

Self-implementation of quality management systems in the National Health Surveillance System: analysis of the strategy applied by the Integravisa III Project

Autoimplantação de um Sistema de Gestão da Qualidade no Sistema Nacional de Vigilância Sanitária: análise da estratégia utilizada no Projeto Integravisa III

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ABSTRACT

Introduction: The implementation of quality management systems (QMS) has been a strategy encouraged by the National Health Surveillance Agency (Anvisa) for bodies within the National Health Surveillance System. **Objective:** This article describes and analyzes a project to support the self-implementation of QMS in state Health Surveillance units (Visas). **Method:** Experience report, which considered the results of an online activity evaluation questionnaire, answered by Visas workers participating in the project, addressing, among other aspects, facilitating and hindering factors for the self-implementation process in the respective institutions, as a corpus of analysis. **Results:** The facilitators were teaching material, consultancy, support for self-implementation, and feedback on documents produced to meet the QMS requirements. The obstacles were the lack of structure, time, and maturity of some teams in dealing with the demands of self-implementation, the excess of work resulting from the overlapping of daily activities with the production of documents for quality management, as well as the absence felt by teams that required more face-to-face time with project consultants. **Conclusions:** The process brought gains to Visas, in general, but it was clear that for the effective continuation of the self-implementation process, commitment and dedication by managers and teams are necessary.

KEYWORDS: Health Surveillance; Quality Management Systems; Distance Learning

RESUMO

Introdução: A implantação de sistemas de gestão da qualidade (SGQ) tem sido uma estratégia estimulada pela Anvisa para Órgãos do Sistema Nacional de Vigilância Sanitária. **Objetivo:** O presente artigo descreve e analisa um projeto de apoio à autoimplantação de SGQ em unidades estaduais de Vigilância Sanitária (Visas). **Método:** Relato de experiência, que considerou como *corpus* de análise os resultados de um questionário *online* de avaliação das atividades, respondido pelos trabalhadores das Visas participantes do projeto, abordando, dentre outros aspectos, fatores facilitadores e dificultadores para o processo de autoimplantação nas respectivas instituições. **Resultados:** Como facilitadores, foram identificados o material didático, a consultoria, o apoio à autoimplantação e os *feedbacks* a respeito dos documentos produzidos para atender aos requisitos do SGQ. Como dificultadores, a falta de estrutura, de tempo e de maturidade de algumas equipes em lidar com as demandas da autoimplantação, o excesso de trabalho decorrente da sobreposição das atividades cotidianas à produção de documentos para a gestão da qualidade, bem como a ausência sentida pelas equipes de mais momentos presenciais com os consultores do projeto. **Conclusões:** O processo trouxe ganhos às Visas, de forma geral, mas ficou claro que, para a efetiva continuidade do processo de autoimplantação, são necessários empenho e dedicação por parte de gestores e equipes.

PALAVRAS-CHAVE: Vigilância Sanitária; Sistema de Gestão da Qualidade; Ensino a Distância

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INTRODUCTION

The Brazilian Health Surveillance (Visa) is constantly faced with the challenge of guaranteeing safe, quality products for human consumption, in a scenario of discovering new technologies to deal with health situations that put the population's health at risk. The objects on which Visa intervenes, of a diverse nature, characterize the complexity of regulatory action, considering the scientific, sanitary, economic and legal aspects that intertwine in the search for the best way to manage and carry out its actions.¹

The need to promote inter-institutional coordination and develop interdisciplinary and multi-professional actions points to the challenge of harmonizing work processes and practices, in the context of the federative systemic conformation that supports the National Health Surveillance System (SNVS) in the state regulatory space.² Meeting this challenge requires the implementation of efficient and effective management models and the transformation of the processes carried out by Visa, with the aim of promoting and converging preventive and inspection actions in the three spheres of government, in a joint effort to qualify action in the territory, both in terms of regulation and sanitary control.³

In this sense, the Brazilian National Health Surveillance Agency (ANVISA), as coordinator of the SNVS, and in line with the recommendations of the World Health Organization (WHO)^{4,5}, which recommend the implementation of quality management systems (QMS) in national regulatory authorities (NRAs), has been promoting the development of projects and actions aimed at implementing a QMS model for SNVS units.

The choice to implement a model based on quality management (QM) in the SNVS is based on the initiatives and experiences worked on by the areas of medicines and medical devices in the first decade of the 2000s⁶. These initiatives prioritized the harmonization of standard operating procedures (SOPs) on a tripartite basis, based on consensus established in working groups that included professionals from ANVISA, states, and municipalities.

