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Integration laboratories-sanitary surveillance: a review Integração laboratórios-vigilância sanitária: uma revisão

ABSTRACT

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KEYWORDS: Laboratories; Sanitary surveillance; Quality control; Integration

RESUMO

Identificar literatura nacional e internacional sobre laboratório e vigilância sanitária para refletir sobre a integração desses serviços no Sistema Nacional de Vigilância Sanitária foi o objetivo da revisão integrativa com busca sistemática em três repositórios: Banco de Teses e Dissertações; Scientific Electronic Library Online - Brasil e Pubmed Central. A seleção seguiu critérios pré-definidos e a análise considerou: tipo de produção acadêmica (mestrado, doutorado ou artigo científico), ano e instituição de origem, tema focalizado. Predominaram trabalhos oriundos do mestrado (64,7%) e, como instituição, a Fundação Oswaldo Cruz (36,5%), sendo 90,0% no Instituto Nacional de Controle da Qualidade em Saúde. O controle da qualidade de produtos é área expressiva das publicações (71,0%), incluindo-se nela alimentos, medicamentos e vacinas. Estudos relacionados a políticas públicas e vigilância sanitária tematizaram: medicamentos genéricos; estudos de equivalência farmacêutica; alimentação e nutrição; e integração da Agência Nacional de Vigilância Sanitária com outros atores na inovação de vacinas e na Rede Brasileira de Laboratórios Analíticos em Saúde. A integração se expressou mediante as atividades cooperativas entre laboratórios e serviços, restando aprimorá-la, tendo-se em vista que, no Brasil, os laboratórios e os serviços de vigilância são diferenciados e vinculam-se a entes governamentais distintos.

- PALAVRAS-CHAVE: Laboratórios; Vigilância sanitária; Controle de qualidade; Integração
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INTRODUCTION

Sanitary surveillance covers many areas of knowledge and several practices and is part of the collective health field. It acts in the prevention of sanitary risks arising from the production processes and the consumption of goods and services. One of its peculiarities is to act within the scope of intervention in the social relations of production and consumption¹. Nonetheless, its effective action conflicts with various interests² and can suffer political interference¹ in its performance.

The actions of sanitary surveillance are under the scope of the Brazilian Unified Health System (SUS), alongside the actions of epidemiological surveillance, occupational health and comprehensive care³. However, the National Sanitary Surveillance System (SNVS) and the role of the federal sphere were defined by the law that created the National Agency of Sanitary Surveillance (Anvisa)⁴, and some roles of the state and local spheres were made explicit in later norms for certain products under surveillance.

Among the products subject to sanitary surveillance there are drugs for human use, food (including beverages, their ingredients, packaging and food additives), cosmetics, personal care products and fragrances, sanitizers intended for cleaning, disinfection or disinfestation in homes, hospitals and collective environments, tool kits, reagents and supplies for diagnosis, medical and hospital equipment, dentistry materials, supplies for hemotherapy and laboratory and imaging diagnostics, blood and blood products, organs and tissues for use in transplants or reconstitutions, fumigants and derivatives. Services include outpatient care, routine or emergency care, hospitalization, diagnostic and therapeutic support services, other healthcare services, as well as services involving the adoption of new technologies⁴.

From an organizational standpoint, as a service in the healthcare sector, sanitary surveillance actions are carried out by Anvisa and the sanitary surveillance bodies of Brazilian states and cities, the National Institute for Quality Control in Health (INCQS) and the Central Public Health Laboratories (Lacen)^{4,5}. In practice, there is also the participation of local public laboratories, which carry out simpler laboratory analyses, such as the physical-chemical analysis of food and the verification of drinking water standards for human consumption. These highly differentiated services - different in structure and institutional scope, territorial coverage, resources - form a national system, which needs articulation and integration⁶, as well as some coordination, to perform the expected activities properly.

The SNVS public health laboratories are involved in health risk assessment. They are supposed to identify risks and propose intervention and control mechanisms⁷ to the regulatory bodies. Through the analytical evaluation of products, they support inspection initiatives, contributing to the investigation of health problems and deviations in product quality. After laboratory analysis of seized product samples, they contribute to the sanitary administrative process⁷ established by the proper departments. The result is the correction of the irregularities or the establishment of sanctions and penalties provided for by the law⁸.

