Policies for control and prevention of infections related to healthcare assistance in Brazil: a conceptual analysis

Políticas de controle e prevenção de infecções relacionadas à assistência à saúde no Brasil: análise conceitual

Políticas de control y prevención de infecciones relacionadas con la asistencia sanitaria en Brasil: análisis conceptual

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ABSTRACT
This article is a theoretical-reflexive study that aims to discuss the development and changes in the quality of healthcare assistance to the patient over the years in Brazil, in light of the policies of control and prevention of Healthcare-associated Infection (HAI). Aspects of HAI and the process of change in health policy in Brazil, as well as the quality of assistance associated with its control, are approached in relation to policies of patient safety. There are various new theoretical and practical proposals created in Brazil. In spite of the difficulty of measuring patient safety, directed to the prevention and control of HAI, we emphasize that to only create policies and establish norms, guidelines, and indicators is not sufficient. If no structural support or conditions exist for interventions in the practices of healthcare professionals, aiming at results in acceptable levels, the control of HAI will not be achieved.

DESCRIPTORS
Health Evaluation; Public Health Policy; Cross Infection; Patient Safety; Public Health Nursing.
INTRODUCTION

The quality of health services linked to the issue of Healthcare-associated Infections (HAI) is a theme that continues to evoke global attention as it is a serious public health problem. It deals with an occurrence that is not only biological, but also historic and social, with a direct impact on healthcare safety, and that constitutes one of the main global challenges for quality in health care(1).

Advances in this area resulted in pioneering initiatives beginning in the seventeenth century, working not only for the controlling and prevention of HAI, but also for the transformation of the hospital from a wholesale assembly of the sick during the Middle Ages, to a place of treatment and cure for illness in the Modern Age(2).

One historic advance was the discovery of the cross transmission of microorganisms through touch by Semmelweis in 1847(3). Empirically, and still without knowledge of microbial theory or of the transmission of infectious disease, he verified that women attended by medical students presented higher rates of morbidity and mortality than among those cared for by midwives. Through the deductive method, he observed that the difference was that the students did not wash their hands after handling cadavers, and afterwards cared for women in birthing or puerperal stages, in contrast to midwives who did not enter the autopsy room. With his findings, he thus established one of the first and most important control and prevention measures of HAI: the necessity of handwashing before and after contact with patients(3).

In the same century, the nurse Florence Nightingale, during the Crimean war around 1865(4), introduced the innovation of basic patient care, such as cleaning the patient’s environment, attention to diet, and separation of patients in individual beds, as well as statistical records of the principal causes of death, thus incentivizing hygiene and defending the premise that the hospital would be a place for promoting the improvement and recuperation of the patient, and not a place that caused harm(4). Such episodes, apart from establishing pioneering measures for the control and prevention of HAI, were also the embryo of quality control in healthcare assistance, in seeking to measure and evaluate the occurrence of phenomena.

Nevertheless, the implementation of specific programs for the control and prevention of HAI (Infection Control Assessment Response programs, or ICAR) only formally began in the mid twentieth century in the United States because of a judicial process, which for the first time made not only the professional but also the hospital responsible for the occurrence of HAI(5).

Also in the United States, the Center for Disease Control (CDC) in Atlanta, by way of the SENIC project (Study on the Efficacy of Nosocomial Infection Control), aimed to evaluate the effectiveness of epidemiological surveillance and of active control programs in the country, and showed that HAI prolongs the stay of a patient in the hospital by at least four days and adds additional cost(6). This was an ambitious CDC project for the control of HAI.

Since then the need for ICAR in hospitals spread worldwide. In Brazil, this occurred via specific governmental actions since the 1980s, culminating in Law 9431/97(7) and Decree 2616/98(8). The first establishes the obligatory existence of ICAR in all hospitals, and the second determines the method of organization and implementation of the ICAR.

Even though the activities of such programs follow the technological development and scientific evidence of healthcare assistance practices, the work process remains similar to its origins, predominantly guided by epidemiological indicators in the occurrence of these infections.

