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## HISTORICAL PATH OF POLICY FOR PREVENTION AND CONTROL OF HEALTHCARE-ASSOCIATED INFECTIONS IN BRAZIL: CHALLENGES AND PERSPECTIVES

Heiko Thereza Santana\*<sup>1</sup>, Magda Machado de Miranda Costa<sup>1</sup>, Maria Dolores Santos da Purificação Nogueira<sup>1</sup>, Lilian de Souza Barros<sup>1</sup>, Mara Rubia Santos Gonçalves<sup>1</sup>, André Anderson Carvalho<sup>1</sup>, Humberto Luiz Couto Amaral de Moura<sup>1</sup>, Luciana Silva da Cruz de Oliveira<sup>1</sup>, Ana Clara Ribeiro Bello dos Santos<sup>1</sup>, Cleide Felicia de Mesquita Ribeiro<sup>1</sup>, Andressa Honorato Miranda de Amorim<sup>1</sup>, Daniela Pina Marques Tomazini<sup>1</sup> and Fabiana Cristina de Sousa<sup>2</sup>

<sup>1</sup>General Management of Technology in Health Services - GGES/Brazilian Health Regulatory Agency (ANVISA), Brasilia, Brazil; <sup>2</sup>General Management of Ports, Airports, Borders and Customs-bonded Spaces - GGPAF/ANVISA, Brasilia, Brazil

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#### \*Corresponding author:

Pinheiro, Jordana de Carvalho

### ABSTRACT

More than three decades The World Health Organization recognizes healthcare-associated infections (HAIs) as a public health problem and urges national and regional authorities to take action to reduce these complications. In Brazil, these actions are vested in the Brazilian Health Regulatory Agency (ANVISA). The objective of this study is to recover the historical path of HAIs prevention and control initiatives in the country, presenting the main legislation and official documents published nearly four decades and the national perspectives to reduce these events. We performed a historical review based on legislation and official data, in addition to a review of the current literature. We discuss the historical aspects of the norms and actions coordinated by ANVISA and developed together with states, municipalities, and the Federal District, such as surveillance, monitoring, and preventive measures taken in health services in Brazil. Although this study investigates a range of health legislation and actions on the subject in the country, we perceive, critically, that further progress is needed to comply with the legal framework and national recommendations for the reduction of HAIs. The study may contribute as a source of historical information on prevention and control of HAIs for patient safety in health services in Brazil, implementation and review of programs on the subject in other countries, and as a basis for research on these events.

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## INTRODUCTION

For centuries, healthcare workers, organizations, and government agencies have been concerned with hospital associated infections. However, in recent decades, the focus on prevention and control of these complications has increased (Allegranzi *et al*, 2011). Currently, these adverse events (AEs) are known as healthcare-associated infections (HAIs) because they are a concern not only for hospitals, but also for clinics, specialized services in diagnosis and treatment, or any place where patient care is provided. Therefore, HAI prevention and control should be a collective effort. The World Health Organization (WHO) recognizes HAI as a public health problem and

advocates that national and regional authorities develop actions aimed at reducing the risk of these complications since they are one of the high morbidity and mortality AEs, which have repercussions on patient safety and quality of health services (WHO, 2004). According to the WHO, it is estimated that annually more than 4 million patients in Europe and 1.7 million in the United States develop some type of HAI, with higher prevalence in developing countries (WHO, 2011). However, approximately 20-30% of HAIs are preventable with the implementation of control and prevention programs (ANVISA, 2017b). In addition to these events, it is worth remembering that the world has been facing a new era of emerging and reemerging infectious diseases (Bedford *et al*, 2019). Recently, the SARS-CoV-2 pandemic, responsible for Coronavirus disease 2019 (COVID-19) is

imposing infection prevention and control measures to prevent or reduce the transmission of microorganisms during any health care performed in health services (WHO, 2021). The national coordination of HAI prevention and control activities in Brazil is the responsibility of the Brazilian Health Regulatory Agency (ANVISA), created in 1999 (ANVISA, 1999). The Agency is also responsible for elaborating and monitoring of the indicators foreseen in the National Prevention Program and Control of Healthcare-Associated Infections (PNPCIRAS). Its actions are coordinated with states, municipalities, and the Federal District (FD) to improve the quality of health care provided to the Brazilian population. The basis of historical information gathered in a scientific article can broaden understanding and provide infection practitioners and the entire community with the necessary knowledge about the creation, implementation, and structuring of the systematization of HAI surveillance, monitoring, prevention, and control processes. The analysis of such information may, in the same way, be useful to managers and health professionals and to society as well. Thus, the historical study of this process is relevant as it can provide a regulatory reference and national programmatic actions developed, aimed at the prevention and control of HAIs. However, studies that show the historical context of the policy of prevention and control of HAIs for patient safety nationwide are still scarce. The objective of this study is to recover the historical path of HAIs prevention and control initiatives in Brazil, presenting the main legislation and official documents published from 1983 to 2021 to reduce these events. We also reflect on the evolution, the current health challenges, and the national perspective for HAI prevention and control in health services in the country.

## MATERIALS AND METHODS

We performed a historical review based on papers and official data from government health institutions about HAIs prevention and control, including legislation such as laws and ordinances, as well as theoretical bases, according to the current literature, published in Brazil from 1983 to 2021. To this end we carried out a historical review based on the literature relevant to the topic with data retrieved from Public/Publish Medline, Latin American and Caribbean Literature in Health Sciences, and Scientific Electronic Library Online. In addition, we also performed a documentary search using official ANVISA documents on HAIs prevention and control, such as normative and non-normative instruments for health services published by ANVISA after the Agency's creation. This study is close to a qualitative approach, in which the bibliographical-documentary survey is carried out within the sociopolitical context and the theoretical elements are historically interpreted and analyzed at a later date for a better understanding of the present facts (Given, 2008). The delimitation of the study period is due to the fact that the first national legislation on infection prevention and control, related to the implementation of Hospital Infection Control Committee (HICC/CCIH) in health services was published in 1983. The year 2021 is justified by the fact that the publication of the most recent and formalized version of the PNPCIRAS was published in 2021 by ANVISA.