Public laboratories have already been considered by some authors as the most critical components of the SNVS⁹, due to their unique complexity, mastery of analytical techniques and specific structural conditions to evaluate products or services of interest to public health. Therefore, these laboratories demand constant adaptation and qualification of their human resources¹⁰. However, despite the challenge in their management, they are strategic entities in the SNVS.

Some laboratories perform more complex activities, like proficiency tests, which enable Brazilian analytical laboratories to assess the reliability of the results they produce, supplementing internal quality control procedures; the production and supply of reference material (chemical and biological), which work as yardsticks in the identification, characterization and/or assignment of property values for analytical determinations; the elaboration or participation in collaborative studies and the development and validation of analytical methodologies. They also play an important role in formulating proposals, drafting or amending legislation, proposing lines of research, technological development and the promotion and organization of events (such as congresses, symposia, workshops, among others). Furthermore, they work in the maintenance of a reference collection of microorganisms and in the training of professionals^{7,11}.

It is generally expected that cooperation and integration between laboratories and sanitary surveillance bodies in the different spheres of government will enable efficient action. This should contribute to the improvement of the population's living conditions. We can state that, by working in an integrated fashion, laboratories contribute to greater safety and quality of the products available in the market, in addition to supporting the process of registration and inspection of products by the surveillance bodies.

Part of the joint operation of these services may be expressed in technical and academic publications. Therefore, the present study uses important sources of information in the literature with the objective of identifying Brazilian and international literature on laboratory and sanitary surveillance in three bibliographic databases to support the reflection on the integration of these services in the SNVS.

METHOD

Type of study and data sources

The method we adopted was the integrative literature review. Our intention was to identify Brazilian and international literature on the topic of "public health laboratories and sanitary surveillance" in different databases. The choice of an integrative review as our method stems from its ability to promote broad understanding of the area of knowledge¹². Moreover, it can recognize gaps and opportunities for the emergence of research on the topic in question¹³. The term "integrative" means there is a collection of opinions, concepts or ideas from previous



selected studies. The steps of this method are: identification of the research topic; problem definition; formulation of a research question; definition of the search strategy; definition of descriptors and databases until the results are presented¹³.

Systematic searches were carried out in three bibliographic databases: Capes Portal - Theses and Dissertations Catalog¹⁴, which contains information provided directly to the Coordination for the Improvement of Higher Education Personnel (Capes) by the postgraduate programs maintained by Brazilian universities and research institutions; Scientific Electronic Library Online (SciELO)¹⁵, which brings together a collection of journals with full-text scientific articles. In the first database, we searched for the abstracts of theses and dissertations produced in Brazil. In the second, we searched for indexed national scientific articles. The third database was PubMed Central (PMC)¹⁶, with biomedical and life sciences archives at the National Institutes of Health of the National Library of Medicine (NLM), which include governmental documents and international open access articles.

Search strategies

In the Capes Portal, a bibliographic search was carried out in May 2013 and December 2014, by topic, using the following search terms: "análise laboratorial" and "vigilância sanitária", "laboratório" and "vigilância sanitária"; "vigilância sanitária" and "análise laboratorial de produtos", "vigilância sanitária" and "avaliação analítica"; "vigilância sanitária" e "controle da qualidade *de produtos*". There was no period restriction, but the language was restricted to Portuguese. In SciELO-Brazil, the terms "*análise de alimentos*" and "*análise de medicamentos*" were added to the search conducted in January 2015. In the PMC database, we did a bibliographic search in November 2014, with the following search keys: laboratories or laboratory and integration or integrated and government regulatory agency and drug regulations or food regulations. The terms "integration" and "regulation" were used in this database because they are associated with sanitary surveillance internationally. The bibliographic materials found according to descriptors and bibliographic basis are described in the Table.

