REVIEW
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Indicators for evaluating health surveillance actions: a narrative review of the literature

Indicadores para avaliação das ações de vigilância sanitária: uma revisão narrativa da literatura

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ABSTRACT

Introduction: The field of health surveillance accumulates experience in building process indicators for monitoring planned actions – managerial, administrative and technical -, and this has contributed to the organization of the work process in the National Health Surveillance System (SNVS). However, it still faces incipience in structuring indicators of the effectiveness of its actions. **Objective:** To identify, in the literature, sources of information and indicators aimed at measuring the effectiveness of the visa action, taking as a reference the theoretical and methodological proposal for the evaluation of visa actions. **Method:** Descriptive exploratory study, as a narrative review of the literature, about the identification of possible effectiveness indicators related to the components of the modeling proposal for visa actions. The search was conducted on the PubMed/Medline, Scopus, Lilacs, Cochrane Library and SciELO databases and in public information systems. **Results:** From the five components that describe the intervention (Management, Regulation, Health Risk Control, Health Risk Monitoring and Information, communication and education), 29 possible indicators that use existing data sources were identified and that can be considered for the development of evaluation research that contributes to the analysis of effects arising from the execution of visa actions. **Conclusions:** Based on the evidence found, of the existence of information sources and indicators related to the five components of the model, it is observed that the construction of indicators for the evaluation of health surveillance actions is possible and feasible. It is essential to face technological challenges such as interoperability between the various information systems and the definition of standards to be followed to exchange information of interest to the management area in searching for the implementation of evaluation practices in the SNVS.

KEYWORDS: Health Indicators; Effectiveness; Health Surveillance; Health Evaluation

RESUMO

Introdução: O campo da vigilância sanitária acumula experiência na construção de indicadores de processos para monitoramento das ações planejadas – gerenciais, administrativas e técnicas – o que tem contribuído para a organização do processo de trabalho no Sistema Nacional de Vigilância Sanitária (SNVS). Entretanto, ainda se depara com incipiência na estruturação de indicadores de efetividade de suas ações. **Objetivo:** Identificar na literatura a existência de fontes de informações e indicadores voltados à mensuração da efetividade da ação de vigilância sanitária, tomando-se como referência a proposta teórico-metodológica para avaliação das ações de vigilância sanitária. **Método:** Estudo descritivo exploratório, do tipo revisão narrativa da literatura, acerca da identificação de possíveis indicadores de efetividade relacionados aos componentes de modelagem proposta para ações de visa. Realizaram-se buscas nas bases de dados PubMed/MEDLINE, Scopus, Lilacs, *Cochrane Library* e SciELO e em sistemas de informação públicos. **Resultados:** A partir dos cinco componentes que descrevem a intervenção (Gestão, Regulação, Controle do risco sanitário, Monitoramento do risco sanitário e Informação, comunicação e educação), foram identificados 29 possíveis indicadores que

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utilizam fontes de dados já existentes e podem ser considerados para o desenvolvimento de pesquisas avaliativas que contribuam para a análise dos efeitos oriundos da execução das ações de vigilância sanitária. **Conclusões:** Com base nas evidências encontradas, da existência de fontes de informação e indicadores relacionados aos cinco componentes do modelo, observa-se que a construção de indicadores para avaliação das ações de vigilância sanitária é possível e factível, sendo fundamental enfrentar desafios tecnológicos como a interoperabilidade entre os inúmeros sistemas de informação existentes e a definição de padrões a serem seguidos para troca de informações de interesse da gestão na busca da implantação de práticas avaliativas no SNVS.

PALAVRAS-CHAVE: Indicadores de Saúde; Efetividade; Vigilância Sanitária; Avaliação em Saúde

INTRODUCTION

Health indicators are fundamental instruments for decision making during the execution, monitoring, and evaluation of health policies, which are affected, at all times, by changes in context, environment, and population dynamics. In this sense, the indicators assist public management in developing the capacity to respond to such changes effectively and efficiently, based on clear and objective evidence of disease patterns, their risk factors, and the effects resulting from their interventions[1].

Historically, health indicators are widely used by researchers and managers, such as mortality, mortality from specific causes, life expectancy, incidence and prevalence rates, among others.[2]. For the construction of indicators, processes are followed whose complexity can vary from the simple direct counting of cases of a certain disease to the calculation of more sophisticated proportions, ratios, rates, or indices.[3].

According to research by Furtado and Vieira-da-Silva[4], health assessment has been constituting a social space of common interest among researchers and managers across the board, which includes the universe of knowledge and practices in the scientific field and the bureaucratic and political fields. Considering the intervention as an "organized action system" and, based on the theory-based assessment, it is possible to understand why a given intervention operated in such a way and to seek answers to numerous questions, such as how was the intervention carried out? What factors can interfere with the expected effects or what changes have occurred? What can be improved and what is the cost-benefit ratio?[5].

In assessing health quality, the systemic approach takes into account the aspect focused on the relationship between the components of structure, process, and result, based on the Donabedian triad and used in addition to the evaluation of medical care[6]. Therefore, it is a reference that considers the causal relationship between the three components, favoring the modeling of health interventions in the search for their effective results.

