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Public financing of human insulins in Brazil: 2009-2017

Financiamento público de insulinas humanas no Brasil: 2009-2017

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ABSTRACT: ***Background:*** From 2006 to 2017, the Brazilian federal government provided free of charge traditional insulins for diabetes treatment. This involved public tendering by the Department of Health Logistics of the Ministry of Health (DLOG-MOH) and the reimbursement after direct contracting for supply with commercial private retailers (Brazilian Popular Pharmacy Program — PFPB). ***Objective:*** We aim to describe the budget of the Brazilian federal government committed to for the acquisition of insulin, as well as corresponding prices and treatment availability from 2009 to 2017. ***Methods:*** Insulin volume and expenditure data were obtained in official administrative databases and in the Electronic System of the Information Service to Citizens. Data were analyzed according to the total provision by the federal government, DLOG-MOH and PFPB. Moreover, data were presented according to insulin type. Volumes were calculated in number of defined daily doses (DDD)/1,000 inhabitants/day. ***Results:*** Budgetary commitments due to insulin over nine years amounted to U$1,027 billion in 2017, with an approximate average of U$114.1 million per year. DLOG-MOH was the main insulin provider, despite the increase in PFPB provision along period. DLOG-MOH and PFBP together provided an average of 6.08 DDD/1000 inhabitants/day for nine years. Average prices in PFPB were higher than those in the DLOG series, with a downward trend over the years, narrowing to 2.7 times in 2017, when compared to 2009. ***Conclusions:*** Brazil evidenced a moderately sustainable and effective, albeit imperfect, policy for public provision of traditional insulins in the period preceding mandatory free supply of insulin analogues. Future studies must address treatment availability and financial sustainability in the new scenario.

Keywords: Diabetes mellitus. Insulin. Healthcare financing. Supply. Drug price.

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RESUMO: ***Introdução:*** Entre 2006 e 2017, o governo federal forneceu gratuitamente insulinas tradicionais para o tratamento de diabetes por meio de licitação pública pelo Departamento de Logística em Saúde do Ministério da Saúde (DLOG-MOH) e reembolso a drogarias privadas credenciadas pelo Programa Farmácia Popular do Brasil (PFPB) após contratação direta para fornecimento. ***Objetivo:*** Descrever o orçamento federal brasileiro empenhado pela aquisição de insulinas, bem como preços e disponibilidade de tratamento correspondentes entre 2009 e 2017. ***Métodos:*** Dados de despesas e volume de insulina foram obtidos em registros administrativos oficiais e mediante solicitação ao Sistema Eletrônico do Serviço de Informações ao Cidadão. Os dados foram analisados de acordo com a provisão total do governo federal e segundo aquisições via DLOG-MOH e PFPB e tipo de insulina. Os volumes de insulina foram calculados em número de doses diárias definidas (DDD) / 1.000 habitantes / dia. ***Resultados:*** Em nove anos, o orçamento empenhado com a insulina totalizou US$ 1.027 bilhões em 2017, média de US$ 114,1 milhões / ano. O DLOG-MOH foi o principal fornecedor de insulina apesar do crescimento do PFPB durante o período. O DLOG-MOH e o PFPB disponibilizaram em média 6,08 DDD / 1.000 habitantes / dia durante o período analisado. Os preços médios no PFPB foram maiores que os do DOG-MOH ao longo do período, com tendência de queda ao longo dos anos, estreitando-se para 2,7 vezes em 2017 em comparação a 2009. ***Conclusão:*** O Brasil evidenciou uma política de fornecimento gratuito de insulina moderadamente sustentável e eficaz, ainda que imperfeita, no período que antecedeu o fornecimento obrigatório de análogos. Recomendam-se estudos futuros para avaliar a disponibilidade de tratamento e a sustentabilidade do financiamento nesse novo cenário.

Palavras-chave: Diabetes Mellitus. Insulina. Financiamento da assistência à saúde. Aprovisionamento. Preço de Medicamento.

INTRODUCTION

Insulin is essential to glycemic control and, often, for patient survival in diabetes mellitus (DM)[1,2]. The estimated global prevalence of DM for 2015 was 8.8% among the population aged 20–79[3]. There are four main clinical types of diabetes: type 1 (DM1); type 2 (DM2); gestational diabetes; and "other" types of diabetes[2].

