Navigating crisis: leadership dynamics and decision-making in emergency vaccine authorization - insights from Brazilian Health Agency (ANVISA) response to the COVID-19 pandemic

Navegando na crise: dinâmica de liderança e tomada de decisão na autorização emergencial de vacinas - percepções da resposta da Agência Nacional de Saúde (ANVISA) à pandemia da COVID-19

Navegando en la crisis: dinámica de liderazgo y toma de decisiones en la autorización de vacunas de emergencia - perspectivas de la respuesta de la Agencia Brasileña de Salud (ANVISA) a la pandemia de COVID-19

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ABSTRACT
This study delved into how contextual factors influenced the emergency authorization of the CoronaVac vaccine in Brazil by the Brazilian Health Agency (ANVISA) amid the COVID-19 pandemic crisis. The investigation specifically focused on the authorization protocol within the strategic decision-making process, examining it from both an experiential standpoint and through the lens of senior management. Utilizing a qualitative empirical approach, semi-structured interviews were conducted with senior executives of (ANVISA), thereby enabling an in-depth exploration of the intricacies surrounding emergency authorization procedures. The findings elucidated that, amidst an emergency impacting the entirety of society, including stakeholders within the agency itself, the authorization framework necessitated adaptation to effectively address the crisis, akin to a wartime scenario. The sobering statistics, exemplified by the staggering toll of over 1,000 deaths in a single day within the country, underscored the critical urgency for
resolution. Additionally, the study underscored the paramount importance of human-centric decision-making facets and the recognition of professionals' contributions, particularly emphasizing the imperative for empathy, solidarity, and collaborative efforts during periods of heightened exigency.

**Keywords:** strategic decision-making, strategic decision-making authorization routine, contextual factors, crisis management, COVID pandemic.

**RESUMO**
Este estudio profundizó en cómo factores contextuales influyeron en la autorización de emergencia de la vacuna CoronaVac en Brasil por parte de la Agencia Brasileña de Salud (ANVISA) en medio de la crisis pandémica de COVID-19. La investigación se centró específicamente en el protocolo de autorización dentro del proceso de toma de decisiones estratégicas, examinándolo tanto desde un punto de vista experiencial como a través de la lente de la alta dirección. Utilizando un enfoque empírico cualitativo, se realizaron entrevistas semiestructuradas con altos ejecutivos de (ANVISA), lo que permitió una exploración en profundidad de las complejidades que rodean los procedimientos de autorización de emergencia. Los hallazgos aclararon que, en medio de una emergencia que afecta a toda la sociedad, incluidas las partes interesadas dentro de la propia agencia, el marco de autorización requería una adaptación para abordar eficazmente la crisis, similar a un escenario de guerra. Las aleccionadoras estadísticas, ejemplificadas por el asombroso número de más de 1.000 muertes en un solo día en el país, subrayaron la urgencia crítica de una resolución. Además, el estudio subrayó la importancia primordial de las facetas de toma de decisiones centradas en el ser humano y el reconocimiento de
las contribuciones de los profesionales, enfatizando particularmente el imperativo de la empatía, la solidaridad y los esfuerzos colaborativos durante períodos de mayor exigencia.

**Palabras clave:** toma de decisiones estratégicas, rutina de autorización de la toma de decisiones estratégicas, factores contextuales, gestión de crisis, pandemia de COVID.

1 STRATEGIC DECISION-MAKING AND AUTHORIZATION ROUTINE

A decision is deemed strategic when it holds significance for the institution in terms of the actions taken, resources committed, or precedents established (Mintzberg, Raisinghani & Théorêt, 1976). Organisations represent coalitions of individuals, each bringing personal goals and cognitive inclinations, and strategy emerges as a product of political agreements and commitments.

Understanding strategic decision-making as a process embedded within a context rather than as an isolated event becomes a crucial element for grasping strategic decisions. According to Pereira and Fonseca (1997), decision-making results from a systemic, paradoxical, and contextual process, inseparable from the circumstances in which it occurs. Mintzberg, Raisinghani, and Théorêt (1976) delineate the strategic decision-making process into three phases: identification, development, and selection, each comprising seven interactive and interdependent routines.

In the context of this study, the investigation focuses on the third phase, specifically on the authorization routine within the selection phase, which occurs when the actors involved in the evaluation process lack the requisite authority to commit the organization to a particular course of action (Bataglia & Yu, 2008; Mintzberg, Raisinghani & Théorêt, 1976). This authorization necessitates approval from higher hierarchical levels or even external to the organizations, by environmental actors empowered to deliberate.

The chosen case study revolves around the approval of the CoronaVac vaccine by senior management at (ANVISA), sanctioned on January 17, 2021. Although the deliberation on this vaccine serves as the focal point, it is understood that the involvement was more extensive, as the agency concurrently dedicated efforts to the approval of
several other critical elements: ventilators, masks, alcohol (experiencing shortages), intubation drugs, anesthetics, logistics for continuous drug supply, port, airport, and border inspections, traveler health, and deportation.

