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REFLECTIVE ANALYSIS ARTICLE

THE CONSTRUCTION OF THE CURRENT MODEL FOR THE EVALUATION OF HEALTH SERVICES: REFLECTIVE ANALYSIS

A CONSTRUÇÃO DO MODELO ATUAL DE AVALIAÇÃO EM SERVIÇOS DE SAÚDE: ANÁLISE REFLEXIVA

LA CONSTRUCCIÓN DEL MODELO ACTUAL DE EVALUACIÓN EN SERVICIOS DE SALUD: ANALISIS REFLEXIVA

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ABSTRACT

Objective*:** to reflect on how some contemporary events, presented and discussed in several productions, can be understood as historical determinants of the process of construction and deconstruction of the current model for the evaluation of health services. ***Method*:** this was a descriptive and qualitative study with a historical reflection based on a narrative literature review. ***Results: the development cycle of hospitals enclosed developments and stagnations, spawning a troubling reality: harm caused to patients. The development of drug therapy and health technologies changed the social role of hospitals. Nightingale, Codman, and Donabedian had a fundamental importance in evaluating the results of assistance. Studies on human error awakened governments and societies to patient safety. ***Conclusion:*** an evaluation model was created aiming at continuous changes in the reality of hospital institutions. Initially proposed to evaluate results of assistance, the process aggregated patient quality assistance and safety as dimensions. It became a Public Policy for the evaluation of health services. ***Descriptors:*** Health Evaluation; Health Services; Patient Safety; Quality Management.

RESUMO

Objetivo*:** refletir sobre como alguns acontecimentos contemporâneos apresentados e discutidos em diversas produções, podem ser entendidos como determinantes históricas do processo de construção e desconstrução do modelo atual de avaliação dos serviços de saúde. ***Método*:** estudo descritivo, qualitativo, de reflexão histórica baseada em revisão narrativa de literatura. ***Resultados: o ciclo de desenvolvimento dos hospitais encerrou evoluções e estagnações, gerando uma preocupante realidade: danos causados aos pacientes. O desenvolvimento da terapia medicamentosa específica e de tecnologias em saúde mudou o papel social dos hospitais. Nightingale, Codman e Donabedian tiveram importância fundamental na avaliação dos resultados da assistência. Estudos sobre erros humanos despertaram governos e sociedade para a segurança do paciente. ***Conclusão:*** objetivando contínuas mudanças na realidade das instituições hospitalares, um modelo de avaliação foi criado. Inicialmente proposto para avaliar resultados da assistência, o processo agregou qualidade e segurança do paciente como dimensões. Transformou-se em Política Pública de avaliação dos serviços de saúde. ***Descritores:*** Avaliação em Saúde; Serviços de Saúde; Segurança do Paciente; Gestão de Qualidade.

RESUMEN

Objetivo*:** reflexionar sobre cómo algunos acontecimientos contemporáneos presentados y discutidos en diversas producciones, pueden ser entendidos como determinantes históricas del proceso de construcción y desconstrucción del modelo actual de evaluación de los servicios de salud. ***Método*:** estudio descriptivo, cualitativo, de reflexión histórica basada en revisión narrativa de literatura. ***Resultados: el ciclo de desarrollo de los hospitales encerró evoluciones y estagnaciones, generando una preocupante realidad: daños causados a los pacientes. El desarrollo de la terapia medicamentosa específica y de tecnologías en salud cambió el papel social de los hospitales. Nightingale, Codman y Donabedian tuvieron importancia fundamental en la evaluación de los resultados de la asistencia. Estudios sobre errores humanos despertaron gobiernos y sociedad para la seguridad del paciente. ***Conclusión:*** objetivando cambios continuos en la realidad de las instituciones hospitalarias, un modelo de evaluación fue creado. Inicialmente propuesto para evaluar resultados de la asistencia, el proceso agregó calidad y seguridad del paciente como dimensiones. Se transformó en Política Pública de evaluación de los servicios de salud. ***Descriptores:*** Evaluación en Salud; Servicios de Salud; Seguridad del Paciente; Gestión de Calidad.

