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THEORY OF CONSTRAINTS AS A DRIVER FOR FRUGAL INNOVATION IN HEALTH

TEORIA DAS RESTRIÇÕES COMO PROPULSOR DA INOVAÇÃO FRUGAL EM SAÚDE

TEORÍA DE LAS RESTRICCIONES COMO PROPULSOR DE LA INNOVACIÓN FRUGAL EN SALUD

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Abstract

Objective of the study: The objective of the research was to identify whether the application of the Theory of Constraints (TOC) reasoning process mobilizes frugal innovation in the process of distributing high value-added oncological drugs, in Brazil.

Methodology: Qualitative-descriptive research that, through the collection of primary and secondary data, was applied to content analysis with a priori categorization.

Originality/Relevance: The relevance of the research points to the complexity of the parties involved, responsibilities, flows, bottlenecks and losses involved in the distribution process of oncological drugs and the intervention specificities necessary for assertiveness in distribution.

Main Results: The alignment of TOC with frugal innovation was evidenced, with regard to the development, production and management of services that present resource constraints, avoiding unnecessary costs.

Theoretical/methodological contributions: As contributions to the study, the association and reinforcement in organizational theory and TOC tool with frugal innovation is pointed out, establishing an operational framework for the discussion and proposition of a future agenda on the use of tools that help the decision-making process, particularly in the health context.

Social/Management Contributions: The research provides insights into the use of tools associated with the development of frugal innovation in processes and services of government agencies with limited resources and limited budget.

Keywords: Frugal innovation. Theory of constraints. Reasoning process. Oncological drugs. Health system.

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Resumo

Objetivo do estudo: O objetivo da pesquisa foi identificar se a aplicação do processo de raciocínio da Teoria das Restrições (TOC) mobiliza a inovação frugal no processo de distribuição de medicamentos oncológicos de alto valor agregado no Brasil.

Metodologia: Trata-se de uma pesquisa qualitativo-descritiva que, por meio da coleta de dados primários e secundários, foi aplicada à análise de conteúdo com categorização a priori.

Originalidade/Relevância: A relevância da pesquisa aponta a complexidade das partes envolvidas, responsabilidades, fluxos, gargalos e perdas envolvidas no processo de distribuição dos medicamentos oncológicos e as especificidades de intervenção necessárias para a assertividade na distribuição.

Principais Resultados: Ficou evidenciado o alinhamento da TOC à inovação frugal, no que diz respeito ao desenvolvimento, produção e gestão de serviços que apresentam restrição de recursos, evitando custos desnecessários.

Contribuições teóricas/metodológicas: Como contribuições do estudo, aponta-se a associação e reforço na teoria organizacional e ferramenta da TOC à inovação frugal, estabelecendo um quadro operacional para a discussão e proposição de uma agenda futura sobre o uso de ferramentas que auxiliem a tomada de decisão organizacional, em particular, na área da saúde.

Contribuições sociais/para a gestão: A pesquisa fornece insights sobre o uso de ferramentas associadas ao desenvolvimento de inovação frugal em processos e serviços de órgãos governamentais com poucos recursos e orçamento limitado.

Palavras-chave: Inovação frugal. Teoria das restrições. Processo de raciocínio. Medicamentos oncológicos. Sistema de saúde.

Resumen

Objetivo del estudio: El objetivo de la investigación fue identificar si la aplicación del proceso de razonamiento de la Teoría de las Restricciones (TOC) moviliza la innovación frugal en el proceso de distribución de medicamentos oncológicos de alto valor agregado, en Brasil.

Metodología: Investigación cualitativa-descriptiva que, a través de la recolección de datos primarios y secundarios, se aplicó al análisis de contenido con categorización a priori.

Originalidad/Relevancia: La relevancia de la investigación apunta a la complejidad de las partes involucradas, responsabilidades, flujos, cuellos de botella y pérdidas involucradas en el proceso de distribución de medicamentos oncológicos y las especificidades de intervención necesarias para la asertividad en la distribución.

Resultados Principales: Se evidenció el alineamiento de TOC con la innovación frugal, en lo que se refiere al desarrollo, producción y gestión de servicios que presentan limitaciones de recursos, evitando costos innecesarios.

Aportes teóricos/metodológicos: Como aportes al estudio, se señala la asociación y refuerzo en la teoría organizacional y herramienta TOC con la innovación frugal, estableciendo un marco operativo para la discusión y proposición de una agenda futura sobre el uso de herramientas que ayuden a la toma de decisiones, particularmente en el contexto de la salud.

Contribuciones sociales/de gestión: La investigación proporciona información sobre el uso de herramientas asociadas con el desarrollo de la innovación frugal en procesos y servicios de agencias gubernamentales con recursos limitados y presupuesto limitado.

Palabras Clave: Innovación frugal. Teoría de las restricciones. Proceso de razonamiento. Medicamentos oncológicos. Sistema de salud.

1 Introduction

In the thematic line of innovation, there is a recent area - frugal innovation - which presents important questions about the nature of innovation from the social, economic, and environmental point of view, being compatible with the context of emerging countries and suggested for developed countries

(Lacerda, 2016). Frugal innovation emerges as an alternative to deal with resource constraints, as it is functional and focused on what adds value, seeking to minimize the use of materials and financial resources at the process level (Weyrauch, & Herstatt, 2016).

Some publications about frugal innovation have some characteristics that, in general, consist of developing or redesigning products, services, and processes that provide considerably lower costs, with minimal use of resources, quick solutions, low environmental impact and that add value to the customer's point of view (Prabhu, 2017; Bhatti & Ventresca, 2013; Agarwal & Brem, 2012; Zeschky, Widenmayer & Gassmannhart, 2011).

On the other hand, the literature is in need of new studies that relate the Theory of Constraints (TOC) as a driver of frugal innovation. TOC was first described by Israeli physicist Eliyahu Moshe Goldratt in his book "The Goal" in 1984, where he emphasizes the importance of managing constraints in an organization to achieve the organization's goals (Vidal & Wanke, 2009).

In this scenario, according to Silva, Genro & Kipper (2015), the TOC is an adequate method to identify and eliminate constraints. As for Wanderley & Congan (2012), the use of the TOC can be considered a competitive differential, allied in the search for increased productivity. In summary, TOC is intended to propose solutions to various processing problems within organizations, through the application of its logic, in order to identify the reasons that prevent the achievement of an objective, developing a solution to a restriction, eliminating the causes of restrictions, without affecting the production flow, ensuring an increase in added value (Goldratt, 2007).

