

The Zika virus emergency in Brazil and the federal response of the National Public Health Surveillance and Brazilian Health Regulatory Systems

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Abstract: The article analyzes the federal response of the National Public Health Surveillance and Brazilian Health Regulatory Systems to the Zika virus epidemic in Brazil, from 2015 to 2018, focusing on the political-institutional contexts and the content of government measures developed during the period. The study was anchored in the historical institutionalist approach, comprising documentary analysis and interviews with key actors. The response was characterized by the initial prioritization of the health emergency on the federal government's political agenda, which was reduced over the period, influenced by the financial and political crises. There was a multiplicity of actors and instances focused on contingency, with a certain articulation between the two systems, based on their own pre-emergency experiences. Vector control had centrality, valuing intersectoral and community actions, induced mainly by the Health Surveillance Secretariat of the Ministry of Health and additionally by the National Health Surveillance Agency. Significant allocation limitations of new financial resources and changes in the organizational response apparatus were observed, with effects on the continuity of post-emergency policies, including the development of medicines, vaccines and tests. The Zika Virus Public Health Emergency in Brazil was marked by limited institutionalization of learning and structuring strategies, reducing opportunities for the (re)organization of surveillance in the Unified Health System.

► **Keywords:** National Public Health Surveillance System. Brazilian Health Regulatory System. Zika Virus. Emergencies.

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Introduction

Public health emergencies (PHE) have had an impact on health systems and imposed response challenges on countries. The International Health Regulations (IHR), revised in the first decade of 2000, seek to enhance coping instruments, involving different organizations, state and non-state; and proposes the creation of focal points for governance of the emergency situation, articulated globally (Brasil, 2009; WHO, 2013; Lima; Costa, 2015; Franco *et al.*, 2017).

The World Health Organization (WHO) recommends actions to prepare surveillance and control systems, involving adequate notification and confirmation of cases, sharing of event communication actions and identification of the installed capacity of the health system (Wilson *et al.*, 2008; Carmo *et al.*, 2008; Teixeira *et al.*, 2012; Ventura, 2016; Bueno, 2017; Teixeira *et al.*, 2018; WHO, 2019; Carmo, 2020).

With varied performances and configurations, health systems and services seek to include preparedness and response actions to health emergencies. Examples include the fight against Ebola on the African continent; respiratory viral diseases, with strong epidemic expression in Asia (H1N1, SARS); and arboviruses, which are evident in the Americas, especially in Latin and Central America (Ventura, 2016; Bueno, 2017). It is also worth highlighting the (re)emergence of diseases previously controlled and/or eradicated, such as measles (Oliveira *et al.*, 2015; Carmo, 2020).

Over the decades, arboviruses have had important consequences for the health of the Brazilian population, demanding policies to combat their epidemic cycles, with emphasis on dengue (Carmo *et al.*, 2008). Later, chikungunya and zika gained prominence, creating a “triple epidemic” situation in the country (Lima-Camara, 2016; Valle *et al.*, 2016; Nunes; Pimenta, 2016; Donalisio; Freitas; Zuben, 2017).

At the end of 2015, the emergence of the Zika virus (ZIKV) and its correlation with microcephaly and other neurological manifestations shed light on old and new challenges for public health, culminating in the declaration by the Ministry of Health (MH) and the WHO, of a public health emergency of national (PHEIN) and international (PHEII) importance, respectively (De Araújo *et al.*, 2016; Teixeira *et al.*, 2016; Vanni *et al.*, 2016; Bueno, 2017; De Oliveira *et al.*, 2017; Faria *et al.*, 2017; Lowe *et al.*, 2018).

Efforts between different actors, national and international, came together to face the health crisis, with different emphases and perspectives. The intentions to enhance

diagnosis, prevention, treatment and control of the epidemic and its effects were evident, in addition to research focusing on gaps in knowledge about arboviruses, highlighting ZIKV and its relationship with microcephaly and other manifestations (Abrasco, 2016; Freitas *et al.*, 2018; Albuquerque *et al.*, 2018; Oliveira *et al.*, 2020).

In this context, Barreto *et al.* (2016) emphasized surveillance actions, among others, as components of a government response plan. They are qualification of evidence on the effects of viral transmission on illness; development of a serological test for rapid and specific diagnosis; reducing the risk of infection through vector control; definition of prevention and care protocols; and vaccine development and other technological strategies.

In the Unified Health System (SUS), health surveillance plays a central role in responses to PHE (Lima; Costa, 2015; Brasil, 2018; Teixeira *et al.*, 2018). Its main components – epidemiological, sanitary, environmental and worker health – are anchored in concepts, knowledge and practices of risk prevention and health promotion and protection (Costa; Rozenfeld, 2000; De Seta; Reis; Pepe, 2011; Franco *et al.*, 2017; Silva; Costa; Lucchese, 2018).

The management of these surveillances at the federal level is the responsibility of the Ministry of Health, involving the National Public Health Surveillance System, under the coordination of the Health Surveillance Secretariat (HSS); and the Brazilian Health Regulatory System, under the responsibility of the National Health Surveillance Agency – Anvisa (Costa; Rozenfeld, 2000; Lucchese, 2006; Souto, 2007; De Seta; Reis, 2011; Lima; Costa, 2015; De Seta; Oliveira; Pepe, 2017; Brasil, 2018).

In this research, it is argued that the ZIKV epidemic in Brazil occurred in a context of political and economic crises, and uncertainty regarding the consequences of the infection and its association with microcephaly, imposing challenges and conditioning the response of government actors. Thus, it aims to analyze the federal response of the National Public Health Surveillance System and the Brazilian Health Regulatory System to the ZIKV epidemic in Brazil, from 2015 to 2018, emphasizing conditions, actors, strategies adopted and developments.