The choice and definition of a management model to be undertaken in the SNVS based on QA³, using ABNT NBR ISO 9001:2015 Quality Management System - Requirements of the International Organization for Standardization (ISO)⁷ as a normative reference, strengthens Brazil's participation in efforts to converge international health regulations, contributing to the identification of global risks and the potentialization of national resources.⁸

The ABNT NBR ISO 9000:2015 standard, which presents the fundamentals and vocabulary applied to the requirements of the ABNT NBR ISO 9001:2015 standard, defines QM as a set of coordinated activities to direct and control an organization, enabling the improvement of products and services, guaranteeing the satisfaction of the needs of citizens and the productive sector, or even the exceeding of expectations. The standard establishes that a management system is made up of a set of interrelated

parts or elements, and that the QMS should be understood as the part of this system that emphasizes quality.⁹

As regulatory support for the implementation of QMS in SNVS units, Anvisa published RDC No. 207, of January 3, 2018⁶, which provides for the organization of health surveillance actions in the SNVS, taking as its guiding principle the degree of health risk intrinsic to various products and economic activities, identifying criteria and requirements necessary for health surveillance action on such objects. One of the structuring requirements set out in Art. 2 refers to the implementation of QMS to qualify the actions carried out by the Union, states, Federal District, and municipalities. In August 2021, RDC No. 560 was published¹⁰, which consolidated the guidelines and requirements on the organization of SNVS actions, revoking RDC No. 207/2018, but maintaining the implementation of the QMS as a structuring requirement for the qualification of health surveillance actions in the three federative instances.

Against this backdrop of the qualification of Visa's actions, and with the aim of helping to transform the management practices used by institutions in the three spheres of government, Anvisa and the Oswaldo Cruz German Hospital (HAOC) established an institutional partnership in 2015, through the Institutional Development Support Program of the Unified Health System (Proadi-SUS), to carry out projects that strengthen management in the SNVS and support Visas to achieve greater effectiveness with health promotion and protection actions and thus strengthen their performance within the scope of the SUS.¹¹

Projects were carried out in three three-year periods (2015-2017, 2018-2020 and 2021-2023) aimed at improving management within the SNVS (Series - IntegraVisa). In the 2015-2017 three-year period (IntegraVisa I), initiatives were worked on identifying critical Visa actions, drawing up plans for harmonization, decentralization, and management of the prioritized critical actions¹¹. The IntegraVisa II project (2018-2020) aimed to propose a method to support the implementation of QMS in state and municipal health surveillance bodies, which resulted in the preparation of the "Guide for implementing QMS in SNVS units"¹². At that time, a study was produced in which the factors favorable and unfavorable to the self-implementation of QMS in the four health surveillance units participating in the project in the 2018-2020 triennium were analyzed, and which is currently being published.

In this context of guidance and regulatory support for the management model based on QA to be implemented in the SNVS, the IntegraVisa III project aimed to contribute to the implementation of the QMS Model for SNVS units in state and municipal Visas, incorporating processes and practices for monitoring and evaluating health surveillance actions. The strategy used was based on the existence of two cycles of guided self-implementation (1st Cycle / 10 states - 2021/2022, and 2nd Cycle / 10 municipalities-capitals 2022/2023) with the provision of



a preparatory course for the implementation of QMS in SNVS units, in the form of distance education (DE), and technical consultancy support, aimed at developing the necessary skills to increase management capacity in the SNVS. The Guide produced in the previous three-year period (2018-2020) was used to guide this process of self-implementation of the QMS in the state and municipal Visa units, to which the experience reported here refers.

The two main tools of this process - the education strategies (DE course and Implementation Guide) and face-to-face and online consultancy - have been used in the QMS implementation process. DE courses have the potential to disseminate knowledge to students anywhere in the world, in a way that is adaptable to their schedules. On the other hand, consultancy, classified here as “process”, is understood as a philosophy and attitude that aims to help individuals, groups, and organizations develop and learn organizationally to improve management and work practices. The consultant invests in building the readiness of workers and managers to learn and change work schemes and improve processes.¹²

In view of the above, the aim of this article is to describe and analyze the strategy used by the IntegraVisa III QMS self-implementation support project, pointing out the factors that are favorable and unfavorable to QMS self-implementation in SNVS units.

METHOD

This study was carried out as part of the project Qualifying the Management of Strategic Health Surveillance Actions in the SNVS - IntegraVisa III, a partnership between Anvisa and HAOC, through Proadi-SUS. The experience report was based on an exploratory and descriptive study, with a quantitative and qualitative approach, referring to the strategy of supporting the process of self-implementation of the QMS model in 10 states included in the 1st Cycle of Self-Implementation of QMS in the SNVS, provided by the IntegraVisa III Project. This is also documentary research, as we used as a *corpus* of analysis materials from secondary sources, which have not received analytical treatment.¹³

The choice of the 10 states to take part in the 1st Cycle was defined together with representatives from Anvisa, based on criteria that included: the initiative to implement a management model based on QA; the availability of a team to form a steering group for the process at Visa, called the Quality Management Group (QMG); the availability of material resources and equipment for access to virtual meetings; as well as participation and adherence to the previous implementation of standard operating procedures harmonized at the tripartite level. The group was then formed by the following states: Amazonas, Ceará, Espírito Santo, Goiás, Maranhão, Paraíba, Pernambuco, Piauí, Rio de Janeiro, and São Paulo.