Inclusion and exclusion criteria

All the papers retrieved using the search strategies described above were included, with the only restriction being the Portuguese language for the theses and dissertations database. We excluded duplicate papers and those related to epidemiological and environmental surveillance, or any other area that was not sanitary surveillance.

Categories of analysis

All the papers were classified as to their area (product quality control, sanitary surveillance of services and other areas) and topic; and for theses and dissertations we considered the type of academic production (master's, doctorate or article), year and institution of origin. Theses and dissertations were also classified according to the year and institution of origin of the academic production.

Chart. Summary of search terms, databases and papers found

Database	Search terms	Papers
Portal Capes	"Análise laboratorial" and "vigilância sanitária"	
	"Laboratório" and "vigilância sanitária"	110
	"Vigilância sanitária" and "análise laboratorial de produtos"	9
	"Vigilância sanitária" and "avaliação analítica"	74
	"Vigilância sanitária" and "controle da qualidade de produtos"	149
	"Laboratório" and "vigilância sanitária "e "integração"	0
SciELO	"Análise laboratorial" and "vigilância sanitária"	0
	"Laboratório" and "vigilância sanitária"	6
	"Vigilância sanitária" and "análise laboratorial de produtos"	0
	"Vigilância sanitária" and "avaliação analítica"	0
	"Vigilância sanitária" and "controle da qualidade de produtos"	0
	"Laboratório" and "vigilância sanitária" and "integração"	0
РМС	laboratory and quality control and products and regulation	20
	integration laboratory (health care system) and quality control and products	1
	integrated laboratory (health care system) and quality control and products	1
	(integration or integrated) and laboratory and (health surveillance or health regulation) and quality control and products	
	(integration or integrated) and laboratory and (health surveillance or sanitary surveillance) and quality control and products	3
	(integration or integrated) and laboratory and (regulatory or health regulation or health legislation) and quality control and products	9

Source: Portal Capes, SciELO-Brazil and PMC (includes materials in duplicity).



RESULTS AND DISCUSSION

In this section we present results and the discussion organized by searched databases, corresponding to the national and international literature. What stands out is the small number of selected publications in the studied topic, namely sanitary surveillance and laboratories (n = 151). The process of selecting papers according to databases is explained in the Figure.

Although the production on sanitary surveillance is increasing^{17,18}, and this paper reiterates this trend also for the topic under study, the small number of studies we found in SciELO and PMC seems to be an indication that the production of theses and dissertations does not always result in scientific papers published in indexed journals with full text and free access.

Even though we did not find the term "integration" in the Brazilian databases related to sanitary surveillance, this study contributes to the reflection on the integration between laboratories and sanitary surveillance bodies, insofar as it lists the activities carried out by them in collaboration to improve the operation of the SNVS. However, it is important to note that the identification of publications with the term "integration" was expected, since in Brazil, unlike Chile and the United States, for example, laboratories are linked to different institutions and governmental bodies.

In Chile, the National Institute of Public Health (ISP) is itself a quality control laboratory, which regulates drugs, food for medical use and other products subject to sanitary control¹⁹, carrying out food, pharmacological and environmental contamination analyses and studies on occupational health. Furthermore, similarly to our Lacen, ISP also acts as a clinical laboratory that performs microbiological and immunological analyses. In the United States, the US Food and Drug Administration (FDA) is a federal agency that operates with 13 field laboratories²⁰.

Brazilian literature

In the Capes Theses and Dissertations Catalog we found papers dating back to 1996, with an upward trend until the year 2012. It represents part of the national academic production classified as "gray literature", which may be embodied in articles published later or not. Based on the results we obtained, we can state that the scientific production on sanitary surveillance in this database is increasing. Although only recently has sanitary surveillance occupied the important forums of scientific production, focused on collective health, its objects of interest (drugs, food, health products, health services and environment, including the work environment) have been studied under various aspects for a long time. Despite the concentration, as well as other health-related areas, sanitary surveillance has appeared in several academic publications. Its growth has been credited to the greater access of sanitary surveillance professionals to postgraduate programs¹⁷.

