

# EVALUATION OF ROTAVIRUS ENHANCED EPIDEMIOLOGIC SURVEILLANCE

*Avaliação da vigilância epidemiológica ampliada do rotavírus*

*Evaluación de la vigilancia epidemiológica ampliada del rotavirus*

Description or evaluation of experiences, methods, techniques, procedures and tools

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## ABSTRACT

**Objective:** To assess the practices of Rotavirus surveillance, identifying the positive aspects and the difficulties found through the evaluation model from the Enhanced Surveillance of Rotavirus Diarrheal Diseases. **Methods:** This is an evaluative and qualitative research performed in two different Brazilian states between March and November 2010. Participated in the evaluation 14 subjects in total (from central, state and municipal level), which were submitted to tape-recorded interviews using semi-structured questionnaires, along with conduction of document analysis and direct observation of routine service within their respective units. This information allowed to feed a judgment matrix, thus highlighting the various aspects comprising the system operation. **Results:** Positive aspects were observed (the sensitivity to capture cases, the system acceptability by the technicians involved, the proper physical structure and the training and updating of technicians), and operational difficulties when conducting surveillance activities (the shortage of human and financial resources and the low opportunity of the information system). **Conclusion:** The results suggest the low effectiveness of the monitoring system adopted, indicating that the sentinel type of surveillance may not be the most appropriate for the health system in the studied states.

**Descriptors:** Epidemiological Surveillance; Rotavirus; Health Evaluation; Diarrhea.

## RESUMO

**Objetivo:** Conhecer as práticas de vigilância do Rotavírus, identificando os pontos positivos e as dificuldades encontradas através do modelo de avaliação da Vigilância Epidemiológica Ampliada das Doenças Diarreicas por Rotavírus (VER). **Métodos:** Tratou-se de uma pesquisa avaliativa realizada em dois diferentes estados brasileiros, entre março a novembro de 2010. Participaram da avaliação 14 atores no total (do nível central, estadual e municipal), sendo submetidos a entrevistas gravadas utilizando questionários semiestruturados, além da realização de análise documental e observação direta da rotina do serviço dentro das respectivas unidades. Essas informações permitiram alimentar uma matriz de julgamento e evidenciar os variados aspectos componentes da operacionalização do sistema. **Resultados:** Foram observados pontos positivos (a sensibilidade de captação de casos, a aceitabilidade do sistema por parte dos técnicos envolvidos, a estrutura física adequada e a capacitação e atualização dos técnicos) e dificuldades operacionais (a escassez de recursos humanos e financeiros, e a baixa oportunidade do sistema de informação) na condução das atividades da vigilância. **Conclusão:** Os resultados encontrados sugerem a baixa efetividade do sistema de vigilância adotado, indicando que a vigilância do tipo sentinela pode não ser a mais adequada para o sistema de saúde desses estados estudados.

**Descritores:** Vigilância Epidemiológica; Rotavírus; Avaliação em Saúde; Diarreia.

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## RESUMEN

**Objetivo:** Conocer las prácticas de vigilancia del Rotavirus identificando los puntos positivos y las dificultades encontradas a través del modelo de evaluación de la Vigilancia Epidemiológica Ampliada de las Enfermedades Diarreicas por Rotavirus. **Métodos:** Se trató de una investigación evaluativa realizada en dos estados brasileños distintos entre marzo y noviembre de 2010. En total 14 actores participaron de la evaluación (del nivel central, estadual y municipal), siendo sometidos a entrevistas grabadas utilizando cuestionarios semi-estructurados y la realización de un análisis documental y observación directa de la rutina del servicio en las respectivas unidades. Estas informaciones permitieron fomentar una matriz de juicio y evidenciar los distintos aspectos de la utilización del sistema. **Resultados:** Fueron observados puntos positivos (la sensibilidad de captación de casos, la aceptabilidad del sistema por parte de los técnicos involucrados, la estructura física adecuada y la captación y actualización de los técnicos) y dificultades operacionales (la escasez de recursos humanos y financieros y la baja oportunidad del sistema de información) en la conducción de las actividades de vigilancia. **Conclusión:** Los resultados encontrados sugieren baja efectividad del sistema de vigilancia adoptado e indica que la vigilancia del tipo centinela puede que no sea la más adecuada al sistema de salud de los estados investigados.

