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National self-assessment process of patient safety practices in service, from 2016 to 2019: an analysis from the perspective of health surveillance

Processo de autoavaliação nacional das práticas de segurança do paciente em serviço de saúde, de 2016 a 2019: uma análise sob a óptica da vigilância sanitária

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ABSTRACT

Introduction: The completion of the Self-Assessment Form for Patient Safety Practices is carried out annually by health services with ICU beds and involves the assessment of structure and process indicators, based on the Resolution of the Collegiate Board of Anvisa No. 36, July 25 2013. **Objective:** To analyze the national self-assessment process carried out by Anvisa from the perspective of surveillance, in the period from 2016 to 2019. **Method:** The information that was common to four reports was analyzed and compared. **Results:** increase in the participation of self-rated hospitals over the years; the goal foreseen in the Integrated Plan was not reached and the process indicators showed less conformity than the structure. **Conclusions:** There is an urgent need to implement strategies of the National Health Surveillance System, both to sensitize managers about the importance of self-assessment of patient safety practices, and to implement improvements in services, as well as consistent public policies. aimed at ensuring quality health care for the Brazilian population.

KEYWORDS: Patient Safety; Intensive Care Units; Health Service; Anvisa

RESUMO

Introdução: O preenchimento do Formulário da Autoavaliação das Práticas de Segurança do Paciente elaborado pela Anvisa é realizado de forma voluntária e anual serviços de saúde com leitos de UTI e envolve a avaliação de indicadores de estrutura e processo, baseada na Resolução da Diretoria Colegiada da Anvisa nº 36, de 25 de julho de 2013. **Objetivo:** Analisar o processo de autoavaliação nacional realizado pela Anvisa sob a óptica da vigilância, no período de 2016 a 2019. **Método:** Realizou-se um estudo retrospectivo, de análise documental no qual foram analisadas e comparadas as informações que eram comuns em quatro Relatórios da Autoavaliação das Práticas de Segurança do Paciente em Serviços de Saúde. **Resultados:** Observou-se que houve aumento da participação dos hospitais da autoavaliação ao longo dos anos; que a meta prevista no Plano Integrado não foi alcançada; e que os indicadores de processo apresentaram menor conformidade que os de estrutura. **Conclusões:** Urge a necessidade de implementação de estratégias do Sistema Nacional de Vigilância Sanitária tanto para sensibilizar os gestores sobre a importância da autoavaliação das práticas de segurança do paciente, quanto para a implementação de melhorias nos serviços, bem como de políticas públicas consistentes que visem garantir assistência à saúde de qualidade para a população brasileira.

PALAVRAS-CHAVE: Segurança do Paciente; Unidades de Terapia Intensiva; Serviço de Saúde; Anvisa

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INTRODUCTION

Since 2016, the National Health Surveillance System (SNVS), led by the Brazilian National Health Surveillance Agency (Anvisa), annually carries out a National Assessment of Patient Safety Practices in health services with intensive care unit beds (ICU), through a self-assessment of structure and process indicators by hospitals, which is based on Anvisa's Collegiate Board Resolution (RDC) 36, of July 25, 2013[1], which institutes the actions of Patient Safety in Health Service. This evaluation process is carried out within the scope of SNVS, following what is foreseen in the Integrated Plan for the Sanitary Management of Patient Safety in Health Services - Monitoring and Investigation of Adverse Events and Evaluation of Patient Safety Practices[2].

The Plan is an SNVS guideline for improving the quality and safety of health services offered in Brazil, with the reorganization of monitoring and incident investigation practices, optimizing the resources available to face the problem, establishing and sustaining a culture of security within the system. Anvisa defines the instrument as an important strategy for the promotion of a culture of safety in the institutional environment, a new perspective on health care, emphasizing risk management, improving quality, and applying good practices in health services, in an educational and non-punitive way[2].