This article is a reflexive theoretical study that aims to verify the development and changes in the quality of patient assistance across the years in Brazil, in light of the policies for the control and prevention of healthcare-related infections (HAI).

HAI AND THE PROCESS OF CHANGE IN HEALTH POLICIES IN BRAZIL

Historically in Brazil, the demand for control and prevention of HAI, initially called hospital infection (HI), began in the middle of the 1970s, by recommendation of the Ministry of Social Security and Assistance (Ministério da Previdência e Assistência Social - MPAS), beginning with professionals who had studied and dealt with this type of occurrence in the country, and who had created the first Councils for Control and Prevention of HI (Comissões de Controle e Prevenção - CCIH) in the hospitals where they worked(8). This demand was, in large part, due to the change in health policy in the period of the military dictatorship, in which curative assistance came to dominate, with the proliferation of hospitals and their eminently interventionist practices in the biological body(2).

The decade of the 1980s marked an exponential growth of this demand, as well as for more effective practices for control and prevention, even becoming the object of governmental actions. The first of these was Decree No. 196/83 of the Ministry of Health (Ministério da Saúde - MS), recommending the creation of Councils for Control of Hospital Infection (CCIH) in each hospital, with the work process guided by epidemiological surveillance in a passive way, dependent on notification by the attending physician, which caused high under-reporting(9).

The most effective demand for control and prevention took place with the death of then president-elect Tancredo de Almeida Neves, in 1985, related to a surgical infection. As a consequence, more specific government actions emerged, principally with the creation of instructional material and introductory courses in the control of infection, carried out in the hospitals most active in the area, but with the intent of extending to other hospitals(2).

Other government actions were also undertaken at the end of the twentieth century, among them the institution of the National Program of Hospital Infection Control in 1987, by decree No. 232/87 by the Ministry of Health(2). This program was converted into the Division of Hospital Infection Control, by way of Decree No. 666/1990(9).
In 1992, the Ministry of Health (MS) issued Decree No. 930/92, in substitution for No. 196/83, recommending that ICAR carry out active surveillance of these infections, rather than passive monitoring. Organic Law No. 8,080/1990, which aims to decentralize healthcare actions, as a first step entailed the fragmentation and dispersion of the bases of support for the control and prevention of these infections, in noncompliance with Decree No. 930/1992. Even so, after this Decree more than 127 ICARs were created, as well as greater professionalization of their executors.

Only in 1997 did the Ministry of Health make the existence of a program of control and prevention of hospital infections obligatory, via Law No. 9431/1997, currently in force.

In the following year, the Ministry of Health published a new Decree, No. 2,616/98, currently in force, in substitution of an earlier decree (No. 920/92), defining the Control of Hospital Infection as: “a combination of deliberately and systematically developed actions, with the aim of the maximum possible reduction in the incidence and seriousness of hospital infections”. In addition to establishing guidelines and measures for control and prevention, it also instituted the creation of an ICAR, demanding, in its structure, the organization of a Commission for Control of Hospital Infection (CCIH) and a Service for Control of Hospital Infection (Serviço de Controle de Infecção Hospitalar – SCIH). The CCIH, with decision-making and organizational functions, coordinates and establishes guidelines of control and prevention of these infections in their hospitals. The SCIH, which has an executive character, is in charge of the actions scheduled by the CCIH. This Decree also determines the specific responsibilities and competencies in the area of the three spheres of government (Federal, State, and Municipal).

Beginning in 1999 with the creation of the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária – ANVISA) an autarchy linked to the MS, the national coordination of control and prevention of these infections came to be their responsibility, with the support of the State Secretariats.

Even with all these governmental actions, the situation of the ICARS in the hospitals was not known. To this end, in 2000, ANVISA issued the Resolution of the Board of Directors, RDC No. 48/2000, dealing with a routine of health inspections for the evaluation of these programs in the country’s hospitals.

