

## Distribution Policies of Insulinic Consumptions and Medicines in the Single Health System

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Submitted : 4 Oct 2023 ; Published : 10 Nov 2023

**Citation :** Rivanha S. P. Saraiva (2023). Distribution Policies of Insulinic Consumptions and Medicines in the Single Health System. *J Diabetes Endocrinol Res*; 4(1):1-8. DOI : <https://doi.org/10.47485/2693-2458/1026>

### Abstract

*Diabetes mellitus is a chronic pathology that evolves slowly and presents different complications. The predisposition to the development of diabetes mellitus involves genetic factors and/or comorbidities, and can be classified as diabetes mellitus TYPE 1 (autoimmune), TYPE 2 (metabolic), among others. The general objective of this research is to understand the factors associated with the organization of insulin input management in public health distribution. The present study is a qualitative literature review, using scientific articles published in the SciELO, VHL (Virtual Health Library) and PubMed databases. It was observed, from reading the articles, that DM is one of the most relevant chronic morbidities in Brazil, with its impact associated with the large number of people affected. Between 2017 and 2021, 649,337 new cases of diabetes mellitus were diagnosed in the country. The present study highlighted the importance of discussing public policies aimed at DM in Brazil in an emerging way, considering that some actions for the distribution of inputs and medicines have already been developed, but have not been carried out effectively.*

**Keywords :** Diabetes. Pharmaceutical ingredients. Health Unic System.

### Introduction

Diabetes mellitus is a chronic pathology that evolves slowly and presents different complications, mainly microvascular changes. The predisposition to the development of the disease involves genetic factors and/or comorbidities, and can be classified as diabetes mellitus TYPE 1 (autoimmune), TYPE 2 (metabolic), among others. The pathophysiological mechanism stands out due to reduced production or resistance to insulin, the hormone responsible for the entry of glucose into cells, consequently culminating in an increase in the concentration of glucose in the bloodstream. Diabetes is then considered to be a chronic, progressive and non-communicable disease (Ocaranza, Ojeda & Aedo, 2022).

Type 1 diabetes mellitus (DM1) is characterized by a deficiency in insulin production by pancreatic  $\beta$  cells, caused by the autoimmune destruction of these cells. This causes a large amount of free glucose in the blood in the body and, consequently, hyperglycemia. Patients with DM are more susceptible to circulatory and neurological disorders (Silva, 2022). Type 2 diabetes mellitus (DM2) manifests slowly and may be of metabolic origin, such as being overweight, which causes insulin resistance. Long-term insulin resistance

can cause impaired insulin secretion due to pancreatic cell disorders (Ullah, 2022).

Insulin resistance in the body triggers vasodilation in patients with decompensation and the activation of lipase (lipid enzyme) that generates the accumulation of free fatty acids in the circulation. This effort makes the liver work harder so that adequate hepatic synthesis can occur. In cases of overweight patients, important changes occur, such as high levels of cholesterol and triglycerides, thus increasing the risk of serious heart disease (Andrade, 2021).

Controlling DM2 involves, like DM1, health education, as well as monitoring and correct medication introduction. Each patient has their own particularities regarding treatment, the importance is acceptance of all procedures in a comprehensive manner that contributes to reducing death and improving quality of life (Oliveira, 2021).

For adequate insulin treatment to occur, in addition to the correct use of medications, the patient must be guided by a qualified team, who can combine nutrition and physical exercise for metabolic control and regularization of glucose

levels. Studies show that the improvements are significant and that there is a reduction in the levels of epidemiological data on morbidity and mortality in these patients (Zhang, 2022).

### Justification

Endocrine disorders, such as diabetes, compromise human physiology. Furthermore, they cause other types of psychological and social disorders, such as changes in social life, self-acceptance, and difficulty in living with a specific and challenging pathology, especially in childhood and adolescence (Aguiar, 2021). A qualified health professional, encouragement during diabetes treatment, family support and psychosocial care are the main pillars in the treatment of diabetes mellitus (Alves, 2021).

In this context, this study seeks to understand the factors associated with the organization of insulin input management in public health distribution. The interest in the topic came from following, in my health experience, problems related to the distribution of antidiabetic supplies through the services of the Unified Health System (SUS). The research could contribute socially, as it will address a problem that many professionals face in their daily lives, in addition to serving as a parameter for the knowledge of health professionals and SUS users related to the distribution of supplies for DM cases.