It is evident that there is a common goal between frugal innovation and TOC, both concepts seek to work with the limitation of resources, that is, restrictions, which require the redesign of processes, products, and services (Zeschky et al., 2011, Basu, Banerjee & Sweeny, 2013, Desa & Basu, 2013, Kuo, 2016), which in turn may mean that TOC can be a driver of frugal innovation. Therefore, the research question of this study is to identify whether TOC in the health context, leads to the possibility of developing frugal innovations specifically through the process at the managerial level of the centralized distribution of oncological drugs in the state of Rio Grande do Sul.

One of the attributions of the Brazilian Unified Health System (Sistema Único de Saúde - SUS) is the free availability of cancer drugs. Through the Ministry of Health of Brazil, the SUS operates in the dispensing of these high value-added medicines in conjunction with the State Health Departments through the pharmaceutical assistance department. Patients who are treated in this modality are involved in a highly complex flow of drug distribution, which involves several entities and generates an environment of difficult management and control of the supply chain by the parties involved. The current flow in which high value-added cancer drugs are dispensed is composed of two systems. The Ambulatory Information System (Sistemas de Informações Ambulatoriais – SIA), which is responsible for communication between hospitals and the Federal Government. The second system is AME Programs (Administração de Medicamentos – AME), which aims to link hospitals with local

management (Secretaria Estadual de Saúde – SES) requests the purchase from the Ministry of Health, which, in turn, checks the procedures registered in the SIA, makes purchases, and transfers it to the local state secretariats to manage the distribution to hospitals.

Through the analysis of this process, it was noted that there are discrepancies in the records sent in the two systems, with two distribution management softwares, loss of information, forgotten records, failures in purchase orders, misplacement of requested medications, among others. In all these situations, the ultimate impact is on the patient. These compounding issues cause a series of concerns and conflicts.

Analyzing national spending on drugs is fundamental in the comprehension of the current and future direction of the National Pharmaceutical Assistance Policy and to understand the budget and health policy as a whole, since this activity has a significant weight and impact on other policies, and why the government has a central role in these policies. The National Pharmaceutical Assistance Policy is responsible for most of the expenditure on health (42.4% in 2019), while municipalities account for 31.3%, and states for 26.3%, in addition to being the one with the highest capacity of revenue creation (Inesc, 2020).

In 2019, spending in Brazil on medicines was R$ 19.8 billion (US$ 3.4 billion), an increase of almost 10% compared to 2018, in real terms. This expense follows an increasing trend compared to previous years and more than doubled when compared to 2008 (R$ 9,1 billion/ US$ 1.7 billion). It consumes an increasing share of the Ministry of Health's budget, which accounted for 14.6% in 2019 (Inesc, 2020). Due to its large and growing financial impact, the adequate organization and management of pharmaceutical care is a tool for managing the public good and optimizing health outcomes.

Whereas frugal innovation in healthcare means the ability to provide safe healthcare as best as possible under certain restrictive circumstances, on condition of expanding access to care and ensuring that care is good enough under current circumstances (Gupta & Thomke 2018), the question is: Can the use of TOC be considered a driver for frugal innovation?

Taking into account the characteristic of frugal innovation, which is to seek solutions, dealing with resource constraints, and adding value to the customer, thus, the general objective of this study is to identify whether the application of the Reasoning Process (RP) of the TOC mobilizes frugal innovation in the management-level process of centralized distribution of high value-added cancer drugs in Brazil, particularly in the local state of Rio Grande do Sul.

As an academic contribution, this study seeks to advance knowledge in the literature on frugal innovation by highlighting the contribution of TOC in the health context, specifically in the process at the managerial level of the centralized distribution of cancer drugs in the local state of Rio Grande do Sul. Through this contribution, highlighting a new process that can be used by organizations to develop frugal innovations. Frugality is not just about cost, but about accessibility, being related to universal coverage and scale and about adaptability, related to use in a local and clinical setting (Krishan & Davis,

2012; Radjou, Prabhu, & Ahuja, 2012; Agarwal & Brem, 2012; Bhatti & Ventresca, 2013; Rao, 2013; Hartley, 2014; Nodari et al., 2019).

In some cases, frugal innovations are the only possible way to solve problems when markets do not work or users cannot afford regular medical technologies. In particular, frugal innovation can be essential to creatively address some constraint issues in developing countries, thus having an impact on social inclusion (Bianco, 2012) and/or value creation for underserved markets (Bhatti, 2012).

Faced with this scenario, the study seeks to contribute to the optimization of the process of centralized distribution of cancer drugs in the local state of Rio Grande do Sul, in southern Brazil, seeking to minimize bureaucracy, rework, and the impact on the patient. Frugal innovation explored together with TOC, may revert to benefits for society, in the context of health in general, not only in the centralized distribution process of medicines but also as a form of innovation for products, processes, and services of public agencies lacking resources and with limitations, with a focus on strengthening efficiency, ensuring the quality and care of the SUS.

2 Theory

2.1 Frugal Innovation

Frugal innovation appeared in emerging or developing markets as a response to the needs of consumers at the base of the pyramid (BoP – Base of Pyramid). The term "frugal innovation" is relatively new, its first occurrences arose in the previous decade, where it gained notoriety, in 2010, in a special report by The Economist magazine, in an article entitled "Health in India: lessons from an innovator frugal" (Tiwari, Kalogerakis & Herstatt, 2016; Bhatti & Ventresca, 2013; Radjou, Prabhu & Ahuja, 2012). Frugal innovations offer market-specific solutions, with high added value and low cost (Radjou & Prabhu, 2012). They innovate quickly, under resource constraints, redesigning products, processes, and business models.

The growth of consumerism, the concern for sustainability, and the high growth rates of emerging markets with low-income consumers have stimulated changes in the vision of traditional innovation, opening the opportunity for the implementation of frugal innovation (Rao, 2013; Prabhu & Gupta, 2014).

Through its approach to developing, producing and managing resource-constrained services, frugal innovation avoids unnecessary costs (Brem & Wolfram, 2014; Prabhu & Jain, 2015), promoting quality and affordable solutions to base customers of the pyramid. Frugal innovations are not quick engineering solutions, but products and services developed for applications in resource-constrained environments, based on new architectures and redesigns of products and processes (Zeschky, 2014).

Frugal innovation can be seen as an output characteristic of a product or service, which is not only low-cost, but also has reduced consumption of resources, whether financial, raw materials, infrastructure, and human skills throughout the value chain. Thus, low resource consumption can be a characteristic of the process of using frugal innovation. Organizations need to adapt their processes and find a scalable and sustainable way to not only offer low-cost products or services, but low resource consumption, high added value to consumers, functional, robust, easy to use, accessible, and local (Bhatti et al., 2013; Rao, 2018).