For a long time, insulin treatment was restricted to DM1 patients and to contexts of metabolic instability, such as surgeries and care of diabetics in intensive care units. However, both current management protocols recommending stricter control of glycemic levels with wider insulin use for all types of diabetes and the growth in disease prevalence have substantially expanded the use of insulin[4–9]. In fact, half of all diabetics in the United Kingdom were insulin users in 2010[8], just like the16.4% of diabetics in the USA in 2011[9].

Insulin may have a great impact on diabetes expenditures, ranging from 0 to 68% of disease costs[10]. This cost has increased over the years due to soaring insulin prices and gradual shifting to newer and more expensive insulin analogues[11–14]. This heightens concerns on the availability and affordability of insulin, particularly in resource-limited countries[15].

Brazil has the fourth largest number of diabetic patients worldwide, and an estimated three in each 1,000 inhabitants have DM1[3,16]. Among Brazilian adults reporting diabetes in

2013, 18% informed insulin use in the preceding two weeks[17]. This number exceeds the estimated DM1 prevalence of 5–10% of the population with diabetes, and already suggests the adoption of protocols recommending expanded insulin use in non-DM1 patients[16].

A pharmaceutical market monitoring report from 2016 ranked traditional human insulins as the 29th highest expenditure in Brazil, with a market of 250M–500 million Brazilian Real (BRL) in 2016 (70–140 million United States Dollars [USD])[18]. Insulin analogues had by then market shares worth 400–800 million BRL (115–230 million USD). Global insulin sales at the time were estimated at 35 billion USD, indicating that Brazil held a low share in the global market considering the disease prevalence in the country[19].

These relatively low levels of expenditure may be credited to public insulin provision policies in place since 2006. Households finance about 80% of pharmaceutical expenditures in Brazil, but the federal government provides insulin for free via the Unified Health System (SUS)[20].

Two provision modes have been adopted by the SUS. The first one, in place since 2006, is the acquisition of insulin via centralized tendering by the Department of Health Logistics of the Ministry of Health (DLOG-MOH) with direct dispensing in SUS facilities[21]. As from 2008, insulin is also provided with reimbursement to private accredited retailers via the Brazilian Popular Pharmacy Program (PFPB)[22]. Up to February 2011, a cost-sharing scheme was in place in PFPB, but since then insulin is provided entirely free of charge and reimbursed by the Federal Government, according to a reference price list[23]. Reimbursement rates are regularly updated and eventually downrated, as a rule based on unilateral government decrees.

Until 2017, traditional human insulins, which are much cheaper than insulin analogues, were the mainstay of treatment for the population living with diabetes in Brazil. The SUS did not provide insulin analogues. Access to them depended mainly on out-of-pocket payments and, eventually, litigation[24-27], often with state and municipal governments being mandated by courts to provide them[28-31]. To avoid the high costs of emergency purchases, some states and municipalities started to include analogues in their procurement lists, together with traditional human insulins, to cover eventual shortages in the provision by the federal government. In 2017 and 2019, respectively, provision of rapid-acting and long-acting insulins by the SUS became mandatory for DM1 diabetics[32,33].

This mandate for incorporation of newer and more expensive versions of insulin coincides with a foreseeably long spell of budgetary restriction on the SUS, due to the Constitutional Amendment 95[34]. This Amendment limits yearly corrections of mandatory government contributions to the SUS to official inflation values, replacing the former and much more favourable indexing increase in government revenues and gross national product growth[34].

This new financing reality may threaten the sustainability of public insulin provision arrangements. The main objective of this study is to describe budget commitment for provision of insulin provision by the Brazilian Federal government, insulin prices and treatment availability from 2009 to 2017, a scenario preceding the mandatory provision of rapid-acting and long-acting insulins and current fiscal constraints.

METHODS

This is a drug utilization study, using retrospective administrative healthcare data on drug purchases and reimbursement. Insulin DLOG-MOH (centralized competitive bidding procurement) and PFPB (decentralized private retail reimbursement) data were used as *proxies* of insulin provision to the population and, hence, for utilization[35].

Expenditures on insulin by other Brazilian federal government agencies, municipalities and states were not included. These usually correspond to hospital acquisitions dedicated to inpatient use of insulin or to small-scale subnational government purchases during shortages in federal-provided insulin, which are not usually recorded in the databases used in this study.

We adopted a bottom-up accounting approach[36] to consolidate data on budgets comitted due to insulin acquisition. The data source for DLOG-MOH insulin procurement expenditures and volumes was the federal procurement administrative database: the Integrated General Services Administration System (*Sistema Integrado de Administração de Serviços Gerais* - SIASG). SIASG contains detailed information on all items purchased by the federal government, including goods and services. In accordance with federal law, every central government agency and organization is individually required to record data on product specification, number of purchases, estimated volume of procured goods, dosage forms and unit prices in SIASG. These variables were collected for Regular and NPH insulin purchases for the years 2009–2017.