In 2004, ANVISA instituted the Information System for Infection Control in Health Services (Sistema de Informações para Controle de Infecções em Serviços de Saúde – SINAIS), based on the National Nosocomial Infections Surveillance System (NNIS) of the Centers for Disease Control and Prevention (CDC). One of the most recent governmental actions was Decree No. 1218/12, which created the National Commission for Prevention and Control of Infections Related to Healthcare (Comissão Nacional de Prevenção e Controle de Infecção Relacionada à Assistência à Saúde – CNIRAS), with the goal “to advise the Board of Directors of ANVISA in the development of guidelines, norms, and measures for the prevention and control of Healthcare-associated Infections (HAI)”, having as an objective the identification of weaknesses in the current structure of ICAR in the hospitals and to propose actions to minimize these weaknesses.

The following chart presents a historical summary of the main governmental actions for the control and prevention of HAI in Brazil.

**Chart 1 – Historical development of the principal actions oriented for the prevention and control of HAI in Brazil. São Paulo, 2015.**

<table>
<thead>
<tr>
<th>Year</th>
<th>Organ</th>
<th>Policy</th>
<th>Action</th>
<th>Relevant points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1983</td>
<td>Ministry of Health (MS)</td>
<td>Decrees from Number 196</td>
<td>Instructions for the control and prevention of hospital infections</td>
<td>An important milestone in the history of ICAR in Brazil, although it needs revision to be executed.</td>
</tr>
<tr>
<td>1987</td>
<td>Ministry of Health (MS)</td>
<td>Decree No. 232</td>
<td>Instituted the National Program for Control of Hospital Infection</td>
<td>Converted into the Division of Control of Hospital Infection by Decree No. 666/1990</td>
</tr>
<tr>
<td>1990</td>
<td>Brazil</td>
<td>Federal Law No. 8080</td>
<td>About conditions for the promotion, protection, and recuperation of health, and the organization and functioning of the corresponding services.</td>
<td>Established the Unified Health System, decentralizing the responsibilities for health services.</td>
</tr>
<tr>
<td>1990</td>
<td>Brazil</td>
<td>Federal Law No. 8142</td>
<td>About the participation of the community in the administration of the Unified Health System (SUS), and with the intergovernmental transferring of financial resources in the area of health.</td>
<td>Guaranteed the participation of the community in health actions.</td>
</tr>
<tr>
<td>1992</td>
<td>Ministry of Health (MS)</td>
<td>Decree 930</td>
<td>About new general norms for the control of hospital infections and revokes Decree 196/83</td>
<td>Proposed that all hospitals maintain PCIH, constituting CCIH and SCIH</td>
</tr>
<tr>
<td>1997</td>
<td>Ministry of Health (MS)</td>
<td>Law 9431</td>
<td>About the obligatory maintenance of Programs of Control of Hospital Infections in the country’s hospitals</td>
<td>Issued documents, guidelines, and norms for the prevention and control of HI, and coordination of CCIH in the three spheres of government.</td>
</tr>
<tr>
<td>1998</td>
<td>ANVISA</td>
<td>Decree 2616</td>
<td>About guidelines and norms for the prevention and control of hospital infections</td>
<td>Established recommendations for their formation, related to the structure and operationalization of PCIH.</td>
</tr>
</tbody>
</table>

continued...
However, in spite of various specific governmental actions for the control and prevention of HAI, as well as other corresponding legislation, many hospitals still have difficulties or do not operationalize the ICAR according to governmental recommendations. One of the reasons is because many hospitals, principally those with a lower bed capacity, do not possess the sufficient infrastructure and human resources to completely attend to the organization and work process demanded by the current Decree, No. 2616/98(8).

There is practically unanimous consensus that the current recommendations according to current Decree No. 2616/98 are significantly out of sync with the development of scientific knowledge and, consequently, the practices of HAI control and prevention. At the same time, we can note the tendency toward integration of these practices with two more wide-reaching and recent movements: healthcare evaluation and patient safety. As an example, Decree No. 529 was issued in 2013, instituting the National Program of Patient Safety, with the general objective of contributing to the qualification of healthcare in all the health establishments throughout the national territory, which anticipates actions that seek to prevent and control HAI in the country(17).