For the World Health Organization (WHO), patient safety corresponds to reducing the risk of unnecessary harm associated with health care to the minimum acceptable, a concept also adopted by Brazil[3]. The National Patient Safety Program (PNSP)[3], established in Brazil in 2013, aims to prevent and reduce the incidence of adverse events related to assistance in health services. These events cause damage to patients and losses associated with health care, resulting from processes or structures of care that must be constantly evaluated, in order to identify the most critical processes and, therefore, with a greater probability of occurrence, so that it is possible to develop effective prevention actions[4].

The official document generated by the self-assessment process carried out under SNVS, the Self-Assessment Report on Patient Safety Practices in Health Care (RAPSPSS), includes information provided to SNVS by hospitals in the country about their level of adherence to practices based on evidence of safety and adequacy to PNSP criteria. This document is intended to be a portrait of the way in which Brazilian hospitals are taking care of patient safety. It is not a mandatory evaluation and is focused on health services with care for critical patients, that is, institutions that have ICU beds[5,6,7,8].

Studies that use self-assessment are common in the area of patient safety but they are more focused on self-assessment by professionals regarding their knowledge, skills, and attitudes related to safe practices[9,10,11,12,13,14,15]. A Brazilian study developed and validated a script for self-assessment of patient safety centers (NSP) composed of 47 items, with nine for the structure domain and 38 for the NSP process[16], which can be a useful tool for self-assessment of all health services, not just those with an ICU. Although they have different focuses, the perception of all researchers is that self-assessment is useful both for establishing situational diagnoses and for designing strategies that aim to expand the culture of patient safety in institutions[9,10,11,12,13,14,15,16].

An American survey used the self-assessment tool on several aspects of structure and processes in eight rural hospitals. In it, the information supported organizational and clinical changes aimed at preventing errors and improving safety[17].

The organization of information about patient safety is an important strategy for the quality of health services and must be constantly used to make decisions that aim to meet the needs and expectations of the health system and the population, whether in the scope of health services, whether from the perspective of the SNVS. Based on this assessment, a patient safety plan must be developed and implemented, in accordance with current health legislation, RDC No. 36/2013[1], containing risk management strategies and actions related to activities developed by the health service[8]. Thus, it is not enough to present the situational diagnosis if improvement actions are not implemented after each assessment, especially when the topic is the safety of health service users.

In this sense, a systematic analysis of the process of self-assessment of patient safety practices in health services carried out in Brazil within the scope of SNVS over the years and the main results presented becomes relevant. Therefore, this study aimed to analyze the results of the national self-assessment process led by Anvisa in the period from 2016 to 2019.

METHOD

This is a descriptive, retrospective study of documentary analysis of the RAPSPSS from the years 2016 to 2019.

Study object

The RAPSPSS are the result of a partnership between the Health Services Surveillance and Monitoring Management (GVIMS) and the General Management of Technology in Health Services (GGTES) of Anvisa, with the State and District Coordinations of NSP of the country, which are allocated to State and District Health Surveillance. The reports are a compilation of the results of the cross-sectional study carried out each year using an electronic form prepared by Anvisa and therefore correspond to the situation of health services in the study period[9].

According to the reports, data sent by priority hospitals in Brazil were considered eligible for analysis of the results, that is, hospitals that have ICU beds, as defined in the Integrated Plan for the Sanitary Management of Patient Safety in Health Services[9]. After filling in by the hospitals and before sending to Anvisa, the data are checked by NSP State and District Coordinations, following

