REVIEW ARTICLE

THE PATIENT SAFETY CULTURE IN THE ADHERENCE TO THE SAFE SURGERY PROTOCOL

A cultura de segurança do paciente na adesão ao protocolo da cirurgia segura La cultura de seguridad del paciente en la adhesión al protocolo de cirugía segura

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ABSTRACT: Objective: To analyze the determining role of the patient safety culture in the adherence to the Safe Surgery Protocol of the Ministry of Health, by the surgical teams in healthcare organizations. Method: It is a theoretical critical reflection, grounded in narrative review of the scientific literature. Results: The global movement of the patient safety promoted in 2004 by the World Health Organization, led to the Second Global Challenge "Safe Surgery Saves Lives", leading the Brazilian government to launch in 2013, the National Patient Safety Program, in which established the Protocol for Safe Surgery. Conclusion: It is necessary to change the paradigm of the blaming culture for a fair culture in the face of the incidents related to health care, so that the Surgical Safety Checklist inserted in this protocol is recognized and valued by the surgical teams.

Keywords: Patient safety. Organizational culture. Checklist. Leadership.

RESUMO: Objetivo: Analisar o papel determinante da cultura de segurança do paciente na adesão do Protocolo para Cirurgia Segura do Ministério da Saúde realizado pelas equipes cirúrgicas nas organizações de saúde. Método: Trata-se de uma reflexão teórica crítica, fundamentada em revisão narrativa da literatura científica. Resultados: O movimento mundial da segurança do paciente, promovido em 2004 pela Organização Mundial da Saúde, culminou com o Segundo Desafio Global "Cirurgia Segura Salva Vidas", levando o governo brasileiro a lançar, em 2013, o Programa Nacional de Segurança do Paciente, no qual instituiu o Protocolo para Cirurgia Segura. Conclusão: É necessário mudar o paradigma da cultura da culpabilização para uma cultura justa diante dos incidentes relacionados aos cuidados em saúde para que a Lista de Verificação de Segurança Cirúrgica inserida nesse protocolo seja reconhecida e valorizada pelas equipes cirúrgicas.

Palavras-chave: Segurança do paciente. Cultura organizacional. Lista de checagem. Liderança.

RESUMEN: Objetivo: Analizar el papel determinante de la cultura de seguridad del paciente en el protocolo de adhesión de cirugía Segura del Ministerio de Salud realizadas por los equipos quirúrgicos en las organizaciones sanitarias. Método: Se trata de una reflexión teórica fundamental, basada en la revisión narrativa de la literatura científica. Resultados: El movimiento global de la seguridad del paciente promovido en 2004 por la Organización Mundial de la Salud, llevaron a la Segunda reto global "Cirugía Segura Salva Vidas", haciendo con que el gobierno brasileño pusiera en marcha, en 2013, el Programa Nacional de la Seguridad del Paciente, en el que ha establecido el Protocolo de Cirugía segura. Conclusión: Es necesario cambiar el paradigma la cultura de culpabilidad para una cultura justa delante de los incidentes relacionados con el cuidado de la salud, de manera que la lista de verificación de seguridad quirúrgica de ese protocolo sea reconocida y valorada por los equipos quirúrgicos.

Palabras clave: Seguridad del paciente. Cultura organizacional. Lista de verificación. Liderazgo.

INTRODUCTION

The concern about patient safety has been a reality for thousands of years, since Hippocrates (460 to 370 b.C.), when he said the maxim *primum non nocere*, understood as "first, do no harm." Although the authorship of this Latin principle is questioned, many scholars rely on it, because they consider that, since Ancient history, those who cared for the ill already had the perception that health care was not free from errors by the professionals¹.

In 2009, the World Health Organization (WHO) developed the International Classification for Patient Safety (ICPS), in which "patient safety" was defined as "the reduction of the risk of unnecessary harm in health care, to a minimum possible". Unnecessary harm was defined as "harm caused by or associated with plans or actions taken during the provision of health care".

Returning to history, in the course of the centuries, humanity has known an enormous development of increasingly complex care in the health area; however, with increasing demands, the potential for the occurrence of incidents increased, and there were also errors or human failures³. A classic example of this context is surgery, which has a history of just over 500 years, and, in the last 50 years, has been undergoing a consubstantial advancement in various aspects⁴.