### Goals

#### Main Goal

Understand the factors associated with diabetes mellitus and the distribution of insulin supplies and medications in the public health network.

#### Specific Objectives

- Identify the determining factors for the occurrence of type 1 and 2 DM.
- Describe the pathophysiology of DM.
- Characterize how insulin supplies are organized by the SUS.

#### Methodology

This is a literature review, which aims to incorporate evidence with the purpose of gathering and synthesizing results of research on a delimited topic in a systematic and orderly manner, contributing to the deepening of knowledge of the topic investigated (Gil, 2017).

The data will be analyzed respecting the steps for preparing an integrative review, based especially on what Souza, Silva and Carvalho (2010) discuss in their study, and as explained in the steps below:

- **1<sup>st</sup> Step:** Choice of topic with the elaboration of the guiding question.
- **2<sup>nd</sup> Step:** Bibliographic survey of the literature, where the data search must be broad and diversified, including searches in electronic databases and manual searches in periodicals. The sample collected to support this review

work focused on specialized academic literature using LILACS (Latin American and Caribbean Literature in Health Sciences), SciELO (Scientific Electronic Library Online) and VHL (Virtual Health Library).

- **3<sup>rd</sup> Step:** Collection of data to support the research, extracting data from selected articles, making it necessary to use a previously prepared instrument, ensuring that all relevant data has been extracted and minimizing errors in transcription, ensuring accuracy in checking the data information and serve as a record.
- **4<sup>th</sup> Step:** Critical analysis of the included studies using hierarchically characterized evidence classification systems.
- **5<sup>th</sup> Step:** Discussion of the results, based on the interpretation and synthesis of the results, comparing the data evidenced in the analysis of the articles to the theoretical framework.
- **6<sup>th</sup> Step:** Presentation of the integrative review, describing pertinent and detailed information, based on a contextualized methodology.

Were included, with publications from January 2017 to June 2022, in Portuguese and which corroborated the objectives of this study. The exclusion criteria were: articles repeated between the databases, which did not deal with the topic or did not corroborate the research objectives and in other languages.

### Literature Review

#### Diabetes Mellitus

Type 1 Diabetes Mellitus (DM1) is characterized as an autoimmune disease in which pancreatic  $\beta$  cells are destroyed by cells of the immune system, causing a severe reduction in the release of insulin into the bloodstream. Factors associated with serious viral infections corroborate the deterioration of pancreas cells through autoimmune responses, as occurred in cases of COVID-19. Scientific studies have proven that SARS-CoV-2 is linked to ACE (angiotensin-converting enzyme), triggering the production of autoantibodies related to pancreatic beta cells (Andrade, 2021).

The production of autoantibodies against pancreatic  $\beta$ -cell epitopes in DM1 can occur many months or years before symptoms develop. Autoantibodies associated with T1D are those that target insulin (anti-insulin antibodies), 65 kDa glutamic acid decarboxylase (anti-GAD65 antibodies), insulinoma-associated protein 2 (anti-IA2 antibodies) or zinc transporter 8 (anti-ZNT8 antibodies). The destruction of endocrine pancreatic  $\beta$ -cells most likely occurs through apoptosis. Before the clinical onset of DM, chronic inflammation is observed within the islets of Langerhans, with the participation of T lymphocytes, macrophages, B lymphocytes and dendritic cells, with consequent atrophy of  $\beta$  cells (Skyler, 2017; WHO, 2016).

DM1 is characterized by a strong genetic predisposition, demonstrating that, in the majority of cases, a hereditary nature is present. The literature states that around 50% of DM1 heredity is represented by the region of the human leukocyte

antigen known as Human Leukocyte Antigen (HLA) on chromosome 6. Furthermore, environmental factors may play an important role in the pathogenesis of T1D, such as viruses, toxins, and nutritional factors (Chen et al., 2017).

Type 2 diabetes also has a strong hereditary component, and the disease can develop through exposure to various environmental factors, with dietary changes and increased sedentary lifestyle increasing the risk of type 2 diabetes by increasing body adiposity. The genesis of DM2 highlights the main pathophysiological defects that involve resistance to insulin action at the muscle and liver level and impaired insulin secretion by pancreatic  $\beta$  cells (Skyler, 2017).

