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Favorable and unfavorable factors for the implementation of Quality Management System in the National Health Surveillance System: the pilot experience of two states and two municipalities in Brazil

Fatores favoráveis e desfavoráveis à implantação de Sistema de Gestão da Qualidade em órgãos do Sistema Nacional de Vigilância Sanitária: a experiência piloto em dois estados e dois municípios brasileiros

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ABSTRACT

Introduction: The implementation of quality management principles in the National Health Surveillance System (SNVS) by developing planning, monitoring, and evaluation strategies, models, and managerial tools, has been presented as a structural requirement for qualifying health promotion and protection actions, aiming at national and international regulatory convergence, as well as continuous improvement of the very actions perpetrated by SNVS. **Objective:** Analyze factors deemed favorable or unfavorable for the implementation of Quality Management System (QMS) in four SNVS institutions. **Method:** Descriptive, bibliographic, and documentary study aimed at identifying and describing aspects related to the implementation of QMS in four SNVS institutions, using documents prepared by its representatives. **Results:** Favorable and unfavorable factors have been grouped according to three dimensions: organizational, methodological, and conjunctural. The commitment of leadership to the implementation of QMS, the commitment of the teams, and the support of an external consultancy have prevailed as favorable factors, whereas the difficulty in understanding the quality management technical language used in the QMS model was the most unfavorable factor. **Conclusions:** The favorable factors may have been previously organized and dealt with by the teams, in order to strengthen the implementation and its effects on the performance of the SNVS. Unfavorable factors, even those related to the intrinsic characteristics of public administration, are equally liable to be overcome, so as not to hamper the implementation of the management model based on the continuous improvement of processes.

KEYWORDS: Quality Management; Health Surveillance; Unified Health System; National Health Surveillance System

RESUMO

Introdução: A implementação dos princípios da gestão da qualidade no Sistema Nacional de Vigilância Sanitária (SNVS) por meio do desenvolvimento de estratégias, modelo e instrumentos de planejamento, monitoramento e avaliação, tem se apresentado como requisito estruturante para a qualificação das ações de promoção e proteção à saúde, visando à convergência regulatória sanitária nacional e internacional, assim como à melhoria contínua das ações executadas pelo próprio SNVS. **Objetivo:** Identificar e apresentar os fatores favoráveis e desfavoráveis à implantação de Sistema de Gestão da Qualidade (SGQ) em quatro instituições do SNVS. **Método:** Estudo descritivo e documental que visou identificar e descrever os fatores relacionados à implantação de SGQ em

quatro instituições do SNVS, a partir de experiência piloto do Projeto Integravisa 2018–2020. **Resultados:** Os fatores favoráveis e desfavoráveis foram agrupados em três blocos: organizacionais, metodológicos e conjunturais. Prevaleceram, como fatores favoráveis, o compromisso das lideranças com a implantação do SGQ, o comprometimento das equipes e o apoio de consultoria externa. Como fatores desfavoráveis, predominou a dificuldade de compreensão da linguagem técnica da gestão da qualidade, contemplada nos requisitos das sete seções do Modelo de SGQ utilizado como referência. **Conclusões:** Os fatores favoráveis poderão ser preventivamente organizados e trabalhados pelas equipes, com vistas a potencializar a implantação e seus efeitos no desempenho do SNVS. Os fatores desfavoráveis, mesmo aqueles relacionados às características intrínsecas da Administração Pública, são igualmente passíveis de superação, a fim de que não impeçam a implantação do modelo de gestão baseado na melhoria contínua dos processos no SNVS.

PALAVRAS-CHAVE: Gestão da Qualidade; Vigilância Sanitária; Sistema Único de Saúde; Sistema Nacional de Vigilância Sanitária

INTRODUCTION

Health Surveillance (Visa) deals daily with situations that can pose risk to population health. As an example, the global SARS-CoV-2 (COVID-19) pandemic, a public health calamity, hugely increased the demand for the Visa actions, especially in sanitary prevention and control measures[1,2].

As an executive agent of the Unified Health System (SUS), the role of Visa is to prevent, reduce, and eliminate health risks, through regulatory action on services, products, and any other health interested items, as well as health promotion in constant communication with society, helping to strengthen fuller citizenship[3].

Since the creation of SUS, the challenges of promoting and converging preemptive and inspection actions in the three levels of government have required a joint effort to qualify surveillance actions in the territory, both in terms of regulation and sanitary control. To meet these challenges, the strategy for organizing and structuring health surveillance in Brazil was conceived with Law No. 9.782, of January 26, 1999[4], which created the National Health Surveillance System (SNVS), comprising the set of actions defined by § 1 of Art. 6 and Arts. 15 to 18 of Law No. 8.080[5], of September 19, 1990, carried out by institutions of direct and indirect Public Administration of the Union, the states, the Federal District, and the municipalities that are responsible for regulation, standardization, control, and inspection activities in health surveillance, based on federative coordination between the entities.

In addition to the necessary federative alignment and convergence of procedures and actions, it is necessary to comply with requirements for converging with international regulatory practices, due to the globalized processes of production and marketing of products subject to Visa, and the effort to expand the market for Brazilian products abroad[6].

