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Results of a national system-wide quality improvement initiative for the implementation of evidence-based infection prevention practices in Brazilian hospitals

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SUMMARY

Background: Quality improvement (QI) methods are recommended to address healthcare-associated infections (HCAIs) in hospitals, but whereas internal initiatives have been widely studied, there is little evidence on the application and effect of a QI approach from an external system-wide perspective.

Aim: To analyse the effect of a national system-wide QI initiative aimed at promoting HCAI prevention via regulatory interventions in Brazil.

Methods: A QI cycle approach designed and assessed with a before-and-after quasi-experimental design was implemented by the Brazilian Health Regulatory Agency (ANVISA), targeting 1869 hospitals. Eleven evidence-based quality indicators related to HCAI prevention and a composite measure were assembled, shared, and assessed; the intervention to improve was then based on participatory multifaceted regulatory actions. Absolute and relative improvements were estimated after the intervention.

Findings: In all, 563 hospitals (30.1% response) totalling 86,837 beds participated in the baseline assessment, and 681 hospitals (36.4% response) totalling 101,231 beds in the second. Ten of the 11 criteria improved ($P < 0.05$), as well as the composite indicator ($P = 0.001$) in all the regions of the country, particularly in the group of hospitals participating at baseline. 'Hand hygiene (HH) infrastructure' reached 100% (baseline: 97.9; $P = 0.001$), 'HH protocol' 96.9% (baseline: 92.9; $P = 0.001$), 'HH monitoring' 70% (baseline: 60.7; $P < 0.001$) and 'existence of antimicrobial prescription protocol' 80.7% (baseline: 73.2; $P < 0.001$), among others. The HCAI rates of the participating hospitals decreased after the intervention ($P < 0.05$).

Conclusion: The QI cycle approach was useful in guiding system-wide interventions for patient safety. External regulation was feasible and effective in promoting internal HCAI prevention nationwide.

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Introduction

Improving healthcare quality is an urgent need for global health, and patient safety is one of its primary components [1]. Among safety priorities, healthcare-associated infections (HCAIs) are a serious problem for patients, health professionals, and health system administrators in both developing and developed countries [2–4]. The burden in terms of morbidity, mortality, and costs is high, and a number of prevention and control measures have been promoted worldwide [5–12]. However, numerous implementation barriers have made it difficult to abate the HCAI epidemic [13–15].

The implementation of quality management and improvement (QI) methods is an important initiative to deal with this problem [16,17]. Quality improvement is not a static concept, but rather a continually emerging, dynamic system property [1]. Many different methods are used to continuously assure and improve quality of healthcare (e.g. broad clinical governance mechanisms; peer review and clinical audit; individual feedback; supervision and training; clinical decision support tools based on guidelines; and multidisciplinary learning collaboratives), but a basic tenet underlying continuous quality improvement is activated learning mechanisms using iterative cycles of change [1].

A systematic review on the effects of quality improvement strategies applied to HCAI prevention found it to be generally effective, even though results seem to vary according to the types of infection [16]. However, these QI interventions have been generally local and usually at the facility level, while there is an increasing concern about the need for effective system-wide interventions.

In the context of developed countries, an example of a successful internal HCAI initiative is the Comprehensive Unit-based Safety Program (CUSP), which includes interventions to improve safety culture, teamwork, communication and a set of evidence-based HCAI prevention interventions [18]. There are also examples of successful HCAI interventions in low-income and middle-income countries, both related to the implementation of World Health Organization Hand Hygiene Guidelines and the control of infection rates [19,20]. However, external and system-wide, but focused, initiatives included in the three groups of quality management activities of the Juran trilogy model (quality planning, control, and improvement) are infrequent and rarely reported and assessed. It is also less frequent to use quality improvement projects using public health improvement interventions, such as government regulation [21,22]. Analysing HCAI prevention in the context of developing countries, it has been concluded that more studies are necessary to evaluate the implementation of programmes and policies that are possible in these countries [23].

In the case of Brazil, the discussion on infection prevention and control started in the 1950s, and was regulated in the 1980s, with the mandatory implementation of Hospital Infection Control Commissions (CCIHs) [24]. Subsequently, the National Hospital Infection Control Program (PNCIH) was established in 1988 and guidelines and indicators were required for the prevention and control of nosocomial infections [24]. During all these years, the implementation of good HCAI prevention practices has been a major challenge. Although much progress has been made, studies have shown poor adherence to good infection prevention practices, problems in structure for prevention, and high rates of HCAI [25–27].

