

**ONAS** 20 ANOS

Organização Nacional de Acreditação

# ONAS AND THE ESTABLISHMENT OF THE BRAZILIAN HEALTH SYSTEM

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In the early 1990s, Brazil was going through a series of transformations and political changes that would be decisive for the nation's future. Among the novelties, there was the new Constitution of the Republic, promulgated in 1988, which began to guarantee health as a right of all and also a duty of the State.

To ensure the fulfillment of this right ("universal and equal access to actions and services for health promotion, protection and recovery"), the so-called Unified Health System (SUS, in the Portuguese acronym) was structured.

Also as a consequence of events related to public health in general, the National Health Surveillance Agency (Anvisa, in the Portuguese acronym) was created in 1999.

"The history of the National Accreditation Organization (ONA, in the Portuguese acronym) is linked to SUS initiatives in the early 1990s. ONA and Anvisa are contemporary entities, directly connected with the construction of today's

SUS and with national health policies, in particular with health services", explains Fábio Leite Gastal, ONA's vice-president.

Meanwhile, the rest of the world was undergoing the maturation of patient safety proposals and the emergence of methodologies for standardizing hospital activities with the creation, in 1951, of the Joint Commission on Accreditation of Hospitals (JCAH) and the International Society for Quality in Health Care (IS-Qua) in 1985.

In Brazil, discussions on accreditation and quality were isolated, and many did not yet understand the concept of accreditation. This began to change in 1990 when the World Health Organization (WHO) signed an agreement with the Pan-American Health Organization (PAHO) to develop a Manual of Accreditation Standards for Latin America and the Caribbean. The compendium was the result of a partnership between Brazilian physician Humberto Novais and the Argentinian José Maria Paganini, then PAHO leaders.

The final document was presented in 1992 to over 120 representatives from 22 countries in the region. In Brazil, the material was distributed to institutions associated with the Brazilian Federation of Hospitals (FBH, in the Portuguese acronym).

Péricles Góes da Cruz, who coordinated the Health Quality Assurance and Improvement Program of the Brazilian Ministry of Health at the time and is currently the technical superintendent of ONA, emphasizes the poor adherence to the manual. "At the time, there was not much focus and concern with the implementation of quality improvement processes within hospitals," he recalls.

Although the PAHO and WHO initiative did not flourish nationally, it was enough for four groups in different regions of the country to establish accreditation as their main study area. Each team worked regionally in the states of Rio Grande do Sul, Paraná, São Paulo, and Rio de Janeiro, studying the subject and proposing the improvement of hospital practices in a targeted manner, per local reality.

Being aware of the groups acting in isolation, the health minister, Carlos Albuquerque, invited physician Humberto Novais to act as a consultant in a project that would result in the creation of a unique Brazilian accreditation manual to standardize regional health initiatives into a single national project.

Thus, based on PAHO's original handbook, existing international methodologies, and the work and experience of the regional groups, the Brazilian Handbook on Hospital Accreditation was published in 1998, and initially tested in 17 hospitals across the country.

It was also in the testing phase that the Ministry of Health understood that, in addition to the preparation of the manual, it would be necessary to develop a Brazilian Accreditation System (SBA, in the Portuguese acronym), which would need to be managed by an institution created for this purpose. Thus, the National Accreditation Organization (ONA, in the Portuguese acronym) was created on June 1, 1999.

The foundation of the ONA was made official in 2001, through a decree of the Ministry of Health that recognized the attributions of the organization.

ONA's basic structure was defined with some points that remain today, such as the Board of Directors. "The basic idea was that the organization should not be directed by specific entities. So, a plural Board of Directors was created, with representatives from healthcare purchasing entities, healthcare providers and governments," recalls Péricles Góes da Cruz.