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INTRODUCTION

According to the terminology of the Ministry of Health, hospitals are institutions that are part of a medical and social organization with the basic function to provide the population with comprehensive medical assistance, curative, and preventive under any assistance arrangement, including at home. Hospitals, educational centers, training of human resources and health research, and referral of patients also have the task of overseeing and directing health establishments technically linked.[1]

The presented definition contains a universe that, in a preliminary analysis, can refer to the current reality of the most recent decades within the advent of SUS. Published in 1977, it could also be understood as a concept built over more than 80 years, during which the Brazilian government worked in health care and social security. In fact, it took centuries for hospitals and health services to reach the profile presented today. Centuries of medicine evolution, years till the birth of nursing as a science, and periods of work for the verification of results from patient care and development of specific drug therapies. The popularity and proliferation of hospitals, and the resulting problems of therapies offered by these institutions have generated a need for social control. Many processes were built and applied until, finally, the current evaluation model was achieved under a new angle: healthcare provided with quality and patient safety.

Therefore, this study aims to reflect on how some contemporary events, presented and discussed in several productions, can be understood as historical determinants of the process of construction and deconstruction of the current model for the evaluation of health services.

METHODOLOGY

This study consists of a reflective approach to the construction of the current model for the evaluation of health services, the Accreditation. The study was conducted as part of a Dissertation for the Master's degree in Academic Program in Health Care Sciences. To analyze and discuss the process of medication designed and carried out by a group of nurses from a neonatal unit, the authors previously conducted a narrative review of the literature; this allowed an expanded and contextualized approach about medicines, hospital medication process, patient safety, and procedures for the evaluation of assistance provided in hospitals. Thus, the conceptual bases of the study were elaborated from a historical perspective. Literature, articles, dissertations, theses, books, and legislation were consulted in the Virtual Health Library (VHL) and Scientific Electronic Library Online (SciELO), in addition to the Digital Library of Theses and Dissertations of the University of São Paulo (USP Digital Library). All collected productions were cataloged and summarized.

The reflective analysis was divided into thematic axes – << Medications: definition, history of development, dissemination as part of the hospital care and its relationship to patient safety >>; << Cycle of hospital development and health care evaluation: individuals devoted to science changed history >>; << Today's history: the revolution caused by the adoption of the model of quality and patient safety with focus on error prevention >> and << The System for Evaluation of Health Services in Brazil and in the world, and its correlation with patient safety management >>.

Next, we present the four axes built for the analysis in order to promote a broad view of the theme.

RESULTS

♦ **Medications: definition, history of development, dissemination as part of the hospital care and its relationship to patient safety.**

Medications are by definition special products developed with the purpose of preventing diseases, curing them, or alleviating their symptoms. Their effects are due to the action of one or more active substances found in their composition, called remedy, drugs, or active principles.[2] According to the definition of ANVISA, medicines are substances or formulations manufactured in industries or manipulated in pharmacies following rigid standards of safety, quality, and effectiveness control.[3]

Until the early 19th century, most treatments were based on the prescription of medications, natural preparations of medicinal use, popular and empirical, used in the most diverse forms, whose chemical structure and nature were unknown.[2] Even today, many use the word remedy as a synonym of medicine. However, the correct association is to relate the word remedy to any type of care used in the relief of diseases and their cure. Therefore, every medicine is a remedy, but not every remedy is a medicine.[3]

The specific drug therapy, one of the most spectacular stages of the development of

modern medicine, can be considered as the result of discoveries made by scientists who, in the early 19th century, were dedicated initially to the fields of Physics and Chemistry, and were responsible for the knowledge that generated the fields of Microbiology and Immunology.[2]

One of those scientists was Louis Pasteur. Thanks to his experiments, the Theory of Spontaneous Generation was overthrown and replaced by the Theory of Germs. Pasteur proved the existence of microorganisms that would be the primary causal agents of some diseases and called them *germs*. He postulated that each disease would be linked to a germ in particular that could be identified and recognized by its constant shape, color, and behavior. He stated that preventing diseases would depend on "*building artificial defenses*" against their agents.[4,5]