On the other hand, a high percentage of the population does not enjoy the benefits of these advances, because the surgical services are unevenly distributed, as only 30% of the world population receives 70% of the extensive surgical treatments. The lack of access to high-quality surgical care is a major problem in much of the world, despite the fact that surgeries are lucrative to the countries, from an economic point of view, when it comes to saving lives and avoiding work disabilities⁵.

Although the surgical treatments aim at saving lives, the failures in safety and the uncontrolled risks during surgical care can cause harm, in many cases, irreparable to the patients.

In 2010, the WHO informed that industrialized countries reported the occurrence of major complications in 3 to 16% of the hospitalized patients. The permanent disability and death rates reach 0.4 to 0.8%. In developing countries, the studies reported mortality rate of 5 to 10% in extensive surgery. It is also estimated that at

least 7 million patients experience surgical complications each year and at least 1 million patients die during or after surgical treatment. This is causing significant public health implications⁵.

In Brazil, a systematic review of medical records of patients admitted in 2003 in three teaching hospitals in Rio de Janeiro indicated an incidence of adverse surgical events of 3.5%, and, of this percentage, 68.3% were considered avoidable⁶. One pilot study carried out in hospitals of Portugal showed adverse events related to surgical procedures in 27% of the total sample⁷.

In the developed countries, the proportion and the consequences of these events, both for the people and for the healthcare systems, are already known, including the high financial cost and increased morbidity and mortality. However, in developing countries, still few studies only exist, and there is little control by the regulatory agencies about the problems associated with surgeries.

For the patient safety experts, "the wrong surgical procedures, in the wrong site, at the wrong patient are events that should never occur". With the resources and the knowledge that the surgical area has today, this type of complication, classified as never event, or an event that should never occur, becomes unacceptable.

Decisive factors that commonly contribute to the occurrence of these serious incidents in surgical care are associated with the organizational and human structure, such as: inexperience of the surgeon, low hospital volume of surgery, excessive workload and fatigue of the professionals, inadequate technology, deficient intern supervision, failures in the communication among the professionals, time of the procedure, and administrative failures.

These factors are the dimensions of the patient safety culture that an organization sets up and reinforces over the years. But, there is another very solid aspect of the safety culture in the health area: it is the belief that the health professional is infallible and, thus, the incidents, with or without harm, are still hardly reported by the professionals, for their competence will be questioned.

In this sense, it is important to reflect on the need for the leadership in health organizations to strengthen the culture of patient safety as an inducer strategy in the implementation of guidelines and clinical and surgical protocols, in order to ensure health care free from harm to the patients.

OBJECTIVE

To analyze the decisive role of the patient safety culture and the importance of strengthening it in the organizational culture of the health institutions in order to improve the adherence to the Safe Surgery Protocol of the Ministry of Health (MH) by surgical teams in the health organizations of the country.

METHOD

This study is a theoretical and critical reflection on the decisive role of the patient safety culture in the adherence to the Safe Surgery Protocol/MS–RDC-36/2013 by the surgical teams in the health organizations from a narrative review of scientific literature about the worldwide movement of the patient safety and the current regulatory standards in the patient safety area of the Brazilian government.

The data collection period occurred from July to December 2014. In the search strategy, we included primary studies published in the period from 2004 to 2014 and indexed in the portal Evidence-Based Healthcare and CAPES Periodicals, using the keywords in Portuguese: segurança do paciente (patient safety), cultura organizacional (organizational culture), lista de checagem (checklist), and liderança (leadership), with the Boolean operator "OR."

The analysis of the extracted studies was completed and was based on the WHO publications and the regulatory standards of the Health Surveillance Agency (ANVISA) and on the general literature, such as books, dissertations, and theses, in order to comply with the proposed objective.

RESULTS AND DISCUSSION

Patient safety history: a worldwide movement

The development of the patient safety follows the evolution in medical and biological sciences in the course of human history, in which personalities ahead of their time left their contributions and discoveries, which led to the knowledge currently used. Some of these personalities are Hippocrates, Galen, Florence Nightingale, Ignaz Sammelweis, Louis Pasteur, Robert Koch, and Joseph

Lister. These names have left great legacies to patient safety, although many have had their theories and studies questioned and misunderstood by the scholars of that time¹⁰.

In the 20th century, the initiative to assess the results of the surgeries carried out by the American surgeon Ernest Codmam (1869–1940), which showed a concern for the safety of the surgical patient, stood out. Another professional who has a great contribution with his studies of evaluation of the quality-of-care provision was Avedis Donabedian (1919–2000), for whom the patient safety was a dimension of the quality in his study.