To this end, the Brazilian National Health Surveillance Agency (Anvisa), in its role as coordinator of the SNVS, issued in 2018, the Collegiate Board Resolution (RDC) of the Brazilian National Health Surveillance Agency (Anvisa) and the Ministry of Health (MS) No. 207, of January 3, 2018[7], later updated by RDC Anvisa/MS No. 560/2021[8], which provides for the organization of health surveillance actions within the scope of the SNVS, taking as its guiding principle the degree of health risk intrinsic to the activities and products subject to the Visa, identifying criteria and requirements necessary for the execution of such actions. In Art. 2, item VI, one of the premises established for the organization of actions within the scope of the SNVS refers to the implementation of Quality Management System (QMS) as a structuring requirement for the qualification of actions carried out by the Union, states, Federal District, and municipalities.

An early experience with the implementation of QMS in the SNVS began in the first decade of the 2000's at the Central Public Health Laboratories (LACEN) network. The federal government encouraged the implementation of a quality management model aimed at strengthening the national Visa laboratories network to meet the increasing demand for analyzes resulting from Visa actions, in order to seek a reliable standard of quality to subsidize health inspection in assessing the conformity of products to current regulations[9].

Quality management has seven principles, which are considered pillars for implementing a management model aimed at continuously improving the processes carried out by organizations to deliver products and services to their stakeholders, always aiming to increase efficiency gains. These principles are: customer focus; leadership; engagement of people; process approach; improvement; evidence-based decision-making; relationship management[10]

The choice of a management model based on quality management as the guiding standard for the SNVS is in line with previous Anvisa initiatives, which have been partially focused on the harmonization of standard operating procedures with states and municipalities.

In the global context, the World Health Organization (WHO) recommends that member states implement QMS in national regulatory authorities. In 2018, the first version of the WHO Global Benchmarking Tool (GBT)[11] was published, for comparative assessment of national regulatory systems for medicines and vaccines. The GBT includes the evaluation of eight regulatory functions, along with the evaluation of the National Regulatory System's effectiveness on ensuring the quality and safety of medical products: registration and marketing authorization; surveillance; market surveillance and control; licensing of establishments; regulatory inspection; laboratory testing;

Chart 1. World Health Organization (WHO) Global Benchmarking Tool (GBT) to assess regulatory capacity for medicines and vaccines, 2020.

Functions	Indicators
1. National Regulatory System	Legal provisions, regulations, and guidelines necessary to define the regulatory framework of the national regulatory system → 9 sub-indicators. Provisions for an effective organization with good governance → 4 sub-indicators. Strategic plan with a clear objective → 5 sub-indicators. Regulatory system supported by the highest authorities and crisis management plans → 5 sub-indicators. QMS applied, including risk management principles → 14 sub-indicators. Human resources for regulatory activities → 4 sub-indicators. Financial resources for regulatory activities → 5 sub-indicators. Infrastructure and equipment for regulatory activities → 3 sub-indicators. Mechanisms in place to promote transparency, accountability and communication → 9 sub-indicators. Mechanism in place to monitor regulatory performance and results → 2 sub-indicators.
2. Registration and marketing authorization	Legal provisions, regulations, and guidelines necessary to define the regulatory framework for registration or marketing authorization activities → 13 sub-indicators. Provisions for an effective organization with good governance → 2 sub-indicators. Human resources for registration and marketing authorization activities → 4 sub-indicators. Procedures established and executed for registration or marketing authorization activities → 10 sub-indicators. Mechanism in place to monitor regulatory performance and results → 2 sub-indicators.
3. Surveillance	Legal provisions, regulations, and guidelines needed to define the regulatory framework for surveillance activities → 7 sub-indicators. Provisions for an effective organization with good governance → 2 sub-indicators. Human resources for surveillance activities → 4 sub-indicators. Procedures established and executed for surveillance activities → 8 sub-indicators. Mechanism in place to monitor regulatory performance and results → 2 sub-indicators. Mechanisms in place to promote transparency, accountability and communication → 3 sub-indicators.
4. Market surveillance and control	Legal provisions, regulations, and guidelines necessary to define the regulatory framework of market surveillance and control activities → 7 sub-indicators. Provisions for an effective organization with good governance → 2 sub-indicators. Human resources for market inspection and control activities → 4 sub-indicators. Procedures established and executed for market surveillance and control activities → 8 sub-indicators. Mechanism in place to monitor regulatory performance and results → 3 sub-indicators. Mechanisms in place to promote transparency, accountability and communication → 3 sub-indicators.
5. Granting licenses to establishments	Legal provisions, regulations, and guidelines necessary to define the regulatory framework of licensing activities → 5 sub-indicators. Provisions for an effective organization with good governance → 2 sub-indicators. Human resources for licensing activities → 4 sub-indicators. Procedures established and implemented for licensing activities → 4 sub-indicators. Mechanism in place to monitor performance and regulatory results → 2 sub-indicators. Mechanisms in place to promote transparency, accountability and communication → 2 sub-indicators.
6. Regulatory inspection	Legal provisions, regulations, and guidelines necessary to define the inspection and enforcement framework → 5 sub-indicators. Provisions for an effective organization with good governance → 2 sub-indicators. Human resources for regulatory inspection activities → 4 sub-indicators. Procedures established and implemented for the inspection → 6 sub-indicators. Mechanism in place to monitor performance and regulatory results → 5 sub-indicators. Mechanisms in place to promote transparency, accountability and communication → 4 sub-indicators.
7. Laboratory testing	Legal provisions, regulations, and guidelines necessary to define the structure of laboratory testing activities → 2 sub-indicators. Provisions for an effective organization with good governance → 2 sub-indicators. Laboratory activities implemented according to well-established plans and policies in accordance with a QMS → 4 sub-indicators. Human resources for laboratory testing activities → 4 sub-indicators. Well-maintained and equipped infrastructure for laboratory activities → 2 sub-indicators. Procedures established and implemented for laboratory tests in accordance with the QMS → 5 sub-indicators. Mechanisms in place to promote transparency, accountability and communication → 1 sub-indicator. Mechanism in place to monitor performance and regulatory results → 4 sub-indicators. Occupational health and safety measures → 3 sub-indicators. Measures for good management of outsourced laboratory activities → 1 sub-indicator.

