ARTICLE
https://doi.org/10.22239/2317-269x.01494

Quality management in hemotherapy services in the interior of Rio Grande do Norte: analysis of the effects of an improvement cycle

Gestão da qualidade nos serviços de hemoterapia do interior do Rio Grande do Norte: análise dos efeitos de um ciclo de melhoria

Ana Virgínia Costa de Medeiros[I]

Isac Davidson Santiago Fernandes Pimenta[II,*]

Isaac Newton Machado Bezerra[II]

Larissa Oliveira Lima Macedo[II]

Viviane Euzébia Pereira Santos[II]

Tamara Peçanha Sharapin Alves[I]

Jane de Medeiros Rodrigues[I]

Wilton Rodrigues Medeiros[II]

Ádala Nayana de Sousa Mata[II]

Grasiela Piuvezam[II]

[I] Subcoordenadoria de Vigilância Sanitária, Secretaria de Estado da Saúde Pública do Rio Grande do Norte, Natal, RN, Brasil

[II] Universidade Federal do Rio Grande do Norte (UFRN), Natal, RN, Brasil

* **E-mail:** isacdavidson29@gmail.com

Received: Mar 30, 2020
Approved: Oct 26, 2020

ABSTRACT

Introduction: Quality management in hemotherapy services is a crucial element for transfusion safety. However, the implementation of quality management is still a challenge in the Brazilian context. **Objective:** To evaluate the effect of a cycle of improvement in hemotherapy services in the interior of Rio Grande do Norte, in compliance with the quality management criteria, elaborated based on the Potential Risk Assessment Method in Hemotherapy Services. **Method:** Quasi-experimental study, before and after, that verified the compliance of 13 quality criteria, elaborated based on the Potential Risk Assessment Method in Hemotherapy Services. Eight hemotherapy services from the interior of the state of Rio Grande do Norte participated in the study, being four Transfusion Agencies, two Collection and Transfusion Units and two Regional Blood Centers. Descriptive statistics and Pareto charts were used to analyze the quality criteria. **Results:** After the improvement cycle, there was a 36.4% reduction in noncompliance. In the analysis by service, there was an increase in compliance with the criteria, varying between 7% and 50%. The implementation of protocols, internal audit procedures and quality monitoring were the criteria that registered relatively greater adherence after the intervention, however they remained the main causes of non-conformities, both before and after the intervention. **Conclusions:** The improvement cycle proved to be a valid intervention in increasing the adherence of services to the quality management activities recommended by health legislation, with health surveillance having an important role in reaching the established standards.

KEYWORDS: Hemotherapy Service; Quality Management; Health Surveillance; Quality Improvement

RESUMO

Introdução: A gestão da qualidade em serviços de hemoterapia é um elemento crucial para a segurança transfusional. A implementação das atividades de gerenciamento da qualidade é um desafio no contexto brasileiro. **Objetivo:** Avaliar o efeito de um ciclo de melhoria nos serviços de hemoterapia do interior do Rio Grande do Norte, na conformidade com os critérios de gestão da qualidade, elaborados com base no Método de Avaliação de Risco Potencial em Serviços de Hemoterapia (MARPSH). **Método:** Estudo quase-experimental, antes e depois, que avaliou 13 critérios de qualidade, elaborados com base no MARPSH da Agência Nacional de Vigilância Sanitária. Participaram do estudo oito serviços de hemoterapia do interior do estado do Rio Grande do Norte, sendo quatro Agências Transfusionais, duas Unidades de Coleta e Transfusão e dois Hemocentros Regionais. Estatísticas descritivas e gráficos de Pareto foram utilizados. **Resultados:** Observou-se redução de 36,4% dos problemas de qualidade após a realização do ciclo de melhoria. Na análise por serviço, houve um aumento no cumprimento dos critérios variando entre 7,0% e 50,0%. A implementação de protocolos, os procedimentos de auditoria interna e o monitoramento da qualidade foram os critérios que registraram relativamente uma maior adesão após a intervenção, todavia

permaneceram como as principais causas de não conformidades, tanto antes quanto após a intervenção. **Conclusões:** O ciclo de melhoria demonstrou ser uma intervenção válida no aumento da adesão dos serviços às atividades de gestão da qualidade preconizadas pela legislação sanitária, tendo a Vigilância Sanitária um importante papel para alcance dos padrões estabelecidos.

