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Research Article

Management and governance structure of technology transfer megaprojects in emergency contexts: a case study of the megaproject Oxford/AstraZeneca/Fiocruz Covid-19 vaccine

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Abstract

Paper aims: We analyze in this study the management and governance structure of technology transfer in megaprojects under an emergency context.

Originality: We analyze an emergency health megaproject's management and governance structure. There is a dearth of studies that explore the management and governance structure of combination megaprojects in emergencies. We focus on analyzing the literature and the management and governance structure in the technology transfer, production, and supply of the Covid-19 vaccine. We then develop a reference model for building the management and governance structure of megaprojects in emergencies.

Research method: We conducted a case study in Bio-Manguinhos/Fiocruz. From the case study, we can analyze real situations that contribute to the development of theories. For this, we systematically reviewed the literature to identify how the megaproject management structure has been used. We interviewed stakeholders of the Oxford/AstraZeneca/Fiocruz vaccine megaproject against Covid-19 and triangulated these data by collecting corresponding documents.

Main findings: We conclude that the management and governance structure of the Oxford/AstraZeneca/Fiocruz vaccine technology transfer, production, and supply megaproject was appropriate. Since this structure should not be reproduced faithfully due to its specific characteristics, we developed a reference model for structure building in emergencies. This model can support institutions and governments in structuring management and governance in critical situations.

Implications for theory and practice: The knowledge obtained from this study will contribute to determining management and governance structures for future megaprojects, especially in emergencies.

Keywords

Vaccine. COVID-19. Megaprojects. Project management and governance.

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1. Introduction

Megaprojects are highly complex, high-cost execution undertakings that impact millions of people and involve the participation of multiple public and private stakeholders (Flyvbjerg, 2014, 2017; van Marrewijk et al., 2008; Zhai et al., 2009). Megaprojects have costs valued in billions or trillions of dollars, while large projects are measured in hundreds of millions and projects in millions or tens of millions (Flyvbjerg, 2014). Megaprojects are growing worldwide because of their significant impacts on social, economic, and environmental development. They involve coordinated capital applications, sophisticated technology, intense planning, and political influence (Gellert & Lynch, 2003).

In this sense, megaprojects are being conducted in situations relevant to human life, such as infrastructure, extraction, production, and consumption, or a combination of these (Gellert & Lynch, 2003). This is the case of technology transfer megaprojects in the area of health that combine the areas of infrastructure, production, and consumption. Technology transfer is the process in which an institution internalizes the specific procedures for producing a particular product (Hamidi et al., 2014; O'Sullivan et al., 2020; World Health Organization, 2011). From technology transfer, the receiving institution becomes independent in producing the product, which can guarantee access to public health (Friede et al., 2011; Hendriks, 2012; Miyaki et al., 2011). Technology transfer is considered an uncommon process in the lucrative pharmaceutical industry (Forman et al., 2021), but it is a promising approach to increasing affordable medications and vaccines production in developing countries (Friede et al., 2011; Hendriks, 2012; Miyaki et al., 2011). From this context, the technological transfer of a vaccine through a megaproject was defined as a viable alternative for Brazil to deal with the health emergency caused by the Covid-19 pandemic.

Early in the Covid-19 pandemic, it was identified that a vaccine against this disease was the most effective way to prevent it (Fundação Oswaldo Cruz, 2022; Funk et al., 2020; Medeiros et al., 2022). In directing efforts to make a vaccine viable, its development history raised concern, since it had a long (Lurie et al., 2020; Plotkin et al., 2018; Velho et al., 2017; World Health Organization, 2013; Fialho et al., 2023). In this sense, researchers and international health institutions have started a race for a vaccine against COVID-19 (Funk et al., 2020). In addition to development, production had to be scaled up to make vaccination affordable for everyone, especially for developing countries (Forman et al., 2021). Once a vaccine is successful, the manufacturers would be under extreme pressure, and technology transfer to developing countries would need to occur as quickly as possible (O'Sullivan et al., 2020).

In the Brazilian context, the Oswaldo Cruz Foundation (Fiocruz), through the Institute of Technology in Immunobiologicals of Fiocruz (Bio-Manguinhos), in partnership with the Brazilian Ministry of Health and other state agencies, has employed efforts to combat the pandemic in the country. Bio-Manguinhos/Fiocruz sought to initiate the development of vaccines, in addition to prospecting the technologies under development for vaccines, to expedite the availability of a solution to the population. The Ministry of Health, supported by studies and the experience of Bio-Manguinhos/Fiocruz, opted for the complete internalization of the vaccine production technology developed by Oxford and produced by the pharmaceutical company AstraZeneca (Instituto de Tecnologia em Imunobiológicos, 2020a; Medeiros et al., 2022).

Technology transfer typically lasts an average of 5 years, as it occurs after full development and registration of the vaccine in the country receiving the technology (Barbosa et al., 2014; World Health Organization, 2011). However, due to the urgency of the existing epidemiological scenario, the technology transfer process began before the results of clinical trials on efficacy and safety and, consequently, the registration of the vaccine, which was, until then, a condition for the initiation of technology transfer. In this context, the Megaproject of Technology Transfer, Production, and Supply of the Oxford/AstraZeneca/Fiocruz Vaccine originated.

A historical analysis of other recent pandemics was conducted to support the conduction of this technology transfer process in pandemic situations. For example, Abelin et al. (2011) and Miyaki et al. (2011) developed studies on conducting Technology Transfer during the H1N1 influenza pandemic. Abelin et al. (2011) conducted global research, which indicated that the annual demand for the H1N1 vaccine was estimated at 4.9 billion doses. Moreover, they warned that greater transparency about the roles of the stakeholders involved in upcoming pandemics could prevent misunderstandings in collaboration. Miyaki et al. (2011) conducted a Technology Transfer study for the Butantan Institute in Brazil, showing that the demand at the time was for 25 million doses of the vaccine for at-risk populations.

In comparative terms, for example, the first contract of the Oxford/AstraZeneca/Fiocruz vaccine technology transfer megaproject demanded 100 million doses of the COVID-19 vaccine (Instituto de Tecnologia em Imunobiológicos, 2020b). This shows that, at first moment, the demand for vaccines during the pandemic of COVID-19 was four times higher than the estimated demand for the last pandemic faced in Brazil. The research

of Abelin et al. (2011) and Miyaki et al. (2011) does not show how the management of the technology transfer process was structured. Thus, although the response to the last pandemic was fast, these studies did not try to provide sufficient contributions to support a technology transfer management structure in emergencies.