These needs have pointed to frugal innovation as a valuable contribution to the development of organizations, associating their practices with management knowledge, reconfiguring the value chain, redesigning products and processes in different ways (Bhatti, 2012; Brem & Wolfram, 2014). Through this interface, meeting the needs of consumers is promoted, economic growth is created, in addition to generating profits for organizations (Knorringa, 2016).

According to Prabhu (2017), among some examples of the development of sectors in which frugality can act, it is possible to highlight the manufacture of better and cheaper products, in the scope of services: redesigned processes, removing barriers, and rework. In agriculture it can solve food waste problems; in the automotive sector, being frugal aims to increase efficiency in fuel consumption; in the energy sector, carbon-free renewable energy; in the health sector, work on optimizing outpatient and hospital care.

2.2 Theory of Constraints

In a globalized and competitive world, organizations are increasingly seeking to improve their production processes to obtain better results, minimize their costs and maximize their profits. In this scenario, according to Silva, Genro, and Kipper (2015), the Theory of Constraints (TOC) is an adequate method to identify and eliminate constraints. As for Wanderley and Conga (2012), the use of the Theory of Constraints can be considered a competitive differential, allied in the pursuit of increased productivity.

TOC can be considered a new philosophy of management thinking, whose main idea is to manage from a scenario of organizational constraints, aiming to maximize gains through the elimination or reduction of inventories, process rework, and operating expenses, and for to achieve this goal, it uses theory tools, such as Current Reality Tree (CRT), which seeks to highlight what must be changed, the Cloud Dispersion Diagram (CDD) and Future Reality Tree

(FRT), which is presented for where to change and finally the Prerequisite Tree (PT) and Transition Tree (TT), which indicates how to change.

Also according to Wanderley and Congan (2012), despite the evolution of studies in this area, TOC is still seen by most people as only applicable to production, since the book "The Goal: A Process of Ongoing Improvement" is based on the production logistics problems of a factory. However, its application is not limited to these areas, it can be applied in administrative processes, services, among others, as there are already TOC applications in the health area.

In England, TOC was successfully applied to reduce the waiting lists that are administered by the national health system, applying the principles of TOC, firstly an analysis of the treatment flow was carried out and the restriction in the surgical process was identified. It was found that the number of patients hospitalized for surgical intervention was greater than the physicians' capacity to provide care. An attempt was made to establish a queue management system and the scheduling of hospitalized patients for surgeries went from 11 to 6. As a result, there was a reduction in the number of emergency surgeries and an increase of 16% in the system's service capacity (Phipps, 1999).

At National Cancer Institute, in Rio de Janeiro, TOC was used to identify bottlenecks in the treatment flow of patients (Gonçalves, 2004). The restriction was identified in the diagnostic imaging process. Based on this observation, actions were defined in order to explore and subordinate all resources to the identified restriction. As a result, there was a 25% reduction in time between patient registration and the start of effective treatment.

2.3 Pharmaceutical assistance of the Unified Health System

Health was established by the Federal Constitution as a right for all and a duty of the State, which was structured through the Unified Health System (SUS) to ensure, among others, comprehensive therapeutic care. Law no. 8,080, published in 1990, regulates health actions and services to guarantee this constitutional right. Among other things, this law established that the SUS should be structured in such a way as to guarantee comprehensive therapeutic assistance, including Pharmaceutical Assistance (Brasil, 1990).

In this context, actions related to Pharmaceutical Assistance (PA) have been guided by public policies, by the logistical management of the drug, and by the care provided to the user, reaffirming that ensuring access to the drug is not the only purpose of PA. Resolution no. 338/2004, defines Pharmaceutical Assistance as a set of actions aimed at the promotion, protection, and recovery of health, both individual and collective, having the drug as an

essential input and aiming at access and rational use. This set involves the research, development, and production of medicines and supplies, as well as their selection, programming, acquisition, distribution, dispensing, quality assurance of products and services, monitoring and evaluation of their use, with a view to obtaining concrete results and improvement in the quality of life of the population (Brasil, 2004).

Thus, the actions of the AF must be supported by two axis, interconnected with each other. The first one comprises activities related to the technical management of the drug, with an important emphasis on logistical management. They are interdependent activities that are focused on access and rational use and that take place before starting to use the medication. Among them, the following can be mentioned: production, selection, programming, acquisition, distribution, storage and dispensing of medicines. The other axis comprises the clinical management of medication and is related to health care and the therapeutic results actually obtained, with the main focus on the user, based on the patient care process (Correr, Otuki & Soler, 2011).

Based on the guidelines of the National Pharmaceutical Assistance Plan, the financing of Pharmaceutical Assistance was organized into three components, as follows: I - Basic Component of Pharmaceutical Assistance; II - Strategic Component of Pharmaceutical Assistance; and III - Specialized Component of Pharmaceutical Assistance. Each component has its own characteristics in terms of scope, objectives, federative responsibilities for funding, implementation, evaluation and monitoring.

With attention focused on the Specialized Component, Ordinance GM/MS No. 1554, of July 30, 2013, which provides for the rules for financing and implementing the CEAF within the scope of the SUS, presents the division of the list of medicines in three groups and defines the financing responsibilities between the federated entities: (a) Group 1: medicines under the responsibility of financing by the Ministry of Health, subdivided into: - Group 1A: medicines for centralized acquisition by the Ministry of Health and supplied to the Health Departments of the States and the Federal District; Group 1B: medicines financed by the Ministry of Health through the transfer of resources for acquisition by the Health Departments of the States and the Federal District. (b) Group 2: drugs financed and purchased by the Health Departments of the States and the Federal District. (c) Group 3: drugs financed in accordance with the regulations of the Basic Component of Pharmaceutical Assistance and indicated by the PCDTs as the first line of care for the treatment of diseases covered by the Specialized Component.

It is noteworthy that the burden of the Federal Government, with regard to financing, corresponds to that of Group 1, where the treatments of greater complexity and greater financial impact are found. In turn, the segregation of drugs within Group 1 itself also follows criteria of complexity and treatment value, and the strategic acquisition of Group 1A drugs - a priori, the most expensive - by the Ministry of Health itself must to its bargaining power in centralized purchasing and acquisition at scale. This group includes oncological drugs that are acquired centrally by the Ministry of Health (Ministry of Economy, 2019).