The retrospective study of the Harvard Medical Practice Study II, carried out in 1984 in New York by the researcher Lucian Leape and his colleagues, publicized the extent of the safety problems of the hospitalized patient. In a random sample of 30,000 medical records, 3.7% of the patients experienced some type of avoidable incident¹⁰.

However, the greatest advancement in studies, researches, and guidelines related to patient safety came from the report "To err is human: building a safer health system", published by the Institute of Medicine (IOM) in 1998, which estimated that between 44,000 and 98,000 Americans die every year owing to errors in health care¹.

After the publication of this report, others from IOM and the Institute for Healthcare Improvement (IHI) came. The campaigns such as 100,000 Lives Campaign and 5 Million Lives Campaign were launched, constituting initiatives that encouraged institutions worldwide to implement improvements in the patient safety and quality of care¹¹.

Thus, at the beginning of the 21st century, the patient safety agencies were created in the United Kingdom, Canada, Australia, and Denmark, which had, among other competences, the search for the dialog about quality and safety of the patient between the WHO and the government of these countries¹².

From this evidence and the magnitude of the patient safety issue, during the resolution of the 55th World Health Assembly in 2002, the WHO stirred the global movement for patient safety, formulating and launching the world campaigns: World Alliance for Patient Safety (2004), Clean is Safer Care (2005), and Safe Surgery Saves Lives (2008)¹³.

In Brazil, the control units of blood component infusions and prevention of hospital infections and the anesthesia services stood out as pioneers in measures and safe practices, which promoted the safety of patients¹⁴.

Among the specific actions and directed to the field of patient safety in the country, one can highlight initiatives promoted by the MH, such as the creation of the Sentinel Network, in 2002, and the System of Notification and Investigation in Health Surveillance (Vigipós) by the ordinance 1.660/2009¹⁵.

In this context, the MH established the National Patient Safety Program (PNSP), through the MS/GM 529 ordinance, of April 1, 2013. This program possess as an objective to contribute for the qualification of the assistance in healthcare establishments and according to the political agenda of the Member States of WHO¹⁴.

In the same semester in 2013, the MH has extended the PNSP guidelines through the Collegiate Board Resolution (RDC) 36/2013 of ANVISA, demanding from the health services the creation of the Patient Safety Center, in order to execute the Patient Safety Plan in Health Services. In addition, the six protocols of care were established: patient identification; prevention of pressure ulcer; safety in the prescription, use, and administration of medicines; safe surgery; practice of hand hygiene in health services; and prevention of falls¹⁶.

Safe Surgery Saves Lives — Second Global Patient Safety Challenge from WHO

Although surgical care has achieved important advances in the recent decades, the results of quality and safety in surgeries are different in every part of the world, which causes the complications of surgical care to become a major cause of death and disability in the world⁵.

According to data from 56 countries in 2004, the annual volume of extensive surgery was estimated between 187 and 281 million, which represented, approximately, one surgery for every 25 people per year. It is a large volume and with significant implications for public health, because serious adverse events are estimated to affect 3–16% of all the admitted patients⁵.

Given the importance of this worldwide public health problem, the WHO realized that there are at least four underlying challenges to improve surgical care worldwide, namely:

- 1. the need to recognize surgical safety as a public health problem owing to the high rates of adverse events and the high costs that these rates entail;
- the lack of access to basic surgical care in low-income settings, deficiency in infrastructure and equipment, and underfunding;

- reliable surgical practices, because the surgical site infections are among the most common surgical complications;
- 4. the problem is the surgical care itself, because an increase in its complexity elevates the clinical and surgical risks to the patient.

Considering this context, the WHO launched in 2008 the "Second Global Patient Safety Challenge" as a global program entitled Safe Surgery Saves Lives, which had as a general objective to solve these issues, in order to mitigate the adverse events of surgical care⁵.

In order to minimize the unnecessary loss of life and serious harm, the Safe Surgery Saves Lives program called for 10 basic and essential objectives for the surgical teams in all surgical procedures (Chart 1)⁵.

Seeking to improve the results of surgical care, the WHO established a core set of safety criteria, which contemplates four great areas that must have great progress

Chart 1. Essential objectives for safe surgery established by WHO (2009).

Objective 1: The team will operate on the correct patient at the correct site.

Objective 2: The team will use methods known to prevent harm from anesthetic administration, while protecting the patient from pain.

Objective 3: The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function.

Objective 4: The team will recognize and effectively prepare for risk of high blood loss.

