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# Alternatives to a Health Surveillance information system: a case study of DIVISA/BA

### Alternativas a um sistema de informação em Vigilância Sanitária: um estudo de caso da DIVISA/BA

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#### ABSTRACT

Introduction: In Brazil, Health Surveillance (Visa) is a subsystem of the Unified Health System (SUS), where each federated entity has responsibilities established through agreements. Therefore, data and information are fundamental to evaluate, monitor, and manage risks, identifying priorities and the impact of Visa actions. Software support allows to organize the construction of indicators that serve this purpose. Objective: To present the information systems used by the Bahia Health and Environmental Surveillance Directorate (DIVISA/BA) and discuss the alternatives used by the institution to understand, analyze and manage the health risk in its territory, identifying the gaps and overcoming strategies presented. Method: 19 Annual Management Reports (RAG) were analyzed, covering the years between 2002 and 2020. Results: Relevant findings regarding the existence and use of information systems or alternatives used to identify and manage health risk were presented in a timeline. It was observed that DIVISA/BA developed some information systems with limited objects and activities, in addition to using systems made available by Anvisa and DATASUS. Some tools were also used to monitor indicators and goals. Conclusions: Although the development of a national Visa information system is a challenge for Anvisa as national coordinator of the National Health Surveillance System (SNVS), States can organize the available information, whether through systems or alternative solutions, in order to deepen knowledge of the territory, identifying risks that guide health surveillance actions, prioritizing areas that are in fact decisive for the population's health problems.

KEYWORDS: Health Surveillance; Health Information System; Risk management

#### **RESUMO**

Introdução: No Brasil, a Vigilância Sanitária (Visa) é um subsistema do Sistema Único de Saúde (SUS), em que cada ente federado possui responsabilidades estabelecidas por meio de pactuações. Dados e informações são fundamentais para avaliar, monitorar e gerenciar riscos, identificando as prioridades e o impacto de ações de vigilância sanitária. Os softwares ajudam a organizar a construção de indicadores que prestem a essa finalidade. Objetivo: Apresentar os sistemas de informações utilizados na Diretoria de Vigilância Sanitária e Ambiental da Bahia (DIVISA/BA) e discutir as alternativas utilizadas pela instituição para conhecer, analisar e gerenciar o risco sanitário em seu território, identificando as lacunas e estratégias de superação apresentadas. Método: Foram analisados 19 relatórios anuais de gestão (RAG) dos anos de 2002 a 2020. Resultados: Os achados relevantes quanto à existência e utilização de sistemas de informações ou alternativas utilizadas para identificação e gerenciamento do risco sanitário são apresentados em uma linha do tempo. Observou-se que a DIVISA/BA desenvolveu alguns sistemas de informação com objetos e atividades limitadas, além de utilizar sistemas disponibilizados pela Agência Nacional de Vigilância Sanitária (Anvisa) e DATASUS. Foram também empregadas algumas ferramentas para o acompanhamento de indicadores e metas. Conclusões: Embora a elaboração de sistema de informação nacional de Visa

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seja um desafio para a Anvisa enquanto coordenadora nacional do Sistema Nacional de Vigilância Sanitária (SNVS), os estados podem organizar as informações disponíveis, por meio de sistemas ou de soluções alternativas, para aprofundar o conhecimento do território, identificando riscos que direcionem as ações da Visa e priorizando áreas que de fato sejam determinantes para os problemas da saúde da população.

PALAVRAS-CHAVE: Vigilância Sanitária; Sistema de Informação em Saúde; Gerenciamento de Risco

#### INTRODUCTION

Health surveillance works to prevent and control risks, protect, and promote health, and is organized on the basis of a legal-normative framework whose starting point is the Federal Constitution<sup>1</sup>.

Health information systems (HIS) are essential for managing health services, producing information for decision-making, formulating, and evaluating policies, which is directly fundamental for planning and monitoring actions<sup>2</sup>.