The specific field of health surveillance has experience in building process indicators for monitoring planned actions - managerial, administrative, and technical - which contributes to the continuous reflection on the work process within the scope of the National Health Surveillance System (SNVS). However, researchers in the field, such as Lucchese[7], stated that the structuring of indicators that assess the impact of their actions, in the form of effectiveness indicators, is still embryonic.

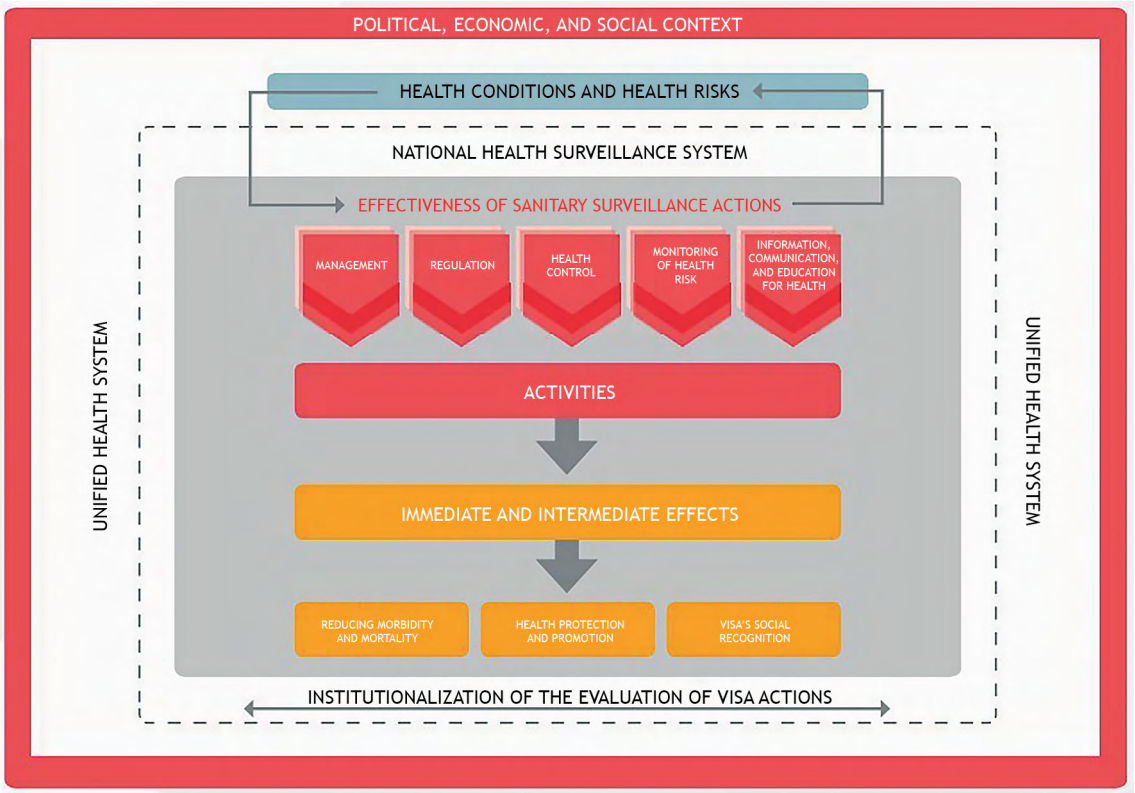
Considering this statement and with the objective of contributing to the construction of indicators for the evaluation of the health surveillance actions, the Brazilian Health Regulatory Agency (Anvisa) in partnership with the Oswaldo Cruz German Hospital (HAOC) built a modeling proposal for the evaluation of the effectiveness of health surveillance actions, with a document published in 2018[8]. The publication is a product of a project of the Development Support Program of the Unified Health System (PROADI-SUS) entitled "Elaboration of Indicators for Evaluating Health Surveillance Actions". In it, the fundamental elements of an organized system of action are described, characterized as an intervention, which presents itself as the set of health surveillance actions.

The modeling proposal, presented in the publication, is represented by the theoretical (Figure 1) and logical models, describes the external factors that can interfere with the expected effects and systematizes the connection between the intervention and the desired results, in addition to constituting five defined components to from/and derived from the respective objectives of health surveillance, namely: (i) Management; (ii) Regulation; (iii) Health Risk Control; (iv) Monitoring of health risk; (v) Health Information, Communication, and Health Education.

The logical model (LM)[8] of health surveillance actions unfolds in a range of possibilities for indicators, which may be developed, applied, or validated in future research, or that point to the need for investments in data source structures and collection methods that can contribute to the evaluation of the effectiveness of health surveillance actions.

As an offshoot of the proposed modeling, the research sought to answer the following question: what is there in the literature about indicators and sources of information that are related to the components of the theoretical model for assessing the effectiveness of health surveillance actions?

Thus, this article aimed to identify in the literature the existence of sources of information and indicators aimed at measuring the effectiveness of the health surveillance actions, taking as a reference the theoretical and methodological proposal for evaluating its actions.



Source: Anvisa[8].

Figure 1. Theoretical model for evaluating health surveillance actions.

METHOD

This is an exploratory descriptive study, of the narrative literature review type, as it makes it possible, in a non-systematized way, to select and update knowledge about a theme and identifies gaps to be explored in certain subjects. It consists of the stages of searching and analyzing the literature, interpreting, and personal analysis of the researchers, not intending to exhaust the topic addressed[9].