Considering the number of resources tied up and the effects of these megaprojects, successful implementation is important for society. However, there are more failures than successes in megaprojects (Flyvbjerg, 2014; van Marrewijk et al., 2008). The literature points out that for every ten megaprojects, only one meets all three success qualifiers: budget, schedule, and desired benefits (Flyvbjerg, 2014). In general, performance problems are caused by misaligned or underdeveloped management and governance mechanisms (Flyvbjerg, 2014; Sanderson, 2012). Thus, proper management and governance increase the likelihood of a megaproject's success. Sanderson (2012) argues that megaproject governance and management can be designed and adjusted as needed, which favors the interaction of project actors and the achievement of expected results. The organizational structure of management and governance of a megaproject is a suitable way for this projection. However, there is a need for more studies that evaluate the organizational structure and the management of megaprojects in emergencies. Thus, it becomes relevant to understand which aspects should be considered in the management and governance of megaprojects in the transfer of vaccine technology in emergencies. In this sense, we intend to answer the following research question: "How should the structure of management and governance of megaprojects in emergency contexts be built?".

This paper aims to identify the management and governance structure of technology transfer in megaprojects under an emergency context. For this, we analyzed the Oxford/AstraZeneca/Fiocruz vaccine technology transfer, production, and supply megaproject. We characterized the responsibilities of each part of the structure to serve as a reference in future pandemic situations. To achieve the research objective, we conducted a unique case study at Bio-Manguinhos/Fiocruz through interviews with stakeholders who worked directly on the vaccine megaproject and document analysis. Thus, we identified the management and governance structure and the main responsibilities of the parts of the structure. Moreover, important considerations on the replicability of this structure were identified.

We organized this article into seven parts. Besides the introduction, in the second part, we address the theoretical background necessary to understand the research. In the third, we present the methodological procedures used. In the fourth part, we present the case results, and in the fifth section, the study results. We present the discussion of the results in the sixth part. Finally, in the last section, we explain the conclusions of this study.

2. Theoretical background

2.1. Management and governance of megaprojects

The organizational structure of management and governance of a megaproject is a suitable way for this projection of megaprojects since the definition of such structures favors the iteration of megaproject actors and the achievement of the expected results (Sanderson, 2012). Governance structure can effectively resolve megaproject management constraints by clarifying responsibilities and benefits among stakeholders.

Li et al. (2019) indicate that project governance manages and controls a project's development from inception to completion. It focuses on the planning, execution, monitoring, and control of projects, intending to ensure that their development is achieved within the specified budget, timeframe, and quality. Feger & Thomas (2012) indicate that project management structures should cover the decision-making process, responsibilities, and authority of those involved. This structure should include the standards, policies, and procedures for managing, monitoring, and evaluating projects. Thus, organizations must develop a megaproject management and governance structure to achieve the success of their megaprojects.

Table 1 presents the synthesis of studies that explore aspects related to the structure of management and governance of megaprojects and the practices of megaprojects in emergencies.

While studies highlight the importance of the management structure and consolidated governance to support and direct the achievement of megaproject objectives, there is a dearth of studies that evaluate both structures in emergency situations. Furthermore, most studies do not focus solely on the management or governance structure which limits their analysis.

3. Methodological procedures

We conducted this study through a case study, which is an appropriate method for fields of knowledge that are little explored and require in-depth knowledge (Dubé & Paré, 2003; Souza et al., 2018; Piran et al., 2021). These

Table 1. Literature overview.

Authors and year	Study focus	Summary of the main contributions
Zhai et al. (2009)	Value of megaproject management	The study addresses the value of megaproject management in a construction agent company. It is highlighted that the project management structure provides adequate resources to managers ensuring that the megaproject is implemented as expected. Although Zhai et al. (2009) reinforce the importance of the management structure in the value of the megaproject, the study presents only the areas that hierarchically make up the structure, and the responsibilities of each area in the operation of the structure are not deepened.
Eweje et al. (2012)	The influence of information for decision making by the project manager to increase the strategic value of the megaproject	The authors conclude that the project manager's ability to access relevant information in a timely manner is critical to the success of a megaproject. Additionally, they identify a strong link between information management and the quality of decisions made in the megaproject. This article addresses how information flows are important for megaproject managers' decision making, especially for value creation.
Kardes et al. (2013)	Approach to managing global megaprojects, focusing on complexity and risk management	The authors evaluate the management of the risks and complexity of megaprojects. Kardes et al. (2013) highlighted the importance of having a holistic and integrated approach to megaproject management, considering factors such as decision making, communication, and collaboration. To support managers' decision-making for the success of megaprojects, the authors propose an integrated framework for risk management in megaprojects.
van Marrewijk & Smits (2016)	Analyzes the role of cultural practices in the governance of the Panama Canal expansion megaproject	The study discusses how culture influences megaproject governance and decision-making processes. The authors present the governance structure adopted in the Panama Canal Expansion megaproject and the impacts of the country's culture on its conduct. The authors argue that the success of the megaproject depends on a governance approach that considers existing cultural practices and adapts to local needs. The text also addresses the issue of social responsibility and how cultural practices can help ensure stakeholders benefit from the project. In addition, the authors explore various aspects of the influence of governance on project management. These include the role of leadership, the decision-making process, communication and discussion among the partners involved, collaboration, project management, people management, and organizational culture.
Li et al. (2019)	Governance model in megaprojects	Li et al. (2019) propose a governance model for construction megaprojects. The model is divided into three criteria: (i) governance structure, (ii) governance mechanism, and (iii) external governance environment. The core objective of the conceptual governance model is to improve the efficiency of megaproject management by using the project governance structure as a framework through the project governance mechanism and in the external mechanism of the project governance environment. Li et al. (2019) use the Nanning Transport Hub in China as an example. Li et al. (2019) point out that the governance structure coordinates and tracks the organizational structure, the role of stakeholders, manages the supply chain and financing of the megaproject and its goals.
Brunet & Forgues (2019)	Explores how governance can be used to promote the success of a specific megaproject	The governance structure used in constructing the Quebec amphitheater presented in the study by Brunet & Forgues (2019) combines the functions of the megaproject governance and management structure. In this case, the government performs the megaproject's governance, while the constructor manager performs the management.
Wang et al. (2021)	Analysis of how the Covid-19 outbreak affected organizational citizenship behavior in emergency construction megaprojects	The study examined two emergency hospital megaprojects in Wuhan, China, and found that these projects were successfully completed thanks to the organizational citizenship behavior of all involved. The study found that new work practices and management processes were developed to promote cooperation between stakeholders and ensure that the projects were completed successfully. The results also indicate that teamwork, resource sharing, and ongoing communication were critical to the success of the projects. The authors concluded that the key success factors of emergency construction megaprojects are organizational citizenship behavior, teamwork, resource sharing, and ongoing communication.

characteristics align with this study's objective and the case study conducted. The Megaproject of Technology Transfer, Production, and Supply of the Oxford Vaccine/AstraZeneca/Fiocruz has unique characteristics because, unlike other technology transfer processes, it was executed in less than two years, while the normal period is an average of 5 years, with high complexity due to a critical epidemiological situation and the technology transfer of a vaccine still under development.

