Reliability of patient safety self-assessment practices established by the National Health Surveillance System: a pilot study

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Resumo: **Introduction**: The Patient Safety Self-Assessment Practices is a regulatory action to enhance quality of care. However, validation of its information requires attention. This study aimed to analyze reliability of the Patient Safety Self-Assessment Practices. **Methods**: Pilot study analyzing the reliability of 21 simple indicators and 1 composite of self-assessment to provide a national sample in future studies. Hospitals with intensive unit care beds participated in the study, and data from self-assessment (SA) and revised self-assessment (RSA) by the health surveillance (HS) were compared with on-site inspection (OSI). Analyses included Kappa and intraclass correlation coefficients. **Results**: Concordance was satisfactory (Kappa ≥ 0.4) in 12 indicators of SA and 18 indicators of RSA compared with OSI. The least reliable indicators were related to infection prevention protocols. Reliability of the adherence level composite indicator improved with HS revision (SA = 0.89 and RSA = 0.94), despite the low concordance of the high compliance classification. **Conclusion**: RSA was essential to improve reliability of SA. In addition, some indicators and assessment tools of the HS need revision.

➤ **Palavras-chave:** Health surveillance. Patient safety. Health regulation and supervision.

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Introduction

Millions of people around the world suffer damages during the health care process. This problem in developing and developed countries leads to high morbidity and mortality and represents 23 million life-years lost annually (JHA *et al*., 2013). Thus, investments for improving health care systems and safety of people who have access to health care services are needed to change this scenario and minimize risks (WHO, 2018).

According to international recommendations, Brazil established the National Patient Safety Program in 2013 to "contribute to health care qualification in all health facilities of the national territory" (BRASIL, 2013a). To exert its role as a health service regulator, the National Health Surveillance Agency (ANVISA) published health standards in 2013 (BRASIL, 2013b) and the Management of Patient Safety in Health Services Integrated Plan in 2015 (BRASIL, 2015). The plan aims to incorporate National Health Surveillance System (NHSS) actions to induce health facilities to adopt patient safety practices and monitor and investigate adverse events.

The Patient Safety Self-Assessment Practices was created to monitor the adoption of safety practices, guide health surveillance operations at the three levels of actions of the NHSS, and encourage improvement actions in services with intensive care unit (ICU) beds (BRAZIL, 2015). Self-assessments in health services are a potentially useful regulatory strategy to improve healthcare quality (HEALY; BRAITHWAITE, 2006). This initiative to minimize risks may enhance performance of the NHSS and change its normative and authoritarian role into a health protector of the population (SANTANA et al., 2020). In addition, the self-assessment is part of a responsive regulation approach since regulators also implement non-normative initiatives to produce regulatory impacts and improve quality of the regulation process. It is a meta-regulation action in which the regulator induces self-regulation based on assessment for the management (KOLIEB, 2015).

Self-assessment (SA) data are revised by the national, state, and municipal health surveillance (HS), which verifies information before publishing results. However, the society, regulated sector, health professionals, and HS may question the reliability of information reported by health services (BRASIL, 2015). Reliability is an essential attribute for quality indicators (BARCLAY; DIXON-WOODS; LYRATZOPOULOS, 2019; MAINZ, 2003), similar to SA, which contains 21 simple

and 1 composite indicator. The composite indicator is of main interest because the NHSS discloses services classified as highly compliant with patient safety practices.

Although the Patient Safety Self-Assessment Practices is a promising regulatory practice applied annually, its reliability has not yet been analyzed. Knowledge regarding reliability strengthens trust between the regulated sector and regulatory body and consolidates this strategy for improving patient safety.

This pilot study aims to analyze reliability of the Patient Safety Self-Assessment Practices as measure for monitoring risks in health services. In this sense, this research may provide a national sample for future studies.[1]

Methods

Background

This study results from an academic master's thesis conducted during 2019 in collaboration with the Sub Coordination of Sanitary Surveillance (SUVISA/RN) and the Graduate Program in Collective Health of the Federal University of Rio Grande do Norte).

The Rio Grande do Norte state (RN) had 29 services with adults, pediatric, or neonatal ICU beds, and 27 of these (97%) responded to the self-assessment in 2019. The RN and other states reached the goal regarding participation in the assessment in 2019 (80%) and stayed above the national average (67%). Among services that responded, five were classified as highly compliant with patient safety practices because they met at least 67% of indicators.