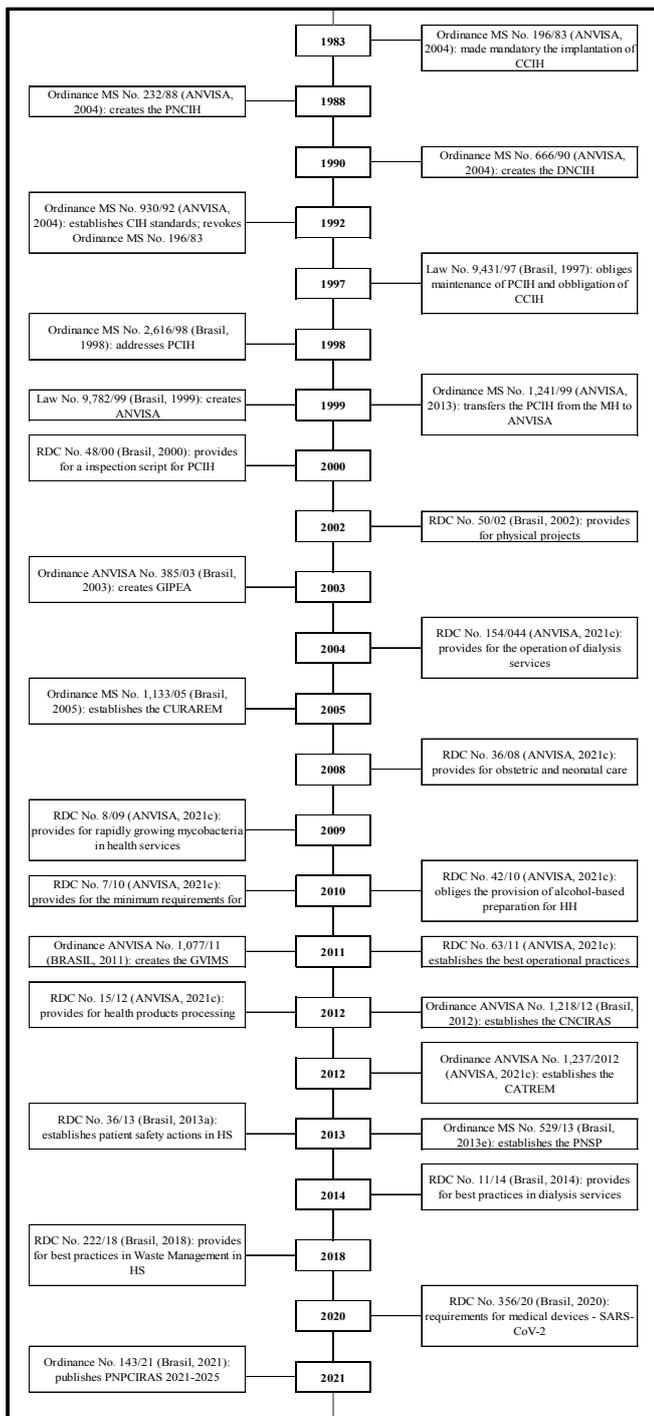
## RESULTS AND DISCUSSION

**Historical aspects of the main laws and actions regulating HAI:** Going back in history is essential to facilitate understanding of the current scenario and the context of public health actions and policies for HAI prevention and control. Thus, our study is of paramount importance for managers, health professionals, and society for rescuing historical conditioning factors that may have influenced the determination of the surveillance model of HAIs in force in Brazil. Although the first discussions on the subject started in Brazil in the 1950s and the first HICC were formed in the 1960s, it was not until the 1980s that specific norms were published. In 1983 the implementation of the HICC in hospitals became mandatory, being regulated by Ordinance No. 196, under the Brazilian Ministry of Health (MS-MoH) (ANVISA, 2004). These committees are instances in health services with the competencies to elaborate, develop, and

monitor HAI prevention and control actions (Brasil, 1998). Currently, there are about 3,000 HICC in the country's public and private health services registered with ANVISA (ANVISA, 2021a), corresponding to about 50% of all Brazilian hospitals, according to the National Register of Health Establishments (CNES). It was only after the death of the Brazilian president-elect, Tancredo Neves, in 1985 from a HAI, a month before taking office, that the topic gained more publicity by the media. As a development, the MoH created, in 1985, the Centers for Training in Hospital Infection Control (ANVISA, 2004). In 1986, the VIII Brazilian Health Conference took place, stimulating the reformulation of Brazilian health policies with Sanitary Reform. During that conference, the issue of prevention and health promotion was evidenced as a duty of the State (Brasil, 1986). In this context, in 1988, the Brazilian program of hospital infection control (PNCIH) was established. After that, the National Division of Hospital Infection Control was created by the MoH (ANVISA, 2004) being part of the Health Surveillance Secretariat.

In order to update the prevention and control norms for HAIs in the country, Ordinance MoH No. 196/1983 was revoked and replaced by Ordinance MoH No. 930/1992 (ANVISA, 2004). A national survey conducted by the MoH in 1994 showed a prevalence of HAI at 13%, with higher rates in public hospitals (18%) (Zanon, 2003). To support preventive measures, in 1994, the MoH published a manual for the processing of medical devices and surfaces in health services (Brasil, 1994). In 1997 Law 9,431, which is still in force in the country, defined the infection control program (PCIH) as the "set of actions developed, deliberately and systematically, with a view to reducing, as much as possible, the incidence and severity of hospital infections," making it mandatory in all hospitals in Brazil (Brasil, 1997). At the end of the 1990s, a regulatory framework of relevance was the publication of the Ordinance MoH No. 2,616/1998 (Brasil, 1998), which replaced Ordinance No. 930/92 (ANVISA, 2004). The new document regulated PCIH and the requirement to maintain the HICC at federal, state, and local levels. The order also established the competencies of the three spheres of government on the prevention and control of HAIs, in accordance with the principles of the Unified Brazilian Health System. In 1999 with the creation of ANVISA (Brasil, 1999), the National Coordination of the PCIH was transferred from the MoH to this agency. Infection control activities were passed on to the then Health Risk Management Office. Thus, ANVISA assumed the attributions and interfaces jointly with the state, district and municipal coordinations of hospital infection control, strengthening these actions (ANVISA, 2013).

