How much to invest in glycemic control of a patient with diabetes mellitus type 2? A constant dilemma for the Brazilian Public Health System (SUS)

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Diabetes mellitus type 2 (DM2) affects millions of people worldwide and causes several complications for the patient, consuming large sums of financial resources from the health services. This study aims to estimate the financial investment of DM2 treatment for glycemic control of the patient, from the point of view of the municipal Public Health System (SUS). The Delphi technique was used to validate the opinion of a team of judges, specialists in DM2, and health service managers, on the investment necessary for glycemic control of patients with DM2 through the application of questionnaires. In order for the patient to achieve glycated hemoglobin (A1c) < 7%, an investment of US$ 2,419.06 (value/patient/year) is necessary. As the value of A1c increases, investment is reduced. This result reveals the intention to allocate resources for the prevention of DM2 and its complications.

Keywords: Diabetes mellitus. Pharmacoeconomics. Health care cost.

INTRODUCTION

Diabetes mellitus (DM) is a multifactorial metabolic disorder (ADA, 2016) that affects about 415 million people worldwide (IDF, 2015) and 12 million people in Brazil. The diabetes mellitus type 2 (DM2) being the most prevalent (90%) (SBD, 2015).

DM causes macro and microvascular complications resulting in clinical, financial and social consequences for the patient and the health system (Pereira, Nogueira, Silva, 2015; Silva *et al.*, 2003). Cezaretto *et al.* (2016) state that a multidisciplinary psychoeducational approach is able to reduce patients' cardiometabolic risks, being a viable strategy for adopting a healthy lifestyle in the long term (Cezaretto *et al.*, 2016).

It should be noted that the direct and indirect costs related to DM increase with time (Henriksson, Agardh, Berne, 2003). In this way, health services need to deal with ever-increasing costs in contrast to scarce resources (Guidoni *et al.*, 2009). It is known that the onset of complications related to DM increases the cost of treatment and it is also known that medication makes up 48.2% of the direct costs of DM treatment (Bahia *et al.*, 2011). Pharmacoeconomics is a component of the economic evaluation of health services that supports decision-making and allocation of resources related to pharmaceutical services/products (ISPOR, 1986).

In order for management to be able to use the results obtained from pharmacoeconomic studies, it is important to know the direct, indirect and intangible costs involved in the costing system of its activities. In a study conducted by Franco *et al.* (2013), 95.5% of public agents (accountants and financial sector employees) interviewed in Paraná consider it very important that a cost system be adopted in public services, however, 32.8% say they do not know the factors that influence the costs of their activities, while 43.3% consider that cost system information has been useful for decision-making by sector managers and leaders (Franco *et al.*, 2013).

In Brazil, data regarding the cost of treatment of a patient with DM and its complications are still scarce (Borges *et al.*, 2011). The absence of this consensus in

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the literature makes it difficult to analyze costing and cost projections in pharmacoeconomic studies. In this sense, the present study seeks to estimate the vision of public health service managers, and DM specialists, regarding financial investment for the treatment of patients with DM2, relating these investments to the patient's glycemic control from the point of view of the SUS. In this perspective it is important to emphasize that this study does not assess the cost of DM treatment, but rather, what financial contribution health services management is willing to make in order to achieve the patient's glycemic control.

METHOD

This is a methodological study carried out from November 2015 to April 2016, in which the Delphi Technique (Helmer, Dakley, 1963) was used to estimate the financial value that should be invested in the treatment of a patient with DM2, according to the values of glycated hemoglobin (A1c). The Delphi technique is a methodology recommended by the Ministry of Health that takes into account the opinion of experts on a certain subject when there is no unanimity of opinion due to the lack of scientific evidence, or when the information is contradictory (Brasil, 2013; Revorêdo *et al.*, 2015).

To estimate these data, a questionnaire was applied to a team of judges composed of managers of the health service of a municipality in the center-west of Minas Gerais state (Municipal Secretary, Finance Director, Director of Health Care, Pharmaceutical Assistance Management, and DM and Systemic Arterial Hypertension Management), which deal directly with the application of resources and with the implementation and evaluation of DM related routines. Specialists working with DM patients were also integrated into the team of judges. For the selection of specialists, the following criteria were considered: specialist with an email address available for contact, and belonging to the research centers that had a partnership with the team of researchers and/or member of the work team of the municipality conducting the research. Physicians, nurses, nutritionists, physiotherapists, psychologists, and pharmacists from the states of Minas Gerais, São Paulo, Paraná and Santa Catarina were invited. Managers and specialists composed the team of judges who were supposed to answer "how much would they be willing to invest (value/patient/year) for a patient to achieve a range of A1c (< 7%; 7.1 – 8%; 8.1 – 9%; 9.1 – 10%; 10.1 – 11%; 11.1 – 12%; >12%)". To support this response, were presented data from the literature regarding the costs of DM and complications, and data of the economy provided by the glycemic control of the patient. The questionnaire was previously analyzed by five DM specialists for content evaluation.