2 CONTEXTUAL PERSPECTIVES

Elbanna, Thanos, and Jansen (2020) introduced four contextual perspectives that serve as influencing factors in the strategic decision-making process (Figure 1): characteristics of top management (both demographic and psychological), specific attributes of the decision (such as its importance, uncertainty, and motive), environmental determinism (including external control, environmental uncertainty, and hostility), and organizational characteristics (comprising performance, company size, and ownership).

This study delves into these four perspectives (Elbanna & Gherib, 2012; Elbanna, Thanos & Jansen, 2020; Hitt & Tyler, 1991), which act as determinants for the speed of decision-making processes, influenced by factors such as the availability of real-time information, consideration of multiple alternatives, input from advisors, attainment of qualified consensus, and the integration of decisions (Eisenhardt, 1989).

Understanding the impact of contextual elements on the dynamics of the authorization routine within the strategic decision-making process serves as the overarching aim of this research. Investigating this influence gives rise to the central question guiding this study:

What is the extent of contextual factors’ interference in the routine authorization process within the strategic decision-making process concerning the CoronaVac vaccine by (ANVISA), amidst the management of a pandemic crisis situation?
Figure 1 Integrative scheme for the study of strategic decisions

The strength of these reviews lies in the awareness that the contextual integrative approach has an influence on the understanding of strategic decision-making processes. Specifically, in the relationship between the process and the results of strategic decisions (Elbanna, Thanos & Jansen, 2020).

3 INTEGRATIVE MODEL: CONTEXTUAL FACTORS X STRATEGIC DECISION-MAKING PROCESS

The integrative model proposed by Elbanna, Thanos, and Jansen (2020) was utilized as a framework for structuring the literature review conducted in this study. Illustrated in Figure 1, this schematic model depicts the interrelation among the context, the decision-making process, and the outcomes. This review contributed significantly from a theoretical standpoint and paved the way for prospective empirical investigations into this influence within an applied framework.
Papadakis, Lioukas, and Chambers (1998) emphasized that these perspectives aid in the identification of opportunities, threats, constraints, and other environmental characteristics, guiding technical decisions and processes.

Organizations often exhibit an inability to adapt as swiftly as their external environments (Hannan & Freeman, 1977; Hannan & Freeman, 1978). Nevertheless, in certain extreme environmental circumstances, such as those precipitated by a pandemic emergency, the importance and urgency of a rapid response can catalyze the change process, fostering swift mobilization and prioritization.

4 RESEARCH CONCEPTUAL MODEL

The study considered, specifically, the case study of the approval of the CoronaVac vaccine by (ANVISA), in the middle of the pandemic peak in Brazil. It focused on investigating the influences of contextual factors (Figure 2), represented by the four perspectives in the strategic decision-making process, addressed by Elbanna, Thanos, and Jansen (2020), on the Authorization Routine proposed in the general model of strategic decision-making by Mintzberg, Raisinghani, and Théorêt (1976).
Yu and Sousa (2012) explored meta-decisions, identifying who will participate in the decision-making process and how the decision will be decided. They used decision analysis to support the process of making complex strategic decisions. In this study, the actors targeted by investigation were the managers involved in the process.

This foundation helps in the development of the conceptual model of this study, as it serves as a basis to investigate the relationship of the elements shown in Figure 2 with the environment of uncertainty and the need for rapid mobilization in a complex crisis environment. During the COVID-19 pandemic, regulatory agencies across the globe developed new—and expanded or modified the use of known—tools, practices, and procedures, and collaborated across regions to an unprecedented degree (Huneycutt, Acha, 2024), Bonelli and Liu (2024) reinforced that there was a need to conduct strategic decision-making research through a process approach for crises where threats, uncertainties, instabilities, pressures, and various negative environmental factors are present or coming.
5 METHOD

In order to validate the proposed conceptual model and to answer the research question, the qualitative method and the strategy of a single, exploratory case study were used, appropriate when the researcher has little control over the events and when the focus is on contemporary phenomena inserted in some real-life context (Yin, 2001, p. 19).

The target scenario of the study corresponded to the pandemic associated with the infectious disease COVID-19 (Coronavirus Disease 2019), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which required a real "race against time" to authorize a new technology, in this case a vaccine, from the Chinese company Sinovac.

It is admitted that case studies, like experiments, are generalizable to theoretical propositions, and not to populations or universes. And that the above experience can serve to improve the decision-making process in complex situations. By making knowledge of the process explicit, other managers can take ownership of the knowledge acquired.

In line with Yin's (2001) proposition for the validity of a case study research, the data that served as the basis for the study of this case considered three principles: use of various sources of evidence, creation of a database for the case study, and maintenance of a chain of evidence, supported by the Atlas Ti tool.

The interviews were guided by a semi-structured script, carried out through face-to-face video conferences, recorded, transcribed in their entirety, supported by an informed consent form.

In the pre-analysis phase, the documents were chosen, the hypotheses and objectives were formulated and the indicators that supported the final interpretation were elaborated. According to Bardin (2016), a hypothesis is a provisional statement that is proposed to be verified and the objective is the general purpose to which it is proposed.

