Implementation of Evidence-Based Patient Safety Practices: 4-Years' Follow-up of a Nationwide Regulatory Intervention in Brazilian Hospitals

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Abstract

Background: Regulatory interventions are widely recommended to improve the quality of health services, but there are few studies on the possible models and their effects. The aim of this study is to describe the implementation process and analyse the results of a nationwide regulatory intervention for the implementation of patient safety practices.

Methods: Four nationwide annual cross-sectional assessments were conducted in Brazilian hospitals with Intensive Care Unit beds. The participants involved all facilities operating during 2016-2019 (average N=1,989). The regulatory intervention theory aimed to increase adherence to safe evidence-based practices through national annual assessment involving a set of 21 validated structure and process indicators related to patient safety practices. At moment 1(Risk assessment), data were collected to classify hospitals according to the risk. In the sequence, the Sanitary Surveillance Centers (VISAS) carried out the analysis of the information sent by the hospitals. VISAS classified services into three groups according to compliance with the composite adherence indicator: High (67-100%); Medium (34-66%); and Low Compliance (0-33%). Moment 2 (Risk management) used responsive actions according to the hospital's classification.

Results: The intervention resulted in six annual cyclic stages and, between 2016-2019, 782 (40.1%), 980 (49.0%), 1,093 (54.3%) and 1,255 (61.8%) hospitals participated, respectively. 17 of the 20 indicators with at least two measurements had a significant improvement after national interventions ($p<0.05$). The overall percentage of compliance increased from 70.7 to 84.1 ($p<0.001$) and the percentage of hospitals with high compliance increased from 59.1 to 83.0 ($p<0.001$).

Conclusion: The regulatory intervention used was a good tool to strengthen the information system and government actions to promote patient safety. The set of low-cost interventions seems to be useful to prioritise hospitals at higher risk and to induce responsive measures to implement patient safety practices in the evaluated context, promoting the efficiency of the regulatory process.

Introduction

Governments around the world have been encouraged to make the quality of care and patient safety a priority.[1,2] The paralysis of actions in this theme can cause great preventable morbidity and mortality,[3] inadmissible costs for health systems[4] and even failure in sustainable development goals for 2030,[2,5] especially in low- and middle-income countries (LMIC) where adverse events (AEs) have the most impact.[3]

We currently have evidence-based patient safety practices to prevent the occurrence of AEs,[6,7] but their implementation is still incipient in many health services. According to the National Quality Forum (NQF), 34 safe practices should be universally adopted,[6] but many barriers delay their dissemination and implementation in clinical practice.[7,8]

Regulation is a key government strategy to promote the adoption of safe practices and control the risks of health services.[1,9] Government agencies have the role of developing laws, standards and other actions to regulate and control these risks, however, regulation does not work alone. As with other interventions to improve quality, regulation needs to be implemented with a multifaceted set of interventions.[1,9]

Best practices for regulating the quality of patient care and safety have been discussed, especially in developed countries.[10–12] Important theoretical advances have occurred with responsive regulation models[13] and, in the context of the UK's Care Quality Commission (CQC), with interesting research on regulatory impact mechanisms.[14] Nevertheless, there are practically no nationwide studies on models of patient safety regulation, especially in LMIC, where the organisational capacity of the health system is usually problematic.

In Brazil, government actors have complementary roles in regulating health services.[15] The Ministry of Health (MoH) coordinates the national regulatory policy of the Unified Health System (SUS),[16] however, the National Health Regulatory System (SNVS) is responsible for regulating the reduction of risks and health problems in these services.[17] Despite the development of standards for patient safety,[18,19] the challenges to achieve impact are immense, considering the continental dimension of the country, the great inequalities and the constant crisis of financing of the health system.[20]

In 2015, the SNVS launched the Integrated Plan for Sanitary Management of Patient Safety with the objective of integrating the actions of the SNVS, ensuring the implementation of the current standards and achieving the objectives of the National Patient Safety Program (PNSP).[21,22] In this plan, an innovative regulatory model was proposed, in addition to law enforcement by inspections, based on the mission of the SNVS and on principles of quality management, risk management and responsive regulation.

Analyses from the public reports of this regulatory model have reinforced the need to study in more detail its characteristics and effects.[23] A study with this perspective may provoke positive reflections in health policy makers, regulators and managers interested in improving the quality of care,[24–26] mainly in LMIC, where the context requires more cost-effective initiatives. Different impact mechanisms seem to act before, during and after the inspection process,[14] but they need to be recognised and evaluated in practice.

Thus, this article aims to describe a summary of the four years of implementation of a national regulatory intervention for the adoption of patient safety practices and to analyse its effects in Brazilian hospitals.