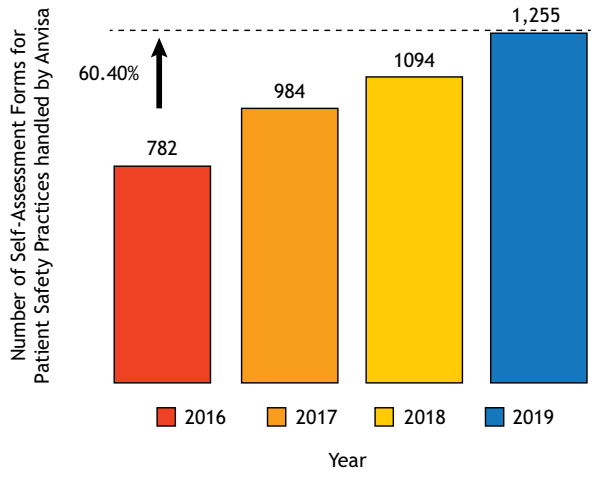
Source: GVIMS/GGTES/Anvisa – RAPSPSS 15[5], 19[7], 20[8] e 21[6].

Figure 1. Structure and process criteria (C1 to C21) assessed in the Self-Assessment process of Patient Safety Practices in Health Services in the years 2016 to 2019. Highlighted in yellow are the added criteria, which did not appear in previous years and started to appear in the following years.

the guidelines contained in the Instruction for the Analysis of the Self-Assessment of Patient Safety Practices[2].

In the report, data are presented from the calculation of the composite indicator of adherence to safety practices, classified by the SNVS as high compliance (67%-100% compliance of the composite indicator of adherence); average compliance (34%-66% compliance of the composite adherence indicator); and low compliance (0%-33% compliance of the adhesion indicator)[5,6,7,8].

The structure and process criteria evaluated in Anvisa's reports are described in Figure 1. A total of 15 in 2016[5], 19 in 2017[7], 20 in 2018[8], and 21 in 2019[6] were analyzed. The criteria are based on RDC No. 36/2013[1].



Source: GVIMS/GGTES/Anvisa - RAPSPSS 15[5], 19[7], 20[8] e 21[6].

Figure 2. Number of Self-Assessment Forms for Patient Safety Practices handled by Anvisa in the years 2016, 2017, 2018 and 2019.

Data collection and analysis

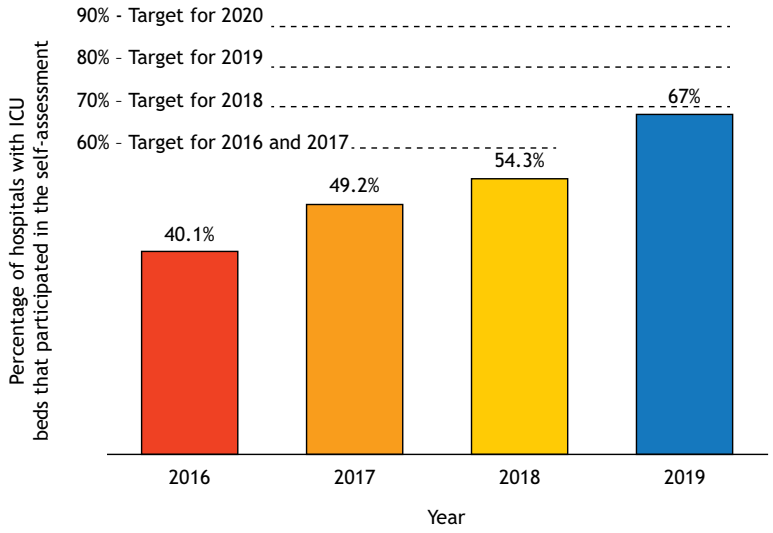
In the present study, information that was common to the four reports issued by Anvisa was analyzed and compared, namely: the number of participating hospitals with ICUs in the country; the level of compliance by hospitals with 15 evaluation criteria; the percentage of bed disposition according to hospital size; goal foreseen in the Integrated Plan; federative units that reached the goal of the year; list of hospitals with adult ICU beds classified as having high adherence to patient safety practices; criteria that presented higher or lower relative frequencies of compliance or non-compliance with practices and which ones were analyzed and/or added throughout the year.

