

History of the development and implementation of a national system for the management of product samples in Health Surveillance

Histórico do desenvolvimento e implementação de um sistema nacional de gerenciamento de amostras de produtos em Vigilância Sanitária

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ABSTRACT

Introduction: Information is an essential tool for decision-making, and contributes to the “information-decision-action” process. **Objective:** To report the National Institute for Quality Control in Health (INCQS, by its acronym in Portuguese) experience in the development and implementation of a national information system for the management of samples of products of interest to health - from receipt in the laboratory to the issuance of analytical reports - and to present the possibility of its contribution to the National Health Surveillance System (SNVS). **Method:** This is a document analysis study on the development and implantation of Harpya (Sample Management System), its evolution and advances from 1986 to 2020. Access to the system by users, the existence of a centralized database, the implantation in the National Network of Laboratories Health Surveillance (RNLVISA, by its acronym in Portuguese) and the creation and use of nationally standardized catalogs were discussed. **Results:** The data and information generated by RNLVISA on the quality of products can generate scientific evidence for the identification of risk, being fundamental for the decision-making of managers. In addition, they contribute to the evaluation of laboratories and to the monitoring of market products, subsidizing health surveillance actions. **Conclusions:** The possibility of accessing data at the national level by different technical areas of the National Health Surveillance Agency stands out, supporting the coordination of the SNVS and also that Harpya’s information can contribute with other information systems in the resolution of public health problems in the country.

KEYWORDS: Information Systems; Health Surveillance; Product Samples; Public Health Laboratory Services

RESUMO

Introdução: A informação é instrumento essencial para a tomada de decisões, e contribui para o processo “informação-decisão-ação”. **Objetivo:** Relatar a experiência do Instituto Nacional de Controle de Qualidade em Saúde no desenvolvimento e na implantação de um sistema de informação nacional para o gerenciamento de amostras de produtos de interesse à saúde - do recebimento no laboratório até a emissão dos laudos analíticos - e apresentar a possibilidade de sua contribuição ao Sistema Nacional de Vigilância Sanitária (SNVS). **Método:** Trata-se de um estudo de análise documental sobre o desenvolvimento e implantação do Harpya, suas evoluções e avanços de 1986 até 2020. O acesso ao sistema pelos usuários, a existência de base de dados centralizada, a implantação na Rede Nacional de Laboratórios de Vigilância Sanitária (RNLVISA) e a criação e utilização de catálogos padronizados nacionalmente foram discutidas. **Resultados:** Os dados e informações gerados pela RNLVISA sobre a qualidade de produtos podem gerar evidências científicas para a identificação do risco, sendo fundamentais para a tomada de decisões

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dos gestores. Além disso, contribuem para avaliação dos laboratórios e para o monitoramento dos produtos do mercado, subsidiando as ações de vigilância sanitária. **Conclusões:** Destaca-se a possibilidade de acesso aos dados em nível nacional por diferentes áreas técnicas da Agência Nacional de Vigilância Sanitária, subsidiando a coordenação do SNVS e, ainda, que as informações do Harpya podem contribuir com outros sistemas de informação na resolução dos problemas de saúde pública existentes no país.

PALAVRAS-CHAVE: Sistemas de Informação; Vigilância Sanitária; Amostras de Produtos; Serviços Laboratoriais de Saúde Pública

INTRODUCTION

Information is an essential instrument for decision-making and contributes to the “information-decision-action” process. Several authors have affirmed the importance of information for the planning, implementation, implementation, and evaluation of health actions and services^{1,2,3,4}.

Information on the morbidity and mortality profile, most frequent risk factors and their determinants, demographic characteristics, and medical and health care services are essential and part of them are commonly available in nationally consolidated information systems^{1,2,3,4,5}, which provide the necessary support so that the managers’ decisions and actions are based on reliable and timely information.

Health surveillance, which is responsible for preventing and minimizing health risks when related to products and services, is organized into national actions through the National Health Surveillance System (SNVS)^{6,7} and, like other areas of the health sector, has information as to its greatest input⁸.

The volume of information produced, as well as the knowledge generated in the regulation process and the need for agile and transparent work processes, make information systems essential tools for the practice of health surveillance in fulfilling its mission⁸.

Access to quality information in the necessary time is essential and providing access to technical and scientific knowledge databases is an arduous and expensive task^{8,9}. In addition, it is essential to publicize health surveillance actions for society as a whole⁹.