The following entities were part of the foundation of ONA:

- Associação Brasileira de Hospitais Universitários (Abrahue)
- Confederação Nacional de Saúde (CNS)
- Federação Brasileira de Hospitais (FBH)
- Associação Brasileira de Medicina de Grupo (Abrange)
- Associação Brasileira de Autogestão em Saúde
- Federação Nacional de Seguros Privados e Capitalização
- Conselho Nacional de Secretários Estaduais de Saúde (Conass)
- Confederação das Unimed



# THE CREATION OF THE BRAZILIAN ACCREDITATION SYSTEM

To develop the Manual of Accreditation Standards for Latin America and the Caribbean, the Pan American Health Organization (PAHO) surveyed more than 15,000 hospitals across Latin America, to identify profiles and regional challenges.

The outcome of the research was quite heterogeneous, with results pointing to the existence of more advanced institutions, but also with the discovery of places with minimal conditions even for the prevention of nosocomial infection. According to the physician and consultant Humberto Novaes, a “reasonable amount” of these hospitals “could not stand the slightest assessment to ensure permanent quality in all their services.”

To respond to the different regional needs, during the preparation of its manual, PAHO hired the Argentinian Technical Institute for the Accreditation of Healthcare Establishments (ITAES, in the Spanish acronym) who suggested the elaboration of phases so that the accreditation process could have better adherence among different health institutions.

Level 1 would be a cut-off mark to certify that the institution was able to provide quality patient care. The goal was that level 1 hospitals would continue to improve their processes to achieve excellence at higher levels.

Another issue raised was the need to adopt specific quality standards and indicators for the different sectors of the hospital, without losing sight of the whole organization.

PAHO then defined that accreditation would be given by the hospital unit in its entirety. Therefore a service could not be accredited if it obtained a sector at level 3, but with other environments that did not meet the requirements to achieve level 1, for example.

For the Brazilian reality of the time, the incorporation of these phases into the quality system was fundamental to the

engagement in the accreditation process. Until then, the international manuals had no similar classification.

In 1998, in the first publication of the Brazilian Accreditation Manual, the classification by levels is maintained. In the second edition, after the application of the manual in 17 hospitals, level 4, which present in the PAHO manual, was excluded.

Thus, the known phases were instituted:

- Accredited Level (ONA 1)
- Full Accredited Level (ONA 2)
- Accredited level with excellence (ONA 3)

## THE LEVELS AND ITS CHARACTERISTICS

<b>ONA 1</b> Accredited	For institutions that meet patient safety criteria in all areas of activity, including structural and care aspects.	Valid for 2 years, with a maintenance visit that happens every 8 months.
<b>ONA 2</b> Full Accredited	For institutions that, in addition to meeting the security criteria, have integrated management, with processes occurring smoothly and with full communication between activities.	Valid for 2 years, with a maintenance visit that happens every 8 months.
<b>ONA 3</b> Accredited with Excellence	The principle of this level is "management excellence". An Accredited with Excellence Health Organization or Program meets the standards for levels 1 and 2, in addition to level 3 specific requirements. The organization must already demonstrate an organizational culture of continuous improvement with institutional maturity.	Valid for 3 years, with a maintenance visit that happens every year.



**HEALTHCARE ORGANIZATIONS** that have ONA accreditation assessed as Level 1 are authorized to use the ONA seal on websites and communications.



**FULLY-ACCREDITED SEAL** that is distributed to hospitals that reached level 2 in ONA accreditation.



**AT LEVEL 3**, hospitals and healthcare institutions have "Acreditação com Excelência" or "Accredited with Excellence" and can use this seal.

Level 1 would address the institution's structure in a comprehensive concept that covers everything from physical space to human resources, legislation, regulatory compliance, and others. Level 2, in addition to incorporating items from the previous level, would add process verification. Finally, level 3, in addition to meeting the previous requirements, would show that the entity achieved differentiated results in health care.

Over the initial years of ONA's activity, the standards for level 1 advocated in the first version of the manual in 1999 were incorporated into hospitals. "The levels served for organizations to incorporate management methods internally, patient safety methods and so on. It was an educational process for organizations that

were building their management across levels," says Jaqueline Gonçalves, who was ONA's Standards and Systems manager between 1999 and 2014.

The guiding principles at each level have not changed over time. Level 1 has kept its focus on standards and requirements involving security; Level 2 is dedicated to processes and integrated management. And phase 3 attests to the institution's excellence in management. However, over the years and the maturation of health organizations, ONA has become stricter about the criteria that make up each of these levels. In other words, the level 1 required at the beginning of the last decade bears no resemblance to what is required by the same seal today.