PFPB reimbursement data (volumes and values reimbursed by the federal government according to insulin product from 2009 to 2017) were obtained from the Central Management Coordination of the Department of Pharmaceutical Services of the Brazilian Ministry of Health, by means of a special query via the Electronic System of the Information Service to Citizens (E-SIC)[37], based on original data contained in Popular Pharmacy Program Authorization System. In accordance with federal law, every accredited retailer in the program is individually required to record data on patient identity, product specification, dosage form and unit price.

Given that data for the initial years in both databases showed inconsistencies, we collected data for both modes of provision from 2009 to 2017 to ensure better quality of data.

Population data was based on the Brazilian Institute of Geography and Statistics (IBGE)[38] estimates, which were collected in the 2000 and 2010 Brazilian population censuses.

For comparing budgets committed to insulin purchases, prices and availability for treatment for the two insulin provision modes we initially determined the total volume of acquired insulin (Regular and NPH) and related budgets in current local currency units (BRL), according to provision mode (DLOG-MOH or PFPB) and year.

Insulin volumes were recorded in international units (IU) of insulin acquired year by year for each provision mode according to the formula expressed by Equation 1:

$$\text{IU of insulin acquired} = \begin{array}{l}\text{Quantity of acquired vials X vial volume (mL) X} \\ \text{insulin concentration/ml in vials (100IU/mL for insulin)}\end{array} \quad (1)$$

Budgets committed to insulin purchases were recorded in USD and BRL. In order to allow comparisons among budgets by year, all monetary values were corrected to the values from December 2017, using the Brazilian National Consumer Price Index (*IPCA-IBGE*) (Supplementary Table S1)[39]. For each year under analysis, the value of the BRL was then converted into average USD, considering the conversion rates of *Banco Central do Brasil* (Supplementary Table 2).

To compare the availability of insulin in each provision mode, we estimated the number of defined daily doses (DDD) per 1,000 inhabitants/day/year[40]. This was performed by initially determining the total number of IU of insulin (both regular and NPH), as described above. We then proceeded to determine the total number of DDD, using the DDD listed value (40UI for all insulin types)[41], as in Equation 2:

$$\text{Total DDD} = \text{Total IU of insulin acquired}/40 \quad (2)$$

We described the availability for treatment as DDD/1,000 inhabitants/day. For finding out the amount of DDD/1,000 inhabitants/day[42], we proceeded as follows (Equation 3):

$$\text{DDD}/1000\,\text{inhabitants}/\text{day} = \frac{\text{(Utilization in DDDs)}}{\text{(Nº of inhabitants) x (Nº of days in the period of data collection)}} \text{ X } 1000 \quad (3)$$

No. of days in the period of data collection = 365 days.

On detailing overall availability for treatment for studied years and provision modes, we reported both gross overall availability and adjusted overall availability in DDD/1,000 inhabitants/day.

Gross availability depicts volumes translated into availability for treatment (DDD/1,000 inhabitants/day), referring to actual years of acquisition.

Adjusted overall availability refers to overall availability, considering the redistribution of DLOG-MOH-acquired insulin for years with no insulin tenders (2015 and 2016), or tenders for very small volumes (2011) of insulin. We assumed that the volumes of DLOG-MOH tendered in 2014 and resulting purchased volumes were evenly dispensed during 2014, 2015 and 2016. This redistribution is warranted by stated manufacturer shelf-life, which defines a 3-year storage period as admissible. Redistribution of availability for treatment with DLOG was made according to the formula (Equation 4):

$$\text{Adjusted DLOG availability} = \text{Treatment availability (DDD/1,000 inhabitants/day) in the year before no tender}/(1+\text{number of years with no tender or low volume tender}) \quad (4)$$

For years with very small volumes of tenders (2011), volumes of tender and the year before it were added and divided by two, also providing equal adjusted volumes for both years.

To obtain adjusted overall availability, PFPB availability was added to DLOG adjusted values for 2010, 2011, 2014, 2015 and 2016. For other years, gross and adjusted values are identical.