Study design

This validation study analyzed the reliability (MEDRONHO, 2009) of information sent by hospitals that participated in the Patient Safety Self-Assessment Practices and compared with data obtained in the on-site inspection (OSI) conducted by the HS.

Population and sample

The study population included public, private, or philanthropic hospitals with ICU beds in the RN state that completed the Patient Safety Self-Assessment Practices Form in 2019.

We used a non-proportional stratified random sampling considering the high compliance (yes or no) stratification variable. The list of participants in 2019 provided by SUVISA/RN and strict for research purposes was used as data source. Ten hospitals (n) were selected from a total of 27 (N) services that responded to the self-assessment. This sample corresponds to 37% of the population, five with high adherence to safety practices and five that did not achieve high adherence. The number of cases was defined using feasibility analysis and considering the research as pilot study. Exclusion criteria were applied to services in which information was incomplete or impossible to collect.

Study variables

The following variables regarding adherence level to safety practices, according to results of the self-assessment, revision (RSA) by HS, and OSI, were included: compliance (yes or no) with the 21 criteria or simple indicators; compliance with the adherence level composite indicator (percentage of compliant indicators = number of compliant indicators / 21 x 100); and high compliance (yes or no), based on compliant indicators ≥ 67% (BRASIL, 2019a).

The following variables characterized hospitals: hospital ownership (public or private); type of administration (direct public, indirect public, for-profit, or non-profit private hospitals); quality management (yes or no); risk management (yes or no); presence of accreditation seal (yes or no); certification as teaching hospital (MEC/MS) (yes or no); inclusion in the Sentinel Network (yes or no); number of health professionals in the institution; municipality; size according to number of beds (small, up to 99 beds; medium, between 100 and 199 beds; or large, over 200 beds); number of ICU beds (adult, pediatric, or neonatal); and surgical procedures (yes or no).

Procedures and tools for data collection

SUVISA/RN provided SA and RSA data. Self-assessment responses were available in the FormSUS, completed in August 2019. RSA was consolidated in October 2019, when the "worksheet for the analysis of the Patient Safety Self-Assessment Practices Form – 2019" was completed (BRASIL, 2019b). The form was created by ANVISA and sent to the state HS. In this revision process, the state HS verifies documents sent by services and classifies the service.

For data collection in the OSI, a structured questionnaire was prepared based on the 21 indicators defined by ANVISA[2]. We also followed a script of activities (available online) performed before, during, and after the visit[3]. Before the inspection, the SUVISA/RN team contacted the service to schedule the visit and separated evidence documents (protocols, charts, and other documents). During the visit, Patient Safety Centers (PSC) and the Hospital Infection Control Committees were visited, and documents were revised (including medical records corresponding to indicators). The inspection was completed after a visit to the ICU, drawn in case of more than one ICU. Data were consolidated in the data collection instrument after inspection.

Structure indicators, such as number of lavatories and presence of alcohol-based hand solutions, were evaluated through direct observation of the ICU service. We also verified whether protocols or summaries were available and accessible to healthcare professionals. The researcher and municipal HS applied the instrument; all were blinded to compliance of indicators according to SA form, except for indicators from medical records. The form for registering OSI data was self-explanatory and created on the Google Forms platform to consolidate the database.

Information regarding variables was collected on the National Registry of Health Establishments website (BRASIL, 2019c) between August and November 2019 and during data collection at the OSI.

Data analysis

Reliability analysis was performed after a descriptive analysis of frequencies and measurements of central tendency and dispersion of indicators and variables that characterized hospitals. Compliance with SA and RSA indicators was compared with OSI, represented as gold standard.

Reliability of the 21 simple indicators and the composite indicator categorized in high compliance was calculated based on general agreement indexes (GAI) and Kappa coefficients, which presented a cutoff point of 95% and 0.40, respectively, according to Landis and Koch (1977). For the composite indicator measured as percentage of adherence, reliability was calculated using intraclass correlation coefficient (ICC), which had a cutoff point indicating good correlation values above 0.75. In addition, concordance was analyzed using Bland-Altman plots. Differences in compliance of

indicators were also evaluated. Significance level was set at 5% (α), in which null hypotheses were rejected when p-value was less than 0.05. Data were analyzed using the Statistical Package for the Social Sciences (IBM SPSS Statistics 22).

Ethical aspects

The study was approved by the research ethics committee (ID 3.360.654) and concluded according to recommendations.