Method

Context

Brazil is a country of continental dimensions (8.5 million km^2) where 208,494,900 inhabitants live in 5,570 municipalities grouped into 27 Units of the Federation (UF). The Brazilian population is entitled to free public health services through the Unified Health System (SUS), and the provision of private services is free and complementary to the SUS.[15] The country has about 7,000 hospitals, of which approximately 2,000 have Intensive Care Unit (ICU) beds.[27]

The Brazilian Health Regulatory Agency (ANVISA) and the Sanitary Surveillance Centers (VISAS) in all UF, among other instances, are part of the SNVS, and the Agency is responsible for coordinating this system.[17] ANVISA exercises sanitary surveillance actions for patient safety, especially with the state, municipal, and district Coordination of Sanitary Surveillance for Patient Safety (NSP VISA) and the Hospital Infection Control Coordination (CECIH).[15,17]

The competencies relevant to regulating the risks of health services risks include a range of actions from persuasion (soft regulation), such as education of health care managers and professionals, to deterrence measures, such as sanctions and withdrawal of operating licenses.

Intervention

Regulatory intervention was based on a theory of change built on the following principles: being participatory, data-driven and multifaceted. The model in Figure 1 was created to present the intervention clearly to all stakeholders.[28] The aim of the intervention was hospitals with ICU beds, considered priority in the first years of the intervention, and the actions had two moments: 1- Risk assessment; and 2- Risk management.

At moment 1, the goal is to collect data efficiently and on a large scale to classify and prioritise health services according to the risk related to the non-implementation of patient safety practices. Risk identification is based on the measurement of structure indicators and processes that protect patients from safety incidents. In the following cases, the VISAS carried out the analysis of the information sent by the hospitals, verifying the supporting documents to the evaluated structure indicators, such as implementation of the Patient Safety Nucleus (NSP), preparation of the Patient Safety Plan (PSP) and implementation of patient safety protocols and internal risk management practices. At the end of this moment, VISAS classify services into three groups: 1- High Compliance (67-100% compliance with the composite adherence indicator); 2- Medium compliance (34-66% compliance whit the composite adherence indicator); and 3- Low Compliance (0-33% compliance with the composite adherence indicator or not having sent the evaluation form).

Moment 2 of risk management uses responsive actions according to the level of access to safety practices and the context of the hospital. For hospitals classified as medium and low compliance, VISAS could conduct inspection visits, locally evaluating the development of the actions provided for in the PSP and the health conditions involved and require the establishment of timely risk reduction measures, setting a deadline for compliance with patient safety practices. Failure to meet the deadline may result in other appropriate health requirements or measures. Hospitals with high compliance with safe practices

should be monitored annually to verify the sustained adherence to the indicators of these practices, and their performance is communicated to internal (NSP and hospital leadership) and external stakeholders (health system management, SNVS professionals and the population), including the publication of the positive list of priority hospitals classified as high compliance with safety practices. In addition, the intervention includes the dissemination of annual reports with state and national analyses, with presentation of Pareto Diagrams that reveal the priorities of each state in the regulation of safety practices, in order to motivate actions to promote safety at the state level in a systemic way.

Assuming that the establishment of mandatory participation would not be sufficient to ensure broad hospital support, the SNVS defined voluntary participation in this process.

Study of the intervention

The intervention study is carried out in a quasiexperimental design and analyses the effect of the initiative from the primary data of the four national evaluations from 2016 to 2019. In each year of the period evaluated, an online self-assessment form was used, consisting of 11 (2016), 14 (2017), 16 (2018) and 15 (2019) items related to the evaluation of the structure indicators and four (2016), five (2017 and 2018) and six (2019) items related to the process indicators (Table1). The indicators were validated in a previous study based on evidence-based recommendations of the NQF and the services should attach proof of compliance to each indicator.[29] VISA analysed the proofs of the indicators and could inspect the service in person to prove the information sent.

Table 1
Year, criteria, type of indicator and safe practices adopted. Brazil, 2016-2019.