The Excel® program was used to arrange the data and perform descriptive statistics. As for the ethical aspects, this work analyzes public data, which were made available by Anvisa in an aggregate way, and it is not possible to identify the source that generates the information, maintaining the confidentiality of the data. Thus, it does not require prior authorization by the Research Ethics Committee, as it is in accordance with the Resolutions of the National Committee of Ethics in Research (Conep) No. 466, of December 12, 2012, and No. 510, of April 7, 2016.

RESULTS AND DISCUSSION

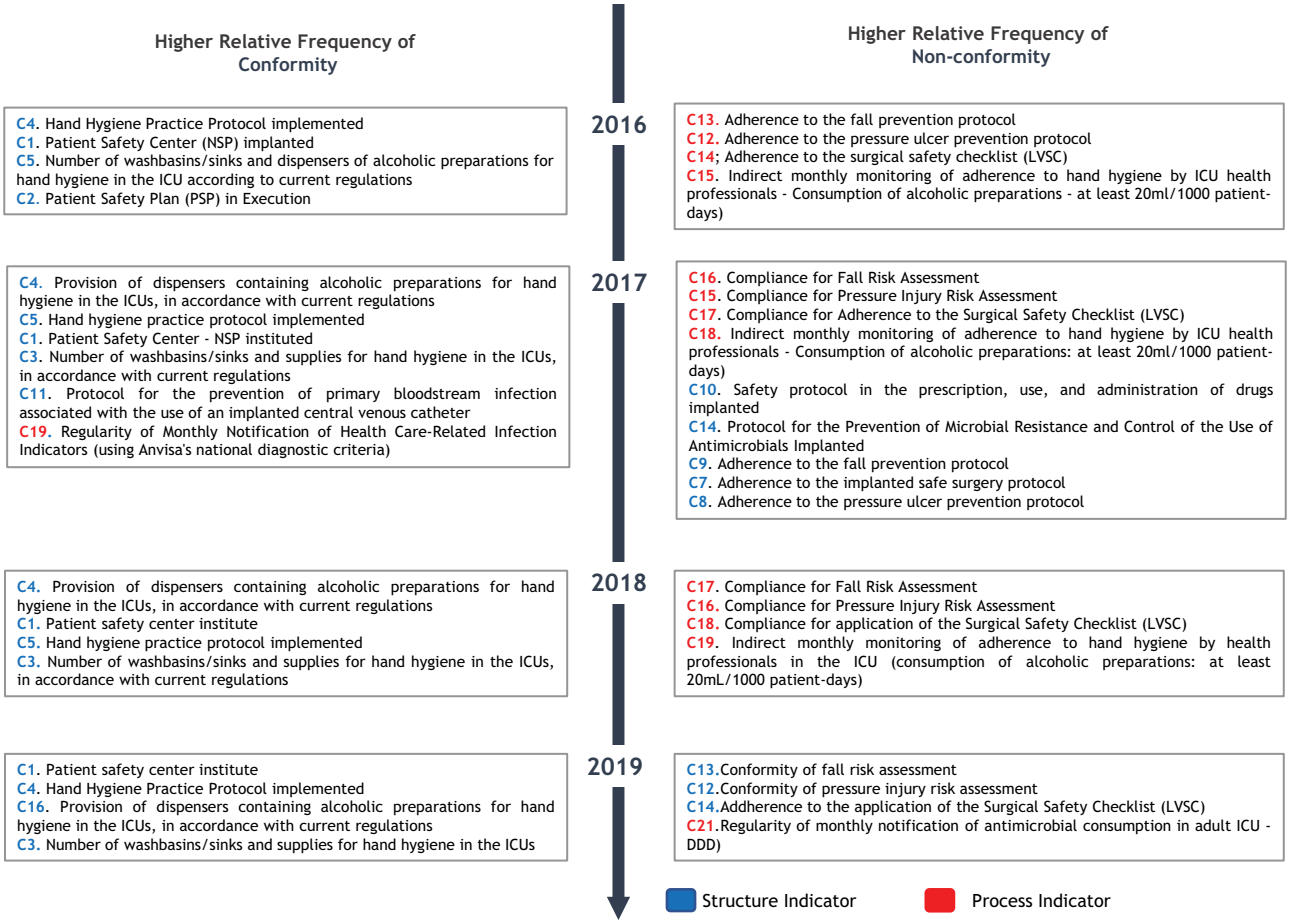
Regarding the number of self-assessment forms of patient safety practices analyzed by Anvisa, there was an increase of 60.40% since the beginning of the process instituted by the Agency, with a gradual increase in the participation of hospitals in the initiative from one year to the next (Figure 2).

