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Healthcare-associated infections: challenges to public health in Brazil

Infecções relacionadas à assistência à saúde: desafios para a saúde pública no Brasil

ABSTRACT

This study presents a critical evaluation of the scientific literature related to this subject, aiming to assess the policies and administrative issues regarding the prevention and magnitude of healthcare-associated infections and discuss the challenges for their prevention in Brazil. The topics discussed included historical and administrative issues, challenges imposed by the characteristics of the healthcare system and the territorial dimension, laboratorial support limitations, costs, institutional culture, professional qualification, and patient engagement. It is urgent to hold a nationwide discussion among government representatives, institutions, and healthcare workers and users to overcome these challenges.

DESCRIPTORS: Cross Infection, prevention & control. Hospital Infection Control. Program Housekeeping, Hospital. Infectious Disease Transmission, Patient-to-Professional. Infectious Disease Transmission, Professional-to-Patient. Health Surveillance. Epidemiological Surveillance.

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RESUMO

Objetivou-se apresentar os principais marcos históricos e regulatórios da prevenção das infecções relacionadas à assistência em saúde, a magnitude do problema no Brasil e uma visão crítica sobre os desafios e necessidades para sua prevenção no País. Assim, foi desenvolvida narrativa crítica sobre infecções relacionadas à assistência à saúde quanto aos elementos normativos e administrativos da prevenção, da magnitude do fenômeno, apontando desafios para o controle de tais infecções no Brasil. São discutidos aspectos históricos do controle de infecções relacionadas à assistência à saúde, as dificuldades impostas pelas características do sistema de saúde e dimensões geográficas do País, as limitações de suporte laboratorial, custos, cultura institucional, capacitação de profissionais e engajamento dos pacientes. Considerou-se premente haver discussão nacional sobre o tema por meio do diálogo entre os segmentos da representação governamental, das instituições, dos trabalhadores e usuários do sistema de saúde, para superação desses desafios.

DESCRITORES: Infecção Hospitalar, prevenção & controle. Programa de Controle de Infecção Hospitalar. Serviço Hospitalar de Limpeza. Transmissão de Doença Infecciosa do Paciente para o Profissional. Transmissão de Doença Infecciosa do Profissional para o Paciente. Vigilância Sanitária. Vigilância Epidemiológica.

INTRODUCTION

Healthcare-associated infections (HAI) were first diagnosed during the so-called "Pasteur revolution" by investigators including Ignaz Semmelweis, Florence Nightingale, and Joseph Lister.[6] During the 21st century, because of the development of increased life support and immunosuppressant therapies, the need to control hospital-acquired infections became apparent. Therefore, hospital-acquired infections have been systematically addressed in developed countries.[10,15] Since the mid-1990s, the term "hospital infection" was replaced with the term "HAI"; the latter designation is a broad concept that incorporates infections that are acquired and associated with healthcare activities in any given environment.[4]

HAI have a great impact upon hospital mortality, duration of hospitalization, and costs. The growing number of conditions that lead to hospitalization of individuals presenting with increasingly severe clinical conditions and immunosuppression, in addition to the increased resistance to antimicrobial agents, indicates the importance of HAI in public health management. In addition, developing countries suffer from a large number of HAI, which can be 20 times larger than that observed in developed countries.[2,13] The factors associated with the lack of qualified human resources, along with an inadequate physical structure for healthcare services and limited knowledge of HAI control measures, contribute to this scenario.

After acknowledging that HAI are a public health problem, the World Health Organization (WHO) recommended that health authorities designate an agency to manage a nationwide healthcare program, which should be aligned with other healthcare goals.[a] In Brazil, the discussions on programmatic actions are essential to acknowledge the advances made to date, identify challenges, and propose strategies to amplify the potential of these actions.

The present study aimed to investigate the historical and regulatory milestones for the prevention of HAI, to recognize the magnitude of the problem, and to make a critical assessment of the challenges and needs for the prevention of HAI in Brazil.