In health surveillance, HIS have characteristics as complex as the complexity of organizing their actions. According to Nogueira<sup>2</sup>, they are fundamental to the effective performance of surveillance and the definition of indicators that represent its scope of action.

A wide and diverse range of information is needed to properly carry out health surveillance actions. Epidemiological data, together with demographic and economic data, make up an important group of information without which it is difficult to know the territory and prioritize health surveillance actions with a view to controlling health risks. Epidemiological information can be obtained from Mortality Information System (SIM), Notifiable Diseases Information System (Sinan), and Outpatient Information System (SIA). The Live Births Information System (SINASC) is used to calculate the Child Mortality Coefficient (CMC), an important indicator of the quality of health care and living conditions. All these HIS are administered by the Department of Informatics of the Unified Health System (DATASUS), a body linked to the Ministry of Health. Demographic data is available on the website of the Brazilian Institute of Geography and Statistics (IBGE), whose smallest unit is the municipality. Economic activity is the subject of various information systems, including: the National Classification of Economic Activities (CNAE), the National Registry of Legal Entities (CNPJ), and the register of the Board of Trade, a body under the State Department of Finance. It is worth remembering that the information provided by these sources is not always up to date and therefore may not accurately reflect the reality of the territory. This possibility has to be considered, especially when working with morbidity and mortality data, whose regularity in feeding the respective information systems and timely availability are relevant factors to be taken into account<sup>2,3</sup>.

Gamarski and Mota<sup>3</sup> (2010) highlighted the challenge of implementing a national information system in countries as continental as Brazil, with so many municipalities with such unequal characteristics and difficulties in having IT professionals responsible locally for ensuring the system's operation and security. In addition, there are working conditions, including precarious hiring arrangements, the small number of professionals and the difficulty of retaining them in the municipality, as Ferraro, Costa, and Vieira-Da-Silva point out<sup>4</sup>.

In 2002, the National Health Surveillance Agency (Anvisa), as coordinator of the National Health Surveillance System (SNVS), took the initiative to build the National Health Surveillance Information System (SINAVISA) based on an existing system in the Goiás state health surveillance office. As a way of encouraging its use, Anvisa provided hardware and software to the State Health Surveillance Offices (Visa), as well as a communication link with Brasília<sup>3</sup>.

For Visa, an information system must support the Regulation and Quality Control processes, avoiding the unnecessary provision of information, but also respond to the processes of agreeing on current health indicators<sup>5</sup>. The financing of health surveillance actions seems to have been the focus of discussions between 2006 and 2010, culminating in the publication of Ministry of Health and Health Care Secretariat (MS/SAS) Ordinance No. 323 of July 5, 2010. The inclusion of health surveillance procedures in the Table of Procedures, Medicines, Orthotics, Prosthetics, and Special Materials (OPM) of the Unified Health System (SUS) allows them to be registered in the SIA and the respective financial transfer<sup>6</sup>.

The Bahia State Health Surveillance System is made up of the health surveillance teams of the 417 municipalities and, at state level, the health surveillance teams located in the nine Regional Health Centers and the Bahia Health and Environmental Surveillance Directorate (DIVISA/BA), which coordinates the system. This body is responsible for strengthening, consolidating and managing sanitary risk control actions, planning, defining priorities, advising, monitoring, and evaluating sanitary and environmental health surveillance actions<sup>7</sup>.

In order to advance the process of decentralizing Visa, the State Health Department carried out the regionalization of the SUS in the state, which resulted in agreements or partnerships that enabled the development of actions such as the administrative modernization process, seeking to adjust work processes to the management model and obtaining resources to implement some local information systems<sup>8</sup>.



