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Budgetary impact of incorporating intermittent glucose monitoring for individuals with type 1 diabetes

Impacto orçamentário da incorporação do monitoramento intermitente de glicose para indivíduos com diabetes tipo 1

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ABSTRACT

Objective: to evaluate the potential budgetary impact – BI resulting from the incorporation of the FreeStyle® intermittent glucose monitoring system for individuals with type 1 diabetes mellitus – DM1. **Methods:** analyzes were carried out using the Excel application for a time horizon of 5 years from the perspective of the state of Mato Grosso, Brazil. The eligible population, individuals aged 18 or over with DM1 and severe hypoglycemia, was selected with the help of an evidence synthesis. The assumed diffusion rates for years 1 to 5 were: 27%; 30%; 33%; 36% and 40%, respectively based on the frequency with which Brazilian diabetics monitor their glucose; in the acceptance of technology and the proportion of diabetic people with access to consultation and exams. A bivariate sensitivity analysis was performed by modifying the population and implantation rate parameters simultaneously. A scenario using smartphones to replace readers was simulated. **Results:** The eligible population was 2,522 individuals with an increase of 2.6% in subsequent years. The annual cost for sensors/individual was R$7,774.00 and for the reader R$299.00/individual for the entire time horizon. In years 1 and 5 the BI was R$5,497,228.62 and R$8,712,561.00, respectively. Replacing readers with smartphones did not prove to be significant for the period considered. **Conclusions:** the BI of a possible incorporation of FreeStyle® is significant when compared to the amount of budgetary resources reserved to operationalize the entire pharmaceutical assistance policy in the state of Mato Grosso, Brazil.

Key words: Diabetes Mellitus Type 1; Analysis of the Budgetary Impact of Therapeutic Advances; Blood Glucose Self-Monitoring

RESUMO

Objetivo: avaliar o potencial impacto orçamentário – IO decorrente da incorporação do sistema de monitoramento intermitente de glicose do tipo *FreeStyle*® para indivíduos com diabetes mellitus tipo 1- DM1. **Métodos:** as análises foram realizadas através do aplicativo Excel® para um horizonte temporal de 5 anos sob a perspectiva do estado de Mato Grosso. A população elegível, indivíduos com 18 anos ou mais com DM1 e hipoglicemia grave, foi selecionada com auxílio de uma síntese de evidência. As taxas de difusão assumidas para os anos de 1 a 5 foram: 27%; 30%; 33%; 36% e 40%, respectivamente, com base na frequência com que os diabéticos brasileiros monitoram a glicose; na aceitação da tecnologia e na proporção de pessoas diabéticas com acesso a consulta e exames. Foi executada uma análise de sensibilidade bivariada modificando os parâmetros "população" e "taxa de implantação", simultaneamente. Um cenário com uso de *smartphones* em substituição aos leitores foi simulado. **Resultados:** A população elegível foi de 2.522 indivíduos com um incremento de 2,6% para os anos subsequentes. O custo anual com sensores foi de R$7.774,00/indivíduo e com o leitor de R$299,00/indivíduo para todo o horizonte temporal. Nos anos 1 e 5 o IO foi de R$ 5.497.228,62 e R$ 8.712.561,00 respectivamente. A substituição de leitores por *smartphones* não se mostrou sensível para o período considerado. **Conclusões:** o IO de uma possível incorporação do *FreeStyle*® é expressivo quando comparado ao montante de recurso orçamentário reservado para operacionalizar toda a política de assistência farmacêutica no estado de Mato Grosso.

Palavras-chave: Diabetes Mellitus Tipo 1; Análise de Impacto Orçamentário de Avanços Terapêuticos; Automonitorização da Glicemia

Introduction

Diabetes is the term used to refer to a group of metabolic disorders characterized by hyperglycemia of multifactorial etiology, including defects in insulin production and/or action, as well as alterations in the metabolism of fats, carbohydrates, and proteins.[1]

In the long term, individuals with diabetes are prone to developing complications such as retinopathy, nephropathy, and neuropathy. Moreover, they are at higher risk of developing heart disease, obesity, peripheral arterial disease, and cerebrovascular disease compared to non-diabetic individuals.[1,2]

Type 1 diabetes mellitus (T1DM) is caused by an autoimmune process that results in little to no insulin production and can occur at any age; however, its onset is most common in childhood and young adulthood.[2]

