EXPERIENCE REPORT
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Profile of Brazilian health establishments participating in the Sentinel Network

Perfil de estabelecimentos de saúde brasileiros participantes da Rede Sentinela

Ana Paula Coelho Penna Teixeira*

Leonardo Oliveira Leitão

Patricia Fernanda Toledo Barbosa

Dolly Milena O.T. Cammarota

Vanessa Louis Camilo Rocha

Agência Nacional de Vigilância Sanitária (Anvisa), Brasília, DF, Brasil

* **E-mail**: anapaula.teixeira@anvisa.gov.br

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ABSTRACT

Introduction: With the objective of creating an observatory of the health services that served as a reference to monitor and report adverse events and technical complaints in the post-use of products subject to sanitary surveillance, the Brazilian Health Regulatory Agency (Anvisa) initiated, in 2002, the Sentinel Network Project. **Objective:** To verify the Network profile in the year 2016, guiding the Agency for planning new accreditations. **Method:** Descriptive and quantitative study, elaborated from the collection of information from documents sent to Anvisa, by health institutions. **Results:** The Network has 221 accredited institutions, corresponding to 3.0% of Brazilian hospitals. These services are in 24 out of 27 federative units in Brazil, 56.0% are large hospitals and 24.0% are medium-sized hospitals. Among the 50 federal university hospitals, 23 joined the Sentinel Network and, from which, 19 are currently administered by the Brazilian Hospital Services Company (EBSERH). Within the Network, there are 161 general hospitals and 60 specialized institutions. It is noteworthy that 126 institutions of the Sentinel Network are certified as teaching hospitals, which represents 64% of hospitals certified by the Ministry of Education (MEC). **Conclusions:** It is important to have a continuous reflection about the representativeness of the group of Sentinel hospitals in Brazil with a view to the continuous improvement of post-marketing surveillance. In this sense, it is necessary to make efforts to accredit other hospitals, even in the states without representation, as well as to develop new strategies for strengthening the Network.

KEYWORDS: Health Surveillance; Anvisa; Health Facilities

RESUMO

Introdução: Com o objetivo de criar um observatório nos serviços de saúde que funcionasse como referência para monitorar e notificar eventos adversos e queixas técnicas no pós-uso de produtos sujeitos à vigilância sanitária, a Agência Nacional de Vigilância Sanitária (Anvisa), iniciou em 2002, o Projeto Rede Sentinela. **Objetivo:** Verificar o perfil da Rede no ano de 2016, para nortear a agência para o planejamento de novos credenciamentos. **Método:** Estudo descritivo e quantitativo, elaborado a partir da coleta de informações dos documentos enviados para Anvisa, pelas instituições de saúde. **Resultados:** A Rede apresenta 221 instituições credenciadas, que correspondem a 3,0% dos hospitais brasileiros. Estes serviços estão presentes em 24 das 27 unidades federativas do Brasil: 56,0% são hospitais de grande porte e 24,0%, de médio porte. Dos 50 hospitais universitários federais, 23 fizeram adesão à Rede Sentinela e, dentre estes, atualmente 19 são administrados pela Empresa Brasileira de Serviços Hospitalares (EBSERH). Do universo da Rede, 161 são hospitais gerais e 60 são instituições especializadas. Destaca-se que 126 instituições da Rede são certificadas como hospitais de ensino, o que representa 64% dos hospitais certificados pelo Ministério da Educação (MEC). **Conclusões:** É importante haver uma contínua reflexão quanto à representatividade do conjunto de hospitais sentinela no Brasil com vistas à melhoria contínua da vigilância pós-comercialização. Nesse sentido, faz-se necessário envidar esforços para o credenciamento de outros hospitais, inclusive nos estados sem representatividade, bem como desenvolver novas estratégias de fortalecimento da Rede.

PALAVRAS-CHAVE: Vigilância Sanitária; Anvisa; Estabelecimentos de Saúde

INTRODUCTION

The Brazilian Health Regulatory Agency (Anvisa) is part of Brazil's Unified Health System (SUS), whose institutional purpose is to promote and protect the health of the population through the sanitary control of products and services subject to health surveillance[1].

Among the dimensions of health surveillance, post-use/post-market surveillance (Vigipós) is essential to monitor the safety of products used in healthcare by monitoring, evaluating, investigating and communicating the risks arising from the use of these products[2]. In order for Vigipós to develop, therefore, it is necessary to collect data through reports of suspected technical issues (IC) and unwanted adverse events (AE), manifested after the use of medicines, health products, cosmetics, sanitizing products, blood and its derivatives and health care, making it possible to generate a database whose technical information on safety and efficacy can subsidize regulatory actions in Brazil.