This report aims to present the information systems used at DIVISA/BA and discuss the alternatives used by the institution to learn about, analyze, and manage health risks in its territory, identifying the gaps and presenting the strategies used to overcome them. It is hoped that the analysis of DIVISA/BA's experience will help other SNVS entities to appreciate the need to organize information systems, which is the primary responsibility of the three spheres of the SUS, as set out in Law No. 8.080, of September 19, 1990 (article 15, item IV)<sup>9</sup>.

#### **METHOD**

This is an experience report. Based on documentary analysis, it recovers the path taken by DIVISA/BA between 2002 and 2020 regarding the need for information in Visa, revealing important facts about the creation, implementation and use of an information system for risk management in Visa in the state and pointing the way towards the formulation of a specific system for its purposes. As a participant in this process, the report includes observations from the researcher's point of view.

The first step was to select institutional documents from DIVISA/ BA, mainly management reports from 2002 to 2020, most of which are available on the institution's website (https:// www.saude.ba.gov.br/suvisa/vigilancia-sanitaria/planejamento-e-programacao-das-acoes-de-vigilancia-sanitaria/), on the intranet, and in folders on the computer network. In this last-mentioned source, searches were carried out using the file explorer's search menu, linking keywords, and dates to find documents related to the promotion or use of an information system by the institution. The keywords used for these searches were: "management report" and "information system". The management authorized access to and use in the research of all the documents. Data collection took place between March 1<sup>st</sup> and March 22, 2022.

In the second step, the selected annual management reports (RAG) were analyzed in order to identify the facts or situations related to the development of an information system for the institution, the difficulties related to its absence, as well as the alternatives proposed or used to overcome them. The results of this search were organized into a timeline (Figures 1 and 2).

Finally, the third step was to discuss the results in the light of the existing literature, providing a theoretical basis for the observations and analysis made.

#### **RESULTS AND DISCUSSION**

From 2002 to 2020, the management of DIVISA/BA worked to keep up with the management and regionalization model of the SUS in the state, which resulted in agreements or partnerships that enabled the development of actions such as the administrative modernization process that prioritized planning, information technology and evaluation (started in 2002), and strategic planning (started in 2012), one of whose priorities was the acquisition/implementation of a State Health Surveillance Information System. However, this process has not resulted in an information system that responds to risk management and managerial decision-making. A number of experiments were carried out, including the creation of systems to collect specific data, without making it possible to connect with other areas and trigger the communication processes needed to manage health risks.

In the 19 RAGs and the selected documents shown in Figures 1 and 2<sup>8,10</sup>, it is possible to find several examples of the existence and use of information systems and alternatives used by DIVISA/ BA to identify and manage health risks. This information was often linked to meeting targets in annual programs.

The findings were grouped into two categories: a) information systems adopted by DIVISA/BA; and b) alternatives sought by DIVISA/BA in response to the lack of information systems. Each information system and alternative sought by DIVISA/BA was commented on and contextualized.

#### Information systems adopted by DIVISA/BA

## Health Surveillance and Sanitary Control Registry System (CadVigSan)

The aim of this system was to organize registration information on establishments linked to Visa, control services, occurrences, and history in a structured way. Not much information was found on its development but the 2002 RAG indicated that the DIVISA/ BA Information Technology Center team was directly involved in its creation<sup>8</sup>. In 2007, the continuity of this system was discussed due to the inconsistencies and incipiency of the registration module, as well as the fact that it was implemented in only a few municipalities in the state, due to difficulties with computer equipment at the time. In addition, its operating system was outdated and was no longer used at DIVISA/BA.

#### DIVISA Evaluation System (SAD)

The 2002 RAG suggests that the creation of this system was part of the agreement signed with the School of Administration of the Federal University of Bahia (EAUFBa). The SAD was used to collect information and issue management reports and was highlighted in 2003 as one of the institution's advances. However, in 2004, it was noted that the SAD's evaluation and performance indicators were not used. In 2005, it was reformulated and in 2007 its discontinuation was discussed due to weaknesses and inconsistencies, and, like CadVigSan, it was implemented in only a few municipalities due to difficulties with computer equipment. The SAD was abandoned in 2008<sup>8,10</sup>.