**Descriptor:** Vigilancia Epidemiológica; Rotavirus; Evaluación en Salud; Diarrea.

## INTRODUCTION

Rotavirus genus, belonging to the Reoviridae family, is associated with the occurrence of diarrheal disease among children under five years of age in both developing and developed countries<sup>(1)</sup>.

Throughout the world, 1.9 million of deaths from acute diarrheal diseases are annually notified, one third of which are associated with Rotavirus infection<sup>(2,3)</sup>. It is estimated that ninety percent of these deaths occur in developing countries, where the conditions of sanitation, nutritional status and access to health services are more deficient<sup>(4,5)</sup>.

In developed countries like the United States, the losses resulting from these infections are estimated at approximately one billion dollars per year<sup>(6)</sup>. In Brazil the infections by this virus account for approximately 30% of all cases of Acute Diarrhoeal Diseases (ADD) that occurred in the country<sup>(7,8)</sup>.

Since 2005, two new oral vaccine of live attenuated viruses have been licensed for use in many countries for control of the rotavirus disease, a monovalent and a pentavalent one. Both have been effective in preventing

severe forms of diarrheal diseases<sup>(4,9-10)</sup>. Brazil was the first country in Latin America to introduce the monovalent vaccine in its national immunization program, in March 2006<sup>(11)</sup>.

In light of the financial and social impact of these infections, the Pan American Health Organization (PAHO) proposed in 2003 a model of Extended Epidemiological Surveillance of Rotavirus Diarrheal Diseases (ESR)<sup>(12,13)</sup>. As other countries in the Americas, Brazil has been implementing the recommended surveillance since 2006, based on the establishment of sentinel units<sup>(14)</sup>.

In Brazil the ESR aims to know the profile of gastroenteritis caused by rotavirus in children under five; estimate the magnitude of rotavirus diarrheal disease in the country; support the implementation of measures needed for control; identify the serotypes and genotypes circulating in the country; and assess the impact of the vaccine introduced in the National Immunization Program schedule for Rotavirus (NIP/Rotavirus)<sup>(4)</sup>.

This model of sentinel surveillance, despite presenting limitations from the viewpoint of representativeness of the general population, can produce fundamental data for epidemiologic studies with reduced cost. According to the Brazilian Ministry of Health, by December 2013, 17 of the 27 states of the country had implemented the ESR<sup>(14)</sup>.

For being under implementation and still showing several points which prevent their full operation, this study was aimed at knowing the practices of Rotavirus surveillance, identifying the strengths and difficulties encountered by the assessment model of Extended Epidemiological Surveillance of Rotavirus Diarrheal Diseases (ERS).

## METHODS

Between March and November 2010 an evaluative research<sup>(15-17)</sup> on the Extended Epidemiological Surveillance of Rotavirus in Brazil (ERS) was held. In a first moment, an evaluation model was adapted from publications between the years 1994 and 2010<sup>(18-24)</sup>. The evaluation model involves in its structure an Evaluation Logic Model and a judgement matrix.

In the first stage of this adaptation, the Evaluation Logic Model (Figure 1) was elaborated, which can be understood as a visual scheme that presents how the program should ideally work to achieve the expected results<sup>(24-26)</sup>. This way, the model helps to visualise and understand how the structure of the system (human, physical and financial resources) can contribute to improve and achieve the program goals<sup>(22,24-26)</sup>. Furthermore, the use of logic models is an effective way

to achieve the success of programs through planning, execution, and implementation of evaluations.