In 2000 Resolution No. 48 of ANVISA's Collegiate Board of Directors (RDC/ANVISA) was published, which establishes the systematics for the evaluation of compliance with the PCIH actions, providing a script for sanitary inspection to evaluate this program in Brazilian hospitals by local Sanitary Vigilance Coordination (Brasil, 2000). Moreover, with the publication of the RDC 50/2002 by ANVISA, emphasis was placed on the evaluation of physical projects in health facilities (Brasil, 2002). In 2003 the Hospital Infection Control Unit (UCISA) was created (ANVISA, 2004). Due to some internal restructuring at ANVISA, UCISA became Management of Research and Prevention of Infections and Adverse Events (Brasil, 2003), later Unit for Research and Prevention of Infections and Adverse Events and, finally, since 2011, Management of Surveillance and Monitoring in Health Services (GVIMS) (Brasil, 2011). At the moment, GVIMS/GGTES coordinates the national actions to prevent and control HAIs. In 2004 RDC No. 154 established the requirements for the operation of dialysis services (ANVISA, 2021c). This regulation was then replaced in 2014 by RDC No. 11, which provides for best practices in the performance of these services (Brasil, 2014). In the same year, RDC No. 306 was published, which deals with waste management, and was later replaced by best management practice regulations (Brasil, 2018). Regarding to the technical regulations for health services in general, since 2008 in order to minimize risks in health services, GGTES/ANVISA has been intensifying the publication of norms that interface with HAI prevention and control measures (Figure 1).



Source: Based on federal legislation (1983 - 2021).

**Figure 1. Timeline of the main national legislations that interface with HAI prevention and control activities in health services (1983 - 2021)**

It is worth mentioning that a new surveillance model for these HAIs, using electronic forms for hospital notification, was implemented in 2010 by GGTES/ANVISA (ANVISA, 2011). Moreover, since 2017 ANVISA has been developing a proposal for a health regulation on best practices in the prevention and control of HAIs in health services with the aim of replacing the outdated provisions of Ordinance MoH No. 2,616/1998 (Brasil, 1998), in response to a demand from the society and the country's infection controllers. Although the need to review and update the regulation is urgent, Ordinance MoH No. 2,616/1998 (Brasil, 1998)<sup>10</sup> still remains as the current norm in the country and has contributed, among others, to the process of decentralization and municipalization of actions for the prevention and control of HAIs. The regulatory character given to Sanitary Vigilance actions for the prevention and control of HAIs since 1999 (Brasil, 1999), manifested by the application of health regulations in

health services in the country can cooperate in part with the adoption of structures that contribute to the implementation of good practices for the prevention of HAIs. However, it is emphasized that only the punitive character coming from the sanitary authorities does not ensure the quality of care, and there must also be a change of culture capable of encompassing other essential components, such as surveillance and monitoring of HAIs, encouragement of patient safety practices, and promotion of education and training of HICCs (Shekelle *et al.*, 2013; Santana *et al.*, 2020). Our study reveals that the normative instruments have been evolving and being improved over the years in the search for proper criteria, indicators, and patterns of best practices for the improvement of the care provided through a diversity of health services in Brazil. Perceived traits in the evolution of regulatory instruments in the management of HAIs include concern for quality, the emergence of risk management in the scope of norms, and the inclusion of infection prevention activities for patient safety, since many HAIs are preventable through the adoption of evidence-based safety practices. Despite several regulatory instruments instituted nationally throughout the period (Brasil, 2000; Brasil, 2002; Brasil, 2018; Santana *et al.*, 2020), and that can support the improvement of care processes and the minimization of the risk of HAI in the diversity of health services, many structural problems still need to be overcome. The involvement of all peers is essential for the actions of HICC to be successful: managers, health professionals and patients. Managers must invest in the prevention and control of HAI, improving the quality of care, reducing expenses, and minimizing the suffering of patients and families. Moreover, HAI prevention requires a multimodal strategy, with broad healthcare collaboration and strong support and accountability of the entire team (Sprague, 2009; WHO, 2018).

Therefore, the progressive participation of patients and their families in the initiatives to elaborate regulatory instruments and in policy-making process of prevention and control of HAIs is fundamental. With this active participation, patients and families will be increasingly instigated in the search for quality care in the country's health services (WHO, 2013). Furthermore, the Sanitary Vigilance Coordination in the states, FD, and municipalities should duly support the surveillance, monitoring, and evaluation of the execution of actions developed by health services, reviewing the PCIH and encouraging good HAI prevention practices. For this, the strengthening of these instances is necessary. Once these instances have the structural conditions to better act, the expansion of the scope of HAI prevention and control actions not only in hospitals but also for other health services may change the focus of punitive sanitary vigilance, allowing progress from the analysis of structural and organizational aspects to the evaluation of processes and risk minimization, promoting the achievement of results in the reduction of HAI (ANVISA, 2004).