In spite of the relevance of its performance, there is still no single information system in health surveillance that provides information on regulatory actions, including the quality control of products and services at the national level. The information is arranged in different systems, such as post-market control - notifications of adverse events and technical product complaints - in the Health Surveillance Notification System (Notivisa)¹⁰ and VigiMed¹¹.

Another system used by Health Surveillance (Visa) is the National Health Surveillance Information System (SINAVISA)¹², which allows the registration of establishments, inspection schedules, and monitoring of the quality of some products.

The information produced by the National Network of Laboratories Health Surveillance (RNLVISA)¹³, formed by the National Institute for Quality Control in Health, 27 Central Laboratories of Public Health (LACEN) and their respective regional and national laboratories five municipal laboratories on products of interest

to health, such as cosmetics, sanitizers, medicines, pharmaceutical supplies, blood, components and blood products, water, food, and health products, are strategic.

The analysis of products carried out in different modalities (tax, control, and monitoring) generate evidence for the identification of health risk, being fundamental for its management, in addition to being necessary for the evaluation of SNVS actions and services¹³.

This information was dispersed and under the coordination of only each federal unit, which caused inconvenience and difficulty in accessing and using it in a timely manner.

Developed at the National Institute for Quality Control in Health of the Oswaldo Cruz Foundation (INCQS/Fiocruz), in partnership with the Brazilian National Health Surveillance Agency (Anvisa) and funded by the United Nations Development Program (UNDP), the Harpya - Laboratory Sample Management System is used to manage product samples submitted to health surveillance, from registration to the issue of analytical reports¹⁴.

It was implemented in 53 RNLVISA laboratories, including 21 regional laboratories and four of the five municipal laboratories, standardizing and integrating in real-time the information related to the analyzes¹⁵. The objective of the present work was to report the INCQS history and experience in the development of computerized systems since 1986 and the implementation of the current Harpya, discussing its contribution to SNVS.

METHOD

Study type and development

It is a document analysis study that describes the INCQS history and experience on the development and implementation of Harpya, its evolution and advances from 1986 to the present day (2020). Initially, a history of the creation and implementation of the system was made, with detailed progress, comparing the systems in terms of characteristics: access, the existence of a centralized base, implementation at RNLVISA, and use of nationally standardized catalogs. Subsequently, the work presents the current and possible contributions of Harpya to SNVS.

Data sources and analysis

Secondary data available at the time (minutes of meetings, manuals of information systems developed and implemented, and published ordinances) on the topic were used^{16,17,18,19}.



The institutional documents were searched according to the year of development and implementation of the systems, and observations made by INCQS technicians assigned to the Information Technology Management Service throughout the process were also incorporated into this report.

The data were analyzed and consolidated in the period from 2019 to 2020.

RESULTS AND DISCUSSION

History and evolution of the sample management system

In the 1980s, INCQS, thinking about the management of the laboratory analysis process, developed the SAMO 4 system that had communication with the National Immunization Program (PNI) of the Ministry of Health (MS)²⁰.

After 10 years, this system was replaced by the Quality Control Laboratory (QCL) (1996 to 1999), developed by the World Health Organization (WHO), and adapted to the needs of INCQS, also with communication with the PNI-MS.

In 1997, the QCL was implemented in LACEN in the states of Ceará, Minas Gerais, Pernambuco, and Paraná. This system was replaced by the Sample Management System (SGA) - SGA2000; developed by an information technology company and by INCQS, still with communication with PNI-MS.

In 2001, all LACEN were trained at SGA2000 but the indication for training professionals who did not have the necessary skills, as well as the turnover of computer technicians, made it impossible to implement or continue local system support. At the end of 2015, 12 LACEN kept it in operation, and each laboratory had its database.

At the beginning of 2008, the architecture of the SGA2000 no longer supported the needs to implement new requirements and, with technological advances, the proposal for updating the SGA2000 to a web version was presented by the INCQS development team. This version took into account the needs of INCQS, the experience of using the SGA2000, and the suggestions of LACEN.

The new version would be a web system with a single database (centralized), and the laboratories would access information from your domain.

LACEN's difficulty in terms of resources to maintain infrastructure and support for the local system, technological evolution, unification, and centralization of the system was an aspect taken into consideration when deciding on the development of the web version, meeting the new requirements, and facilitating use, without having to worry about maintenance.

SGAWeb was created with the intention of being RNLVISA's information system, integrating the analytical data produced by the official public health laboratories.