The judgment matrix is a tool that determines the requirements for the ESR to be considered a system that operates to increase the effectiveness of the evaluated actions. This matrix consists of the following components:

*Dimension* – Eight dimensions were assessed for this study, being: program and planning, financial and human resources, information systems, structure, logistics resource, supervision, and vaccine. Within each dimension, all operational levels were assessed, aiming to respond to the proposed indicators;

*Operational Level* – the structural components that comprise the Rotavirus surveillance, in various operational levels, being: Sentinel Health Units (SHU), Municipal Epidemiological Surveillance (ES-MHS), Central Public Health Laboratories (LACEN), Regional and National Reference Laboratories (RRL, NRL), State Health Secretariats (SHS), Coordination of food- and waterborne diseases Surveillance (COVEH/SVS), General Coordination of Public Health Laboratories (GCLAB) and National Immunization Program for Rotavirus (NIP/Rotavirus);

*Indicators* – variables, characteristics or attributes assessed within the units that comprise the system of ERS. These indicators, as well as their evaluation criteria were elaborated from guidelines, documents and manuals provided by the Ministry of Health<sup>(5)</sup> and the Pan American Health Organization<sup>(12)</sup>. The indicators *data acceptability* and *data quality* were elaborated based on the experience described by the interviewed actors. A total of 26 indicators (Chart I) were evaluated by the end of the study;

*Reference Standard* – the criteria used to judge the indicator as appropriate or inappropriate. For some indicators, it was not possible to define a standard reference value, due to its qualitative character. As a result, the judgement was based on a particular criterion defined by the interviewed actors;

*Category* – defines whether the reference standard is present or absent, appropriate or not, with good acceptability or not, and whether or not with adequate sensitivity.

In combination with the technical department of the Ministry of Health responsible for the ERV, for the application of the evaluation model, two Brazilian states participated in the evaluation, according to criteria of operational performance, geographic representation and autonomy. Their identification being omitted, they became designated by the letters A and B.

Between April and November 2010, in order to operationally evaluate the ERS, 14 technicians were interviewed in total, covering all operational levels of surveillance of Rotavirus, being: 4 technicians at the federal level, one technician at the state level in each state, and 4 technicians in each participating municipality. In this research, the participating cities were the capitals of the states, because it was where the Sentinel Health Units and the municipal and state secretariats were located.

In each level, the actors underwent taped interviews using semi-structured questionnaires, which contained open and discursive questions, and closed ones, relating to the various dimensions identified by the logic model, such as: Program and Planning (existence of documents, regulatory milestone, or protocol to guide on the roles and proceedings for the activities; action plan; occurrence of meetings for discussions about goals and problems; and mechanisms of intra-institutional coordination), Financial and Human Resource (types of financial sources; types of financial allocations; availability and allocation of resources; existence of adequate number of technicians to fulfill the tasks; existence of training plan), Information System (existence of: document detailing how the flow of information and materials functions; case definition, documents, and protocols on how to fill out the notification and enter data in the designated bank system; and presence of feedback to the reporting units), Logistic Resources (how the equipment for collecting samples is purchased, conduction of sample storage and how these are stored; destination and sending of samples, frequency of sending), Supervision (existence of: some kind of supervision; available technical standards), Structure (questions regarding the existence of structures required to conduct the activities in each operating level), and Vaccine (questions regarding the knowledge on the vaccine adopted in Brazil and the age range for vaccination).

Furthermore, a document analysis was carried out (Training Plan, Action Plans, Technical Regulations, Budget Worksheet, Treatment Protocol for Patient with Rotavirus, Operational Regulatory Milestones) and a direct observation of the service routine within the respective units<sup>(18,25)</sup>. The evaluation consisted of classifying the components of the ESR in its various dimensions and levels as appropriate or inappropriate, according to the indicators of the judgement matrix.

This research received approval from the Research Ethics Committee of Sergio Arouca National School of Public Health – under approval number CEP/ENSP N. 78/10.