Continued

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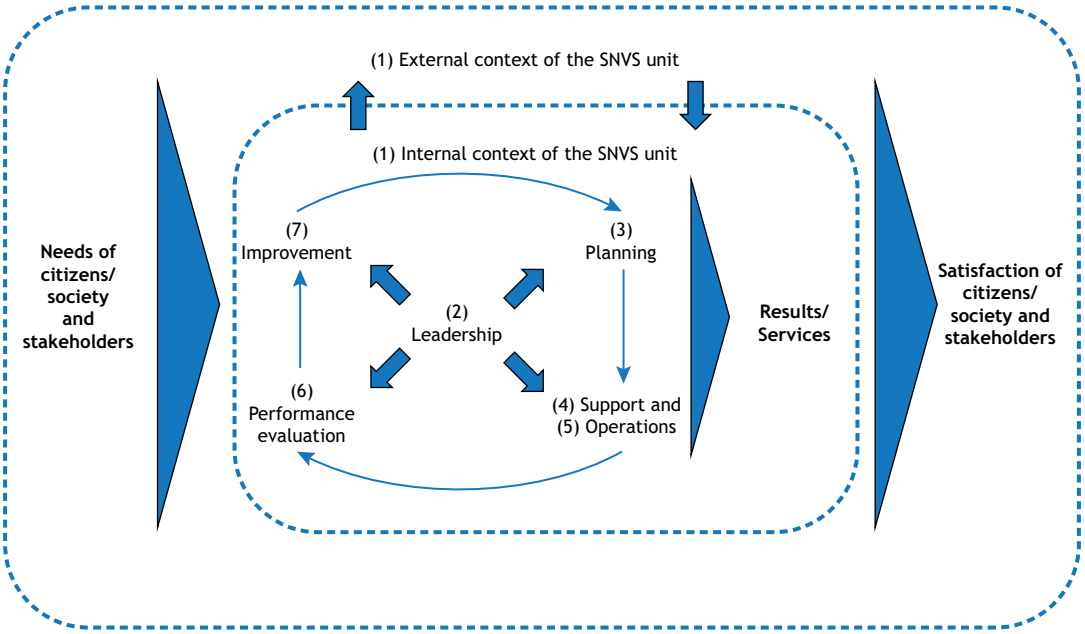
8. Supervision of clinical trials	Legal provisions, regulations, and guidelines necessary to define the framework for supervising clinical trials → 11 sub-indicators. Provisions for an effective organization with good governance → 2 sub-indicators. Human resources for clinical trial supervision activities → 4 sub-indicators. Procedures established and implemented for the supervision of clinical trials → 7 sub-indicators. Mechanisms in place to promote transparency, accountability and communication → 2 sub-indicators. Mechanisms in place to monitor performance and regulatory outcomes → 4 sub-indicators.
9. Batch release	Legal provisions, regulations, and guidelines necessary to define the framework for batch release by the National Regulatory Authority → 2 sub-indicators. Provisions for an effective organization with good governance → 2 sub-indicators. Human resources for the release of the batch by the National Regulatory Authority → 4 sub-indicators. Procedures established and implemented for batch release by the National Regulatory Authority → 3 sub-indicators. Information sharing mechanisms to promote transparency and accountability → 2 sub-indicators. Mechanisms in place to monitor performance and regulatory outcomes → 4 sub-indicators.

Source: Prepared by the authors, adapted from WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products, revision VI, 2021.
QMS: Quality Management Systems.



Source: Reference model drawn up as part of the IntegraVisa Project, 2019.
Note: The Integravisa Project, 2018-2020, aimed to support the qualification of health surveillance action from the perspective of planning and quality management, through the development of guiding documents and strategies that contribute to greater efficiency, efficacy and effectiveness of SNVS actions, within the scope of SUS. The guide for implementing QMS in SNVS units has been made available, presenting the reference model to be followed based on this management model.

Figure. Quality Management System (QMS) model for units of the National Health Surveillance System (SNVS), 2019.

Chart 2. Workshops and virtual meetings held at the four Health Surveillance institutions participating in the IntegraVisa Project, 2019-2020.