The increase in the submission of forms represents a greater interest of hospitals with ICU beds to participate in the



Source: GVIMS/GGTES/Anvisa - RAPSPSS 15[5], 19[7], 20[8] e 21[6].

Figure 3. Percentage of hospitals with ICUs that participated in the self-assessment in 2016, 2017, 2018, and 2019 in relation to the total number of hospitals with ICU beds.



Source: GVIMS/GGTES/Anvisa – RAPSPSS 15[5], 19[7], 20[8] e 21[6].

Figure 4. Structure and process criteria (C1 to C21) evaluated in the Self-Assessment process of Patient Safety Practices in Health Services that presented the highest relative frequencies of compliance and non-compliance with patient safety practices in the years 2016, 2017, 2018, and 2019.

process, which may have been due to the incentive to be included in the positive list of hospitals with high adherence, which is released after each cycle of self-assessment and that contains the list of hospitals that present results of high adherence to safety practices. The incentive to increase the participation of hospitals can also be the result of the dissemination of the process over the years, as well as the direct action of local Health Surveillance (Visa) with hospitals, in order to make them aware of the importance of continuous improvement to qualify health care.

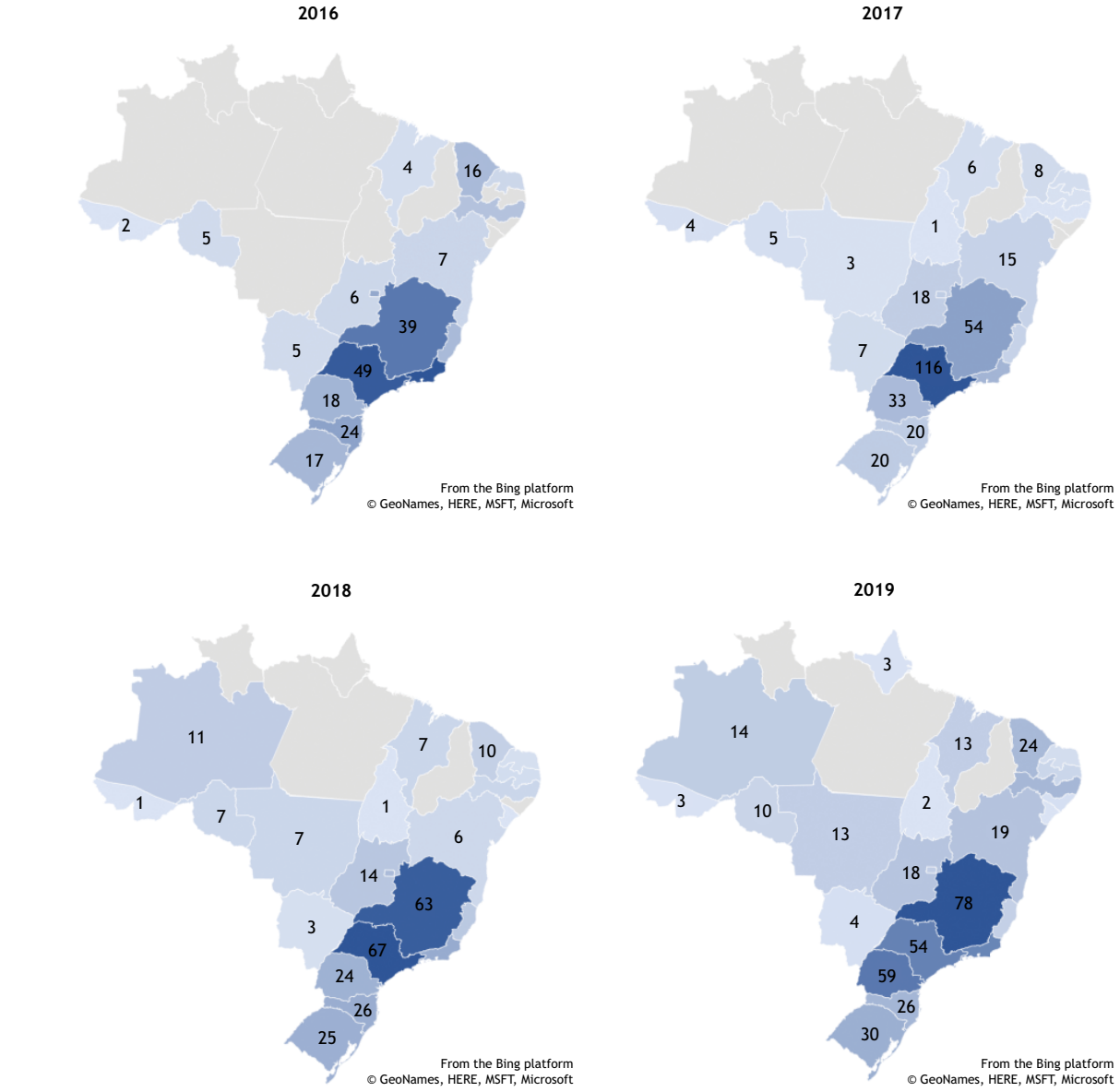
Although this result can be considered quite positive, the target set in the Integrated Plan for the Sanitary Management of Patient Safety[2] of achieving 60% in 2016 and 2017, 70% in 2018, and 80 % in 2019 of hospitals with ICU beds in the country responding to the instrument (Figure 3). Failure to reach the goal may be related to the voluntary nature of the process, that is, there is no obligation for hospitals to carry out their self-assessments.