In 2021, it was estimated that in Brazil, 15.7 million adults (20–79 years old) had diabetes, placing the country sixth in the ranking of nations with the highest number of diabetes cases among adults. The number of prevalent and incident cases of T1DM in children and adolescents aged 0 to 19 years is 92.3 million and 8.9 million per year, respectively.[2]

The treatment of T1DM includes, in addition to the mandatory use of insulin, blood glucose monitoring, disease education, and nutritional support.[1] Careful glucose control and its maintenance within normal serum levels have the potential to delay the onset and progression of microvascular and macrovascular complications.[3,4]

Currently, the healthcare market offers intermittent glucose monitoring systems, which consist of a sensor inserted subcutaneously into the skin and a reader device responsible for displaying the data. Such systems are capable of measuring glucose in the interstitial fluid at programmed intervals without the need for finger pricks. These instruments, such as the FreeStyle® Libre, are based on amperometric electrochemical sensors with the ability to read glucose levels in the range of 40 to 500 mg/dL, featuring an 8-hour memory and a 14-day lifespan. Readings can be performed using a specific reader or a smartphone; in the latter case, the device must be equipped with Near Field Communication (NFC) technology.[5]

The intermittent glucose monitoring system has the same therapeutic indication as glucose monitoring through capillary blood glucose measurement with finger pricks. Moreover, its set of glucose readings provides useful information for evaluating the glycemic profile and for decision-making regarding insulin use, diet, and physical exercise.[5]

Studies indicate that the use of intermittent glucose monitoring systems reduces exposure to hypoglycemia in well-controlled adult patients with T1DM, with no reports of serious adverse events when compared to capillary glucose monitoring. However, some sensor users may experience itching/allergic rash, erythema, and edema.[6,7,8]

Objectives

The objective of this study was to evaluate the potential budgetary impact of incorporating an intermittent glucose monitoring system for patients with T1DM into the Unified Health System (SUS) of the State of Mato Grosso, Brazil.

Methods

The potential budgetary impact (BI) of a possible incorporation of a flash glucose monitoring system for adult individuals with T1DM and severe hypoglycemia was evaluated over a 5-year time horizon, from the perspective of the payer, the government of the State of Mato Grosso.

The budgetary impact was calculated as the difference between the alternative scenario, involving flash glucose monitoring, and the reference scenario, defined as the absence of any glucose monitoring technology. This is because, at present, the provision of glucose monitoring through test strips is not under the responsibility of state management.

The analyses were conducted using Microsoft® Excel® with a deterministic method, assuming the following premises: (a) the flash glucose monitoring system would serve as a substitute for self-monitoring with capillary glucose; (b) no new blood glucose monitoring methods would be introduced within the next 5 years. The model did not take into account costs associated with sensors lost due to early removal; costs of backup strips for capillary glucose,

which would be used in situations requiring confirmation with another method; nor the availability of a healthcare professional to monitor reports and data from individuals participating in the self-monitoring program through flash technology.

Eligible Population

A synthesis of evidence carried out for this study found that the new technology provides greater benefits for adult individuals when assessed for the outcome of time spent in hypoglycemia. Additionally, it is known that hypoglycemia is responsible for complications in diabetes, and its reduction by 30% or more is considered clinically relevant.[9] Moreover, 30% to 40% of people with type 1 diabetes experience, on average, one to three episodes of severe hypoglycemia per year.[10] Based on these data and on a consensus meeting with specialists, the eligible population was defined as individuals aged 18 years or older with T1DM and severe hypoglycemia. The eligible population was therefore estimated based on epidemiological demand, and the parameters used are presented in Table 1.**

Costs

Only direct medical costs related to the technology were considered, from the payer's perspective, given that the technology consists of a sensor with an applicator and requires either a specific reader to obtain the data or, alternatively, a mobile phone.

The following assumptions were made in the cost calculation: (a) the use of the FreeStyle® Libre technology requires the availability of a specific reader; (b) the FreeStyle® Libre reader would be provided in the first year to all users, and in years 2 to 5 only to the incremental population; (c) the reader is a reusable, permanent product with a lifetime warranty; (d) the cost of the sensor and reader, as well as the quantity required for consumption, are presented in Table 2; (e) a glucose sensor has a lifespan of 14 days.