Studies estimate that incidents related to healthcare - and in particular to AE – affect from 4% to 16% of hospitalized patients in developed countries. Similar data has led to increased awareness of health systems around the world to improve patient safety in order to prevent harm and promote advances in the quality of care they provide[3]. In this context, the occurrence of these AE is understood as a result of failures associated with a varied and intricate range of factors of systemic origin, including those related to work processes in health services[4].

In order to minimize the damage caused by care and process failures, we must develop a patient safety culture, which means seizing opportunities for improvement of AE and IC occurred and identified in health services. According to the World Health Organization (WHO), the safety culture is based on three pillars: a fair culture, in which the difference between unacceptable acts and errors due to system failures is clear; a reporting culture in which data collection, analysis and dissemination are carried out on identified health care incidents; and a culture of learning, based on the reflection on the incidents experienced in the health services for the development of improvement initiatives[5].

The difficulty in obtaining data on the reports of adverse reactions, injuries and IC related to the use/consumption of products subject to health surveillance has led Anvisa to define a strategy capable of improving the monitoring of these events. The Sentinel Network was created in this context; its objective was to establish a network of health institutions that would work as observatories of post-use surveillance. This would encourage the identification of AE and IC and promote a culture of safety to minimize risks through the action of teams that operate in risk and patient safety management in the accredited units. With this project, Anvisa proposed to itself work in net with the health services to facilitate and expedite the collection and sharing of information on product performance[6].

The project started in 2002, with a pilot project. It included 96 large hospitals, mainly public university hospitals that perform medical procedures of medium and high complexity. In order to expand and consolidate the pilot experience, the project was renewed for a period of five years, from 2005 to 2009[6].

In the following years, there was an expansion of accredited services to other health establishments to develop actions related to the promotion, protection, maintenance and recovery of health, regardless of their level of complexity, whether in hospitalization regime or not, including care in offices, homes and mobile units[7].

The conformation of the specific regulatory framework for the Sentinel Network began through the search for sustainability and the expansion of the scope of the Sentinel Network. In April 2011, the Criteria for Institution Accreditation were published, whereby any institution that complies with the new criteria for participation could be a sentinel service for the National Sanitary Surveillance System (SNVS)[8]. In 2014, Anvisa published the Resolution of the Collegiate Board of Directors (RDC) n. 51, of September 29, 2014, and Normative Instruction (IN) n. 8, of September 29, 2014. RDC n. 51/2014 establishes the Sentinel Network for SNVS and IN n. 08/2014 deals with the criteria for registration, participation and permanence of health services in the Sentinel Network[9,10].

According to article 15 of IN n. 8/2014, the accreditation in the Network is valid for 24 months. The first accredited institutions have already finished this period, so a study was prepared to verify the profile of the network in the year 2016. With the results we hope to contribute to network quality improvement, re-accreditation and accreditation of new health institutions, based on the needs and expectations of Vigipós.

METHOD

The study is descriptive, quantitative, based on the collection of information from the documents sent to Anvisa by health institutions at the moment of registration, active search for complementary information in the portals of the institutions, collected at the National Register of Health Establishments (CNES) and subsequent confirmation of the information with the Risk Managers of each institution via email.

The screening applied for data collection was: year of accreditation, geographical location of the institution, size, legal nature of the service (public or private), private or public care level of attention, service specialty, whether it is a teaching hospital, a university hospital and whether it has a contract with the Brazilian Hospital Services Company (EBSERH), number of active beds, whether it has an Intensive Care Unit (ICU), number of employees (own staff and outsourced), whether it has a hospital accreditation certificate and, if so, by what institution, whether it does clinical research and average number of monthly hospitalizations.

As an inclusion criterion, we considered the institutions accredited in the Network until September 2016. Institutions that requested accreditation after that period were in the exclusion criterion and the corresponding data was not accounted for this study. Thirty-seven institutions did not confirm the requested data. We also

used the information found in the documents sent by the institutions to Anvisa at their time of registration as sentinel services.

RESULTS

We analyzed the profiles of 224 institutions. We verified that of these services one was accredited twice, one institution was merged after being accredited with another sentinel hospital and one institution that was run by the state passed to municipal management and there was no positioning of the new directors as to whether it will remain as a sentinel hospital or not. In view of the foregoing, these services were excluded, totaling 221 accredited institutions.