Visa body	Date of workshops (WS) and virtual meetings (VI)									
VE1	Sep 10 and 11, 2019	Oct 23 and 24, 2019	Nov 12, 2020	Dec 11, 2019	Oct 10 and 11, 2020	May 29, 2020	June 15, 2020	July 13, 2020	August 4, 2020	August 27, 2020
VE2	Sep 10 and 11, 2019	Oct 15, 2019	Nov 18 and 19, 2019	Dec 9, 2019	June 9, 2020	June 30, 2020	July 17, 2020	August 11, 2020	Sep 1, 2020	
VM1	Sep 5 and 6, 2019	Oct 14 and 15, 2019	Nov 11, 2019	Dec 12, 2019	Mar 5 and 6, 2020	May 28, 2020	July 30, 2020	August 21, 2020	Sep 11, 2020	
VM2	Sep 19 and 20, 2019	Oct 16 and 17, 2019	Nov 20, 2019	Dec 10, 2019	May 22, 2020	July 3, 2020	August 7, 2020	Sep 4, 2020		

Source: Prepared by the authors, 2020.
Note: Face-to-face workshops were held in 2019 and virtual meetings with the four institutions in 2020.

supervision of clinical trials; and batch release. Specific indicators are used to identify the degree of implementation and existing gaps within the QMS in national regulatory authorities[11].

To support member states in their efforts to implement QMS in their respective national regulatory authorities, the WHO published its guidelines on the implementation of quality management systems for national regulatory authorities in 2020[12], which aims to help these authorities develop and implement QMS, based on the principles of the International Organization for Standardization - ISO 9001:2015[13]. In this version, the GBT uses the concept of "maturity level", allowing both the WHO and regulatory authorities to assess the overall maturity of the regulatory system on a scale of 1 (existence of some elements of the regulatory system) to 4 (operating at an advanced level of performance and continuous improvement)[12]. Chart 1 summarizes the regulatory functions with their respective indicators, and brings information on the total number of sub-indicators per indicator for each of the regulatory functions.

Another noteworthy international initiative aimed at regulatory convergence concerns Brazil's accession to the Pharmaceutical Inspection Convention Scheme (PIC/S)[14], which gathers regulatory authorities from different countries for mutual recognition of Good Manufacturing Practice Certificates (GMPC) between nations that have comparable systems for verifying good manufacturing practices (GMP) in the production of medicines and active pharmaceutical ingredients. Among the PIC/S rules, the existence of QMS in regulatory authorities is an indispensable requirement for this mutual recognition[14].

The implementation of the principles of quality management, through the development of shared and continuous strategies and instruments for planning, monitoring, evaluating, and auditing, is a tool for improving management in the SNVS, including states and municipalities, for achieving greater effectiveness in health promotion and protection actions, with the primary purpose of strengthening the work of Visa an its role in SUS[6].

Based on the national and international initiatives described above, Anvisa decided to adopt a management model for the qualification of the whole SNVS based on the principles and guidelines of quality management and following ABNT NBR ISO 9001:2015 Quality Management System - Requirements[6,8,13].

This standard defines quality management as a set of coordinated activities for managing and controlling an organization, making it possible to improve products and services and guaranteeing that the needs of citizens and the companies are met or its expectations are exceeded. It also establishes that a management system is a set of interrelated parts or elements, and that the QMS should be understood as the part of this system that emphasizes quality[13].

In this scenario of initiatives focused on strengthening national regulatory authorities and contributing to the transformation of management practices in Visa institutions, and considering the systemic context of Brazilian inter-federative action in the SNVS, Anvisa, in partnership with the Hospital Alemão Oswaldo Cruz (HAOC), through the Institutional Development Support Program of the Unified Health System (PROADI-SUS), developed, between 2018 and 2020, the project Qualification of the Management of Strategic Health Surveillance Actions in the SNVS - IntegraVisa[6], which developed a method to support the implementation of QMS in the SNVS, including states and municipalities.

To this end, the IntegraVisa Project has published the Guide[10] for implementing QMS in SNVS institutions, presenting a management model based on the structure and requirements of the ABNT NBR ISO 9001:2015 Standard - Quality Management System[13], and adapted to the reality of the Brazilian health surveillance, to favor a didactic and systemic understanding of the set of requirements (Figure).

The aim of this article is to identify and present the favorable and unfavorable factors to the implementation of QMS in four SNVS institutions. Given the scarcity of studies alluding to these factors, especially considering state and municipal health surveillance institutions, which are little studied, the findings could contribute to better effectiveness and performance of future initiatives to incorporate this management technology in the Visas of the three levels of government in Brazil[8].

METHOD

Research design

This is a descriptive documentary study[15]. In terms of purposes, it is descriptive, as it aimed to identify and describe favorable and unfavorable factors to the implementation of QMS in four state and municipal SNVS institutions. In terms of means, it is documentary because it uses secondary sources as the corpus of analysis, i.e. materials that have not yet been analyzed[16]. We used the 32 reports from the workshops and virtual meetings held at the four institutions as part of the QMS implementation pilots under the IntegraVisa Project, which ran from 2018 to 2020[6].

Chart 2 summarizes the dates of the 12 workshops held, as well as the 20 virtual meetings, a strategy based on remote technology used since March 2020, due to the COVID-19 pandemic.

To support data analysis, literature review was carried out with bibliographic research on Emerald Insight, Latin American and Caribbean Literature in Health Sciences (Lilacs), and Scientific Electronic Library Online (SciELO) databases, using the following keywords: "quality management", "ISO 9001:2015 standard", "quality implementation", and "health surveillance".