Results

Sample characterization

Hospitals from four municipalities, representing the four largest health regions (Grande Natal, Mossoró, Caicó, and Pau dos Ferros) out eight in the state, composed the study. The number of public and private health services was the same. Four private hospitals were for-profit, and three public hospitals had direct administration. Seven of ten services were medium-sized, and the average number of health professionals in each establishment was 713. Most services claimed quality and risk management (70%), and no hospital had an accreditation seal. Table 1 details the characteristics of included hospitals.

Table 1. Sample characterization of hospitals included in the study. Natal-RN, 2019.

Qualitative variables	n
Hospital ownership	
Public	5
Private	5
Type of administration	
Direct public	3
Indirect public	2
For-profit	4
Non-profit	1

continue...

Qualitative variables	n
Quality management	
Yes	7
No	3
Risk management	
Yes	7
No	3
Accreditation seal	
Yes	0
No	10
Certified as teaching hospital (MEC/MS)	
Yes	3
No	7
Part of the Sentinel Network	
Yes	2
No	8
Performs surgical procedures	
Yes	10
No	0
Municipality	
Caicó	1
Pau dos Ferros	1
Mossoró	2
Natal	6
Size according to number of hospital beds	
Small (≤ 99 beds)	2
Medium (100 - 199 beds)	7
Large (≥ 200 beds)	1

continue...

Quantitative variables	Median / Mean	Interquartile range / Standard seviation
Number of health professionals in the institution	522 / 712.9	1,415 / 494.4
Total number of hospital beds	122 / 134.8	58.3 / 49.3
Number of adult ICU beds	9.5 / 2.0	4.8 / 6.0
Number of pediatric ICU beds	0 / 2.0	5 / 3.5
Number of neonatal ICU beds	0 / 5.5	11.8 / 8.4
Total number of ICU beds	19.5 / 17.7	14.3 / 7.4

Source: elaborated by the author.

Compliance of indicators according to different data sources

Results regarding compliance of indicators in the SA were overestimated compared with RSA and OSI. Regarding simple indicators, variation was high among levels of compliance, whereas one of the indicators showed compliance in the three data sources. Adherence to safety practices in SA was 83.5%, 54.8% in the RSA, and 35.8% in the OSI. Although SA revealed seven services with high compliance, RSA considered five, and OSI considered only one. Table 2 shows the percentage of compliance for each indicator according to different data sources (SA, RSA, and OSI).

Table 2. Compliance of Patient Safety Self-Assessment Practices indicators according to SA, RSA by HS, and OSI. Natal-RN, 2019.

Criteria	Self-assessment	Reviewed self-assessment	On-site inspection
	n	n	n
1. Patient safety center	9	9	9
2. Patient safety plan	8	3	3
3. Number of lavatories in the ICU	9	9	7
4. Availability of alcohol solution	9	9	7
5. Hand hygiene protocol	8	5	3
6. Patient identification protocol	9	5	3

continue...

Criteria	Self-assessment	Reviewed self-assessment	On-site inspection
	n	n	n
7. Safe surgical protocol	6	4	3
8. Pressure injury prevention protocol	8	3	2
9. Fall prevention protocol	6	4	4
10. Safe medication protocol	7	2	2
11. SSI due to ICVC prevention protocol	8	6	3
12. UTI due to IUC prevention protocol	7	7	4
13. VAP prevention protocol	8	7	2
14. SSI prevention protocol	6	3	0
15. Microbial resistance prevention protocol	5	2	0
16. Pressure injury risk assessment	6	6	4
17. Fall risk assessment	6	6	4
18. Full completion of the SSC	7	7	5
19. Indirect hand hygiene monitoring	5	3	3
20. Regular reporting of HAI	8	7	7
21. Regular notification of DDD of antimicrobials	5	3	3
% Compliance with Patient Safety Practices			
High	7	5	1
Not high	3	5	9
	Median	**Median**	**Median**
% Compliance with Patient Safety Practices	83.5	54.8	35.8

ICU: Intensive care unit; SSI: Surgical site infection; ICVC: Implanted central venous catheter; UTI: Urinary tract infection; IUC: Indwelling urinary catheter; VAP: Ventilator-associated pneumonia; SSI: Surgical site infection; SSC: Surgical safety checklist; HAI: Healthcare-associated infections; DDD: Defined daily dose.

Source: elaborated by the author.

Reliability estimates according to different data sources

Based on GAI cutoff point, when SA was compared with OSI, only one indicator was considered directly reliable (> 95%). In this comparison, eight indicators showed

relatively high GAI (> 80%). When comparing RSA with OSI, six indicators reached the maximum agreement value (100%), whereas ten indicators showed GAI > 80%. Regarding the high compliance indicator, agreement was 40% when SA was compared with OSI and 60% when RSA was compared with OSI. Table 3 presents reliability values for simple and composite indicators.