It is important to highlight in this segregation of groups the national initiative contained in the specific criterion of Group 1 of the Specialized Component: "IV - medicines included in productive development actions in the health industrial complex". Associated with this initiative, the Partnerships for Productive Development (PPD) aim at the production of medicines in the country, through the incorporation of technology transferred by private laboratories (national or multinational) to official laboratories, fostering the development of the health industrial complex (Ministry of Economy, 2019).

3 Method

This research is characterized as qualitative-descriptive, and field research that aims to obtain information and/or knowledge about a problem, for which an answer is sought, or a hypothesis, that one wants to prove, or even, to discover new phenomena or the relationships between them (Lakatos & Marconi, 2010).

The study took place from March to July 2021, based on primary and secondary data, the primary data is collected through semi-structured interviews with servers involved in the process of distribution of centralized cancer drugs under the responsibility of the State Health Department of Rio Grande do Sul and secondary data, through documentary information, obtained from reports, guidelines, ordinances, and manuals at the municipal, state and federal levels.

The data collected through interviews and documents were analyzed through qualitative content analysis, with the steps proposed by Bardin (2016): pre-analysis, material exploration and treatment, and interpretation of results. In the pre-analysis, the first contact with the documents occurs, in this case, the transcription of the interviews and secondary data such as reports, guidelines, ordinances and manuals at the municipal, state and federal levels.

In the material exploration phase, a priori categorization was not performed to highlight future perspectives. Based on the documents, an attempt was made to identify the parties

involved, responsibilities, flows, bottlenecks, and losses, in order to apply, from this set of information, the use of the TOC tool called the Reasoning Process.

3.1 Theory of constraints reasoning process

The Reasoning Process relies on a logic of cause and effect to discover the real problem causing the restriction, and thus answer three questions: What to change? What to change to? How to change? To answer the three questions already formulated, the Reasoning Process uses five tools based on logical reasoning. These tools can be used together to solve a specific problem or individually, depending on what you are trying to solve. According to Goldratt (2007), the 5 tools of the Reasoning Process are the Current Reality Tree (CRT); Cloud Dispersion Diagram (CDD); Future Reality Tree (FRT); Prerequisite Tree (PT); Transition Tree (TT).

Noreen, Smith, Mackey (1996) summarize the application of this tool, which starts with a complete analysis with a List of Undesirable Effects that the preparer would like to see eliminated. The Current Reality Tree is used to identify one or more core problems that are apparently the cause of these Unwanted Effects. The immediate goal, or the first step toward a solution, is the opposite of the core problem. If the goal seems impossible, a Cloud Scatter Diagram is used to expose the underlying assumptions that make it seem unattainable. An injection is a change that, once implemented, will modify the environment in such a way that the assumptions in the Cloud lose their value. The Future Reality Tree is used to check if the injection will eliminate the original Unwanted Effects without creating more problems. The Prerequisite Tree is used to identify obstacles for implementing the injection. The Transition Tree is a detailed plan for overcoming these obstacles.

In this context, the application of the TOC reasoning process in the management level process of the centralized distribution of oncology drugs in the state of Rio Grande do Sul is presented, seeking to identify restrictions and identify possible solutions through the trees. One of the programs implemented by the SUS is the free availability of oncological drugs for centralized purchase by the Ministry of Health. In Rio Grande do Sul (RS), the flow of management, acquisition and availability of these drugs is complex, with low tracking power for operations and it involves several actors, such as the Ministry of Health of Brazil, the Secretary of Health of RS, hospitals, and patients. As it is a process that has more than one entity acting together, which requires effective communication between them, there is a concern to avoid the occurrence of some problems along this distribution chain, such as expiration of

medicines, failures in product requisitions and distributions, difficulty in purchasing and using the system, lack of supply forecast, repressed demands, lack of understanding of hospital needs, among others. Such problems in the supply chain can generate extremely negative impacts, as they directly affect people's lives, in addition to causing financial damage.

3.2 Management process, acquisition, and availability of oncological drugs for centralized purchase by the sus

Pharmaceutical Assistance is a set of actions that the SUS makes available to the Brazilian population (Brasil, 1990), including the distribution of oncological drugs. The SUS was structured to provide comprehensive and integrated treatment to cancer patients. Currently, the Oncology Care Network is formed by health establishments qualified as a High Complexity Oncology Care Unit (UNACON) or a High Complexity Oncology Care Center (CACON). In this context, the Ministry of Health and the Municipal and State Health Secretariats do not directly provide cancer drugs. The supply of these drugs occurs through their inclusion in the chemotherapy procedures registered in the SIA/SUS subsystem and must be offered by hospitals accredited in SUS and qualified in Oncology at Health Department of the State of Paraná (SES/PR, 2019).

Also, according to SES/PR (2019), the distribution process for these drugs is divided into two: one for decentralized drugs and another for centralized ones. The following items detail the processes of the two groups of drugs:

> a) Decentralized: it is the process of distributing a large volume of cancer drugs. In this case, hospitals accredited by the SUS and qualified in oncology, after entering the chemotherapy procedure in the SIA/SUS, are responsible for supplying the drugs necessary for the treatment of cancer. They standardize, acquire and prescribe prescriptions, observing the protocols and therapeutic guidelines of the Ministry of Health, when these exist. After that, they are reimbursed by the Ministry of Health according to the procedure code registered in APAC SIA/SUS. The respective Health Department (Municipal or State) is the one who transfers the resource received from the Ministry of Health to the hospital, according to the code of the procedure informed.
>
> b) Centralized: it is the exceptional purchase process of oncological drugs, which are part of: Imatinib Mesylate, Dasatinib, Nilotinib, L-Asparaginase, and Rituximab. In this case, the Ministry of Health carries out centralized purchase and distribution to the State

Health Departments, for subsequent submission to the CACONs and UNACONs, according to the demand and conditions required for each drug. For this group, the Ministry of Health does not reimburse amounts to the Health Secretariats. It purchases medicines and sends them to the requesting agencies.

The object of study of this work is exclusively the process at the managerial level of the distribution of centralized cancer drugs, based on what happens in the Health Department of the State of Rio Grande do Sul (SES/RS).

4 Results and discussion

4.1 Distribution process

The distribution of cancer drugs centralized in the Rio Grande do Sul was mapped based on official documents from the public bodies involved and interviews with employees of the Pharmaceutical Assistance Policy Coordination (CPAF) of SES/RS, who are directly part of the process. Three people were heard, namely: the pharmacist responsible for the sector; the assistant coordinator of CPAF; the assistant pharmacist.