Data was collected from October to December 2022 using electronic forms applied to students on the Preparatory Course for the Implementation of QMS in SNVS units and members of the guided self-implementation team in the 10 Visa bodies. The

electronic tool for analyzing the guided self-implementation of the QMS in SNVS units was made available on the e-learning course platform and included eight blocks of questions: characterization; relevance and application of the concepts and practices presented in the DE modality; relevance and contribution of the consultancy to the guided self-implementation of the QMS; understanding of the requirements according to the sections of the QMS model; understanding of the practices worked on during the 1st Cycle, according to the sections of the QMS model; understanding of the management model; situation of the guided self-implementation of the QMS model in the IntegraVisa Project; and perceived effects on the management of the Visa unit.

The data was presented in aggregate form, maintaining the confidentiality of the respondents, and arranged in an Excel® spreadsheet. A descriptive statistical analysis was carried out which considered the following identification variables: gender, age, federated unit of professional activity, position, and length of time working at Visa. The answers were systematized by region of the country, considering the four regions that included federal units in the survey (Central-West, North, Northeast, and Southeast). Questions were then presented with the following themes: relevance and application of the concepts and practices presented in the distance education modality; relevance and contribution of the consultancy to the guided self-implementation of the QMS; understanding of the requirements according to the sections of the QMS model; understanding of the practices worked on during the 1st self-implementation cycle, according to the sections of the QMS model; understanding of the management model. These questions could be answered with the options “not very relevant”, “relevant”, and “very relevant”. Another two closed questions were presented at the end: level of self-implementation, with specific options on this topic, and perceived effects on the management of the Visa unit, with the options for relevance as presented above.

The qualitative analysis was based on the content analysis method¹⁴ and took as its *corpus* the answers to two open questions: criticisms and suggestions about the relevance and application of the concepts, content, and practices; and criticisms and suggestions about the consultancy's contribution. Similar answers were gathered into empirical categories which were then analyzed considering two analytical categories: facilitators for learning and implementing the QMS; and obstacles to learning and implementing the QMS, as proposed by Santos¹⁵ for the analysis of the implementation of a QM program, inspired by the initial stages of an implementation evaluation¹⁶. To interpret the data, we used Kirkpatrick's model¹⁷, which aims to assess the transfer of learning. According to the author, there are four possible levels for measuring the dimensions of learning: reaction evaluation, which considers how the participants feel about the training activities or experiences they have had; learning evaluation, which aims to measure the increase in knowledge, comparing before and after; behavior evaluation, which considers the application of the student's learning in their work environment;



and results evaluation, which seeks to measure the effect of the training in terms of the change in the student's behavior¹⁷. The interpretations were also based on authors who have presented experience in implementing QMS and who have produced research on consultancies.

As for ethical aspects, this study analyzed public data, as it is a Proadi-SUS project. These data make up the production report of the Integravisa project¹⁸, which is sent to the requesting body (ANVISA) and the Department of Technical Cooperation and Development in Health (Decoop), linked to the Executive Secretariat of the Ministry of Health, and is therefore in the public domain. The data was made available by the HAOC in aggregate form, and it was not possible to identify the subject who generated the information, maintaining the confidentiality of the data and, therefore, dispensing with prior authorization by the Research Ethics Committee, in accordance with the Resolutions of the National Research Ethics Commission (Conep).¹⁹

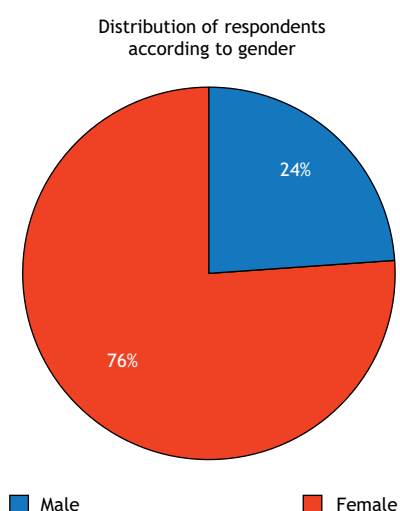
RESULTS

Ninety-five people completed the e-learning course and 67 answered the questionnaire, which corresponded to 70% of the total number of people who completed the course, all of them workers from Visa agencies that are components of or linked to state health departments. Of the respondents, 16 were male (23.9%) and 51 female (76.1%). The majority were aged between 35 and 44 (23 people, 34.3%), and there was a considerable percentage between the ages of 45 and 54, and 55 and 64 (15 and 16 respectively, 22.4% and 23.9%) (Figures 1 and 2).