DM2 is characterized by the presence of relative hypergluconemia and an increase in hepatic sensitivity to glucagon, resulting in an increase in hepatic glucose production. In the pathophysiology of this type of diabetes, there is an alteration in the peripheral response to the action of insulin, often associated with other conditions of insulin resistance, such as central obesity, arterial hypertension, dyslipidemia, steatosis, among others. It is also important to emphasize that 80% of people with DM2 are obese or pre-obese (Kolbi & Martins, 2017).

Insulin resistance is used as a laboratory test to differentiate diabetes mellitus of autoimmune or metabolic origin. The decompensation of insulin in the bloodstream is what determines, at the time of diagnosis, the immunological response of each patient and adapts the exogenous use of insulin therapy or other drug therapies so that the action of the stimulus occurs on the cellular receptor (Taboada, 2003).

### Diabetes Epidemiology

DM is one of the most relevant chronic morbidities in Brazil, with its impact related to the number of people affected demonstrated by epidemiological data. Diabetes complications are responsible for countless hospital admissions and generate significant financial and social damage to the State and the Union. It is estimated that there are around 415 million adults with diabetes, which could reach more than 642 million by the year 2035, representing more 10% of health spending (Magalhães et al., 2017).

Table 1 below lists the total distribution of Diabetes Mellittus cases in Brazil in the years 2017 to 2021, highlighting, especially, the total number of new DM cases.

**Table 1:** Distribution of the number of new DM cases diagnosed in Brazil.

Year processed	Total New Cases
2017	131,292
2018	133,625
2019	136,276
2020	124,537
2021	123,607
TOTAL	649,337

**Source:** DATASUS, Brazil, 2022.

It is clear to see, in view of the table, that statistically in 2020 and 2021 there was a decrease in the number of new cases of DM in Brazil, which can be justified by the pandemic period to which Brazil and the world were affected, where a large part of the care electives and consultations were minimized due to the risk of contamination, prioritizing urgent and emergency cases and illness due to COVID-19. Also, according to Filho *et al.* (2022) there was an underreporting of cases due to professional illness during the pandemic.

Table 2 presents the number of cases of diabetic patients among females and males in the period from 2017 to 2021. It can be seen, from the analysis of this table, that from 2017 to 2018 the number of cases diagnosed in Brazil had a higher prevalence between females compared to males, however, in 2018 and 2019, the number of men diagnosed with DM surpassed females by around 10%. These data are important as they enable the adoption of public policies aimed at the population with the highest proportion of data, with health institutions being responsible for monitoring and actively searching for cases, in addition to working with preventive actions aimed at diabetes (Hou *et al.*, 2020).

**Table 2:** Distribution of the number of cases between males and females from 2017 to 2021.

Year processed	Masculine	Feminine
2017	63,650	67,642
2018	63,650	68,115
2019	68,376	67,900
2020	64,862	59,675
2021	64,494	59,113
TOTAL	326,892	322,445

**Source:** DATASUS, Brazil, 2022.

It is important to understand that DM can lead to serious problems that lead to a depreciation of health-related quality of life, weakening the individual and their physical state, also causing losses in functional capacity and physiological difficulties especially linked to pain in the limbs (Negreiros et al., 2021).

Diabetes mainly leads to problems of a metabolic nature and physical limitations, causing serious conditions due to hyperglycemia, which culminates in acute complications, such as metabolic ketoacidosis, non-ketotic hyperosmolar coma and hypoglycemia, and chronic complications, such as peripheral neuropathy, retinopathy, coronary artery disease, cerebrovascular and peripheral vascular disease and others (Pereira & Abi, 2019).

All people with DM, regardless of glycemic levels, should be instructed on the importance of adopting MEV (Lifestyle Change) measures for the effectiveness of the treatment. Healthy lifestyle habits are the basis of diabetes treatment, to which pharmacological treatment may or may not be added. Its fundamental elements are maintaining an adequate diet and regular physical activity, avoiding smoking and excess alcohol

and establishing weight control goals (BRASIL, 2013, p. 49).

The public health service monitors patients with diabetes through specific platforms run by the Ministry of Health, which are fed by records related to primary medical care. The introduction to the use of insulin demonstrates that there is a significant reduction in blood glucose levels, however resistance to the hormone progressively alters the lifestyle. The importance of insulin action for the body is what it calls cellular absorption to generate energy and there are no chronic or irreversible complications in important organs (Pereira & Abi, 2019).