Method

The study was based on contributions from historical institutionalism (Marques, 1997; Ham; Hill, 1993), with an emphasis on the contexts, actors and

content of the measures carried out by the federal government in the chronology of the response to the ZIKV PHE in Brazil, having as reference to the performance, experiences and organizational structure of national health surveillance and health regulatory systems.

Eighty-four government documents on the federal response to PHE were analyzed, including: two presidential decrees, one law, 23 ordinances, one resolution, 20 epidemiological bulletins, 21 plans and protocols and 15 institutional reports and reports. The material was collected between 2016 and 2020 on the websites of the Ministry of Health (www.gov.br/saude/pt-br), Anvisa (www.gov.br/anvisa/pt-br) and the Brazilian Health Legislation System (saudelegis.saude.gov.br/saudelegis/secure/norma/listPublic.xhtml).

Seven interviews (Feb/2018 to Jul/2020) were carried out with government actors involved in the federal response to the emergency, especially those linked to the two systems studied. A semi-structured script was applied, with recording and transcription of the audio previously authorized by the interviewees. Chart 1 details the strategies (procedures and sources consulted) and the materials used during the research work.

Chart 1. Detailed strategies and materials used in the research work. Brazil, 2015-2018

Research Strategy	Materials
<p>Survey and document analysis</p> <p>Procedures:</p> <ul style="list-style-type: none"> - Search, selection and systematization of government documents according to year of publication, type, syllabus and origin; - Categorization according to analytical dimensions (context and content). <p>Sources:</p> <ul style="list-style-type: none"> - Saúde Legis (saudelegis.saude.gov.br/saudelegis/secure/norma/listPublic.xhtml) - Ministry of Health (www.gov.br/saude/pt-br) - Anvisa (www.gov.br/anvisa/pt-br) 	<p>Federal Law (1) Lei nº 13.301, June 27, 2016.</p> <p>Presidential Decrees (2) Decreto nº 8.612, December 21, 2015; Decreto nº 8.662, February 1st, 2016.</p> <p>Federal ordinances (23) Portaria GM/MS nº 2.757, Dec. 11, 2014; Portaria GM/MS nº 1.167, Aug. 7, 2015; Portaria nº 1.813, Nov. 11, 2015; Portaria nº 2.121, Dec. 18, 2015; Portaria nº 2.162, Dec. 23, 2015; Portaria nº 204, Feb. 17, 2016, Portaria nº 779, Apr. 20, 2016, Portaria GM/MS nº 1.046, May 20, 2016; Portaria nº 1.834, Oct. 11, 2016; Portaria GM/MS nº 2484, Nov. 18, 2016; Portaria GM/MS nº 3129, Dec. 28, 2016; Portaria nº 3, Jan. 11, 2016; Portaria Interministerial nº 405, Mar. 15, 2016; Portaria Interministerial nº 1.115, June 3, 2016; Portaria Interministerial nº 2.209, Oct. 26, 2016; Portaria nº 894, Mar. 31, 2017; Portaria nº 1.682, July 30, 2017; Portaria nº 3.502, Dec. 19, 2017; Portaria nº 3.958/2017; Portaria nº 1.313, Aug. 3, 2017; Portaria nº 4.073/2018; Portaria nº 4426/2018; Portaria nº 3254/2018.</p> <p>Resolution (1) Resolução da Diretoria Colegiada – RDC nº 72, Mar. 30, 2016</p> <p>SVS/MH Epidemiological Bulletins (21) Bol Epidemiol. 2015;46(34):1-3; Bol Epidemiol. 2015;46(36):1-9; Bol Epidemiol. 2015;46(37):1-5; Bol Epidemiol. 2015;46(41):1-7; Bol Epidemiol. 2015;46(42):1-9; Bol Epidemiol. 2015;46(44):1-9; Bol Epidemiol. 2015;46(45):1-7; Bol Epidemiol. 2015;46(50):1-5; Bol Epidemiol. 2016;47(1):1-4; Bol Epidemiol. 2016;47(2):1-9; Bol Epidemiol. 2016;47(6):1-7; Bol Epidemiol. 2016;47(15):1-9; Bol Epidemiol. 2016;47(20):1-10; Bol Epidemiol. 2016;47(23):1-10; Bol Epidemiol. 2016;47(38):1-10; Bol Epidemiol. 2017;48(3):1-11; Bol Epidemiol. 2017;48(10):1-10; Bol Epidemiol. 2017;48(12):1-9; Bol Epidemiol. 2017;48(31):1-11; Bol Epidemiol. 2018;49(3):1-10; Bol Epidemiol. 2018;49(12):1-13.</p>