To obtain prices per DDD of human insulin in the two delivery modes in USD currency from 2017, we determined the yearly average acquisition prices per DDD for each provision mode, according to the following formula (Equation 5):

$$\text{Price per DDD in USD currency from 2017 in provision mode} = \frac{\text{Total budget committed to insulin per year in USD currency from 2017 according to provision mode}}{\text{DDD acquired in the year according to provision mode}} \quad (5)$$

Weighed overall prices in USD currency from 2017 per DDD stand for the average price per DDD paid by the federal government each year, considering the varying yearly provision mode mixes. These were calculated as follows (Equation 6):

$$\text{Weighed overall prices in USD currency from 2017} = \frac{\text{Total overall budget committed every year for both provision modes in USD currency from 2017}}{\text{Total overall DDD acquired in both provision modes in the year}} \quad (6)$$

Results for budgets committed to insulin acquisition in million BRL and USD from 2017, insulin volumes and types in 1,000 IU, availability for treatment (DDD of insulin/1,000 inhabitants/day) and prices (in USD currency from 2017) per DDD were shown for the two provision modes on a yearly basis using tables and graphs generated in Microsoft Excel (Microsoft Corp 2013).

This study did not involve human subjects and is based solely on publicly available administrative secondary data, devoid of sensitive data and, thus, has not undergone a formal ethics committee evaluation, according to Brazilian ethical legislation (Resolution 510, from April 7th, 2016)[43].

RESULTS

Budgetary commitments due to insulin acquisition over nine years amounted to 1,027 billion USD currency from 2017, averaging 114.1 million USD/year. Budgetary commitments due to DLOG tendering were rather erratic, falling to particularly low levels in 2011, with a complete absence of tenders in 2015 and 2016. As a contrast, PFPB yearly comitted budgets steadily increased and, by the end of the series, the average committed budgets due to PFPB was higher than the DLOG average (Table 1).

Despite the increase in PFPB provision along the study time frame, DLOG-MOH was the main insulin provider (Table 2). Tenders were won by Novo Nordisk (for 5 years, for

Table 1. Brazilian federal government comitted budgets due to insulin acquisition by provision modes (in million BRL and USD currencies from 2017). 2009–2017.

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Average
DLOG-MOH (million BRL)	96.18	76.3	8.72	125.98	368.52	312.62	-	-	211.58	133.32
PFPB (million BRL)	40.32	32.07	64.18	113.5	154.47	193.02	223.92	227	236.59	142.79
Overall (million BRL)	136.5	108.37	72.9	239.48	522.99	505.64	223.92	227	448.17	276.11
DLOG-MOH (million USD)	48.34	43.35	5.22	64.61	170.62	133.03	-	-	66.28	59.05
PFPB (million USD)	20.26	18.22	38.43	58.21	71.51	82.14	67.24	65.26	74.13	55.04
Overall (million USD)	68.6	61.57	43.65	122.82	242.13	215.17	67.24	65.26	140.41	114.09

DLOG-MOH: Department of Health Logistics of the Ministry of Health; PFPB: Brazilian Popular Pharmacy Program.
Source: Integrated General Services Administration System – SIASG; Central Management Coordination of the Department of Pharmaceutical Services of the Brazilian Ministry of Health; 2000 and 2010 Censuses by IBGE.[38]

Table 2. Federal government-financed insulin volumes and types according to provision modes, in 1,000 international units. Brazil, 2009–2017.

	2009	2010	2011	2012	2013	2014	2015	2016	2017
DLOG-MOH NPH insulin	13,500,000	15,500,000	0	17,000,000	19,805,000	24,000,000	0	0	16,922,508
DLOG-MOH Regular insulin	1,500,000	1,330,000	1,500,000	2,000,000	3,500,000	3,500,000	0	0	2,627,388
DLOG-MOH Total	15,000	16,830	1,500	19,000	23,305	27,500	0	0	19,549,896
PFPB NPH insulin	866,335	733,598	1,461,394	2,737,218	3,949,399	5,068,421	6,145,895	61,185,224	67,609,271
PFPB Regular insulin	0	17,115	116,393	234,348	377,418	650,496	903,661	9,488,031	11,003,087
PFPB - Total	866,335	750,713	1,577,788	2,971,566	4,326,817	5,718,916	7,049,556	70,673,255	78,612,358

DLOG-MOH: Department of Health Logistics of the Ministry of Health; PFPB: Brazilian Popular Pharmacy Program.
Source: Integrated General Services Administration System – SIASG; Central Management Coordination of the Department of Pharmaceutical Services of the Brazilian Ministry of Health; 2000 and 2010 Censuses by IBGE.[38]

both insulin types), Lilly (for one year, for both insulin types) and Aspen Pharma (for one year, for regular insulin).