The process starts with the CACONs and UNACONs, which register the treatments individually per patient in the SIA/SUS subsystem and request the drugs in the AME Programas system. After receiving the request at the AME, the SES/RS performs a previous check of the treatment and, if approved, forwards the request to the Ministry of Health. The Ministry, in turn, after receiving and approving the request from the SES/RS, of quarterly, it transfers the medicines to the State Secretariat's Warehouse. After receiving the goods, the warehouse sends the medicines to the CACONs and UNACON on a monthly basis, which are passed on to the patients.

4.2 Problems identified in the process

The distribution process of cancer drugs centralized in Rio Grande do Sul is somewhat complex, as it involves several actors: the patient, hospitals, the AME and SIA/SUS systems, the CPAF, the SES/RS oncologist, the warehouse and the Department of Pharmaceutical Assistance (DAF) of the Ministry of Health, with many interactions and data exchange between them, using more than one computer and physical tool for this purpose. The current flow allows communication failures and information mismatch, which can lead to problems, such as:

wrongly requesting medications and their loss, directly impacting the treatment of patients and, also, causing damage to the purse. In addition, there are sometimes delays in the delivery of cancer medications by the Ministry of Health.

There is no standardization in the way entities exchange information. Hospitals (CACON and UNACON) are in contact with the Ministry of Health using software, which is different from the one used for their contact with the SES/RS. The relationship between CPAF (SES/RS) and DAF (Ministry of Health) occurs via an Excel spreadsheet. On the other hand, DAF's contact with the SES/RS Warehouse is made exclusively by email or telephone.

During the entire process, the only time a communication tool receives any data from another tool is when the AME hospitals request medications when the APAC number is informed. However, there is no validation that identifies whether the number is actually valid. Therefore, bottlenecks occur in this context: the use of different tools for communication between those involved and the lack of a protocol for exchanging information between them.

As there is no protocol for the relationship between the entities, the appearance of divergent information can become common in this flow. In the case of high-cost cancer drugs, the consequences generated are extremely negative. Not treating a patient due to misplacement or non-request of medication is a serious failure that often occurs due to disorganization in the process and that directly impacts the treatment of the patient, whose health, in most cases, is already very fragile due to the severity of the disease. Furthermore, when this occurs, the Federal Government's financial expenditure also increases, resulting in a reduction in the possibility of investments in other areas of health.

4. 3 Application of the theory of constraints

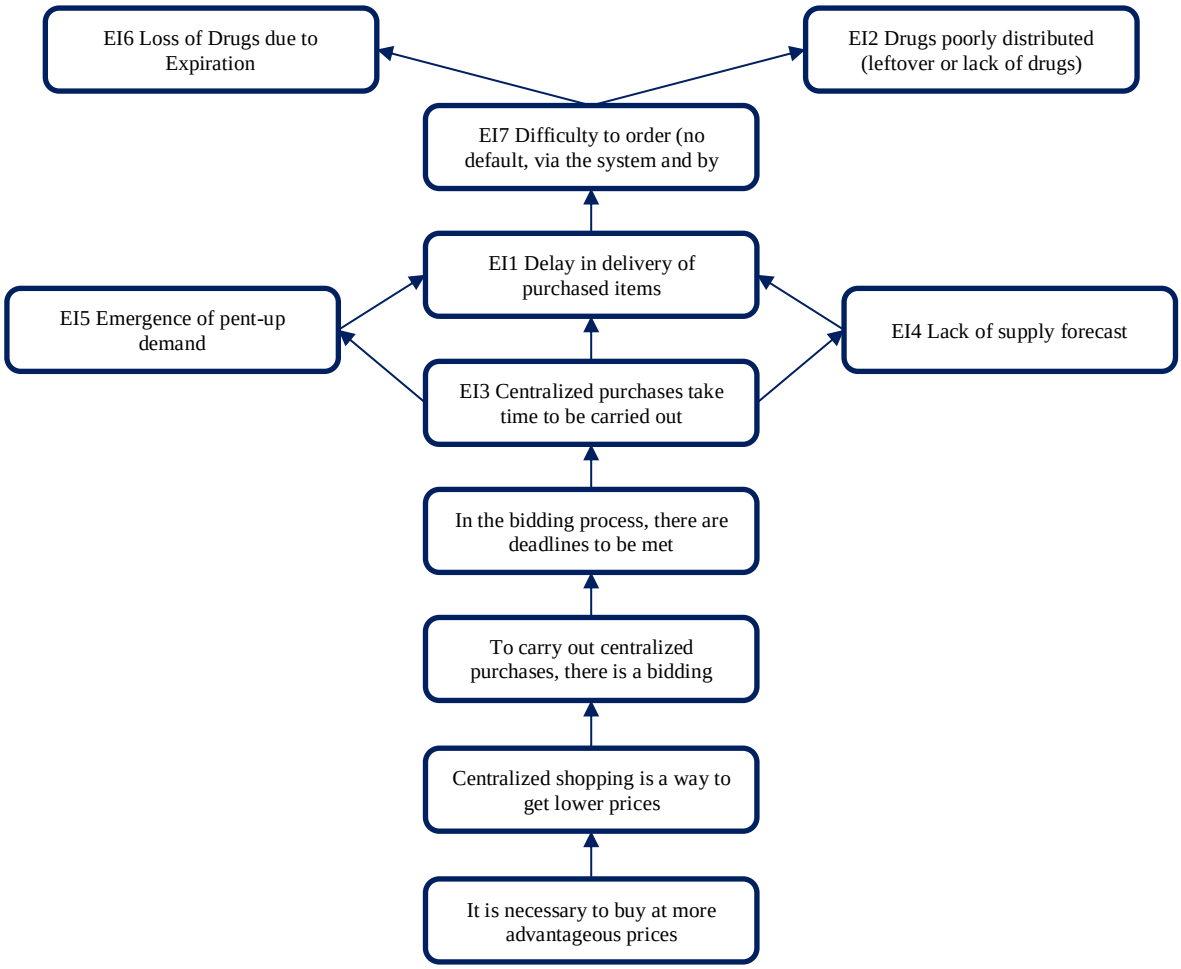
After identifying in the materials which problems were found in the supply chain, aimed at the centralized acquisition of cancer drugs in the state of Rio Grande do Sul, the following undesirable effects or restrictions were identified:

EI1: Delay in delivery of purchased items
EI2: Drugs poorly distributed (leftover or lack of drugs)
EI3: Centralized purchases take time to be carried out
EI4: Lack of supply forecast
EI5: Emergence of pent-up demand
EI6: Loss of Drugs due to Expiration
EI7: Difficulty to order (no default, via the system and by email)

By reading the CRT (figure 1), it can be understood that the root problem is around the centralized purchase terms of oncological drugs, triggering a series of undesirable effects in the supply chain. CRT answered the first of the three basic questions of the Reasoning Process: What to change? However, finding the root cause does not mean that the solution is simple, there must be a conflict that prevents a simple solution from being implemented. To find out which conflict prevents the implementation of a simple solution, we built the Cloud Scatter Diagram, which will help us to answer What to change?