After these pioneering discoveries, many scientists and doctors were dedicated to the discovery of new pathogenic microorganisms. Moreover, following the precepts of Pasteur, they sought to study them in order to discover the necessary defenses to destroy them, preventing the disease or preventing its natural course, which was often a lethal event. Twenty-two etiological agents of infections were discovered between 1879 and 1900 alone.[4,5]

In 1899, as a collaborator of Koch, the Polish scientist Emil Von Behring, discovered, in the blood serum of patients affected by infectious diseases, the presence of what he called *active agents*, substances whose constant production and permanence in the blood would be the barrier to prevent new outbreaks of the same disease in the same individual. At the same time, Doctor Paul Ehrlich published that some germs were producers of **toxins** and that individuals exposed to them produced *antitoxins*. In collaboration, Behring and Ehrlic postulated that these produced toxins would be transmissible and may be extracted, purified, and applied to third parties. These scientists teamed up to launch the base of an industrial production of anti-diphtheria serum. They proved its thesis and "medicine" by reducing mortality rates in half among patients with diphtheria. Recognized as the fathers of Immunology, Behring in 1901 and Ehrlich in 1910, were granted the Nobel Prize in Physiology/Medicine.[2-5-6]

Once again Pasteur and his brilliant experiments were fundamental in another event when proving scientifically that the inoculation of small amounts of germs in animals prevented diseases, and that this process would be identical in humans. He began a new era that preserved the lives of millions of people: the vaccination.[4,5]

Thus the 20th century was beginning and in the following years more infectious diseases had their etiological agents determined. However, vaccines were created slowly. Moreover, produced serum did not show the same effectiveness of the anti-diphtheria serum, or caused unexpected effects. In the search for better results, research diversified and focused on chemical therapy. Ehrlich himself researched and developed compounds against prevalent diseases such as syphilis. He systematically tested two products that showed to be 100% effective curing patients and preventing the spread of a stigmatizing disease, which condemned children to the misfortune from birth and adults to a long path until madness. The success was so relevant that the two substances were called "magic bullets" and were produced on large scale. The pharmaceutical industry was born.[2-5-6]

Still in the first half of the 20th century, in the troubled 40 decade, there were numerous advances in research in the area of Pharmacology driven by financial capital injection from the pharmaceutical industry. As products of these researches, an unparalleled amount of new drugs was produced and introduced in the treatment of diseases taking the cure to a population still beset by infectious and parasitic diseases. The production of drugs on an industrial scale enabled pharmaceutical products to achieve an importance never seen before bringing increased worldwide life expectancy in the following decades. Prescribing drugs became synonymous with good medical practice. Not by chance, the earliest records of irrational use of medicines date back to this time, both on the part of the population as those who prescribed them.[2-6] The concern about the risks of such unregulated use was already promoting discussions.

The emergence of episodes of severe adverse reactions to medicines such as the case of thalidomide caused a worldwide commotion. The use of this medicine in pregnant women was responsible for the birth of children with congenital malformations, which before were considered rare. The estimated number of cases reached 10,000. About 500 children died with severe defects in internal organs like kidneys, lungs, intestines, and heart. In addition, experts attributed an alarming increase in the occurrence of miscarriages to the use of the drug in 46 countries where the drug was marketed. All of

these events occurred in the short period between 1957 and 1962. The world's reaction was proportional to the damage: forbidding the drug from being sold, reviewing experimental studies, and raising the bar required for new drugs to be released into the market.[7] Controlled clinical trials were adopted as the standard in the process of new medicine evaluation. Coupled with this and other episodes of adverse reactions, the growing economic costs of drugs in social security systems drew the attention of health authorities who definitely returned their attention to the issue of the use of medicines.