The advantages of implementing this system were the use of free software, free of charge with information technology

tools and equipment for the network laboratories, and the possibility of the data being hosted on a central server (at INCQS, initially), without the need for infrastructure of local servers in the labs.

Any computer with internet access could access the system without the need for special local configurations, minimizing the work of computer support.

SGAWeb was implemented at INCQS in August 2010 and, in April 2011, it was presented to the General Management of Public Health Laboratories (GGLAS) and other technical areas at Anvisa.

On the occasion, the possibility of Anvisa financing the implementation of the system for other RNLVISA laboratories was discussed, as well as the need to define criteria for access.

In June 2011, the SGAWeb's National Steering Committee¹⁹ was created and a test environment for system evaluation was made available to LACEN.

In spite of the previous efforts in working with national catalogs, which contributed to SGAWeb's success, the need for availability and standardization of catalogs (tests, references, methods, program, and products) was also pointed out, with the use of Modular Object Oriented Distance Learning tool (Moodle).

The SGAWeb's National Steering Committee initially consisted of seven representatives (one from Anvisa, one from INCQS - coordinator -, and five representatives from LACEN, one by region of the country), although, on that occasion, it was not officially established.

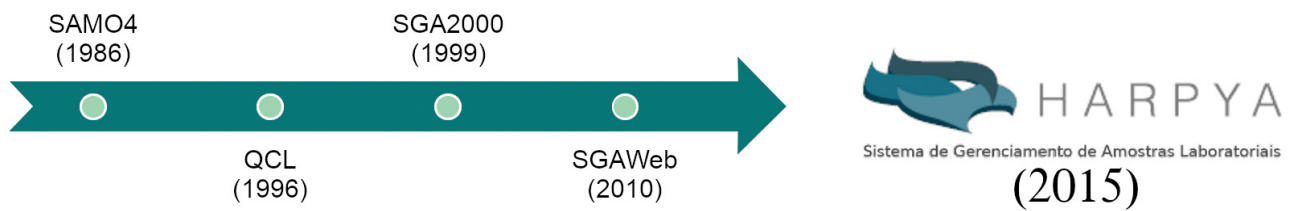
Its duties were: to improve the process of analyzing product samples and the SGAWeb system, receiving suggestions for new features, validating and discussing their implementation, and conducting the information standardization process between laboratories.

INCQS' main responsibilities were training, support, implementation of suggestions from the management committee, and corrective and evolutionary maintenance. The samples registered in SGA2000 were not migrated to SGAWeb due to incompatibility in the information architecture.

In November 2013, the Municipal Public Health Laboratory of Rio de Janeiro (LASP/RJ) participated in the pilot project to implement SGAWeb for RNLVISA, which made it possible to test the system, giving it more reliability.

In 2014, a partnership was established between INCQS and Anvisa to execute a project to redesign the SGAWeb's interface, focusing on usability and user experience and to implement the system in LACEN¹⁴.

With this reformulation, SGAWeb changed its name to Harpya - Laboratory Sample Management System. The system creation timeline is shown in the Figure.



Source: Elaborated by the authors, 2020.

Figure. Timeline of the evolution of the sample management system.

Implementation of Harpya at RNLVISA

Harpya began to be implemented in LACEN in November 2015 and ended in October 2016, culminating in all LACEN and their respective regional offices using the centralized system and sharing the same national catalogs.

It is also planned the implementation of the system in the Official Laboratory of the municipality of Belo Horizonte, which is the only laboratory of RNLVISA that still does not use it, until now¹⁵.

The implementation in the laboratories was carried out by the INCQS Systems Development team with the support of the Projects and Infrastructure teams of this Institute. When the local administrators of the laboratories were able, the implantation and training of professionals was scheduled.

The implantation took place in two days and two stages. In the first stage, Harpya was introduced to the professionals who would use it, and doubts were resolved.

In the second, the system for registering and monitoring the flow of samples by laboratory professionals was released under the supervision of an INCQS systems analyst. After that, the system was approved by two laboratory professionals, generally the Director and the Product Manager.

In the process, some problems arose, requiring immediate response. The first occurrence was the existence of two work shifts in some LACEN, with the need to optimize the presentation and training so that the professionals of the two shifts could follow all the stages.

The second occurrence was the instability or not in the existence of an internet network in the days of the implementation, requiring the routing of the cellular connection of INCQS technicians to complete the service.