The Network has 218 hospitals, two blood centers and one hematology and hemotherapy center. These services are present in 24 states, with no representation in the states of Amapá, Piauí and Roraima. Regarding the geographic location, 62 (28%) of the institutions are located in São Paulo, 22 (10%) in Minas Gerais and 20 (9%) in Rio de Janeiro. The other institutions are in other Brazilian states, as shown in the Figure.

We observed that 56% of the accredited institutions are large-sized (150 to 500 beds), 24% are medium-sized (50 to 150 beds), 13% have extra capacity (over 500 beds) and 7% are small-sized (under 50 beds)[11]. The total number of active hospital beds in the Network is 59,972 and only 14 services do not have ICU. The Network presents an average of 189,900 hospitalizations per month (sum of the means of the institutions with hospital admission) and totals 420,027 employees and outsourced staff.

Within the Sentinel Network, 161 members are general hospitals and 60 are specialized institutions. It is noteworthy that 131 institutions of the Network are certified as teaching hospitals, whereas 23 of the 139 public hospitals (16.5%) and 39 of the 82 private hospitals (47.6%) are certified with hospital accreditation.

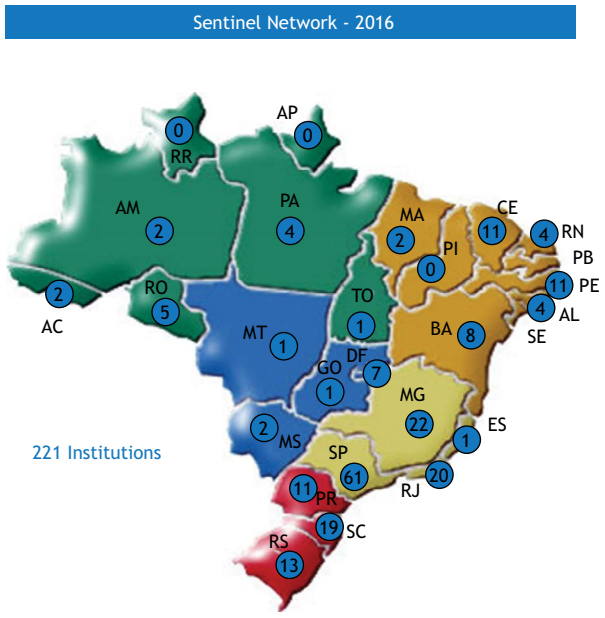

Figure. Distribution of Sentinel Services per state, Brazil 2016.

Regarding clinical research, 109 institutions responded positively to the question, and of this group, 90 are certified as teaching hospitals.

DISCUSSION

Comparing the data found in the survey with the information extracted from the CNES for the year 2016, we note that the number of hospitals accredited as Sentinels corresponds to 3% of the institutions in Brazil and represents 12% of the active beds[13]. At CNES, 83% of the hospitals are classified as general hospitals and only 17% are specialized hospitals (Table 1). This data reflects the current situation of the Network, with 72% of general hospitals

Regarding the levels of attention of the health services, 187 institutions are of high complexity, 33 of medium complexity, and one institution focused on basic care[12].

We verified that 139 accredited institutions have public management, of which 126 only treat SUS patients. Of the 50 federal university hospitals in Brazil, 23 joined the Sentinel Network and, among these, 20 are currently managed by EBSERH. and 28% of specialized services. It is noteworthy that, of the 205 institutions registered as teaching hospitals in CNES, 131 are registered in the Sentinel Network.

Among the institutions accredited as Sentinel Hospitals, 187 are institutions that perform high complexity procedures. This demonstrates the importance of the Sentinel Network because it deals regularly with a wide variety of light and harsh technologies[14]. Therefore, these institutions are observatories of risk management associated not only with the use of the technologies themselves, but also regarding the organizational processes related to it.

At present, technological innovation in health services is increasingly fast and provides a great challenge for Anvisa, as a regulator, to establish new strategies to obtain information about medicines, equipment and health products regarding their effectiveness and safety during use in hospitals. With the creation of sentinel services, Brazil hoped to fill the existing gaps in the quality of the information regarding the performance of these products and that could help Anvisa's decision-making process[15].

In 2006, the Notification System for Health Surveillance (Notivisa) was created to receive computerized notifications of incidents, AE and IC related to the use of products and services under health surveillance. It is important to remember that AE surveillance and communication with the SNVS is the responsibility of all services

Table 1. Comparison of the Sentinel Network with information extracted from CNES for the year 2016.

