

Risk management as an improvement for the acquisition and distribution of insulins by SUS

RESUMO | Objetivo: identificar a melhoria por meio da gestão de risco aplicada aos processos de aquisição e distribuição de insulinas humanas NPH. Método: O estudo foi realizado por etapas: em 1º momento foram realizadas reuniões (Brainstorming) e em 2º momento foi elaborado um formulário eletrônico em forma de questionário sendo mostrado os “eventos” de riscos com os pesos inerentes à probabilidade e ao impacto que geraram o risco inerente aos processos de aquisição e distribuição de insulinas humanas NPH e Regular pelo Ministério da Saúde. Resultados: Considerando os processos houve maior incidência de riscos médios. Não foi apontado risco muito baixo, não foi identificado risco extremo e foram apresentados apenas 02 (dois) riscos altos. Conclusão: A gestão de risco do referido estudo é uma ferramenta de melhoria para os processos de aquisição e distribuição de insulinas humanas NPH e Regular pelo Ministério da Saúde.

Descritores: Gerenciamento de Risco; Insulina Regular Humana; Insulina NPH; Sistema Único de Saúde.

ABSTRACT | Objective: to identify improvement through risk management applied to the acquisition and distribution processes of NPH human insulins. Method: The study was carried out in stages: in the 1st moment, meetings were held (Brainstorming) and in the 2nd moment, an electronic form was elaborated in the form of a questionnaire, showing the risk “events” with the weights inherent to the probability and impact they generated the risk inherent in the acquisition and distribution processes of NPH and Regular human insulins by the Ministry of Health. Results: Considering the processes, there was a higher incidence of medium risks. No very low risk was indicated, no extreme risk was identified and only 02 (two) high risks were presented. Conclusion: The risk management of the aforementioned study is an improvement tool for the processes of acquisition and distribution of NPH and Regular human insulins by the Ministry of Health.

Keywords: Risk Management; Human Regular Insulin; NPH insulin; Health Unic System.

RESUMEN | Objetivo: identificar la mejora a través de la gestión de riesgos aplicada a los procesos de adquisición y distribución de insulinas humanas NPH. Método: El estudio se realizó por etapas: en el 1er momento se realizaron reuniones (Brainstorming) y en el 2do momento se elaboró un formulario electrónico en forma de cuestionario, mostrando los “eventos” de riesgo con los pesos inherentes a la probabilidad e impacto que generaron los riesgos inherentes a los procesos de adquisición y distribución de insulinas humanas NPH y Regular por parte del Ministerio de Salud. Resultados: Considerando los procesos, hubo una mayor incidencia de riesgos medios. No se indicó riesgo muy bajo, no se identificó riesgo extremo y solo se presentaron 02 (dos) riesgos altos. Conclusión: La gestión de riesgos del mencionado estudio es una herramienta de mejora para los procesos de adquisición y distribución de insulina humana NPH y Regular por parte del Ministerio de Salud.

Palabras claves: Gestión de Riesgos; insulina humana normal; insulina NPH; Sistema único de Salud.

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INTRODUCTION

According to the Federal Constitution (FC), health is everyone's right and must be guaranteed through public policies, in order to ensure universal and equal access to actions and services for health, promotion, protection and recovery.

Law nº 8.080/1990 regulated the Unified Health System (SUS) with the aim of guaranteeing comprehensive health care.

Within the scope of SUS, Pharmaceutical Assistance is organized into three components: Basic Component of Pharmaceutical Assistance (CBAF), Strategic Component of Pharmaceutical Assistance (CESAF) and Specialized Component of

Pharmaceutical Assistance (CEAF). Each of the Components has unusual characteristics, form of organization, funding and list of medicines, as well as different criteria for access and availability of medicines.

Diabetes mellitus (DM) consists of a metabolic disorder characterized by persistent hyperglycemia, resulting from a deficiency in insulin production or in its action, or in both mechanisms, causing long-term complications².

DM is a significant cause of morbidity and mortality in individuals of different age groups and social conditions. Factors such as population growth and aging, increased obesity, physical inactivity and

urbanization contribute to the worsening of this scenario⁽¹⁾.