The culture change in the use of a system on the institution's local network to a web system - with which many were not familiar, and the loss of domain of part of the catalogs (base register) - previously defined by the institution and then defined nationally for the unification of information - initially it was uncomfortable in some LACEN.

However, these difficulties were quickly resolved, and the system was well accepted.

The software was deployed at the Management of Public Health Laboratories (GELAS) of Anvisa in 2017. Trained professionals now have access to sample data from all RNLVISA laboratories, in real-time; thus, being able to generate indicators to assist in the evaluation of actions, programs, and decision making.

In 2017, the Harpya Steering Committee²¹ was created in order to manage the flow of information and coordinate the necessary actions to guarantee the functioning and maintenance of the system between the laboratories, as well as to authorize and manage the access profiles for system participants and SNVS managers.

The committee was composed of the following representatives: two from GELAS/Anvisa; one from Anvisa's Directorate of Health Control and Monitoring (DIMON); three from INCQS; one of LACEN (Instituto Adolfo Lutz - IAL); one of the accredited laboratories (Laboratory of Evaluation and Development of Biomaterials of the Northeast - CERTBIO/Federal University of Paraíba); one of the municipal laboratories (Rio de Janeiro Municipal Laboratory); one of the Health Surveillance (Health Surveillance of the state of Rio de Janeiro); and one from the Informatics Department of the Unified Health System (DATASUS).

In 2018, the Harpya Advisory Committee became official in order to issue recommendations and/or suggestions to guide operational activities within the scope of INCQS²².

Before SGASWeb and Harpya, laboratories needed equipment to host the (local) system and database, in addition to information technology professionals to take care of this environment and configure the systems on each user's workstations.

The initial structure of the information management systems for sample management in health surveillance laboratories in the country, which were decentralized and non-standardized, required a great deal of work from Anvisa to consolidate information, and it was necessary to request it from each RNLVISA laboratory, as needed.

The lack of standardization in the names of products, tests, and catalogs of the laboratories hindered the work of managers, demanding time in consolidating more accurate information.

All systems prior to Harpya were essential in their times, but it was necessary to evolve to keep up with technological advances



and support the SNVS. Managing health surveillance information was expensive.

State laboratories needed to request from their respective regional laboratories, the sample reports analyzed to consolidate the analytical information of their respective states, as well as Anvisa, nationwide.

Although some catalogs need to undergo adjustments and standardizations, it is possible to generate information from Harpya of great relevance for strategic health surveillance actions, providing more assertive decision-making for the benefit of the population.

Anvisa and INCQS have been establishing measures to control the quality of the data entered in the system, aiming to mitigate the incorrectness, incompleteness, and timeliness of the information generated; as well as improving the registration of samples of products subject to sanitary surveillance, their manufacturers, data from the holders of the registry, if any, and analytical data¹⁵.

Such improvement tends to enable the generation of more reliable indicators within the scope of the SNVS. Chart 1 summarizes the characteristics of the evolution of the Sample Management System over the years.

Harpya's contributions to the SNVS

The first contributions to be highlighted are the management of the sample flow in the laboratories and the development of indicators for the evaluation and monitoring of the quality of these services.

RNLVISA's laboratories are strategic entities in the SNVS, as they act in the assessment of health risk, identifying it, and proposing intervention and control mechanisms with the regulatory agencies. Laboratory analyzes generate

scientific evidence for monitoring products and establishing new control parameters²³.

Harpya allows the management of the flow of samples registered in the laboratory, which culminates in the issuing of the analysis report to the applicant.

The performance of analyzes, especially fiscal ones, requires safe and traceable procedures throughout the process, which start with the collection of samples by Visa and culminate in the issuing of reports by RNLVISA Laboratories; and such results can trigger sanitary actions^{24,25}.

Harpya allows the elaboration and monitoring of indicators at each stage of the sample flow, contributing to the evaluation and monitoring of the quality and performance of the laboratories that use it, as well as for monitoring the RNLVISA.

The structure (resources used to carry out the laboratory analysis), the process (description of the stages of performing the service), and the results of the laboratories²⁶ can be evaluated, and some possible indicators to be followed are proposed in Chart 2.