Table 2 below details the costs involved in the incorporation of FreeStyle® Libre

Table 1. Parameters used to calculate the population eligible for use of flash glucose monitoring technology, state of Mato Grosso.

Population ≥ 18 years old with type 1 diabetes mellitus and severe hypoglycemia			
Description of Parameters	**Parameter**	**Data**	**Source**
Individuals aged 18 years or older who reported a medical diagnosis of diabetes and received medical care for diabetes in the past 12 months in Mato Grosso [a]	130,857	130,857	IBGE – National Health Survey[11]
Proportion of type 1 diabetes among individuals with diabetes[b]	5% a 10% (7.5%) [c]	9,814	WHO, 2019[12]
Frequency of severe hypoglycemia in individuals with type 1 diabetes in Brazil	25.	2,.522	Lamounier RN, 2018[13]
Annual increase in the population with type 1 diabetes[c]	2.6% ao ano	2.6% /ano	IDF Diabetes Atlas 2018[14]

[a] Base on 2019 data

[b] An arithmetic mean of 7.5% was used for calculaton purposes

[c] Calcula based on the estimated 74% increase in the Brazilian population of individuals with diabetes aged 20 to 79 years between 2017 and 2045.

Table 2. Freestyle® Libre Costs per Patient

Description	Price (R$)	Monthly amount	Annual quantity	Annual cost per patient (R$)
Sensor cwith applicator (kit)	299.00 *	02	26	7,774.00
FreeStyle Libre reader kit containing reader, USB cable, and power adapter	299.00*	1/60	1/12	299.00

*Source: manufacter's quoted price[15]

Diffusion Rate

For the calculation of the diffusion rate, the following considerations were made: (a) Only 32.8% of adults perform self-monitoring of blood glucose at a daily frequency of 4 or more times, based on a Brazilian study conducted among individuals with T1DM.[16] (b) The follow-up of diabetic patients remains deficient in Mato Grosso. Data from the Primary Health Care Information System (SISAB) indicate that the proportion of individuals with diabetes who had a consultation and an HbA1c test requested in the first quarter of 2023 was 27%.[17] (c) The acceptance of FreeStyle® Libre among individuals with T1DM is high. The study by Edge et al. (2016) reported that individuals who expressed full or partial acceptance of the technology ranged from 84.3–92.1% for sensor application; 87.2–100% for sensor wear and use; 85.4–97.5% when compared with capillary blood glucose monitoring via finger prick; and 68.3–96.3% regarding the device itself.[18]

Thus, the assumed diffusion rates for years 1 through 5 were: 27%; 30%; 33%; 36%; and 40%.

Sensitivity Analysis

A sensitivity analysis was performed through scenario modeling, simultaneously modifying the following parameters: population and technology diffusion rate.

The eligible population was varied by ±30%, considering that the indicator "Individuals aged 18 years or older who reported a medical diagnosis of diabetes and received medical care for diabetes in the past 12 months, by sex and household situation" – used to calculate the eligible population as 130,857 individuals (95% CI: 91,253 to 170,460) – shows a variation of 30.2% according to the 95% confidence interval.11 The diffusion rate was varied by ±5%.

An alternative scenario with a reduced supply of readers was also considered. To this end, the number of individuals who might possibly own a mobile phone with technology capable of replacing the reader was calculated. This assumption was based on the premise that mobile phones with M2M (machine-to-machine) technology represent a growing trend among new devices. The proportion of mobile phones with M2M technology, as well as the annual growth of this technology, was also taken into account (Table 3).

Results

Budget Impact

The budget impact (BI) of a potential adoption of intermittent glucose monitoring technology for individuals with T1DM aged ≥18 years and severe hypoglycemia in the state of Mato Grosso is estimated at R$ 5,497,228.62 in year 1, potentially reaching R$ 8,712,561.00 by the fifth year (Table 4).

Table 3. Parameters considered to calculate the need for a reader in a scenario of competition with mobile phones, State of Mato Grosso (Years 1 to 5).

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Population of Mato Grosso without access to a mobile phone for personal use[a]	4.4%	4.4%	4.4%	4.4%	4.4%
Percentual de aparelhos celulares com tecnologia M2M[b]	16.1%	19.6%	23.2%	26.8%	30.4%
Percentage of mobile devices with M2M technology[b]	83.9%	80.5%	76.6%	73.2%	69.6%
Percentage of mobile devices without M2M tecnology[b]	88.3%	84.9%	81%	77.6%	74%

[a]Based on PNAD 2021[19]
[b]Based on mobile phone statistics in Brazil[20]
[c]Sum of the percentage of people without access to a mobile phones without access to M2M technology.