We conducted the case study in six phases, as oriented by Miguel (2007), which were divided into ten stages. The phases and stages of conduct are presented in Figure 1.

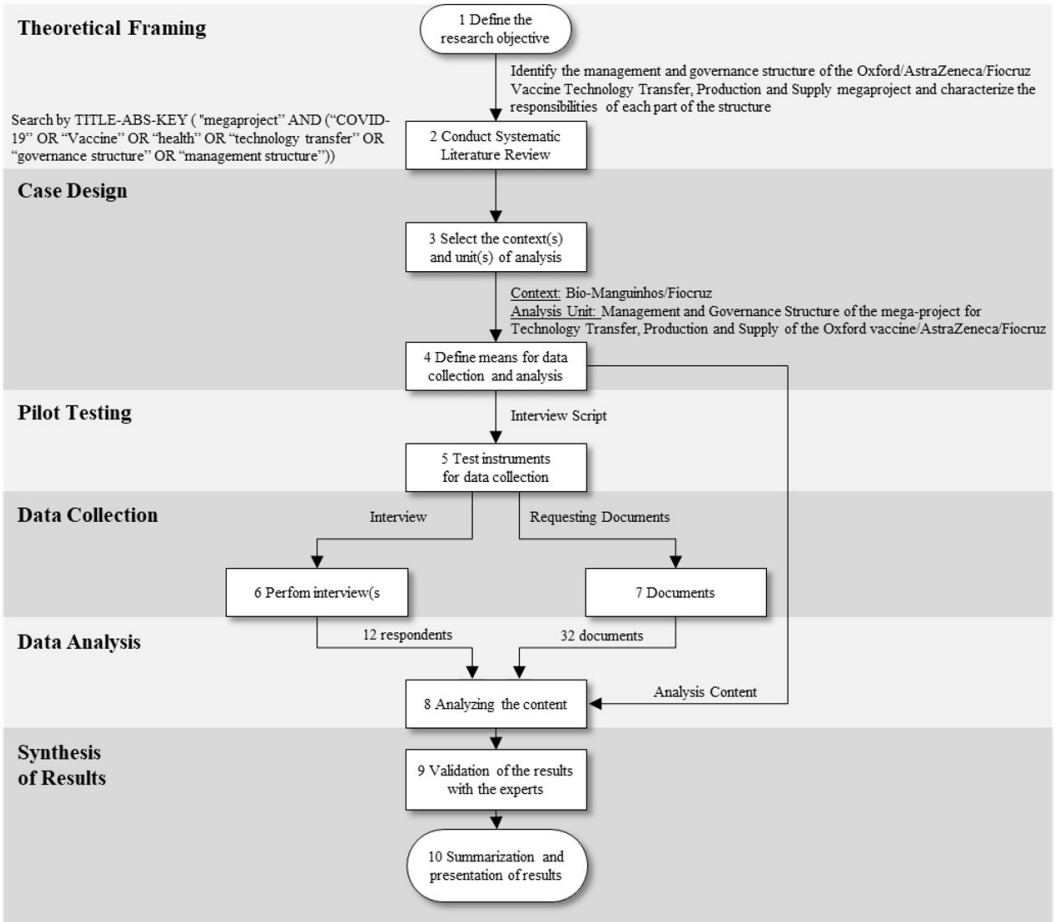

Figure 1. Methodological procedures.
Source: prepared by the authors based on Miguel (2007).

Next, we conducted a Systematic Literature Review according to the procedures indicated by Ermel et al. (2021). In the search process, we performed the searches in the Scopus and Web of Science databases. We chose to search in the titles, keywords, and abstracts the terms that related megaprojects to health situations, Covid-19 (for being related to our case study), or management and governance structure. We initially used the search strings with Boolean operators "and" between the terms of health and management structure and governance, so we chose to use Boolean operators "OR" between these terms. We initially found 44 articles and selected only 7 for meeting any of our inclusion criteria: (i) to address megaprojects in the health area or emergencies; (ii) to present the management and governance structure of a megaproject; (iii) to present information directed to organizational management and information flow in megaproject structures; and (iv) studies that presented concepts on the division of responsibilities in megaprojects. The Systematic Literature Review provided relevant insights for the understanding of the case. These insights were presented in section 2.1 to support the study's understanding. In addition, the results of the analysis of the articles were used as a basis for the contributions of this study.

In the second phase, we selected the unit of analysis and context and defined the data collection and analysis. Regarding the context unit, Bio-Manguinhos/Fiocruz was chosen for four reasons: (i) the institution's experience in technology transfer processes since 1976 (Barbosa et al., 2014); (ii) being the largest producer of vaccines in Latin America (Furlaneto, 2020); (iii) Fiocruz being in 35th place in the ranking of vaccine patents in the world and first place in Brazil (Gadelha et al., 2020); and (iv) Fiocruz and Instituto Butantan being the main Brazilian institutions that provide vaccines to the National Immunization Program (PNI) (Gadelha et al., 2020). Bio-Manguinhos is the Fiocruz unit responsible for producing vaccines, diagnostic tests, and biopharmaceuticals for the Brazilian National Health System and other countries. Bio-Manguinhos/Fiocruz has experience in pharmaceutical and biological product technology transfer. Over the years, Bio-Manguinhos/Fiocruz has instituted

a technology transfer process carried out in three phases, according to Barbosa et al. (2014). The first phase involves signing the technology transfer contract and receipt of the product dossier registered at the National Health Surveillance Agency (ANVISA), Brazil's regulatory agency. The quality control tests are incorporated and validated, and the product is registered as a product of the institution. In the second phase, the product is received, processed, and only labeled and packaged at Bio-Manguinhos/Fiocruz. Subsequently, in the third phase, the vaccine processing is absorbed, which includes formulation, packaging, lyophilization, and active pharmaceutical ingredient (API). In general, these processes are conducted after the vaccine is fully developed and the results of clinical trials. However, due to the urgency of the Covid-19 pandemic scenario, this process had to be carried out simultaneously, increasing the complexity of the mega project of technology transfer from the vaccine developed by Oxford and marketed by the pharmaceutical company AstraZeneca to Bio-Manguinhos/Fiocruz. In this sense, the unit of analysis was determined as the "Management and governance structure of the Oxford/AstraZeneca/Fiocruz megaproject for technology transfer, production, and supply of the vaccine" due to the importance of understanding this structure for future pandemic situations.