Without doubt, there is still much to be done in the area of prevention and control of HAI, and we find the future to be open-ended, considering the new possibilities in relation to the current movements for quality and patient safety.

### The quality of healthcare assistance associated with control of HAI

A brief retrospective demonstrates that the principal movements for healthcare evaluation originated in the United States(18). In 1910, the Flexner Report evaluated medical education and denounced the precarious conditions of professional practice. In 1916, a proposal for a methodology of routine evaluation of patients’ health state, to establish the end results of medical intra-hospital interventions, was published, titled “A Study in Hospital Efficiency: the first five years,” written by Ernest Codman. In 1918, an evaluation by the American College of Surgeons was made of surgical practice and of American hospitals with more than 100 beds, in which only 82 of the 600 hospitals evaluated met the minimum standards. In 1928, a program for hospital standardization was created, the embryo of the Joint Commission on Accreditation of Hospitals (JCAHO), created in 1951. During the 1960s in the United States, the federal social programs in healthcare (Medicare and Medicaid) were created(19).

In the middle of the twentieth century in England, the National Health Service (NHS) was created, with studies of efficacy and efficiency of the diagnostic and therapeutic procedures(18).

In 1966, Donabedian(19) proposed the evaluation of the quality of medical attention, by way of a model that systematized the attributes that delivered quality in the services (efficacy, effectiveness, efficiency, optimization, acceptability, legitimacy, and equity). In 1988/1990, the same author developed a conceptual chart fundamental for understanding the evaluation of healthcare quality, using the concepts of structure, process, and result, classically considered a triad that corresponds to the notions of General Systems Theory: input-process-output(20). In this way, health services also came to be thought of as products and, therefore, subject to a standardization in quality(20).

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### TABLE 1: Relevant Points of Decree No. 158

<table>
<thead>
<tr>
<th>YEAR</th>
<th>ORGAN</th>
<th>POLICY</th>
<th>ACTION</th>
<th>RELEVANT POINTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>ANVISA</td>
<td>RDC No. 48</td>
<td>About the routine inspection of PCIH</td>
<td>Aside from the efforts of ANVISA, this guideline presents limitations in its application, and there is no document with its recorded validation</td>
</tr>
<tr>
<td>2000</td>
<td>ANVISA</td>
<td>Information System for the Control of Infection in Healthcare Services</td>
<td>Absence of national criteria for standardization of notification of infection and registration of few hospitals, which caused inconsistency in the data reported in all regions of the country, with the resulting suspension of the use and maintenance of the system.</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>São Paulo</td>
<td>Manual of Quality Evaluation for Practices of Control and Prevention of Hospital Infection</td>
<td>With indicators of structure, process, and result. Already validated and applied in studies carried out in the state of São Paulo, the city of Ribeirão Preto, and the state of Paraná.</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>Ministry of Health (MS)</td>
<td>Decree No. 158</td>
<td>National Commission for the Prevention and Control of Infection Related to Healthcare Assistance</td>
<td>With the goal “to advise the Board of Directors of ANVISA in the development of guidelines, norms, and measures for the prevention and control of HAI.”</td>
</tr>
<tr>
<td>2013</td>
<td>Ministry of Health (MS)</td>
<td>Decree No. 529/2013</td>
<td>Instituted the National Program of Patient Safety</td>
<td>With the general goal of contributing to the qualification of healthcare in all the health establishments in the national territory, and anticipates actions that seek to prevent and control HAI in the country.</td>
</tr>
</tbody>
</table>

Source: based on official Federal and State documents.
Thus, the innovation, synthesized by Donabedian by way of this triad not only measured the results or outcomes of situations or occurrences, but also the structure (physical area, equipment, inputs, human resources) and processes (procedures and technology correctly applied). This movement for quality in healthcare came to be synonymous with evaluation.\(^{(20)}\)

Predominantly in the area of institutionalized healthcare assistance, and also in the beginning of the twenty-first century, the World Health Organization (WHO) came to consider that quality of care and patient safety constitute a single horizon. Such a consideration begins with the need of recognizing the high global incidence of adverse events in healthcare assistance, estimated to be between 5 and 17% in their occurrence, among which 60% are preventable. As a result, the WHO determines that the adverse events can be recognized as a shortcoming in patient safety.\(^{(20)}\) Thus begins the most recent movement of healthcare quality, today known as patient safety.