Historical and regulatory milestones related to HAI in Brazil

Although the first HAI Prevention and Control Committee (HAIPCC) appeared in the 1960s, the programmatic and governmental actions only began at the end of the military dictatorship by norms established by the Brazilian Ministry of Health (MoH).[b] In the 1980s, several national technical guidelines involving the assessment of healthcare facilities were published, when the use of epidemiological methods to deal with HAI was still in its infancy. In addition, in this period, this

[a] World Health Organization. Practical guidelines for infection control in healthcare facilities. Geneva; 2004 [cited 2012 Dec 4]. Available from: http://www.wpro.who.int/publications/docs/practical_guidelines_infection_control.pdf

[b] Brasil. Lei nº 9.431, de 6 de Janeiro de 1997. Dispõe sobre a obrigatoriedade de manutenção de programas de controle de infecção hospitalar pelos hospitais do país. *Diario Oficial Uniao*. 7 jan 1997:265.

subject was discussed among various health authorities, and MoH implemented a training program focused on the training of 14,000 healthcare professionals.[5] However, the impact of this initiative was not assessed, and the project was discontinued. This initiative was followed by a gap in terms of government training activities, and only in 2004, new training programs were offered to health surveillance professionals via distance learning.[3]

A Regional Conference on Prevention and Control of HAI was held in 1990 and emphasized the need to implement national HAI prevention and control committees.[c] In Brazil, this committee was established by the implementation of the National HAI Prevention and Control Program (NHAICP),[c] which resulted in the creation of the *Divisão Nacional de Controle de Infecção Hospitalar* (National Division of HAI Control).[1] A few reports on the effective actions performed by this division are available, and a new national committee was implemented only 20 years later (Table). The following other directives were created during this regional conference: (a) binding hospital accreditation to the establishment of HAI programs; (b) inclusion of the topic in the health sciences curriculum and in continued education programs; (c) cooperation between state institutions and universities for the development of epidemiological research; (d) identification of regional reference microbiology laboratories; and (e) implementation of working groups focused on the use of antimicrobial agents and microbiological diagnosis of HAI. Despite the many advances in this sector, the recommendations established in this conference were not achieved.

At present, the legislation that determines the general guidelines for the prevention and control of HAI are Law 9,431 (1997),[b] Ordinance 2,616 (1998),[d] and Resolution RDC 48 (2000).[e] The key element of these guidelines is the requirement to implement HAIPCC in hospitals. Ordinance 2,616 introduced the proposal to develop structured programs at the federal, state, and municipal levels. However, there was heterogeneity in the state coordination for the control of HAI, and improvement in this scenario was one of the main proposals of NHAICP since the beginning of 2000.[f]

From 2000, PNCIH linked with the National Health Surveillance Agency (ANVISA), which promotes the interface with other health surveillance (Table). The transfer of the National HAI Program to ANVISA was an emblematic hallmark and indicated that at the federal government level, the management of HAI should be maintained within the sphere of sanitary audit. Unlike other public health problems, HAI have been perceived as a problem that requires normalization and auditing. The results of this approach were ambiguous. On one hand, there was a notable improvement in the legislation applied for the prevention of HAI and increased health surveillance. On the other hand, the control of HAI was perceived as an activity focused on compliance to standards and solely related to the attitude of individual healthcare services under the law. This weakened the perception of HAI control as a public health problem or shifted the collective perspective about the problem. This factor partly contributed to the initial failure of the attempts made to quantify the impact of this strategy nationwide.