Regarding the length of time they have been working at Visa, the answers were more evenly distributed. Professional experience of up to two years was answered by 12 people (17.9%); from two to five years, by 16 people (23.9%); from five to 10 years,

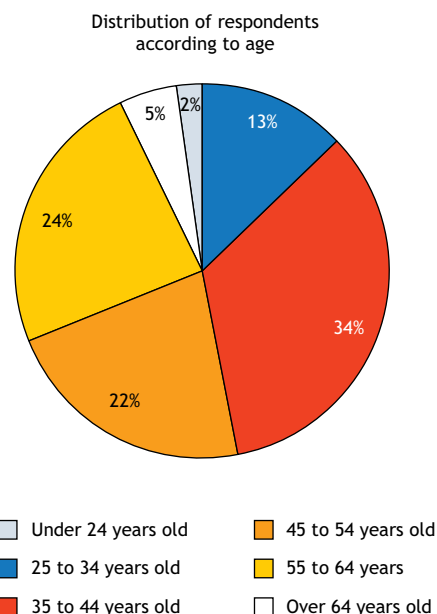
11 answers (16.4%); from 10 to 20 years of experience, 15 people (22.4%); and with over 20 years of experience, there were 13 respondents (19.4%), as illustrated in Figure 3.

As far as job titles are concerned, the vast majority (51 or 76.1%) are higher education professionals, 12 of the respondents (17.9%) are managers, and only four (6%) are mid-level professionals, according to Figure 4.



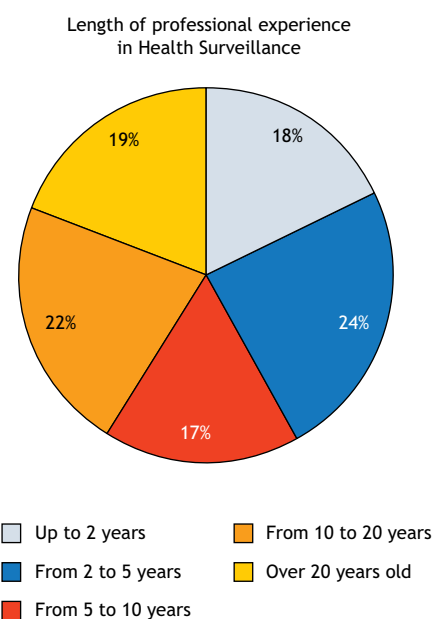
Source: Prepared by the authors, 2023.

Figure 1. Percentage of respondents according to gender.



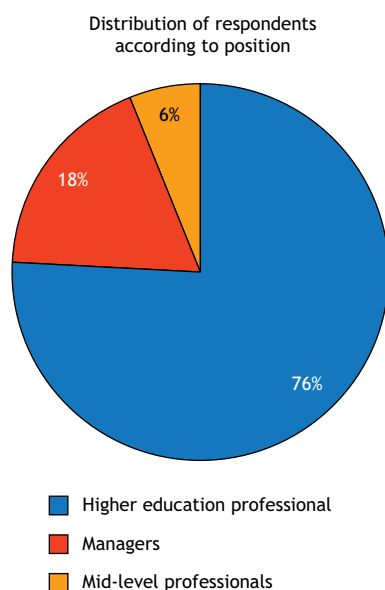
Source: Prepared by the authors, 2023.

Figure 2. Percentage of respondents according to age group.



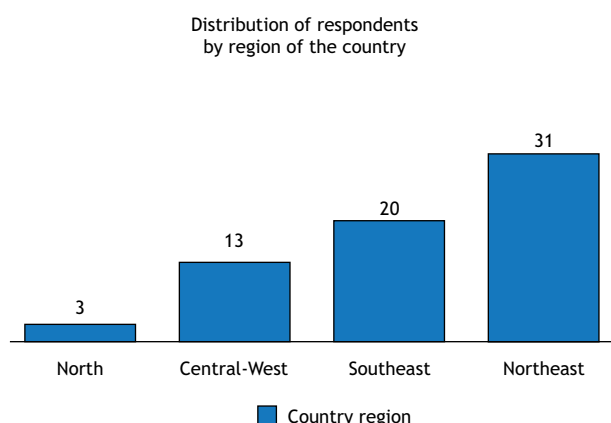
Source: Prepared by the authors, 2023.

Figure 3. Percentage of respondents according to length of time working in Health Surveillance.



Source: Prepared by the authors, 2023.

Figure 4. Distribution of respondents according to position.



Source: Prepared by the authors, 2023.

Figure 5. Distribution of survey respondents according to region of the country.

The respondents were distributed across four regions of the country - North, Northeast, Southeast, and Central-West. In the Northeast there were a greater number of state Visas participating in the project and, as a result, a greater number of people in that region: Central-West Region (one state) 13 respondents = 19.4%; Northeast Region (five states) 31 respondents = 46.3%; North Region (one state) three respondents = 4.5%; Southeast Region (three states) 20 respondents = 29.9%. Figure 5 illustrates this distribution.

Regarding the respondents' perception of the course, Table 1 shows the results according to the components of the questionnaire applied to the students.

It can be seen that the teaching material was considered more relevant to learning than the video lessons and other course activities (76.1% of respondents), with no scores identified as "not very relevant".