The research took place during the project[8] and gray literature (theses, dissertations, sites, reports) on health surveillance in scientific journals, in institutional publications by Anvisa and by the Health Surveillance bodies of states and municipalities, in conference proceedings and publications by national and international organizations, with no predetermined period.

The inclusion criteria defined were to be available electronically and to address the subject under study - indicators for the evaluation of health surveillance actions -, in Portuguese and English, without delimiting the period of publication or the source of information. As a fundamental criterion, it was considered that the possible indicators should translate an orientation towards results, that is, what is intended to transform or change in the population's health scenario and not aimed only at measuring middle activities or instruments - characterized as indicators of processes.

Were excluded articles and technical and product-specific publications; on drug preparation methods; bioequivalence, pharmacokinetic or pharmacodynamic studies; methods for detecting diseases or for dosing drugs, as well as those that were not related to indicators.

Data collection was carried out from May 2016 to August 2017. The databases used were PubMed/MEDLINE, Scopus, Latin American and Caribbean Health Sciences Literature (Lilacs), Cochrane Library and Scientific Electronic Library Online (SciELO), with no specific predetermined period. The following keywords and keywords were searched "Vigilância Sanitária" or "Health Regulation" or "Sanitary Surveillance", "Agência Nacional de Vigilância Sanitária" or "Anvisa", "National Health Regulatory Agency" or "National Sanitary Surveillance Agency", "Regulatory Agency", "Brasil" or "Brazil", "Efetividade" or "Effectiveness", "Public Health", "Health indicators" and "Health assessment", associated with the Boolean operators "AND" and "OR".

The titles and reference abstracts were systematized and classified by the researchers, to identify studies that contained relevant information and ordered according to the degree of proximity to the research topic. After applying the inclusion and exclusion criteria, 207 publications were selected (Figure 2), being grouped into the following themes: pesticides, food, medicines, post-marketing surveillance actions, inspection, toxicity,

cosmetics and sanitizing, blood transfusion, equipment, patient safety, and management.

In an attempt to increase the scope of the research, a free, non-systematized search of the sources and databases of public information systems was carried out, available on sites and portals, constituting an information bank and evidence for possible indicators of health surveillance actions, as shown in the Chart. It should be noted that this search was not intended to be exhaustive, nor to exhaust all available sources at the time of the research.

From these sources and databases, information was collected on the actions for reporting adverse events and technical complaints; health inspections; related to the use of information technologies and the quality of recorded data; as well as referring to the theoretical basis and technical feasibility for measuring health indicators that point to the effectiveness of health surveillance actions.

The analysis of the data sought to answer the proposed questioning and the objective of the study, identifying the relationship between the indicators and the components of the theoretical model, considering their expected effects. The results were grouped into the five components of the theoretical model and the discussion presents the gaps and challenges, based on the literature, so that it is possible to build/define indicators for the evaluation of health surveillance actions.

The study was conducted with public domain data, and it is not necessary to submit the project to the appreciation of an ethics committee in research.

RESULTS AND DISCUSSION

The narrative review of the literature presented contents/themes based on conceptual proposals that converge to measure the effects resulting from the action of health surveillance

Source: Elaborated by the authors, 2020.

Figure 2. Scheme for the selection of publications included in the study.

Chart. Researched sources and information systems. Brasília, 2020.

Source	Information system/Database/Programs
Brazilian National Health Surveillance Agency (Anvisa) http://portal.anvisa.gov.br/	• Health Surveillance Notification System (Notivisa) • Information system on processes, products, and companies subject to health regulation (Datavisa) • Risk management system in ports, airports, and borders (Sagarana) • National System of Management of Controlled Product (SNGPC) • National Implant Registry (RNI) • Regulatory Impact Analysis (RIA) • Drug Market Monitoring System (SAMMED) • Pharmaceutical Market Statistical Yearbook • National Drug Control System (SNCM) • National Program for the Prevention and Control of Healthcare-Associated Infections
Center for Strategic Health Information and Decisions - Zilda Arns Neumann (ConectaSUS) https://www.saude.go.gov.br/sistemas-de-saude/conecta-sus	• Health and socioeconomic data and information for the state of Goiás
Oswaldo Cruz Foundation (Fiocruz) https://www.proadess.icict.fiocruz.br/ https://proqualis.net/	• Health System Performance Assessment Program (PROADESS) • Collaborating Center for Quality and Patient Safety (PROQUALIS) • Laboratory Sample Management System
Brazilian Institute of Geography and Statistics (IBGE) https://www.ibge.gov.br/	• Demographic Census • Survey of Basic State Information (ESTADIC) • Survey of Basic Municipal Information (MUNIC)
National Institute of Metrologu, Standardization and Industrial Quality https://www.gov.br/inmetro/pt-br	• Index of irregularities of inspected products
Ministry of Health (MS) http://www2.datasus.gov.br/DATASUS/index.php	• Brazil Mortality Information System (SIM) • Live Birth Information System (Sinasc) • Hospital Information System (SIH) • National Demography and Health Survey (PNDS) • Surveillance of risk and protective factors for chronic diseases by telephone survey (Vigitel) • National Registry of Healthcare Establishments (CNES) • National Patient Safety Program (PNSP) • National List of Essential Medicines (Rename)
World Health Organization (WHO) https://www.who.int/eportuguese/publications/pt/	• WHO Observatory on International Health Regulations (IHR) • WHO Global Statistics Report

Source: Elaborated by the authors, 2020.

systematized through the five components of the Logical Model. 29 possible indicators were identified that use existing data sources and serve for the development of evaluative research that contributes to the analysis of the effects and results arising from the execution of health surveillance actions.