♦The development cycle of hospitals and health care evaluation: individuals devoted to science change history

The worrisome reality of hospitals was part of this historic, contemporary setting. The development cycle of these institutions, although it occurred in parallel with the progress of science, included developments and stagnation in several countries.[8] In the second half of the 20th century, still during the industrial revolution, the reorganization of hospital institutions occurred, which until then were mere deposits of patients without resources where infectious and parasitic diseases predominated out of control at the time.[6-8-9]

The person responsible for changing the history of hospitals and care was Florence Nightingale. With a solid training acquired in the Catholic hospitals of England and Germany, she devoted herself to the care of the poor and infirmed. Against the wishes of her family, she paid volunteer service in the Crimean War. Her data collection method, developed while paying service to wounded soldiers, is recognized as the first scientific, epidemiological, and statistical method devised and applied to indicate the efficiency of health care strategies.[9]

With the prestige achieved with the English government in recognition of her work, Nightingale acquired conditions to perform the great transformative mission of hospitals and schools of nursing, becoming a pioneer in nursing as a professional and scientific activity. Florence obtained the conditions for the creation of the School of Nursing of the Saint Thomas Hospital in London, a model for the schools that emerged worldwide. Likewise, she became a hospital consultant. Before long, every hospital built in England after the Crimean War worked under the direct or indirect influence of Florence.[6-10]

Her Environmentalist Theory, amazing and visionary because it was before the Germ Theory of Pasteur, was the basis used to change the hospital environment. Florence added the value of organization and leadership exercised by nurses to hygienists concerns such as "clean air, clean water, efficient drainage, cleanness, and light."[11] She continued extracting data from a careful observation of patients, which were statistically analyzed and would demonstrate the effectiveness of her method of care that "put patients on the best conditions for nature to act on them."[10-2] She proved the importance of knowledge on the part of nurses about techniques and administrative instruments for the organization of the therapeutic environment and systematization of techniques and procedures in nursing care. She was considered the first hospital administrator and delimited the competence of *ladies nursies*.[9,10,1]

In maintaining the same historical profile of evolutionary irregularity, the improvement of processes of services occurred unevenly in hospitals around the world.[8] The most positive scenario, after the Nightingale era, and whose reality would eventually influence other hospitals around the world, was the North American. From the beginning of the 20th century, technological and scientific advances produced a *boom* of new pharmaceuticals and therapies changing the course of the history of mankind and hospitals. Drugs for various diseases, vaccines to prevent epidemics and combat prevalent childhood diseases joined progress with aseptic technique in surgeries, infusional therapies, and diagnostics with the aid of laboratory and imaging exams. All these advances expanded the range of therapeutic options and began to compose the arsenal of resources offered in hospitals that, since the Nightingale era, were created to serve the sick in a more structured, clean, and organized way with the application of scientific knowledge. Hospitals spread under the new vision of society, which recognized them as institutions for effective treatment.[6]

The United States, the last country in the Americas to build this type of institution, became the country with the highest number of hospitals in operation.[4] However, the more they expanded, the greater was the occurrence of undesirable effects caused by the strategies of care. In 1910, surgeon Ernest Codman published the first studies that pointed to the necessity and importance of ensuring quality interventions and medical procedures proposing a system of hospital standardization.[12] The doctor was inspired by Florence Nightingale to advocate for quality of results from medical interventions in hospitals. Thus, the credit for the

standardization of American hospitals that occurred at the beginning of the 20th century can be given to Nightingale and Codman.[13]

Since 1913, American hospitals started to follow guidelines from the American College of Surgeons (ACS), newly established by Codman and other collaborators. This collegiate drafted the first cast of hospital standards in 1917 named as minimum standards. In 1918, the first evaluation of American hospitals occurred nationwide. Out of the 692 evaluated hospitals all with 100 or more beds - only 89 complied with the standards recommended by the ACS. In 1924, the Hospital Standardization Program (HSP) was created. Compliance with the rules established by this program, treated as minimum standards, began to be required for all hospitals in the United States and the results were evaluated systematically. It took many years, but the work provided positive effects. Thus, in 1950, the number of hospitals approved by the evaluation of HSP reached 3,290 throughout that country.[14]

The programs created by ACS went through frequent modifications in the following years to become the foundation of the evaluation strategy of health services called Accreditation.[14,5] However, some problems persisted and others emerged later as a result of the advancement of technologies in health. The number of cases involving institutions and professionals grew with requests for compensation by iatrogenic issues.