#### **Main findings related to the essential components for the implementation of strategies and actions foreseen in the PNCHH:**

The Agency's trajectory towards patient safety and quality in health services – in particular regarding HAI prevention and control actions and strategies – is also marked by historical aspects worthy of elucidation. Regarding to the movement for patient safety, proposed by WHO in 2002 and as a signatory country to the WHO and acting within the framework of the Southern Common Market, in particular after the commitment signed by the then Minister of Health of Brazil in 2007, ANVISA initiated the implementation of the Global Challenges in health services. The first global challenge, clean care is safer care, focused on hand hygiene (HH) to reduce HAIs (Allegranzi *et al.*, 2007). In view of this, GGTES/ANVISA initiated the implementation of the WHO multimodal strategy for the improvement of HH in Sentinel Network Hospitals (Bello *et al.*, 2017). In 2008 safe surgical procedures were prioritized by the WHO, creating the second global challenge for patient safety (WHO; WHO Patient Safety, 2008). With this in mind, GGTES/ANVISA developed the Safe Surgery Saves Lives Project in 2012, participating in the validation of the WHO Surgical Safety Checklist in Brazil and applying this tool (Santana *et al.*, 2016).

**Table 1. Main national actions of ANVISA for HAI and MR prevention and control**

Year	Action	Title	Objective	Notes
<i>Programs</i>				
2013	Program	PNPCIRAS (2013 – 2015) (ANVISA, 2013)	Reduce, at the national level, the incidence of HAI	Specific objectives: to reduce BSI; reduce SSI; establish control mechanisms on MR and increase adherence to the PNPCIRAS, according to the WHO criteria
2016	Program	PNPCIRAS (2016 – 2020) (ANVISA, 2016a)	Reduce, at the national level, the incidence of HAI	Specific objectives: to consolidate the SNVE of HAI; reduce the incidence of priority HAI; prevent and control the dissemination of MR and consolidate PNPCIRAS
2021	Program	PNPCIRAS (2021– 2025) (Brasil, 2021)	Reduce, nationwide, the incidence of HAI and MR in HS	Specific objectives: to promote the implementation of programs for HAI prevention; improve the SNVE of HAI and MR; monitor adherence to national guidelines; reduce the incidence of HAI; prevent the spread of MR in HS
<i>Projects, Networks, Challenges, Plans and Guidelines</i>				
2005	Network	MR Network (ANVISA, 2021c)	To guide the adequate use of antimicrobials and detect, prevent, and control MR in HS in the country	Partnership between PAHO/WHO and CGLAB/SVS/MS
2006	Project	MR Monitoring and Prevention Project in HS (ANVISA, 2021c)	To prevent the spread of MR in HS in the country	Partnership with CGLAB/SVS/MS
2007	Project	HH in HS (Bello <i>et al.</i> , 2017; ANVISA, 2021c)	To promote HH to prevent HAI	National campaign with posters on the subject and precautionary measures
2008	Challenge	First Global Challenge of the WHO for PS: Clean Care is Safer Care (Allegranzi <i>et al.</i> , 2007); Bello <i>et al.</i> , 2017)	To stimulate HH to prevent HAI	Participation of Brazil in the PAHO/WHO and ANVISA research for the application of the WHO's multimodal strategy for improvement of HH
2010	Challenge	Second Global Challenge of the WHO for PS: Safe Surgery Saves lives (WHO, 2008; Santana <i>et al.</i> , 2016; Bello <i>et al.</i> , 2017)	To prevent surgical damage in HS	Partnership between SAS/MS, ANVISA, Fiocruz, ANS and the PAHO/WHO
2015	Plan	Integrated Plan for Sanitary Management of PS in HS (ANVISA, 2015)	Integrate SNVS actions for PS management	The Plan includes, among others, the step-by-step process for the monitoring of HAI and outbreaks by the SNVS
2015	Project	National Project States in Focus (first stage) (WHO, 2008; ANVISA, 2016a)	To promote the alignment of actions between the State Programs of IC and the PNPCIRAS	Visits to the CECIH of the North and Northeast regions of Brazil for evaluation of the state programs of IC, based on the key components of the WHO
2017	Plan	National Plan for Prevention and Control of MR (ANVISA, 2017c)	To define national strategies for detection, prevention, and reduction of MR in HS	Specific objectives: to improve MR awareness; strengthen surveillance and investigation of infections and MR; reduce the incidence of infections; promote the rational use of ATM
2017	Project	National Project States in Focus (second stage) (ANVISA, 2021c)	To promote the alignment of actions between the State Programs of IC and the PNPCIRAS	Visits to the CECIH of the Central-West, Southeast and South regions of Brazil for evaluation of the state programs of IC, based on the key components of the WHO
2017	Guideline	National guideline for the elaboration of management program for the use of ATM in Health Services (ANVISA, 2021c)	Guide the development and implementation of ATM use management programs	The Guideline encourages the clinical management of ATM use ( <i>Antimicrobial Stewardship Program</i> ) in HS
2018	Project	National Project States in Focus (third stage) (ANVISA, 2021c)	To promote the alignment of actions between the State Programs of IC and the PNPCIRAS	Holding of regional workshops with CECIH to monitor action plans related to the programs
2021	Plan	Integrated Plan (2021– 2025) (ANVISA, 2021b)	Integrate SNVS actions for the management of patient safety in the country's HS	Specific objectives: to promote the strengthening of the SNVS; surveillance, notification, and investigation of patient safety incidents; adherence to patient safety practices

Source: Based on official documents published by GVIMS/GGTES/ANVISA on HAI and MR prevention. Abbreviations: ANS: National Agency of Supplementary Health; ANVISA: Brazilian Health Regulatory Agency; ATM: Antimicrobial; BSI: Primary Bloodstream Infection; CECIH: State Coordination of Hospital Infection Control; CGLAB: General Coordination of Public Health Laboratories; Fiocruz: Oswaldo Cruz Foundation; GGTES: General Management of Technology in Health Services; GVIMS: Health Surveillance and Monitoring Management; HAI: Healthcare-associated infections; HH: Hand Hygiene; HS: Health services; IC: Infection Control; MR: Microbial Resistance; MS: Ministry of Health - MoH; PAHO: Pan American Health Organization; PNPCIRAS: National Program for Prevention and Control of Healthcare-associated infections; PS: Patient safety; SAS: Department of Health Care Services; SNVE: National Epidemiological Surveillance System; SNVS: Brazilian Health Regulatory System; SSI: Surgical Site Infection; SVS: Department of Health Care surveillance; WHO: World Health Organization.