In this situation, we decided to implement and assess a system-wide QI cycle, including all the characteristics of this approach, complemented by strategic interventions in accordance with the results of the baseline evaluation and the explicit goal of contributing to the achievement of internal improvements [21,28]. QI cycles start with the identification of the problem to improve, and conclude with the assessment of the effect of the implemented intervention for improvement, which can be subsequently monitored [29–31]. They are presented in different models, such as the Plan–Do–Study–Act cycle [21,29,31,32]. The intervention model, from the external point of view, may consider all the possible strategies that could be implemented for quality improvement, in accordance with the level of responsibility in the health system [29].

This study reports on the foundations, steps, and results of this unique experience led by the Brazilian Health Regulatory Agency (ANVISA), a government institution linked to the Brazilian Ministry of Health, conducted in partnership with the representatives of the infection prevention and control units in Brazilian hospitals with intensive care unit (ICU) beds.

Methods

This report of an improvement project follows SQUIRE guidelines [33]. It consists of a national quality improvement cycle conducted between January 2015 and April 2016 using a before-and-after quasi-experimental design with no control group [34].

The project was carried out by the Brazilian Health Regulatory Agency (ANVISA), a government entity linked to the Brazilian Ministry of Health whose mission is to protect the population against risks related to products and services. The agency coordinates the Brazilian Health Regulatory System (SNVS), a subsystem integrated into the National Health System (SUS), whose management and activities are national (ANVISA), state, and municipal.

ANVISA oversees the quality and safety of health services through regulation, inspection, and licensing. This includes monitoring HCAI prevention as well as other patient safety issues. The organizational structure to prevent HCAI comprises the Hospital Infection Control Commission encompassing four levels: hospital (HC), municipal (MC), state (SC), and national (ANVISA).

During our study, Brazil had 4784 hospitals, with 608 specialized hospitals, 4050 general hospitals, and 126 day hospitals. Among these, 48.5% were public hospitals and 39.1% had at least one of the 41,067 ICU beds in the country. Legislation requires that all of these hospitals have HC.

HCAI prevention was identified at central level as the topic for a QI cycle, using the Nominal Group Technique [35]. The ensuing phases of the project followed the logic of improvement science: (1) work group qualitative analysis of the problems and difficulties in implementing HCAI prevention at all levels; (2) construction of evidence-based quality criteria for national assessment of the structure needed for HCAI prevention; (3) baseline assessment to quantify the problem and establish intervention priorities; (4) planning and implementing improvement interventions; (5) reassessment to analyse

the new level of quality after the interventions. Throughout the project, several change management and quality management approaches and tools were used, as explained below.

Qualitative analysis and construction of quality criteria for baseline assessment

Using a cause-and-effect diagram to map-out current barriers for HCAI prevention, the group decided to focus on the assurance of the existence of the structural requirements for HCAI prevention in all hospitals. After reviewing the Brazilian norms and the scientific literature on HCAI prevention, a set of 11 criteria was assembled and proposed (Table I) [7–12]. We also decided to prioritize facilities with ICU beds, given their higher potential risk for HCAI. The target population then comprised all the 1869 hospitals with at least one adult, paediatric, or neonatal ICU bed.

Four experts from ANVISA (three nurses, one pharmacist) who regulate the prevention and control of HCAIs in the country and a specialist in quality management from the Federal University of Rio Grande do Norte (UFRN) participated in the validation of the criteria. These were assessed for face (logical relevance for HCAI prevention), content (related to reducing risks in health services), and criterion validity (scientific evidence for HCAI prevention). The evidence levels of the criteria were: I (criteria 1–4, 6, 9, and 10), IB (criteria 5, 7, and 8) and III (criterion 11). Reliability was promoted by detailed clarification of each one and video conferencing with those in charge of gathering the information. The criteria were shared and discussed with representatives of all levels of the Hospital Infection Control Commission. In addition, a composite indicator ('HCAI prevention quality'), estimated as a simple arithmetic mean of the compliance of the 11 criteria, was proposed to facilitate aggregate comparison among hospitals and regions.

Baseline measurement and analysis

Data collection consisted of an electronic self-assessment form containing closed questions characterizing the services and assessment criteria. The form was widely disseminated by all the HCs and hospitals with ICU beds, and was available from March 1st, 2015 to April 15th, 2015. Data reporting was the responsibility of HC. The completed forms were sent to ANVISA via FormSUS, that is a service of the Ministry of Health for the creation of forms on the Web.

Some additional requirements were established to verify and accept compliance data: proof of data notification (criterion 1, HCAI cases; and criterion 9, monitoring of handwashing adherence); a maximum of three years from last update of institutional protocols (criteria 2–6); a maximum of one year past data and attendance lists of training activities (criteria 7 and 8); minimum pre-established essential content (criteria 2–8, 10, and 11); and copy of educational materials (criterion 11). These requirements had to be uploaded with the assessment form, were reviewed by health surveillance inspectors in the states and were validated by the project team at ANVISA.