In step 4, we defined that data would be collected using interviews with professionals involved in the megaproject and documents indicated by these professionals. We tested the interview script and validated it in stage 5. We conducted two preliminary interviews to assess whether the questions met all study aspects. The final script was composed of 5 semi-structured open questions with the intention of these people portraying the functioning of the management and governance structure of the megaproject studied. In step 6, we conducted 12 interviews, and in step 7, we received 32 documents indicated by the interviewees. The people interviewed were determined according to their involvement in the megaproject, including the manager in charge, people responsible for specific areas, senior management, and stakeholders. The interviews were conducted until we reached information saturation, a situation in which less new information became relevant with each interview. Subsequently, in the next step, we conducted a Content Analysis of the interviews and the documents. This analysis is used to understand and identify communications' objective and systematic characteristics (Bardin, 2012). We coded the interviews and the documents in the Atlas.ti software, then we understood and identified the megaproject's management and governance structure, the participants, the responsibilities and different relationships. In step 9, the impressions of the case were validated with the critical people involved in the megaproject. In the last stage, we synthesize and present the results of the case study and compare them with the literature, in which it was possible to propose a model that considers relevant aspects of megaproject management and governance.

4. Case study results

In 2004, Bio-Manguinhos/Fiocruz created the Institution's Project Office, which developed a set of methods, techniques, and tools to support project management, governance, and portfolio management. The Institute's project portfolio is organized into four portfolios: (i) technology transfer; (ii) product/service and technological development; (iii) infrastructure; and (iv) institutional development. Initially, the vaccine megaproject was considered a conventional technology transfer project to be managed by the Technological Coordination (COTEC) of Bio-Manguinhos/Fiocruz, just like the other projects of the same nature, being executed according to the existing structures in the Institution for this type of project. However, due to its specific characteristics, the vaccine megaproject required a specific management and governance structure that required adaptations about those used by Bio-Manguinhos/Fiocruz. To support the methodological adjustments and the follow-up of the megaproject deliveries, a consulting firm was hired. This new management and governance structure became necessary due to the urgency of the technology transfer of a vaccine still under development, in which Bio-Manguinhos/Fiocruz participated in parallel activities such as clinical trials, regulatory registrations, and production dimensioning. Internally, this megaproject management and governance structure was considered a specific program for technology transfer, production, and delivery of the Covid-19 vaccine. This was critical to the success of the megaproject.

In the new management structure, a structure composed of towers was defined, representing the macro areas of the megaproject's management. The term towers was used at Bio-Manguinhos to differentiate the megaproject areas. Six towers were defined according to their specific activities, being: (1) technology partnership management; (2) integrated management; (3) administrative management; (4) infrastructure management; (5) technology transfer management; and (6) regulatory compliance.

These towers were managed by the general coordinator of the project as subprojects, which have responsible (tower managers), that is, in the logic of a program, in which all subprojects are aligned to the same final goal of the megaproject. For the megaproject to succeed, all towers must succeed. For this reason, due to the scale and complexity of some towers, they were divided into specific work fronts, for which leaders were defined. The towers of the vaccine megaproject and their respective work fronts are presented in the project's organizational structure (Figure 2).