Data collection

The study considered the records of the QMS implementation work in four SNVS institutions, located in two states and two capital municipalities. During the QMS implementation process, from September 2019 to September 2020, the Project team periodically recorded in a specific reports the driving and

restrictive forces experienced during the implementation of the QMS in the four agencies, a method inspired by Kurt Lewin's force field theory[17].

According to Lewin, the individual is subject to the influences of forces acting on the environment and resistance to change occurs when restrictive psychological forces are greater than driving forces. In this sense, objects, people and situations end up receiving positive or negative values depending on the individual's psychological condition. Restrictive forces can be considered to be negative behaviors, such as: resistance to participating in meetings, unwillingness to review routines, low encouragement from leaders to carry out implementation tasks. And the driving forces would be the elements that elucidate the need for change, such as: the team's interest and willingness to make changes to work processes, availability for the task agenda, encouragement from the leadership.

The reports, which are secondary sources for this study, make up the formal documentation of the project's implementation, in which all the activities carried out were also recorded, describing the progress of the work with the aim of providing accountability for the project. At the end of the implementation experience, these documents were analyzed by the authors of this manuscript and served as a source for collecting research data.

Information processing

For each of the agencies, the favorable and unfavorable factors for the implementation process were identified in the records, similar to what Santos[18] did for the implementation of a quality management program, and Pimenta et al.[19] for the hearing conservation program, both inspired by Champagne et al.[20]. Knowing the context in which the intervention is being implemented is an important step for this analysis, since it helps to understand whether the elements of such contexts pose barriers or not to the QMS implementation as planned[20]. This study is not intended to be an implementation analysis, given the limited use of secondary sources. However, the method of context analysis, which is part of the initial stage of implementation studies, helped analyzing the favorable and unfavorable factors.

Data analysis and discussion of the results were carried out by the authors at the end of the data collection period, by organizing the information and analyzing the content. To analyze the results, the agencies were identified anonymously as State Visa (VE) and Municipal Visa (VM), followed by an increasing identification number. To structure the data analysis categories, the authors started from the context analysis for implementation[20] and opted to classify favorable and unfavorable factors based on the sections of the QMS model[10] for SNVS institutions and the methodology adopted by the project[6], summarizing them in three categories: organizational, methodological and conjunctural. The organizational category included the content from the "Organizational Context - Internal Environment, Leadership, and Planning" sections, as the factors were related to the organizational and technological structure, the role of the leadership, the work team and the institution's previous experience with QM. The methodological factors refer to the practices and tools used in implementation, and therefore stem from the content highlighted in the "Support and Operations" sections of the management model. The situational factors, finally, relate to the conditions that are outside the institutions' control and which have directly interfered in the implementation of the project, and are characterized from the "Organizational Context - External Environment" section.

It is important to note that the contents of the reports from the virtual meetings that dealt with the "Performance Evaluation and Improvement" sections of the management model did not present any factors to be considered favorable or unfavorable. This may have been due to the period during which the project was being finalized, in which there was no feasible time to set up periodic critical analysis meetings and draw up improvement plans at the institutions taking part in the project.

The findings regarding favorable and unfavorable factors extracted from the reports for each agency participating in the project were analyzed and compared with each other to identify similarities and repetitions. After grouping the content of the three categories, the records were compared with similar studies published over the last eight years on Emerald Insight, Latin American and Caribbean Health Sciences Literature (Lilacs), and Scientific Electronic Library Online (SciELO) databases, as already mentioned.

Ethical considerations

This article is in accordance with the provisions of Article 1º, sole paragraph, Item VII, of Resolution No. 510, of April 7, 2016, of the National Health Council (CNS), which deals with specific considerations applicable to research in social sciences and humanities.

RESULTS AND DISCUSSIONS

Two charts were drawn up to summarize the data on the presence or absence of favorable and unfavorable factors for implementing the QMS.

Regarding favorable factors, four items were found (three belonging to the "organizational" category and one to the "methodological" category), which were unanimously identified by the four SNVS institutions.

However, in the analysis of the unfavorable factors, only one unanimous item was identified, belonging to the "methodological" category. The two blocks of factors, favorable and unfavorable, will be presented and discussed separately below. It is important to clarify that these results, which come from the 32 reports, reflect the evolution in maturity of the project participants, as the implementation continued with

ongoing learning about the principles, tools and practices of quality management.

Favorable factors for implementing the QMS

Chart 3 summarizes the information on the presence or absence of factors favorable to the implementation of the QMS in the four Visas analyzed.

Three organizational factors were identified, related to each other and of the same nature, which were seen as facilitators of the QMS implementation process: the commitment of senior leadership, either within the Visa body itself or at the broader organizational levels of the government structure; the involvement of middle management; as well as the involvement and commitment of the teams at different levels.

It is important to clarify that these factors were measured *a priori* by retrieving the consultant team's records of these situations in the reports. We then sought to confirm the situations by retrieving the statements produced by the Visa teams themselves, which were also present in the reports. By bringing the data from these two sources closer together, we tried to reduce the bias that may have existed in the team members' statements, given that, in the working meetings with the consultants, the groups were mostly made up of technical-level Visa professionals, although in some meetings managers, direct managers, and intermediate managers were present.