Point and confidence interval (95%) estimates were calculated for the 11 quality criteria and the composite HCAI prevention indicator at facility and state levels.

Hospitals were characterized according to number of beds and type of patients served (general and adult, paediatric, or neonatal ICU) and the composition of the HC regarding number of professionals, nurses, and other high- or intermediate-level professionals. Overall non-compliance analysis was performed with Pareto chart (Figure 1), to guide priority interventions.

Planning and implementing interventions to improve

The intervention to improve was devised following a change theory based on three principles: (i) data-driven (baseline assessment Results); (ii) participatory, coordinating efforts between the central (ANVISA) and state committees (SCs); and (iii) multifaceted, considering the groups of strategies for QI proposed by the WHO namely: Leadership reinforcement, Regulations and standards, Organizational capacity, Information, and Population participation [28,29]. The specific actions included:

- Leadership: raising awareness about accountability and skills for HCAI prevention for HCs;
- Regulations and standards: reinforcing dissemination of HCAI protocols and inspection of compliance with required quality criteria;
- Organizational capacity: developing educational material and implementing online training for hospital-based health professionals;
- Information: reinforcement of external assessment and feedback of Results to hospitals;
- Population participation: preparation and dissemination of educational materials to promote patient participation in preventive measures.

The intervention was implemented between April 2015 and February 2016. The Results section explains how the implementation of these planned actions occurred.

Reassessment

Reassessment of HCAI prevention criteria was carried out from March 1st, 2016 to April 15th, 2016 (a year after baseline assessment), with the same methodology as for baseline assessment. To increase hospital response, from February 2016 onwards, ANVISA sought support from three professional associations in Brazil to disseminate the data gathering form via social media and e-mails to thousands of professionals. Furthermore, ANVISA sent weekly reminders to the HCs to encourage responses.

Improvement was estimated in absolute (difference in compliance between the second and the baseline evaluation) and relative (in relation to the room for improvement at the baseline evaluation) terms, for each of the 11 criteria and the composite indicator. Statistical significance of differences in compliance was tested by calculating the z-score, one-tail hypothesis, and *t*-test to test homogeneity of the characteristics of the before-and-after samples of hospitals, even though we performed an additional specific analysis of the improvement for the group of hospitals participating in both the baseline and the second evaluation. Action Stat® software, version 3.1, and SPSS®, version 21.0, were used. A before-and-after Pareto chart was used for graphical analysis of overall improvement and identification of new improvement

Table I
Overall compliance with hospital-associated infection (HCAI) prevention quality criteria before (2015) and after (2016) the intervention

Criteria	p1 (95% CI) ($N = 563$)	p2 (95% CI) ($N = 681$)	Absolute improvement (p2 − p1)	Relative improvement (p2 − p1/100 − p1)	*P*-value[a]
HCAI surveillance					
1. Regular HCAI notification, based on national diagnostic criteria.	91.8 (89.9–93.7)	92.4 (90.8–93.9)	0.6	7.3	0.407
Protocols					
2. Institutional protocol implemented to prevent central-line-associated primary bloodstream infection.	82.6 (80.0–85.2)	90.4 (88.7–92.2)	7.8	44.8	0.001
3. Institutional protocol implemented to prevent catheter-associated urinary tract infection.	83.5 (80.9–86.0)	87.9 (86.0–89.9)	4.4	26.7	0.015
4. Institutional protocol implemented to prevent ventilator-associated respiratory tract infection.	83.5 (80.9–86.0)	88.7 (86.8–90.6)	5.2	31.5	0.005
5. Institutional protocol implemented for medically prescribed antimicrobials.	73.2 (70.1–76.2)	80.7 (78.4–83.1)	7.5	28.0	0.001
6. Institutional protocol implemented for hand hygiene.	92.9 (91.1–94.7)	96.9 (95.9–97.9)	4.0	56.3	0.001
Training					
7. Periodic training for ICU personnel on HCAI prevention and control.	83.7 (81.1–86.2)	91.8 (90.1–93.4)	8.1	49.7	0.001
8. Periodic training for cleaning staff on HCAI prevention and control.	80.1 (77.4–82.9)	88.4 (86.5–90.3)	8.3	41.7	0.001
Monitoring					
9. Regular monitoring of hand hygiene adherence by ICU personnel.	60.7 (57.4–64.1)	70.0 (67.3–72.7)	9.3	23.7	0.001
Hand hygiene facilities					
10. ICUs equipped with adequate hand hygiene facilities for the professionals working in these areas.	97.9 (96.9–98.9)	100 (100–100)	2.1	100	0.001
Patient participation					
11. HC professionals promote strategies to increase patient/companion/family participation in HCAI prevention and control in the ICUs.	76.6 (73.6–79.5)	82.8 (80.5–85.1)	6.2	26.5	0.004
Composite indicator					
HCAI prevention quality – QualiHCAI	82.4 (79.2–85.6)	88.3 (85.8–90.6)	5.9	33.5	0.001
QualiHCAI – Centre-West	82.4	90.2	7.8	44.2	0.001
QualiHCAI – Northeast	83.1	84.9	1.8	10.9	0.001
QualiHCAI – North	73.3	83.8	10.5	39.4	0.001
QualiHCAI – Southeast	84.1	90.5	6.4	40.3	0.001
QualiHCAI – South	81.6	89.1	7.6	41.0	0.001