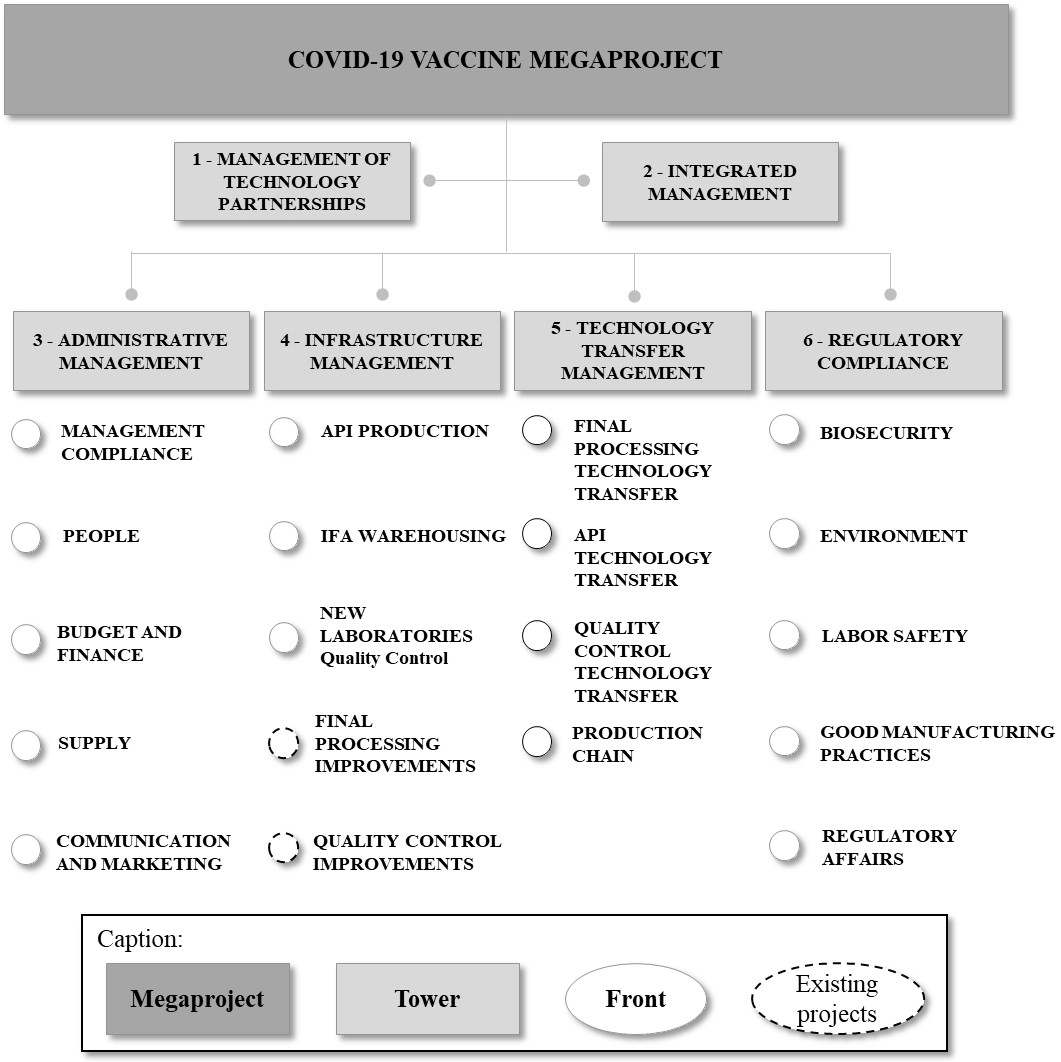

Figure 2. Organizational structure of the project.
Source: Bio-Manguinhos/Fiocruz.

4.1. Megaproject towers

Tower (1) integrated management is the tower responsible for the coordination, integration, and monitoring of the project, besides the methodological support in alignment with the Project Office and the hired consultancy. Among the main responsibilities of this tower is the systemic view of all the fronts and towers of the project, both in scope and in execution time, considering the need for integration of actions to achieve the megaproject's objectives. To do so, it monitored the main indicators of execution of the megaproject.

The tower (2) management of technological partnerships deals specifically with the negotiations, legal instruments, and management of the partnership between Bio-Manguinhos/Fiocruz and AstraZeneca. It involves the search for a contracting model to internalize the technology in Brazil since there was no developed and registered vaccine, which made it unfeasible to sign a transfer contract traditionally. This tower was responsible for enabling the Technological Ordering Contract (ETEC), supported by Law 12.527/2011 and Decree 7.724/12, even before the clinical trials of the vaccine and its registration in Brazil were completed.

Tower (3) administrative management coordinates all the resources to internalize the technology, produce and supply the COVID-19 vaccine. This tower is divided into 5 fronts, which are compliance, people, budget and finance,

supply, and communication and marketing. The compliance front concerns the guarantee of the legal aspects and institutional norms in the administrative processes, in this way, it is characterized as legal support and internal control of the project. The people front is responsible for providing the workforce and analyzing the staff needed for the megaproject's execution, including personnel movement, hiring, and training of new collaborators. The budget and finance front aims to follow up the use of public and private budgets (donations) destined for the megaproject. Issues related to the supply chain and vaccine supply concern the supply front, which carries out the strategy of purchasing inputs and equipment, as well as contracting services for the megaproject. The communication and marketing front is responsible for supporting the formulation of the communication strategy of the megaproject in alignment with the institutional communication of Fiocruz for the various target audiences involved.

In tower (4) infrastructure management, new areas are built, and physical adaptations are analyzed and implemented to enable the internalization of technology in existing areas that are part of the vaccine production and delibery chain. This tower was divided into 5 fronts: API Production, API Storage, New Quality Control Laboratories, Final Processing Improvements, and Quality Control Improvements. The API Production front was responsible for the necessary layout and facilities adaptations in existing areas of the Henrique Pena Center (CHP), originally built for the production of biopharmaceuticals, to enable the production of the vaccine API. The activity of adapting an existing environment at Bio-Manguinhos/Fiocruz for the storage of API imported and produced at the Institution was assigned to the API Storage front. The New Quality Control Laboratories front was responsible for the construction of a new physical-chemical laboratory to guarantee the expansion of the existing laboratory's facilities, enabling the internalization of the analytical methodologies needed for the entry of the COVID-19 vaccine into the Bio-Manguinhos/Fiocruz product portfolio. In addition, the Final Processing Improvements and Quality Control Improvements fronts were projects in the Bio-Manguinhos/Fiocruz portfolio before the COVID-19 vaccine megaproject. In this way, they were matrix integrated into the project, ensuring the interfaces with the other fronts of this tower to make the necessary adaptations to the existing final processing and quality control areas.

The (5) Technology Transfer tower is responsible for incorporating the knowledge, skills, technologies, processes, and quality control involved in the production and delivery of the Oxford/AstraZeneca/Fiocruz vaccine. This tower is divided into four technology transfer fronts, focused on the transfer of API production processes, final processing, vaccine quality control, and a front with responsibility for implementing the entire production chain specific to the vaccine at Bio-Manguinhos/Fiocruz.

In tower (6) Regulatory Compliance, the activities are focused on the legal and regulatory requirements for the execution of the project, in the context of the production of highly controlled biologicals. This tower was also split into fronts to ensure the compliance of processes about biosafety requirements, environment, occupational safety, good manufacturing practices, and regulatory issues, in addition to the strategy and registration of the product with ANVISA.

This management structure allowed the achievement of the main goal of the megaproject studied: the availability of a vaccine against COVID-19 produced in Brazil for the NIP in compliance with the National Operationalization Plan for the COVID-19 Vaccine (Brasil, 2020). For the structure to work in a goal-oriented way, each tower and front generated specific results for the whole, the main results are described in Table 2.

Table 2. Main deliveries by towers and fronts.

Technology Partnership Management	Integrated Management
· Memorandum of Understanding with AstraZeneca for the preliminary formalization of the ETEC	· Design of the project's management and governance method
· Technological Order Contract (ETEC)	· Design of the integrated vision of the towers, fronts, and project deadlines
· Additive term of the ETEC contract	· Permanent alignment of the towers and project fronts
· Technology Transfer Contract (CTT)	· (Re) Planning of milestones
· Additive Term of the CTT	· Creation and monitoring of project indicators
	· Monitoring and mitigation of risks to the achievement of the project's objective

TT FP: final processing technology transfer; TT API: API technology transfer; TT QC: quality control technology transfer; ERP: enterprise resource planning.
Source: prepared by the authors, based on Bio-Manguinhos/Fiocruz.

Table 2. Continued...