PALAVRAS-CHAVE: Serviço de Hemoterapia; Gestão da Qualidade; Vigilância Sanitária; Melhoria de Qualidade

INTRODUCTION

Blood and its components are essential in healthcare. The availability of different units, their blood groups (ABO) and Rhesus antigen (Rh) in inventory, as well as the intrinsic quality of each of these units, are two basic conditions to increase the chances of success of health interventions in this area.[1]

Hemotherapy services are complex healthcare facilities that bear striking similarities to the industry of biological products, since they are both responsible for handling blood components.[2,3] The use of blood as a therapeutic product and the recognition of the risks associated with blood transfusion—which, in most cases, are not perceived or known by the general population—require qualified regulatory action by the State.[4]

Despite advances in Brazilian legislation and in production practices, the quality of hemotherapy products can be compromised in some of the stages of the blood cycle and, therefore, increase the potential risks to the health of end customers.[3,5]

In this sense, hemovigilance plays a fundamental role as a set of surveillance procedures to identify and prevent adverse events during the blood cycle and improve the quality of processes and products.[6,7]

In order to identify potential risks in hemotherapy services, Brazil's Health Surveillance Agency (Anvisa) has designed an instrument called Potential Risk Assessment Method in Hemotherapy Services (MARPSH) to be used in health inspections. The instrument contains 471 control items that encompass the risks related to product, patient, donor, and healthcare worker, classified by severity, probability of occurrence, and possibility of harm.[8]

A study using the MARPSH has shown that procedures related to quality management have a higher frequency of non-compliance in hemotherapy services.[9] This fact has also been observed in the Brazilian state of Rio Grande do Norte (RN) by routine inspections done by the Subcoordination of the State Health Surveillance (SUVISA/RN).

In this context, quality improvement cycles can be used to achieve the quality standards required by the health regulation. The literature shows that this method of quality improvement is valid and useful in different healthcare settings,[10,11] however, the effects of this type of intervention in hemotherapy services have not yet been properly explored.

With that in mind, the present study sought to evaluate the effect of an improvement cycle in hemotherapy services in the state of RN, in compliance with the quality management criteria proposed by SUVISA/RN and based on the MARPSH.

METHOD

The design of the study was of a quasi-experimental before-and-after type[12] to assess the effect of the improvement cycle on the rate of compliance with the components of the quality management system recommended by Anvisa's current health standards. The steps and tools of a quality improvement cycle[13] were strictly followed.

According to the Master Plan for the Blood Policy of the State of RN,[14] the state public hemotherapy network comprises 17 hemotherapy services, nine of which are located in the capital and eight in inland municipalities. The study was carried out in the eight services located in inland municipalities whose responsibility for inspection lies with SUVISA/RN. These services conduct activities related to the blood cycle and provide hemotherapeutic support in virtually all state health regions.

The services located in the state capital were not included in the study because their inspection is the responsibility of the municipal Health Surveillance body of Natal.

The services participating in the study include two Regional Blood Centers (HR1 and HR2) located in Mossoró/RN and Caicó/RN; two Collection and Transfusion Units (UCT1 and UCT2), one in Currais Novos/RN and the other in Pau dos Ferros/RN; in addition to four Transfusion Agencies (AT1, AT2, AT3 and AT4) of regional public hospitals, located in the municipalities of Parnamirim/RN, Santa Cruz/RN, Santo Antônio/RN, and Apodi/RN.