Among the drugs for the treatment of DM that the SUS makes available to patients are NPH human insulin and regular human insulin. These drugs were recommended in 2007, through Ministry of Health Ordinance No. 2,583, of October 10, 2007, in compliance with Law 11,347, of October 10, 2006

Regarding drugs for the treatment of diabetes, especially insulin, it is observed that acquisitions occur centrally, with a high financial value, in large quantities and with monthly delivery estimates. Thus, these acquisitions are complex, and it is essential to use a management tool that identifies and contributes to the efficient use of resources, as well as assists managers in establishing strategies to achieve objectives and efficiency in decision-making.

This way, a very useful technique in these processes is the elaboration of risk management. This study was based on the Risk Management Policy (PGR), disclosed through Ordinance GM/MS No. 1,185, of June 9, 2021⁴, which institutes the Risk Management Policy within the scope of the Ministry of Health and aims to objectives reinforce internal management monitoring to achieve “micro objectives” and help decision-making to achieve macro objectives, collaborating to improve institutional processes.

Therefore, this study proposes to identify the improvement of risk management applied to the processes of acquisition and distribution of NPH and Regular human insulins by the Ministry of Health.

METHOD

This is a longitudinal study carried out between 2021 and 2022 by technicians from the Ministry of Health (Brasília/DF). The tools used in the process were completed and applied by public agents who monitor the risk management process within the scope of the Department of Pharmaceutical Assistance and

Strategic Inputs (DAF) of the Secretariat of Science, Technology, Innovation and Strategic Inputs in Health (SCTIE) of the Ministry of Health.

At first, meetings (Brainstorming) were held in order to discuss:

1. The internal and external environments of the organization;
2. The possible risks inherent in the acquisition and distribution processes of NPH and Regular human insulins by the Ministry of Health;
3. Potential causes and consequences inherent to the risks discussed;
4. Probability and impact matrix model to be used;
5. Possible responses to the risks discussed.

In a 2nd moment, an electronic form was elaborated, in which, through a questionnaire, it was possible to record the information that is part of the risk management of the processes of acquisition and distribution of NPH and Regular human

insulins by the Ministry of Health. During the completion of the aforementioned form, the need for a tool to facilitate the results of “probability x impact” and inherent risk, referring to the processes of acquisition and distribution of NPH and Regular human insulins by the Ministry of Health, was verified. This tool was created using formulas from Microsoft Excel 365 software.

Probability reflects the possibility that a given risk will occur, considering the following assumptions:

Regarding the impact, to achieve the objective of the study, the following assumptions were considered:

RESULTS:

At this stage, the results were reported according to the purpose of the study. Table 3 shows the risk “events” of the acquisition and distribution processes of NPH and Regular human insulins

Table 1: Probability scale, 2022.

Probability	Description of the probability, considering the lack of controls	Weight
Unlikely	May occur in exceptional circumstances	1
Rare	Rare possibility to occur unexpectedly	2
Possible	It might happen. Circumstances point to a moderate possibility	3
Likely	It must happen at some point. Circumstances strongly point to this possibility.	4
Practically right	At some point the event will occur, the circumstances clearly indicate this possibility	5

Source: Risk Management Methodology (CGU, 2018) cited in the Risk Management Plan of the Ministry of Health, adapted by the authors, 2022.

Table 2: Impact scale, 2022.

Impact	Description of the impact, considering the lack of control	Weight
Extremely low	Minimal impact on goals	1
Low	Small impact on goals	2
Medium	Moderate impact on objectives, but recoverable	3
High	Significant impact on objectives and difficult to reverse	4
Extremely high	The impacts will be tragic. Irreversible.	5

Source: Risk Management Methodology (CGU, 2018) mentioned in the Risk Management Plan of the Ministry of Health, adapted by the authors, 2022.

by the Ministry of Health discussed in the meetings (Brainstorming), as well as the weights inherent to probability and impact, consequently generating the

inherent risk.

In view of this, the “probability x impact” matrix (Chart 4) resulted, considering that it represents a figurative

and schematized tool, in which each “risk event” described in Chart 03 is automatically allocated in the “field” as your rating.