Year	Criteria	Indicator types	Number and name of NQF-endorsed safe practices (6)
2016	C1. Patient Safety Nucleus established	Structure	1: Leadership Structures and Systems 4: Identification and Mitigation of Risks and Hazards.
	C2. Implemented Patient Safety Plan	Structure	1: Leadership Structures and Systems
	C3. Number of washbasins and supplies for HH in ICUs	Structure	19: HH
	C4. HH protocol implemented	Structure	19: HH
	C5. Patient identification protocol implemented	Structure	14: Labelling diagnostic studies
	C6. Safe surgery protocol implemented	Structure	26: Wrong-Site, Wrong-Procedure, Wrong-Person Prevention Surgery
	C7. Prevention of pressure ulcers protocol implemented	Structure	27: Pressure Ulcer Prevention
	C8. Prevention of falls protocol implemented	Structure	33: Falls Prevention
	C9. Safety protocol in the drug prescription, use and administration implemented	Structure	18: Pharmacist Leadership Structures and Systems
	C10. Protocol for the prevention of CLABSI implemented	Structure	21: CLABSI Prevention
	C11. Protocol for the prevention of VAP implemented	Structure	23: Care of the Ventilated Patient
	C12. Compliance of the risk assessment of pressure ulcers	Process	27: Pressure Ulcer Prevention
	C13. Compliance of the risk assessment of fall	Process	33: Falls Prevention
	C14. SSC completed	Process	26: Wrong-Site, Wrong-Procedure, Wrong-Person Prevention Surgery
	C15. Monthly indirect monitoring of HH in ICUs	Process	19: HH
2017	C16. Availability of dispensers containing alcoholic preparations for HH in the ICU	Structure	19: HG
	C17. Protocol for the prevention of CAUTI	Structure	25: CAUTI Prevention

Year	Criteria	Indicator types	Number and name of NQF-endorsed safe practices (6)
	C18. MDRO prevention and control protocol implemented	Structure	24: MDRO Prevention
	C19. Regularity of monthly notification of HAI indicators	Process	21 to 25: Prevention of HAI
2018	C20. Protocol for the prevention of SSI implemented	Process	22: SSI Prevention
2019	C21. Regularity of monthly notification of antimicrobial consumption in adult ICU	Process	22: SSI Prevention

HH: Hand Hygiene; CLABSI: Catheter line-associated blood stream infection; SSI: Surgical Site Infection; HAI: Healthcare-Associated Infections; SSC: Surgical Safety Checklist; MDRO: Multidrug-Resistant Organism; ICU: Intensive Care Unit; VAP: ventilator-associated pneumonia; CAUTI: Catheter-associated urinary tract infection.

Note: the indicators were maintained in all assessments from the year of incorporation and all are based on some health services standards.

To enable the measurement of process indicators, based on the review of medical records, the hospital respondent used the Lot Quality Assurance Sampling (LQAS) method. Small samples of 17 random cases of medical records based on the list of patients discharged from the last year were used and, to achieve compliance with the indicator, it would have to reach a minimum of 12 compliances (standard of 85% and threshold of 55%).[30] Detailed guidance on the completion of the instrument and indicator forms were provided to the participating health services.[21,31] In addition, a detailed instruction was elaborated on how VISAS should review the validity of the data sent by the services, for possible consolidation.[33]

Data analysis

To analyse the effectiveness of regulatory interventions and the significance of the improvement in each quality criterion, the difference between the percentage of compliance between the last and first year of evaluation (absolute improvement) and its statistical significance was calculated with the Z value test for a unilateral hypothesis of improvement, since it was not the hypothesis of the study that the intervention could worsen the compliance of the indicators. The level of significance adopted was 5% and the null hypothesis was rejected when the p-value was less than 0.05. To compare the criteria that improved the most, the relative improvement was calculated, which is equivalent to the percentage of improvement in relation to the possible space for improvement. The tests were performed in program R version 4.0.2.

Patient and public involvement

This study is of interest to patients in general, as it provides information on how to improve health care safety through regulatory interventions. However, this study did not involve patients during its design or development.

Results

Evolution of intervention and improvement of the adoption of safety practices

Initially, the actions were presented to other instances of the SUS (e.g. National Council of Health Secretaries - CONASS, PNSP Implementation Committee and Health Regulatory Working Group - GT VISA), allowing to expand the process of discussion of national actions of quality and patient safety. Then, annually, the intervention evolved according to the cyclical steps in Table 2.

Table 2
Stages, documents and peers involved in the implementation of the intervention. Brazil, 2016-2019.

Stages of intervention each year	Actions	Peers involved
Step 1	Preparation of the Self-Assessment Form of Patient Safety Practices and Guidelines for completing[31]	ANVISA NSP VISA WG Integrated Plan
Step 2	Annual completion of the Self-Assessment Form, following guidelines available[31]	Hospitals with ICU beds
Step 3	Preparation of the Instruction and Spreadsheet for the analysis of the Self-Assessment Form[32]	ANVISA NSP VISA WG Integrated Plan
Step 4	Evaluation of completed Self-Assessment Forms	NSP in conjunction with CECIH
Step 5	Preparation and availability of the National Report with the List of High Compliance Hospitals to Safe Practices[33]	ANVISA
Step 6	Responsive regulatory interventions carried out by health inspectors, according to the result of the evaluation, especially for low and medium compliance services.	VISA inspectors

ANVISA: Brazilian Health Regulatory Agency; NSP VISA: Regulator´s Patient Safety Nucleus in the units of the federation; WG: Work Group; ICU: Intensive Care Unit; CECIH: State Commission of Healthcare-Associated Infections Control.