In 2002, the 55\(^{th}\) World Health Assembly granted the WHO the responsibility to establish norms and give support to countries for the development of policies and practices oriented toward patient safety, by way of Resolution 55.18/2002. In 2004, the project titled “Global Alliance for Patient Safety” was created, whose fundamental framework is the prevention of harm to patients, and the central element is the action called “Global Challenge,” which every two years prioritizes a theme to be approached.\(^{(21)}\)

In the biennial 2005/6, the challenge theme was “clean care is safer care,” with HAI as its focus, and its main campaign concerned hand hygiene.\(^{(21\text{-}22)}\) The following global challenge, 2007/8, was “safe surgery,” including among its measures the prevention and control of surgical site infection (SSI)\(^{(21)}\). In this way, HAI also came to be considered and classified as an adverse event.

In 2007, at the XXII Meeting of the MERCOSUL Health Ministers, the delegations of Argentina, Brazil, Paraguay, Uruguay, Bolivia, Chile, and Ecuador supported the first goal established by the Global Alliance for Patient Safety; and established an international commitment to develop and apply the respective “National Plans of Patient Safety,” focused on the reduction of risk and harm to the patient and guaranteeing the right to health. This included signing a declaration of commitment in the fight against HAI.\(^{(20)}\)

Part of recent interest in quality emerges in response to transformations in healthcare assistance, with the advent of new technologies and structures in the strategies of hospital services, considering that the harm caused by assistance to the patient can be incapacitating, with permanent after-effects and premature death, as well as a significant increase in hospital costs.\(^{(24\text{-}25)}\) For Donabedian, quality is “the acquisition of the most benefits with the least risks to the patient, and at the least cost.”\(^{(20)}\)

In the case of HAI, notwithstanding progress in control and prevention, and having in mind a multi-causal event, there is great difficulty in totally eliminating its occurrence. At the same time that the introduction of new knowledge and the development of assistance procedures for the treatment of illnesses determine cures and greater survival, it can also expose the individual to even more serious HAI, as a result of new modalities of occurrence in varied topographies and with highly resistant microorganisms, both in the human microbiota as well as environmental sources.\(^{(21)}\) In other words, in spite of all the scientific evolution, no hospital is exempt from HAI, as there exist unalterable risk factors that include both eminently invasive procedures as well as the health conditions of the patients themselves. Thus, the efforts of researchers and administrators turn to the reduction of HAI with actions of prevention and control of preventable infections, approaching different aspects in the environment as well as safe practices and improvement of patient conditions.\(^{(20)}\)

The 2008 report of the Institute of Medicine (IOM) in the United States noted that the number of HAI was unacceptably high: 1.4 million people annually acquired infections, and in developing countries the risk can be four times greater.\(^{(22)}\)

Specialists propose that the reduction of HAI to avoidable levels will depend on four strategic pillars of action: 1) adhesion to practices based on evidence, educating, implementing, and carrying out investments; 2) increase sustainability by way of financial incentives and reinvestment in strategies that demonstrate success; 3) fill in the lacunae in knowledge in order to respond to emergent threats through basic epidemiological and translational studies; 4) collect data to direct efforts at prevention and measure progress.\(^{(27)}\)

However, addressing these concerns demands development of the action model of ICAR. In Brazil, the current model, following Decree No.2616/98, has in recent years been the object of almost unanimous criticism and demands that it be updated by specialists in this area.\(^{(9)}\) This is because its dominant activity is oriented toward active epidemiological surveillance and registering incidences of HAI. Based on this data, they can establish actions directed to their control and prevention.