As noted, there was an increase in the percentage of participating hospitals, but the below-expected result indicates that there should be an increase in efforts to disseminate self-assessment, both by Anvisa and by other SNVS actors. Among the efforts, it is important to assess whether regulatory measures would be adequate as an evolution of this process, such as making the participation of all Brazilian hospitals in the evaluation mandatory, since PNSP established the process of qualifying health care as mandatory[3].

One way to expand the voluntary participation of hospitals in self-assessment is to disseminate the positive list among health managers, as well as the assessment instrument. Top management support is critical to improving the patient safety culture and NSP performance[18,19].

Additionally, making the report more friendly to the different levels of functional health literacy or even publishing a version aimed at the citizen could encourage social control of the quality of care offered by hospitals, which should apply methodologies capable of placing the user at the center of the system, as a subject aware of their rights and duties, and not as an object[20].

From the point of view of public health policies, coordinated action within the scope of the national program, with greater



Source: GVIMS/GGTES/Anvisa.

Figure 5. Number of hospitals that showed high adherence to safety practices in the years 2016 to 2019.

rigor in the evaluation of health results for compliance with sanitary standards, and a policy of recognition of the quality of services provided with differentiated remuneration to hospitals with high adherence to good practices in patient safety[21], are other forms of incentive.

The operationalization of this measure should be discussed extensively within the scope of the PNSP Implementation Committee[3], a body formally constituted with reference institutions in the matter and led by the Ministry of Health and Anvisa. However, the committee was extinguished by a Presidential Decree of the year 2019 and was not recreated, as would be possible, according to the same legal instrument[22]. The fact that patient safety was considered a global public health priority during the 72nd World Health Assembly in 2019[23] and Brazil is a signatory to the initiative consistently justifies the re-creation of the committee. In the opportunity, its composition must be defined according to the multidisciplinary vision that the subject requires, as well as with different bodies and institutions that work with the theme and also those capable of modifying the current conditions through the implementation of public policies that enable actions coordinated for the improvement of health services in the country.