In this way, the reports show the constant presence of leaders at meetings, for example at VM1, where the consultants identified "Direct involvement of the director of health surveillance and the undersecretary in the process" as a driving force. An example of this was also identified in the partial follow-up report on the implementation of the QMS at VE1. The participants in this Visa were asked to describe the factors that contributed positively in their institution to the proper implementation of the suggested tasks. The first response was: "Support and adherence from managers (superintendent, directors)".

In a study analyzing the implementation of QMS in a General Coordination Office at the Ministry of Health, Santos[18] identified the commitment of leaders and their main function of mobilizing the teams, as well as the commitment of middle managers, as decisive factors in the success of the implementation. Other studies related to the analysis of the implementation of QMS systems in public or private organizations have also identified the Leadership factor as a key element for successful implementation[9,21,22,23].

In the report "*Referencial Teórico de Gestão da Qualidade para Ações de Visa em Serviços de Saúde*" (Theoretical Framework for Quality Management for Visa Actions in Health Services),

Chart 3. Presence of factors favorable to the implementation of QMS in SNVS bodies, 2020.

Favorable factors	VE1	VE2	VM1	VM2
Organizational				
Commitment of senior leadership to the project	Y	Y	Y	Y
Involvement of middle management	Y	Y	Y	Y
Team involvement/commitment (including regional directors)	Y	Y	Y	Y
Use of previous documents relating to past experiences	Y	Y	N	N
Team autonomy is based on a high degree of trust in the leadership.	N	N	N	Y
Methodologycal				
Choosing the scope of the teams' domain	Y	Y	N	N
External consultancy support	Y	Y	Y	Y
Affinity with the subject of quality due to experience in the regulated sector	N	Y	N	Y
Opening a communication channel with the regulated sector	N	N	Y	N
Provision of models of practices and methods by the Consultancy	N	N	N	Y
The tasks were divided into smaller groups, allowing the subject to be explored in greater depth and proposals to be drawn up for subsequent approval by the larger group, with managerial representation.	N	N	N	Y
Conjuncture				
Alignment of the project with the municipality's strategic planning	N	N	Y	N
Adapting the deployment effort to address issues related to combating the SARS-CoV-2 pandemic (COVID-19)	N	N	Y	N

Source: Documents and reports of the "*Qualificação da Gestão das Ações Estratégicas de Vigilância Sanitária no SNVS - IntegraVisa II*" (Qualification of the Management of Strategic Health Surveillance Actions in the SNVS - IntegraVisa II) project, 2018-2020.
VE: State Visa; VM: Municipal Visa; Y: Yes, presence of this factor in the process of implementing the Quality Management System; N: No, presence of this factor in the process was not identified.

Gama[24] takes the issue further, analyzing WHO documents and guidelines and indicating the support of leaders as an "indispensable factor for achieving improvements in health services", and in some cases it is necessary to develop these leaders and reinforce accountability. Gama even proposes the "4 As" model as a useful tool for gaining the support of leaders in organizations pursuing quality improvement: awareness, accountability, ability, and action.

Another favorable factor highlighted in the records of the four Visas studied was the support of external consultants, an item considered in the "methodological" category. In the QMS implementation reports, among the factors that contributed to the proper implementation of practices, VM2 cited "Competence and support of facilitators", and VE1, "Commitment of consultants".

In a study carried out by the National Institute of Metrology, Standardization and Industrial Quality (Inmetro), cited by Souza and Tanabe[25], external consultancy can become either a barrier, when it doesn't fulfill its role, or a "key element" in implementation, confirming the factor highlighted by the services. Specifically, other methodological factors that were not unanimously agreed upon by the four Visas, but which have been recognized as contributing to a good implementation, were the team's affinity with the subject of quality and the selection of an implementation scope (work process) well-known by the teams involved, and the organizational aspect of using materials and documents produced in previous initiatives. VE2 and VM2 highlighted "affinity with the subject of quality due to experience with the regulated sector" as a factor facilitating the process. This may show that, even with some knowledge of or previous experience with quality management documents and tools, difficulty in interpreting the requirements of ISO 9001/2015 and the terms and definitions is common in QMS implementation processes[9,26].

It is worth noting that three of the four institutions surveyed did not mention the provision of models of documents as a favorable factor, which highlights the strategy used by the IntegraVisa Project of having the local teams build their own of quality documents, considering the specifics of health surveillance. These documents were compiled as examples of the Guide for implementing QMS in the SNVS.

Conjunctural factors were related to external conditions; alignment with the municipality's strategic planning and the need to adapt work processes as a result of combating the COVID-19 pandemic were only addressed by one municipal Visa, VM1.

Unfavorable factors for implementing the QMS

Chart 4 systematizes the presence or absence of factors that hindered the implementation of the QMS at the Visas analyzed.

The difficulty of understanding the requirements of the standard to be implemented, as a methodological factor, was unanimous among the four Visas. Most of them had difficulties understanding the language of quality management and the requirements of the ISO 9001/2015 standard, even though they identified as favorable the use of documents created in the context of previous experiences with quality practices.