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Research Strategy	Materials
	<p><u>Plans, protocols, guidelines and technical notes (21)</u></p> <p>Plano de Resposta às Emergências em Saúde Pública (2014); Diretriz Geral SNCC/2015; Diretriz SNCC nº 2/2015 - Apoio das Forças Armadas; Nota Técnica Conjunta nº 001 2015 GSH/GGPBS/GGMON; Protocolo para implantação de unidades sentinelas para Zika vírus; Protocolo de atenção à saúde e resposta à ocorrência de microcefalia relacionada à infecção pelo vírus zika; Protocolo de vigilância e resposta à ocorrência de microcefalia relacionada à infecção pelo vírus Zika; Diretriz SNCC nº 1.1/2016; Diretriz SNCC nº 1.2/ 2016; Diretriz SNCC nº 3/2016 – Saneamento Básico; Diretriz SNCC nº 4/2016 – Proteção e Defesa Civil; Instrução Operacional Conjunta nº 1 MS-MDS, Feb. 25, 2016; Instrução Operacional Conjunta nº 2 - MS-MDS, Mar. 31, 2016; Nota Técnica Conjunta n.º 001 2016 CGSH/GGMON; Nota Técnica Conjunta n.º 008 2016 CSTCO/GGMED/DIARE; Nota Técnica Conjunta CGSH-ANVISA/SAS/MS nº 002/2016; Protocolo de atenção à saúde e resposta à ocorrência de microcefalia; Protocolo de vigilância e resposta à ocorrência de microcefalia e/ou alterações do sistema nervoso central (SNC); Protocolo de investigação de óbitos por arbovírus urbanos no Brasil - dengue, chikungunya e zika; Recomendações técnicas ao Sistema Nacional de Vigilância Sanitária para colaborar no combate ao <i>Aedes aegypti</i> e prevenção e controle da dengue, chikungunya e infecção pelo vírus Zika; Orientações Integradas de Vigilância e atenção à saúde no âmbito da Emergência de Saúde Pública de Importância Nacional. Ministério da Saúde.</p> <p><u>Reports and institutional reports (15)</u></p> <p>Relatórios de Atividades Anvisa 2015 a 2018; Relatório de gestão Anvisa 2015 a 2018; Relatório de Gestão SVS 2015 a 2017; Zika: abordagem clínica na Atenção Básica (material educativo); Relatório estatístico sintético Ouvidoria/Anvisa 2016; Sala Nacional de Coordenação e Controle para o combater ao <i>Aedes aegypti</i>: um país mobilizado no combate ao mosquito (folder, 2017); Vírus Zika no Brasil – a resposta do SUS (livro; 2017); Relatório de Gestão Ministério da Saúde 2018.</p>

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Research Strategy	Materials
<p>Interviews</p> <p><u>Procedures:</u></p> <ul style="list-style-type: none"> - Mapping, inviting, scheduling and conducting interviews with key actors, considering insertion, position and function/role in the systems studied, at the federal level; - Application of a Free and Informed Consent Form and prior request for authorization to record the interviews; <p>Use of a semi-structured interview guide;</p> <ul style="list-style-type: none"> - Textual transcription of the interview audio; - Analysis of the transcription, according to components of the analytical dimensions (context and content). 	<p><u>Semi-structured interview guides (7)</u></p> <p><i>The scripts were structured into the following blocks of questions:</i></p> <ul style="list-style-type: none"> • Block A – Repercussions for Health Surveillance/Health Surveillance • Block B - Structure and Organization of the National Health Surveillance System/Health Surveillance • Block C - Definition of Action Plan(s) to Address the Zika Epidemic • Block D - Articulation with other Sectors (intersectorality/partnerships) • Block E – Financing of actions/Action plan • Block F - Results of the Actions/Action Plan (Learnings, strengths and challenges)

Source: own elaboration.

The information extracted from the documents and interviews was interpreted together and organized for each of the systems studied. The institutional political context was considered (bodies and organizations involved; spaces for formulating, coordinating and evaluating actions; and prioritized themes); and the content of government policy (plans, programs and strategies implemented; guidelines and recommended implementation instruments).

The analysis involved the identification, in the empirical material, of events that marked the pre-emergency period (2014 to Oct./2015), bringing together antecedent actions and experiences in preparing surveillance; as well as those evidenced in the emergency (Nov./2015-Jul./2017). The post-emergency period (Dec/2017 to Dec/2018) was also considered, with the aim of verifying the permanence of the Zika issue on the agenda of the two national systems; and possibilities for

institutionalizing actions. In the discussion, an overview of the federal response is presented, in light of the analytical framework and in dialogue with the literature.

The research was approved by the Ethics Committee of the academic institution involved under Opinion 2.180.892 and CAAE 67311617.8.0000.5240.

Results

The response of the National Public Health Surveillance System

At the end of 2014, epidemiological monitoring of dengue and chikungunya led to federal actions to prepare and respond to possible events related to these diseases. The initiatives involved federal financial transfers for surveillance, prevention and control to states and municipalities, combined with centralized acquisition for the distribution of insecticides and diagnostic kits. The Health Surveillance Secretariat of the Ministry of Health (HSS/MH) intensified support for chikungunya contingency plans in early 2015, given the recent introduction in the country and confirmation of autochthonous transmission of the virus in some municipalities; and dengue, due to the co-circulation of the four viral serotypes in Brazil and border countries.

In the same period, the circulation of ZIKV was identified in Bahia, with confirmation of national autochthonous transmission. In that state, the simultaneous occurrence of the three viruses and concerns about the existence of a causal relationship between arboviruses and the increase in cases of Guillain Barré in adults, from March to August 2015, motivated the sending of federal resources for emergency actions.

In October, evidence of a change in the pattern of microcephaly occurrence between January and September in Pernambuco led to the activation of the HSS/MH rapid response team, to investigate the possible causes of increasing notifications of this condition in the state, compared to years previous ones. This event was communicated to the WHO by the Ministry of Health, in compliance with IHR regulations.

The worsening of the situation, marked by the increase and spread of suspected cases, resulted in the declaration of PHEIN by the MH in November 2015. The WHO declared PHEII in February 2016, upon confirming the spread of cases of ZIKV infection in the Americas, demanding a response international index based on the IHR.

In the documents researched, the first response actions to PHEIN considered the WHO Global Outbreak Alert and Response Network strategy. The National Guidelines for Prevention and Control of Dengue Epidemics, published in 2009, supported surveillance and control actions, covering chikungunya, dengue and zika.