Regarding Kappa coefficient, 12 indicators from SA and 18 from RSA showed a satisfactory agreement (> 0.40) compared with OSI. Kappa coefficient was not calculated for indicators 14 and 15 in both comparisons due to lack of variability. Kappa coefficient of the composite indicator for classification of high compliance in SA was 0.10 compared with OSI, whereas RSA compared with the OSI was 0.20, indicating low level of agreement.

The ICC for percentage of adherence corroborated with agreement found in the classification of high compliance. Results showed excellent ICC values (> 0.75), indicating a strong correlation in the two comparisons (SA vs. OSI = 0.899 and RSA vs. OSI = 0.941).

Table 3. General agreement index (GAI), intraclass correlation coefficient (ICC), and Kappa coefficient of the Patient Safety Self-Assessment Practices indicators comparing SA, OSI, and RSA by HS. Natal-RN, 2019.

Criteria	Self-assessment vs. on-site inspection		Revised self-assessment vs. on-site inspection	
	GAI (%)	Kappa	GAI (%)	Kappa
1. Patient safety center	100	1.00	100	1.00
2. Patient safety plan	50	0.19	100	1.00
3. Number of lavatories in the ICU	80	0.41	80	0.41
4. Availability of alcohol solution	80	0.41	80	0.41
5. Hand hygiene protocol	50	0.19	80	0.60
6. Patient identification protocol	40	0.09	80	0.60
7. Safe surgical protocol	70	0.44	90	0.78
8. Pressure injury prevention protocol	40	0.11	90	0.73
9. Fall prevention protocol	80	0.61	100	1.00
10. Safe medication protocol	50	0.19	100	1.00

continue...

Criteria	Self-assessment vs. on-site inspection		Revised self-assessment vs. on-site inspection	
	GAI (%)	Kappa	GAI (%)	Kappa
11. SSI due to ICVC prevention protocol	50	0.19	70	0.44
12. UTI due to IUC prevention protocol	70	0.44	70	0.44
13. VAP prevention protocol	40	0.11	50	0.19
14. SSI prevention protocol	40	-*	70	-*
15. Microbial resistance prevention protocol	50	-*	80	-*
16. Pressure injury risk assessment	80	0.61	80	0.61
17. Fall risk assessment	80	0.61	80	0.61
18. Full completion of the SSC	80	0.60	80	0.60
19. Indirect hand hygiene monitoring	80	0.60	100	1.00
20. Regular reporting of HAI	90	0.73	100	1.00
21. Regular notification of DDD of antimicrobials	70	0.57	70	1.00
Adherence to patient safety practices				
High adherence	40	0.10	60	0.20
	ICC		**ICC**	
% Adherence to patient safety practices	0.899		0.941	

* The value of the criteria did not change.

ICU: Intensive care unit; SSI: Surgical site infection; ICVC: Implanted central venous catheter; UTI: Urinary tract infection; IUC: Indwelling urinary catheter; VAP: Ventilator-associated pneumonia; SSI: Surgical site infection; SSC: Surgical safety checklist; HAI: Healthcare-associated infections; DDD: Defined daily dose.