Chart I - Matrix of judgement used for evaluation of Rotavirus surveillance in two Brazilian states, 2010.

	Operational Level	Indicator	Reference Standard	Judgement*	
				Central Level	State A State B
Program and Planning	SHU	Treatment Protocol	Minimum of 01 per SHC	-	A A
	SHU, LACEN, NRL	Sensitivity	85%	-	A A
	SHU, ES-MHS, LACEN, NRL, SHS, GCLAB, COVEH	Presence of technical regulations and regulatory milestones detailing the action plan, goals and objectives of the ESR	Minimum of 01 document per operational level	I	I I
Financial and human resources	SHU	Chief medical officer, epidemiologists, nurses, and medium level technicians	Minimum of 01 chief medical officer, 01 epidemiologist, 01 nurse e 01 medium level technician	-	A A
		Number of technicians enough to fulfil the tasks related to the ERS	-	I	I I
		Staff hiring	-	I	I I
Information System	SHU, ES-MHS, LACEN, NRL, SHS, GCLAB, COVEH	Training plan for the technical staff and newly hired workers	Minimum of 01 training event per semester for the technical staff, and training event for all newly hired technicians	I	A A
		Acceptability	-	A	A A
		Presence of regulatory documents detailing financial sources, financial ceiling and form of resources transfer	Minimum of 01 document per operational level	I	I I
Information System	SHU	Technician responsible for filling and completeness of the investigation forms	Minimum of 01 technician	-	I I
	ES-MHS	Technician responsible for entering data in Sinan	Minimum of 01 technician	-	I I
	SHU, ES-MHS, LACEN, NRL, SHS, GCLAB, COVEH	Presence of documents explaining the flow of information and materials.	Minimum of 01 document per operational level	I	I I
Structure	ES-MHS, SHS, GCLAB, COVEH	Opportunity	60 days to close the suspect cases from the notification date on	I	I I
		Data quality	-	I	I I
		Production and disclosure of technical reports	-	I	I I
Logistics Resource	NIP/Rotavirus	Production and disclosure of technical reports on the current vaccine coverage	-	A	I A
	SHU	Hospital unit with monitoring of implanted acute diarrheal diseases; Bed for admission due to diarrhea; Center for Hospitalar Epidemiological Surveillance	Presence of these structures in the SHU	-	A A
	LACEN, NRL	Pois to collect feces samples; Network for cold storage of samples	-	-	A A
Coordination and Supervision	SHU, LACEN, NRL	Equipment and supplies needed for laboratory testing, diagnostic Kit (ELISA)	-	A	A I
		Plan of maintenance and replacement of inputs	-	A	A I
		Transportation of materials from the SHU to the laboratories	-	A	A A
Vaccine	SHS	Meetings to discuss goals and problems and supervision of the SHU, ES-SHS	Minimum of 04 annual meetings or according to the needs of the units.	-	A A
	GCLAB	Supervision and Meetings to discuss goals and problems with LACEN and NRL	Minimum of 04 annual supervisions	A	- -
	SHU, ES-MHS, LACEN, NRL, SHS, GCLAB, COVEH	Meetings with the heads of each operating level to discuss goals, issues and information exchange between the operational levels	-	I	A A
		Knowledge about the vaccine introduced into the NIP schedule	-	A	A A

\*Adequate (A): indicator present / Inadequate (I): indicator absent

SHU: Sentinel Health Units, ES-MHS: Municipal Epidemiological Surveillance, LACEN: Central Public Health Laboratories, RRL and NRL: Regional and National Reference Laboratories, SHS: State Health Secretariats, COVEH/SVS Coordination of Foodborne and Waterborne Diseases Surveillance, GCLAB: General Coordination of Public Health Laboratories, NIP/Rotavirus: National Immunization Program for Rotavirus.