Table 2. Main means of communication of national actions on prevention and control of HAIs and MR

Year	Title	Objective	Notes
<i>Newsletters</i>			
2010	NL No. 1: HAI Prevention and Control (ANVISA, 2011)	To present the activities focused on patient quality and security in HS	Summary of the main actions of GGTES/ANVISA for PS in Brazil in an orderly sequence
2011	NL No. 2: HAI Prevention and Control (ANVISA, 2021c)	To present the HAI surveillance and monitoring activities	Structuring, validation, and evaluation of HAI prevention and control activities
2011	NL No. 3: National indicator of HI - 2010 (ANVISA, 2021c)	To present the results of the analysis of associated ID of BSI notifications	Patients using CVC admitted to the ICU
2012	NL No. 5: Analysis of BSI notification data - 2011 (ANVISA, 2021c)	To present the results of the analysis of associated ID of BSI notifications	Patients using CVC admitted to the ICU
2013	NL No. 6: Analysis of BSI notification data - 2012 (ANVISA, 2021c)	To present the results of the analysis of associated ID of BSI notifications	Patients using CVC admitted to the ICU
2014	NL No. 7: Report on MR in BSI - 2012 (ANVISA, 2021c)	To present the etiologic agents and ATM resistance phenotypes of laboratory-confirmed CLABSI notifications	Patients using CVC admitted to the ICU
2014	NL No. 8: Analysis of BSI notification data - 2013 (ANVISA, 2021c)	To present the results of the analysis of associated ID of BSI notifications	Patients using CVC admitted to the ICU
2014	NL No. 9: Report on MR in CLABSI - 2013 (ANVISA, 2021c)	To present the etiologic agents and ATM resistance phenotypes of laboratory-confirmed CLABSI notifications	Patients using CVC admitted to the ICU
2015	NL No. 11: Analysis of BSI notification data - 2014 (ANVISA, 2021c)	To present the results of the analysis of associated ID of BSI notifications and SSI - CD	Patients using CVC admitted to the ICU; SSI notification - cesarean delivery by hospitals with SC and OC
2015	NL No. 12: Report on MR in CLABSI - 2014 (ANVISA, 2021c)	To present the etiologic agents and ATM resistance phenotypes of laboratory-confirmed CLABSI notifications	Patients using CVC admitted to the ICU
2016	NL No. 14: Evaluation of the national indicators of HAIs and MR - 2015 (ANVISA, 2016b)	To present the results of the analysis of associated ID of BSI notifications and SSI - CD and MR mapping	Patients using CVC admitted to the ICU; SSI notification - cesarean delivery by hospitals with SC and OC
2017	NL No. 16: Evaluation of the national indicators of HAIs and MR - 2016 (ANVISA, 2017a)	To present the results of the analysis of associated ID of BSI notifications, VAP notifications, UTI, and SSI - CD and MR mapping	Patients using CVC, MV, and VDP admitted to the ICU; SSI notification - cesarean delivery by hospitals with SC and OC
2020	NL No. 22: Evaluation of the national indicators of HAIs and MR - 2019 (ANVISA, 2020a)	To present the results of the analysis of HAI indicators and MR	ICU and SSI notification; microbiological profile; antibiotic resistance profiles
<i>Reports</i>			
2016	PS: National Report on HH Self-Assessment Framework (ANVISA, 2021c)	To present the results of self-Assessment for HH	WHO criteria
2016	National Quality Improvement Cycle of HAI Prevention and Control - 2015/2016 (ANVISA, 2021c)	To improve HAIs prevention actions through CCIH	HS with at least one ICU bed
2020	National Report on Patient Safety Practices Assessment in HS ( ANVISA, 2020b; ANVISA, 2021c)	To present the results of the compliance of patient safety practice indicators	Including indicators of HAI prevention and control
2021	Analytic Panel (ANVISA, 2021c)	To present results of Notifications of Hospital-Acquired SARS-CoV-2 Infections	ANVISA's diagnostic criteria
<i>Technical Notes and Risk Statements</i>			
2013	Technical note No. 01 (ANVISA, 2021c)	Measures of prevention and control of infections caused by multidrug-resistant enterobacteria	Criteria for detection of carbapenemases (KPC and NDM types) in HS
2014	Technical note No. 01 (ANVISA, 2021c)	HAI and MR surveillance and monitoring in HS	Focus on the main changes in HAI and MR notification to SNVS
2014	Technical note No. 03 (ANVISA, 2021c)	Measures to prevent Ebola virus infection	To avoid transmission of this infection within the HS
2014	Risk statement No. 02 (ANVISA, 2021c)	RGM infection	HS and cosmetic clinics (January 2010 to September 2014)
2015	Technical note No. 02 (ANVISA, 2021c)	Orientations on MR Analytical Sub-Network in HS	GGTES, GELAS, and LACEN group
2016	Risk statement No. 01 (ANVISA, 2021c)	Detection of the gene responsible for plasmid-mediated polymyxin resistance (mcr-1) in Brazil	Identification, notification, prevention and control of mcr-1 in HS
2017	Risk statement No. 01 (ANVISA, 2021c)	Reports of outbreaks of <i>Candida auris</i> in HS in Latin America	Identification, notification, and prevention of <i>C. auris</i> in HS
2018	Technical note No. 01 (ANVISA, 2021c)	General guidelines for HH in HS	To orient requirements for product selection, aiming at HH good practices
2020	Technical note No. 044 (ANVISA, 2021c; Costa et al. 2021)	Guidelines to prevent COVID-19 in HS	To recommend prevention and control measures for suspected or confirmed cases of infection by the new coronavirus
2020	Technical note No. 07 (ANVISA, 2021c; Costa et al. 2021)	Guidelines to prevent COVID-19 in HS	To establish epidemiological surveillance of infection by SARS-CoV-2 in HS
2021	Technical note No. 04 (ANVISA, 2021c)	Guidelines to prevent COVID-19 in HS	To orient surveillance, identification, prevention, and control of invasive fungal infections in HS