Registered sample: the one that the laboratory receives together with the Sample Collection Term and records in the system; canceled sample: sample whose analysis was not possible for some reason. After informing the reason, the system changes the status to canceled; completed sample: the one that, after registering the final evaluation of the sample, has its status changed by the system to completed; closed sample: the one that does not allow changes. At any future time that it is necessary to generate the analysis report again, it will be printed with the same information^{24,25}; RNLVISA: National Network of Laboratories Health Surveillance

The collection of samples in their original, closed, and intact packaging, without signs of violation and deterioration of the

Chart 1. Characteristics of the evolution of the Sample Management System over the years (1986-2019).

Stages (start year)	Information system	Access to the information system	Centralized base	Implementation in laboratories	Nationally standardized catalogs
1986	SAMO4	Local network	No	INCQS and PNI	No
1996	QCL	Local network	No	Four LACEN (CE, MG, PE, and PR), INCQS, and PNI	No
1999	SGA 2000	Local network	No	27 LACEN, INCQS, and PNI	No
2010	SGAWeb	Web	Yes	INCQS and a municipal laboratory	Yes
2015	Harpya	Web	Yes	27 LACEN, INCQS, 21 regional laboratories, four municipal laboratories, PNI, CGLOG, and Anvisa	Yes

Source: Elaborated by the authors, 2020.

SAMO IV: Sample System 4; QCL: Quality Control Laboratory; SGA2000: Sample Management System 2000; SGAWeb: Web Sample Management System; Harpya: Laboratory Sample Management System; INCQS: National Institute for Quality Control in Health; LACEN: Central Laboratories of Public Health; CE: Ceará; MG: Minas Gerais; PE: Pernambuco; PR: Paraná; PNI: National Immunization Program; CGLOG: General Coordination of Logistics for Strategic Health Supplies. Anvisa: Brazilian National Health Surveillance Agency



Chart 2. Possible indicators to be monitored for evaluating the laboratories of the National Network of Health Surveillance Laboratories through consultation with Harpya.

Stages of the sample process	Indicators
Pre-analytic	Total registered samples Total or percentage of canceled samples
Analytic	Average test analysis time Total or percentage of tests performed by product category Total or percentage of satisfactory tests Total or percentage of unsatisfactory tests
Post-analytic	Average sample analysis time Total or percentage of satisfactory samples by product category Total or percentage of unsatisfactory samples by product category Total or percentage of completed samples by product category Total or percentage of closed samples by product category Total or percentage of samples analyzed by product category Total or percentage of samples analyzed per year Total or percentage of samples analyzed by location Total or percentage of samples analyzed by RNLVISA laboratory Total or percentage of samples analyzed by applicants Total or percentage of samples analyzed by laboratory program Total or percentage of samples by analysis mode (fiscal, orientation, special) Monitoring programs carried out Total or percentage of samples analyzed by state, region, country

Source: Elaborated by the authors, 2020.

product; with a readable label; same batch number, label, presentation, expiration date, net content; that are stored according to the manufacturer’s recommendations; properly packaged, sealed - in order to guarantee inviolability - are possible requirements to be evaluated^{24,25, 24,25}.

Samples that need adjustments (lack of documentation, insufficient quantity) or that cannot be analyzed have specific mechanisms in the system (pending issues), which can be placed on demand or canceled (samples received and not analyzed). The reasons for the requirement or cancellation serve as an opportunity to improve the work process. The tests performed, the methods used and the references, and reference values can also be monitored.

A laboratory is a complex service and keeping each of its processes aligned helps to promote continuous improvements and reduce unwanted expenses, aiming at the optimization of resources and the contribution to the health of the population²³.

The analysis of indicators allows the quantification and qualification of failures, implementation of corrective and preventive measures, and verification of the effectiveness of the processes and procedures²⁶.

The performance evaluation of the network laboratories provided by Anvisa¹⁵ has the potential to support a solid financing policy for RNLVISA; which has been identified as necessary²⁷, including information on the participation of laboratories in monitoring programs and the performance of specific analytical tests.

In addition, through the construction of productivity and level of complexity indicators in the laboratories based on recorded analytical data, it is possible to define the criteria for the reorganization of the laboratory networks for analyzing products and services provided by public health laboratories.

It is noteworthy that Harpya will be mandatory for accredited laboratories, and optional for laboratories of the Brazilian Network of Analytical Health Laboratories (REBLAS) that need to transmit analytical data to Anvisa¹⁵.

Harpya’s second contribution is related to the monitoring of analyzes that assist the registration of products, verifying their conformity with the respective identity and quality standard.

Access to data at the national level by Anvisa supports the coordination of the SNVS, thus allowing the monitoring of product quality in the pre- and post-market²⁸.