Administrative Management				Infrastructure Management		
People	Finance and Budget	Supply	Communication and Marketing	API CHP	API Warehouse	New Laboratories Quality Control
· Identification of qualitative and quantitative workforce needs for technology transfer, production, and delivery of the COVID-19 vaccine	· Planning and budgetary and financial execution of the budget received through extraordinary credits, in Provisional Measures	· Identification of the needs for the acquisition of inputs, services, equipment, works, and engineering services, among others, to support the technology transfer process, and production and supply of the vaccine against COVID-19Definition of supply strategies	· Development of the marketing plan for the vaccine against COVID-19	· Adequacy of an API production area of approximately 1200 m2	· Area, with 400 m2, 32 freezers for API storage, and 8 cryobanks (cell bank storage equipment)	· New Physical-Chemical Laboratory: the building has approximately 1,450 m2 of constructed area, with two functional floors and a technical floor. It includes civil works, utility installation, including special gases, air conditioning systems, furniture, and some equipment belonging to the facilities (exhaustion hoods and autoclave for example).
· Workforce prospection plan	· Planning, execution, and monitoring of the resources coming from donors	· Description of procurement and service contracting items	· Development and updating of the communication plan with actions related to the fight against the pandemic, including a definition of a target audience, media, and instruments, among others	· Mechanical and automation systems adaptation of 16 air handling units, balancing and certification of approximately 1900 m2 of classified areas for API production	· Monitoring system for API storage equipment and cell banks;	
· The hiring of new and/or moving employees	· Elaboration of the project's Economic and Financial Feasibility Study	· Alignment of critical materials arrival expectations to the overall project schedule	· FAQ development	· Installation and qualification of about 75 new process equipment for API production;		
· Familiarization process for new employees		· Alignment with various stakeholders to ensure critical logistics operations (e.g. Importation of API)	· Publications in Social Networks			
· Operational Technical Training Program			· Creation of editorials for better understanding of the public			
· Internal communication plans for employees			· Creation of visual identity for vaccine communications			
· Monitoring Panel for costs and investments in personnel related to the transfer of technology, and production and supply of the vaccine against COVID-19.			· Elaboration of press releases;			
			· Media training for spokespeople			

TT FP: final processing technology transfer; TT API: API technology transfer; TT QC: quality control technology transfer; ERP: enterprise resource planning.
Source: prepared by the authors, based on Bio-Manguinhos/Fiocruz.

Table 2. Continued...

Technology Transfer				Regulatory Compliance
TT FP	TT API	TT QC	Production Chain	
· Creation of the functional logic and operationalization of the API storage area	· Elaboration of Process and Validation Documents for API production and quality control	· Elaboration of procedures and analytical reports and validation protocols	· Incorporation of production and quality control processes into the routine	· Vaccine Pre-registration
· Receipt of the first shipment of API	· Receipt of cell bank for thawing test	· Performance of assays for training and viability of methods	· Definition and sequencing of the production chain activities	· Authorization for Emergency Use of the vaccine and the
· Production of the first batches of the Covid-19 vaccine	· Receipt of cell and virus banks sufficient for the production of 10 batches of API	· Performance of tests for analytical validation and preparation of reports	· Definition of the production master data (e.g., material tree) and registration in the ERP	· Definitive vaccine registration
· First delivery to the Ministry of Health of the batches produced with imported API	· Preparation of the first batch of culture medium	· Internalization of the tests for the liberation of inputs, raw materials, and imported API received		· CTO (Technical Operational Certificate) of the national API production area
· Delivery of over 155.1 million doses of the vaccine by 02/04/2022.	· Conducting the first thawing test	· Internalization of in-process control tests of final processing		· Guarantee of good practices, Biosafety, Occupational Safety, and environmental conditions in the facilities and the production process, quality control of the vaccine against COVID-19
	· Production of pre-validation batches	· Internalization of the tests for releasing lots of national API		
	· Production of validation batches	· Internalization and/or contracting of in-process control tests of API production		
	· Preparation of regulatory documentation			
	· Delivery of final product doses produced with national API.			

TT FP: final processing technology transfer; TT API: API technology transfer; TT QC: quality control technology transfer; ERP: enterprise resource planning.
Source: prepared by the authors, based on Bio-Manguinhos/Fiocruz.

4.2. Megaproject committees

In addition to the megaproject's management structure, four internal committees were developed to complement and monitor the megaproject's execution, results, deadlines, and critical points, including advisory and decision-making committees. The composition and functioning logic of these committees, associated with the decision flow that they subsidize, supported the governance structure of the megaproject, internally at Bio-Manguinhos/Fiocruz. The committees were structured as: (i) strategic; (ii) management; (iii) operational; (iv) advisory.

The strategic committee's attribution is to monitor the project, such as, for example, the risks to the schedule. This committee is responsible for making strategic decisions for the project and acting together with the technological partner and other external actors (e.g., the Ministry of Health) in the conduction of critical issues of the projects. The management committees (People; Procurement and Finance; and Infrastructure and Regulatory) involve, besides the project's team, the Deputy Directors most affected by each theme. In this way, from the monitoring of the project's progress, risks, problems, and decision points are identified, allowing a quick response to issues that impact the project. The operational committees, in turn, were responsible for monitoring the demands and specific actions of the project, together with the functional areas of the Institute, making technical and operational decisions. Moreover, defining and following up the detailed execution schedules, registering the deliveries, and evaluating their quality. Two advisory committees were created throughout the project. First, the Communication and Marketing Committee, composed of members of the Board of Directors of Bio-Manguinhos, the coordination of the megaproject, the Administrative Tower, the Communication and Marketing front, the Communication Advisory Board of Bio-Manguinhos, the Clinical Advisory Board, the Market

Relations Department, and other actors summoned according to demand, which was implemented to discuss and propose communication strategies for the megaproject and following up critical issues that could impact them. The other advisory committee was composed of the project coordination, the TT tower, and COTEC to outline the strategy and define artifacts of technology transfer to determine how to carry out the such process.

The strategic, management and operational committees were developed to promote greater agility in the decision-making flow of the project and monitoring of the management structure. While the advisory committees were developed to support specific themes, whose needs emerged during the project. The responsibilities and participants of each committee are presented in Figure 3.