In the early 50s, ACS created partnerships with other associations because it was difficult to sustain its Accreditation Program. The Joint Commission on Hospital Accreditation was created (JCHA). In 1952, JCHA officially delegated the Accreditation Program to the *Joint Commission on Accreditation of Hospital* (JCAH) composed of professional associations and hospitals in the United States and Canada. Progress was being achieved. From the work of Deming and Juran in Japanese companies in the Post-war, the concept of total quality management applied in the industries emerged. Subsequently, several authors developed concepts of total quality management in health services.[16]

In 1966, the researcher Avedis Donabedian, a pediatrician by training, born in Lebanon, and living in the United States published an article with an integrative review of the literature, an uncommon type of research at the time, entitled *Evaluating the Quality of Medical Care*. The author used material from 70 scientific articles published between 1950 and 1960 and identified, described, and evaluated the most used methods (at that time) to measure the quality of health services.[17] He won instant recognition and incentives to continue his studies.

In his studies, developed over nearly 30 years, the author systematized the knowledge about quality in hospital services and pointed out the need for concepts and nomenclature standardization suggesting the adoption of one unique concept of quality. He defined quality as "getting the greatest benefits with the lowest risk to the patient and the lowest cost."[17,8] He proposed that the evaluation of the quality of medical attention should be conducted through a model that systematize seven attributes, pillars that would translate into quality in hospital services: efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity. In addition, he established the steps of construction/production, through which this quality could be measured: structure, process, and outcome.[18,9]

In the definition of Donabedian, **structure** is the set that involves physical, human, and material resources and financial assistance for medical and hospital assistance; **processes** are medical assistance activities with pre-established standards between professionals and patients; and **outcomes** are the final products of assistance to the patient, this product represents the result from the interaction between process and structure. Health services began to be thought of as products as well and, therefore, liable to quality standardization. [18,9,20]

In the 1970 decade, with the totality of American hospitals at minimum standards, the Hospital Accreditation Manual began to recommend criteria and optimum quality standards. This decade was also marked worldwide by the expansion of medical attention in regards to coverage, expertise, and technological density. However, the studies of Donabedian and other authors, which began to work with quality, were only significantly widespread after the 1980 decade already as part of the deception/revaluing movement of health services.[19]

♦ Today's story: the revolution caused by the adoption of the model of quality and patient safety with focus on error prevention

The Accreditation process, which was projected internationally and is practiced today in many countries, represents a form of control and evaluation with a view to a continuous improvement in the quality of health services. However, in the early years of its use, it had as its main objective verifying

the effectiveness of the care provided and establishing its minimum standards. Years later, this process evolved for the establishment of maximum standards, however, without increased focus on protection and preservation of their patients concerning **error prevention**. The security roles that, according to the precepts of modern Administration formulated by Fayol, is the basic division of every company was not fully developed yet in health institutions.[21] To reach this level, another very contemporary revolution was necessary for the healthcare industry: that which originated from the deepening of studies on medication errors and its prevention.

It is correct to say that between the decades of 60 and 90 several studies were published in the United States on the topic of medication error. Most of them approached adverse events and their frequency discussing causes and proposing measures for the reduction of damage. However, it was in the 90s that more research groups devoted work to the subject. These were also representative years in the rising of sensational media approaches about errors in the area of health, growth in the number of lawsuits, and the astonishing increase in the cash value required as indemnity. Healthcare became a form of provision of services subject to contractual laws and their consequences, both in the civil as criminal law. The patient became more contesting, which demanded a change in behavior on the part of service providers.[22]