Step 1 aimed to elaborate and review annually the instrument for data collection. To count on the broad participation of SNVS throughout the country, ANVISA organised in 2015 an international seminar in Brazil to discuss the topic and present the first version of the Self-Assessment form of Patient Safety Practices. A working group was set up with representatives of ANVISA, NSP VISA, researchers and specialists in the area. The group worked in face-to-face and videoconference meetings to approve the indicators for each evaluation year.

In Step 2, the forms and the completion guidelines were reviewed and made available through links on the ANVISA website and e-mailed to the NSP of hospitals. The NSP VISA also emphasised to hospitals the need for timely response. In the first evaluation of 2016, 782 (40%) of the 1,955 hospitals with ICU participated. In the following years (2017-2019), participation increased continuously 980 (49%), 1,093 (54%) and 1,255 (62%), respectively. In all years, mainly private hospitals with or without profit (69-71%), general hospitals (>80%) and hospitals with 100-199 beds (38-39%) participated. Most hospitals had 20 or more ICU beds (48-51%). Detailed data of the participants are in Appendix 1.

An instructional and an Excel® spreadsheet were also prepared and updated annually for data analysis in order to standardise and ensure reliability of the evaluation (Step 3).[32] The NSP VISA annually used the spreadsheet to calculate the score of each hospital, according to the established criteria, and the vouchers attached by the hospitals, to forward to ANVISA the list of hospitals classified as high compliance (Step 4). It is emphasised that the participation of the CECIH in the activities of this stage was essential for the verification of the criteria established for the indicators of IRAS.

ANVISA annually published the report with the list of hospitals with high compliance with patient safety practices[33] and priority indicators in each state (Step 5). In the first year, three of the 15 indicators had compliance greater than 90% (C1 Patient Safety Nucleus; C3 Washbasins and hand hygiene supplies; and C4 Hand Hygiene Protocol) and there was clear weakness (<50% compliance) in the process indicators C12 Risk assessment of falls, C13 Assessment of the risk of pressure ulcers and C14 Complete the safe surgery checklist (Table 3).

The most direct intervention by the inspectors occurred in Step 6. The risk management process was started (4th column of Figure 1) and responsive actions were implemented according to the risk of the evaluated services. Since the early years, NSP VISA has sent detailed reports with comments on hospital non-compliances, setting targets and monitoring the implementation of adaptations.

Compliance with patient safety practices increased significantly ($p<0.05$) between the first and fourth year of regulatory intervention (Table 3). The composite indicator of percentage of adherence increased from 70.7 to 84.1, covering 45.7% of what was missing to achieve total compliance. As for health services classified as high adherence, frequency increased by 23.9 percentage points.

Table 3 shows that 19 of the 20 simple indicators with at least two measures had Absolute Improvement (AI) of compliance and in 17 of them this improvement was significant ($p<0.05$). The safety practice that increased the most in percentage points was to monitor hand hygiene indirectly through the consumption

of alcoholic solution, because the number of hospitals that proved it went from 51% in 2016 to 76% in 2019 (AI=26; Relative Improvement=51; $p<0.001$). However, to compare the indicators, the best measure is Relative Improvement (RI), because the indicators start from different levels of compliance in the first evaluation. Regarding this aspect, the indicators that improved the most were related to the implementation of the C1 Patient Safety Nucleus (AI=7; RI=80; $p<0.001$), from the C5 Patient Identification Protocol (AI=12; RI=61; $p<0.001$) and the C8 Protocol for Prevention of Falls (AI=17; RI=57; $p<0.001$).

Table 3
Compliance with the evaluation criteria and improvements during the national regulatory intervention. Brazil, 2016–2019

	2016 N=782	2017 n=980	2018 n=1.093	2019 n=1.255	Absolute Improvement	Relative Improvement	*P-value*
	P_1	P_2	P_3	P_4	P_4-P_1	P_4-P_1/ 100-P_1	
Simple indicators							
C1: patient safety nucleus	91	94	97	98	7	80	<0.001
C2: patient safety plan	84	84	89	91	8	44	<0.001
C3: washbasins and hand hygiene supplies	93	93	94	95	2	29	0.035
C4: hand hygiene protocol	94	95	97	97	3	50	0.001
C5: patient identification protocol	82	87	92	93	12	61	<0.001
C6: safe surgery protocol	73	80	84	87	13	52	<0.001
C7: pressure ulcer prevention protocol	77	80	87	88	11	48	<0.001
C8: falls prevention protocol	70	79	85	88	17	57	<0.001
C9: medication safety protocol	60	70	78	80	20	50	<0.001
C10: CLABSI prevention protocol	84	88	90	92	8	50	<0.001
C11: VAP prevention protocol	84	87	87	91	7	44	<0.001