According to Wright and Giovinazzo (2000) a 50% abstention is expected in the first round and 30% in the second round of evaluation. Due to the high abstention rate, it is recommended that a large number of people be invited to participate in the team of judges (Revorêdo *et al.*, 2015; Scarparo *et al.*, 2012), therefore, considering the research group's prior experiences, all managers and specialists who met the established criteria were invited to integrate into the team of judges. The questionnaire was sent by email or personally handed to the judges. The team of judges assessed whether the questionnaires had been answered in the correct way and, in case of inconsistency, the judge was notified. If the mistake remained after three tries, the questionnaire was excluded. After the first round of questions, a compilation containing the average, median, minimum, and maximum was resent to each judge that could assess whether their previous answer would be modified or maintained according to the panel of specialists. The answers were considered valid when a concordance of 80% was obtained considering the answers of all the judges. The concordance was calculated by means of the total answers of all the researchers and the total of modified answers after each round (Figure 1). The normality of the data was evaluated using the Kolmogorov Smirnov test.

The monetary amounts presented in the results expressed in dollars were converted using the quotation on April 30, 2016 (R$ 3.451).

RESULTS AND DISCUSSION

The invitation to respond to the questionnaire was sent to six managers and 64 specialists via e-mail. Five managers and 20 specialists responded (64% abstention). The questionnaires were delivered personally to judges from the state of Minas Gerais and the city of Ribeirão Preto (SP) and sent via e-mail to judges from the other states (São Paulo, Santa Catarina and Paraná). Four managers and 17 specialists returned the completed questionnaire (16% abstention). A questionnaire was excluded for noncompliance with the response guidelines. It is observed that the abstention rate was higher than expected in the first round of questions, however, in the second round this index is lower (Wright, Giovinazzo, 2000). It is expected that the high abstention of the first round will not impact the results. In the second round, two managers and a specialist made changes to the answers.
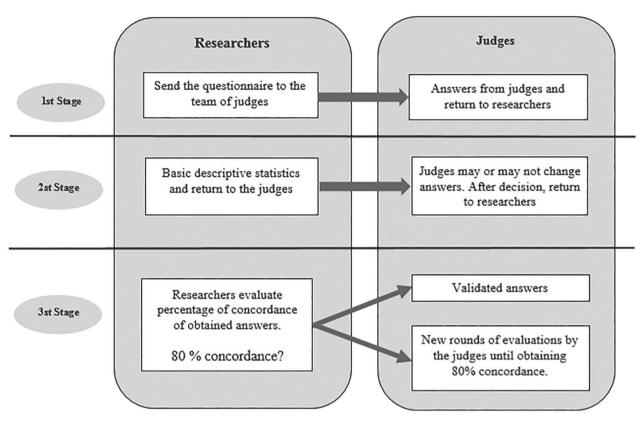
FIGURE 1 - Description of the evaluation stages of the judges in the Delphi technique. Source: Prepared by the author. Adapted from Sousa and Turrini, 2012 (16). Legend: DM2 - Diabetes Mellitus Type 2.

The agreement was 83.3% and the answers were validated by the Delphi technique. The medians of the answers make up the final result presented below.

According to the consensus of experts, US$ 2,419.06 should be invested annually (value/patient/year) so that the patient achieves A1c < 7%. The value of the investment decreases as the value of A1c increases, as can be seen in Table I.