The regulatory role of ANVISA has been intensive since its inception. The regulation of marketed products such as sanitation and healthcare products (including equipment) is one of the strongest areas, along with the normalization of physical areas for healthcare services (Table). In recent years, the creation of guidelines has intensified; until 2012, 10 guidelines were already available in ANVISA's website.[g]

The recent history of HAI control in Brazil has suffered the impact of large-scale epidemics. The outbreaks of rapidly growing mycobacteria in invasive procedures[h] have shed light on important failures in the reprocessing of articles, aggravated by the detection of resistance of rapidly growing mycobacteria resistant to glutaraldehyde.[7-9,11] In addition, outbreaks of carbapenemase-producing *Klebsiella pneumoniae* and *Enterococcus spp.* resistant to vancomycin[i] were widely covered by the press, culminating in the prohibition of purchase of antimicrobial agents without medical prescription and the obligatory use of alcohol-based disinfectants in healthcare units (Table). With regard to laboratory support and management of microbial resistance, board committees composed of specialists were created; however, to date, their actions are scarce, considering the extent of the problem (Table).

In 2007, in line with the development of global strategies for the prevention of HAI, MoH officially engaged in the Global Patient Safety Initiative proposed by WHO.

[c] Santos AAM. O modelo brasileiro para o controle das infecções hospitalares após vinte anos de legislação, onde estamos e para onde vamos? [master's dissertation]. Belo Horizonte: Faculdade de Medicina da UFMG; 2006.
[d] Ministério da Saúde. Portaria nº 2.616, de 12 de maio de 1998. *Diario Oficial Uniao*. 13 maio 1998;Seção1;133.
[e] Agência Nacional de Vigilância Sanitária. Roteiro de inspeção do programa de controle de infecção hospitalar. RDC nº 48, de 2 de junho de 2000. *Diario Oficial Uniao*. 6 jul 2000;Seção I:1415.
[f] Sociedade Brasileira de Infectologia. São Paulo; 2014 [cited 2012 Nov 5]. Available from: http://www.sbinfecto.org.br
[g] Agência Nacional de Vigilância Sanitária. Segurança do paciente e qualidade em serviços de saúde. *Bol inform Segur Pac Qual Serv Saude*. 2011 [cited 2013 Feb 2];I(1):1-12. Available from: http://portal.anvisa.gov.br/wps/wcm/connect/f72c20804863a1d88cc88d2bd5b3ccf0/BOLETIM+I.PDF?MOD=AJPERES
[h] Agência Nacional de Vigilância Sanitária. Relatório descritivo de investigação de casos de infecções por micobactérias não tuberculosas de crescimento rápido (MCR) no Brasil no período de 1998 a 2009. Brasília (DF); 2011 [cited 2011 Nov 25]. Available from: http://www.anvisa.gov.br/hotsite/hotsite_micobacteria/relatorio_descrito_mcr_16_02_11.pdf
[i] Agência Nacional de Vigilância Sanitária. Investigação e controle de bactérias multiresistentes. Brasília (DF); 2007 [cited 2012 Nov 3]. Available from: http://www.anvisa.gov.br/servicosaude/controle/reniss/manual%20_controle_bacterias.pdf

Table. Main legislation and technical documents on healthcare-associated infections according to the issue and topic.