It is noteworthy that both in the choice of indicators and in the implementation of evaluative practices, it is "important to analyze the result indicators from the indicators of efforts and allocated resources, which allows for the dimensioning of the efficiency of the programs"[10] or interventions, as in the case studied here.

According to Jannuzzi[10]:

> the good practice of social research recommends that the procedures for the construction of indicators are clear and transparent, that methodological decisions are justified, and that subjective choices - invariably frequent - are made explicit in a very objective manner[10].

Thus, Figure 3 summarizes the main findings of the literature review, organized according to the components, immediate effects, and impacts of the logical model.

It is important to note that the proposed indicators are aggregated by component, and there is not necessarily an indicator for each isolated effect arising from the action but for the set of effects related to each of the five components, as described below.

Component - Management

The Management component is made up of planning, skills training, and knowledge management activities in health surveillance. In this component, the perspectives for the development of indicators can derive from the comparison between scientific production and the formation of competences, such as the "Evolution of health surveillance research over a certain period".

Also, in this sense, an indicator similar to that of the World Health Organization (WHO) observatory could be developed: an "index of capacity to apply the International Health Regulations (IHR)", which assesses the degree of strengthening of the public health team, through the development of knowledge, skills, and competences appropriate to the effective implementation of the IHR[11]. This indicator is aimed at training professionals to implement sustainable public health surveillance and response practice at all levels of the health system[12].

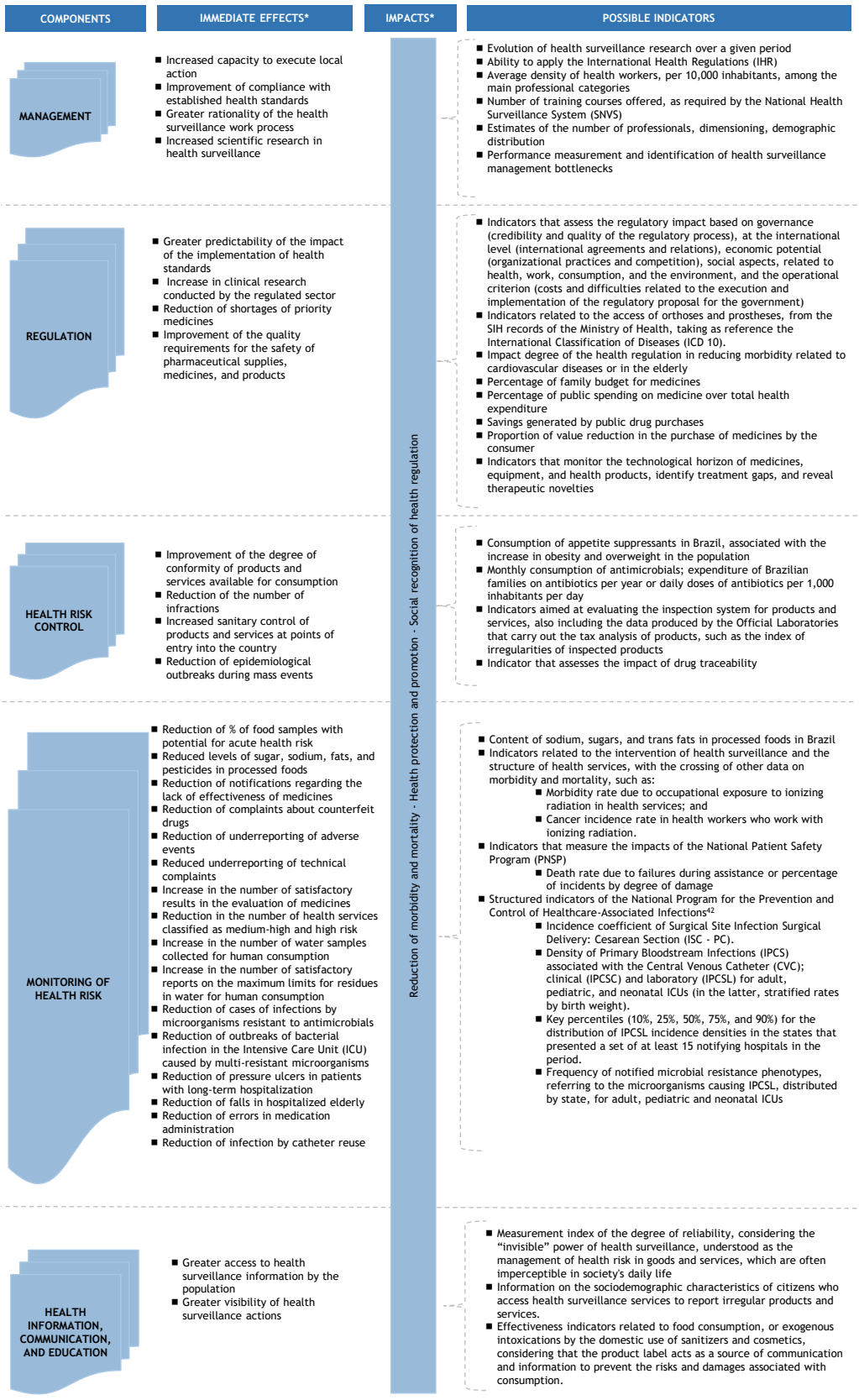
The WHO Global Statistics Report[13] presents an interesting indicator which is the "Average density of health workers, per 10,000 inhabitants, among the main professional categories", which can inspire the construction of an indicator for health surveillance. However, for this specific situation, one of the challenges presented is the updating of the database of the National Registry of Healthcare Establishments (CNES) and the standardization of the Brazilian Occupational Classification (CBO), which identifies the health surveillance professional in different codes: public health agent, sanitation agent, sanitary agent, hygiene inspector, product marketing inspector, or sanitation inspector.