### INSULIN and Oral Antidiabetics

The pancreas is the organ that secretes the hormone insulin, which is produced by pancreatic beta cells. Tissue assessment of insulin production is done through laboratory tests. The analysis of insulin secretion and sensitivity is carried out through peripheral blood collection and clamp evaluation. euglycemic, HOMA (*Homeostasis Model Assessment*) and Bennet index (Skyler, 2017).

The glycolic vision of a patient who has annual laboratory tests can be initially monitored by the HbA1c parameter (glycohemoglobin or glycated hemoglobin). The levels of this test show correlations between the base/average glucose and the late levels of any person, whether diabetic or non-diabetic (Pontes, 2018).

Good glycemic control is only possible when there is replacement of pancreatic function, which aims especially to supply exogenous insulin according to the body's needs. There are several types of insulin that will be administered according to the patient's needs and which basically boil down to ultra-fast-acting insulin, fast-acting insulin, intermediate-acting insulin and slow-acting insulin, with different types of manufacturers and forms. therapies (Oliveira, 2017).

Patients who use insulin complexes for replacement must have dietary monitoring to prevent dysfunctions such as hypoglycemia and hyperglycemia from occurring. Therefore, therapeutic treatment by ingestion or infusion is routinely monitored by establishing whether or not there is overload of free glucose in the blood (Oliveira, 2021).

Metabolic control reduces cardiovascular risks according to the DCCT (The Diabetes Control and Complications Trial) and the EDIC (*Epidemiology of Diabetes Interventions and complications*). Insulin therapy, when started quickly, prevents the pathological chronicity that diabetes can develop. An example of insulin therapy used after the initial diagnosis is insulin analogues, which are pharmacodynamic groups, which reach the plateau of actions between 4 and 6 hours and can last up to 24 hours depending on metabolic deficiency and intake (Pires, 2008).

Oral antidiabetics are the first choice for the treatment of type 2 DM that is not responsive to isolated non-pharmacological

measures, as they promote, with strict control, a reduction in the incidence of complications, are well accepted by patients, are simple to prescribe and lead to less weight gain compared to insulin (BRASIL, 2013, p. 50 – 51).

The main oral hypoglycemic medications made available by the Unified Health System are biguanides (metformin hydrochloride) and sulfonamides (glibenclamide and glicazide) (BRASIL, 2013).

If metabolic control is not achieved after using metformin in combination with a sulfonylurea for three to six months, a third medication should be considered. Insulin is also considered when plasma glucose levels are greater than 300 mg/dL, at the first assessment or at the time of diagnosis, especially if accompanied by weight loss, ketonuria and ketonemia. The classes of medications that can be used at this stage are intermediate or long-acting insulins. As all classes have similar efficacy (average reduction of 1% in HbA1c), the use of intermediate insulin is recommended due to the long experience with its use and the lower cost. The insulins available in the SUS are rapid-acting (regular) and intermediate-acting (Neutral Protamine). Hagedorn – NPH (BRAZIL, 2013, p. 55).

### NPH, Regular and Analogues

The insulin best known by the population and initially used for patients who use monotherapy associated with oral insulins is NPH (Neutral Protamine Hagedorn). According to Villarreal (2020), the Latin American Diabetes Association (ALAD) as well as the American Diabetes Association (ADA) recommend combining NPH with rapid insulin in prandial doses to achieve therapeutic objectives, since this type of rapid-acting insulin It is called bolus insulin because it has faster action in a short absorption time, avoiding post-prandial hyperglycemia. In the same context, the author also mentions that the pre-mixed suspension of insulin lispro protamine, also known by the acronym NPL, is a fast-acting product standardized by ALAD and ADA, its use occurs based on basal and/or prandial need. of each user.

Thus we find in the literature that:

The basal-bolus regime (multiple NPH+R doses) is similar to the physiological secretion of insulin, that is, it is a response to food intake starting during fasting and after eating. The dosages are redistributed throughout the day, always after capillary glycemia (Gabbay, 2004, p. 12).

According to Pires & Chacra (2008), regular insulin takes effect between 30 and 60 minutes after use with intermediate peaks of 2 to 4 hours and can last up to 10 hours if used subcutaneously. This demonstrates that the objective of taking the hormone is to reduce sudden glycemic peaks, having greater control over the subsequent dosage.

