determine that the population effectively covered by the public policies is smaller or larger than the population estimated. Analyzing the impact and size of these factors will be the focus of our future research.

DISCUSSION

The results observed in the municipality of Bahía Blanca suggest that the policies of free distribution of drugs to patients affected by T2DM in the province of Buenos Aires have strengths and weaknesses.

One of the strengths is related to the mechanism of distribution used, as the main part of the oral anti-diabetic tablets demanded from the public system were delivered through the first level of health care which, according to the evidence, is the appropriate level for managing the detection, treatment and prevention of this disease.

The main weakness is the fact that the treatments provided publicly by the national and provincial level in the municipality under study are not sufficient to satisfy the need for metformin. This fact motivated the intervention of the local government, thereby demonstrating that the access of many diabetic patients was ensured by a voluntary decision at the lowest level of government and not by the highest levels that are legally responsible for the provision of drugs and the coordination of policies regarding this disease.

These results show that, in a key aspect of the health sector as is the acquisition of drugs, the lowest levels of government intervene even when the theory of decentralization, based on the argument of economies of scale, does not recommend local involvement in this allocation function.

The economic consequences of the national and provincial levels not satisfying the demand and the need for treatments are: 1) in the short term, and in relation to the demand, the technical inefficiency of the public subsector, because the prices paid by the local level are higher than the prices obtained by programs at the national level (via international public bids) or the provincial level (via production in provincial laboratories), and 2) in the medium term, the results suggest that even with public policies implemented in the three levels of government, only a small percentage of the patients needing pharmacological treatment was covered by the public sector. This will result in direct, indirect and intangible costs associated with future health complications of the patients who are not currently receiving uninterrupted treatment of the disease.

FINAL NOTES

a. The risk of dispersing efforts within public policies is assessed within scenarios making up four models: the hierarchical coordination model, the dispersion model, the donor-recipient model and the multilevel government model. In the case of

Latin America, it is recognized that there is a latent risk of dispersion.

b. This percentage equates to 119,140 tablets and represents more than half of the tablets delivered by PRODIABA in the first level of health care (230,000).

c. Average unit prices (expressed in Argentine pesos) paid in the two municipal public bids carried out during the period under study, in which metformin was purchased. This information was provided by the Coordination of Pharmaceuticals within the Sub-directorate of Management and Programs of the Department of Health of the Municipality of Bahía Blanca.

d. Average of the final unit prices paid in 2008 and 2009 bids through which metformin was purchased. This information was provided by the Planning Management Office of Remediación + Redes.

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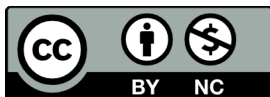
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