p1, compliance percentage in the first assessment; p2, compliance percentage in the second assessment; CI, confidence interval; ICU, intensive care unit.
[a] z-Test to compare percentages.

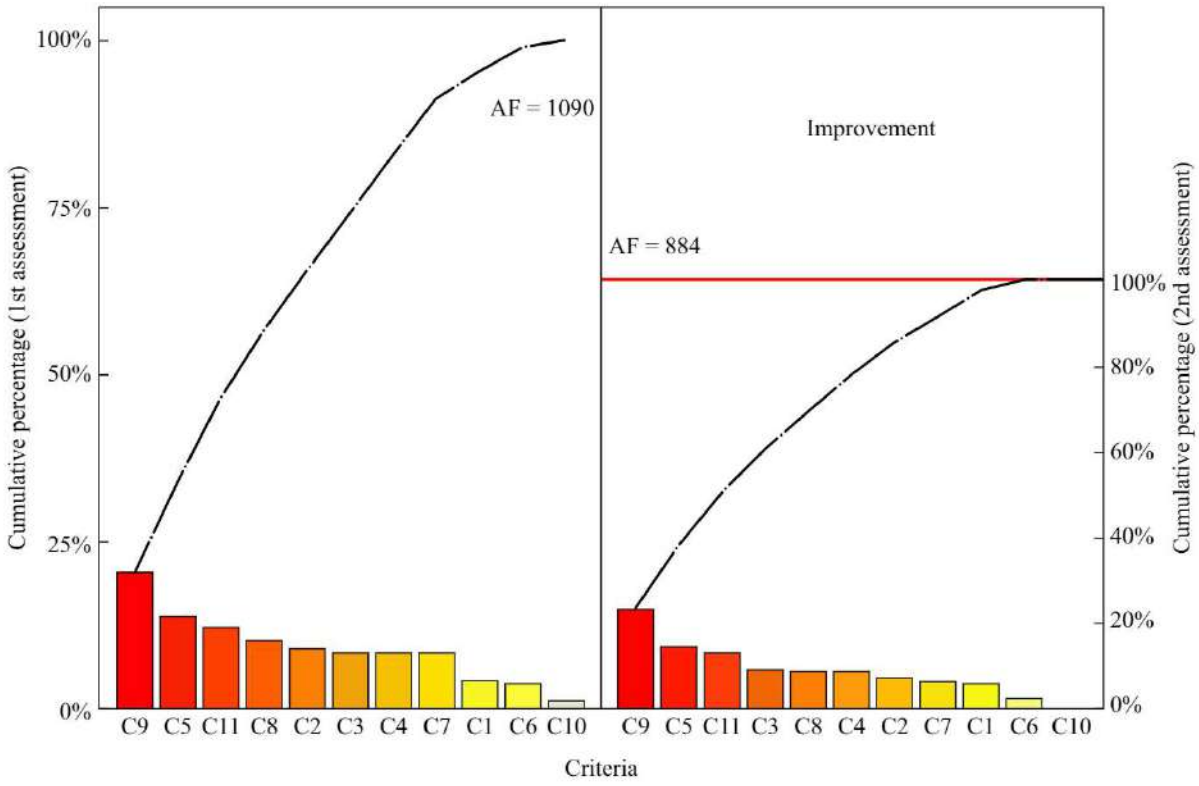

Figure 1. Overall non-compliance analysis. For criteria C1–C11, see Table I. AF, absolute frequency.

priorities, and a before-and-after geographical cartogram to visualize in a map of Brazil the baseline situation and improvements after the intervention, at state level.

Although the direct purpose of the intervention was not the assessment of changes in infection rates, we also collected and present additional information about the official HCAI data sent by participating hospitals in both evaluations and all the other hospitals. Data include central-line-associated bloodstream infection (CLABSI), ventilator-associated pneumonia (VAP), and catheter-associated urinary tract infection (CAUTI). All data were adjusted by central venous catheter utilization rate, patients on mechanical ventilation, and patients using bladder catheter. After accepting the normality of the data with Kolmogorov–Smirnov test, the adjusted HCAI rates before (2015) and after the intervention (2016) were compared with *t*-test for paired samples.