Insulins are substances that aim to maintain blood glucose levels within or close to normal values for the individual. It is important that when administering this type of medication, the

individual characteristics of each subject are always respected in order to understand and seek the best treatment for their therapeutic needs (Lopes, Santos-Junior, Santos-Junior & Santana, 2012).

These types of drugs are the first choice for the treatment of DM2, as they promote glycemic control and reduce the incidence of complications, especially due to the fact that they are well accepted among individuals diagnosed with the disease as they are easy to administer. , classifying according to their mechanism of action as oral hypoglycemic agents, sensitizers of insulin action, reducers of neoglucogenesis and reducers of the speed of carbohydrate absorption (Lopes, Santos-Junior, Santos-Junior & Santana, 2012).

### Pumps/Devices

The continuous insulin infusion system – PSCI, popularly known as an insulin pump, first appeared in 1970, undergoing several changes over the years with the main aim of optimizing the clinical practice of using this equipment and enabling better results (Puga *et al.* , 2021).

These devices are small, portable electronic devices that release fast-acting insulin 24 hours a day. They are placed on the outside of the body and release insulin from a small tube or cannula placed under the skin. Thus, the amount of insulin released will depend on the dose programmed by the doctor and according to the needs of the patient using this device (Granadeiro *et al.*, 2020).

Due to the risk of serious chronic complications related to uncontrolled diabetes, infusion pumps and devices are possible and viable alternatives related to the rapid action of insulin. Among all the technological treatments in recent years, insulin pumps have stood out, especially due to the improvement in glycemic conditions in diabetic patients (Azevedo *et al.*, 2019).

The insulin pump and other similar devices are advantageous for the treatment of diabetes as they improve HbA1c levels, achieve better variations in blood glucose levels, facilitate diabetes control, allowing more rigorous adjustments of insulin levels and offering more accuracy of the doses required by the body. Over time and with the various modifications to infusion pumps, little has been noticed about the negative effects of this device, since they allow even fewer effects resulting from hypoglycemic episodes and others (Ribeiro *et al.*, 2016).

Device failures are very rare, especially due to the fact that they contain a self-control mechanism, alarms and others.

The most common occurrence, in the case of insulin pumps, concerns insulin leakage through the catheter, however, this still occurs in few cases. The only contraindication to using a pump is the lack of intellectual competence to learn how to use it or the absence of technical support for this, as in the case of a caregiver or family member with experience using a pump and adolescents with psychiatric or eating disorders (Granadeiro *et al.*, 2020).

### Organization and distribution of inputs in the SUS

The rights to health are prescribed in the Federal Constitution of 1988, which highlights the State as the main provider of guaranteeing these rights in legislation and universal and equal access to health actions and services. The concept of health has become comprehensive in the way it describes health not only as the absence of disease, but also through the conceptual logic of the search for a better quality of life, including for the individual at different stages of life (Brasil, 2014).

The SUS is the main gateway for treatment of individuals affected by DM, being the system responsible for the distribution of oral antidiabetics through pharmaceutical care. With the increase in the elderly population and new cases of DM, there is a tendency to increase these high-cost medications, lacking emerging public policies related to the dispensing of antidiabetic medications and other clearer policies aimed at diabetic patients (Prado, Francisco & Barros, 2017).

Currently, the SUS provides the population with options such as NPH human and regular human insulin, as well as medications such as metformin, glibenclamine and glicazide, delivered free of charge from programs such as Hiperdia, which actively searches for diabetic and hypertensive individuals. The distribution of these supplies occurs through medical supervision with distribution in SMS (Municipal Health Department) accredited pharmacies and according to the patient's needs (BRASIL, 2014).

Public policies focused on diabetic care within the scope of the SUS are relatively recent and were incorporated by the multidisciplinary systemic vision only after the 1988 constitution, which caused many losses in the organization and distribution of resources (Tavares *et al.*, 2016 ).

The main public policies related to DM are summarized below, in table 3, and which concern the organization and management of the SUS related to programs to strengthen actions aimed at patients with DM and other NCDs.