Although this data for results or outcomes would be highly relevant, they constitute only retrospective information, not favoring proactive or preventative actions. Aside from this, they are shown to be limited in their recognition of other aspects that may be complicating or favoring more qualified assistance and which can involve these occurrences, directly or indirectly. Among these are the conditions in which healthcare assistance procedures are carried out.

Thus, new and broader operational modalities, including those arising from the movement for quality healthcare itself, can and should be incorporated into ICAR.

In 2006, the project entitled “Manual for Quality Evaluation of Control and Prevention Practices for Hospital Infection” was concluded. Guided by the Donabedian evaluation system, 61 evaluation indicators of structure, process, and result were created and validated, distributed in five subgroups of assistance practices, according to types of specific procedures.\(^{(20)}\) These indicators are able to also carry out a monitoring and prospective evaluation, and not only a retrospective one.

Both the original model as well as new proposals included to broaden activity of ICAR need to be monitored in loco, during their realization. There is also a need to create a system to “evaluate what is being evaluated”.

In 2000, the Resolution of the Board of Directors of the National Agency of Health Surveillance – RDC No. 48 – was...
approved, which developed Health Inspection Guidelines, directed at the evaluation of hospitals’ ICAR programs throughout the country (14). This guideline, however, presents limitations. One of them is that its content is based on the current Decree No. 2616/98, known to be out of date and insufficient. In addition, there is no evidence that this instrument of inspections was submitted to a validation process, in order to guarantee interpretations and allow different evaluations to reach similar temporal results at the same institution (12).

Other attempts to evaluate or qualify the processes of HAI control and prevention were developed by ANVISA, such as the Information System for Infection Control in Health Services (SINAIS) in 2004, based on the National Nosocomial Infections Surveillance System (NNISS) of the Center for Disease Control and Prevention (CDC). Due to the absence of national criteria of standardization for notification of infection and the registration of few hospitals, there were inconsistencies in the notification data in all the regions of the country, with subsequent suspension of the use and maintenance of the system (13). Even if this had not been the case, once again the system was generally oriented by retrospective indicators of HAI occurrence.

From 2013–2015, the CNIRAS has as its main objective the reduction of HAI occurrences, with the following actions: 1. Reduce primary infections of the bloodstream; 2. Reduce infections at the surgical site; 3. Establish mechanisms of control over Bacterial Resistance; 4. Increase the rate of conformity of the ICAR, according to criteria of the WHO (29).

Other lines of research advocate the target zero, or zero rate of infection, that has become the new order in prevention of infections, a theme discussed in recent conferences in this area in Brazil.

The specialist in infection prevention William Jarvis, MD, of Jarvis and Associates, based in Hilton Head, South Carolina, noted and alluded to the fight against so many infections that are avoidable. Research has shown that we can avoid more infections than previously thought (28). The intention of researchers is not to eliminate the infection, but to not permit them to occur, investigate the weaknesses in the process, and intervene (30).

CONCLUSION

It is known that HAI occurrences cause a social and financial impact, but investing in policies for their prevention and control also implies a cost. In addition to the difficulty in measuring patient safety in monetary terms, to only create policies and establish norms, guidelines, and indicators is not sufficient if there is no structural support and conditions for interventions in the practice of professionals during patient care in search of acceptable levels of these infections.

Preventing HAI involves a variety of segments, such as management of quality and resources to guarantee a work structure, attention to hygiene, training of health professionals and personnel, and constant knowledge of the changes in infectious agents (that leads to the growing risk of infection in ever more vulnerable patients) associated with the advances in medical care. The cooperation and help of patients, their families, and their friends is also important.

Actions that involve the washing of hands, cleaning of patient areas, and sterilization of instruments are the best ways to prevent hospital infections. Nonetheless, we know it is not as simple as that, but requires a commitment from everyone involved to maintain a complex environment, in a safe space for the patient, workers, and family members, according to the local reality.

New and varied theoretical and operational proposals are being created, henceforth better known or denominated as healthcare evaluation. In other words, the establishment of new modalities of organization and action in healthcare assistance is not sufficient in itself, but also, and principally, requires ascertaining how the assistance is occurring.
REFERENCES