It is also worth reflecting on the approaches that discuss indicators aimed at people management based mainly on estimates of the number of professionals, dimensioning, demographic distribution, and the expansion and improvement of professional training processes, such as the number of training offered, as needed by SNVS[14].

Possible indicators related to the management of Health Surveillance may use the data produced by the Survey of Basic State Information (ESTADIC) and Survey of Basic Municipal Information (MUNIC) carried out by the Brazilian Institute of Geography and Statistics (IBGE), in the 27 federation units and in the 5,570 Brazilian municipalities, respectively. The 2015 results highlighted relevant aspects of the management and structure of federative entities, covering several thematic axes, including health and health surveillance. The document provides information on the characterization of the Health Surveillance bodies and their competencies; training and education of its holders and the workforce employed, with emphasis on aspects related to the employment relationship, level of training, and qualification[15].

Still in the Management component, it is essential to develop and measure indicators that may have the Laboratory Sample Management System as a source of information - a web version software, developed by the National Institute for Quality Control in Health (INCQS) of the Oswaldo Cruz Foundation (Fiocruz) and coordinated by Anvisa. This system is used to manage the analysis of products subject to health surveillance, from registration to the issuing of analytical reports. It is implemented in 100% (n = 53) of the official laboratories of the National Network of Health Surveillance Laboratories (RNLVISA), standardizing and integrating in real-time the information referring to the analysis of products across the country[16]. From this system, information is generated on tax and control analyzes carried out to determine the infraction or verify the occurrence of deviation in terms of the quality, safety, and effectiveness of the products and/or raw materials. This system allows governance and monitoring, allowing the crossing of information from national planning with the flow of demands, average attendance, categories of requests, laboratory performance, and health risk indicators.

Indicators such as "Volume of samples analyzed in the period, according to product category" or "Percentage of rejected samples" point to data that support the manager's decision making, whether due to the need for standardization of sample collection, or provision of materials/resources, either by training professionals so that samples are collected according to the rite established by Law No. 6,437, of August 20, 1977[17], during an inspection. Such actions may have effects, such as greater rationality of the health surveillance work process, an increase in the level of knowledge in the area, and the expansion of the population's safe access to products and services subject to sanitary control.



Source: Elaborated by the authors, according to Logical Model[8], 2020.
*Taken from LM[8]

Figure 3. Synthesis of the possible indicators for the evaluation of health surveillance actions, according to the components, immediate effects, and impacts of the logical model (LM).

Component - Regulation

The Regulatory Impact Analysis (RIA) is defined as a "systematic process of analysis, based on evidence, which aims to evaluate the possible impacts of the action options available to achieve the intended objectives, in order to support decision making"[18]. It is essential to understand that RIA is a process of diagnosing the problem, reflecting on the need for regulatory action, and investigating the best way to execute it, and not just a tool or a questionnaire for comparing regulatory options[18].

It is observed that, in the RIA cycle, there is a selection of potential indicators that assess the regulatory impact based on governance (credibility and quality of the regulatory process), at the international level (agreements and international relations), at the economic potential (organizational practices and competition), in the social aspects related to health, work, consumption, and the environment, and in the operational criterion (costs and difficulties related to the execution and implementation of the regulatory proposal for the government).

The development and application of the RIA methodology is complex and comprehensive, with the measurement of the impacts of the alternatives of action on the different groups and actors; the impacts that affect a large part of the budget or international trade, and those that have implications for decentralized actions or carried out by other actors of SNVS and SUS[18].

Still in the Regulation component but with the cut for the subcomponent "Access of the population to products subject to health surveillance", one can prospect the applicability of two indicators, both suggested by the Health System Performance Assessment Program (PROADESS)[19] and that use the Hospital Information System (SIH) as a source of data: access by the elderly to implant a hip (or knee) prosthesis and access to angioplasty and myocardial revascularization (with use of cardiac stents).

It is noteworthy that Brazil is going through a demographic transition process, with an increase in the elderly population, demanding, increasingly, treatments for chronic diseases and palliative care in people over 60 years of age. The importance of coronary heart disease and technological developments in the field of medical care are factors that make the rates of use of reperfusion surgeries the frequent indicators in the performance evaluations of health systems in different countries[19].

It is necessary to explain the contribution of health regulation to the dimension of access to health. PROADESS[19] conceptualizes access as "the capacity of the health system to provide the necessary care and service, at the right time and in the right place". The regulatory function of health surveillance includes the control and inspection of products available to the population and is therefore a fundamental requirement for access to health services and goods. If the patient needs a cardiac stent, a hip prosthesis, or an innovative treatment, health surveillance regulates their access, in order to allow these technologies to be available with quality, safety, and efficacy[19]. Thus, the development of indicator(s) related to access to orthoses and prostheses is valid based on the SIH records of the Ministry of Health (MS), taking as reference the International Classification of Diseases (ICD 10) which presents the coding of diseases related to the use of health products regulated by health surveillance.