The Strategic Health Surveillance Information Centers (SHSIC) of states and municipalities received guidance on how to report suspected cases in the Public Health Event Registration (PHER) system, structured with this objective. The HSS/MH developed microcephaly surveillance protocols, standardizing the case definition, and intensified monitoring of rumors in the media. In parallel, transfers of federal resources supported contingency actions by states and municipalities.

Health care protocols and the implementation of sentinel units for ZIKV were established, with successive updates due to uncertainties about the behavior of the virus. During the course of the epidemic, progress was made towards understanding other neurological manifestations resulting from viral infection, which led to redefinitions in the patterns of cases to be considered during pregnancy and postpartum.

The planning, organization, coordination and control of health surveillance actions were the responsibility of the Public Health Emergency Operations Center (PHEOC), linked to HSS/MH, and whose activation was foreseen in the Public Health Emergency Response Plan, in force since 2014. The SUS National Force was called upon; temporary hiring and training of health professionals; and acquisitions of goods and services required by the emergency.

Zika reached priority on the presidential agenda, guiding federal government actions, such as the National Plan to Combat Microcephaly (NPCM), launched in December 2015. Its design consisted of mobilization and combat against the mosquito; attention to those affected; and technological development, education and research. Transversally, a communication plan was planned, aimed at interventions in public spaces and events; the preparation and distribution of graphic material; and advertising campaigns.

The NPCM prioritized the population's engagement in the mobilization and fight against *Aedes*, involving communities, religious institutions, the press and governments, by carrying out joint efforts and caravans in the most affected states at that time. To support the logistics of transporting inputs and professionals, and during home visits, the Armed Forces, Civil Defense teams and community health agents (CHA) and endemic diseases combat (EDA) were mobilized. Of particular note is

the introduction, through a ministerial decree, of duties linked to environmental management and vector control in the standardized activities of the CHA.

The fulfillment of the NPCM was associated with the structuring of the National Coordination and Control Room (NCCR), linked to the National Center for Risk and Disaster Management, of the National Civil Defense Secretariat of the then Ministry of National Integration. Coordinated by the MH, it was made up of representatives from the Civil House, the Government Secretariat of the Presidency of the Republic, and the Ministries of Defense, Education and Social Development.

SNCC defined rules and directed the initiatives of federal agencies and support activities for the Armed Forces. In addition, it published guidelines for a coordination and control system, including devices for creating state, district and municipal rooms, with similar composition and mode of operation. Another priority point was the establishment of intersectoral measures, such as the creation of guidelines focused on basic sanitation policy.

In laboratory diagnosis, we sought to train the Central Public Health Laboratories (CPHL), with a view to expanding the use of molecular biology, involving reference laboratories such as the Evandro Chagas Institute (ECI/PA), the Adolfo Lutz Institute (ALI/SP) and those of the Oswaldo Cruz Foundation (Fiocruz/MH) in Pernambuco, Paraná and Rio de Janeiro. Subsequently, supplies and reagents for serological and molecular biology diagnosis of Zika were distributed.

The need to expand knowledge about the virus and its repercussions on the health-disease process and improvements in diagnosis and vector control, prioritized in the NPCM, led to the creation of the National Network of Specialists in zika and related diseases (RENEZIKA), in May 2016. It aimed to integrate actors from public management, research and society in the integrated construction of surveillance, prevention, control, social mobilization and scientific and technological development interventions.

In order to intensify preventive, assistance and social protection actions for those affected in the territories, integration initiatives were used between the SUS and the Unified Social Assistance System (SUAS). The surveillance action consisted of working with notifications of suspected cases, to support interventions by the State Command and Control Rooms. During this period, the Ministry of Health included Zika in the national list of diseases and conditions that must be notified.

In this context, in March 2016, the Rapid Action Strategy (RAE) was launched, with the aim of speeding up the diagnostic elucidation of microcephaly cases under investigation and the search for confirmed ones, for inclusion in assistance actions. To this end, the Registration System for Assistance to Children with Microcephaly (RSACM) was created, which, although operational and management linked to health care, also aimed to improve epidemiological investigations.

The RAE and RSACM implementation designs were delegated to the states, aiming to incorporate locoregional specificities. A financial incentive was provided for the cost of the actions, with apportionment conditional on approval by the Bipartite Inter-Management Committees. For RSACM, technical support, protocols and record standardization manuals were offered, ensuring centralized consolidation of the National Public Health Surveillance System, integrated with healthcare.

Actions to combat mosquitoes were also prioritized in federal legislation approved in June 2016, which authorized forced entry into properties, in cases of refusal of prior requests from health authorities at the three government levels; and application of sanctions for recurrences in vector outbreaks. The aerial dispersion of insecticides was also allowed, to have its effectiveness proven by a MH working group, coordinated by SSH/MH and composed of other ministerial secretariats, Fiocruz, Inca, Anvisa, CONASS, CONASEMS, CNS, Ibama and Ministry of the Environment.

The legislation also established the National Support Program for Combating Diseases Transmitted by *Aedes* (PRONAEDES), whose regulation would be the responsibility of the MH, with a focus on the development and evaluation of new technologies for controlling *Aedes*. We sought to finance vector control projects in areas with a higher incidence of arboviruses and/or with less availability of financial resources for health surveillance.

The presidential impeachment, with changes in ministerial positions, had repercussions on the response to the emergency. In October 2016, the MH created a working group, coordinated by SSH/MH, to discuss and update current instruments and strategies. Other initiatives involved making the deadlines for completing the RAE and the transfer of its financial incentives more flexible; and the integration of RPHE-Microcephaly, RSACM and RAE monitoring spreadsheets to facilitate case monitoring.