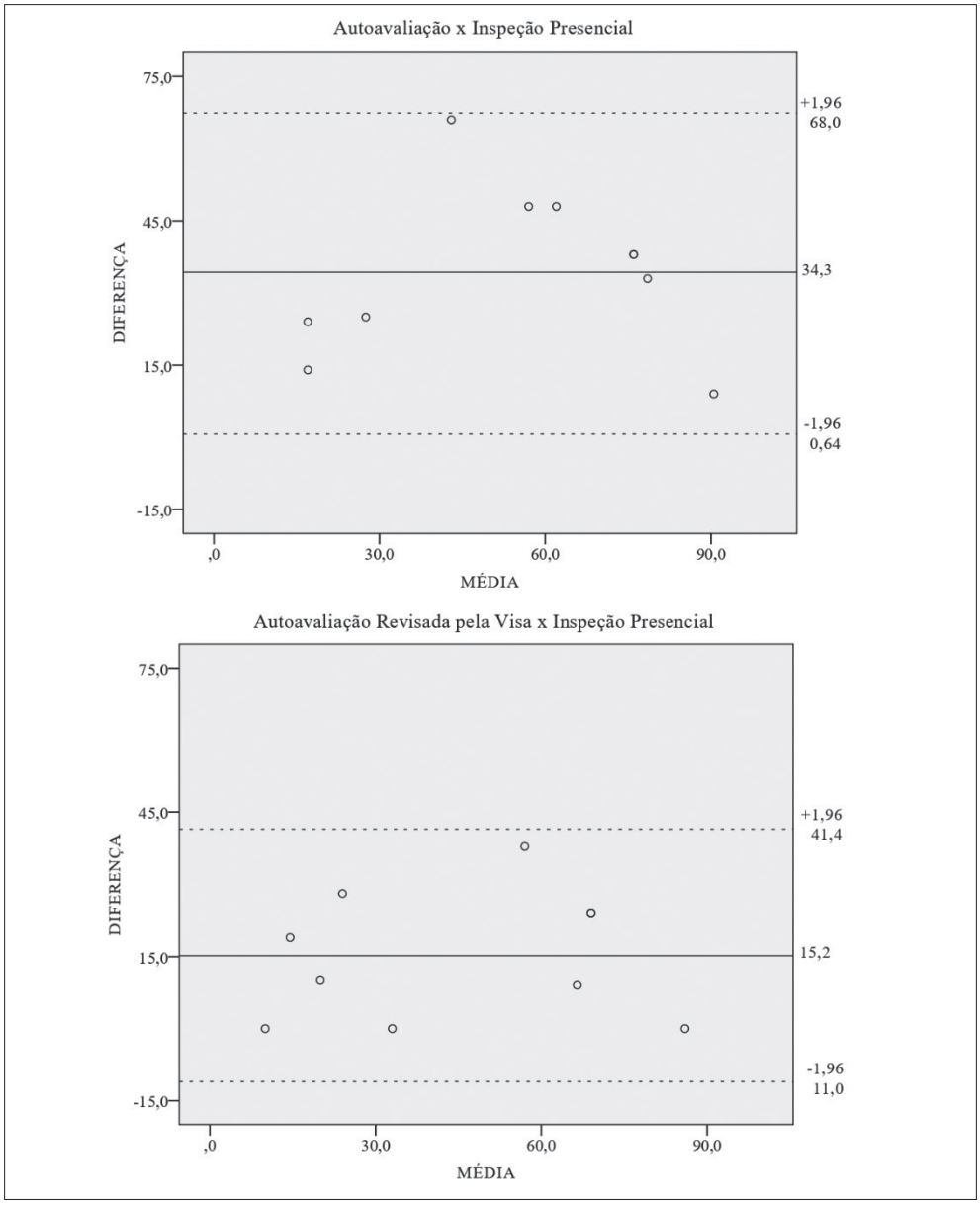
Source: elaborated by the author.

Information from Table 3 is presented in Figure 1 (Bland-Altman plots) to better understand data. Bland-Altman evaluates the mean difference between two variables (MARTÍNEZ-GONZÁLEZ; SÁNCHEZ-VILLEGAS; FAJARDO, 2006; HIRAKATA; CAMEY, 2009). Figure 1 shows data dispersion in both plots. The 95% confidence interval was short, with few cases, and no outliers were observed.

While mean difference in the first plot was approximately 34.3% (p=0.000), the second graph shows a value of 15.2% (p=0.000). This result indicates that HS

revision reduces differences compared with OSI. In both situations, Mann-Whitney U test was used for independent samples (CONTADOR; SENNE, 2015).