It is important to mention, within the scope of regulation, that the National Implant Registry (RNI) information system, which systematizes surgical procedures for implantation of osteoarticular prostheses (hip and knee) and coronary stent carried out in the country, is in an advanced stage of implantation. This system presents enough information for the development of an indicator that assesses the effects not only related to the issue of access but also points to the reduction or not of the health risk in the use of these products.

Finally, the importance of the indicators that will evaluate, in the near future, the impacts of the Medical Device Single Audit Program (MDSAP), created by the International Medical Device Regulators Forum (IMDRF), in which it allows manufacturers of products for health, hire an audit body, authorized under the program, to perform a single audit valid for all member countries - currently there are five: Brazil, Australia, Canada, United States, and Japan. One of the main advantages of this type of initiative (notably for large players) is the saving of resources since the company needs to adapt to the guidelines of an audit body and not for five audits from five different countries.

In the subcomponent of market regulation, there is a set of data that could support the definition of effectiveness indicators related to the theme, in the Statistical Yearbook of the Pharmaceutical Market[20], published in 2017, with data from 2015, by the Drugs Market Regulation Chamber (CMED) of Anvisa. In this publication, there is the number of companies operating in the national market, the degree of competitiveness in the sector, the types of medicines most consumed by Brazilians, and the volume of resources handled. The information comes from the Market Monitoring System of Medicines (SAMMED), which accumulates a considerable amount of data and constitutes a valuable source of information, providing subsidies for regulatory actions, applied research, and development of indicators. It was verified the existence of studies and research or the prospecting for new ones, which points to some indicators related to the theme, such as (i) percentage of the family budget destined to medicines; (ii) percentage of public spending on medicine over total health expenditure; (iii) savings generated by public purchases of medicines and (iv) proportion of reduced value in the purchase of medicines by the consumer[21,22,23].

CMED establishes the ceiling prices for medicines in the private market, promotes price stability by regulating annual adjustments, and generates savings for the State, fixing a mandatory discount to be practiced on public purchases and judicial demands - the Price Adequacy Coefficient (CAP),

calculated annually according to the formula, also provided for in the regulation.

It is also a huge challenge to assess the risks of shortages of priority medicines for SUS. Anvisa Collegiate Board Resolution (RDC) No. 18, of April 4, 2014[24], obliges manufacturers and importers of medicines to notify their intention to withdraw products from the market, at least, six months in advance. The purpose of this regulation is to allow the necessary measures to be taken in advance to reduce the impacts on the population due to the lack of medication. With this, companies that decide to stop the production of a specific medicine, whether for technical or marketing reasons, must guarantee the regular supply of the product during this period. The requirement covers, for example, products that have no substitutes on the national market and whose withdrawal may leave patients without proper treatment.

With this information, it can be said that prospective studies are essential to identify the opportunities and needs for investment in the production of drugs with a high risk of shortages, leaving the population without adequate assistance. Indicators that monitor the technological horizon of medicines, equipment and health products, identify treatment gaps and reveal therapeutic novelties may work as important markers with the Ministry of Health.

Component - Health risk control

The disciplines of Pharmacoepidemiology and Pharmacovigilance can contribute significantly to the development of indicators of health surveillance actions, as one of the objectives is "to identify and gather consistent evidence about the associations between the use of medicines and the occurrence of adverse events"[25]. These pieces of evidence may be incorporated into the daily practice of sanitary control and support the decision-making processes for the withdrawal or not of products on the market[25,26].

In general, these Drug Use Studies (EUM) are surveys that provide information on drug use at a specific time and place. They are the main tool for detecting misuse, pointing out possible responsible factors, assisting in the design of effective improvement interventions, and evaluating the results of these interventions[27]. According to the WHO, they aim to study the commercialization, distribution, prescription, and use of medicines in society, with special emphasis on the medical, social, and economic consequences. This definition recognizes the influence of socio-anthropological, behavioral, and economic factors in the use of medicines, which are important aspects that must be considered in the health control process.

According to the Anvisa Pharmacoepidemiology Bulletin[28], the National Controlled Products Management System (SNGPC) monitors the movements of input (purchases and transfers) and output (sales, transformations, transfers, and losses) of medicines sold in pharmacies and private drugstores in the country, particularly medicines subject to Ordinance of MS nº 344, of May 12, 1998[29], such as narcotics and psychotropic drugs, and antimicrobials. One can, for example, monitor the consumption of appetite suppressants (such as sibutramine) in Brazil, associated with the increase in cases of obesity and overweight in the population.

It is essential to use prescription data and the consumption of various medications to control health risks and assess the health impact of a community, contributing to the development of health surveillance that works based on evidence. The indicators can be mentioned: "Monthly consumption of antimicrobials", "Expenditure of Brazilian families with antibiotics per year", or "Daily doses of antibiotics per 1,000 inhabitants per day"[30,31,32]. The information produced from these indicators helps to identify trends in prescription and consumption of medicines, in the early detection of signs of distortions in the use of these products, in the definition of priorities for actions/decisions in health surveillance, and effective communication strategies regarding the risk to segments of society, and in providing information on the burden of a disease, necessary to prioritize the development and/or strengthening of health services in a location[32,33].