Entity	Subject	Legislation/Technical document
ANVISA	Germicidal solutions: regulation of active principles; cleaning products	Resolução 211, de 18 de junho de 1999; Resolução RDC 39, de 28 de abril de 2000; Resolução RDC 107, de 19 de dezembro de 2000; Resolução 1.514, de 19 de setembro de 2001; Resolução RDC 13, de 28 de fevereiro de 2007; Resolução 14, de 28 de fevereiro de 2007; Resolução RE 3.353, de 26 de outubro de 2007; RDC 55 de 10 de novembro de 2009; Resolução RDC 33, de 16 de agosto de 2010; Resolução RDC 34 de 16 de agosto de 2010; Resolução RDC 35 de 16 de agosto de 2010; Resolução RDC 31, de 4 de julho de 2011; RDC 55 de 14 de novembro de 2012. Available from: http://www.anvisa.gov.br
	List of inspection of the hospital-acquired infection control program	Resolução RDC 48, de 2 de junho de 2000. Diário Oficial da União, 6 de julho de 2000. Seção I, p. 1415.
	Physical area: regulations	Resolução RDC 50, de 21 de fevereiro de 2002, atualizada pela Resolução RDC. 307, de 14 de novembro de 2002. Available from: http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2002/res0050_21_02_2002.html
	Health products: regulation of manufacturing and processing	Resolução RDC 45, de março de 2003; Resolução RDC 156, de 11 de agosto de 2006; Resolução RE 2.605, de 11 de agosto de 2006; Resolução RE 2.606, de 11 de agosto de 2006; Resolução RDC 15, de 15 de março de 2012. Available from: http://www.anvisa.gov.br
	Internal regulations: regiments; board committees	Portaria 385, 4 de junho de 2003; Portaria 620, de 7 de junho de 2009 (CATREM); Portaria 1.218, de 14 de agosto de 2012 (CNCIRAS). Available from: http://www.anvisa.gov.br
	Services: technical regulations (dialysis, older patients, ICU, use of alcohol-based disinfectants)	Portaria 154, de 15 de junho de 2004, alterada pela Resolução RDC 6, de 14 de fevereiro de 2011; Resolução RDC 283 de 26 de setembro de 2005; Resolução RDC 7, de 24 de fevereiro de 2010; Resolução RDC 42, de 25 de outubro de 2010. Available from: http://www.anvisa.gov.br
	Technical documents: epidemiology and recommendations of healthcare practices	Informe Técnico 1, Infecção por *Mycobacterium abscessus* - Diagnóstico e tratamento, fevereiro de 2007; Informe Técnico 2, Medidas para a interrupção do surto de infecção por MCR e ações preventivas; Informe técnico 3, Alerta sobre infecções por micobactéria não tuberculosa após videocirurgia, março de 2007; Informe Técnico 4, Glutaraldeído em estabelecimentos de assistência à saúde - Fundamentos para a utilização, fevereiro de 2007; Investigação e Controle de Bactérias Multiresistentes, maio de 2007; Ações prioritárias para prevenir e interromper infecções por micobactérias não tuberculosa em Estabelecimentos de Assistência a Saúde; novembro de 2007; Informe Técnico 05/07, Surto de Enterococo resistente à vancomicina em estabelecimentos de assistência a saúde: fundamentos e esclarecimentos gerais, fevereiro de 2008; Nota técnica - Assunto: micobactérias; agosto de 2008. Available from: http://www.anvisa.gov.br