The closure of PHEIN, in July 2017, was based on a technical opinion aligned with the IHR, in an epidemiological scenario of a reduction in new cases, but with a

high number of records under investigation. There was deactivation of PHEOC and redirections in the various MH secretariats to assess the continuity of NPCM actions.

The post-emergency period was marked by the creation, in December 2017, of the Surveillance and Care Action Strategy for Children Diagnosed or Suspected of Congenital Syndrome associated with infection by the Zika virus (SCZV) and other syndromes caused by syphilis, toxoplasmosis, rubella, cytomegalovirus and herpes virus (STORCH). It aimed to support states in strategic plans for evaluating and monitoring children, through financial incentives for the qualification of Family Health Support Center (NASF) teams, enabling the acquisition of early stimulation kits by municipalities; and for diagnostic conclusion, monitoring and support for children with SCZV and STORCH. The finalization and presentation of plans by the states was extended by ministerial orders until the end of 2018.

Aiming to continue monitoring *Aedes* infestation in Brazilian municipalities, we sought to link financial transfers to the implementation of this practice. In addition, educational activities related to the clinical management of arboviruses were updated. Table 2 summarizes the elements of the political-institutional context and the content of government policy that characterized the federal response of the National Public Health Surveillance System, in the pre-emergency, emergency and post-emergency moments.

Chart 2. Political-institutional context and content of government policy associated with the federal response of the National Health Surveillance System to the Zika virus emergency. Brazil, 2015-2018

Moment	Political-institutional context	Content of government policy
Pre-emergency (end of 2014- Oct./2015)	Epidemiological monitoring of dengue and chikungunya; federal preparation and response to possible emergencies. Identification of the circulation of the Zika virus (Bahia) and simultaneous occurrence with chikungunya and dengue; causal relationship with Guillain Barré. Change in the pattern of occurrence of microcephaly (Pernambuco) and association with Zika virus.	Support for dengue and chikungunya contingency plans in states and municipalities. Sending financial resources for emergency actions and distribution of insecticides and diagnostic kits. Microcephaly: activation of the rapid response team of the Health Surveillance Secretariat of the Ministry of Health (SVS/MS); communication of the event to the World Health Organization.

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Moment	Political-institutional context	Content of government policy
<p>Emergency (Nov./2015- July/2017)</p>	<p>Uncertainties about the disease. Valuation of previous actions for dengue; Surveillance-Attention articulation; intersectorality. Zika prioritized on the presidential agenda; focus on vector control, community mobilization and laboratory diagnosis; encouraging the decentralization of decisions and execution of actions to states. Changes with presidential impeachment: review of the national coping strategy and extensions of ongoing initiatives. Decrease in the number of new cases of ZIKV infection: closure of the emergency.</p>	<p>Remaining a high number of cases under investigation. Guidelines for Strategic Health Surveillance Information Centers (SHSIC) for case notification; rumor monitoring; activation of the Public Health Emergency Operations Center (PHEOC). Financial transfers to states and municipalities; Creation of the Public Health Event Registration system; and the Registration System for Assistance to Children with Microcephaly; Training of Central Public Health Laboratories in molecular biology by reference laboratories. Development and updating of surveillance and care protocols for microcephaly and sentinel units. National Plan to Combat Microcephaly; National Command and Control Room; National Network of Experts on Zika and Related Diseases (RENEZIKA); Rapid Action Strategy. Authorization for forced entry into properties and application of sanctions; use of aircraft for vector control; National Support Program to Combat Diseases Transmitted by <i>Aedes</i>.</p>
<p>Post-emergency (Aug./2017 to Dec./2018)</p>	<p>Remaining a high number of cases under investigation. Deactivation of PHEOC, redirections at the Ministry of Health and assessment of the continuity of the NPCM.</p>	<p>Creation of the Strategy for Surveillance and Care Actions for Children Diagnosed or Suspected of Congenital Syndrome associated with Zika virus infection and other STORCH. Financial transfer conditioned on continued monitoring of <i>Aedes aegypti</i> infestation in municipalities. Educational strategies on arbovirus management.</p>

Fonte: own elaboration.

Note: STORCH: syndromes caused by syphilis, toxoplasmosis, rubella, cytomegalovirus and herpes viruses.

The response of the Brazilian Health Regulatory System

In August 2014, the Information Management Center for Emergency Health Surveillance (eVisa) came into operation at Anvisa, aiming to carry out this surveillance in PHE. The aim was to form the National Network of Alerts and Responses to Public Health Emergencies and cooperate with SHSIC/MH. Its structuring was influenced by experiences with the 2014 Ebola epidemic in West Africa and the context of mass events in Brazil: the Football World Cup (2014) and the World Indigenous Peoples Games (2015).

In the federal response, eVisa worked to articulate PHEOC's demands, distributing them internally at Anvisa. The actions to mobilize federal agencies to combat mosquitoes and alert the population, within the scope of the NPCM, included the participation of the Agency, highlighting "Cleaning Day" and "National Zika Zero Mobilization Day".

The work focused primarily on topics relating to vector control, assisted reproduction, blood surveillance, repellents and diagnostic tests. Technical recommendations were produced for state and municipal health surveillance, on the adoption of measures to combat mosquitoes in health inspections and inspection and monitoring of repellents and insecticides on the market, in addition to initiatives aimed at recording and proving the effectiveness of the action of *Aedes aegypti* mosquito repellents and insecticides.