The analysis of the 142 papers we selected showed the predominance of master's degrees (64.7%) over doctorate (16.9%) and specialization courses (2.8%). In two papers the level of the course was not informed. About the institutions of origin of the academic production, the Oswaldo Cruz Foundation (Fiocruz) plays an important role in the training of students in the field of sanitary surveillance. The work done at Fiocruz in its various technical-scientific units accounts for 36.5% of the total, with more than 90% of the studies done at the INCQS. This predominance of the academic production on sanitary surveillance in the INCQS can be due to its cooperation with the network of laboratories and with the state and local bodies of sanitary surveillance and Anvisa¹¹. In addition, it is the only program called Postgraduate Program in Sanitary Surveillance, including the area of Quality of Health Products.

All the regions of the country have institutions with studies on the area of sanitary surveillance. However, the Southeast, Northeast and South regions stand out in relation to the number of papers and academic institutions.

We could verify that there is a significant concentration of publications on the topic of quality control of products (71%), which is an important area of joint action between laboratories and sanitary surveillance bodies. In order to perform this type of action, sanitary surveillance bodies collect samples and send them to the laboratories to assess the conformity of the product. This contributes to safer products on the market and supports the process of product registration and inspection by the surveillance bodies.

In the product quality control, food-related topics prevail, mainly

in relation to master's and doctorate studies. With the same fre-

quency of the "food" topic, the topic of "study, development or

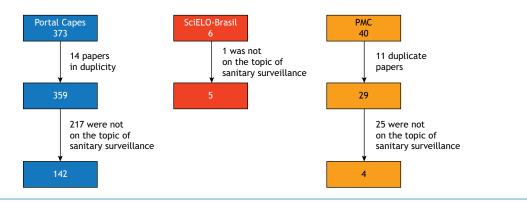


Figure. Flowchart of the selection process and result according to bibliographic databases.



validation of analytical methodology of products subject to sanitary surveillance" stands out. Quality control also includes the topics of "drugs", "medicinal plants, herbal medicines", "diagnostic kits", "hemodialysis water", "cosmetics", "sanitizers", "health products (condoms)" and "vaccines" (Table).

Still in relation to the topic of "study, development or validation of analytical methodology of products", we must emphasize that, after the development of a methodology for laboratory analysis, a validation process must be conducted to ensure that the new analytical method produces reliable information. Validation is an ongoing process that begins in the planning of the analytical strategy and continues throughout the development and transfer of a method. For new product registration, the Brazilian regulatory agency, Anvisa, requires the validation of analytical methodologies and, for this, there are official documents that guide the criteria to be adopted in this process.

The category of "other areas of sanitary surveillance" contains papers on "public policies", "waste management", "techno-surveillance", "occupational health", "risk assessment", "pharmacovigilance" and "irregular animal breeding".

In the topic of "food quality control", we addressed the control of microbiological and chemical parameters as well as pesticide residues. "Mandatory nutritional labeling of foods" and "food quality in the context of food safety policy" were also analyzed. Several food matrices were studied (fruit and vegetables, meat, poultry, cheese, milk, fish, eggs, ice cream, baked goods and other processed products). In the "quality control of drugs", we investigated antiretroviral drugs, herbal medicines and aspects related to good manufacturing and handling practices of these products.

We included development and validation of analytical methodologies, both the phenotypic and molecular characterization methods of microorganisms, as well as the chromatographic (liquid chromatography and gas chromatography) and spectrophotometric methods. Methodologies for the analysis of vaccine components were also discussed.

In "sanitary surveillance of services" (22 papers), we studied human milk banks, pharmacies, hemotherapy services, hospitals and laboratories. In this service area, we also considered papers on management, including the management of a laboratory cleaning service and quality management tools (benchmarking and external customer satisfaction assessment).

Five dissertations were found on the topic of "public policies". Three papers were on the topic of drug-related policies. Some of the themes we addressed were the need to encourage investment in the production and control of drugs, knowing the factors that undermine the production of generic drugs in Brazil and the need for studies on pharmaceutical equivalence as strategic elements for the implementation of the generic drug incentive policy. Another paper analyzed the main channels of communication between Anvisa and the various stakeholders involved in innovation in vaccines, aiming to understand the processes that hinder progress in this area. Another one referred to the Food and Nutrition Policy of the Ministry of Health, which determines the fortification of wheat flour with iron and folic acid and the collective perception, by the regulated sector, of this Brazilian standard.