Regarding the applicability of the course to professional practice, more than half of the respondents considered it "very relevant" (61.2% of respondents), while 38.8% considered the course to be "relevant".

In the open question, which asked for criticism and suggestions about the relevance and application of the concepts, contents and practices, some of the answers are presented below, according to common themes:

- a. Reaffirmation of the relevance of the course and materials to learning (25 responses):

The material is good and easy to understand (P1).

A course rich in content, which enabled continuous implementation of the QMS (P13).

[...] the methodology applied in this course meets our needs for exchanging knowledge and learning (P16).

I think the concepts, contents, and practices were relevant. Our Visa unit has established a work process to implement the QMS (P24).

Given that most health regulations already have a structure that requires companies to have a Quality Management System, it is extremely important that the Visa bodies also have a Quality Management System in place. In this way, the course is of great relevance to our day-to-day work (P28).

Throughout the teaching-learning process, the necessary adjustments were made to improve learning, for example regarding the methodologies used in the seminars, and the end result was very positive in terms of reconciling theory and practice. Although we still have many challenges ahead of us in consolidating the QMS at Visa, the content and activities carried out along the way have provided us with essential theoretical support for understanding our work processes (P32).

- b. Lack of more practical activities in the course, with examples of how to apply the QMS at Visa (10 answers):

It would be important to review the didactics of the course so that there was more interaction between the group, considering more practical activities linked to the QMS implementation process (P36).

More practices to ensure greater safety in learning (P38).

I believe that the practical application of the concepts and content would be more appropriate once the theoretical part of the course has been completed in full. It increases understanding of the QMS as a whole (P39).

[...] there is no "recipe"; for the practical application of all the requirements for a QMS Implementation, where there is a lot of theory, a lot of reading, what would be interesting would be videos of possible practices, actions, simulations, or demonstrations of how to operate in an implementation. For example: video dramatization, simulating a theater in a company with actors, etc., would be very cool! (P58).

**Table 1.** Contribution of the 1st Preparatory Course for the Implementation of QMS in SNVS units to the application of concepts and practices in state health surveillance agencies.

DE course component	Location/Attribution of relevance														
	Central-West Total = 13			Northeast Total = 31			North Total = 3			Southeast Total = 20			Total = 67		
	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3
Didactic material/ learning guide	0	6	7	0	5	26	0	0	3	0	5	15	0	16 = 23.9%	51 = 76.1%
Video lessons for learning	0	8	5	1	16	14	0	2	1	1	6	13	2 = 3%	32 = 47.8%	33 = 49.3%
Learning activities/ assessments	0	7	6	0	15	16	0	2	1	2	9	9	2 = 3%	33 = 49.3%	32 = 47.8%
Seminars on the learning sections of the model	0	8	5	0	10	21	0	3	0	2	9	9	2 =	30 = 44.8%	35 = 52.2%
Perception of the course's applicability	Central-West Total = 13			North East Total = 31			North Total = 3			South East Total = 20			Total = 67		
	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3
Application of the QMS concepts and practices studied in professional practice	0	7	6	0	9	22	0	2	1	0	8	12	0	26 = 38.8%	41 = 61.2%
Implementation of the QMS at Visa	0	8	5	0	7	24	0	0	3	1	7	12	1 = 6.7%	22 = 32.8%	44 = 65.7%

Source: Prepared by the authors, 2023.

QMS: Quality Management System; DE: Distance Education; Visa: Health Surveillance.

(1) Not very relevant; (2) Relevant; (3) Very relevant.

- c. Difficulty in engaging or lack of capacity on the part of Visa participants with the implementation of the QMS (six responses):

A course with a lot of material and little time for activities, as we continue with our work routine (P5).

Regarding the implementation of the QMS at the Visa where I work (last question), the course was of great value, but the institution is not mature and does not have enough HR to accept and apply it, according to the QMS requirements (P6).

Although the leadership of our unit has presented limitations to the implementation of the QMS at the present time, it has been extremely important for the performance of the activities I carry out (planning and information) (P11).

The members of Visa XXX lacked more commitment to the course. Few were up to speed on the subjects (P26).

Difficulties in bringing together professionals to self-implement the QMS (P52).

- d. Criticism and suggestions on the content and format of the materials - course and guide (six responses):

It would be interesting to make the classes more dynamic and some concepts more in-depth (P9).

The downloadable material for the course lessons doesn't contain all the information that was presented in the lessons, especially on how to implement the practices. I feel that this information will be missing when the time comes to implement the practices, since these details are not in the Guide and the course will no longer be available (P33).

Put up more attractive videos.

[...] Regarding content, I would like all the audio lessons to be available for later consultation during implementation, as well as in physical form. It would be interesting if they already defined a scope to start with, which would be common to all (P19).

The assessment activities could be improved to encourage a better understanding of the concepts (P20).

- e. No comments or nothing to add: 10 answers.

- f. Requests per classroom course (three responses):

I suggest that the course has more face-to-face meetings to strengthen learning (P4).

If possible, a greater number of face-to-face meetings (P18).