	2016 N=782	2017 n=980	2018 n=1.093	2019 n=1.255	Absolute Improvement	Relative Improvement	*P-value*
C12: fall risk assessment	38	48	54	58	20	32	<0.001
C13: risk assessment of pressure injury	37	47	53	57	21	33	<0.001
C14: surgical safety checklist completed	45	56	59	64	19	35	<0.001
C15: indirect monitoring of hand hygiene	51	67	72	76	26	53	<0.001
C16: alcohol preparation dispensers	-	96	97	96	0	0	0.459
C17: CAUTI prevention protocol	-	85	88	91	5	33	<0.001
C18: MDRO prevention protocol	-	75	76	78	3	12	0.054
C19: HAI notification	-	-	89	91	2	18	0.062
C20: SSI prevention protocol	-	-	79	82	3	14	0.024
C21: notification of antimicrobial consumption	-	-	-	75	-	-	-
Composite indicators							
Total compliance percentage	70.7	78.4	82.2	84.1	13.4	45.7	<0.001
Hospitals with high Compliance (67-100% compliance)	59.1	74.2	81.7	83.0	23.9	58.4	<0.001

	2016 N=782	2017 n=980	2018 n=1.093	2019 n=1.255	Absolute Improvement	Relative Improvement	*P-value*
P_1, P_2, P_3, P_4 : percentage of compliance in 2016, 2017, 2018 and 2019, respectively.							
For the calculation of the relative improvement in criteria 16-20, since they had no measure of P_1, this value was replaced by the value of the first evaluation.							
CLABSI: Catheter line-associated blood stream infection; SSI: Surgical Site Infection; HAI: Healthcare-Associated Infections; MDRO: Multidrug-Resistant Organism; VAP: ventilator-associated pneumonia; CAUTI: Catheter-associated urinary tract infection.							

Figure 2 shows the consistency of the improvement directionality and the indicators ordered from the lowest to the highest compliance in the last evaluation, indicating the intervention priorities.

Contextual elements and unanticipated consequences

Difficulties that had an impact on the process of national implementation of the intervention were found, such as: lack of prioritisation of quality and patient safety actions in health services by managers, noted by the non-completion and submission of the Form within the stipulated period; non-formalisation of NSP VISA in two states of the country, hindering communication and commitment of joint efforts; and deficiencies of human, financial and logistical resources to ensure the full functioning and execution of health actions formalised by the NSP VISA, as pointed out by the Coordinators.

On the other hand, openings were observed that contributed to this implementation, which are: greater debate on the subject, provided by local events, enabling knowledge and awareness of professionals working in the SNVS and health services to comply with national guidelines for minimising risks for patient safety; remote training on the theme of patient safety and quality with a focus on safe practices; the possibility of local monitoring of the Self-Assessment instrument by the NSP VISA and encouraging the elaboration of state, district and municipal Patient Safety Plans, aligned with local health needs and priorities, observed after the evaluation of safe practices by hospitals; provision of support of health inspectors to the national initiative; sharing of successful experiences of the activities of the NSP VISA in national events, involving safe practices; support of associations and scientific societies, in addition to instances formalised by ANVISA, such as committees, technical chambers and WG Patient Safety and insertion of the National Assessment of Patient Safety Practices in the 2019 management contract, signed by ANVISA and MoH.

Discussion

This study contributes to the debate about and understanding of the implementation, mechanisms of change and potential effects of regulatory interventions to improve the quality of care and patient safety.[10–14,24,25,34] Despite the great contextual challenges and difficulties encountered, the original

initiative developed and applied on a large scale in Brazilian hospitals was successful, with a growing involvement of participating institutions and increased adherence to indicators of safe practices.

In addition, the work provides for the first time an overview of the situation of safe practices in Brazilian hospitals with ICU beds measured with structure and process indicators. In the SUS information system, there are virtually no patient safety indicators, and these data have been fundamental to guiding the actions of the PNSP. The national and stratified information provided by the 27 UF has also empowered the SNVS and helped in data-driven decision-making for the promotion of the safety culture in the health system.

Learning about the effect of regulatory intervention and mechanisms of change

An important result was the consistent increase in the number of participating hospitals. This may have occurred due to the greater commitment of the NSP VISA in this activity, by conducting inspections focused on patient safety, wide dissemination of the instrument in communication networks and greater knowledge of the instrument by professionals working in the NSP of hospitals. Despite these advances, the national target of obtaining 80% participation in 2019 has not yet been achieved.[33]