Table 03: Spreadsheet of risk “events” in the acquisition and distribution processes of NPH and Regular human insulins by the Ministry of Health, containing the results of “probability x impact” and inherent risk, 2022

Processes	Risks	Impact	Probability	Inherent Risk
Purchase of medicines	Shortage of suppliers capable of providing the necessary amount of insulin to be purchased	3	3	9
	Difficulty meeting the proposed delivery schedule in the procurement process	4	3	12
	Incorporation of innovative technologies to be acquired	4	3	12
	Difficulty storing acquired insulin	3	3	9
Distribution of medicines	Difficulty in adhering to new incorporated technologies	4	4	16
	Lack of physical space to store distributed insulins	4	3	12
	Need for anticipation of insulin distribution	4	2	8
	Inconsistency of insulin distribution data	5	4	20
	Limitation of trained personnel to expand information about the use of the device (embedded technology)	4	3	12

Source: Prepared by the authors, 2022.

Table 04: “probability x impact matrix, 2022.

		Extremely low 1	Low 2	Medium 3	High 4	Extreme 5
		Probability				
Impact	Extreme 5				Inconsistency of insulin distribution data	
	High 4		Need for anticipation of insulin distribution.	Difficulty meeting the delivery schedule proposed in the acquisition process. Incorporation of modern technologies to be acquired. Lack of physical space to store distributed insulins. Limitation of trained personnel to expand information about the use of the device (embedded technology)	Difficulty in adhering to new incorporated technologies	
	Medium 3			Shortage of suppliers capable of providing the necessary amount of insulin to be purchased. Difficulty storing acquired insulin		
	Low 2					
	Extremely low 1					

Fonte: dados dos autores, 2022.

Legend of risks:

Very Low Risk - Probability x Impact from 0 to 5

Low Risk - Probability x Impact from 6 to 10

Medium Risk - Probability x Impact from 11 to 15

High Risk - Probability x Impact from 16 to 20

Extreme Risk - Probability x Impact from 21 to 25

It is worth mentioning the use of the legend of risks “by color” considering that their classification was determined by the result of calculating the impact x probability.

According to the classification of inherent risks related to that study, a higher incidence of medium risks was noticed, that is, they were the most present among all identified risks. It is worth mentioning that no extremely insignificant risk was indicated. The risks that presented the highest probability weight were “Inconsistency of insulin distribution data” and “Difficulty in adhering to the new incorporated technologies”, being classified as high and the risk with the lowest probability weight was the “need to anticipate the distribution of insulin”. insulins,” being classified as low.

When considering only the impact, the risk with the highest weight was “Inconsistency in insulin delivery data” and the risk with the lowest weight was “Need to anticipate insulin delivery, both related to the process of NPH Human insulin delivery and Regulated by the Ministry of Health.

The study presented only 02 (two) high risks “Inconsistency of insulin distribution data” and “Difficulty in adhering to new incorporated technologies”, which, despite being critical, represents little incidence considering the processes of acquisition and distribution of Human insulins NPH and Regular by the Ministry of Health “as a whole”.

DISCUSSION

Brazil is in fifth position among 10 countries with 16.8 million adults (20-79 years) with diabetes, it is expected that by 2030 there will be 21.5 million. In addition, it ranks sixth in Brazil, among 10 countries with 7.7 million adults (20-79 years old) with undiagnosed diabetes⁵.

According to what was reported in

VIGITEL 20196, “in the set of 27 cities, the frequency of diabetics who declared pharmacological treatment of the disease was 89.3%, being higher in women (90.8%) than in men (87, 4%)”.

One of the results of this study was the identification of risks that may impact the processes of acquisition and distribution of Human NPH and Regular insulins by the Ministry of Health, among them, the “Inconsistency of insulin distribution data,” classified as one of the high risks. It is worth mentioning that planning the acquisition of insulin by the Ministry of Health is to predict the quantity to be purchased to meet a demand⁷.

As the States have access to the quantity of insulin distributed to the cities and that the continuous change of personnel in these locations impacts on the distribution information inserted in the systems (inputs and outputs), there may be implications in the quantity of the purchasing process, since for this quantity, “historical series” composed of monthly distribution data to the States are used.