Figure 1. Bland-Altman graphs



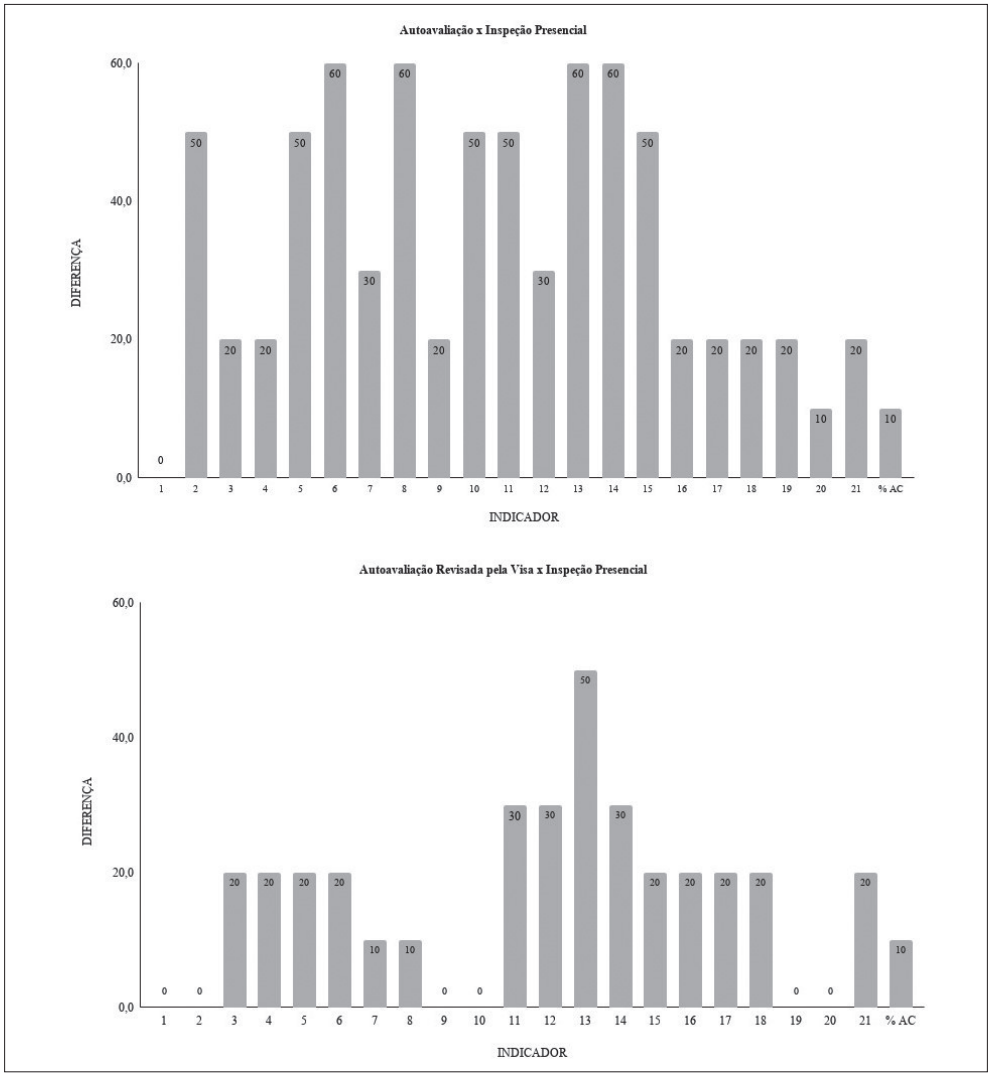
Dashed line: 95% confidence interval; Black line: Mean difference.

Differences in compliance between data

Differences between variations of data sources were observed between SA and OSI (from 0 to 60) and between RSA and OSI (from 0 to 50). Regarding p-values (in which low values indicate greater evidence against the null hypothesis), the indicator 20 (SA vs. OSI) and indicators 2, 19, and 20 (RSA vs. OSI) were significantly different ($p < 0.05$).

Figure 2 illustrates differences in compliance according to criteria between data sources. Differences in percentage of high compliance (% HC) were also found. The thirteenth indicator presented the greatest difference in both comparisons, while the composite indicator of adherence to patient safety practices (% HC) resulted in a 10% difference in both comparisons (SA vs. OSI and RSA vs. OSI). In the first figure, the indicator 13 and other indicators (6, 8, and 14) were different. The second figure showed no differences in indicators 1, 2, 9, 10, 19, and 20.

Figure 2. Differences in compliance according to criteria between data sources



1. Patient safety center; 2. Patient safety plan; 3. Number of lavatories in the ICU; 4. Availability of alcohol solution; 5. Hand hygiene protocol; 6. Patient identification protocol; 7. Safe surgical protocol; 8. Pressure injury prevention protocol; 9. Fall prevention protocol; 10. Safe medication protocol; 11. SSI due to ICVC prevention protocol; 12. UTI due to IUC prevention protocol; 13. VAP prevention protocol; 14. SSI prevention protocol; 15. Microbial resistance prevention protocol; 16. Pressure injury risk assessment; 17. Fall risk assessment; 18. Full completion of the SSC; 19. Indirect hand hygiene monitoring; 20. Regular reporting of HAI; 21. Regular notification of DDD of antimicrobials. ICU: Intensive care unit; SSI: Surgical site infection; ICVC: Implanted central venous catheter; UTI: Urinary tract infection; IUC: Indwelling urinary catheter; VAP: Ventilator-associated pneumonia; SSI: Surgical site infection; SSC: Surgical safety checklist; HAI: Healthcare-associated infections; DDD: Defined daily dose; HC: High compliance.