Results of this study were widely disseminated to all the states, districts, and participating hospitals. The use of the data for this manuscript was authorized by ANVISA, who also provided detailed information about the interventions to improve that were implemented.

Results

Participating hospitals

We received 590 data forms for baseline assessment and 1101 for the second assessment. After excluding repeated or incorrectly filled-out forms and hospitals without ICU, data were analysed from 563 hospitals (86,837 beds) in the first assessment (30.1% response) and 681 (101,231 beds) in the second (36.4% response). All the 26 states and the Federal District were represented in both assessments, with a range of 2–83% of hospitals by state in the first evaluation, and from 3% to 100% in the second. A group of 388 hospitals (20.8% of the target facilities), also representing all the 26 states, participated in the two assessments.

There were no significant differences in the characteristics of the hospitals participating in the first and second assessments. In the first assessment, the hospitals had an average of 154.2 beds, 23.1 of which were ICU beds. In the second assessment, the average was 148.6 beds, 22.3 ICU beds. The distribution of ICU beds by type (adult, paediatric, neonatal) and the composition of the HC in the participating hospitals in the first and second evaluation were also similar in both assessments (Supplementary Appendix A).

Baseline assessment

The first assessment revealed rather high compliance (>90%) in three of the 11 measures (first column of Table I): adequate infrastructure for hand hygiene (HH); implementation of institutional protocol for HH; and regular monthly notification of HCAIs in the last six months. Another four measures had a compliance of >80% (see Table I). However, there was noticeable room for improvement in some key measures such as: implementation of an institutional protocol for antimicrobial prescription; promotion of strategies to increase patient/companion/family participation in HCAI prevention and control in the ICUs; and regular monitoring of HH adherence by ICU personnel, which was the measure with the lowest compliance. The graphical analysis of non-compliance

data with Pareto chart (Figure 1) further illustrated the criteria that should be prioritized for improvement. The geographical distribution of the composite indicator revealed a noticeable variability among states (Figure 2), and the North region as the one most in need of improvement (Table I).

Implementation of interventions to improve

A Gantt chart was used to help plan and execute the measures foreseen by ANVISA in the intervention phase in collaboration with the SC and specialists, systematically and within the deadline proposed. A series of measures was successfully adopted within the deadline established, such as: holding meetings with working groups to prepare National HCAI Prevention Protocols; technical visits of SC to the health services to promote the creation and implementation of these protocols; reinforcing the importance of sanitary regulation to the HC and SC; reporting the Results of the first assessment to the 27 states at a face-to-face event in Brasília; underscoring the local priorities to the leaderships; inspections for education, persuasion, and law enforcement; conducting video conferences to assess the improvement measures promoted and proposing solutions.

Despite the effort expended, the following activities were more difficult to implement within the deadline established and required special attention: validation of National HCAI Prevention Protocols and antimicrobial use; bibliographic review, layout, and publication of National HCAI Prevention Protocols; video classes on the ANVISA site discussing infection prevention and activities aimed at encouraging patient/family participation. Budgetary constraints, difficulty in reconciling the professionals' schedules, the high workload of ANVISA technicians, and bureaucratic barriers in hiring professionals to execute the educational and training strategies, limited somewhat the extension and intensity of the intervention.

Quality level after the improvement intervention

There was a significant improvement in 10 of the 11 criteria assessed after the intervention, when comparing the group of hospitals participating in the first evaluation with those participating in the reassessment (Table I), and in all the criteria when comparisons were restricted to the hospitals participating in both evaluations (Table II). The only criterion that did not improve in the unrestricted comparison was 'regular notification of HCAIs', that had high compliance at baseline (91.8%), and remained equally high (92.4%) in general, but reached 96.2% in the hospitals participating in both evaluations. 'Patient participation' improved significantly in absolute terms, but had the lowest relative improvement in the group of hospitals participating in both assessments (Table II), and the second lowest (after 'regular monitoring of HH adherence') when comparing the before and after groups (Table I). It remains as a priority area for further improvement, as shown in the before-and-after Pareto chart (Figure 1) – even though it significantly improved in the overall analysis (all hospitals) and in the analysis for the group of hospitals that participated in both evaluations (82.4% vs 88.3%, and 84.0% vs 91.4%, respectively; $P < 0.001$ in both cases). The composite indicator improved significantly in the general analysis and in the specific analysis only with the hospitals that participated in both evaluations (82.4% vs 88.3%, and 84.0% vs 91.4%, respectively; $P < 0.001$ in both). Most noticeably, geographical variability decreased when comparing states (Figure 2), and regions, with significant improvements in all of them (Tables I and II).