During the coding phase, the focus was on the treatment of the collected material, the raw data were systematically transformed and aggregated into units. This made it possible to carry out a thematic analysis to discover the "nuclei of meaning" and, thus, made it possible to analyze the communication and the frequency of appearance of these themes.
Finally, the discourses were analyzed and the expressions and relationships were considered, according to Bardin (2016).

6 DATA ANALYSIS

The study involved interviews with five executives who held senior leadership positions within (ANVISA's) senior management team and were actively engaged in strategic decision-making processes. The objective of these interviews was to explore the elements outlined in the theoretical model underpinning the research. Transcripts of these interviews were collated into a single hermeneutic unit using Atlas Ti software, alongside other pertinent documents.

A floating content analysis, as outlined by Bardin (2021), was initially conducted, followed by the commencement of categorical analysis—a technique within content analysis methodology. In this stage, categories were designated as super codes, with subcategories referred to as codes, aligning with the terminology used in the employed analytical tool. Textual data were dissected into units represented by nine super codes, which were further delineated into 23 codes, reflecting adjusted categories based on analogous groupings. Consequently, the 407 quotations extracted from the transcripts were linked to these codes, as illustrated in Figure 3.

Figure 3 Codebook

Source: Prepared by the author
The code cloud (Figure 4) generated from this analysis was structured based on the frequency of code assignment within the hermeneutic unit creations, prioritizing the groundedness of the codes.

Figure 4 Word Cloud Organized by Groundedness for Empirical Analysis of Contextual Perspectives

6.1 LEGACIES OF STRATEGIC DECISION-MAKING IMPACTED BY CONTEXTUAL FACTORS

Legacies were construed as the enduring influences of actors and factors that facilitated the emergency approval process amidst crisis circumstances. Following the examination of the case study, specifically the routine authorization for the approval of the CoronaVac vaccine by (ANVISA), nine legacies were delineated: leadership, co-creation, holistic vision, communication, prioritization, human aspects, optimization, transparency, monitoring, and legitimacy.

Quotations were attributed to these legacies utilizing an inductive approach, wherein they were linked to the corresponding super code and code. Subsequently, after
coding and revising the data, efforts were directed towards identifying relationships among the super codes, codes, and quotations. During the analysis of contextual factors’ impacts on the strategic decision-making routine, codes associated with the legacies stemming from this relationship were elucidated.

Consolidation of findings was facilitated through the utilization of a code link consolidator tool, enabling the generation of a Co-occurrence Matrix for cross-referencing selected codes. Once connections were established, the codes were positioned within the matrix to illustrate associations for analysis, facilitating review and confirmation.

Among the legacies identified, those with the most profound impact in this process included: the establishment of robust, cohesive, and directive leadership; the imperative of prioritizing actions aligned with overarching goals; and the opportunity to foster co-creation, characterized by collaborative engagement among stakeholders to realize shared objectives.

6.2 SANKEY OF INFLUENCE

Figure 5 displays the Sankey diagram extracted from the Atlas Ti tool. It illustrates that the specific characteristics of decision-making in crisis environments exhibit the highest level of connectivity in relation to the identified legacies.
The specific characteristics of decision-making in crisis environments emerge as the most prominent perspective in this study, followed by the characteristics of top management, organizational characteristics, and environmental determinism. This finding resonates with Papadakis, Lioukas, and Chambers (1998), who observed the dominant role of specific decision characteristics in certain decision processes.

The magnitude of decision-making, as gauged by its importance, familiarity with the topic, and degree of uncertainty in threatening and crisis-ridden environments, significantly outweighs other perspectives. In the case of the routine authorization for the approval of the CoronaVac vaccine, the decision's criticality prompted the organization to mobilize resources towards addressing this imperative.

Aligned with theorists advocating organizational ecology, the emergency approval of the CoronaVac vaccine epitomized a survival imperative. Managers likened their situation to wartime conditions, necessitating the summoning of human resources and specialists from various areas to tackle technical challenges. This underscored the
importance of allocating appropriate resources, particularly those of a technical nature, to facilitate the decision-making process.

The imperative for swift action was directly linked to the specific characteristics of the decision, driven by the urgency for a solution. Cost-benefit analysis emerged as the predominant factor guiding decision analyses. (ANVISA’s) leadership, embodied by the collegiate board, advocated for changes in legislation to legitimize actions undertaken in response to the crisis.

In the absence of a predefined manual for crisis situations, collaborative efforts and individual experiences were instrumental in crafting solutions within an unprecedented context. Active managers assumed leadership roles, fostering internal alignment and navigating external pressures through political interactions.

Three primary legacies were identified: leadership, prioritization, and co-creation. Leadership played a pivotal role in decision-making, particularly in the context of the decision's significance and the emotional toll of the crisis. Top management's leadership was instrumental in coordinating multifaceted responses and legitimizing decisions through legal mechanisms.

The study underscores the complexity of strategic decision-making processes, which are influenced by various factors. Specific decision characteristics exert a significant influence, guiding decision processes tailored to each scenario.
REFERENCES