Source: Based on official documents and bulletins published by GVIMS/GGTES/ANVISA on HAIs and MR prevention. Abbreviations: ANVISA: Brazilian Health Regulatory Agency; ATM: Antimicrobials; BSI: Primary Bloodstream Infection; CD: Cesarean Delivery; CLABSI: Central line-associated Bloodstream Infection; *C. auris*: *Candida auris*; CCIH: Hospital Infection Control Committee - HICC; COVID-19: Coronavirus disease 2019; CVC: Central Venous Catheter; GELAS: Management of Public Health Laboratories; GGTES: General Management of Technology in Health Services; GVIMS: Health Surveillance and Monitoring Management; HH: Hand Hygiene; HAI: Healthcare-associated Infection; HI: Hospital Infection; HS: Health Services; ICU: Intensive care unit - adult, neonatal and pediatric; ID: Incidence Density; KPC:  $\beta$ -lactamase producing *Klebsiella pneumoniae*; LACEN: Central Laboratory of Public Health; NL: Newsletter; mcr: Mobilized Colistin Resistance; MR: Microbial Resistance; MV: Mechanical Ventilation; NDM: New Delhi Metalobetalactamase; OC: Obstetric Center; RGM: Rapidly growing mycobacteria; SC: Surgery Center; SNVS: Brazilian Health Regulatory System; PS: Patient Safety; SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2; SSI: Surgical Site Infection; UTI: Urinary Tract Infection; VAP: Ventilator-associated pneumonia; VDP: Vesical delay probe; WHO: World Health Organization.

The WHO subsequently launched the third global challenge: medication without harm (Donaldson *et al.*, 2017). In parallel to the national initiatives in terms of the World Alliance for Patient Safety took place in 2004, there was an advance in the surveillance and monitoring of HAIs, with incrementation of the National Network for Microbial Resistance Monitoring (MR Network - Rede RM), created in 2005 (formed by ANVISA, the Pan American Health Organization - OPAS/OMS, and the General Coordination of Public Health Laboratories/MoH) and the National Network for Investigation of Outbreaks and AEs in Health Services (Reniss) (Bello *et al.*, 2017).

Before that, a study to investigate HAI control in Brazil was carried out from 2001 to 2004, involving 61.3% (ANVISA, 2017b) of the hospitals, in all the states. Fifty percent of the hospitals had up to 50 beds and 70% of them, 100 beds. Structural fragilities for HAI control were evidenced: 33% of the hospitals lacked microbiology laboratory support; 33% failed to carry out epidemiological surveillance; only 44% carried out specific training, and only 33% applied outbreak containment measures (Santos, 2006). In the sequence, the National Information System for the Control of Infections in Health Services (SINAIS) was made available by ANVISA in 2004 and could be used to report HAI to the Brazilian Health Regulatory System (SNVS) (ANVISA, 2004). The SINAIS utilized the National Nosocomial Infections Surveillance of the Centers for Disease Control and Prevention (Emori *et al.*, 1991), currently integrated into the National Healthcare Safety Network (NHSN), aiming at systematizing HAI surveillance in Brazil. Due to technical problems such as difficulties with the use of the system by hospitals and lack of a Web system, maintenance of SINAIS was suspended 5 years later. Also regarding to the epidemiological surveillance of HAIs, in an attempt to standardize the diagnostic criteria of HAIs, allowing the necessary harmonization for case identification, systematized collection, and interpretation of data by professionals from all over the country, since 2008, GGTES/ANVISA coordinated several Work Groups (WGs) that resulted in the publication of several guidelines (Bello *et al.*, 2017).

In September 2010, cases of HAI were notified by hospitals in 10 or more: Intensive Care Unit (ICU) beds through 27 online forms. All notifications are simultaneously accessed by ANVISA, states, the FD, and municipalities (ANVISA, 2011). Since 2012 new electronic forms have been available to collect notifications of the phenotypic profiles of the microorganisms identified in central line-associated bloodstream infections (CLABSI). Subsequently, the monitoring of MR at other sites of infection was started. In 2014, the national monitoring of HAIs was expanded, as all hospitals with any number of ICU beds had to report compulsorily their monthly data to ANVISA. The effectiveness of a PCI must cover all health services in the country, with special emphasis on hospitals. It is important to note that Brazil has around 6,030 general or specialized hospitals, of which about 2,000 have adult, pediatric, or neonatal ICU beds, distributed in different regions of the country.

The majority (40.5%) are from private entities, 31.5% from non-profit entities, and 28% are public (CNES, 2021). According to the WHO, knowledge about the progress of a PCI should involve the core components for infection prevention and control programs: structural organization; HAI surveillance; monitoring and evaluation; microbiology laboratory support and capacity; national and facility level infection prevention and control guidelines; built environment and linked to national and regional public health programmes (WHO, 2016). Considering the core components with regard to the PNPCIRAS, based on Ordinance MoH No. 2,616/1998 (Brasil, 1998), it is worth remembering that in 2012 the National Commission for Prevention and Control of Healthcare-Associated Infection (CNCIRAS) was established to support the elaboration of national guidelines, standards, and measures for the prevention and control of HAIs (Brasil, 2012; ANVISA, 2021c). Through the technical support of CNCIRAS (Brasil, 2012) and the Technical Chamber of Microbial Resistance (CATREM) (Brasil, 2015), GGTES/ANVISA created the PNPCIRAS also in 2012 (ANVISA, 2013). The Program established strategic goals and actions to reduce the occurrence of HAIs in Brazilian health services, which were in accordance with the State Coordinations of Hospital Infection Control (CECIH). Four years

later, a new version of the PNPCIRAS was published by the country (ANVISA, 2016a), and one of the goals was to reduce by 15% the incidence density (ID) of central line-associated bloodstream infection (CLABSI) in adult, pediatric or neonatal ICUs with infection rate above the 90th percentile. To achieve the goal, strategic actions were defined, such as the implementation and monitoring of HAI Prevention Protocols by health services and support to the CECIHs in the actions to reduce HAI in health services. In 2021, the most recent version of this Program was published by GGTES/ANVISA (period 2021 – 2025) with the objective of reducing HAIs at the national level (Brasil, 2021).