Table 4. Budget impact for the baseline scenario from the first to the fifth year according to the considered population, State of Mato Grosso (Years 1 to 5).

Year	Population aged ≥ 18 years type 1 diabetes (T1D) and severe hypoglycemia
Year 1	R$ 5.497.228,62
Year 2	R$ 6.055.467,60
Year 3	R$ 6.831.223,10
Year 4	R$ 7.644.126,36
Year 5	R$ 8.712.561,00
Cumulative impact	R$ 34.740.606,68

Sensitivity Analysis

For a scenario in which all assumptions of the baseline case are preserved and the mobile phone serves as an alternative to the FreeStyle® reader, the budget impact (BI) for the next 5 years is presented in Table 5.

Table 5. Budget impact for a scenario with replacement of readers by mobile phones, State of Mato Grosso (Years 1 to 5).

Year	Impacto orçamentário
Year 1	R$ 5.464.448,73
Year 2	R$ 6.051.599,60
Year 3	R$ 6.826.575,10
Year 4	R$ 7.638.597,36
Year 5	R$ 8.706.107,00
Cumulative impact	R$ 34.687.327,79

The result of the sensitivity analysis for a scenario in which there is simultaneous variation in the eligible population and the implementation rate presents three scenarios: (1) an optimistic one, where both the population and the implementation rate are low; (2) an intermediate one, corresponding to the baseline scenario; and (3) a pessimistic one, with high implementation rates and a larger population (Figure 1).

Discussion

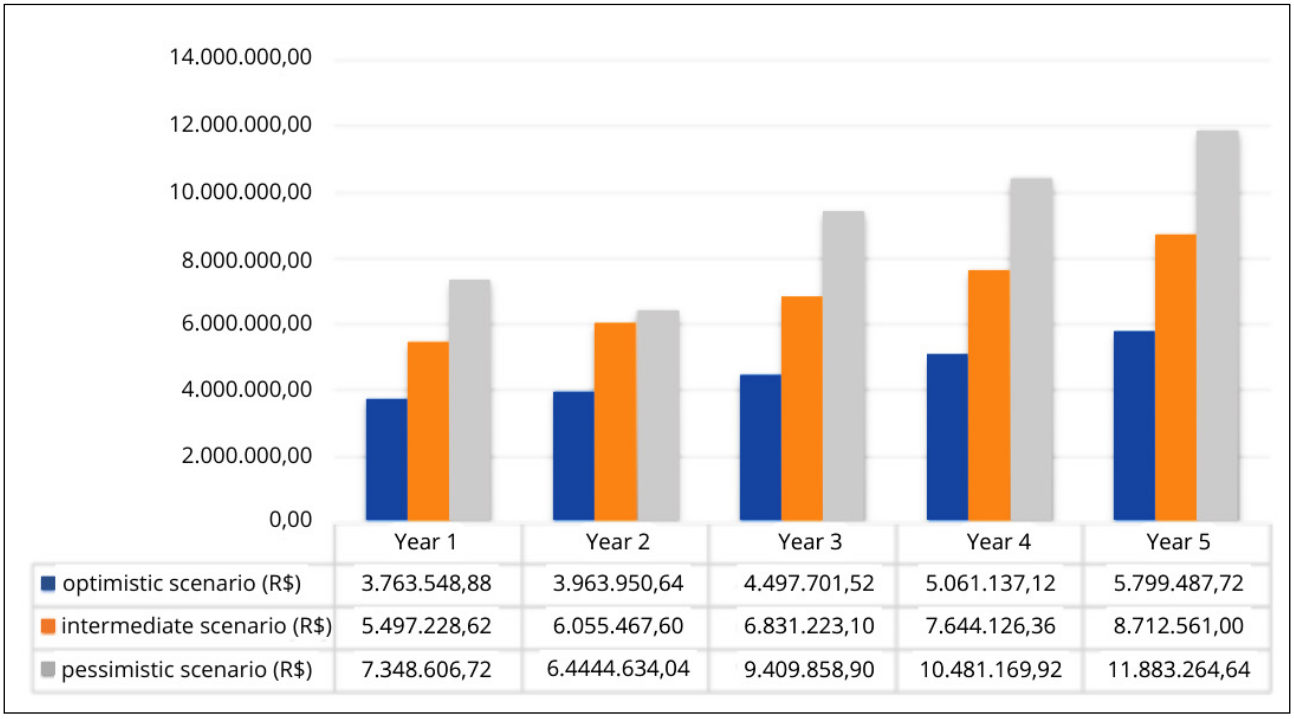
Individuals with T1DM require strict monitoring of blood glucose levels, and it is well established that controlling these glycemic levels is essential for preventing both acute and chronic diabetes complications.21 The Clinical Protocol and Therapeutic Guidelines for type 1 diabetes mellitus indicate that glycemic control can be assessed through fasting and postprandial capillary blood glucose and glycated hemoglobin (HbA1c), in addition to continuous glucose monitoring and intermittent monitoring methods, such as FreeStyle®.22 In this context, the present study evaluated the budget impact (BI) resulting from the incorporation of FreeStyle® for individuals with T1DM in the state of Mato Grosso.