Five technicians from SUVISA/RN linked to the Health Surveillance in Health Services (one pharmacist, two dentists, one nurse, and one biologist) participated voluntarily in the project and were directly or indirectly involved in health inspections in the area of hemotherapy.

The quality improvement cycle was used as an intervention strategy to carry out the project. This intervention can be implemented on an internal initiative, when the improvement cycle comes from the institution itself, or on an external initiative, when the cycle is promoted by the health surveillance body, for example. Basically, improvement cycles include the following five steps: identification and prioritization of the

improvement opportunity, analysis of the quality problem, quality assessment, intervention to improve, and reassessment and recording of the improvement.[15]

Identification and prioritization of the improvement opportunity

Based on data collected by health inspections done by SUVISA/RN during 2016, we used the following strategies to identify and prioritize the opportunities for improvement in the study's hemotherapy services: brainstorming, nominal group technique, and prioritization matrix without hierarchical criteria. The meetings at this stage were held in February 2017, with the participation of technicians from the Health Services department of SUVISA/RN.

The analysis of the techniques we employed resulted in a consensus on the prioritization of the following problem: "Non-compliance of hemotherapy services with the Quality Management processes of the MARPSH".

Analysis of the quality problem

The priority improvement opportunity was analyzed by the technicians qualitatively in February 2017, using the Cause and Effect Diagram or Ishikawa Diagram. Subsequently, the causes of the opportunity for improvement were classified as non-modifiable and modifiable—either hypothetical or with prior scientific evidence—to inform decision making in relation to direct interventions or the need to assess the causes of the problem.

Quality assessment

Building quality criteria

The SUVISA/RN team responsible for inspecting hemotherapy services in inland municipalities of RN developed 13 quality criteria based on the MARPSH. The criteria are described in the Chart.

Quality assessment and data collection

Quality assessments were performed by two previously trained technicians from the SUVISA/RN team who were also members of the research team. The initial assessment (T1) was based on data from health inspections carried out in 2016. It was, therefore, retrospective.

The reassessment phase (T2) occurred prospectively in October 2017, with the assessment of technicians during routine health inspections. Complementary visits to the facilities were made specifically for further data collection.

The following data sources were used: spreadsheets for internal quality control of the techniques used in immunohematology; proof of participation in the External Quality Assessment Program; training and personal qualification records; Operational Procedures Manual for blood cycle activities; schedules and records of preventive and corrective maintenance of equipment and devices, as well as other documents that could be relevant to the assessment.

Quality improvement interventions

The interventions to improve quality consisted of external initiatives that were designed, programmed, and conducted by SUVISA/RN technicians, and performed in the hemotherapy services participating in the project. This phase initially consisted of designing a plan based on the results of the quality assessment (T1) and using the Gantt Diagram to organize the planned actions.

The interventions included training sessions and support and guidance activities conducted by two technicians from the SUVISA/RN team in the eight hemotherapy services. They were carried out over a period of two months, between July 6 and September 1, 2017, and included about 30 professionals from the technical and administrative areas of the participating services.

Chart. Quality criteria for the assessment of hemotherapy services.

Criteria	
C1	Defined organizational structure with responsibilities assigned to each sector
C2	Professionals who are properly qualified/trained to work in the hemotherapy service
C3	Existence of Training Programs, including quality management activities
C4	Provision of Operating Procedures Manual for all blood cycle activities
C5	Defined internal audit processes
C6	Defined processes for handling non-compliant items and corrective measures
C7	Defined processes for handling complaints
C8	Defined processes for handling cases of non-compliant products
C9	Defined processes to identify and notify the National Health Surveillance System of any non-compliance related to product quality and safety
C10	Internal quality control of the techniques used in the service
C11	Participation in External Quality Assessment (AEQ)
C12	Schedule of records of preventive and corrective maintenance of equipment and devices
C13	Set of indicators and goals that assess the quality of the hemotherapy service

Source: Prepared by the authors, 2020.