#### Radiological Surveillance System (SVR)

With a view to implementing Federal Ordinance 453 of June  $1^{st}$ , 1998, the CEFET/DIVISA Project was developed in 2002 in





# Source: RAG DIVISA, 2022.

TAM: Term of Adjustments and Goals; Res CIB/BA: Resolution Bipartite Intermanagers Commission Bahia; EAUFBA: School of Administration of the Federal University of Bahia; PRODEB: Data Processing Company of Bahia; CADVIGISAN: Health Surveillance System; SINEPS: Adverse Events Products Notification System; SINAVISA: National Health Surveillance System; SINEPS: Adverse Events Products Notification System; NOTIVISA: Health Surveillance Notification System; SISNEA: Adverse Event Notification Information System; SISMC: Controlled Medicines Information System; PPI: Integrated Agreed Programming; PES: State Health Plan; SCNES: National Health Establishment Registration System; SIA/SUS: SUS Ambulatory Information System. -

http://www.visaemdebate.incqs.fiocruz.br/





System.

Administrative Modernization Directorate; PRODEB: Data Processing Company of Bahia; REDESIM: National Network for Simplification of Registration and Legalization of Companies and Businesses; SIVISA/SP: São Paulo Health Surveillance Information System; SIVISA/RS: Rio Grande do Sul Health Surveillance Information System; SEI: Electronic Information System; TR: Term of Reference; VIGIMED: Adverse Drug Event Reporting

SAEB: Secretariat of Administration of the State of Bahia; SNGPC: National System of Controlled Product Management; SINAVISA: National Health Surveillance Information System; PPA: Multiannual Plan; DMA:

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http://www.visaemdebate.incqs.fiocruz.br/

Source: RAG DIVISA, 2022.



partnership with the Federal Center for Technological Education of Bahia (CEFET/BA). The SVR was developed in 2006 as a software program for managing inspections in the area of radio diagnostics. However, there are no records of its use in the RAGs surveyed. Only manuals and forms for this system were found on the old DIVISA intranet page, without any data<sup>10</sup>.

#### SINAVISA

Implemented at DIVISA in 2003, SINAVISA represented a breakthrough for the entire SNVS. In 2005, a web version was implemented, requiring the application and interconnection of the DIVISA/BA network to that of Anvisa<sup>10</sup>. It was noted in 2008/2009 that there was no module capable of generating management reports, which made it difficult to monitor indicators. In 2015, Anvisa decided to reformulate and restructure the system to also identify risk situations by monitoring the quality of products circulating on the market<sup>11</sup> but no progress was made. The system went offline in the second half of 2021.

#### NOTIVISA

In 2005, Anvisa set up a system for reporting technical complaints and adverse events called Adverse Events related to Health Products Notification System (SINEPS), which was partially made available to state health surveillance agencies. In 2006, SINEPS was replaced by NOTIVISA and its functionalities were expanded. By 2009, NOTIVISA had already established itself as an important system for post-market surveillance, and its modules and functions were expanded in 2010<sup>10</sup>.

#### Adverse Event Notification Information System (SISNEA)

Developed by DIVISA in 2005 at the same time as NOTIVISA, SIS-NEA aimed to expand the sources of notification and provide greater agility in sending and receiving notifications and starting the process of epidemiological-sanitary investigation of adverse events. From 2006 onwards, it was used via the web, making it possible to report adverse events involving medicines and health products. In 2007, Anvisa expanded NOTIVISA's functions and invited DIVISA to take part in a working group to develop a new module for the system. With its expanded functions, NOTIVISA surpassed the functions of SISNEA, which was discontinued<sup>10</sup>.