Discussion

Contribution of the study

Regulation is a recommended strategy to improve quality of care in health systems (WHO, 2018); however, its methods and results are still discussed internationally (FLODGREN; GONCALVES-BRADLEY; POMEY, 2016; SMITHSON; ROBERTS; WALSHE, 2018). This research contributes to validating an innovative method implemented by HS of health services in Brazil, which uses self-assessment, revision of data by regulators, control actions, and publication of services with high adherence to standards (BRASIL, 2015).

This pilot study is the first in Brazil to assess reliability of the Patient Safety Self-Assessment Practices. The study identified signs of reliability in most indicators, issues in other indicators, and essential information for revising measurement instruments. Although these are early findings, they are important because they guide this large-scale national policy and indicate the need to periodically revise the reliability of assessments in upcoming years. The risk monitoring model through assessment of patient safety practices can be useful for protecting the health of the population and promoting regulatory efficiency, mainly if methods are improved and conducted with precaution (PECI, 2011), considering financing barriers of the HS in the Unified Health System (SUS, *Sistema Único de Saúde*) (CELUPPI et al., 2019; BATTESINI; ANDRADE; SETA, 2017).

Reliability of self-assessment

A consistent interpretation of all analyzes of this study that will probably be confirmed in the future is related to the indispensable need for HS (national, state, and municipal) to revise information sent by the health service. Efforts are needed to improve performance of NHSS when monitoring this activity (SANTANA; COSTA; NOGUEIRA, 2020).

In general, results of all indicators were close to reality (OSI) when undergoing HS revision. Many indicators were similar to reality (Tables 2 and 3; Figure 2).

The improved reliability of indicators after revision by HS may have been caused by 1) error due to communication problems in requirements of health services; 2) error due to divergences in criteria used by the hospital and by other assessments considered in this study; or 3) intentional submission of erroneous information

by the health service. Regarding the first possibility, for example, guidelines on the "patient safety plan" indicator requested a series of requirements that seemed unrealistic for services initiating PSC activities; centers sent plans even without these requirements. This issue was reconsidered in the new assessment conducted in 2020, and criteria are now better suited to different contexts. Requirements for validating HS revision are based on a local analysis and a set of realistic objectives for each situation (BRAZIL, 2020).

The second possible explanation for reliability issues and improvement after HS revision relates to data collection guidelines for this study (SA, RSA, and OSI). The first guidance was sent to hospitals (BRASIL, 2019d), the second was the instruction and revision worksheet for HS (BRASIL, 2019ab), and the third was the instruction for on-site data collection. Differences in the orientation of these three sources and systematization for consolidation of responses may have led to reliability issues (MATOS, 2014). Also during data collection, representatives of PSC required clarity about writing of protocols and proof of implementation. The importance of harmonizing information of these official documents was discussed in the revision of the new 2020 assessment (BRAZIL, 2020) to achieve a single direction (BLACK, 2002).

Differences in evaluation criteria also occurred compared to OSI, which reduced reliability. In the indicators related to implementation of protocols, which presented more reliability issues, OSI was more demanding and presented two additional criteria: easy access to the protocol during inspection and proof of training of professionals. This decision was taken because requirements were essential to ensure implementation of the self-assessment protocol, according to the assessment indicator. Thus, protocols sent and remotely approved were considered non-compliant with OSI. Since protocols were not available, professionals were unaware of their existence, or no evidence of training was found (KRAUZER et al., 2018).

The third probable reason for reliability issues was related to services that may have intentionally sent a limited or unreal form to reach a high adherence indicator (BARCLAY; DIXON-WOODS; LYRATZOPOULOS, 2019). Although the evaluation of patient safety practices encourages a non-punitive culture (REIS; PAIVA; SOUSA, 2018), falsifying data to a regulatory body (especially if repeatedly and evident) may lead to undesirable consequences and prompt

regulators to climb to the top of the responsive regulatory pyramid (HEALY; BRAITHWAITE, 2006; KOLIEB, 2015).

After revision by the HS, only the ventilator-associated pneumonia prevention indicator showed an unsatisfactory Kappa value. Kappa coefficient was not calculated for surgical site infection prevention and microbial resistance prevention, and they also showed no compliance after OSI. This finding raises doubts about these protocols – whether they are realistic for the services or clearer protocol models are needed to facilitate adaptation and adherence of the regulated sector since this is a relevant change mechanism (HEALY; BRAITHWAITE, 2006; FLODGREN; GONCALVES-BRADLEY; POMEY, 2016).