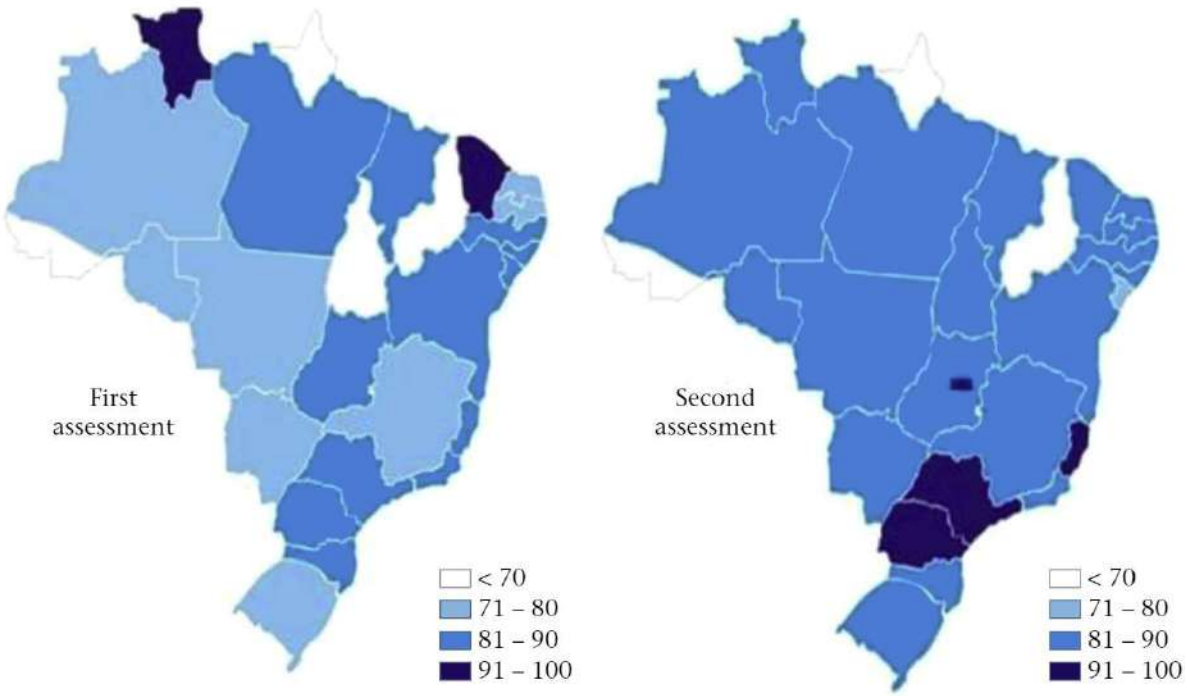

Figure 2. Geographical distribution, by state, of the composite indicator (arithmetic mean of the compliance of the 11 criteria).

Table II
Overall compliance with hospital-associated infection (HCAI) prevention quality criteria before (2015) and after (2016) the intervention

Criteria	p1 (95% CI) ($N = 338$)	p2 (95% CI) ($N = 338$)	Absolute improvement (p2 − p1)	Relative improvement (p2 − p1/100 − p1)	*P*-value[a]
HCAI surveillance					
1. Regular HCAI notification, based on national diagnostic criteria.	92.3 (90–95)	96.2 (94–98)	3.9	50.6	0.023
Protocols					
2. Institutional protocol implemented to prevent central-line-associated primary bloodstream infection.	85.8 (82–89)	93.2 (91–96)	7.4	52.1	0.001
3. Institutional protocol implemented to prevent catheter-associated urinary tract infection.	85.2 (82–89)	91.4 (89–94)	6.2	41.9	0.008
4. Institutional protocol implemented to prevent ventilator-associated respiratory tract infection.	84.0 (80–88)	92.3 (89–95)	8.3	51.9	0.001
5. Institutional protocol implemented for medically prescribed antimicrobials.	74.0 (70–78)	83.1 (79–87)	9.1	35.0	0.002
6. Institutional protocol implemented for hand hygiene.	93.8 (91–96)	98.5 (97–99)	4.7	75.8	0.001
Training					
7. Periodic training for ICU personnel on HCAI prevention and control.	85.8 (82–89)	95.3 (93–97)	9.5	66.9	0.001
8. Periodic training for cleaning staff on HCAI prevention and control.	82.2 (79–86)	91.4 (89–94)	9.2	51.7	0.001
Monitoring					
9. Regular monitoring of hand hygiene adherence by ICU personnel.	64.5 (60–69)	79.6 (76–83)	15.1	42.5	0.001
Hand hygiene facilities					
10. ICUs equipped with adequate hand hygiene facilities for the professionals working in these areas.	99.1 (98–100)	100.0 (100–100)	0.9	100.0	0.123
Patient participation					
11. HC professionals promote strategies to increase patient/companion/family participation in HCAI prevention and control in the ICUs.	79.0 (75–83)	84.3 (81–88)	5.3	25.2	0.045
Composite indicator					
HCAI prevention quality – QualiHCAI	84.0 (80–88)	91.4 (88–94)	7.4	46.30	0.001
QualiHCAI – Centre-West	83.5	92.4	8.9	53.9	0.001
QualiHCAI – Northeast	86.5	91.1	4.6	34.2	0.001
QualiHCAI – North	73.0	82.4	9.4	34.7	0.001
QualiHCAI – Southeast	85.5	92.6	7.1	48.8	0.001
QualiHCAI – South	85.1	92.6	7.5	50.5	0.001