#### Controlled Medicines System (SISMC)

Created by DIVISA/BA in 2005 as a prototype for the control of drug-related activities under Federal Ordinance No. 344 of May 12, 1998. Initially, its main focus was thalidomide. Anvisa, in turn, developed the National System of Controlled Product Management (SNGPC) and, like SISNEA, SISMC's functionalities were superseded by SNGPC, leading to its discontinuation and abandonment<sup>10</sup>.

#### SCNES and SIA/SUS

These two systems became mandatory as of 2010<sup>12</sup>, when the transfer of financial resources to the Visa was linked to them. In

2017, it was found that the SIA/SUS did not have reliable numbers of establishments subject to Visa in the state; however, until 2018, the transfer of funds from the Health Surveillance Component remained conditional on the SCNES being updated and the SIA/SUS being fed monthly<sup>10</sup>. Although it wasn't the most representative system for demonstrating the actions of Visa, it did allow the generation of files compatible with the Tabnet and Tabwin applications, allowing the tabulation and analysis of databases<sup>2</sup>.

#### National System of Controlled Product Management (SNGPC)

Developed by Anvisa, it was implemented at DIVISA in 2013. The SNGPC is an important system in Visa's actions, given the need to monitor the prescription and consumption of controlled medicines in the country, contributing to health risk management in this area. Since 2016, issues related to the shortage of human resources have weakened the management of this system at the state level<sup>10</sup>.

It was noted that systems such as SAD, SISNEA, SVR, SISMC, and CadVigSan were developed with DIVISA/BA resources and used for some time until they lost their functionality due to lack of updating or adaptation to the needs of the service. These tools need to meet specific criteria and also respond to the updating of the necessary information, as Quitério pointed out<sup>13</sup>. According to De Souza Machado and Cattafesta<sup>14</sup>, managers need to develop policies to overcome challenges so that quality, reliable information can be used systematically for decision-making.

Alternatives sought by DIVISA/BA in response to the lack of information systems

#### Excel spreadsheets

In 2008, technicians in the planning area developed a spreadsheet, using Microsoft's Excel application, as an alternative for data collection, called "Consolidated Visa actions"<sup>10</sup>. It is still in use at the institution and its main function is to monitor the indicators of the State Health Plan (PES) and the 56 health surveillance procedures in the SIA/SUS. However, this is a purely quantitative arrangement that does not allow the information to be organized to find out, for example: the main non-conformities, the health infractions committed, the universe of companies that are subject to Visa in the state. Furthermore, it is subject to many errors and it is not possible to build up a history of information about establishments.

National Network for Simplification of Registration and Legalization of Companies and Businesses (REDESIM)

It is a network of computerized systems that allows companies to be opened, closed, altered and legalized in all of Brazil's Boards of Trade<sup>15</sup>. The Integrated Registration System (REGIN) allows the interested party to enter data via the internet and send this information to the various bodies involved in the



operation of that company. DIVISA/BA, through an agreement with the Bahia Board of Trade (JUCEB), joined REDESIM and defined the CNAEs it was interested in. Thus, in 2018, it was decided to create an ordinance to align the codification of the CNAEs with the description of the activities of interest to Visa<sup>10</sup>.

The system is currently available for consultation at DIVISA but it still doesn't allow the company to file processes with Visa using REGIN. In other words, the system needs to be adapted to comply with health licensing procedures. According to Costa, Jorge, and Donagema<sup>16</sup>, computerized systems that allow services to be automated, such as the one provided by REDESIM, can facilitate procedures and make the actions of health surveillance more agile, improving access to information and the regularization of companies.