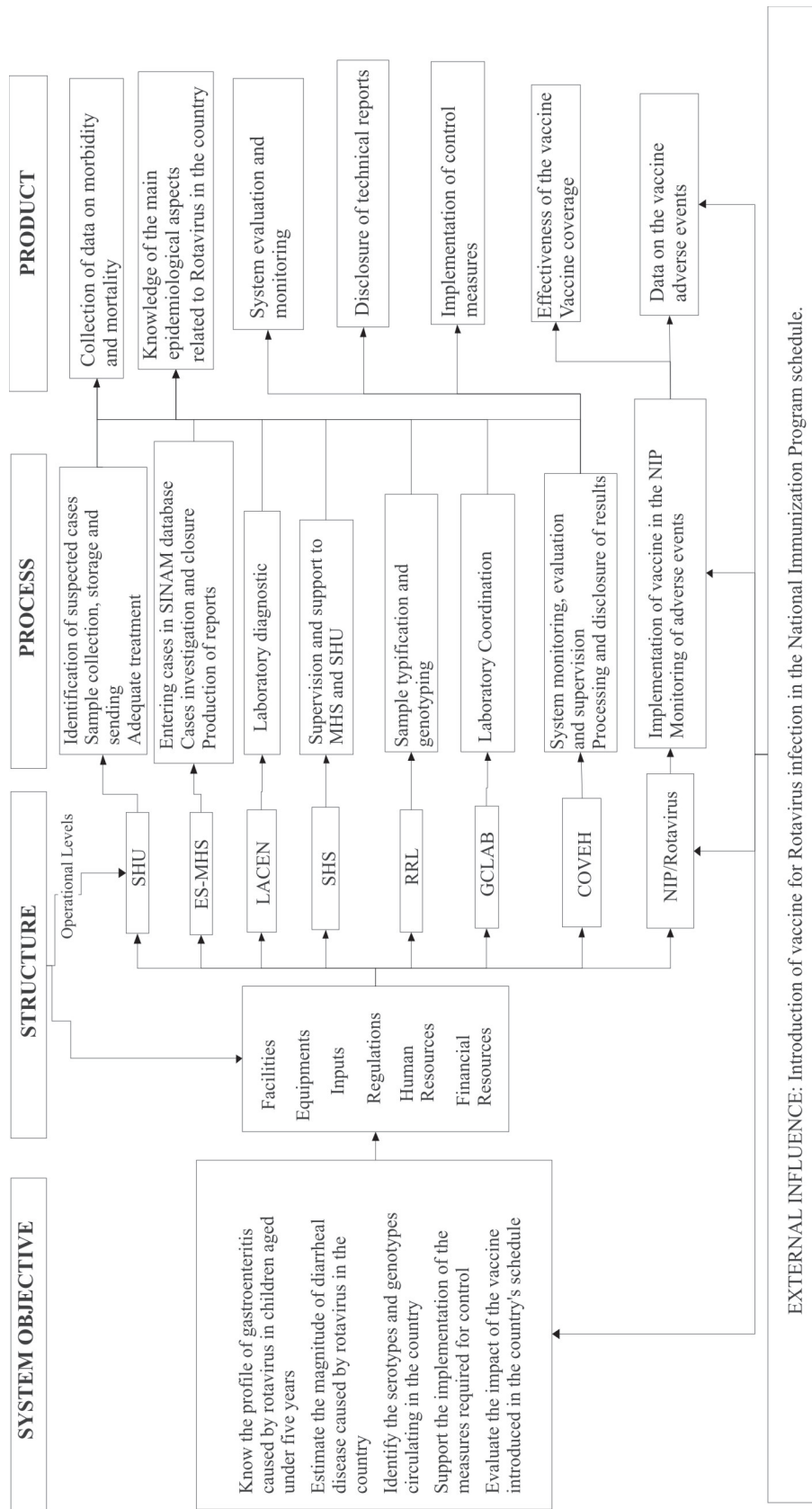


Figure 1 - Logic model of Extended Epidemiological Surveillance of Rotavirus in Brazil (ERS) SHU: Sentinel Health Units, ES-MHS: Municipal Epidemiological Surveillance, LACEN: Central Public Health Laboratories, RRL and NRL: Regional and National Reference Laboratories, SHS: State Health Secretariats, COVEH/SVS Coordination of Foodborne and Waterborne Diseases Surveillance, GCLAB: General Coordination of Public Health Laboratories, NIP/Rotavirus: National Immunization Program for Rotavirus.