Figure 1

Current Reality Tree Application



Source: Elaborated by the authors.

By reading the CDD (figure 2), some assumptions were identified: (1) By optimizing purchases, we reduced the resources needed for them; (2) By adjusting the stocks of medicines,

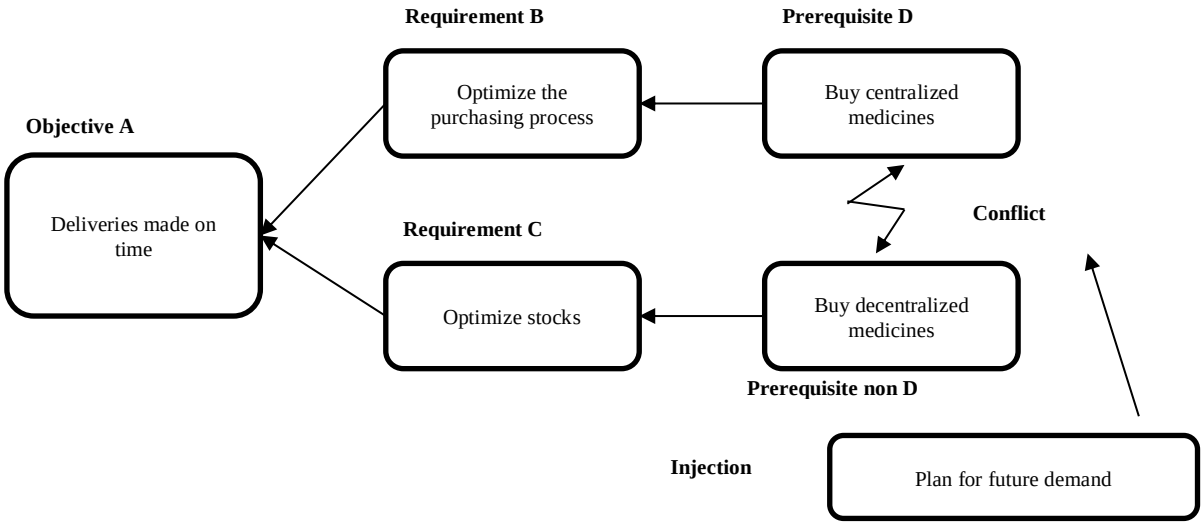
the probability of these medicines being lost is also reduced, reducing the expense with them; (3) With decentralized purchases, each hospital would buy only the medicine necessary for its needs; (4) When we carry out a centralized purchase, the quantities purchased are greater, making the price more advantageous.

Thus, the conflict that prevents a simple solution from being implemented to meet the goal of on-time drug delivery is between making centralized purchases or decentralized purchases. The solution found, based on the assumptions, was to carry out centralized purchases, but making some changes to minimize the restrictions of this process of centralized purchasing of oncology drugs.

For the implementation of these changes, four injections will be applied: Reduce the drug refill time; Carry out drug purchases with installment deliveries; Centralize drug requisitions in a single location; Plan the future demand for drug requisitions; To implement these changes, the Future Reality Tree (FRT) is used. Using the four injections presented, we turned unwanted effects into desirable effects (table 1). So, answering TOC's second question: What to change for?

Figure 2

Cloud dispersion diagram application



Source: Elaborated by the authors.

As for injections, the following analyzes were performed to reduce restrictions:

a) Reduce medication refill time: With the application of this injection, we understand that the time between two refills is reduced, thus eliminating the emergence of pent-up demand for medication (EI5), and the loss of medication due to expiration date (EI6).
b) Make drug purchases with deliveries in installments: With deliveries in installments, distributors of these oncological drugs will have more time to organize themselves and will be able to meet the scheduled delivery dates (EI3), another advantage is that hospitals and the State of Rio Grande do Sul will be able to receive the drugs with manufacturing dates closer to the delivery dates, thus increasing the shelf life and optimizing the stock, avoiding loss due to expiration (EI6).

Table 1

Undesirable effects vs. desirable effects

Undesirable Effects	Desirable Effects
1. Delay in deliveries of purchased items	1. Purchased items delivered on time
2. Misdistributed medicine (leftover or missing)	2. Well-distributed medicine
3. Centralized purchases take time	3. Centralized purchase deliveries made within the agreed deadline
4. Lack of supply forecast	4. There is a supply forecast
5. Emergence of pent-up demand	5. No pent-up demand
6. Loss of medicines due to expiration	6. There is no loss of medicines due to the expiration
7. Difficulty in purchasing (lack of standard, system	7. Standardized drug requisition system