p1, compliance percentage in the first assessment; p2, compliance percentage in the second assessment; CI, confidence interval; ICU, intensive care unit.
[a] *z*-Test to compare percentages.

Regarding infection rates, Table III shows that there was a significant reduction of CAUTI and VAP in the group that participated fully in the project and in the group that did not participate ($P < 0.05$). However, all the mean differences after the intervention were slightly higher in the group that participated in both evaluations (CLABSI: 0.46 vs 0.15; VAP: 5.76 vs 4.94; CAUTI: 0.63 vs 0.37).

Discussion

This study contributed to the knowledge of the level of implementation of HCAI prevention measures in an important sample of Brazilian hospitals, guiding the planning of initiatives targeting this serious patient safety problem. In addition, the study presents evidence of the viability and utility of improvement cycles in external quality enhancement policies, implementing regulations that comply with international standards [22,28].

Locally, the improvement cycle model made an important contribution, since it demonstrated a new perspective for the science of quality improvement in daily ANVISA activities. Implementing measures based on specific assessments and subsequently re-evaluating whether they had had a positive effect motivated the work team to develop them further and plan future projects.

The criteria with a high compliance level seem to reflect the priorities of the guidelines and regulations since the 1980s, which emphasized the infrastructure, inputs, and implementation of institutional protocols to encourage HH, as well as the organization of systems to monitor HCAI epidemiological indicators [11,23,24]. There may be some information bias in our study, since we did not perform an external audit to ensure the reliability of the data. However, we believe that there is a low probability of this happening, as the data were requested by the health authority and providing false information, if detected, may result in fines or other penalties to the hospital.

On the other hand, a number of factors account for the main weaknesses. Indirect monitoring of HH adherence by assessing the use of alcohol-based hand rubs was an optional activity up to 2013 and, as such, this monitoring was not routinely required. Furthermore, the non-existence of a national protocol for the prescription of antimicrobials by health professionals hindered the creation of local protocols. Moreover, given the difficulty in adapting to the patient-centred paradigm, few hospitals promoted strategies to increase the participation of these important subjects in preventing HCAIs [36].

The project could have used other instruments to assess the quality of HCAI prevention measures, but part of the strategy was the participatory development of a feasible, ad-hoc national assessment based on quality criteria with a high level of evidence [37–39].

The multifaceted intervention was apparently effective in inducing improved compliance with quality criteria at participating hospitals in all the regions of the country. Only criterion 1 (regular HCAI notification) did not significantly improve (Table I). However, this criterion already had high compliance in the first assessment (91.8%), a finding reported also in another ANVISA document [40].

In addition, the data revealed a significant decrease in HCAI after the intervention. This reduction was not a direct objective of this study and we cannot attribute it to our intervention.

Table III
Adjusted healthcare-associated infections (HCAIs) before (2015) and after (2016) the improvement intervention

Groups of hospitals	Healthcare-associated infections	No. of hospitals	2015 (before)	2016 (after)	Paired difference		*P*-value[a]
					Mean	95% CI	
Group did not participate in both evaluations	CLABSI per 1000 catheter-days	902	4.40	4.25	0.15	−0.12–0.41	0.287
	VAP per 1000 ventilator-days	890	14.70	9.77	4.94	4.20–5.68	0.000
	CAUTI per per 1000 catheter-days	887	5.11	4.74	0.37	0.08–0.66	0.014
Group participated in both evaluations	CLABSI per 1000 catheter-days	239	4.71	4.25	0.46	−0.04–0.96	0.068
	VAP per 1000 ventilator-days	238	15.34	9.59	5.76	4.46–7.05	0.000
	CAUTI per per 1000 catheter-days	235	5.31	4.68	0.63	0.08–1.17	0.024
Overall	CLABSI per 1000 catheter-days	1141	4.47	4.25	0.21	−0.03–0.45	0.080
	VAP per 1000 ventilator-days	1128	14.84	9.72	5.11	4.47–5.76	0.000
	CAUTI per per 1000 catheter-days	1122	5.15	4.73	0.42	0.16–0.68	0.001

CI, confidence interval; CLABSI, central-line-associated bloodstream infection; VAP, ventilator-associated pneumonia; CAUTI, catheter-associated urinary tract infection.
HCAI was adjusted by rate of dispositive use in each year.
[a] Paired-sample Student's *t*-test.