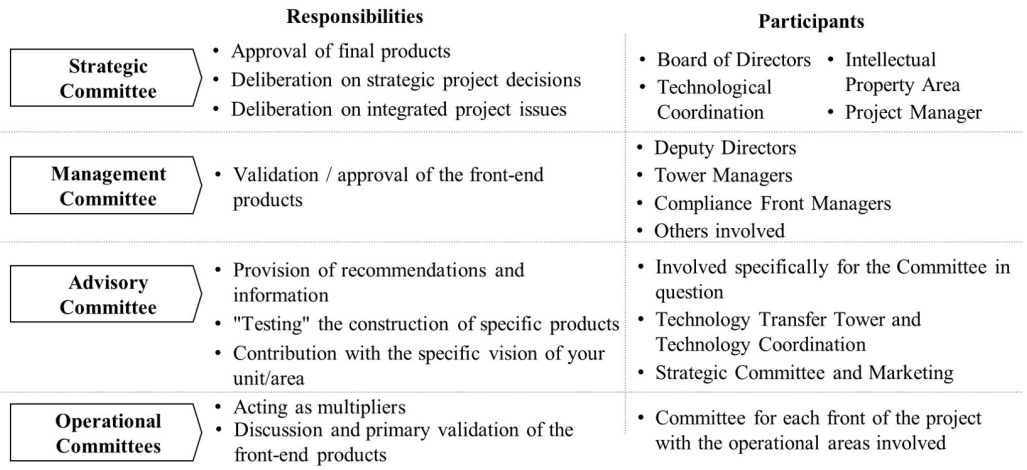

Figure 3. Responsibilities and participants committees.

The management and governance structure developed for the Oxford/AstraZeneca/Fiocruz vaccine production and technology transfer megaproject contributed to the success of this megaproject. The three success qualifiers: time, budget, and benefits described by Flyvbjerg (2014) were attended. The complete technology transfer took place in 16 months. In less than two years Bio-Manguinhos/Fiocruz delivered to the PNI more than 155 million doses of the vaccine against COVID-19 following the available budget.

The participants of the megaproject emphasized that this structure is adequate only in emergencies. This is because in these situations all internal and external resources are directed to the same objective, and other initiatives are slowed down or even stopped, allowing a great mobilization around the megaproject.

5. Study results

The results of this study point to the importance of a robust management and governance structure to ensure the success of megaprojects. These results come from the case of the Oxford/AstraZeneca/Fiocruz megaproject on technology transfer, production, and supply of the vaccine in an emergency epidemiological situation and from the literature reviews on megaproject management and governance structure, which include the studies by Wang et al. (2021), Brunet & Forgues (2019), Li et al. (2019), van Marrewijk & Smits (2016), Kardes et al. (2013), Eweje et al. (2012), and Zhai et al. (2009).

We note that the management and governance structure of the Oxford/AstraZeneca/Fiocruz megaproject of vaccine technology transfer and production and supply fits three of the four megaprojects identified in the literature: infrastructure, production, and consumption. Although the management structure provides adequate resources for managing megaprojects, our research revealed that there is still a need for studies exploring the combined management and governance structure in emergencies.

We observed that the structure used by Bio-Manguinhos/Fiocruz has similarities with the structure directed to megaprojects identified by Zhai et al. (2009). The authors suggest the existence of a management that supports the activities of project managers and that they should have a sub-management responsible for specific activities. Thus, it is observed that the division by towers with work fronts adopted by Bio-Manguinhos/

Fiocruz helps in delegating tasks by thematic specificity, given the complexity, volume, and simultaneity of the activities of the towers that constitute the project. In addition, the management and governance structure used by Bio-Manguinhos/Fiocruz contributed to the management of the pressure imposed on the rapid availability of a COVID-19 vaccine. This pressure was one of the main problems highlighted by O'Sullivan et al. (2020) in managing a technology transfer process for a vaccine.

The combined analysis of the case with the literature indicates, as a result of this study, that the management and governance structure of megaprojects should be built according to the goal of the megaproject. This structure should consider seven dimensions: (i) prioritization of activities and definition of responsibilities; (ii) system information flow; (iii) organizational culture and local culture; (iv) monitoring and control; (v) resource supply flow; (vi) identification of stakeholders; and (vii) the established execution contracts (Wang et al., 2021; Brunet & Forgues, 2019; Li et al., 2019; van Marrewijk & Smits, 2016; Kardes et al., 2013; Eweje et al., 2012; Zhai et al., 2009).

6. Discussion

The results of this study contribute to support in structuring the management and governance of future technology transfers in emergencies. Before the pandemic of COVID-19, the fastest technology transfer in a pandemic situation in Brazil had been the Butantan Institute's transfer of 25 million doses for H1N1 influenza (Miyaki et al., 2011). However, despite presenting how technology transfer was conducted in this process Miyaki et al. (2011) did not attempt to present information that would contribute to technology transfer management and governance. Thus, the present work extends existing knowledge in this regard. We present and discuss the management and governance structure of the Oxford/AstraZeneca/Fiocruz megaproject for technology transfer, production, and supply of the vaccine. The analysis of this case contributes to the practice of megaproject management and governance by presenting how structures, responsibilities, and activities were organized in a real emergency. The Bio-Manguinhos/Fiocruz case was successful, even facing limitations such as a vaccine still under development, searching for equipment, and training people amid the isolation imposed by Covid-19, which made the need for a clear and efficient management and governance structure even greater. However, megaprojects have specific characteristics that must be considered, so a faithful reproduction of this megaproject's management and governance structure is not recommended.

To assist in the construction of management and governance structures in possible emergencies, we propose a model that can serve as a basis. This model is presented in Figure 4.

The model proposed to support the construction of the management and governance structure of megaprojects in emergencies was developed from the analysis of the case and the literature. This model, unlike most studies, comprises a single representation of the governance and management structure, which allows for identifying the relationships on the megaproject. The hierarchical structure of megaproject management proposed in the model of Figure 4 was proposed based on the case study and on the study by Zhai et al. (2009), in which the megaproject is composed of a manager, a megaproject integration area (area that keeps all the information integrated), then the coordinators of specific areas and the subareas leaderships. The structured view of the areas supports managers in determining the activities and responsibilities of each area.