TABLE I - Annual investment of the health service management according to glycemic control of the patient with diabetes mellitus type 2 (DM2), after consensus of specialists. Source: Prepared by the author. N = 21, 2015-2016

A1c (%)	Median (min. – max.) (U$)
< 7	2,419.06 (1,159.15 – 3,767.24)
7.1 - 8	2,236.73 (1,014.26 – 3,152.89)
8.1 – 9	1,683.67 (869.36 – 2,680.54)
9.1 – 10	1,263.48 (145.71 – 2,405.24)
10.1 – 11	744.75 (145.71 – 2,086.47)
11.1 – 12	667.67 (145.71 – 3,152.89)
> 12	595.22 (145.71 – 3,783.47)

Legend: A1c - glycated hemoglobin. Min. - minimum. Max. - maximum

In a survey conducted by Bahia *et al.* (2011) in eight Brazilian cities, considering different levels of complexity, the annual cost of a patient with DM for the health service is US$ 2,108.00. Henriksson, Agardh and Berne (2000) concluded that patients with associated microvascular and macrovascular complications may have treatment costs tripled when compared to patients without these complications. Compared with the present study, it is presumed that the prevention of complications is the main objective of the managers, since there is an intention to place the largest volume of financial resources for the patient to achieve glycemic control (A1c <7%).

In a Brazilian study by Obreli-Neto *et al.* (2015), it was verified that the reduction of 0.7% in A1c provides a saving of US$ 660.00 per patient per year.

A study by Arredondo and Icaza (2011) in Mexico predicted a 33% increase over three years in direct and indirect costs related to DM, and the modification of risk factors and care models for DM treatment is the only alternative for these costs not to become unsustainable for health services (Arredondo, Icaza, 2011).

Another recent study that assessed the DM cost for 2015 in Latin America and the Caribbean found a value of 123 billion dollars/year, with resources mostly destined to the treatment of complications and with an estimated

per capita cost between US$ 1,088.00 and US$ 1,818.00 (Barcelo *et al.*, 2015).

The American Diabetes Association survey estimated a 245 million/year cost, with a US$ 7,900.00 per capita cost, and with 61% of the resources being destined to the payment of hospitalizations and of drugs related to DM complications (ADA, 2013). A systematic review carried out in the Netherlands estimated that the direct and indirect costs of DM treatment in 2016 was 6.8 billion euros, and that about 4 billion of that amount was destined to the treatment and loss of productivity related to DM complications (Peters *et al.*, 2017). A recently performed systematic review which considered the costs involved in DM treatment concluded that prevention, early DM detection and good quality of the services provided to the patient are essential for the reduction in the occurrence of complications (Mustapha *et al.*, 2017). Considering the afore-mentioned, and the findings of this study, it is important to highlight that the greater the number of complications, the higher the cost of treatment and the less managers will be willing to invest. This stresses the need for DM-complication prevention strategies.

Observing the results of the present study, it is noted that the values suggested by the team of judges are in accordance with the per capita cost values practiced in Brazil. However, they are higher than the Latin American and Caribbean values and lower than the USA values. It is also noted that, when the possibility of investing is stratified according to the A1c values, prevention of complications is the main goal of the judges, as the intention is to allot more resources so that patients can achieve glycemic control (A1c≤ 7%). This fact corroborates the literature, since complications related to DM consume a considerable amount of financial resources. Thus, preventing complications from arising is consequently the rational way to apply and optimize the resources available.

This scenario highlights a paradox for the healthcare system, as the need for resource allotment for DM prevention is understood. However, it is necessary to deal with a reality in which patients struck by the disease show complications and require large sums of money for their treatment. From the point of view of equity, resources are allotted in order best to serve those who are most in need; nevertheless, from the point of view of integrality, it is necessary to implement health promotion and worsening prevention actions so that all healthcare needs can be met (Brasil, 1990).

This is why it is necessary for healthcare services to constantly seek more efficient alternatives for glycemic control of DM patients, since preventing complications provides the patient with better quality of life.

The use of quality databases and information in the management of health services is a necessity reinforced by several authors (Drachler *et al.*, 2003; Bittar *et al.*, 2009; Lima *et al.*, 2009). Guidoni and collaborators (2012) used database searches to trace the pharmacological profile of patients with DM in Ribeirão Preto (SP, Brazil). Data and information analyzes were used in the creation of an epidemiological and economic profile for patients in renal replacement therapy (Szuster *et al.*, 2009). Berretta, Lacerda, Calvo (2011) proposes an evaluation model of municipal management for health planning and puts information management as one of the main axes in assessing the quality of management. during the development of this model, among the participating municipalities, the satisfaction with updating the databases was higher than 70%, however, in the final result of the evaluation, only 23.6%. The management for health planning was considered effective in 23.6%.

In this sense the result of this study becomes innovative, as it correlates willingness to invest financially, and glycemic control capability. This provides reflection about the implementation of new health technologies, thus highlighting the need to assess the costs and benefits of adopting a healthcare technology or process to be offered at a healthcare unit, something that rarely happens in the Brazilian healthcare system.

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