In addition, the sum of reliability issues of simple indicators is reflected in the composite indicator that classifies services of high adherence, which is a predicted/predictable problem (BARCLAY; DIXON-WOODS; LYRATZOPOULOS, 2019; SATURNO-HERNANDEZ, 2004). Even after revision by the HS, a reduction of high adherent services was observed (from five cases to one case), and Kappa was 0.20. If results of this study are representative of the country, it would suggest low reliability of the high adherence list published in the annual Patient Safety Self-Assessment Practices report of ANVISA (BRASIL, 2020b). This indicates the need to assess the reliability of this instrument before further publications.

In the face of these challenges, the new 2020 assessment of patient safety practices, formerly called "self-assessment", is now called "assessment" because its judicial process must consider data from self-assessment, revision by HS, and selection of hospitals for on-site verification. This new assessment changed the configuration of indicators after considering preliminary results of the study in discussions with the NHSS. In this sense, indicators that could not be proven remotely (indicators 4 and 5) were replaced by new indicators, revision criteria were adjusted to make the assessment more realistic (indicators 1 and 2), and proof of training was required for all protocol indicators. These adjustments enhance expectations for improving reliability of the initiative in upcoming years (BRASIL, 2020a).

Limitations of the study

Due to sample size, 95% confidence intervals were not calculated, which would certainly be inaccurate. Therefore, results should not be interpreted as evidence

of reliability of the initiative but as pilot study (SATURNO HERNÁNDEZ; CARMEN SANTIAGO; ANTÓN BOTELLA, 2017). Precautions must also be taken when extrapolating data to other federation units. The study design, including ten hospitals randomly selected, refers only to the RN state. However, the study raised relevant hypotheses to be tested on a larger scale.

Future studies can also compare the reliability of public and private services, consider conflicts of interest of the private sector (BRASIL, 2011), and assess accuracy indicators (e.g., positive and negative predictive values, sensitivity, and specificity) not calculated in this initial analysis.

Final contributions

Reliability of the Patient Safety Self-Assessment Practices, innovation in health surveillance of health services for monitoring risks, and sanitary regulation of the quality of health services is a topic that must be explored. Results showed the need for the HS to revise data provided by these services and presented reliability issues that should be considered in future evaluations. These results reinforce the common sense that regulators should not rely directly on information provided by the service when sanitary control actions involve self-inspection initiatives because, although this model supports sanitary adaptations toward good practices and legal requirements, HS action in the on-site verification/revision is still required. Furthermore, future cycles of evaluation and improvement of patient safety practices should analyze the reliability of results before disclosing the ranking of hospitals with high compliance with safety practices.[4]

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Notes

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Resumo

Confiabilidade da autoavaliação das práticas de segurança do paciente instituídas pelo Sistema Nacional de Vigilância Sanitária: um estudo piloto

Introdução: A Autoavaliação das Práticas de Segurança do Paciente é um ato regulatório para melhoria da qualidade do cuidado. Porém, há dúvidas sobre a validade das suas informações. O objetivo deste estudo foi analisar a sua confiabilidade. **Método**: Estudo piloto de análise da confiabilidade de 21 indicadores simples e um composto da autoavaliação como forma de embasar uma amostra nacional em estudos futuros. Participaram hospitais com leitos de terapia intensiva e comparou dados da Autoavaliação (AA) e Autoavaliação Revisada (AR) pela vigilância sanitária (Visa) com a Inspeção Presencial (IP). A análise incluiu os coeficientes Kappa e de correlação intraclasse. **Resultados**: Comparando com a IP, a concordância foi aceitável (Kappa≥0,4) em 12 indicadores da AA e em 18 da AR. Os indicadores menos confiáveis são relativos a protocolos de prevenção de infecções. Quanto ao indicador composto do nível de adesão, a confiabilidade melhorou com revisão da Visa (AA=0,89 e AR=0,94), embora a concordância da classificação de alta conformidade tenha sido baixa. **Conclusões**: A AR se mostrou essencial para melhorar a confiabilidade da Autoavaliação. Ademais, identificou-se necessidade de revisar alguns indicadores e o instrumento de verificação pela Visa.

➤ **Palavras-chave:** Vigilância sanitária. Segurança do paciente. Regulação e fiscalização em saúde.