DLOG-MOH and PFBP together provided an average of 6.08 DDD/1000 inhabitants/day over the study years. Gross overall availability for treatment peaked at 11.22 DDD/1,000 inhabitants/day in 2017, whereas expenditures were the highest in 2013 (242.13 million USD). The minimum adjusted overall availability of insulin occurred in 2010, with 3.47 DDD/1,000 inhabitants/year (Table 3).

Average prices/reimbursement rates in PFPB were higher than in DLOG along the series, but differences showed a decisively downward trend throughout the years. Reimbursement rates for PFPB were 7.2 times higher than DLOG tendering prices in 2009, but gradually fell to 2.7 times in 2017. An analysis of the prices weighed by volume provides actual overall mean prices/DDD paid each year by the federal government. Peak prices/DDD for DLOG were seen for 2013. Weighed overall prices were the highest in years of greater participation of the PFPB mode in provision, namely, 2011, 2015 and 2016 (Table 4).

Table 3. Federal government-financed availability for treatment (defined daily doses of insulin/1,000 inhabitants/day) for diabetes in the Unified Health System. Brazil, 2009–2017

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Average
DLOG-MOH	5.31	5.9	0.52	6.53	7.94	9.29	0.00	0	6.45	4.66
PFPB	0.31	0.26	0.55	1.02	1.47	1.93	2.26	2.35	2.59	1.41
Gross overall yearly availability	5.62	6.16	1.07	7.55	9.41	11.22	2.26	2.35	9.04	6.08
Adjusted overall yearly availability	5.61	3.47	3.76	7.55	9.41	5.03	5.36	5.45	9.04	6.08

DLOG-MOH: Department of Health Logistics of the Ministry of Health; PFPB: Brazilian Popular Pharmacy Program. Source: Integrated General Services Administration System – SIASG; Central Management Coordination of the Department of Pharmaceutical Services of the Brazilian Ministry of Health; 2000 and 2010 Censuses by IBGE.[38]

Table 4. Traditional (NPH and Regular) human insulin prices (in USD currency from 2017) per defined daily doses, according to provision mode Brazilian federal government acquisitions for the Unified Health System. 2009-2017.

Provision mode	2009	2010	2011	2012	2013	2014	2015	2016	2017
DLOG-MOH	0.13	0.10	0.14	0.14	0.29	0.19	-	-	0.14
PFPB	0.94	0.97	0.97	0.78	0.66	0.57	0.38	0.37	0.38
Weighed overall -both provision modes	0.17	0.14	0.57	0.22	0.35	0.26	0.38	0.37	0.20

DLOG-MOH: Department of Health Logistics of the Ministry of Health; PFPB: Brazilian Popular Pharmacy Program. Source: Integrated General Services Administration System – SIASG; Central Management Coordination of the Department of Pharmaceutical Services of the Brazilian Ministry of Health; 2000 and 2010 Censuses by IBGE.[38]

DISCUSSION

The average availability of 6.08 DDD/1000 inhabitants/year for federal-government financed insulin was twice the estimated prevalence of DM1 (insulin-dependent) diabetes in Brazil. This means that patients who cannot live without the drug would be easily covered by the government-financed scheme and some non-DM1 patients under stricter glycemic control protocols would also benefit from it. Given the disease prevalence and the size of the global insulin market, it seems that Brazil managed to achieve reasonable availability of insulin at affordable costs during the study period.

There were significant differences in patterns of provision according to provision mode. Although PFPB dispensed a third of the treatments provided by the SUS by 2017, there were consistent treatment availability increases in this provision mode since the beginning of the program in 2008. The centralized tendering process in DLOG, on the other hand, showed very erratic patterns. Insulin shelf-life in closed vials may extend from 2-3 years according to the manufacturer[6]. This may explain the existence of years for which no insulin tender is recorded. However, there are reports of delivery disruption in several states in these same years.

In other low-income countries, centralized tenders show robust price-elasticity[44], meaning countries tend not to buy if prices rise. Increase in price in the international market[45] coincides with years of missing insulin tenders. The last year of the study (2017) stands out for the very favorable DLOG tendering prices. Novo Nordisk provided the insulin, probably based on the company's equity pricing scheme to reduce price for government-provided 10mL vial of human insulin in least developed and middle-income countries[46].