As for the effects of the intervention, some theoretical mechanisms of regulatory impact support the intervention and may help explain why the indicators have improved significantly.[13,14,28,35] First, “evidence-based inspection” was strengthened by the collection of objective information to guide priorities;[35] second, the concise set of evidence-based indicators complied with the desirable principle of “selectivity” for inspections, rather than focusing on less important issues;[35] third, there was an improvement in “clear communication about requirements”, complementing legislation, through the theoretical model, self-assessment and collection guidelines, and promoting self-regulation;[13,14,35] fourth, “efficiency” was promoted by self-assessment and prioritisation of the services to be inspected;[35] fifth, the modulation of regulatory interventions according to risk used “responsiveness and proportionality”;[13,35] sixth, when necessary with medium and low compliance services, a “direction” mechanism was applied;[14] seventh, the non-punitive report on the compliance of practices with adequacy guidelines used the “relational” mechanism, where inspectors contribute their expertise to change services for the better;[13,14] eighth, the publication of the positive list of high-compliance services uses the “informational” mechanism;[13,14] ninth, the “systemic” mechanism was used to bring together several social actors in actions aimed at improving patient safety practices that the Pareto Diagrams indicated as priorities in the region.[14]

The strategy of publishing lists of hospitals classified as high compliance with safe practices in each year of the study deserves to be highlighted.[36] Whereas most institutions were private, this public information may have encouraged healthy competition for better performance and helped patients and family members choose hospitals based on the level of safety. The feedback chosen was of the positive

type only for hospitals with good evaluation. This type of feedback aims to balance principles of accountability and transparency with a non-punitive culture.[37]

In general, this multifaceted set of principles and mechanisms breaks with strongly ingrained command and control practices within the SNVS and must have come together to stimulate the improvement of evidence-based structures and processes. The success of the intervention model reinforced the conviction that regulatory interventions need to have a clear theory of change, be participatory, be based on large-scale data and use a range of multifaceted interventions of responsive regulation.[13,24,25,28] In addition, the experience in the four years has confirmed that it is people who make care safer for patients, hence the need to value the assessment, feedback and intervention in the patient safety culture in the system. Solid achievements will only be possible in an environment where safety is valued, changing attitudes and behaviours of health professionals.

As for the level of adherence, the initial compliance on HH indicators was expected, as the MoH and ANVISA have been encouraging the adoption of the HH practices to avoid HAI. In addition, it was a successful national regulatory experience of the prevention of HAI in the immediately preceding year that supported part of the methodology adopted in this regulatory intervention.[38]

In addition, the criteria with greater compliance with safe practices were those related to structure indicators (Table 3). This is logical, because the structure is antecedent to the appropriate processes, which precede, in turn, to the results. However, in the context of the country, many hospitals were still lacking in basic structures, signalling the need for support to improve processes and outcomes. In turn, the low compliance of process indicators was decreasing during the years (Table 3). The lower proportions found of non-compliance with these criteria may have occurred due to the lack of training and local institution of routines and protocols, but mainly due to the low culture of safety in hospitals. In this sense, ANVISA encouraged in 2019 and 2021 a national evaluation of the safety culture with a validated electronic questionnaire.[39]

Limitations

However, it is important to consider that this study has limitations: 1) We measure structures and processes based on scientific evidence, but we do not measure clinical outcomes or adverse events, which are much more complex to use in regulatory interventions[40] and unavailable in the Brazilian hospital information system. 2) It is not possible to generalise the estimates of the indicators to the approximately 2,000 Brazilian hospitals with ICU, as selection bias associated with voluntary response may have occurred. 3) The methodological design is not the most recommended for testing the effect of interventions,[41] but it is suitable for studying national regulatory interventions where it is not possible to use control groups. 4) The nature of the external approach to quality improvement has limitations, because “from the outside we can evaluate, but only from inside we can evaluate and improve”.[42] Nevertheless, we trust that regulation should be a “driver of a flow of events”, performing meta-regulation and inducing self-regulation for the implementation of safe practices.[13] 5) There is a potential

information bias related to falsehood or poor completion of self-assessment data, but this possibility is reduced by the fact that it is a questionnaire of a regulatory authority with face-to-face inspection and sanction power.

Conclusions

Many challenges continue to hinder patient safety in Brazil, however, the regulatory model of evaluation and intervention for patient safety instituted in this study consisted of a good tool to strengthen the information system and the governmental policy agenda for promoting the actions in the PNSP. In addition to the large participation of hospitals and the involvement of SNVS inspectors, there was an improvement in compliance with indicators of structures and processes related to evidence-based patient safety practices. The continuity of actions should emphasise the improvement of safety in surgeries, by the use of the checklist of safe surgery and the assessment of the risk of falls and pressure injuries, in addition to the consumption of alcoholic preparation for the hands to avoid HAI.