Throughout the emergency, topics related to the assessment of the risk of using new technologies were highlighted, with regulatory challenges involving vaccines, diagnostic tests, modified mosquitoes, mosquitoes infected by *Wolbachia*, textile products and bracelets with repellent, and paints with antimicrobial action. Specific activities included the prohibition of the manufacture, distribution, dissemination, commercialization and use of herbal products without registration for ZIKV.

In August 2016, a joint technical note was prepared with the Department of Healthcare of the Ministry of Health, regarding the management of health risks in the use of blood components in blood transfusions. The aim was to guide Hemotherapy Services in observing clinical symptoms of Zika when screening donation candidates; and the importance of information on cases of post-donation infection. The hemovigilance system had already recorded probable transmission of ZIKV in blood product transfusions in March of that year.

The operating rules of germinal cell and tissue banks were updated, aiming to limit the collection of gametes or germinal tissues, which is now allowed only after confirmation of non-reactive or negative laboratory tests for ZIKV. Along with the Coordination of the National Transplant System of the Ministry of Health, an Anvisa resolution redefined criteria for selecting donors of cells, tissues and organs for transplantation, in addition to their therapeutic use and clinical research.

Focusing on pregnant women, informative materials were produced in response to the growing demand regarding the purchase, use and quality of repellents, captured by the Anvisa ombudsman. In relation to sanitizers, the Agency prepared documents explaining the use and care of environmental repellents and insecticides, with the participation of the Department of Consumer Protection and Defense of the National Consumer's Secretariat.

In an environment of cooperation fostered by the WHO and the International Coalition of Medicines Regulatory Authorities (ICMRA), priority was given to analyzing the registration of diagnostic tests for zika, dengue and chikungunya in the country, aiming to intensify supply and access, in a timely testing. This context also favored the sharing of research protocols to accelerate the development of new diagnostic tests, vaccines and treatments. Records of in vitro tests for Zika virus occurred in February 2016 and the first research dossier for an experimental vaccine against ZIKV was approved by Anvisa in 2017.

In the area of Ports, Airports and Borders (PAF), analyzes of import licenses for inputs and research materials on ZIKV were a priority; and the issuance of clarifications on the safety of products exported by Brazil, given the commercial concern regarding the possibility of sending inputs with the presence of contaminated mosquitoes. The 2016 Rio de Janeiro Olympic and Paralympic Games led to the production of communication material for travelers, focusing on actions to eliminate *Aedes* breeding sites.

After the closure of the ZIKV PHE, eVisa was reformulated, starting to work on the preparation of emergency plans in the area of health surveillance, with a lesser role in communication and internal coordination at Anvisa. In 2018, there were changes in the Agency's directors and organizational structure. From the material analyzed, the existence of eVisa or an instance with a similar function in the new structure was no longer observed.

In the post-emergency period, strategies to improve preparedness and response to public health emergencies involved training Anvisa professionals in the Training Program in Epidemiology Applied to Services of the Unified Health System (EpiSUS) and their participation in PHE simulations; and the exchange of knowledge with regulatory agencies from other countries, on action in public health emergency situations on an international scale. Occasionally, the body resumed discussions about the risks of contamination by the virus in assisted reproduction and autohemotherapy.

Chart 3 systematizes the political-institutional context and the content of government policy in the federal response of the National Public Health Surveillance System, in the pre-emergency, during the emergency and post-emergency moments.

Chart 3. Political-institutional context and content of government policy associated with the federal response of the National Sanitary Surveillance System (Anvisa) to the Zika virus emergency. Brazil, 2015-2018

Moment	Political-institutional context	Content of government policy
<p>Pre-emergency (end of 2014- Oct./2015)</p>	<p>Integration into the National Network of Alerts and Responses to Public Health Emergencies.</p> <p>Cooperation with the Epidemiological Surveillance Monitoring Center of the Ministry of Health.</p> <p>Learning from the response to the Ebola epidemic (2014).</p> <p>Experiences with organizing mass events in Brazil (World Cup and Indigenous World Games).</p>	<p>Creation of the Information Management Center for Health Surveillance Emergencies (eVisa).</p>

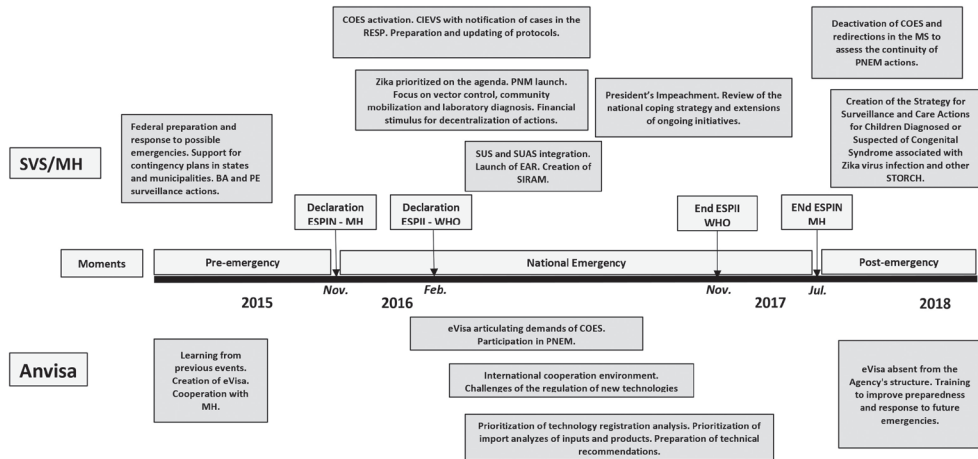
continue...