Patient safety, as a global public health priority[23], should be a state policy and not a government program. It must be a continuous action for the evaluation and monitoring of health results, which need well-established structure and processes[11,24] in order to enhance favorable outcomes and minimize unfavorable ones, especially avoidable adverse events.

In the self-assessment process, the object of this study, Anvisa and the other SNVS actors chose to define that adherence to patient safety practices would be measured by assessing structure and process indicators. Over the years, there were few variations among the 15 criteria evaluated in the present study and which are common to the four reports, when comparing those that represented the highest relative frequencies of conformities (greater adherence) and non-conformities (less adherence) to the practices of patient safety (Figure 4).

It was observed that the indicators related to safety practices that achieved greater compliance in the four years, 2016 to 2019 were those of structure (highlighted in blue): C4 (Hand hygiene practice protocol implemented, 2016)[5]; C4 (Provision of dispensers containing alcoholic preparations for hand hygiene in the ICU, according to the current regulations, 2017 and 2018)[6,7]; and C1 (NSP instituted, 2019)[8].

The indicators with the lowest adherence were those related to the process (highlighted in red): C13 (Adherence to the fall prevention protocol, 2016)[5]; C15 (Compliance for pressure injury risk assessment, 2017)[6]; C17 (Conformity for the fall risk assessment, 2018)[7]; and C13 (Conformity of the fall risk assessment, 2019)[8].

Structure indicators are the basis for achieving expected results, but they must be accompanied by processes based on best practices, on scientific evidence, such as the risk classification for health incidents, which are fundamental to guide risk management, with actions to prevent an adverse event from occurring during patient care. Falls, for example, can be minimized with the appropriate risk classification on admission and in the transition of care, when preventive measures are taken for this incident. In a study in a Brazilian private hospital, falls with damage represented 43% of the total number of events, with about 20% of them considered to be of moderate and severe damage[25], which reinforces the importance of prevention of this type of event for the quality of health care.

The low adherence to the risk assessment for pressure injuries also drew attention in this study. Measures are no longer taken if the risks are not previously identified. Once unidentified, adverse events can have direct consequences and sometimes increase costs to the health system and are not even identified. A Brazilian study found that 96.7% of the injuries identified in the medical records were not duly notified by the passive health incident surveillance system, the type of system most used in Brazil and in the world[26]. Perhaps the use of an electronic notification system in hospitals will facilitate the reporting by health institutions, which has already proved to be advantageous in relation to the manuscript[27].

According to Berwick[28], it is necessary to analyze, monitor, and learn from information about quality and patient safety. In addition to diagnosing problems, it is necessary to identify opportunities and seek solutions to improve services[29]. It is necessary to check why the structures exist, but the processes are not fulfilled. It is important to assess whether the existing NSPs are fulfilling their role of supporting the direction in the implementation and management of actions to improve quality and patient safety, but also if managers are willing to favor the implementation of patient safety plans that should be implemented, according to health legislation[1].

Health professionals reported a lack of support from the leadership[30] when they identified possibilities for improvement in their work environments, which can impact the patient's safety climate and, consequently, the effective compliance with protocols that avoid adverse events. However, the implementation of these actions is a minimum condition to move towards safer assistance.

The criteria for compliance with patient safety evaluated were demonstrated in the Anvisa report through the Diagram based on the Pareto Principle, which allows prioritizing problems. Its greatest utility is to allow easy visualization and the identification of the most important causes or problems, allowing the concentration of efforts on them[4].