Motivated by these issues and reflecting on the importance given to the subject, many were the results of published researches that acquired ample propagation. Among these studies, those by the pioneer Leape in 1991 and 1994,[23] and Phillips, Christenfeld, and Glynn in 1998 should be mentioned. These studies, in addition to fostering interest in the subject, contributed to improving the definitions of concepts about these events.[24]

In 2000, the work that represented a confluence of that movement was published adding a differential in the theme of quality of assistance by including patient safety as a dimension of quality to be achieved. The book entitled "*To Err is Human: Building a safer health system*, prepared by the Committee on the Quality of Health Care in America from the *Institute of Medicine* (IOM) in Washington obtained repercussions not only in the United States but also gaining notoriety worldwide. It focused on the impact caused by avoidable errors in American patients. It disclosed alarming data including statistics of 7,391 deaths of Americans caused by medication errors in 1993 against 6,000 caused by accidents at work. Moreover, it pointed out that a number between 44,000 and 98,000 deaths occurred in 1997 that could be related to errors in the care process, which would make this occurrence the eighth cause of deaths in that year. In addition, it stated that more than half of the adverse events could have been prevented.[22] The data presented in this report led to the mobilization of governments and international organizations with the World Health Organization taking an outstanding role. Many subsequent studies carried out in the United States and in other countries, pointed to the same results. Moreover, they also converged in their conclusions indicating the need for creating a culture of patient safety.[16]

The work of the Pan American Health Organization (PAHO/WHO) have taken on great importance in the last decade providing assistance based on evidence-based interventions and focused on patient safety and quality of health services to all populations of the Latin America and Caribbean countries. The concepts of Avedis Donabedian adopted by the World Health Organization were incorporated into the Accreditation process of JCAH. Management of structure, processes, and outcomes began to be jointly evaluated for the recognition of the institution as one with great quality standards, i.e. as an accredited institution.[18-20] The monitoring of these results through performance indicators is the institution's focus, which from 1988 acquired the name of JCHO - *Joint Commission on Accreditation of Healthcare Organization*[15]. In addition, JCHO takes the initiative to include the patient safety management system as a prerequisite for Accreditation.[16-25]

Patient safety is a theme of international relevance, widely discussed in organs and health institutions, which is the focus of not only the work of non-governmental organizations but also public policies aimed at the reduction and elimination of unsafe acts within the assistance system. The World Alliance for patient safety was created in 2004, which, through campaigns called global challenges, guide the identification of actions to prevent risks to the patient.[16]

The System of Evaluation of Health Services in Brazil and the world, and its correlation with patient safety management

The growth in demand for health services combined with continuous changes in clinical practices, adoption of technological innovations, and consequent increased costs

and restrictions expanded the interests of countries into monitoring the quality of these services. Through coordinated actions between governments and international organizations, policies and systems were set up throughout the 20th century establishing norms and standards for the evaluation of effectiveness and quality of care provided by health services.[26]

In Brazil, in the decade of 1990, the *Program* of *Control* of *Hospital Quality* (*CQH*) was created with sponsorship of the *São Paulo Association* of *Medicine* (*APM*) and the *Regional Council* of *Medicine* of the State of São Paulo (CREMESP).[15] The National Health Surveillance Agency (ANVISA) starts working with the theme of quality health services taking a coordinating and regulatory role in the health industry. The project's goals were to ensure better products in the market, safer, and with high quality for patients and healthcare professionals. In 1998, patient safety was finally placed on the country's political agenda with the creation of the National Program for Health Care Evaluation - PNASS. ANVISA and WHO are mobilized to achieve worldwide goals. In parallel, Non-governmental Organizations (NGOs) continued performing evaluation processes for Hospital Accreditation. In 1999, the Sentinel Hospital Project was created by ANVISA aiming to form a network of services for the entire Brazil, enabled to notify adverse events and technical complaints of the so-called health or similar products.[16-27]