# THE EVOLUTION OF ACCREDITATION MANUALS

The first publication by ONA, the Manual of Hospital Service Providers / Organização Nacional de Acreditação - ONA - Brazilian Manual Accreditation Collection - Volume 1, was released in 2001.

Overall, the Brazilian Accreditation Manual is reviewed every 4 years, with new versions published in 2004, 2006, 2010, 2014 and 2018.

Whenever there is a manual update process, ONA's technical team visits some key institutions to do research, and they also open up opportunities for

feedback on previous manuals and processes. In addition, representatives of health service organizations are involved to engage in dialogue with ONA's technical staff to understand expectations and needs.

Accreditation Institutions (AI) and their evaluators are also involved in updating the manual. They support ONA in understanding the reality of hospitals that are already accredited and those that are still going through the process. As will be seen below, AI are ONA-accredited companies that represent it with customers throughout Brazil.



In the final stages of the preparation of the manual, public consultations are opened for people who'd like to comment on the proposed content.

From 2001 onwards, a series of agreements signed with Anvisa demanded that standards and manuals should be prepared not only for hospitals but for other types of establishments.

Through partnerships with institutions such as the Brazilian Society of Hematology and Hemotherapy (SBHH, in the Portuguese acronym), the Brazilian Society of Clinical Analysis (SBAC, in the Portuguese acronym) and the Brazilian Society of Nephrology (SBN, in the Portuguese acronym), specific manuals have been launched for related areas and activities, such as the Accreditation Manual for Hemotherapy Service Providers, the Accreditation Manual for Clinical Laboratory Service Providers, and the Accreditation Manual for Nephrology and Substitute Renal Therapy Providers, all launched in 2003.

In 2006, ONA had already launched different manuals according to specific segments: hemotherapy services, clinical laboratory, nephrology and renal therapy, hospital, radiotherapy and outpatient services. In 2010, manuals mentioned above were all consolidated into a single publication.

In 2011, adjacent health services such as sterilization and reprocessing of materials, antineoplastic drug handling and parenteral service, laundry, and diet therapy services were given a specific publication: the Health Services Assessment and Certification Manual. The services are now certified with the

ONA Qualification Seal.

In the following year, dental services earned their own manual, resulting of an ONA partnership with Accrediting Institutions (AI), the Faculty of Dentistry of University of Sao Paulo and the Brazilian Association of Dental Surgeons.

In 2013, the first international recognition came to ONA manuals through the seal of the International Society for Quality in Health Care (ISQua). In the following year, the edition of the manual certified by the international body was launched. Among the changes made to the manual is the incorporation of the concepts of the World Health Organization International Classification for Patient Safety.



**ISQUA CERTIFIES**  
accreditors that  
follow internationally  
recognized standards.

The most recent version of the manual, published in 2018, has also been submitted and endorsed by ISQua.



# THE IMPORTANCE OF LICENSED ACCREDITING INSTITUTIONS (AI)

At its inception, ONA operated from an office located in Brasília, the administrative capital of Brazil. To face the challenge of bringing the culture of quality to all health institutions in a country the size of Brazil, ONA relied on the fundamental work of licensed Accreditation Institutions (AI).

The AIs were responsible for providing the necessary capillarity for the expansion of the system and, at the same time, for efficiently promoting and executing the Brazilian Accreditation System methodology.

“A single organization in a country with continental dimensions like ours would not be able to evaluate the large number of existing organizations. We have almost 7,000 hospitals in Brazil, 12,000 laboratories, and so many other health organizations,” says Péricles Góes da Cruz, ONA’s technical superintendent. “With this premise, ONA established the cooperation with licensed Accrediting Institutions (AI),” he adds.

From the outset, the AIs have functioned as ONA’s representation in the

health sector. They are responsible for diagnosing, performing tasks, assessing and certifying institutions according to the SBA guidelines, and for capacitating evaluators who perform the fieldwork.