The training sessions were held in a seminar format and had a workload of 4 hours for ATs and 6 hours in HRs and UCTs. The meetings were scheduled in advance, one for each service, so as to include all employees in the ATs and all those responsible for the relevant departments in the HRs and UCTs.

The training content included service performance in T1, legislation on the evaluated criteria, quality management applied to hemotherapy services, improvement cycles, design of protocols, and strategies to achieve higher quality standards.

During this period, these services also received support and guidance activities, clarification sessions, and shared knowledge about quality-related topics. In addition, project members from both SUVISA/RN and intervention services attended training on the Qualification Program for the State Public Hemotherapy Network (PQHE), which took place in July 2017, at the Dalton Barbosa Cunha Blood Center, in the city of Natal. The training was an initiative of the Ministry of Health (MS), formalized by a term of adhesion with the manager of the State Public Hemotherapy Network. It took place concurrently with the intervention stage and reinforced concepts and assumptions of quality management provided for in the current health legislation.

Analysis and presentation of assessment data in the pre-intervention and post-intervention periods

The level of compliance with each criterion was assessed based on relative and absolute frequencies. We used the data to create Pareto charts, which are widely used in quality assessment because they show the main non-compliant items, as well as the improvement achieved between two separate assessments (T1 and T2). In the Pareto chart, the x axis corresponds to the quality criteria assessed, ordered from most to least frequent. The left y axis contains the absolute number, and the right y axis contains the relative frequency of non-compliance with the criteria.

The research was conducted with the consent of the Dalton Barbosa Cunha Blood Center and the State Department of Public Health of RN. The study was approved by the Research Ethics Committee of the Onofre Lopes University Hospital (HUOL/UFRN), according to the Certificate of Presentation for Ethical Appreciation (CAAE) 78732117.5.0000.5292 and opinion n. 2.364.028. All Brazilian and international protocols for research with human beings were respected.

RESULTS

There was an increase in the fulfillment of the criteria in seven of the eight hemotherapy services that participated in the intervention. This increase varied between 7.0% and 50.0% among the services, as shown in the Table. The exception among the evaluated services was AT3, with a 50.0% decrease in compliance with the criteria between the period before de cycle of improvement (T1) and the period after it (T2).

UCT1 was the only service that managed to fulfill all 13 criteria (100.0%) at the end of the intervention, followed by AT4 and HR2, both with 12 criteria (92.3%). Nevertheless, the units that had the most significant increase in the fulfillment of the criteria were AT1 (50.0%), AT2 (46.0%) and UCT1 (38.5%).

Regarding the analysis by criteria, in general, the level of compliance was maintained or increased, with improvement in the implementation of internal audit processes (C5), protocols (C6 - C10), equipment maintenance (C12), and implementation

Table. Assessment and reassessment of levels of compliance with quality criteria by hemotherapy service in inland municipalities of Rio Grande do Norte - 2016/2017.

Quality criteria	Hemotherapy services															
	AT 1		AT 2		AT 3		AT 4		UCT 1		UCT 2		HR 1		HR 2	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
C1	C	C	C	C	NC	NC	C	C	C	C	C	C	C	C	C	C
C2	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
C3	NC	NC	NC	NC	C	NC	C	C	C	C	C	C	NC	C	C	C
C4	NC	NC	NC	C	C	NC	C	C	C	C	C	C	C	C	C	C
C5	NC	NC	NC	C	NC	NC	NC	C	NC	C	C	C	C	C	C	C
C6	NC	C	NC	C	NC	NC	C	C	NC	C	NC	NC	C	C	C	C
C7	NC	NC	NC	C	NC	NC	C	C	NC	C	NC	NC	NC	NC	NC	C
C8	NC	NC	NC	C	NC	NC	C	C	NC	C	NC	NC	NC	NC	NC	NC
C9	NC	NC	NC	NC	NC	NC	NC	C	C	C	NC	NC	NC	NC	NC	C
C10	NC	NC	NC	C	NC	NC	C	C	C	C	NC	C	NC	C	C	C
C11	NC	NC	C	C	C	C	C	C	C	C	C	C	C	C	C	C
C12	NC	C	NC	NC	NC	NC	NC	NC	C	C	C	C	C	C	C	C
C13	NC	NC	NC	NC	NC	NC	NC	C	NC	C	NC	NC	NC	NC	NC	C
Total compliance	15.4% (2/13)	30.8% (4/13)	23.1% (3/13)	69.2% (9/13)	30.8% (4/13)	15.4% (2/13)	69.2% (9/13)	92.3% (12/13)	61.5% (8/13)	100.0% (13/13)	53.8% (7/13)	61.5% (8/13)	53.8% (7/13)	69.2% (9/13)	69.2% (9/13)	92.3% (12/13)