Reimbursement is apparently less price-elastic than tenders. Prices/DDD for PFPB were substantially higher than for DLOG-MOH, but showed a decreasing trend, in line with reimbursement rates adjustments by the federal government. Differences in prices/reimbursement rates between the two provision modes must be adequately contextualized. Dispensing fees, logistics to outlet[47] and eventual product losses due to insulin cold chain storage requirement must be considered in pricing differences. Moreover, PFPB drug acquisition is the responsibility of retail pharmacies, which tend to have less purchasing power than DLOG-MOH.

Decreasing reimbursement rates for human insulins may discourage distribution via PFPB in remote areas of the country, possibly increasing reliance on the tender-based provision mode. This would demand closer attention to tendering practices and point of care delivery processes–including both securing an adequate budget and supply chain monitoring. Effects of PFPB reimbursement rates should be contrasted with the increased transaction costs involved in enhancing supply chain performance for DLOG-tendered insulin to define the most cost-effective approach.

Many factors may interfere in individual insulin requirements, such as age, weight, meal ingestion and physical activities[6]. There is a striking inter-country variation across DM2 treatment regimens, which depends both on patient's profiles and on differences in countries' healthcare environments[48].

The SUS provision scheme for human insulins seems to be a decisive factor in explaining patterns of insulin use in Brazil. In an 18-country study on insulin-using DM2 patients, Brazil had the lowest use of pens (17% *versus* 74% all countries) and 79% of insulin regimes were based on basal insulin only (all countries 51%). This pattern possibly reflects the provision of insulin to a substantial number of Brazilians by the SUS[48].

This scenario may be undergoing significant change. Preliminary data for 2018[49] show tendering of 3mL insulin cartridges for use with injection pens not previously available via DLOG. The 2018 DLOG comitted budget due to insulin purchase was more than doubled in relation to previous years, with a modest reduction in the number of DDD provided[49].

Most of the world's insulin is produced by three major pharmaceutical companies, and their market power is not to be underestimated[50–52]. The average price of insulin skyrocketed in recent years, nearly increasing threefold between 2002 and 2013[45]. Additionally, we are apparently witnessing a trend toward wider use of 3mL insulin cartridges, injection pens and analogues.

Expenditures on insulin were already substantial relative to SUS overall pharmaceutical budget in 2017. It is thus increasingly necessary to understand how expenditures on insulin impact the SUS budget to plan future actions and purchasing policies. With the increasing incorporation of newer devices and analogues, the Brazilian federal government expenditures on insulin will tend to rise. This could gradually jeopardize the availability for treatment and pharmaceutical budgets in very similar ways to antiretroviral (ARV) and oncologicals.

Thus, models for dealing with insulin provision should increasingly follow those adopted in ARV negotiations[52]. Pressure of international disease associations should be placed not only on governments but also on laboratories to allow balance in demand and provision. Some low and medium income countries are already working on joint strategies for ARV and insulin acquisition[53].

To the best of our knowledge, this is the first study to estimate insulin procurement volume and expenditures based on purchasing data. Prior studies[54,55] examined overall insulin expenditures, but none have analyzed federal drug provision based on comprehensive procurement and reimbursement data.

The present study has some limitations. Actual data on delivery and consumption, number of diabetics and number of insulin users in Brazil are lacking, and tendering and reimbursement data are utilization proxies. Assuming the federal government is the main provider of human insulin in Brazil and that 100% of this volume is available to users, we may also accept that we have a *proxy* for consumption. However, as insulins require a cold chain structure for distribution, which can lead to loss, its utilization may easily have been overestimated.

The use of DDD to estimate treatment provision must also be approached carefully. The DDD is a unit of measurement, employed for comparability, and real-life doses may substantially differ from standardized DDD. Continuous consumption may be reflected in average DDDs over time, but the number of DDDs may not reflect actual number of patients under treatment. Besides that, employing the entire population, number of diabetics or number of insulin users in the denominator changes the interpretation of this indicator.

Impact of the recent incorporation of insulin analogues and increasing expenditures on newer insulin-delivery devices by the SUS is still not measurable in this study, which may serve as a baseline for future comparisons.

In conclusion, Brazil has apparently managed to hold a moderately successful, although imperfect, public provision arrangement for insulin in place, striving with the trade-offs of private and public provision modes and prices. Future studies need to address availability for treatment and financial sustainability in the new scenario of analogue incorporation.

The ascending number of insulin users among the diabetic population and the development of DM2 treatment protocol[56] will result in more intensive use of insulin and may significantly burden financing by the SUS. Therefore, a last recommendation addresses integrated diabetes care and prevention policies, which must be strengthened to rationalize population insulin requirements[11,57].

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