In Brazil, Law No. 11,347 of 2006 guarantees the distribution of medicines and supplies for individuals with diabetes through the Unified Health System (SUS). In 2007, Ordinance No. 2,583/GM/MS defined the list of medicines and supplies that must be made available, including glucometers, test strips, and lancets for finger-prick blood collection (supplies necessary for capillary blood glucose measurement).23,24 The state of Mato Grosso does not bear specific costs related to the acquisition and distribution of these supplies, as they are established in SUS legislative instruments as the responsibility of municipalities.

In 2023, the state of Mato Grosso allocated R$ 74,405,532.00 for the management of pharmaceutical assistance in the state.23 Regarding FreeStyle®, it was identified that its potential incorporation would benefit 2,522 individuals aged 18 years or older with T1DM and severe hypoglycemia. However, this incorporation would result in a significant budget impact (BI), given that, in the first year of implementation, the cost of the technology would represent 7.38% of the pharmaceutical assistance budget, potentially reaching 16% by the fifth year in the most pessimistic scenario. The BI of supplies for capillary blood glucose measurement, when compared with the potential adoption of FreeStyle® in Mato Grosso, is considerable.

The analyses indicated that replacing the reader with the use of mobile phones did not prove to be significant over the 5-year period. It is believed that this result is due to the still limited number of mobile phones with M2M technology, the short time horizon considered, and the fact that the sensor is provided on a one-time rather than continuous basis.

Figure 1. Budget impact for optimistic, intermediate, and pessimistic scenarios, State of Mato Grosso (Years 1 to 5).



	Year 1	Year 2	Year 3	Year 4	Year 5
optimistic scenario (R$)	3.763.548,88	3.963.950,64	4.497.701,52	5.061.137,12	5.799.487,72
intermediate scenario (R$)	5.497.228,62	6.055.467,60	6.831.223,10	7.644.126,36	8.712.561,00
pessimistic scenario (R$)	7.348.606,72	6.4444.634,04	9.409.858,90	10.481.169,92	11.883.264,64

Given that the focus of this study was on assessing the BI of incorporating FreeStyle®, one limitation is that direct and indirect costs of individuals with T1DM during hypoglycemic events and their consequences were not analyzed. Other limitations of the model include the use of self-reported diabetes diagnosis data, adjusted by the proportion of T1DM among diabetics, as a proxy for the T1DM population in Mato Grosso. Furthermore, the diffusion rates were assumptions based on limited data from the literature.

It is believed that studies focusing on this health technology, supplemented with cost-effectiveness analyses and real-world evidence, may provide results that justify the costs of this technology for the state of Mato Grosso.

Conclusion

The BI of a potential incorporation of intermittent glucose monitoring technology for individuals with T1DM, from the perspective of the state of Mato Grosso, is considerable.

The replacement of readers with mobile phones did not prove to be significant for the period considered in the analysis. However, the analysis was sensitive to both the population and the diffusion rate.

Authors' contributions

KCFN: project administration and supervision, study design, data collection and analysis, drafting and revision of the manuscript; TMG: methodology validation, data collection and analysis, drafting and critical revision of the manuscript; GYN: methodology validation, data collection and analysis, drafting and critical revision of the manuscript.

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