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	Technical documents: epidemiology data	Relatório descritivo de investigação de casos de infecções por micobactérias não tuberculosas de crescimento rápido (MCR) no Brasil no período de 1998 a 2009, fevereiro de 2011; Boletim informativo Segurança do Paciente e Qualidade em Serviços de Saúde 2011;1(1):1-12; Boletim Informativo Segurança do Paciente e Qualidade Assistencial em Serviços de Saúde 2011;1(2):1-11; Boletim Informativo Segurança do Paciente e Qualidade Assistencial em Serviços de Saúde 2011;1(3):1-5; Boletim Informativo Segurança do Paciente e Qualidade Assistencial em Serviços de Saúde 2012;1(4):1-22; Boletim Informativo Segurança do Paciente e Qualidade Assistencial em Serviços de Saúde 2012;1(5):1-22. Available from: http://www.anvisa.gov.br/serviços de saúde
	Technical documents: situational diagnosis; diagnostics criteria	Diagnóstico do controle de infecção hospitalar no Brasil, maio de 2005; Análise do Inquérito Nacional sobre infraestrutura, recursos humanos, equipamentos, procedimentos, controle de qualidade e biossegurança nos Laboratórios de Microbiologia, julho de 2007; Corrente sanguínea - Critérios Nacionais de Infecções Relacionadas a Assistência a Saúde, setembro de 2009; Relatório sobre o recadastramento das coordenações estaduais de controle de infecção hospitalar - CECIH, maio de 2012. Available from: http://www.anvisa.gov.br/serviços de saúde
	Regulamento sanitário internacional (RSI – International Health Regulations)	Portuguese version approved by Congresso Nacional by the Decreto Legislativo 395/2009, publicado no DOU de 10/7/2009. Available from: http://portal.saude.gov.br/portal/arquivos/pdf/rsi2005.pdf
	Medicines: antimicrobial agents	Resolução RDC 20, de 5 de maio de 2011; Informe técnico s/n junho de 2011, atualização em 10 de agosto de 2011. Available from: http://www.anvisa.gov.br
Ministry of Health	Infection prevention programs: regulation; technical board committees	Portaria 196 de 24 de junho de 1983. Diário Oficial da União 1983; Portaria 930, de 27 de agosto de 1992. Diário Oficial da União 1992; Lei 9.431, de 6 de Janeiro de 1997. Diário Oficial da União, 6 de janeiro de 1997; Portaria 2.616 de 12 de maio de 1998. Diário Oficial da União 13 de maio de 1998; Portaria 1.133/GM, de 6 de julho de 2005 (CURAREM). Available from: www.anvisa.gov.br
	Germicidal agents: regulations	Portaria 15, de 23 de agosto de 1988; Portaria 05, de 13 de junho de 1989; Portaria DTN 122, de 29 de novembro de 1993; Portaria 453 de 11 de setembro de 1996; Portaria 327/SNVS/MS, de 30 de julho de 1997; Portaria 843, de 26 de outubro de 1998. Available from: www.anvisa.gov.br
	ANVISA: creation	Lei 9.782, de 26 de janeiro de 1999. Diário Oficial da União, 1999
Ministry of Health and Ministry of Labor and Employment	Ethylene oxide: regulations	Portaria Interministerial 482, de 16 de abril de 1999. Available from: http://www.anvisa.gov.br/legis/portarias/482_99.htm
Ministry of Labor and Employment	Occupational health and safety in healthcare services	Norma Regulamentadora 32, 2005. Available from: http://portal.mte.gov.br/data/files/8A7C812D36A280000138812EAFCE19E1/NR-32%20(atualizada%202011).pdf

ANVISA: National Health Surveillance Agency; RDC: Collegiate Directive Resolution

However, most of these actions have been implemented by ANVISA, with the recent involvement of MoH.[g]

Magnitude of the HAI problem in Brazil

To date, the only known national assessment performed in Brazil is that by Prade et al (1995), wherein a HAI prevalence of 15.0% was found in 99 tertiary hospitals.[14]

After 2001, ANVISA started assessing situation of HAI programs in Brazilian hospitals.[j] The findings underscored structural fragilities in HAI control: 1/3 of the hospitals did not have microbiology laboratory support. This fragility in the Northeast (46.0%) was accentuated compared with that in the Southeast (24.0%).[c] Furthermore, essential requirements were not met by all institutions, such as the accreditation of CCIH (76.0%) and performance of epidemiological surveillance (77.0%). In 2002, a national survey was conducted to assess the suitability of microbiology laboratories in Brazil and helped to identify pertinent fragilities in this area.[k]

Moreover, it is acknowledged that only an effective nationwide epidemiological surveillance system could define the real magnitude of the HAI problem in Brazil.[10] The first surveillance systems created at the governmental level that achieved concrete results occurred in the states of Sao Paulo and Paraná.[12,16]

From 1998, the overall understanding of programmatic actions began to incorporate the epidemiological management of HAI. In 2010, ANVISA implemented the surveillance of primary bloodstream infections associated with central venous catheters. The 2012 data on 1,128 hospitals identified an incidence of 5.5 and 2.0 for primary bloodstream infections per 1,000 central venous catheters per day using laboratory and clinical data, respectively. These data were collected at adult intensive care units (ICU), and coagulase-negative *Staphylococcus* strains were the most common etiological agents.[g] In 2013, the National HAI Prevention and Control Program was launched.[l]

Challenges for the future of HAI prevention and control in Brazil

HAI monitoring by ANVISA implies a different approach from that used for the management of other health problems that are currently under the competence of the National Surveillance Department at MoH. In practice, there is a lack of human resources in this area, and no specific funding has supported the National HAI Prevention and Control Program.