In order to profile the MR and the distribution of pathogens in health services in the country, in addition to the RM network, the Advisory Technical Committee for Antimicrobial and Microbial Resistance (CURAREM) was also created by ANVISA (Brasil, 2005). It is worth mentioning that in 2013, the Analytical Sub-network of Microbial Resistance in health services was created. It was composed of a Central Public Health Laboratory group and was established to support MR surveillance and monitoring actions, such as the identification and molecular typing of multiresistant microorganisms in situations of outbreaks (Brasil, 2013d). Also, the provision of a National Plan for the Prevention and Control of MR in Health Services, effective until 2021, was an action addressed to prevent MR in 2017 (ANVISA, 2017c). Still regarding to the structural organization of the PNCIH, the joint work has been developed by ANVISA and CECIH. Currently, all the Federative Units of the country have these instances, as can be seen in the Agency's Portal (ANVISA, 2021c). However, it is not enough that these instances are properly formalized. It is essential that they are acting proactively, developing actions planned in the State Plan for the Prevention and Control of HAI. Although Brazil still does not have a specific information system to capture data on HAIs, and taking into account possible underreporting, 2,036 hospitals with ICU beds notified HAI data to ANVISA in 2015. The ID of CLABSI in adult and pediatric ICUs was 0.6 and 2.4 infections per 1,000 CVC-day, respectively, and the respective ID of laboratory-confirmed CLABSI were 4.8 and 5.7 infections per 1,000 CVC-day. In neonatal ICUs, according to the weight range, the ID of CLABSI varied from 5.8 to 6.7 and for laboratory-confirmed CLABSI, from 6.8 to 8.6 infections per 1,000 CVC-day (ANVISA, 2016b). In 2016 the results analysis of 1,389 reports evidenced ID of laboratory-confirmed CLABSI in adult ICUs as 4.6 infections per 1,000 CVC-day. High rates of carbapenem resistance were observed. In nonfermenting Gram-negative bacilli, carbapenem resistance was reported in 85.0% of *Acinetobacter* spp. and in 42.9% of *Pseudomonas aeruginosa*. In the Gram-negative strains belonging to the *Enterobacteriaceae* family, resistance rates to carbapenems and wide-spectrum cephalosporins (third and/or fourth generations) were 46.8% for *K. pneumoniae* and 18.2% for *Enterobacter* spp (ANVISA, 2017a).

Recently, a reduction in the overall ID of CLABSI in adult and pediatric ICUs was evidenced when evaluating the period from 2012 to 2019. The ID of CLABSI in adult ICU decreased from 5.7 in 2012 to 3.9 in 2019; as for the pediatric ICU, decreased from 7.2 to 4.4 in 2019, while the neonatal ICU decreased from 9.2 in 2012 to 7.8 in 2019 (ANVISA, 2020a). As for the results obtained from the analysis of HAIs data notified by citizens in the Notivisa system (Citizen module), it was evidenced that, of the total number of AEs notifications (1,355) made to the SNVS in the period 2014 - 2019, 36.3% were due to HAIs, the most frequently event notified by citizens (Santana *et al.*, 2021). The notification of surveillance data from the national epidemiological indicators allows the SNVS to trace the national, regional, state, and municipal scenarios. Results can even be filtered according to notifying service and type of HAI. In addition, it allows one to know the distribution and resistance profile of microorganisms to antimicrobials, as well as to verify the geographical trends with the purpose of adopting intervention measures. With regard to the return, all the results from the annual analysis of the notifications made by the Brazilian health services on HAIs and MR are included in the Official Information Bulletins that are reviewed by CNCIRAS and CATREM, and published by

GGTES/ANVISA. Partial data categorized by states are periodically made available on the Agency's Portal (ANVISA, 2021c). National initiatives with voluntary participation instituted since 2012 involve the self-assessment system. This approach is a key complement to the surveillance system for HAIs. In 2012 the National Report on Self-assessment for HH was published using an instrument developed by the WHO (Kilpatrick *et al.*, 2018). Most of the participating health services (N = 901) were classified as basic level of HH (45.4%). About 10% of the participating institutions were rated as inadequate regarding HH practices (Bello *et al.*, 2017). To increase adherence to these practices, GGTES/ANVISA has been expanding the application of the WHO multimodal strategy for improvement of HH in hospitals in Brazil (ANVISA, 2021c).