Characteristics		Sentinel Network	National Register of Health Establishments
Total Institutions		221	6,690
Number of beds		59,972	491,587
Profile	General	161	5,552
	Specialized	60	1,138
Teaching Hospital		131	205

subject to health surveillance[2,21]. However, according to the data obtained from the computerized system, we can see the importance of the Sentinel Network: the notifications made by these health institutions accounted for 43% of the total notifications made in 2016, as shown in Table 2. In the Sentinel Network, the value is in the systematization to obtain the information from services that are continually stimulated and able to, among other factors, qualify the data to be informed. The member institutions, in turn, are offered onsite and remote education activities about ongoing risk management and patient safety.

When they were questioned about being university hospitals or certified as educational institutions, we emphasize that these services can be agents of change and transformation. These institutions are hubs that train human resources, conduct research, develop techniques and procedures for Public Health, and incorporate new technologies that contribute to the improvement of the health conditions of the Brazilian population[16].

Given the above, we can see that these services are favorable sites for observing the behavior of new health technologies, as well as for training human resources with a "sentinel vision" to report the occurrence of failures involving health services and products.

The purpose of knowing if the institutions of the Sentinel Network have a hospital accreditation certificate is to understand if these certifications are implementing quality care through predefined standards, seeking better procedures and more reliable results, in addition to the search for continuous service improvement[7].

Accredited services do not guarantee that failure will not happen, however, they have norms that provide preventive actions, that when an AE occurs, it must be analyzed and a corrective action must be immediately determined to prevent this type of failure from occurring again. This workflow facilitates risk management and minimizes the uncertainty related to the differentiation between the failure of the work process and the failure of the product used[15].

Table 2. Category of notifications in Notivisa and number of notifications made in the year up to 2016.

Category of notifiers	N. of notifications
Citizen	16
Cell and germ tissue bank	40
Public health laboratory	79
Clinical analysis laboratory	102
State Department of Health	158
Others	312
Universities/research centers	590
Outpatient facilities	695
Healthcare establishment	2,782
Municipal Health Office	5,166
SNVS	16,505
Hemotherapy service	22,356
Healthcare professional	31,844
CIAT	39,057
Company	44,884
Hospital	77,930
Sentinel Network	184,331
Total	426,847

SNVS = National Health Surveillance System; CIAT = Toxicological Information Center.

Another important point is that the accreditation process, as the Sentinel Network, assumes that it is an ongoing education program and not a form of supervision[7,17]. Both are based on culture change with proactive action and, in the specific case of the Network, on the change related to the topics of Vigipós.

About the results, we observed that, although the Network is formed by several public services, the number of accredited public hospitals is very low. This reflects the Brazilian reality, in which Hospital Accreditation is still more common among private institutions. This was observed in a study in which only 46 (13.3%) of the 345 (100%) services accredited by the National Accreditation Organization (ONA) were from the public sector[18]. This differs from the reality of countries like Australia, Canada or the United Kingdom, where accreditation is increasingly approaching government action and extended to state-run health institutions[19].

The importance of the knowledge of accredited institutions conducting clinical research lies in the fact that these hospitals do investigation in humans, with the objective of evaluating/identifying the pharmacodynamics, pharmacological and clinical effects, as well as the emergence of new adverse reactions to the product under investigation or even to confirm the frequency of the occurrence of already known reactions, ascertaining their safety and/or efficacy[20,21].

Regarding the survey, although 187 institutions confirmed the information collected by Anvisa, 37 establishments did not confirm the requested data, which may have resulted in limited and incomplete data. Another limiting factor is the lack of studies with the same objective and target population for comparability purposes.

CONCLUSIONS

The Sentinel Network serves as an observatory inside the health establishments for the management of health risks, in joint and effective action with the SNVS. It is an important strategy to strengthen Vigipós. Notifications from the Sentinel Network are qualified information that integrate post-marketing SNVS and support health surveillance bodies in the regulation of these products on the market.

It is also important to strengthen partnerships such as the Sentinel Network in order to promote a patient safety culture in the country's health institutions, with the improvement of the work processes involved in the surveillance and monitoring of healthcare-related incidents.

Considering that sentinel institutions play an important role in the production of information to support health surveillance actions, we should think about the representation of the sentinel institutions in Brazil, in order to extend Vigipós to 100% of the Brazilian states. We must also consider the possibility of increasing the number of private institutions, since in these services new technologies are usually adopted earlier and more frequently.

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Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.