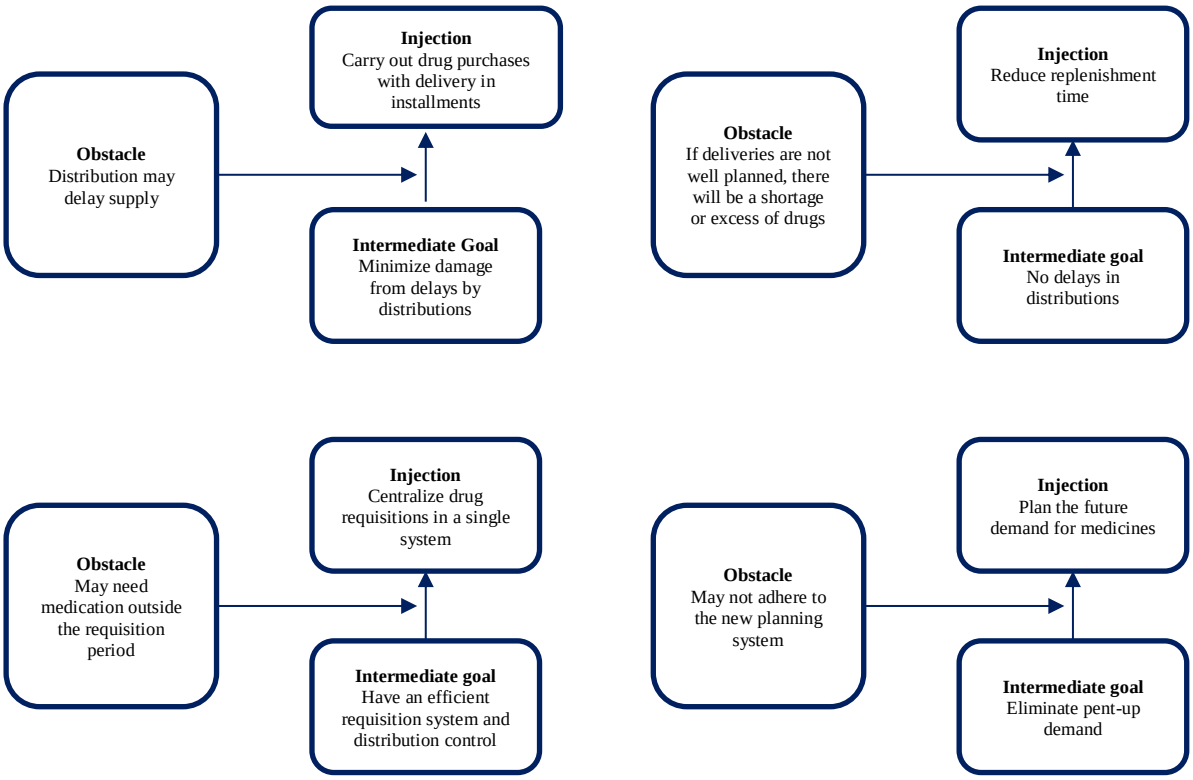
Source: Elaborated by the authors.

c) Centralize drug requisitions in a single location: With hospital requisitions centralized in a single system, the control of requisitions and the distribution process of these drugs becomes safer and more effective, solving the problem of difficult requisitions (EI7), of the bad distribution of medications (EI2), in addition to being able to also control the expiration dates, supplying the medication according to its validity, avoiding losses (EI6).
d) Plan the future demand for drug requisitions: Through efficient planning, there is more time for action to predict, negotiate and carry out centralized purchases, thus reducing the delay in deliveries (EI1) and consequently the supply of the purchased drug (EI4).

With the construction of the FRT, the Prerequisite Tree (PT) was Applied (figure 3) to identify the obstacles in relation to the application of injections and the intermediate objectives that must be met to eliminate such obstacles, answering TOC's third question: How to do to change?

Figure 3

Application of the Prerequisite Tree (PT)



Source: Elaborated by the authors.

After identifying the obstacles and intermediate objectives, the last tree of the TOC Reasoning Process, the Transition Tree (TT), was Applied (figure 4). As PT 3 presented an intermediate objective, already present in PT 1, only three Transition Trees are needed, since the action is suggested will be the same.

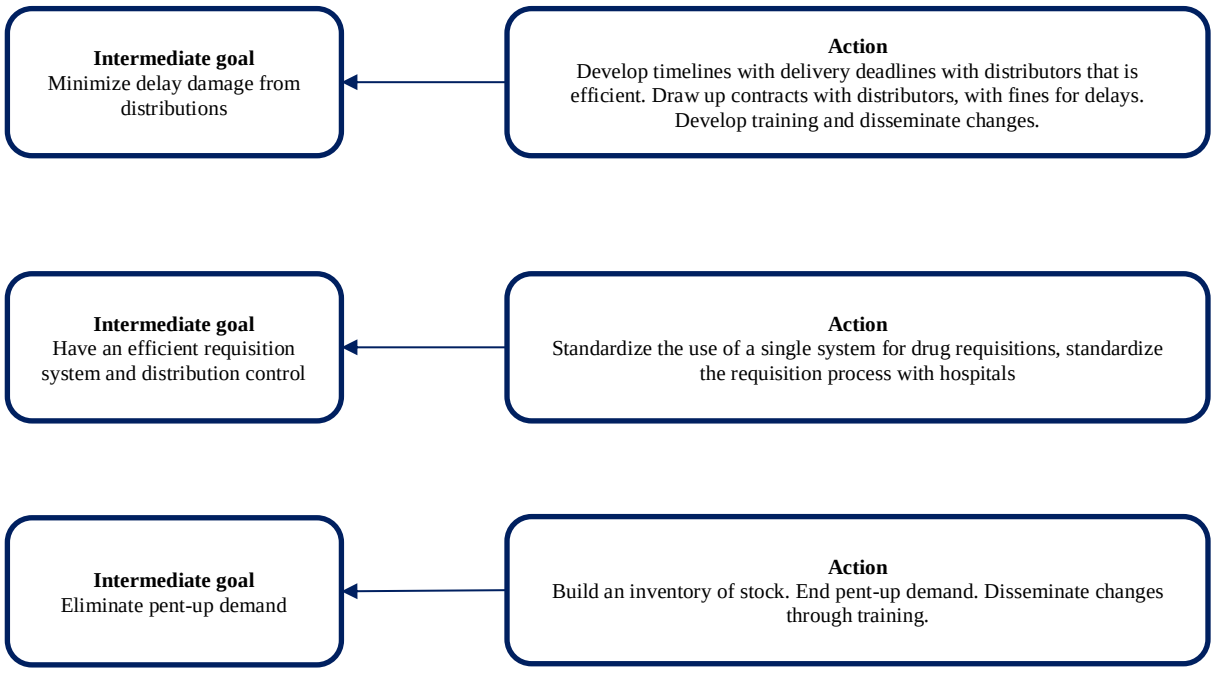
With the application of the Transition Tree and identified the actions, the study below presents the data analysis, identifying the TOC interface with Frugal Innovation.

Through the analysis of secondary documents, seven Undesirable Effects (UE) in the centralized procurement process of cancer drugs were listed. The EIs indicate that there are process problems, such as medication expiration, failures in requisitions and product

distribution, difficulty in purchasing and using the system, lack of supply forecast, repressed demands, not understanding the needs of hospitals, among others. With the application of the Current Reality Tree (CRT) it is understood that the root problem is around the centralized purchase terms of oncological drugs, triggering a series of undesirable effects in the supply chain, thus, it was necessary to apply the Dispersion Diagram to be able to identify the conflict that prevented an accessible solution. The conflict found was that at the same time that centralized purchases are carried out, decentralized purchases should also be carried out.

Figure 4

Application of the Transition Tree (TT)



Source: Elaborated by the authors.

For the problem situation under study, there is no way to reduce the legal deadlines foreseen for bidding processes, nor how to increase the available resources, as they depend on the Ministry of Health's budgets. Decentralizing medicine purchases would not be the solution, as each a hospital making its purchases can avoid a bidding process, but it won't get better prices unless it buys in large quantities, but this would aggravate the unwanted effects, as mentioned above.