## RESULTS

The two analysed states did not present the same operating performance evidenced by the judgement matrix (Chart I). At all levels, the *Program and Planning* dimension appeared inadequate as for the indicator 'Presence of official documents and regulatory milestones', due to the absence of action plans, goals and objectives. The health facilities in both states possess operational and technical regulations for clinical management of suspected cases, with sensitivity to identify and capture cases, conduct treatment, collect and store samples.

*Human Resources* represented the greatest limitation of surveillance performance observed in all operational levels. There was no availability of technicians, which caused function overloading of professionals who performed other activities not related to the ERS. However, at each level evaluated, there was at least one professional responsible for coordinating and developing the activities, although without specific training.

The *Financial Resources* dimension was appraised as inadequate at all levels, since there is not the availability of regulatory documents specifying financial sources, financial ceiling and form of resources transfer, with the exception of laboratories. For the LACEN, the financial resources come from FINLACEN (Factor of Incentive to LACEN), established by Decree 2606 of year 2005 by the Ministry of Health, Brazil. It is a funding system that defines the transfer of resources to these laboratories in all states of the country. The transferred amount is determined by the classification of laboratories into five levels, which take into account the complexity of the tests they do, their quality level, the compliance with biosafety regulations, and the establishment of a system of quality management.

The *Information System* proved inadequate in several indicators and operational levels. Except in the SHU of State B, there is no production and disclosure of epidemiological bulletins, leaving various operational levels without feedback. The insertion of data into the information system and information exchange between the operating levels does not occur in a systematic way yet, undermining the fulfilment of the investigation form fields; the opportunity of closing cases; and the quality of data in general.

The *Structure* dimension was evaluated as adequate at various levels and indicators. The only exception was the LACEN of State B, which lacks the installed capacity to perform diagnostic tests. The laboratory functions only as an intermediate that stores the samples and sends them to the Regional Reference Laboratory.

All indicators in the dimensions *Logistics Resource*, *Coordination and Supervision*, and *Vaccine* showed adequate results in the visited operational levels. The only

indicator that was evaluated as inadequate 'Meeting with the heads of each operating level to discuss goals, problems, and information exchange between the operational levels.' This suggests little assistance, guidance, and supervision on the part of the central level.

## DISCUSSION

This evaluative research on the Extended Epidemiological Surveillance of Rotavirus in Brazil (ERS), implemented in the country since 2006, showed many positive aspects, among which one can highlight: sensitivity to capture cases, acceptability of the system by the technicians involved, adequate physical infrastructure to carry out the routine, training, and updating of the technicians' activities. However, operating difficulties were also evidenced, such as the absence of a timely and functioning information system; and the scarcity of financial and human resources, still evidencing a weakness in the system.

An epidemiological surveillance can provide information to detect changes in determinants and subsidizing recommendations is critical to the control of any grievance. The Extended Epidemiological Surveillance of Rotavirus is thus a key part within the activities developed for monitoring the disease profile, especially after the implementation of the vaccine on the basic schedule of infant immunization in Brazil<sup>(27)</sup>.

According to WHO<sup>(28)</sup>, the opportunity and quality of data from the Rotavirus surveillance can provide initial estimates of the disease burden, and thereby subsidize the adoption of control measures and assist in monitoring the impact of vaccine introduction. Operational difficulties encountered in the present study showed that the ESR was implemented with little planning, with no creation of differentiated structures, or allocations of financial and human resources for the development of specific activities of such surveillance. These structural limitations undermine support for the information-decision-action process, going against the principle of opportunity and dynamism of surveillance.