During the period from 2016 to 2019, there was only the publication of a guiding document by Anvisa, which could guide the hospitals participating in the research to improve the indicators evaluated in the reports. This document dealt with Safe Practices for the Prevention of Pressure Injury in healthcare services[31], published in 2017. Anvisa published a technical note with data that, in that year, 72.6% of the adverse events were due to pressure injury stage 3 (loss of skin in its total thickness, in which the adipose tissue is visible without exposure of fascia, muscle, tendon, ligament, cartilage, and/or bone) and 22.0% resulting from pressure injury stage 4 (loss of skin in its full thickness and tissue loss with direct exposure or palpation of the fascia, muscle, tendon, ligament, cartilage, or bone). Together, they represented about three thousand notifications.

Still, the document points out that 34 Brazilians lost their lives as a result of the pressure injury, from January 2014 to July 2017. This adverse event is classified as *never event*, that is, serious adverse events that should never occur in health services[2]. This type of event should be investigated immediately by SNVS[2] and improvements should be requested to health facilities. The technical note was intended to guide managers and professionals working in the NSP of health services for general measures of surveillance and monitoring of adverse events, especially pressure injuries, but it seems not to have been enough to avoid low compliance with the risk assessment for pressure injuries, which continued as one of the requirements with the lowest adherence in the subsequent years, 2018 and 2019.

These results point to the need to combine educational measures with health surveillance, as well as public policies that, in fact, encourage institutions to continually seek better health outcomes, as previously discussed.

Institutional managers should be encouraged to promote improvements in the various aspects of patient safety, not only through health surveillance inspection interventions. One way is a change in the health compensation process that encourages reimbursement for quality, due to favorable health outcomes. The current fee-for-service model is not the best way to stimulate investments in quality[27] and to promote changes that generate value in health, that is, the relationship between the results obtained and the cost to achieve them[32].

Finishing the evaluation of the results of the reports, it was possible to observe an increase over the years in the total number of hospitals with adult, pediatric, or neonatal ICU beds that showed high adherence to patient safety practices (Figure 5), which are those who achieved high compliance with the evaluated structure and process indicators (67-100% compliance). In addition, the number of regions participating in the process increased, which, considering the increase in hospitals that participated in the evaluation, expands the country's perspective for access to safer care.

Such result makes it possible to affirm that the self-assessment encouraged hospitals to evaluate their practices for patient safety, even if it is not a mandatory process, nor does it generate wider economic and social consequences than the simple possibility of recognition in a positive list disclosed to those interested in the subject matter.

The success of the strategy to promote the self-assessment process within the scope of the SNVS reinforces the role of Visa distributed throughout the country, which is involved in decentralizing the dissemination of the process and in the collection and verification of information provided by hospitals. It demonstrates that Visa goes far beyond meeting the formal demands of regulated segments with little or no link to the health system[33].

Finally, it should be noted that the analysis of the consolidated data of the reports over the years was a limitation of this study, however, we believe that it was possible to verify SNVS's role of educator and health promoter, which fills the gap due to the absence of consistent public policies that encourage continuous improvement in the quality of health care for the Brazilian population.

CONCLUSIONS

In the present study, it was verified that the self-assessment instrument of patient safety practices has been gradually increasing the participation of health services with ICU beds, as well as a proportional increase in adherence to patient safety practices. However, the participation targets of hospitals with ICU beds in the country responding to the instrument have not yet been reached, in addition to the existence of important indicators of structure and processes with low adherence by hospitals.

Despite this, there is an urgent need to implement SNVS strategies in order to sensitize health service managers about the importance of self-assessment of patient safety practices as a potentializing tool for improving the quality of care provided in health services and reducing waste of resources in health, as well as consistent public policies that aim to guarantee quality health care for the Brazilian population.

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Author's Contributions

Tsai J –Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. Pontes LCF - Data interpretation and writing of the work. Capucho HC - Conception and planning (study design), analysis, data interpretation, and writing of the work. All authors approved the final version of the work.

Conflict of Interests

The authors inform that there is no potential conflict of interest with peers and institutions, politicians, or financial in this study.