According to VM1's final QMS implementation report, one of the restrictive forces pointed out was "Difficulty in interpreting some requirements; Difficulty in understanding what to consider as evidence". Similarly, VE1 pointed out in its report: "The language and vocabulary of the requirements made it difficult for the group to interpret the requirements (need to adapt the language of the material for application in Health Surveillance)".

On the other hand, the lack of prior training for team members, insufficient staffing, and work overload - organizational factors - were highlighted by two of the four Visa institutions, with one state Visa and one municipal Visa always mentioning the same thing (Chart 2). For VM2, there should have been a strategy to "ensure general harmonization of basic concepts between everyone involved before starting the project", as pointed out in its partial report.

VM2 identified the "lack of specific knowledge and skill/practice in implementing the proposed models and QM concepts" as a factor that hindered implementation. As far as can be seen, the initiative of "dividing the tasks into smaller groups, allowing the subject to be studied in greater depth and the proposals to be drawn up for subsequent approval by the larger group, with the representation of managers", presented in Chart 1 of favorable factors, possibly contributed to the execution and completion of the tasks. Thus, it should be noted that the participation of a multidisciplinary team, with different thinking and knowledge, can help in the drafting of documents and the implementation of quality management practices, reducing the difficulty presented in relation to the lack of QMS knowledge.

In fact, both in Santos' findings[18] and in various studies carried out in different organizations, understanding the standard and aspects related to human resources - training and availability - are pointed out as important barriers. Maekawa et al.[21], in their study on the motivations, benefits, and difficulties of ISO 9001/2015 certification in Brazil, identified difficulties such as: employee resistance, little involvement from middle management, little support from top management, high implementation costs, difficulties in understanding the method and techniques involved, lack of technical training for workers, and lack of organizational infrastructure.

Team resistance was not identified as a factor during the pilot implementation of the QMS at the four Visa institutions. This issue was attributed to the methodology applied throughout the implementation, which sought to mitigate this element through monitoring by technical consultants and the exclusive participation of the teams appointed to make up the Quality Management Groups (QMGs), which were responsible for carrying out the implementation locally, without the direct involvement of all the professionals at each institution. The gradual introduction to the subjects, the practical activities and the constant offer of

Chart 4. Presence of factors unfavorable to the implementation of QMS in SNVS institutions, 2020.

Unfavorable factors	VE1	VE2	VM1	VM2
Organizational				
Lack of prior training for the internal team to facilitate the implementation of the pilot project.	Y	N	Y	N
Insufficient training material for understanding the requirements.	Y	N	N	N
Insufficient human resources and no team dedicated to the QMS.	N	Y	Y	N
Lack of a parameterized information system to meet the needs of QMS implementation.	N	N	Y	N
Obsolete technology park.	N	N	Y	N
Staff overloaded with other activities.	Y	N	Y	N
Resistance to the implementation of the QMS model on the part of professionals due to the history of implementing quality practices in the Products Division, making it difficult to sensitize the entire team.	N	Y	N	N
Methodologycal				
Difficulty understanding the language of quality management and the requirements of the standard ISO 9001/2015.	Y	Y	Y	Y
Difficulty in preparing the Situational Diagnosis, especially in identifying evidence of practices compatible with the requirements.	Y	N	N	N
Doubts in defining the scope of the project, based on the criteria "importance/abundance and governability of Visa".	N	Y	N	N
Lack of specific knowledge and skill/practice in implementing the proposed models and quality management concepts.	N	N	N	Y
Interruption of the work routine, with numerous demands, to analyze so many requirements.	N	N	N	Y
The availability of *podcasts* as guidance material helped, but it wasn't enough.	N	N	Y	N
Short deadlines for preparing and carrying out the tasks of a very complex project.	Y	N	N	N
Conjuncture				
Identification of problems that are not within the remit of the health surveillance area and that have an impact on the work carried out.	Y	N	N	N
A change of government with adjustments to work processes and the need for rapid responses to demands made it difficult to dedicate time to the start of the project.	N	Y	N	N
Coping with the pandemic by declaring a state of emergency meant that face-to-face meetings to draw up QMS documents were discontinued.	N	Y	Y	Y

Source: Documents and reports of the "*Qualificação da Gestão das Ações Estratégicas de Vigilância Sanitária no SNVS - IntegraVisa II*" (Qualification of the Management of Strategic Health Surveillance Actions in the SNVS - IntegraVisa II) project, 2018-2020.
VE: State Visa; VM: Municipal Visa; Y: Yes, there is the presence of this unfavorable element in the QMS implementation process; N: This factor was not identified in the process; QMS: Quality Management System.

support were important in this process of linking the teams to the QMS implementation proposals.

In a study on obstacles to the implementation of ISO 9001/2015 in the public sector, Abdullah et al.[26] found that the increased workload following the introduction of the management model was a barrier that hindered the progress of the implementation itself. Stoimenova et al.[27], analyzing ISO 9001/2015 certification in hospitals, identified overload and the volume of new documents as hindering factors, in contrast to the perceived benefits related to greater operational efficiency, reduction of errors, advancement of a more preventive than reactive approach and improved patient safety.