In the SciELO-Brazil database, we selected five full articles. The papers addressed the topics of "product quality control" (food and drugs, including phytotherapy), "occupational health" and "decentralization of sanitary surveillance actions".

The paper on food addressed the ingestion of mycotoxins in contaminated food as a public health problem²¹. The laboratory results presented are the result of joint actions between the sanitary surveillance body and the public health laboratory (Lacen-DF). The presence of aflatoxins was detected, with higher contamination in the samples of peanuts and derivatives, Brazil nuts and popcorn corn. It should be noted that aflatoxins B1 and G1 were found, in addition to B2 and G2. At the time of the study, B2 and G2 were not present in Brazilian legislation. Although Brazilian legislation does not provide for maximum levels of these mycotoxins (B2 and G2) and ochratoxin in food, the authors already pointed out that monitoring programs are necessary to subsidize human exposure studies and to assess the need to establish the appropriate levels. It brings to the discussion the possibility that laboratory results can subsidize the discussion on the need to elaborate new norms.

A study conducted at the INCQS with injectable drugs submitted to fiscal analysis²² identified 75% of the losses were related to the sanitary surveillance service and 25% of the losses were related to laboratory issues. The paper highlights the importance of seizing samples in a strict and judicious manner, as ruled by the legislation, since any irregularity in the administrative or technical procedure may invalidate the measure, even in scheduled seizures. Some drugs failed to be analyzed due to irregularities at the time of seizure, with highlights to: poorly stored or broken samples, improper collection, product not recognized by the company as its own, batch with different records, violated container, a different batch from that in the seizure term, mix of batches, product without registration in the Ministry of Health, insufficient quantity, product without the term of seizure and expired validity. These problems in the collection of drugs may be related to the poor training of human resources or to the insufficient infrastructure of the control centers, as well as to the lack of adequate materials to submit the samples.

Laboratory issues were related to lack of reagents, lack of analytical methodology described in official compendium, absence of reference chemicals (SQR) and duplicity of analysis. All these reasons are circumstantial and have been remedied, according to the authors. The sanitary surveillance bodies with the highest percentage of success in the use of the collected samples stood out because of their strategic institutional planning, quality indicators and goals to be achieved annually, among them, the training of the entire team²².

The paper on phytotherapeutic surveillance in the Brazilian state of Minas Gerais describes the results of laboratory tests performed on different commercial samples of chamomile²³. The Brazilian



Sanitary surveillance area	Sanitary surveillance topics	Capes Theses and Dissertations Catalog	SciELO-Brazil	РМС	Total
	Food	38	1	1	40
	Drugs	9	2	-	11
	Medicinal plants	1	-	-	1
	Vaccines	1	-	-	1
	Diagnostic kits	1	-	-	1
	Hemodialysis water	2	-	-	2
	Cosmetics	1	-	-	1
Production and quality control of products	Health articles (condoms)	1	-	1	2
•	Natural products	3	-	-	3
	Sanitizers	2	-	-	2
	Study, development or validation of product analytical methodology	40	-	-	40
	Production of reference material	2	-	-	2
	Proficiency test		-	1	1
	Subtotal (production and control)		107		
Conitony surveillance of convices		22		-	22
Sanitary surveillance of services	Subtotal (surveillance of services)		22		
	Public policies	5	-	1	6
	Waste management	2	-	-	2
	Technosurveillance	4	-	-	4
	Occupational health	1	1	-	2
	Irregular breeding of animals	1	-	-	1
	Study of strains	1	-	-	1
Other areas of sanitary surveillance	Pharmacoepidemiology	1	-	-	1
	Pharmacovigilance	1	-	-	1
	Risk management	1	-	-	1
	Planning	1	-	-	1
	Risk assessment	1		-	1
	Decentralization of actions		1	-	1
	Subtotal (other areas)		22		
TOTAL		142	5	4	151

Table. Distribution and frequency of bibliographic materials selected according to areas and topics of sanitary surveillance and searched bibliographic databases.

samples did not meet the quality standards required by official codes and literature. The authors point out that part of the samples are marketed in pharmacies, which may compromise the importance they may represent in Brazilian public health, in addition to reinforcing the importance of inspecting this product in the country.