I'd like a face-to-face course (P34).

- g. Comments on the seminars (three answers):

As a suggestion, the seminars could be more dynamic, as the last two were, encouraging more active participation from all the Visas representatives in carrying out and evaluating the proposed tasks (P31).

In the seminars, I believe that providing a longer period of time to carry out the practices, always with the help of the consultants, makes it possible to develop the activities better (P48).

Regarding the relevance and contribution of the consultancy to the targeted self-implementation of the QMS by the Visa teams, we present the table below.

For both the item "support from consultants" in virtual meetings and "contribution of

**Table 2.** Contribution of the HAOC consultancy to the guided self-implementation of QMS in Health Surveillance units participating in the 1st implementation cycle, 2021-2022.

Item	Location/Attribution of relevance														
	Central-West Total = 13			Northeast Total = 31			North Total = 3			Southeast Total = 20			Total = 67		
	1	2	3	1	2	3	1	2	3	1	2	3	1	2	3
1. virtual meetings															
Technology and format used	0	10	3	0	13	18	0	2	1	1	7	12	1 = 1.49%	32 = 47.7%	34 = 50.7%
Drawing up the improvement plan	0	11	2	0	16	15	0	2	1	2	8	10	2 = 2.9%	37 = 55.2%	28 = 41.7%
Support from consultants	0	8	5	0	4	27	0	0	3	0	4	16	0	16 = 23.8%	51 = 76.1%
2. Contribution of monitoring visits to the self-implementation of the QMS	0	7	6	0	4	27	0	0	3	0	5	15	0	16 = 23.8%	51 = 76.1%
3. Non-face-to-face monitoring by the HAOC focal point	0	9	4	0	12	19	0	3	0	1	7	12	1 = 1.49%	31 = 46.2%	35 = 52.2%
4. Support for drawing up QMS documentation	0	7	6	0	8	23	0	1	2	1	6	12	1 = 1.49%	22 = 32.8%	44 = 65.6%
5. Feedback given by the project team to the material prepared by the Visa unit	0	4	9	0	7	24	0	2	1	0	7	13	0	20 = 29.8%	47 = 70.1%

Source: Prepared by the authors, 2023.

QMS: Quality Management System; DE: Distance Education; Visa: Health Surveillance; HAOC: Oswaldo Cruz German Hospital.

(1) Not very relevant; (2) Relevant; (3) Very relevant.

follow-up visits to self-implementation”, most participants answered that these were “very relevant” strategies (51 = 76.1%), while 16 of them answered only “relevant”. The “improvement plan” tool, developed with the teams during the support activities, was considered “relevant” by 55.2% of the participants (37 responses) and “very relevant” by 41.7% (28). For two people, the tool was “not very relevant”. Non-face-to-face support from the focal point for the teams was declared “very relevant” by 52.2% of the respondents (35 people), while 46.2% (31) of the participants identified this support as “relevant” and only one person considered it “not very relevant”. Regarding “support for the preparation of QMS documentation”, the vast majority of participants answered that this activity was “very relevant” (44 = 65.6%), while 22 respondents (32.8%) identified it as “relevant”. There was only one “not very relevant” response. Associated with this process, most respondents stated that the feedback given by the project team was “very relevant” (70.1% of respondents or 47 people) while 29.8% considered it only “relevant” (20 respondents).

In the field of descriptive answers “criticisms and suggestions about the consultancy’s contribution”, below are some of the answers that seemed most relevant.

h. Positive statements about the consultancy’s contribution (32 responses):

I found the consultancy accessible and the material very good (P1).

The contributions were very enlightening and guided the progress of the process (P9).

The consultancy added to the construction of knowledge by bringing important experience reports on the implementation of the QMS (P20).

The guidance and support of the team of consultants was very important for the implementation of the QMS at Visa XXX. Our acknowledgement to everyone! (P31).

The Guide and the course provide a good learning path for the concepts and practices of the QMS, but only with the support of the consultants were we able to identify the ideal sequence for developing the practices for implementing the QMS (P46).

The consultancy contributed a lot and pointed out the ways in which I found it interesting and relevant to adapt to Visa’s processes (P46).

i. Considerations regarding face-to-face activities (12 answers):

The face-to-face meetings were the ones that contributed most, within the method used, to the discussion and consolidation of the learning content. The virtual meetings also played an important role, as the discussion took place on the products presented by the QAG (P6).

Certainly, the impossibility of face-to-face meetings, in smaller groups, especially in seminars, compromised the depth of the topics, given the limited time of the activity when carried out virtually (P11).

Virtual meetings provide opportunities for more frequent agendas, reducing costs for the project, but they are limited tools for guiding and directing the activities of each stage (P16).



The face-to-face consultancy was fundamental for a better understanding of the reality of working at Visa (P26).