Moment	Political-institutional context	Content of government policy
Emergency (Nov./2015- July/2017)	<p>eVisa: articulation of PHEOC demands; participation in the NPCM 'Cleaning Day' and 'Zika Zero National Mobilization Day'.</p> <p>Growing demand for information about repellents.</p> <p>International cooperation environment.</p> <p>Challenges in regulating new technologies.</p>	<p>Recommendations for local health surveillance (vector control in health inspections and inspection of repellents and insecticides on the market).</p> <p>Development of technical criteria for risk management in the use of blood components; and the functioning of cell and germinal tissue banks.</p> <p>Actions to register and prove the effectiveness of the action of repellents and insecticides; clarifications on use and care.</p> <p>Prioritization of diagnostic test record analysis; acceleration of research into new tests, vaccines and treatments.</p> <p>Prioritization of import analyzes of research inputs and materials; clarifications regarding the contamination of export products.</p> <p>Publicity and communication aimed at travelers (Olympic Games).</p>
Post-emergency (Aug./2017 to Dec./2018)	<p>Organizational and directive changes at Anvisa; eVisa reformulated in 2017: less articulating role and absence in the Agency's structure.</p> <p>Improving preparedness and response to future public health emergencies.</p> <p>Exchange with regulatory agencies from other countries.</p>	<p>Training of Anvisa professionals in the Training Program in Epidemiology Applied to Services of the Unified Health System (EpiSUS).</p> <p>Discussions about risks of contamination in assisted reproduction and autohemotherapy.</p>

Source: own elaboration.

Figure 1 presents a timeline with the temporal milestones of the federal response of the National Health Surveillance and Sanitary Surveillance Systems to the Zika epidemic in Brazil, considering the pre-emergency, emergency and post-emergency moments observed in the analyzed period.

Figure 1. Time frames of the federal response of the National Health Surveillance and Sanitary Surveillance Systems to the Zika virus health emergency. Brazil, 2015-2018



Source: own elaboration.

Discussion

The study of the federal response of national public health surveillance and health regulatory systems to the 2015 ZIKV emergency in Brazil identified a diverse political-institutional context, with multiple actors and institutional spaces activated, and an emphasis on specific themes. The content produced expressed strategies and mechanisms related to the political agenda, institutionality and legacies that inform the organization of the two systems, with variations occurring in the recommended designs.

The actions of the National Public Health Surveillance System were guided by global mechanisms for managing health emergencies, enhanced by the review of the IHR in the 2000s (Teixeira *et al.*, 2012). In Brazil, some milestones are the SHSIC network and the national plans and programs for qualifying surveillance and its interface with healthcare, informed mainly by experiences with dengue (Brasil, 2003; 2011; 2014; Franco *et al.*, 2017).

This scenario favored pre-emergency actions to detect the circulation and autochthonous transmission of the Zika virus and the change in the pattern of occurrence of microcephaly, as well as the correlation between events (Garcia,

2018). Integration with care highlighted the role of the public hospital network in reporting cases of newborns with microcephaly of unknown infectious cause, initially identified in Pernambuco (Lima *et al.*, 2018; Albuquerque *et al.*, 2018).

In the emergency, these legacies were expressed in the activation of PHEOC and in coordination with the WHO, following actions protocolled by the IHR, under the coordination of the Health Surveillance Secretariat of the Ministry of Health. The leading role of SSH/MH in conducting the response to the emergency, recognized by the WHO (Garcia, 2018), instrumentalized the agenda of the Presidency of the Republic in 2015-2016, which gave priority status to the Zika issue, in the midst of initiatives that sought to reverse the political crisis, which intensified at the time.

A strategy of national projection was invested in, the National Plan to Combat Microcephaly, as part of a positive agenda, based on popular mobilization campaigns to combat mosquitoes, with the tone of “war on *Aedes aegypti*” (Ventura *et al.*, 2020). Other fronts, closely associated with the diversity of mobilized actors, consisted of research efforts, development and use of new vector control strategies and technologies and strengthening laboratory diagnosis.

This context had repercussions on the main response policies, strongly oriented towards streamlining and guaranteeing the implementation of contingency plans. Centralization of the acquisition of rapid tests and repellents, for example, was combined with delegation of commitments and incentives to states, involving integration of registration and notification systems; inter-management agreements regarding the use of federal financial incentives; and the structuring of state situation rooms (Henriques, 2017; Garcia, 2018).

The 22 state coordination and control rooms implemented or being implemented in 2015 attested the rapid adherence of states to this federal guideline (Oliveira, 2017; Garcia, 2018). The focus on intersectorality and the prediction of a diverse composition of actors, governmental and non-governmental, in these spaces, indicated a certain concern with structuring policies in confronting the socio-sanitary impacts of the epidemic (Nardi, 2017; Bueno, 2017).

In the Brazilian Health Regulatory System, dengue control institutions had less influence. The pre-emergency context was informed by its integration into health emergency preparedness strategies, with inspiration from external epidemic events and international mass events based in Brazil. Anvisa’s Information Management Center for Health Surveillance Emergencies (eVisa), resulting from this process,

concentrated response initiatives in the body, whose activities were mostly limited to the contingency structured by PHEOC.

The action was developed in a more centralized manner, with less delegation of actions to state and municipal health surveillance, indicating the prioritization of demands under the direct responsibility of the federal actor. The lesser emphasis on decentralized actions represented action limited to issuing guidance documents to local health surveillance, without provision for monitoring, control and training strategies for including *Aedes* control in health inspections.

In terms of financing, the incentives identified only included support for monitoring *Aedes* infestation and the contingency of arboviruses in some states and municipalities (Brasil, 2016). As a reflection of the economic and financial crisis, federal action was limited to relocations between SUS financing blocks, making new allocations unfeasible in a context of proportional loss of resources for surveillance (Vieira; Benevides, 2020).