One study addressed strategies to decentralize the actions of sanitary surveillance adopted by the State Department of Health in the process of decentralization to the cities²⁴. The study highlighted the challenges that surveillance workers have to face to carry out these actions, namely: insufficient human resources in number and capacity; poor infrastructure in terms of facilities, equipment, material and funds; lack of joint planning and communication between the three spheres of management of sanitary surveillance²⁴.

The last paper included in this selection uses the example of a study on the presence of "endocrine disruptors" (ED) in products of interest to sanitary surveillance²⁵ to highlight the importance of improving the relationships between institutions. It mentions the need not only for normative commitment, but also for partnerships

between the State, the academic community, consumers, workers, producers and commerce, monitored by the public interest. Some measures that have already been adopted and targeted at ED were reported, such as the establishment of a reference laboratory for the analysis of persistent organic pollutants (POPs), the interruption of the use of several POPs in Brazil and the beginning of the review of the requirements for registration of pesticides by Anvisa²⁴.

International literature

In the analysis of the international publications of the PMC database, only four papers were selected^{25,26,27,28,29}. One of them addressed quality control of medical products, specifically medical devices and in vitro diagnostic tests (IVD), as vital components of healthcare systems. It points out the difficulty of national regulatory authorities in dealing with these products in some countries, highlighting the existence of laboratories to guarantee the quality of the products. Some activities to evaluate IVD are carried out in research laboratories. Training in key areas is considered essential to strengthen the regulatory capacity regarding IVD and other medical devices²⁶.



The global situation of the legislation and regulation for the control of pesticides in public health was also evaluated²⁷. When present in the country, legislation often lacked scope, for example, on basic aspects such as pesticide labeling, storage, transportation and disposal. Guidelines or essential requirements for the pesticide registration process were missing in many countries. This paper emphasizes that half of all countries had no pesticide quality control laboratories, and two-thirds reported high concern about the quality of the products on the market²⁷.

A paper²⁷ dealt with laboratory proficiency testing. The proficiency test is an important tool to evaluate the performance of the method used in the analysis of the products under investigation. The paper brings to our attention the discussion on the implementation of quality management system in laboratories, since, in addition to performing analysis, laboratories need to produce reliable results²⁸.

Another paper was the result of a master's dissertation in Brazil, published in English, and presented a proposal for articulation between sanitary surveillance bodies and the national drug policy when addressing the National Program for the Verification of the Quality of Medicines (Proveme), a drug quality control program. Thus, this fourth article addresses the discussion about some integration with drug policies, highlighting the role of Anvisa together with INCQS and Fiocruz²⁹.

CONCLUSIONS

Although the term "integration" was not found in publications related to sanitary surveillance in Brazilian databases, based on the identification of the papers we could understand that it appears in activities carried out in an articulated and cooperative manner by the public health laboratories with sanitary surveillance bodies, albeit with considerable room for improvement. Furthermore, one of the meanings of the term "integration" is to be part of a whole and to adapt to it³⁰. In the case in hand, we have the legal definition of the system and the evidence of joint work. However, there is still a great challenge to improve this articulation in the daily work of these services, considering that, unlike other countries, in Brazil laboratories do not belong to the regulatory agency and are linked to other governmental entities.

It is noteworthy that, in Brazilian and international literature, there are few papers on "laboratories" not related to the quality control of products through analytical laboratory procedures and their results, as well as on the national sanitary surveillance policy and management.