As early as the 2000s, ONA began to accredit certifiers. The pioneers were:

- Fundação Carlos Alberto Vanzolini;
- Instituto de Administração Hospitalar e Ciências da Saúde (IAHCS);
- Instituto de Planejamento e Pesquisa para Acreditação em Serviços de Saúde (IPASS);
- Det Norske Veritas Germanischer Lloyds (DNV/GL);
- Instituto Qualisa de Gestão, today known as IQG Health Services Accreditation.

These companies work alongside ONA to this day. Later, the Instituto Brasileiro para Excelência em Saúde (IBES) joined the group of licensed certifiers. Together, the six were responsible for the 800 accreditations given until the beginning of 2019.

## THE ADHESION OF HOSPITALS

In the early 2000s, the demand from hospitals and health institutions for the accreditation process was still low and incipient. "At that time, hospitals needed a period of maturation and preparation to be ready for the accreditation process," says Péricles Góes da Cruz, ONA superintendent.

At the beginning of the accreditation movement, a few factors influenced hospitals to seek more information on the topic and subsequently to undergo evaluation. One was the concern of the entities with patient safety and improving their quality system. The other motivating factor was the search for the certificate as a way to highlight the competitive differential of the institution.

In 2001, the creation of the National Association of Private Hospitals (Anahp, in the Portuguese acronym) gives the accreditation movement another boost by requiring that hospitals interested in becoming associated with the institution go through the accreditation process.

At the same time, the National Supplementary Health Agency (ANS, in the Portuguese acronym) starts to encourage more quality policies in the sector. In 2011, the organization publishes Normative Resolution 277, which establishes a voluntary health insurance carrier accreditation program. To gain accreditation with ANS, the organization requires from its providers information proving the qualification of the service.

## INNOVATION PROCESS

To fulfill the challenge of bringing quality culture to all health institutions in the country, ONA had to innovate in its structure.

The first innovation came through ONA Educare, a web-based distance education program with content on quality concepts, analysis and evaluation for accreditation, by using criteria based on the ONA methodology.

"ONA was one of the first health institutions that bet on distance education supported by the web. We intensively use distance education to train health professionals in municipal and state sanitary surveillance and also to train evaluators," says Fábio Gastal, who at the time of the creation of ONA Educare acted as the organisation's superintendent.

Another technology-related innovation was the launch of the ONA Integrare system in March 2013. Developed exclusively by ONA to automate the entire accreditation process, it enables faster documentation, submission and exchange of information over the Internet.

The main asset of the tool is that it enables the integration of all those involved in accreditation in a safe and easily navigable environment. Evaluators, AI, accredited organizations, and organization in the process of evaluation have access to data and documents from each ongoing step, ensuring greater agility, transparency and security.

"ONA Integrare is the only system specialized in the accreditation process in the world. This statement came after an international assessment by ISQua. At the time, following the presentation of ONA Integrare features, the evaluators praised the system and said it was the first time they had come across a systematized accreditation process," reports Cássia Manfredini, ONA Standards and Systems Manager.

## ONA'S LEGACY

From the beginning, ONA has been concerned with adapting the accreditation methodology to the reality of the Brazilian health sector. The proposal has always been to encourage improvements in organizations and to encourage continuous improvement within a learning process towards ONA 3, the level of management excellence.

By conquering ONA's validation process, no matter what the level, the health care organization signals its commitment to recognized standards of quality and safety. In accredited institutions, patients, for example, can enjoy a safer environment. Doctors, in turn, feel more confident about performing procedures in an organization with certified processes, knowing that the patient is well assisted. This perception also extends to suppliers, as continuing to ser-

ve a certified entity means meeting the necessary requirements to do so - which is measured in level 1.

ONA's current administration and board of directors wants to reach 1,000 accredited institutions by March 2021.

To do so, the organization works to improve the technology and data system by streamlining the evaluation and monitoring process, and by adopting a new strategy for communicating with the market. "We understand that ONA should strengthen its leading role in Brazilian and world health, collaborating for the development of the health sector in our continent", analyzes Cláudio Allgayer, ONA® president.

## TIMELINE