Thinking about the profile of the professional who works in surveillance, the day-to-day weaknesses of the service and the complexities of the areas of work and activities they carry out, I believe the course should be rethought in a hybrid modality. The face-to-face support made all the difference in terms of better directing the discussions and carrying out the activities (P61).

j. Considerations on the conditions of the Visa teams (two answers):

As we are decentralized, our participation has been compromised (P5).

[Improvement in the working environment and conditions; greater integration between employees; improving internal communication (P15).

k. Considerations on improving the process in relation to meetings and materials (11 responses):

Regarding the Seminars, which bring together Visa from different FUs, perhaps the program and the content discussed need to be revised, as I felt that the experiences could be better explored (P6).

The instructors were very present, they were all committed to resolving the issues, but in some meetings, I felt that they didn't direct everyone in the same way (P19).

As for feedback, there was a lot of back and forth, even following the models presented in the guide (P21).

It would be interesting if it were possible to maintain some kind of contact for the general implementation of the quality system in the state of São Paulo, as there will certainly still be many doubts throughout the process (P25).

We are grateful for the support and the suggestion is to include technicians from Anvisa or other Visas with more experience in Health Surveillance in the Advisory Team, as a way of continuously improving the rethinking and understanding of our work processes and the implementation of the QMS aimed at Visa actions (P33).

It would be interesting to hold workshops in the institution with the support of the HAOC team, to strengthen the process of implementing the QMS (P36).

I felt the need for more feedback from the project team not only on the material prepared, but also on the corrected material. As this is my first contact with QMS material, it would be necessary to work on the activities more to ensure better learning (P38).

There were nine responses without comment or criticism.

Finally, Table 3 summarizes the responses regarding the situation of self-implementation of the QMS, as declared by the respondents.

Table 3. Perception of the status of the guided self-implementation of the QMS model, comparing the initial and final situations of the Visas, during participation in the 1st Self-implementation Cycle of the IntegraVisa project, 2021-2022.

Situation at the end of the project	Region				Total (%)
	Central-West	North East	North	South East	
The Visa where I work had no Quality Management practices in place before the IntegraVisa Project and was unable to implement the logic in its management model.	0	1	-	2	3 (4%)
The Visa where I work did not have any Quality Management practices in place before the IntegraVisa Project and managed to implement some practices during the IntegraVisa Project.	0	6		4	10 (15%)
The Visa where I work had no Quality Management practices in place before the IntegraVisa Project and managed to implement the logic for its management model.	0	6	1	1	8 (12%)
The Visa where I work had only incorporated the SOPs harmonized at the tripartite level in the execution of its actions and was unable to implement the logic of the management model based on Quality Management during the IntegraVisa Project.	4	5	1	5	15 (23%)
The Visa where I work had only incorporated the SOPs harmonized at the tripartite level in the execution of its actions and managed to implement the logic of the management model based on Quality Management during the IntegraVisa Project.	5	7	-	5	17 (26%)
The Visa where I work had implemented a management model based on Quality Management, reinforced the appropriation of the concepts and perfected the implementation of other practices and the continuous improvement cycle during the IntegraVisa Project.	3	6	1	3	13 (20%)

Source: Prepared by the authors, 2023.

SOP: Standard Operating Procedure; Visa: Health Surveillance.



DISCUSSION

Facilitators of learning and self-implementation of the QMS

As can be seen from the answers in Table 1, the majority considered the DE course to be a very relevant strategy, which leads us to understand it as a facilitator for the implementation of the QMS, especially the teaching material provided. This was confirmed by the qualitative responses, the majority of which praised the training, the content provided and the suitability of the course to the reality of Visas. In some responses, it was possible to understand that taking part in the course in parallel and combined with the consultancy activities was an important strategy for implementing strategies and techniques linked to the QMS.

The support of the consultants, the on-site visits, and the feedback on the production of the documents were also considered to be very important for learning and implementing the QMS. Among the elements pointed out by the 32 respondents who made purely positive comments in their descriptive answers, the main points stated about the consultancy were: availability, easy access to the consultants and the proper conduct of the activities and groups to encourage self-implementation. Most of these respondents (26) stated that, at the end of the course evaluation tool (Table 3), they had managed to implement QM practices in their respective Visas, which leads us to infer that readiness for change seems to have been stimulated¹², confirming the consultancy's contribution to the implementation of the QMS.

Considering the total number of responses with positive content to the two open questions (23 about the Guide and the DE course and 32 about the consultancy), there were more responses in the second group, which highlighted the consultancy's contribution to learning and implementing the QMS. This may be associated with the importance that meeting the consultants in person has compared to taking an online course, which was confirmed by 11 of the respondents, who said that the face-to-face meetings with the consultants were essential for a better understanding of the content. In fact, external consultants have been highlighted in literature as a fundamental factor in the implementation of a QMS, when they fulfill their role of helping the teams.^{15,20}

As well as a better understanding of the content by the participants, this approach favored the consultants' knowledge of the day-to-day practices of the Visas (as pointed out by some of the respondents) and, as a result, better correspondence with the contents of the QMS. This confirms the attitude expected of consultants, of understanding the reality in which they are working to help with joint diagnostic activities and propose the necessary changes.¹²

When it comes to analyzing the degree of learning, according to the descriptive answers, there were 17 answers that only pointed out the understanding of the concepts and the cognitive gains from learning, without mentioning the use of the knowledge. In

this group, it was possible to verify the students' spontaneous declaration that they understood the content, i.e. that there had been learning according to Kirkpatrick's level 2¹⁷, which refers to the absorption of knowledge. Cross-referencing this data with the answers obtained in the question about the implementation of QMS practices, 15 of the respondents reported that they had implemented some practices or the QMS logic in their Visas, already advancing to level 3 of Kirkpatrick's assessment, i.e. indicating a change in behavior as a result of learning.