In order to have a broader view of the topic of "laboratories and sanitary surveillance", we recommend doing some research that addresses the matter in a systemic fashion. Although the academic production on sanitary surveillance is increasing, we presume there is some invisibility in the production due to several factors. Among them, the fact that it is usually easier to publish and find advisory in subjects that are somehow related to sanitary surveillance (pharmaceutical sciences, health services, collective health). This can be explained by the identification of the descriptors used in final papers, which revealed a more frequent adoption of specific keywords than those referring to the area of sanitary surveillance or laboratory services.

It may be that the multiple meanings of practical and theoretical ideas in the field of health surveillance also contribute to this invisibility. The existing sanitary surveillance model in Brazil is unique, because: 1) it incorporates three spheres of government into the SNVS, two of which are very important for the laboratories: the states and the federal sphere. In the city level, public health laboratories are not particularly engaged in sanitary surveillance; 2) the practices included in sanitary surveillance in Brazil are significantly different from those in force in other countries. It should also be noted that this uniqueness makes it difficult to draw international comparisons and is a challenge to the search in international bibliographic databases.

REFERENCES

- Costa EA. Vigilância sanitária: temas para debate. Salvador: EDUFBA; 2009. Fundamentos da vigilância sanitária; p. 11-36.
- De Seta MH, Silva JAA. A gestão da vigilância sanitária. In: De Seta MH, Pepe VLE, Oliveira GO, organizadores. Gestão e vigilância sanitária: modos atuais do pensar e fazer. Rio de Janeiro: Editora Fiocruz; 2006. p. 195-217.
- Brasil. Lei N° 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. Diário Oficial União. 20 set 1990.
- Brasil. Lei N° 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. Diário Oficial União. 27 jan 1999.

- De Seta MH, Dain S. Construção do Sistema Brasileiro de Vigilância Sanitária: argumentos para debate. Cienc Saúde coletiva. 2010;15(Supl 3):3307-17. https://doi.org/10.1590/S1413-81232010000900002
- Costa EA. Políticas de vigilância sanitária: balanços e perspectivas: texto elaborado como subsídio aos debates da I Conferência Nacional de Vigilância Sanitária, Brasília, 26 a 30 de novembro de 2001[acesso 3 fev 2017]. Disponível em: https://pt.scribd.com/document/116941470/ Politicas-de-Vigilancia-sanitaria
- Silva ACP, Oliveira CVS, Cavalheiro MVS, Miranda MCC. Desafios para a rede nacional de laboratórios de vigilância sanitária: o caso dos medicamentos manipulados. Cienc Saúde Coletiva. 2010;15 (Supl 3):3371-80. https://doi.org/10.1590/S1413-81232010000900012



- Brasil. Lei N° 6.437, de 20 de agosto de 1977. Configura infrações à legislação sanitária federal, estabelece as sanções respectivas, e dá outras providências. Diário Oficial União. 24 ago 1977.
- Lucchese G. Globalização e regulação sanitária: os rumos da vigilância sanitária no Brasil [tese]. Rio de Janeiro: Escola Nacional de Saúde Pública da Fundação Oswaldo Cruz; 2001.
- Pepe VLE, Silva ACP. Vigilância sanitária: campo da promoção e proteção da saúde. In: Giovanella L, Escorel S, Lobato LVC; Noronha JC, Carvalho AI, organizadores. Políticas e sistemas de saúde no Brasil. Rio de Janeiro: Fiocruz; 2012. p. 709-38.
- 11. Fundação Oswaldo Cruz Fiocruz. Relatório de gestão da Fiocruz. Rio de Janeiro: Fiocruz; 2016.
- 12. Ercole FF, Melo LS, Alcoforado CLGC. Revisão integrativa versus revisão sistemática. Reme Rev Min Enferm. 2014;18(1):9-12.
- Botelho LR, Cunha CCA, Macedo MO. O método da revisão integrativa nos estudos organizacionais. Rev Eletr Gestão e Sociedade. 2011;11(5):121-36. https://doi.org/10.21171/ges.v5i11.1220
- 14. Portal Capes. Banco de teses e dissertações. Brasília, DF: Capes; 2013[acesso maio 2013]. Disponível em: http:// bancodeteses.capes.gov.br/banco-teses/#!/
- Scientific Electronic Library Online SciELO. São Paulo: SciELO; 2015[acesso jan 2015]. Disponível em: http://www.scielo.org/php/index.php
- US National Library of Medicine, National Institues of Health, PMC. Washington, DC: National Institues of Health; 2014[acesso nov 2014]. Disponível em: https://www.ncbi. nlm.nih.gov/pmc/
- 17. Pepe VLE, Noronha ABM, Figueiredo TA, Souza AAL, Oliveira CVS, Pontes Junior DM. A produção científica e grupos de pesquisa sobre vigilância sanitária no CNPq. Ciênc Saúde Coletiva. 2010;15(Supl 3):3341-50. https://doi.org/10.1590/S1413-81232010000900009
- Paim JS, Teixeira CF. Política, planejamento e gestão em saúde: balanço do estado da arte. Rev Saúde Pública . 2006;40(spe):73-8.
- Sandri MMS, De Seta MH, Luiza VL. Autoridades reguladoras de medicamentos sul-americanas: uma análise a partir de regras organizacionais. Rev Panam Salud Publica. 2013;34(3):169-75.
- 20. U.S. Department of Health and Human Services, U.S. Food & Drug Administration FDA. Washington, DC: U.S. Food & Drug