#### Bahia Electronic Information System (SEI Bahia)

Developed by the Federal Regional Court of the 4th Region (TRF 4), it is a tool for managing electronic files and documents. In 2017, the Government of the State of Bahia established SEI as the official system for managing electronic and digital administrative processes and documents within the bodies and entities of the State Executive Branch and, in 2020, 20 processes specific to Visa actions were implemented in SEI Bahia, providing better organization, standardization, and monitoring of information and, consequently, greater agility. This system has some important functionalities that contribute to verifying service statistics<sup>10,17</sup>, such as the number of health license processes completed in the last year. In the last guarter of 2022, the electronic petition function was implemented, allowing companies to use the system to submit their demands and sign them electronically quickly, simplifying procedures for granting health licenses, which, according to Costa, Jorge, and Donagema<sup>16</sup>, is also a major step forward. In addition, SEI Bahia has made it possible to know the number of cases being processed by DIVISA/BA. However, it does not allow us to know the universe of companies and their types of activities, which is important information for planning and prioritizing Visa actions.

#### CONCLUSIONS

This report shows that both technological development and the growing demand for regulatory objects require Visa to be increasingly responsive, so as not to represent an obstacle to the establishment of economic activities<sup>3</sup>. In this sense, following the guidelines of the Ministry of Economy and the national harmonization of risk classification proposed by Collegiate Board Resolution (RDC) No. 153, of April 26, 2017<sup>18</sup>, DIVISA/BA has moved forward by drawing up the risk classification ordinance<sup>19</sup> using the CNAE code to categorize economic activities, since this is an important condition for organizing an information system<sup>13</sup>.

The case of DIVISA/BA showed that there were investments in information technology. However, these efforts were isolated

projects that needed to be better adapted to objectives and integrated to generate information for the benefit of risk control. In this way, the development of information systems must be carried out with defined and clear objectives, as well as funding, evaluation, and maintenance to achieve the desired results.

In Bahia, there are important regional differences that need to be taken into account when thinking about the process of decentralizing Visa actions. In addition, the territory is very dynamic and heterogeneous and, consequently, the monitoring of actions by means of an information system also needs to take this reality into account. It is important to remember the need to invest in training human resources so that the systems can be used properly, inserted into the routine, collecting quality information and data.

DIVISA/BA, as coordinator of the State Health Surveillance System, needs an information system that is fed by all its entities (state and municipalities), gathering information under the responsibility of each SUS management sphere, since all of them are relevant to guaranteeing the population's access to the safest services and products and thus effectively contributing to risk control in Bahia.

There is no ready-made formula for structuring/developing an information system in Visa but it is very important that experiences in adopting existing information systems and also the alternative tools developed are references for the guiding thought behind the development of this system.

It should be noted that alternative tools such as Excel spreadsheets, REDESIM, or even SEI Bahia are isolated, non-integrated, and specific to certain activities, making it difficult to systematize data in an agile and effective way to help managers identify and analyze a situation and make decisions. However, by using them, DIVISA/BA gains maturity and knowledge about the information that should be prioritized, the programming tools that can be used, the types of reports that need to be generated, and which data will serve as the basis for the indicators, among other relevant issues for the composition of a Visa information system.

Although this is a challenge for Anvisa as the coordinator of the SNVS, the other entities in the system are independent in creating or proposing alternatives. The information that is already available in the various existing systems (NOTIVISA, SNGPC, VIGIMED, and REGIN) can be organized to communicate and deepen knowledge of the territory, identifying risks that make it possible to prioritize actions. It is also important to consider the transparency of information in order to strengthen social control, and thus empower consumers to demand that the market complies with health rules and regulations.

By carrying out risk communication actions through health alerts, Visa fulfills its role of protecting health. In order to enhance this purpose, it is essential to develop a system with transparent, timely, and reliable information so that society can use it to exercise its citizenship<sup>20</sup>.



This study pointed out some obstacles to the development of an information system, such as the lack of qualified human resources, high financial costs, and the technological updates required for maintenance. It is recommended that these limitations be the subject of further research, generating scientific knowledge capable of supporting solutions capable of overcoming them and thus maximizing the benefits of Visa actions.

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#### Authors' Contribution

Costa I, Carvalho G - Conception, planning (study design), analysis, data interpretation, and writing of the work. Paiva J - Conception, planning (study design), and writing of the work. 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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