In the current investigation, it was thus observed that surveillance of rotavirus in some operational levels has been proven to be incipient for several reasons, including the fact that the activities at those levels are being conducted in submission to others, not necessarily linked to routine activities of ERS, and there is no availability of human and/or financial resources specific to the conduction of surveillance activities in key units such as the sentinel units and the RRL.

These conditions are disadvantageous for consolidation of the ESR activities, since the dependence on calls for

research to obtain resources for hiring technicians and purchase of inputs renders the surveillance activities extremely vulnerable<sup>(23,25,26)</sup>.

Health Information Systems (HIS) can be understood as tools for the production of information that guide the decision-making process of professionals from different levels of healthcare services. Therefore, the information detected in real time assists in the planning and execution of actions, according to the reality and specificity of the service<sup>(29)</sup>. Within that context, the information system of the ESR is not working in a timely manner in the states evaluated in this study, since this is directly affected by the shortage of human resources, considered as the biggest bottleneck of surveillance. Technicians cannot obtain basic epidemiological indicators, and consequently, with the exception of the SHU in State B, reports or epidemiological bulletins are not prepared, leaving the system without feedback.

In general, the exchange of information is being accomplished through the dissemination of worksheets with the results of the regional reference laboratory and, within the design of epidemiological surveillance, dissemination of raw data through worksheets is not sufficient to detect the grievance profiles or even to assist in decision-making<sup>(30)</sup>.

For the improvement of the information system, it is fundamental that operational levels like ES-MHS, SHS e COVEH process data and disseminate information in the form of epidemiological bulletins contextualized by their regions or even comparing the various regions of the country. In addition, one must seek to strengthen the exchange of systematic information between the operational levels of ESR and the NIP/Rotavirus.

The present evaluation presented limitations, so that it was not able to get information to respond to all the indicators proposed by the judgment matrix. Indicators such as sensitivity, timeliness and quality of data could not be measured or analysed in this research. The evaluation did not have access to the databases to calculate and obtain those indicators, this being a limitation of the study. However, in future evaluations, it is essential to consider this stage of data analysis, which can reveal important deficiencies in surveillance. Moreover, the model was efficient in detecting the shortage of financial and human resources in the units, but inadequate to explain the logic of resource allocation and propose recommendations.

The results found in this research suggest the inadequacy of the type of surveillance adopted. Therefore, the search for adequate surveillance of Rotavirus is essential to obtain epidemiologic data that guides health policies for the grievance control. Adopting a syndromic type of epidemiological surveillance may be the most suitable for

its robustness and compatibility with the organization and dynamics of the Brazilian Unified Health System.

This type of surveillance can use many forms and sources of data, which are not necessarily the suspected or confirmed cases, aiming the early detection of alteration in this grievance profile<sup>(30-32)</sup>. In the case of rotavirus, the structuring of syndromic surveillance would rely primarily on detecting cases of diarrhea in units of low and medium complexity and samples would be sent to laboratories<sup>(30)</sup>. It would be advantageous having the source of information not concentrated at a single point in the state.

This aspect is very important when seeking to raise the epidemiologic profile of this grievance, since samples will be collected at multiple points with diverse characteristics and from populations with different vaccination coverage. It would also be possible, in a short period, to extend this model to all federal units in the country, since it does not require differentiated structures.

Finally, the approach used in this study involved in all its stages the actors of different dimensions and operational levels of the ERS. Thus, for the actors, the assessment has left aside a disturbing and punitive nature of the developed activities<sup>(33)</sup>. Instead of that, it became perceived as an important tool to improve the quality of routine activities<sup>(19)</sup>.

## CONCLUSION

The results found suggest the low effectiveness of the monitoring system adopted, indicating that sentinel surveillance may not be the most appropriate type for the health system in these studied states.

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The authors declare that there are no conflicts of interest.

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