**Table 3:** Main legislation related to DM in Brazil.

Legislation	Description
Plan for Reorganization of Care for Hypertension and Diabetes Mellitus – 2001.	Establishes guidelines and goals for care for people with these conditions in the SUS.
Ordinance No. 371 of March 4, 2002.	Hiperdia with services for the promotion, prevention, diagnosis, treatment and control of DM and SAH.
Federal Law No. 10,858/04	Creation of the Popular Pharmacy program.
Ordinance No. 687/06 MS/GM	National Health Promotion Policy – PNPS, expanding and qualifying health promotion actions in SUS services and management.
Federal Law No. 11,347/06	Free distribution of medicines, materials for insulin administration and capillary blood glucose monitoring.
Surveillance of chronic diseases by telephone survey.	Factor Surveillance System for chronic non-communicable diseases (NCDs).
Ordinance No. 184/2011/11 GM/MS	“Health is priceless” program increasing the distribution of medicines for hypertension, DM and asthma.
Ordinance No. 252/13 GM/MS, updated by Ordinance No. 483/14 GM/MS	Health Care Network for People with Chronic Illnesses.
Federal Law No. 13,895/19	National Policy for the Prevention of DM and comprehensive assistance for diabetic people.
Ordinance No. 2,979/19 GM/SM	Previne Brasil Program with a new funding model for Primary Care within the SUS.

**Source:** Prepared by the Author.

As described in the table, Law No. 11,347 of September 27, 2006 “ provides for the free distribution of medicines and materials necessary for their application and for monitoring capillary blood glucose levels to people with diabetes enrolled in education programs for diabetics” ( BRAZIL, 2006, np). In 2007, through Ordinance No. 2,583, under the terms of Law 11,347 of 2006, the main inputs and medications made available by the SUS to patients with Diabetes mellitus were defined. According to this ordinance, the following must be made available:

#### I - MEDICINES

- glibenclamide 5 mg tablet;
- metformin hydrochloride 500 mg and 850 mg tablets;

- glicazide 80 mg tablet;
- NPH human insulin - injectable suspension 100 IU/mL; It is
- regular human insulin - injectable suspension 100 IU/ mL .

#### II - INPUTS:

- syringes with an attached needle for applying insulin;
- reagent strips for measuring capillary blood glucose; It is
- lancets for digital puncture (BRASIL, 2007, np).

It is worth mentioning that the free distribution of insulin infusion pumps to patients with Diabetes Mellitus has also been evaluated through Bill No. 12 of 2022 (BRASIL, 2022). If not treated correctly, diabetes mellitus can lead to several complications such as kidney disease, diabetic neuropathy, amputations, retinopathy and others. In 2017, ordinances No. 10 and 11, through the National Commission for the Incorporation of SUS Technologies – CONITEC, established the incorporation of fast-acting analog insulin for the treatment of DM1 and the NPH human insulin pen within the scope of the SUS. However, despite this guarantee, in everyday practice this does not happen due to a series of bureaucratic problems attributed to service management (Loch *et al.*, 2021).

The lack of effectiveness of the SUS legislation related to the distribution of inputs is notorious, further burdening the responsibility of the disease towards the individual and relating to the lack of adherence to treatment due to economic issues, since the treatment of diabetes has a high cost and can be decisive for the subject’s health issues. Due especially to this fact, many diabetes treatments are only guaranteed through the judicialization of health as a means of guaranteeing medical treatment for DM (Costa *et al.*, 2016). The literature shows that the two most requested medications in court were insulin Glargine and insulin Aspartame, especially due to their non-incorporation into SUS legislation (Cheffi, Barradas & Golbaum, 2017).

#### Final Considerations

DM care must be treated in a comprehensive and integrated manner, based on the formulation of new proposals in order to overcome the bottleneck especially related to the distribution of inputs and monitoring in the treatment of diabetic individuals, considering that there is an imbalance in SUS spending in order to leave chronic non-communicable diseases aside. It is important to understand that diabetes control depends on initiatives from public primary care institutions, the state and society, which must work with issues of adherence to treatment and self-care on the part of the subject with regard to blood glucose control and appropriate use. of inputs offered by SUS.

The study highlighted the importance of discussing public policies aimed at DM in Brazil in an emerging way, considering that some actions for the distribution of inputs and medicines have already been developed, but have not been implemented since their institution. Given that DM is a chronic problem of great scope and relevance, even greater attention to promotion, prevention and diagnosis activities is necessary, as well as

guaranteeing access to treatment free of charge since this is considered a disease that Even today, it can lead to death in children and adults.

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