Some major challenges include the large territory, presence of difficult-to-access regions, large number of healthcare institutions (particularly in the larger states and municipalities), large number of small-sized hospitals (≤ 50 beds) with difficulty in implementing CCIH, heterogeneity of healthcare services, and insufficient number of ICU. In addition, economic and cultural differences and distinct political views regarding HAI occur in distinct regions and hinder the establishment of homogeneous normative standards in Brazil. For example, CNES (National Registry of Health Institutions)[m] listed 6,266 hospitals in June 2012, distributed in a heterogeneous manner throughout the Brazilian territory, and more than 50.0% of them were located in the Southeast and South regions.

The Brazilian constitution acknowledges that healthcare is a right of every citizen and a state responsibility; however, it does not prohibit the creation of private healthcare services.[n] The Brazilian Unified Health System functions at the municipal, state, and federal levels by directly management or agreements or contracts with private healthcare units. On the other hand, the private sector (supplementary healthcare services) organizes itself by healthcare plans or by direct reimbursement of healthcare costs to the users. Therefore, important factors such as the dual healthcare system, implementation of alternative health management strategies, and decentralized management model indicate that many interlocutors will need to discuss prevention strategies.

The lack of reference laboratories to adequately provide healthcare support and the growing need of microbiological research, particularly that aimed at providing a rapid response to outbreaks, are challenges that urgently need to be overcome. Considering that high-level microbiological research is being conducted at Brazilian universities, it is a paradox how most of these results are not being directed toward public health priorities in the country.

The growing health costs and limited availability of material resources and skilled labor involved in the control of HAI are relevant adversities. With regard to professional health training, academic courses that provide training in this area are rare. Regardless of academic training, providing permanent in-service professional education is essential and is a challenge for governments, health institutions, and

[j] Agência Nacional de Vigilância Sanitária. Diagnóstico do controle de infecção hospitalar no Brasil. Brasília (DF); 2005 [cited 2013 Feb 2]. Available from: http://www.anvisa.gov.br/servicosaude/controle/Infectes%20Hospitalares_diagnostico.pdf

[k] Agência Nacional de Vigilância Sanitária. Análise do Inquérito Nacional sobre infra-estrutura, recursos humanos, equipamentos, procedimentos, controle de qualidade e biossegurança nos Laboratórios de Microbiologia. Brasília (DF); 2007.

[l] Agência Nacional de Vigilância Sanitária. Programa Nacional de Prevenção e Controle de Infecções Relacionadas à Assistência à Saúde. Brasília (DF); 2013 [cited 2014 Jun 24]. Available from: http:// http://portal.anvisa.gov.br/wps/portal/anvisa/anvisa/home/servicosdesaude

[m] Ministério da Saúde. CNES: Cadastro Nacional dos Estabelecimentos de Saúde. Brasília (DF); 2000 [cited 2014 Jun 24]. Available from: www.cnes.datasus.gov.br

[n] Conselho Nacional de Secretários de Saúde. Legislação do SUS. Progestores 2003 - Programa de Informação e Apoio Técnico às Novas Equipes Gestoras Estaduais do SUS de 2003. Brasília (DF); 2003.

healthcare workers, who should be proactive and constantly trained. The managers of institutions sometimes underestimate the magnitude of the problem, and the support for preventive measures is not always robust.

Despite some positive initiatives,[o] citizens have limited access to information on HAI, including the role of patients and family members. The press is generally sensationalist and frightening when addressing the issue of HAI. It is necessary to stimulate community representation on advisory committees to government institutions and health.

It is urgent to hold a thorough nationwide discussion about what should be the concrete manifestation of the State regarding HAI prevention in Brazil. The dialogue between the segments of representative government, health institutions, health workers, and users of the system is a key element to overcome these challenges.

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