Another result of the study identified as a high risk was “Difficulty in adhering to new incorporated technologies”. According to Maya; Araújo (2002)⁸, the use of insulin pens in Minas Gerais became a habit through their use in the Diabetes Weekend summer camp, an educational project that promoted leisure and culture in children and adolescents with type 1 diabetes through the acquisition of knowledge and exchange of experiences among the participants. Even though this event occurred before the incorporation of this device in the list of medicines made available by the Unified Health System (SUS), it was possible to perceive the importance of adherence to the new technology. It is worth mentioning the study⁹ in which, in relation to the total demand of the Regional Health Coordination, it pointed out that, at the end of 2019, the consumption of NPH insu-

lin pens was 5.4%, at the end of 2020 it was 13.3% and in 2021, 14.2%. For Regular insulin pens, the percentage in 2019 was 10.4%, in 2020, 2.7% and in 2021, 14.9%.

It should be noted that, in March 2021, the dispensing criteria for insulin pens and vials were described in Technical Note CGAFB/DAF/SCTIE/MS No. 84/202110, issued by the Ministry of Health, which suggested dispensing 50% in insulin pens and 50% in bottles, considering DM1 or DM2 users in the age groups i) less than or equal to 19 years old; and ii) greater than or equal to 50 years old. As can be seen, the Regional Health Coordination of the aforementioned summary presented a consumption of 35.8% less for NPH human insulin and 35.1% less for regular human insulin, considering the 50% dispensing criterion suggested in the aforementioned Technical Note.

It is worth mentioning the study on medication adherence and knowledge about insulin therapy of patients using an insulin pen monitored by pharmaceutical teleservice in a basic health unit¹¹, in which he reported on the service in the city of Porto Alegre, through the city health department, which developed the Local Program for the Distribution of Supplies for Diabetes. Patients included in the program receive, among others, glucometers, reagent strips and lancets. Pharmacists who make up the multidisciplinary team in primary care, co-responsible for educating and monitoring patients in the handling of these technologies, particularly insulin pens, available by the city of Porto Alegre for patients over 60 years old.

Finally, and considering the Cuidar (care)+¹² manual, the State Department of Health of Rio Grande do Sul, specifically the Department of Pharmaceutical Assistance, received several reports from pharmaceutical professionals regarding the difficulties faced in guiding users regarding the use of a pen to ad-

minister insulin. In these reports, it was found that there was resistance from users to use this new technology and a lack of educational materials aimed at health professionals, which would instruct on the necessary guidance for the correct use of the device.

In view of this, it is clear in this study, the classification resulting as high risk "Difficulty in adherence to new incorporated technologies", related to the process of distribution of insulins by the Ministry of Health.

CONCLUSION:

This study proposes to identify the improvement of risk management applied to the processes of acquisition and distribution of NPH and Regular human insulins by the Ministry of Health.

It is worth noting that, to carry out the analyzes carried out in this study, it is evident the need to know all the stages of the acquisition and distribution process of NPH and Regular human insulins.

The risk management of the study is considered as a proposed model for improving the processes of acquisition and distribution of NPH human insulin and regular insulin, as it makes it possible to identify and reduce "weaknesses", "exploit" opportunities and mitigate the threats inherent to the aforementioned processes. During the development of the study, it was possible to perceive the importance of risk management to the organization's strategic planning. In addition, through the analysis and classification of risks, it was also noticed that risk management can be used in a detective or preventi-

ve way, making it easier for the manager to implement, monitor and execute actions related to processes efficiently and effectively.

It is concluded that the proposed risk management is an improvement tool for the acquisition and distribution processes of NPH and Regular human insulins, as it contributes to the efficiency of these processes and contributes to the organization regarding the formulation of strategies and actions in the decision-making.

Finally, the importance of this study is visible due to its relevance to the efficiency of the acquisition and distribution process of NPH and Regular human insulins, as it contributes to the main objective, which is the supply of insulins in the Unified Health System network to patients' insulin dependents.

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