According to Martins and Teixeira²⁹, Harpya generates relevant information for post-market monitoring of product quality, as it favors the reliability, safety, and traceability of the analyzes performed by the laboratories, providing unification, standardization, and availability of the quality control analytical reports of the products monitored in the SNVS.

Several authors have highlighted its relevance and usefulness in product quality control in different states of the federation and in different areas.

Some of the examples are the authors who have studied microbiological contamination and the physical-chemical aspects in food^{30,31,32}, syringe aspect assessment³³, determination of plasticizers in blood bags³⁴, determination of citrate and phosphate in anticoagulant solutions of blood bags³⁵, evaluation of kits used in serological diagnosis of dengue³⁶, *in vitro* cytotoxicity tests in the quality control of biomaterials used in gloves³⁷, physical control of blood bags³⁸, corrosion in hypodermic needle cannulas and the appearance and labeling of syringes and needles³⁹.

The third contribution is the use of Harpya data with other information systems.



The existence of a nationwide information system is in line with the World Health Organization's report on the monitoring of irregular products, which calls for an integrated approach at national, regional, and even global levels for efficient surveillance⁴⁰.

Data on product quality control can be related to information about adverse events - incidents that result in unintended damage, a direct consequence of health care and unrelated to the natural evolution of the disease, being considered an unexpected or undesirable effect that compromises the health security of the citizen/patient - and technical complaints - any suspicion of alteration/irregularity of a product/company²⁹.

There are possibilities and intention of crossing data from Harpya to other databases useful to SNVS, with a view to planning, monitoring, and evaluating public policies, especially those related to health regulation, in real-time, generating alert indicators and specific monitoring panels^{41,42,43}.

The list below, which is not exhaustive, points out some of the information systems with a possible interface with the SNVS: Notivisa (Anvisa); Bank of Operating Authorizations (Anvisa); Product Registration and Notification Bank (Anvisa); Family Budget Survey of the Brazilian Institute of Geography and Statistics (POF/IBGE); National System of Toxic-Pharmacological Information (SINITOX); Pesticide Information System (MAPA); PARA Sample Management System (SISGAP) - this system supports the Pesticide Residue Analysis Program (PARA); Agronomic prescription made available by the Regional Council of Engineering and Agronomy (CREA); Phytosanitary Pesticide System (Agrofit/Ministry of Agriculture); Mortality Information System (SIM/DATASUS); Hospital Information System of the Unified Health System (SIHSUS/DATASUS); Foreign Trade Systems (SISCOMEX); National Registry of Healthcare Establishments (CNES).

The path to extract knowledge from the crossing of databases can be the use of Data Science, a very disciplined study in relation to data, which can assist in the discovery of useful information from large or complex databases.

Data Science can be defined as a set of strategies, tools, and techniques for collecting, transforming, and analyzing data carried out by multidisciplinary teams of researchers with substantive knowledge of the problem under analysis, statisticians, mathematicians, and computer scientists^{41,42,43}.

In this way, the information entered into Harpya by RNLVISA can contribute to other information systems in solving public health problems.

As future perspectives, new system functionalities are being developed, configuration of the environments, hosting service, and customer service.

Improvements to the system are foreseen, such as digital signature in the analysis report, access of Visa from all over the country to analysis reports, display of news and indicators for laboratories and Anvisa, unsatisfactory sample notifications for Visa and Anvisa, and inclusion of images and spreadsheets with the sample register.

CONCLUSIONS

The documentary analysis carried out allowed the historical recovery of the development of a computerized system for the management of laboratory samples by the INCQS, in addition to highlighting its benefits and utilities for RNLVISA and SNVS.

Several challenges had to be overcome during the development of the various versions of the system, such as the availability of financing, specialized labor, material resources, interaction with stakeholders, among others. The infrastructure in the laboratories often hampered the work process.

Harpya is a tool that must be continued and improved, being strategic for the health surveillance actions, coordinated by Anvisa. The management of the samples allows the quantification and qualification of the failures, implementation of corrective and preventive measures, and verification of the efficiency of the processes and procedures performed, contribution to the management.

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Author's Contributions

Silva AL, Lopes RGA - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. Aquino NC - Conception, planning (study design), data interpretation, and writing of the work. Romão CMCPA, Almeida AECC - Conception and writing of the work. All authors approved the final version of the work.

Conflict of Interests

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



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