The context of political crisis determined a certain institutional instability, especially with the confirmation of the presidential impeachment, having an impact on the conduct of the emergency response by SSH/MHS. Contradictions, redundancies in plan content and reduced implementation potential of some initiatives were evident. At Anvisa, this scenario did not define changes in direction, possibly because it did not play a leading role in commanding the response and due to its legal and administrative nature, which ensures mandate and autonomy for its directors (Brasil, 1999; De Seta; Oliveira; Pepe, 2017).

In the post-emergency period, institutionalization incentives were scarce, with revisions of ongoing measures and fragile concerns about qualification for future emergencies predominating, which indicates Zika's loss of space on the government agenda. On the other hand, it is worth highlighting Anvisa's continued coordination with other regulatory agencies to share knowledge, data and experts, in order to deal with scientific evidence related to new technologies, favoring decision-making (Brito; Flexa, 2019).

Temporary systems for collecting information about cases, such as RPHE and RSACM, although relevant during the emergency, did not incorporate improvements in official systems. There still remain challenges related to data quality and the adoption of new analysis tools from the perspective of data science and precision technologies (Lowe *et al.*, 2018; Coelho; Codeço, 2019; Lana *et al.*, 2020).

Despite being encouraged, intersectoral actions to reduce (or eliminate) mosquito infestation have not progressed, with gaps remaining in the implementation of strategies to combat social and environmental constraints, such as water supply and piped water, and adequate sewage and sanitation systems. (Henriques; Duarte; Garcia, 2016; Zara *et al.*, 2016; Osorio-de-Castro *et al.*, 2017; Donalisio; Freitas; Zuben, 2017).

Obstacles remained in investments in the laboratory network, as well as weaknesses in testing to confirm suspected cases and cases under investigation, due to gaps in the recommended criteria and in guaranteeing the quality and accuracy of the tests used (Verotti *et al.*, 2017; Carvalho *et al.*, 2018; Garcia, 2018). There was also no evidence of developments regarding vaccine development projects and the incorporation of new technologies.

In this paper, the immediate post-emergency period (2017-2018) highlighted elements that pointed out trends and possibilities regarding institutionalization and continuity/advancement in the implemented measures. A longer analytical period is required in order to observe medium and long-term outcomes.

Conclusions

The federal response of the National Public Health Surveillance and Brazilian Health Regulatory Systems to the emergence of the Zika virus was characterized by the multiplicity of actors mobilized, the diversity of contingency instances in operation and priority inclusion in the government's political agenda. Its construction, including pre-emergency initiatives, was influenced by legacies and the existing institutionality in the fight against arboviruses, within the scope of Health Surveillance, in addition to being anchored in the guidelines of the International Health Regulations.

Although with different starting points, there was a convergence of objectives and coordination between the federal actors of the two systems studied, with the Health Surveillance Secretariat taking a leading role and Anvisa's complementary position in defining coping strategies. Vector control was the central theme prioritized in the response, present in community mobilization actions and the development of new technologies.

The financial and political crises were expressed throughout the period, imposing allocation limitations on new financial resources, organizational changes after the

presidential impeachment and uncertainty regarding the direction of the proposed initiatives, with repercussions in the post-emergency period.

The devices that induce intersectoral policies did not advance, as well as those for research into the development of medicines and vaccines, despite their prioritization by SSH/MH and Anvisa. In general, little progress was made in institutionalizing learning and initiatives defined as strategic, signaling a loss of opportunity for organizing surveillance and space for Zika on the agenda, after the end of the emergency.¹

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Note

¹ C. V. dos S. Oliveira, V. L. E. Pepe, L. G. a C. Reis, M. V. Albuquerque and H. S. Dias: conception, critical review of the intellectual content and approval of the final version to be published.

Resumo

A emergência do Zika vírus no Brasil e a resposta federal dos Sistemas Nacionais de Vigilância em Saúde e de Vigilância Sanitária

O artigo analisa a resposta federal dos Sistemas Nacionais de Vigilância em Saúde e de Vigilância Sanitária frente à epidemia do Zika vírus no Brasil, de 2015 a 2018, com foco nos contextos político-institucionais e no conteúdo das medidas governamentais desenvolvidas no período. O estudo ancorou-se na abordagem institucionalista histórica, compreendendo análise documental e entrevistas com atores-chave. A resposta se caracterizou pela priorização inicial da emergência sanitária na agenda política do governo federal, reduzindo-se ao longo do período, influenciada pelas crises financeira e política. Verificou-se multiplicidade de atores e instâncias voltadas à contingência, com certa articulação entre os dois sistemas, a partir de experiências pré-emergência próprias. O controle vetorial teve centralidade, valorizando ações intersetoriais e comunitárias, induzidas sobretudo pela Secretaria de Vigilância em Saúde do Ministério da Saúde e complementarmente pela Agência Nacional de Vigilância Sanitária. Observaram-se expressivas limitações alocativas de recursos financeiros novos e mudanças no aparato organizativo de resposta, com efeitos para a continuidade das políticas no pós-emergência, incluindo o desenvolvimento de medicamentos, vacinas e testes. A Emergência em Saúde Pública do Zika Vírus no Brasil foi marcada por limitada institucionalização de aprendizados e estratégias estruturantes, reduzindo oportunidades para a (re)organização das vigilâncias no Sistema Único de Saúde.

► **Palavras-chave:** Sistema Nacional de Vigilância em Saúde. Sistema Nacional de Vigilância Sanitária. Zika Vírus. Emergências.