It should also be noted that the process of implementing QMS in the four Visas was impacted by the advance of the COVID-19 pandemic and the restrictive social measures needed to combat it, consolidating itself as an important circumstantial condition of difficulty in implementation. Guidance, consultancy and meetings moved to the virtual mode, and the institutions themselves suffered an excessive increase in workload and restrictions on their operation, which, for three bodies, was an obstacle to implementation. In VM1's final report, the following was recorded as a restrictive force on the implementation of the QMS: "The high volume and pace of work during the pandemic has reduced the frequency with which the group is able to dedicate to the implementation of the QMS itself".

The coping strategy used in the situation resulted in a favorable factor: the adaptation of QMS practices to deal with issues related to the COVID-19 pandemic (Chart 1). In this experience, it should be considered that quality management tools are important strategies to be applied to help managers in times of crisis and unfavorable scenarios, and that the implementation of QMS contributes to effective management by preparing the organization for the worse.

VE2 identified as unfavorable factors insufficient human resources and the lack of a team dedicated to the QMS - organizational factors - and, as a favorable factor, the involvement and commitment of the teams that took part in the work carried out. It should be noted that an involved and committed team, even if not numerous or exclusively dedicated, makes a significant contribution to the effectiveness of the system's implementation. VM1 corroborates this analysis by agreeing with the same aspects described here.

Evaluating the application of ISO 9001/2015 standards and certifications in Brazilian public organizations, especially regarding the compatibility between these management technologies and the particularities that characterize these organizations, Bergue[28] explains that the conceptual assumptions of ISO 9001/2015 and the "structuring guidelines of the bureaucratic organization" are "essentially compatible". The success or failure of the implementation does not, therefore, stem from "conceptual incompatibility in the strict sense, but from how the process of appropriating and assimilating the managerial content is conducted". According to this author, a successful implementation necessarily involves defining a clear aim or purpose, which must transcend the merely symbolic aim of seeking formal certification[24].

Changing an organization's management model is a complex and challenging task[29]. However, the current national and international scenario regarding the management of health regulatory systems provides consistent evidence of the need and feasibility of implementing quality management in the services that constitute these systems[11]. Among these elements, we should highlight the PIC/S guidelines[13]; the publication of the WHO guideline on the implementation of quality management systems for national regulatory authorities[11]; and also the publication of RDC Anvisa/MS No. 560/2021[8], which provides for the organization of health surveillance actions carried out by the Union, states, Federal District, and municipalities, relating to operating authorization, licensing, registration, certification of good practices, inspection, and standardization, within the scope of the SNVS.

The favorable scenario does not eliminate the need for adopting a critical stance during training, planning and the incorporation of quality management practices by the teams involved, as pointed out by Ramos[30], in a classic essay on Sociological Reduction, as well as assessed by Bergue and Klering[31], applying this concept specifically to the use of ISO 9001/2015 in public organizations. Some of the important unfavorable factors presented are not difficult to overcome, although they are present and commonly manifest in the Brazilian public administration.

CONCLUSIONS

The methodological path described in this article allowed us to identify the favorable and unfavorable factors for implementing QMS in the four SNVS institutions under analysis. The role of leadership in motivating the team, fostering their engagement, and the support of external consultants were essential and decisive factors. The unfavorable factors faced were the difficulty in understanding the language of quality management, including the description of the requirements of the seven sections and the tools and practices suggested for implementing the continuous improvement cycles. This points to the importance of having a continuous training plan for the teams, as a fundamental strategy for successful implementation.

The scientific contribution and findings of this study, in addition to highlighting elements already identified in research related to the implementation of QMS in public and private organizations, favor the planning and preparation of Visas to advance the guidelines proposed by RDC Anvisa/MS No. 560/2021, regarding the implementation of QMS as a management technology, the greatest benefit of which is to ensure the quality of health products and services consumed by the Brazilian population.

As a limitation of this study, it is prudent to consider that the institutions under analysis were part of a project being carried out to apply the QMS model to SNVS institutions, which is due to end in December 2020. This deadline restricted the holding of more meetings, and limited the recording of information and the collection of data and information to a period of one year, a short time for the implementation of a QMS Consequently, this reduced the possibility of other factors arising that could facilitate or hinder the implementation of this management model in the four Visas participating in the project, in the midst of dealing with a pandemic.

The Visas started the preparation of documents and instruments relating to competence management practices, internal auditing and non-conformities, which usually generate strong resistance and hinder the QMS implementation process, but it was not possible to carry out at least one complete improvement cycle. The same happened with the application of the satisfaction survey, a requirement of the Standard that can provide both integration between the organization's teams and the involvement of interested parties, which favors the process of implementing the QMS.

As a general conclusion, it should be noted that the facilitating factors can be preventively organized and worked on by the respective teams, with a view to boosting implementation and its effects on the performance of SNVS institutions. The unfavorable factors, even those related to the intrinsic characteristics of public administration, such as changes of government, are equally capable of being overcome.

Finally, in the quest to advance knowledge on the subject, further studies could be carried out to assess the effects of implementing this management technology in different SNVS institutions, especially regarding the satisfaction of the regulated sector and citizens with the execution of health regulation and control actions carried out by the three levels of government.

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Authors' Contributions

Barca DAAV, Santos CM, Santos MBS, Zanetta BL - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the paper. Sousa AIA, Silva WM, Borysow IC - Planning (study design) and writing of the paper. All the authors approved the final version of the manuscript.

Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.