We consider that the gains in rationality of the regulatory process were positive and can provide insights for managers and regulators, particularly in health systems that have needs and characteristics similar to the Brazilian one. The theoretical model used, the concise assessment of minimum requirements and the cyclical steps of intervention can be a useful and low-cost alternative to prioritise higher risk hospitals and promote regulatory efficiency, while minimizing the problems arising from the lack of funding and the low organizational capacity of the health system. Future studies should deepen the analysis of regulatory mechanisms that influence compliance with safe practices and the promotion of a safety culture, in order to maximize the contribution that regulation can make to patient safety.

Declarations

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CONTRIBUTORS

MMMC, HTS, ACRBS, CFMR and ZASG participated in the conception and design of the intervention model and analysis of annual data. MMMC supervised the design of the intervention model and annual data analysis. HTS wrote the first draft of the manuscript and ZASG did a critically relevant review of the intellectual content. AAC and ZASG was responsible for data analysis. HTS, ACRBS, CFMR and MDSPN conducted data collection, maintained contact with NSP VISA and health services during the project, as well as prepared data analysis reports. All authors approved the final version of the manuscript.

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ETHICAL APPROVAL

This study was based on secondary data in the public domain and without identification of the health institution and professionals, therefore exempted from analysis by the Research Ethics Committee, according to CNS Resolution nº. 510/2016.

DATA AVAILABILITY STATEMENT

Data are available upon reasonable request. You can ask Magda Machado de Miranda Costa, manager of the Gerência de Vigilância e Monitoramento em Serviços de Saúde (GVIMS/GGTES) of the Brazilian Health Regulatory Agency (ANVISA). E-mail: magda.miranda@anvisa.gov.br.

COMPETING INTERESTS

None declared.

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Figures

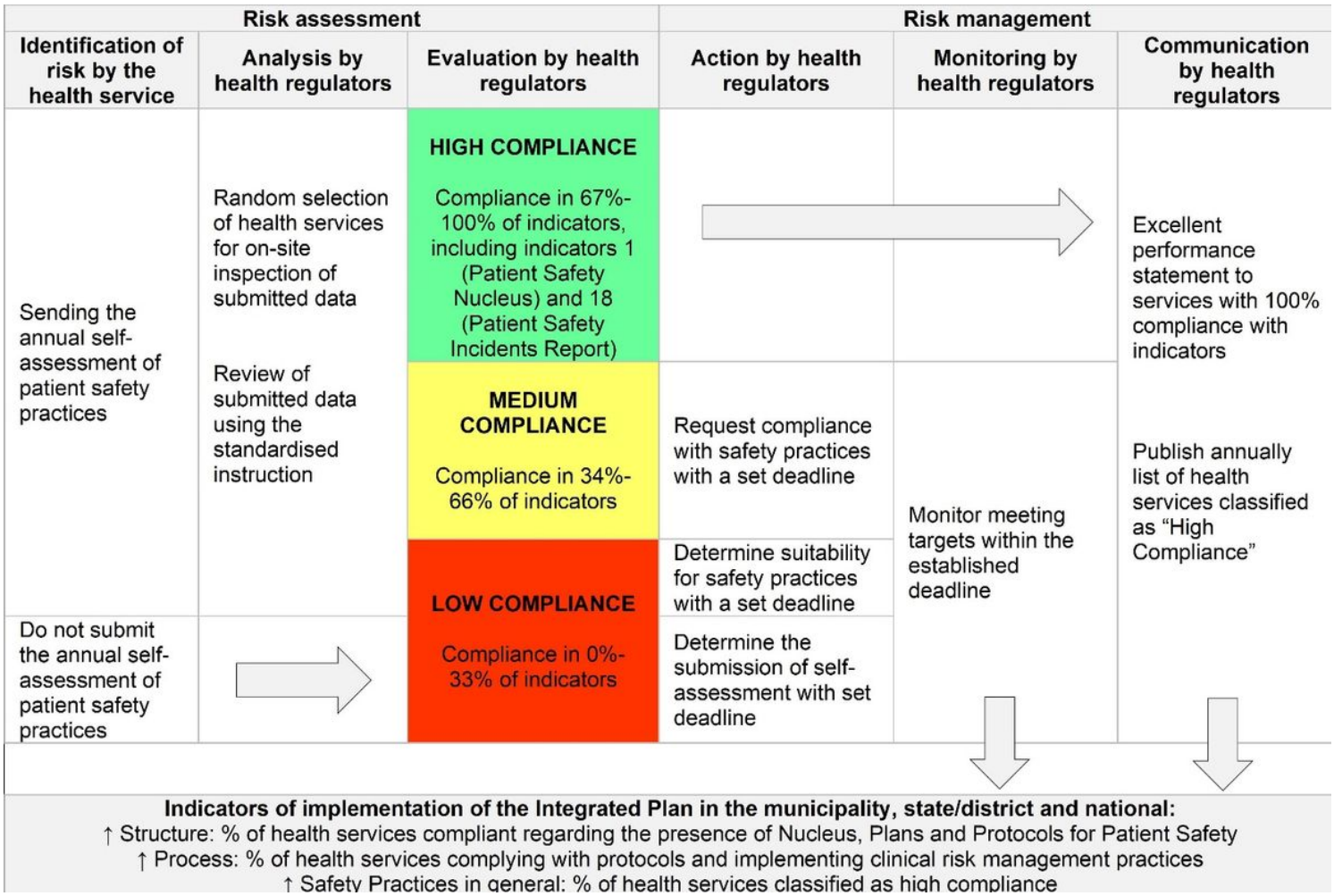

Figure 1

Theoretical model of risk management based on monitoring the implementation of Patient Safety Practices. Source: Integrated Plan [21]