In addition to these respondents, there were six who spontaneously stated in the question "criticisms and suggestions about the relevance and application of the concepts, contents, and practices" that they had used this knowledge to start implementing the QMS, and five of them confirmed this information by stating that they had implemented the logic or some practice of the QMS in their Visa in the last question of the instrument. In this sense, they confirmed, in another way, the change in behavior as understood by Kirkpatrick.¹⁷

Although there were three respondents to this question who requested more face-to-face meetings for better learning, they said they had applied the QMS logic in the Visas where they work. Although the activities were not 100% face-to-face, learning was favored to the extent that the participants were able to apply the knowledge built up in practice, even with hybrid activities, obtaining good results at levels 2 and 3 on the Kirkpatrick scale.¹⁷

Obstacles to learning and self-implementation of the QMS

The way the quantitative data was produced and presented made it impossible to analyze the obstacles to self-implementation of the QMS from this source. However, the descriptive, qualitative responses pointed to important elements for verifying possible obstacles.

In the question "criticisms and suggestions about the relevance and application of the concepts, content, and practices", 10 participants said that they would have liked the course and seminars to present more practical activities and examples of implementation. Their statements revolved around the perception that the content was too theoretical, the text of the requirements unclear and that there was a lack of examples to solidify understanding. Of this total, seven said they had implemented the QMS logic or actions, and three had not. In this sense, we can understand that although they found the content difficult to understand, most of them managed to make progress, even if only partially, in implementing the QMS. Even so, these criticisms could serve to improve the activities offered by the project, as we know that very theoretical content may not be well assimilated by some of the project participants. There is relative difficulty in understanding and appropriating QA concepts, as other experiences have shown^{21,22,23}. In the case of civil servants, many of them lack the time and opportunities to carry out improvement activities and further their studies, given that the civil servant training agenda has not been a priority for governments, including the fact that they end up not emphasizing the more systemic analysis of the problems they



face, which would consider training as an important strategy for solving these problems.²⁴

Other studies have also shown these difficulties when implementing ISO 9001 in the public sector. The workload, which is already exhausting, becomes heavier when the implementation of QA practices begins. These changes take time to be incorporated into existing processes, requiring more willingness and study on the part of workers and managers. In this sense, the voluminous production of new documents and workflows burdens workers, who will only be able to see or perceive the benefits of greater operational efficiency, with the reduction of errors and problem prevention strategies, some time later.^{23,25,26,27}

As for the eight answers to the same question - "criticisms and suggestions about the relevance and application of the concepts, contents, and practices" - which dealt with the organizational context of the Visas, seven of them reported a lack of commitment or maturity on the part of teams and leaders, and one was more directed at general working conditions. Of these seven respondents, five said that they had not managed to implement QMS logic or practices at the Visas where they work. It is understood that this element was a significant obstacle to the implementation of the QMS, the success of which requires minimum working conditions, availability of time and team organization, as well as support from the leadership, as has already been seen in other experiences of implementing the QMS.^{23,28,29,30,31}

The three respondents who criticized the length of the seminars and the lack of a dynamic model said that they had managed to implement QMS actions. In this sense, although the comments were used to improve the seminars in the next cycle of the project, the format of these activities did not seem to be an element that hindered learning and the implementation of the QMS.

CONCLUSIONS

Analyzing the facilitating and hindering factors for QMS self-implementation based on the DE course, face-to-face and distance consulting, and the support of focal points revealed the potential that multiple and interconnected strategies have for team learning and the application of knowledge to improve work techniques. On the one hand, the availability of good teaching material, specialized support from consultants, support visits, and feedback on the production of documents, as well as support from leaders, were highlighted as essential strategies for the progress of self-implementation. On the other hand, the lack of face-to-face consultancy, the lack of structure, maturity and time for some teams to devote to studying and implementing QMS strategies and techniques, as well as the excessive production of documents to meet requirements, were factors identified as obstacles to be overcome in new self-implementation cycles to be developed at SNVS.

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Authors' Contribution

Borysow IC, Barca DAAV, Santos CM, Santos MBS, Zanetta BL - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the paper. Silva WM, Matta ASD, Cunha JS - Elaboration and writing of the paper. All the authors approved the final version of the work.

Conflict of Interest

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



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