Many factors must have interfered in this result, mainly internal actions of hospitals that we do not control in our work. This can be seen in the reduction of infection rates even in hospitals that did not participate in the improvement project. Patient safety is ensured at the frontline of healthcare; however, regulation can be an important contextual intervention to induce these actions [1,28].

Current discussion on factors associated with success in improvement initiatives emphasizes the importance of context as a modulator for improving quality [41]. Our approach for this aspect, which analysed improvement in different states and regions of the country, was indirect. We found a significant improvement in all the regions with different socioeconomic status and structural levels of the Brazilian health system, including absolute improvement in the poorest region, thereby favouring equity.

A number of the characteristics of the intervention are aligned with some of the key strategic domains identified by WHO to improve healthcare quality [28]. It is likely that this multifaceted strategy modulated, favouring the effect of the improvement cycle and the Results achieved. One of these strategic domains is 'regulations and standards', which was the essence of the improvement intervention, and the more indispensable since ANVISA is in charge of regulating risks in health services and the project reinforced the need to adapt the services to existing regulations. The effect of establishing standards can be observed in the HH protocol, the only one that was mandatorily implemented and one of the best-assessed criteria.

Another strategic domain is 'leadership development' [28]. Initiatives in this domain are deemed essential, since leaders generate values, and values generate collective attitudes and behaviours that establish the culture of organizations [42]. In our project, SC in the states and HC leaders in the hospitals were made aware, accountable and trained to collaborate during the entire project in order to execute and assess the interventions.

Finally, the intervention also included initiatives in relation to the 'information system' domain [28]. The effect of monitoring and feedback on improving the quality of health services is well known primarily when associated with multifaceted interventions [17,43]. In this case, since it is an external initiative, an external assessment and feedback were performed, specifying the needs and priorities of each state after the first assessment, so that those in charge could join forces in order to improve the initial Results obtained [1].

Despite the contribution of the external interventions that we identified, it is important to acknowledge the words of Palmer: 'from the outside we can evaluate, but internally we can evaluate and improve' [44]. This means that the HCs of the hospitals themselves adapted to comply with the criteria, after regulation, external assessment and inspections, which seemed to be successful in fostering internal initiatives to improve.

It was a challenge to reconcile a national project in such a large and heterogeneous country with highly autonomous states. It was important from the outset to enlist all the parties involved. However, in the first improvement cycle, a number of relevant states did not adhere, likely due to the inexperience of the group with this type of strategy and the little time spent on activities meant to encourage them to join during the intervention phase. This compromised the participation of some SCs, thereby limiting the number of participating hospitals.

We realize in our assessment of the project that in spite of the success of the intervention, it was somewhat hampered by bureaucratic and financial obstacles to hiring external personnel and purchasing educational and training material that would have enhanced the participation of patients and the organizational capacity for HCAI prevention. We underestimated the importance of these bureaucratic barriers, a lesson learnt for future projects. The expected period for implementation was also an important issue. Some SCs and HCs reported that the 45 days to carry out assessments and less than one year to implement the intervention project were insufficient. It seems that this type of broad and nationwide initiative needs more time to mature and produce better results.

Due to ANVISA's legal responsibility to regulate risks in all Brazilian health services, we were unable to randomize the experimental and control group hospitals. As such, the study could not control the influence of parallel national strategies that may have influenced the effect observed, such as implementation of the National Patient Safety Program in 2013 [45]. In terms of sustaining the improvements achieved, the SNVS should repeat the assessments in order to determine whether quality will be maintained over time.

With respect to estimates of criteria compliance, given that approximately one-third of the hospitals with an ICU responded, caution must be taken when generalizing the results to the 1846 institutions with an ICU, nor is it appropriate to extrapolate these findings to the 4784 Brazilian hospitals. We assessed only the responses of health services that volunteered to perform the self-assessments, which may have caused selection bias. However, the higher and more consistent improvement in hospitals that participated from the outset and in both assessments is a good outcome, even if it only occurred in this group of hospitals.

In conclusion, baseline assessment of HCAI prevention quality revealed improvement priorities that were addressed nationally by the states and ANVISA. The improvement cycle was considered feasible and important in changing the situation of the health services and encouraging evidence-based practices. The effect observed in the level of compliance with quality criteria is attributed to regulatory interventions, external assessment and feedback that were implemented. This external management and regulatory model for improvement may be useful to other public agencies in both developing and developed countries seeking short-term national results.

Conflict of interest statement
None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jhin.2020.03.005.

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