Source: Prepared by the authors, 2020.
C: compliant with the criterion; NC: non-compliant with the criterion; AT: transfusion agencies; UCT: collection and transfusion units; HR: regional blood centers; T1: before the improvement cycle; T2: after the improvement cycle.

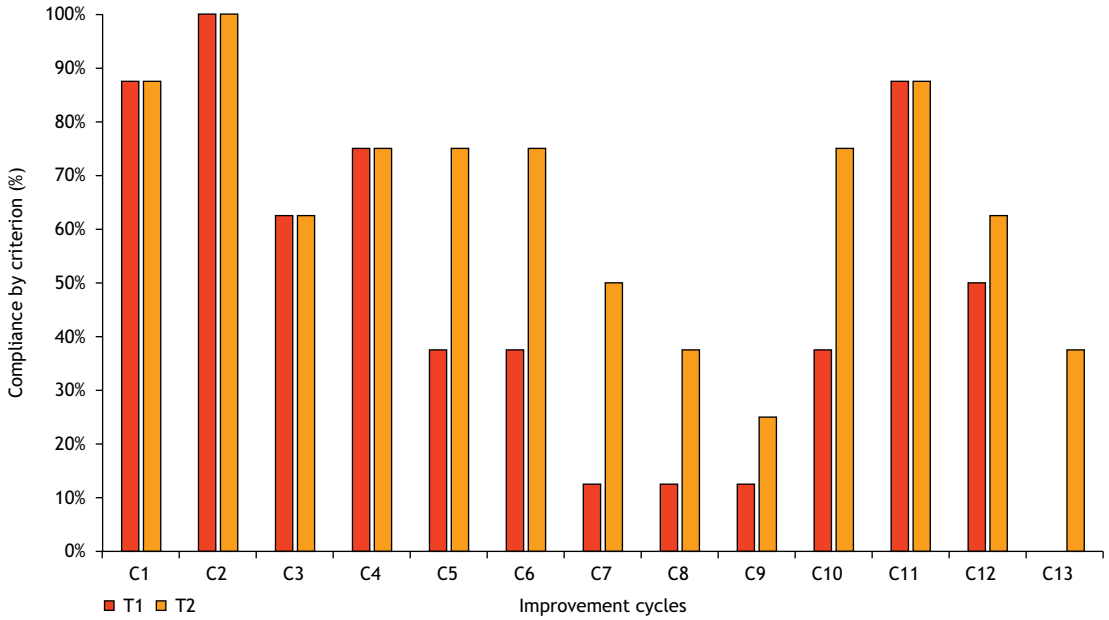
of quality indicators (C13), as described in Figure 1. However, the implementation of protocols (C7 - C9) and indicators (C13) continued to be the criteria with the lowest rate of compliance.

This aspect is also perceived on the Pareto chart shown in Figure 2. There was a decrease in the absolute number of non-compliant items or quality defects—from 55 to 35—after the intervention in the eight participating hemotherapy services, with a 36.4% reduction in quality problems. However, we can see that criteria C7 - C9 and C13 continue to be the most significant quality defects, both before and after the intervention, accounting for 53.0% of the total non-compliant items in T1 and 56.0% in T2.