Administration; 2017[acesso 3 fev 2017]. Disponível em: https:// www.fda.gov/scienceresearch/fieldscience/default.htm

- 21. Caldas ED, Silva SC, Oliveira JN. Aflatoxinas e ocratoxina A em alimentos e riscos para a saúde humana. Rev Saúde Pública. 2002;36(3):319-23. https://doi.org/10.1590/S0034-89102002000300010
- Souto CR, Silva AS, Magalhães MS, Huf G. Região Centro-Oeste se destaca na apreensão de medicamentos injetáveis encaminhados ao INCQS/FIOCRUZ. Rev Bras Epidemiol. 2010;13(2):363-8. http://dx.doi.org/10.1590/S1415-790X2010000200017
- Brandão MG, Freire N, Vianna-Soares CD. Vigilância de fitoterápicos em Minas Gerais: verificação da qualidade de diferentes amostras comerciais de camomila. Cad Saúde Pública. 1998;14(3):613-6. https://doi.org/10.1590/S0102-311X1998000300018
- Marangon MS, Scatena JHG Costa EA. Vigilância sanitária: estratégias para sua descentralização em Mato Grosso, 1996-2005. Ciênc Saúde Coletiva. 2010;15(Supl.3):3587-601. https://doi.org/10.1590/S1413-81232010000900034
- Waissmann W. Health surveillance and endocrine disruptors. Cad Saúde Pública. 2002;18(2):511-7. https://doi.org/10.1590/S0102-311X2002000200016
- 26. Rugera SP, McNerney R, Poon AK, Akimana G, Mariki RF, Kajumbula H et al. Regulation of medical diagnostics and medical devices in the East African community partner states. BMC Health Serv Res. 2014;14:524. https://doi.org/10.1186/s12913-014-0524-2
- 27. Matthews G, Zaim M, Yadav RS, Soares A, Hii J, Ameneshewa B et al. Status of legislation and regulatory control of public health pesticides in countries endemic with or at risk of major vector-borne diseases. Environ Health Perspect. 2011;119(11):1517-22. https://doi.org/10.1289/ehp.1103637
- Lasky FD. Proficiency testing linked to the national reference system for the clinical laboratory: a proposal for achieving accuracy. Clin Chem. 1992;38(7):1260-7.
- 29. Pontes Junior DM, Silva RS, Pepe VLE, Osorio-de-Castro CGS, Massena EP, Portela MC et al. A definição de medicamentos prioritários para o monitoramento da qualidade laboratorial no Brasil: articulação entre a vigilância sanitária e a Política Nacional de Medicamentos. Cad Saúde Pública. 2008;24(9):2081-90. https://doi.org/10.1590/S0102-311X2008000900014
- Dicio: Dicionário online de português. Integração. 2017[acesso 26 maio 2017]. Disponível em: https://www.dicio.com.br

Conflict of Interest

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



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