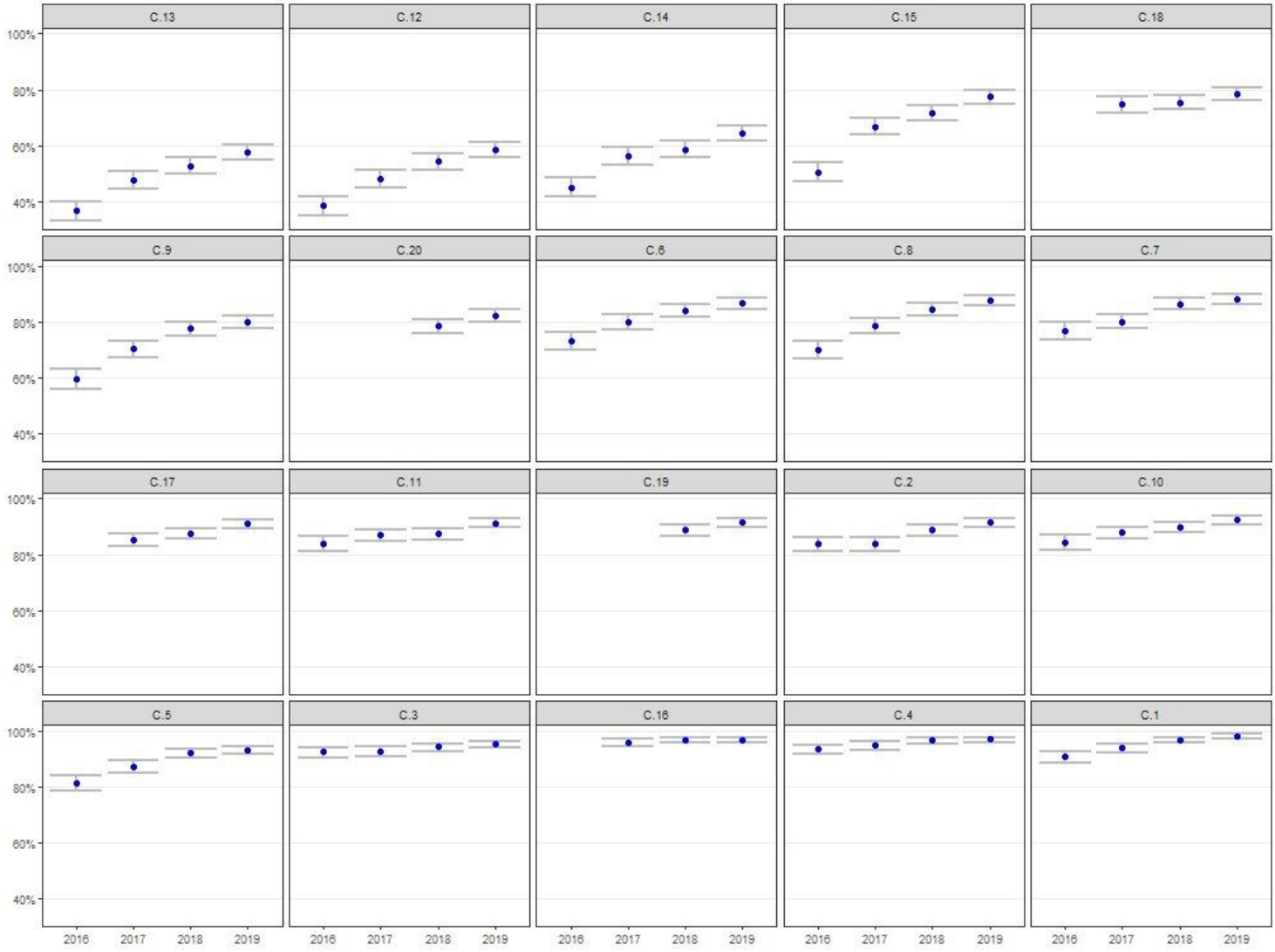

Figure 2

Compliance for safe practices in participating hospitals. Brazil, 2016 - 2019. Legend: C1 - C21 (see Table 1)

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