Objective 5: The team will avoid inducing an allergic or adverse drug reaction known to be a significant risk to the patient.

Objective 6: The team will consistently use methods known to minimize the risk of surgical site infection.

Objective 7: The team will prevent inadvertent retention of sponges or instruments in surgical wounds.

Objective 8: The team will secure and accurately identify all surgical specimens.

Objective 9: The team will effectively communicate and exchange critical patient information for the safe conduct of the operation.

Objective 10: Hospitals and public health systems will establish routine surveillance of surgical capacity, volume, and results.

Source: World Health Organization (WHO). Second global patient safety challenge: safe surgery saves lives. Rio de Janeiro: Pan American Health Organization and Ministry of Health, National Health Surveillance Agency; 2009.

in order to improve the safety in surgery: prevention of infections in surgical sites; safe anesthesia; efficient surgical teams; and measurement of indicators of surgical care.

From the evidence of the results about these essential components of surgical care, the WHO established the Surgical Safety Checklist (SSC), which is a basic, simple, and practical tool that any team in the world can apply⁵.

The SSC, also called checklist by its creator, can be adapted and modified by adding other important and specific data, according to the specialty of certain surgeries, such as orthopedics, transplantation, and oncology⁹.

According to the WHO, this checklist in the operating room contains the essential components of surgical care and acts as a barrier to prevent human error; as a memory aid to improve the performance of the task and to standardize the tasks in order to facilitate the coordination of the surgical team; as a means to create and maintain a safety culture in the operating room; and as a support for quality control actions by hospital managers, government, and inspectors.

The Brazilian Society of Surgical Center Nurses, Anesthesia Recovery, Sterilization, and Center of Material Storage (SOBECC) states that "the WHO Surgical Safety List has been useful and used successfully in various environments" but, on the other hand, recognizes that its implementation and adherence from the professionals working in the Surgical Center (SC) requires commitment and adaptation.

One can observe that the recognition and adherence to this protocol by the SC professionals constitute a tool for team work, in order to provide a safe surgical care and free of harm to the patient.

Brazil Regulation: Safe Surgery Protocol — Annex 3 of the DRC 36/2013

In 2013, facing the global context boosted by WHO, the Brazilian government mobilized through ANVISA, the Department of Health Care (SAS), the Oswaldo Cruz Foundation (FIOCRUZ), the Supplementary Health Agency (ANS), and the Pan American Health Organization (PAHO) and joined the Safe Surgery Saves Lives, setting the Safe Surgery Protocol, attached to the RDC 36/2013. This addresses specifically the systematic use of SSC as a strategy to reduce the risk of surgical incidents⁵. It describes, in a didactic and explanatory way, the application of SSC, with the surgical care in the intraoperative period divided into three stages:

- 1. before the induction of anesthesia (entrance or sign in);
- 2. before surgical incision (surgical break or timeout);
- 3. before the patient leaves the operating room (exit or sign out).

This protocol is self-explanatory and has all the stages and items that the designated professional should follow and confirm with the patient and the surgical team, consisting of anesthesiologists, surgeons, and perioperative nurse. At each stage, the professional conducting the application of SSC should confirm if the team has completed its tasks before proceeding to the next step. If any checked item does not comply, the verification should be interrupted, and the patient should be kept in the operating room until the problem is solved.

For the creator of this checklist, Atul Gawande, its objective will not be reached if the execution is a mechanical task, if one of the professionals in the operating room just marks the items off the list. For him, it is necessary to have a culture of patient safety and team work consolidated in the institution⁹.

This protocol has, in its description, in addition to the SSC, the strategies of monitoring and the safety indicators in surgery, namely: percentage of patients who received antibiotic prophylaxis at the adequate time; number of wrong site surgeries; number of wrong patient surgeries; number of wrong procedures; in-hospital surgical death rate adjusted to risk, and adherence rate to the SSC.

However, for ANVISA, this protocol is not a regulatory device but a tool to be used by the surgical team in order to improve the safety of its activities and reduce surgical deaths and unnecessary complications.

Strengthening Patient Safety Culture: a strategy to ensure the adherence to the Safe Surgery Protocol

In this complex and dynamic scenario of surgical care, in which the potential for the occurrence of incidents, errors, and failures to the patient is high, the safety culture gains prominence and importance, as we understand it according to the following concept: "the result of values, attitudes, perceptions, abilities and individual and group behavior patterns, which determine the commitment, style and proficiency of the health administration regarding the patient safety management"¹⁸.