In view of this scenario, the suggestion to resolve the conflict was to carry out centralized purchases, but making some changes to minimize the restrictions of this centralized purchase process for oncological drugs, together with the following four injections: Reduce the time for refilling drugs; Carry out drug purchases with installment deliveries; Centralize drug requisitions in a single location;

Plan future demand for drug requisitions. Requisitions for oncological drugs could be made in smaller orders and supplied in less time, in installment deliveries, however, there is a need to work on the trust link between the hospital and the distributor, drug requisitions need to be precise and the distributions of these take place within the agreed term.

From this perspective, by understanding that frugal innovation can be seen as a characteristic of a product or service, which is not only low-cost but also has a reduced consumption of resources, whether they are: financial, raw material, infrastructure and can be a feature of the process of using frugal innovation. Organizations need to adapt their processes and find a scalable and sustainable way to not only offer low-cost products or services but low resource consumption, high value-added human skills throughout the value chain. Thus, the low consumption of resources is also for consumers, functional, robust, easy to use, accessible, and local (Bhatti, 2012; Rao, 2018).

Afterward, these injections were tested by applying the Future Reality Tree (FRT) and none of them had negative branches. Then, using the Prerequisite Tree (PT), obstacles that may arise with the application of injections and the intermediate objectives were identified. Finally, the Transition Tree (TT) was applied, which showed what actions will be necessary to achieve the intermediate objectives.

Through the use of Logical Reasoning tools, it was possible to review undesirable situations such as rework, among many others, providing innovation with the recognition of the current situation and favoring the representation of the desired situation, formulating new and valuable opportunities through frugal innovation. In this object of study, there are identified restrictions, such as the budgetary condition of the Ministry of Health, which needs to acquire and make available demand for oncological medications that only grows year after year, either in volume or in financial resources used. As well as the process of distributing these high-cost medications wants a redesign with a view to guaranteeing the efficiency, quality, and care of SUS patients.

Grebel (2011) emphasized that healthcare services markets are highly intermediated by specialized knowledge that acts between providers and end-users that affect the evaluation criteria, both for novelty and usefulness. Technological solutions are often not adequate for the health needs of underdeveloped countries because they are focused on health problems that are not prevalent among their populations or because they understand solutions only under large investments of resources (Howitt et al., 2007; Albuquerque, 2012), in this case, an association with the problem of this research. The distance and intermediary mechanisms between end-users and innovation producers can affect the ability of innovations to solve a problem, as it does not meet the specific needs of users, as evidenced in the situations identified in the research.

Thus, the application of TOC becomes an ally in the search for “doing more with less” in the context studied. There are several bottlenecks that need to be eliminated for the process to reach the desired result, which would be no delay in delivering these medications to hospitals that treat cancer patients, nor losses that may occur due to loss or expiration date. Thus, there is an alignment with frugal

innovation, in terms of developing, producing and managing services that have resource constraints, avoiding unnecessary costs (Brem & Wolfram, 2014; Prabhu & Jain, 2015).

Faced with the challenges and taking into account the budget of government agencies at the national, regional, or local level in developing countries, frugal innovation can play a significant role in securing jobs, tackling poverty, and providing adequate public service delivery whether in urban or rural areas, taking into account issues of inclusion and sustainability (Leliveld & Knorringa, 2018).

In the health environment, particularly, the growth in expenses, such as the particularity of high value-added cancer drugs, is forcing global health systems to learn from more accessible models and technologies (Bhatti, et al., 2017), triggering a growing number of researches that should include frugal innovation in health, this being an alternative to conventional innovation (Bianchi et al., 2017).

With the application of TOC in the context of this study, the interface with frugal innovation can be established, in the sense that the analyzed process focuses on the client/patient and that the organization needs guidance to minimize the costs and time of the process, and it needs to establish cooperation mechanisms so that there is space for frugal innovations. Thus, the relationship with Prabhu's (2017) position is established when he says that frugal innovation is based on and extracted from the practical reality of companies and that it takes into account the role of various inputs: financial and human resources, as well as, material resources and time. Thus, adding value, always seeking to minimize the use of resources involved in the processes (Weyrauch et al., 2016).

5 Conclusions

This research aimed to identify whether the application of the Theory of Constraints (TOC) Reasoning Process (RP) mobilizes frugal innovation in the managerial process of centralized distribution of oncology drugs in the State of Rio Grande do Sul. TOC was shown to be closely associated with frugal innovation, identifying restrictions or undesirable effects in the process of centralized distribution of cancer drugs. This identification of undesirable effects allows the action to improve the process under the perspective of frugal innovation, seeking to resolve restrictions, without requiring high investments in resources, whether financial, material or human.

The study demonstrates a new perspective on using process improvement tools such as TOC to achieve frugal innovation. The association of the RP to promote frugal innovation has been shown to be satisfactory. This research contributed to the literature in the area of organizational theories and tools by investigating the association of TOC with the development of frugal innovations. Thus, the research also has its academic representation: first, this study uses TOC to explain the development of frugal innovation in a process in an empirical way.

And second, this investigation is groundbreaking in associating TOC with the development of frugal innovations.

At the managerial level, this study provides insights into the use of tools associated with the development of frugal innovation in processes and services of public bodies lacking resources and budget constraints, with a focus on strengthening efficiency, ensuring the quality and service of the Health Unic System – SUS.

As a limitation of this study, the fact that it is concentrating on the process at the managerial level of the centralized distribution of oncological drugs in the State of Rio Grande do Sul is considered: Theory of Constraints (TOC) Reasoning Process (PR) as a mobilizer of frugal innovation.

This study establishes an operational framework for the discussion and proposition of a future agenda on the use of tools that help organizational decision-making, particularly in the health context, including Lean philosophy, Theory of Constraints, design thinking, as drivers of the development of frugal innovations.

Authors' contributions

Contribution	Nodari, C.H.	Alves, K.T.	Lutz, L.	Froehlich, C.
Contextualization	X	X	X	X
Methodology	-	X	X	-
Software	-	-	-	-
Validation	X	-	-	X
Formal analysis	X	X	X	X
Investigation	X	X	-	-
Resources	X	X	-	-
Data curation	X	X	X	X
Original	X	X	-	-
Revision and editing	-	-	X	X
Viewing	X	X	X	X
Supervision	X	X	-	-
Project management	-	X	X	X
Obtaining funding	X	-	-	-

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