Observing the immediate and intermediate effects aimed at improving the quality, safety, and efficacy of products and services, aimed at this component, it would be essential to design indicators aimed at evaluating the product and service inspection system, also including the data produced by the Laboratories Officials who carry out the tax analysis of products, according to the rite recommended by Law No. 6,437/1977[17]. The challenge is to develop indicators that go beyond the classic "Volume of fiscal analyzes carried out in the period" or "Percentage of samples with unsatisfactory results".

It was found that, at the National Institute of Metrology, Standardization, and Industrial Quality (Inmetro)[34] - - an institution that has a mission similar to that of Anvisa, with a regulatory, certifying, and supervisory role regarding the safety of products used by society -, there is an indicator called "Index of irregularities of inspected products", which aims to measure the percentage of units of irregular products, relative to the total of inspected products. In this sense, the indicator seeks to reflect the adequacy of the products made available to society, in relation to quality and safety requirements established in standards or regulations. It means that the increase in the adequacy of the applicable requirements will lead to a gradual decrease in the rates of irregularities in the field of health surveillance[34].

Another possibility of qualified information in the field of health control arises with the perspective of building an indicator that assesses the impact of drug traceability since, with the implementation of Laws No. 11.903, of January 14, 2009[35], and nº 13.410, of December 28, 2016[36], which provide for tracking the production and consumption of medicines and the National Drug Control System (SNCM), it will be possible to control the production, distribution, commercialization,

dispensing, and medical and dental prescription, through an individualized drug identification system, with the use of technologies for the capture, storage, and electronic transmission of data. As an advantage of this system, there is the possibility of detecting duplications, counterfeits, adulterations, thefts, and smuggling. In addition, this system strengthens the inspection mechanisms, reduces expenses and waste in the health system, making it possible to record all transactions in the chain and monitor the path taken by the medicine, from manufacture to delivery to the consumer[37].

Component - Monitoring of health risk

Despite the number of indicators identified for this component, some possibilities were selected, considering the context of development and the implementation of strategies that may have an impact on several immediate effects listed in this component and summarized in Figure 3.

As an example of a strategy for this component, there are actions to reduce the sodium content in processed foods in Brazil, as in other countries. Among these actions, we can mention the voluntary agreement between the Ministry of Health and the associations that represent the processed food producers. This agreement established a plan for a gradual reduction (2011–2016 and 2017–2022) in the amount of sodium present in 30 food categories, such as school lunch rolls, bread loaves, deep-fried, cold cuts, soups, and hot dogs, and makes the SNVS responsible for monitoring the goals[38].

Nilson et al.[39] proposed that, in the medium and long term, there is information from population surveys and data from health information systems, mainly aimed at evaluating the

> impact of the plan on sodium intake by the Brazilian population and on indicators of morbidity and mortality from diseases and conditions associated with excessive sodium consumption (particularly arterial hypertension and cardiovascular diseases)[39].

This is corroborated by a study carried out in China, in which associations were identified between impact indicators related to high sodium consumption, which could be used by health surveillance. The study found that, in 2013, 1,430,000 deaths were attributed to the high-sodium diet, representing 15.6% of deaths from all causes in China, including cardiovascular disease and chronic kidney disease. These early deaths represented 2.17 years of loss of life expectancy[40].

There is other strategic information that could encourage the construction of indicators related to the intervention of health surveillance and the structure of health services: a list of information that can assist in the crossing with other data on morbidity and mortality, allowing the development of interesting analyzes and correlations in the direction of effectiveness indicators, such as[41]: (i) morbidity rate due to occupational exposure to ionizing radiation in health services[42] and (ii) incidence rate of cancer in health workers who work with ionizing radiation[43].

In addition to these initiatives and thematic possibilities, the application of Potential Risk Assessment Models (MARP) aimed at the classification of hemotherapy, radiotherapy, and mammography services is being expanded. This type of method uses multicriteria modeling, which integrates diverse items related to the structure and process of services to its analytical mechanism. With this tool, each control measure is evaluated according to the estimate between the possibility of failure and its consequent damage, using a table or matrix for prioritizing potential risks, based on the health inspection script[44].

Also important is the search for indicators that measure the impacts of the National Patient Safety Program (PNSP), cited as a subcomponent in the logical model. Established by Ordinance GM/MS No. 529, of April 1, 2013[45], the Program aims to contribute to the qualification of health care in all health establishments in the national territory, having its actions coordinated by health surveillance. Thus, examples of indicators that could assess the results of the PNSP would be: “rate of deaths resulting from failures during assistance” or “percentage of incidents by the degree of damage”[46].