The current landscape of the country, which is actually the world scene in which Brazil is inserted, is of building a safety culture where advances that allow professionals, institutions, organizations, and governments to have data and tools to work in the quest for improved health care.[28] In 2014, ANVISA began to coordinate the Brazilian System of Accreditation through the National Program for the Evaluation of Health Services – PNASS. The works are carried out with partners such as the National Accreditation Organization – ONA, the Pan American Health Organization (PAHO), and the World Health Organization. Thus, the Brazilian Accreditation System is identical to the one practiced worldwide (FIGURE 1). Its theoretical bases are: structure, processes, and results management where planning, actions, achievements, and results are analyzed systematically through attributes that define the quality of health care. The goal is to achieve, always starting from risk management actions, an optimum level of excellence in health services management including the measurements of impacting effects from the adoption of systematically proposed structures.[16-8-20-9]

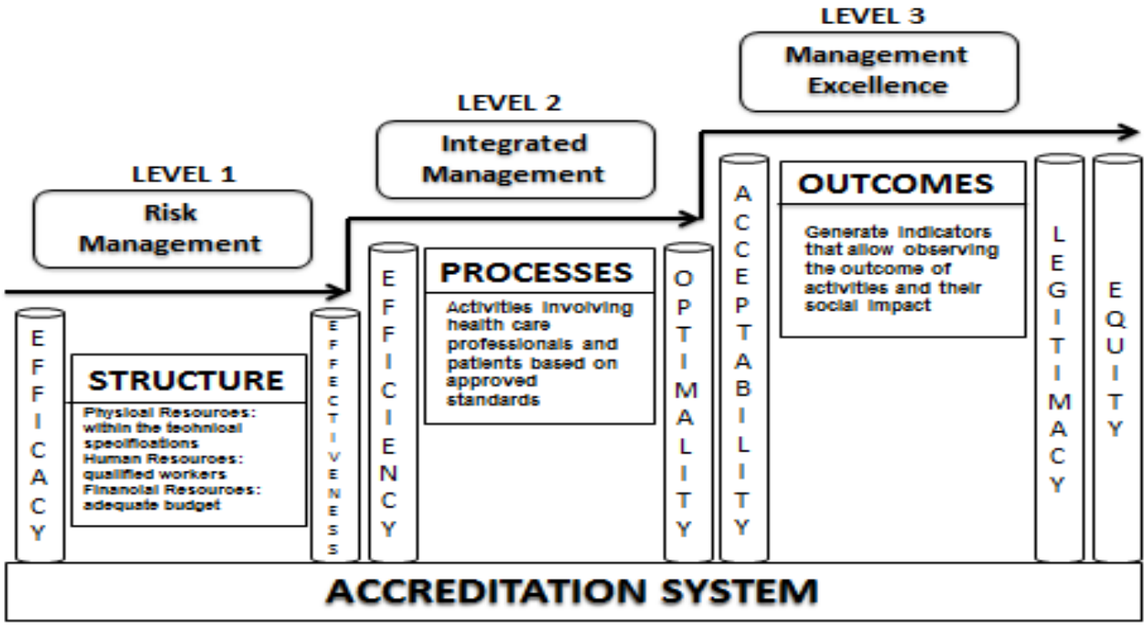

Figure 1. Accreditation System based on the concepts of Donabedian for quality evaluation of health services. Source: Elaboration by the authors adapted from Hospital Accreditation Manuals from the Ministry of Health[28] and the National Accreditation Organization.[29] Conceptual bases: Systemic approach for the evaluation of quality of health services;[17,8] Seven Pillars of Quality;[20] Levels of Accreditation[28,9]

CONCLUSION

Aiming at the changing of the historical landscape adversities, a model for the evaluation of health services was created. Initially proposed to evaluate hospital institutions, developed and managed by non-governmental organizations, this evaluation process is now coordinated and regulated by governments and part of worldwide public policies.

The Accreditation process used today is a result of numerous efforts by the government and health organizations aimed to prevent the deterioration of the Health system, a tendency of any system. New strategies are continuously established in the interests of patient safety with the prospect of maintaining the Healthcare System with the quality and social satisfaction.

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