Regarding the governance structure, which establishes the control of the megaproject's progress, it was structured based on the studies of Brunet & Forgues (2019), van Marrewijk & Smits (2016), Zhai et al. (2009) and on the knowledge about the governance committees of the case study. Our model proposed that this structure be managed by the government and/or public and private institutions. In the study by Brunet & Forgues (2019), the governance structure was managed by Steering Committee City of Quebec. Like the Megaproject for technology transfer, production and delivery of the Oxford vaccine/AstraZeneca/Fiocruz conducted by a public institution. In the study by van Marrewijk & Smits (2016) by the President of the Republic of Panama, both megaprojects had public interest attached to their execution. In the case of the study by Zhai et al. (2009), this was coordinated by a company. For this reason, we highlight that the governance structure of the megaproject may include governments and public and private institutions.

Moreover, as this proposed model is directed to emergencies, it is of interest to public and private agencies the good progress of the same. As for the other groups, councils or committees proposed in the governance structure, these were thought from the experience of Bio-Manguinhos/Fiocruz in the definition of groups of control, support, and decision-making that support the actions of megaproject management. When conducting the case study, we identified that the structuring of support and decision making committees was relevant to speed up the decision-making process and monitor the project management structure. In addition, the committees

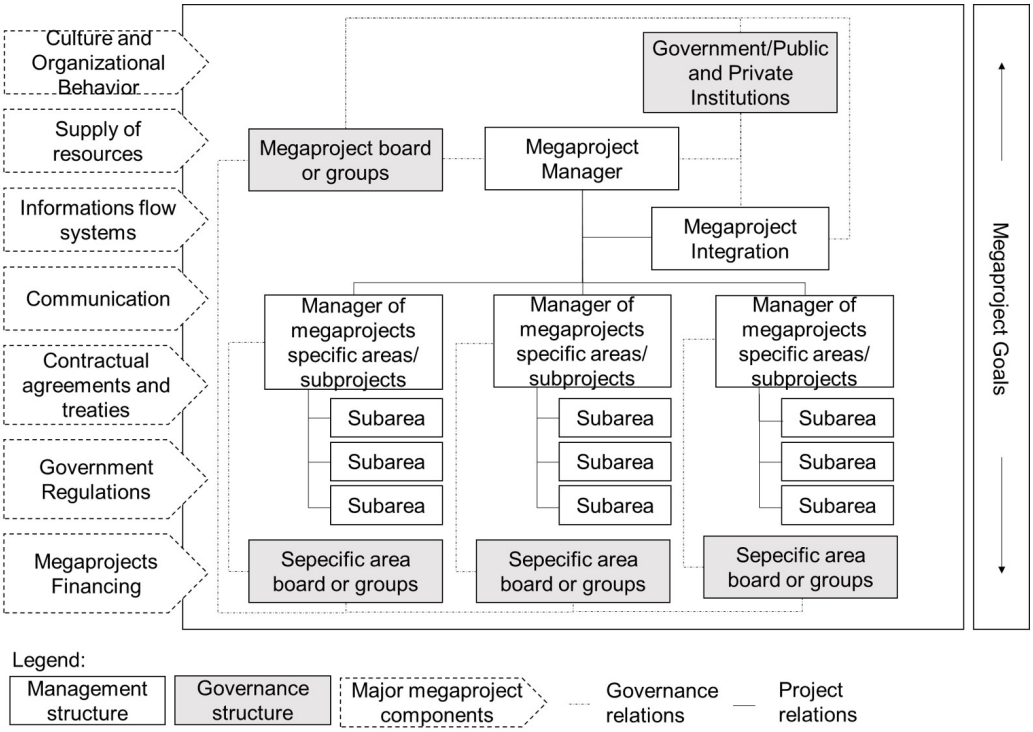

Figure 4. Model for building the management and governance structure of a megaproject in an emergency situation.
Source: prepared by the authors.

had an overview, allowing the integration between the internal governance and management structure and the external issues that could impact the megaproject's outcome.

Because each megaproject has specific characteristics, some aspects must be considered to define the structure, activities and responsibilities and definitions of each group, for this reason, the main components of the megaproject were listed. The local and organizational culture is suggested by Kardes et al. (2013), van Marrewijk & Smits (2016) and Wang et al. (2021), the flow of information adequate for decision making by managers for the megaproject is the focus of Eweje et al. (2012) studies and is highlighted in Kardes et al. (2013) study. Communication mechanisms, the internal funding structure of the megaproject, and external factors such as government regulations should be considered in this framework, as studied by Li et al. (2019) and Brunet & Forgues (2019). Kardes et al. (2013) also presents that contracts and treaties should be considered, although their study is focused on risk management in megaprojects the aspects listed contribute to the structuring of the management and governance structure in emergency situations.

Finally, one of the most mentioned aspects in the literature and that we have verified in this case is related to the megaproject's objectives. The structuring of the megaproject must consider the overall goal, and how this goal will be made clear to the different levels of the structure.

In this sense, our work contributes to the theory by presenting a reference model for building megaproject management and governance structures. We propose that after defining the structure, the activities, responsibilities and goals of each area should be defined and recorded, so that this information is clear to all participants in the megaproject.

7. Conclusion

The management and governance structure of megaprojects is important to achieve long-term success. In this study, we aimed to identify how to structure the management and governance of megaprojects for emergencies. To this end, we conducted a systematic review of the literature to understand the aspects that have been studied on the subject, and then we conducted a case study in Bio-Manguinhos/Fiocruz to analyze a real case on the subject. In this process, we identified the management and governance structure of the Oxford/

AstraZeneca/Fiocruz megaproject for technology transfer, production, and supply of the Covid-19 vaccine and characterized the responsibilities of each party.

About the case, we understand that the management and governance structure was appropriate for the technology transfer, production, and supply of the Oxford/AstraZeneca/Fiocruz vaccine. This structure allowed for simultaneous activities, which was critical to the timing of the vaccine technology transfer process. This process, which usually takes an average of five years, took less than two years, in a focused and systematic way after the emergence of the SARS-CoV-2 Coronavirus. Moreover, the general coordinator had systematized and integrated information from all towers and fronts, his performance was focused on the critical points, especially on integration, to ensure the achievement of the objectives of the whole megaproject. And, thus, contributing to the success of this megaproject.

Although the management and governance structure used in the COVID-19 pandemic can support future pandemics or emergencies, this structure cannot be generalized, given its specific characteristics. We propose a reference model for building the management and governance structure in emergencies integrated into a single scheme. In this proposal, we list the main components that must be analyzed to define this structure, and to support different institutions and governments in the conduction of successful megaprojects in critical situations.

Our study is limited to the analysis of a case and the proposal of a base model for the construction of the management and governance structure. We suggest that future studies test the proposed model so that this knowledge can be refined.

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