Other feasible fronts are the development and monitoring of the structured indicators of the National Program for the Prevention and Control of Infections Related to Health Care[47]. Anvisa has received electronic notifications since 2010 on the control of microbial resistance, analyzes and publishes data in the form of annual bulletins, as well as develops projects such as that of the analytical subnet of microbial resistance in health services, composed of a group of Central Laboratories of Public Health (Lacen), whose objective is to subsidize actions of surveillance and monitoring of microbial resistance and infection control in health services. Thus, the indicators resulting from notifications, calculated for Brazil and by state[47] are already a reality: (i) incidence coefficient of surgical site infection surgical delivery: cesarean section (ISC-PC) ; (ii) density of primary bloodstream infections (IPCS) associated with the central venous catheter (CVC) clinical (IPCSC) and laboratory (IPCSL) for the adult, pediatric, and neonatal intensive care unit (ICU) (in the latter the rates were stratified by birth weight); (iii) key percentiles (10%, 25%, 50%, 75%, and 90%) for the distribution of IPCSL incidence densities in the states that presented a set of at least 15 notifying hospitals in the period and (iv) frequency of notified microbial resistance phenotypes, referring to the microorganisms causing IPCSL, distributed by state, for adult, pediatric, and neonatal ICUs.

Component - Health Information, Communication, and Education

In this component, it is possible to go beyond image research to assess the degree of social recognition of health surveillance actions. It is also possible to design an index that can measure the degree of reliability, considering the “invisible” power of health surveillance, understood as the management of health risk in goods and services, which are often imperceptible in society’s daily life. As a benchmark, Inmetro takes action once more, which has operated based on two

indices[34]. The first would be the social recognition index, which seeks to assess whether the population knows Inmetro and at least one of its activities, with a collection carried out through an opinion poll. And the second would be the reliability index, which seeks, in turn, to assess the degree of knowledge and confidence of the population in the consumption of products with the Inmetro seal, with data collection also through opinion polls.

It would also be useful to manage the information on the sociodemographic characteristics of the citizens who access Health Surveillance services to report irregular products and services. With this profile, there is the possibility of outlining new actions or improving existing ones, which have the potential to impact, to a lesser or greater degree, the expected effects on the logical model, related to information, communication, and education, such as, for example, improving conscious consumption of products and services.

For this same result - the promotion of conscious consumption -, it is possible to develop effectiveness indicators related to food consumption, or to exogenous intoxications by the domestic use of sanitizing products and cosmetics, considering that the product label works as a source of communication and information to prevent the risks and damages associated with consumption.

The study carried out with families of patients with cow's milk allergy showed that more than a third of allergic reactions are related to mistakes in reading the labels of industrialized products - labels that are approved prior to product registration and are evaluated during the actions of sanitary inspection[48].

Incidence or prevalence indicators, in turn, could support the need to evaluate dyes and additives, as well as changes in the labels of products regulated by health surveillance.

The package inserts of the medication are also characterized as a source for the development of indicators in the Information, Communication, and Education component, considering that the misinterpretation can cause serious damage to the population's health. In a survey carried out in 2012, of the 168 package inserts for 41 drugs selected by the National List of Essential Medicines (Rename), 91.4% were considered unsatisfactory for Patient Information (Part I) and 97.0% for Technical Information (Part II), mainly due to incomplete and incorrect information[49].

CONCLUSIONS

Based on the literature and the researched sources, the results obtained in this study, mapped in the form of indicator proposition, point to the initial discussion of 29 indicators from existing data sources and the development of evaluative research that contribute to the analysis of the effects arising from the execution of health surveillance actions, referenced by the proposed evaluation model[8].

During the development of this research, important information gaps were identified, such as the effects related to underreporting of adverse events and technical complaints resulting from the use of medicines and products subject to sanitary control, for example. Another similar case relates to data on outbreaks existing during mass events, which could be improved to serve as a basis for new monitoring and evaluation indicators.

It was found that the high number of available information systems and the lack of interoperability between them, added to the lack of standards to be followed for the exchange of information of interest to the SNVS management - and also to the weakness of some computerized tools, whether by lack of technological robustness, either due to the low adherence to notifications by users -, constitute challenges that directly affect the evaluative practice of health surveillance actions.

As a limitation of this study, it is possible to identify the fact that the use of techniques to verify the update of the data available in the suggested information sources was not foreseen, which may cause the existence of outdated information, either due to the lack of regular data feeding, either due to the discontinuity of the availability and use of these sources.

In this sense, some recommendations can be pointed out aiming at improving the evaluative practice in health surveillance, such as (i) the updating of the CNES database regarding the fields related to Health Surveillance; (ii) updating the CBO regarding the designation of different occupations for the health surveillance professional; (iii) improving coverage, quality, and timeliness of information managed by health surveillance; (iv) the strengthening of health surveillance information management with robust tools, IT support, and data publication for health professionals, managers, researchers, and the general population; and (v) the promotion of research directed to priority themes.

Finally, what can be taken as learning during the review is that the field of health surveillance must routinely prioritize the managerial and technical use of monitoring and evaluation processes of the actions developed. Initially, with the development of institutional and technical (professional) skills for the incorporation of such practices, until the definitive structuring of an informational base that guarantees the structuring and calculation of measurable indicators, from the fulfillment of the classic criteria of pertinence, relevance, methodological reliability, sustainability, and comparability.

Contemporary society is in an accelerated evolution. We live in the age of information and new technologies that appear every minute. The challenges for health surveillance are innumerable and, perhaps, even countless, since at all times society is faced with a new health risk, a new threat to human health. Thus, prioritizing the implementation of evaluation processes is an essential condition for the qualification of the action developed in the daily life of the national health system.

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Author's Contributions

Martins MAF, Barca DAAV - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. Brito RL de, Felisberto E, Samico IC – Conception, planning (study design), and writing of the work. All authors approved the final version of the work.

Conflict of Interest

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