On the other hand, the safety culture paradigm still present seeks to find a culprit when a human error occurs, aiming to banish the person from the organization, setting up very archaic organizational culture structures. The blame culture must change, following the example of other areas where the risk to human life is high, such as the nuclear industry, commercial aviation, motor racing, space engineering, and others, which have been an example for the health area¹.

Thus, to implement the WHO program Safe Surgery Saves Lives in a health-care organization that provides surgical care, one must do more than just applying a checklist of flow and steps of the anesthetic–surgical procedure. A change in the patient safety culture is essential so that all the professionals in the surgical team and the organization management comprehend the need and benefits of this protocol for all the people involved.

It is only recently the understanding that the health sector should take ownership of the concepts and techniques of the safety culture was adopted in the High Reliability Organizations (HRO), known traditionally as organizations that efficiently manage the high risks of work processes in complex and dangerous areas, with the aim of mitigating the risk of incidents and adverse events³.

Among some aspects of how the HROs deal with errors, we highlight: anticipation and risk awareness; sense of fallibility, ability to learn from mistakes; reluctance to simplify (create shortcut); involvement of everyone in the security practices; and resilience or constant redesign of the system¹².

The relevant changes at the organizational level that health institutions should carry out, in the attempt to come closer to the characteristics of the HROs, considering the improvement of the safety area, consist in the commitment of leaders to disseminate the idea of change in behavior and organizational culture, in the search for a safety culture anchored in trust, report, and search for improvement, adopting robust process analysis tools, of root cause and others, to identify the causes and magnitude of the incidents¹⁹.

Another relevant aspect is the role of the leaders or supervisors on the ends of the services. They should direct their leadership behavior patterns to a paradigm shift, seeking to promote a safety culture that embraces and values the motivations, attitudes, perceptions, and behaviors, which determine the commitment to patient safety¹².

We also add a component of the human factor and decisive to the safety culture in the HROs, very evident

inside the SC units: the high gradient level of authority and high hierarchy, which often undermine the communication between the professionals of the surgical team and commonly increase the risk of incidents.

The organizations that have a robust and consolidated patient safety culture seek to maintain these gradient levels of authority and hierarchy low; in other words, there is not much a psychological distance between a professional at the extreme and the supervisor of a team¹. In the SC units, this characteristic is very obvious, because of the significant presence of professionals specialized in surgery and, on the other hand, of technical level professionals.

There are also many strategies to promote the patient safety culture already experienced and disclosed, such as executive walk round, program TeamSTEPPS®, and interdisciplinary round, besides the evaluation of the existing safety culture in the organization, which can be replicated in the form of strategies to improve or strengthen the safety culture in the organization.

According to WHO, health organizations need to consolidate a paradigm shift in the patient safety culture following these assumptions: to create a just culture, leaving behind the blame culture, where there is a balance between culpability and accountability and where the "systemic thinking" by James Reason²⁰ is adopted in the human error analysis; to create a culture of notification of incidents and errors, so that people report and notify the incidents and where there is a feedback to the professionals about the result; and to create a learning culture, in which professionals can learn from previous failures, which are always in the organization's memory.

It is essential for the patient undergoing surgical care that the anesthetic–surgical procedures occur with better quality and that the possible errors are mitigated by a patient safety culture that supports the implementation of the Safe Surgery Protocol from the MH.

FINAL CONSIDERATIONS

Since Ancient history, the society has established as a professional ethics in the care for the ill people the principle of nonmaleficence, when stating *primum non nocere* for those caring for their patients.

This assumption corresponds to the principles of the Unified Health System (SUS), providing assistance in all the levels

of health care and regulating the health services in Brazil. Consequently, the patient safety during the surgical care, established as a government policy, should be implemented and monitored with the same strictness in all the health services, whether public or private, associated or not with SUS.

Although there is no single solution to improve surgical safety, it is important to emphasize how necessary a surgical care in a multidisciplinary team is, with team work, disciplined and supported by an organizational culture, with the patient safety recognized and valued by all the leaders.

The leadership and the professionals must also understand that the practice of the safe surgery is an indicator of quality of the provided care and that the beneficiaries are not only the patients and their family but also all the members of the multidisciplinary team and the health organization itself.

What we cannot tolerate is that avoidable harm, arising from the steps of surgical care, keeps happening without a movement of change or consolidation of the patient safety culture being constructed within the country's health organizations.

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