Since 2016, a self-assessment instrument containing structure indicators related to patient safety practices, including those for the prevention of HAIs, has been applied in hospitals with ICU beds in Brazil (ANVISA, 2021c). Results obtained from the analysis of 1,255 national form for self-assessment of patient safety practices conducted in 2019 showed that the highest relative frequencies of compliance to safety practices were related to indicators of HH practices. On the other hand, lower compliance was perceived for the indicator "Regularity of monthly reporting of antimicrobial consumption in adult ICU –defined daily dose (DDD)", waving that improvements are needed to increase compliance to this patient safety practices indicator related to MR prevention (ANVISA, 2020b). Regarding to the national HAI prevention and control guides, several educational materials have been published by the National Coordination of PNCI, fruit of the joint effort of WGs integrated by specialists (ANVISA, 2021c). It should be recalled that numerous face-to-face and distance training sessions were given to HICC professionals and to those working in the SNVS. In addition, international events have been promoted by the GGTES since 2000, with the participation of professionals from the SNVS, specialists in the subject, and health services managers. One example is the International Seminar on Patient Safety and Quality in Health Services, which had its fifth meeting in 2017 (ANVISA, 2021c). The debates held in these events favor safe care by reinforcing initiatives in the field of prevention of these complications. As for the national scenario of public health programs, with the execution of PNPCIRAS's actions and others focused on the global challenges to patient safety and with the widespread media coverage of several AEs occurrences, GGTES/ANVISA realized the need for the participation of others stakeholders in the process. With that came the institution of a National Patient Safety Policy to consolidate these actions throughout Brazil. With the consequent involvement of the MoH in the issue, Ordinance MoH No. 529, establishing the National Patient Safety Program (PNSP) was published in 2013 (Brasil, 2013e). To strengthen the actions foreseen in the PNSP, RDC No. 36/2013 was published, which establishes patient safety actions.

Its provisions reinforce the need to implement risk management and HAI prevention actions (Brasil, 2013a). Subsequently, patient safety protocols were published, emphasizing HH practices for the prevention of HAIs and safe surgery, which can also prevent Surgical Site Infection (Brasil, 2013b; Brasil, 2013c). In 2015 the National Project States in Focus was launched, which aims to promote the alignment of actions between State Programs and PNPCIRAS. It is based on the WHO's essential components for PCIH, such as program organization, guidelines, surveillance, human resources, and microbiology laboratory support (WHO, 2016). The Project has four stages: a situational diagnosis of the structure for HAI prevention and control at a state level with on-site visits; promotion of action plans; monitoring of the actions proposed by the states, and evaluation of these actions (ANVISA, 2016a). In 2015 the IC State Programs of the North and Northeast regions of Brazil were evaluated. In the following years, the Programs of the South, Southeast, and Midwest regions were evaluated. Moreover, regional workshops were also promoted by the CECIH to monitor the action plans related to the programs. In the same year, an Integrated Plan was made available by GGTES/ANVISA, with the aim of integrating SNVS actions for the management of patient safety in the country's health services, aiming

at the identification and reduction of healthcare-related risks (ANVISA, 2015). The plan includes, among other provisions, a step-by-step process for the monitoring of HAIs and outbreaks by SNVS. A new version of the Integrated Plan was recently published by GGTES/Anvisa (ANVISA, 2021b).

Moreover, in the current international pandemic scenario experienced in 2020, it was verified the publication of a range of Technical Notes (TN) and Risk Communications, prepared by GGTES/ANVISA with the support of associations and scientific societies supporting national actions for prevention of COVID-19. The guidance documents address the main measures for the prevention and control of SARS-CoV-2 dissemination in health services, in surgical procedures, in long-stay institutions for the elderly, and in field hospitals (Costa *et al.*, 2021). Table 1 shows the main actions for the prevention and control of HAIs developed by GGTES/ANVISA in partnership with CECIH and the Municipal Coordinations of Hospital Infection Control, members of WG, CNCIRAS, and CATREM. Table 2 illustrates the historical dynamics of GGTES' main national actions in the field of HAI and MR prevention and control. It is possible to verify that the PNPCIH has advanced over time, supported by the core components for the implementation of strategies and actions provided in the Program. It is noteworthy that in 2012, an evaluation according to the core components of the PNPCIRAS was applied by the members of CNCIRAS and identified that the components that were in the highest proportion of compliance and in accordance with such components were: HAI surveillance, technical guides, and built environment. On the other hand, the components "monitoring and evaluation" and "linking to national and regional public health programmes" did not meet any of its elements in the period evaluated (ANVISA, 2013). Although it was not possible to evaluate the impact of the national strategies and actions listed in the period proposed by this study, there seem to be indications of recent improvements in most of these components, which should be proven by researches on the subject.

A historical national advance has been the annual and quarterly publications of results obtained from the analysis of HAI data, even in the absence of a national information system to capture these indicators, demonstrating joint efforts by the SNVS and the health services. It is noteworthy that a national information system is a strategic element to guide public policies, articulate VISA actions with other sectors and update health professionals to exercise good practices more appropriate to the health of the population, and its scope should be pursued, enabling the HICC to report these data to the SNVS. In response to growing evidence on morbidity, mortality, and rising costs associated with HAIs, some countries are now committed to not only reducing but eliminating HAIs, and actions should be supported by four pillars: 1) promoting the implementation of evidence-based practices; 2) investing in successful infection prevention strategies; 3) encouraging research to address emerging threats; and 4) collecting data to guide prevention efforts and measure progress (Cardo *et al.*, 2010). Overall, despite data findings that show reductions in the ID of CLABSI in ICUs, it is still necessary to intensify the efforts made by health services, especially by HICC, to achieve further reduction and perhaps, elimination of CLABSI in Brazilian ICUs. This work requires full engagement between federal, state and municipal levels, besides CCIHs and other health professionals in favor of good practices of prevention and control of HAIs. Moreover, greater investment in the training of professionals should be prioritized, in addition to encouraging the development of research on the subject, helping to find new and promising strategies for prevention and control of HAIs and MR. Despite the national initiatives in place, there are still insufficient human resources and no specific funding for PNPCIRAS (Padoveze, Fortaleza, 2014). In addition, there are still opportunities for improvement in order to strengthen the relationship between PNPCIRAS (Brasil, 2021) and public health, enhancing dialogue and building solid partnerships of the SNVS with appropriate peers involved such as: MoH, State Health Secretariats, Health Councils, Tripartite Interagency Commission (CIT) and National Council of Health Secretaries (Conass); Public Ministry and Consumer Defense Bodies;



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