DISCUSSION

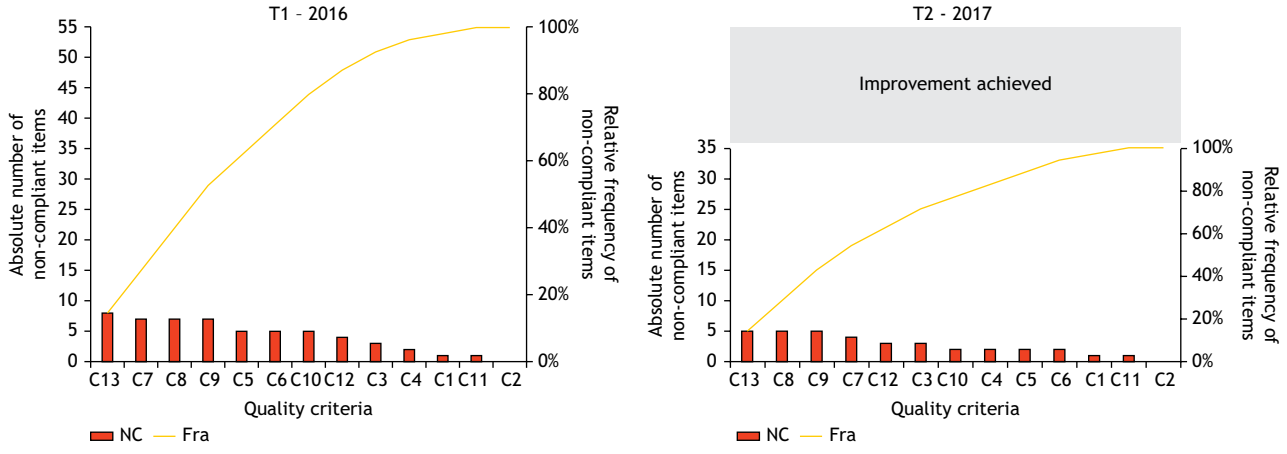
The improvement cycle carried out in hemotherapy services in the state of Rio Grande do Norte had a positive effect on most of the assessed criteria. This shows that the proposed intervention can enhance the compliance of such services with the quality management system.

The improvement cycle contributed to reducing the quality problems found in the initial assessment, with an improvement of about 40.0% or more in half of the participating institutions. We observed that the criteria with the lowest levels of compliance in



T1: before the improvement cycle; T2: after the improvement cycle.
Source: Prepared by the authors, 2020.

Figure 1. Percentage of hemotherapy services in inland municipalities of Rio Grande do Norte that met the quality criteria in the 1st (T1) and 2nd (T2) assessments, by criterion.



NC: non-compliant with the criterion; Fra: cumulative relative frequency.
Source: Prepared by the authors, 2020.

Figure 2. Pareto charts of the prevalence of non-compliant items before (T1) and after (T2) the improvement cycle in hemotherapy services in inland municipalities of RN, 2016-2017.

T1 were those that had the most noticeable increase in compliance in T2. This demonstrates the importance of carrying out the improvement cycle, that is, the methodology used was effective.

However, the results indicate that the participating institutions struggled to design and adopt protocols to standardize procedures, implement an internal audit program, and monitor quality indicators. These activities are essentially managerial and provide the foundation for the correct development of work processes. They were responsible for at least 50.0% of the quality problems both before and after the completion of the improvement cycle.

Creating and adopting protocols help us understand the processes that will be carried out and enable the establishment of a standard to be followed and assessed.[16] The protocols, together with internal audit procedures and quality indicators and goals, are a precondition for quality assurance in blood products.[17]

The protocols that the services struggled to adopt can directly interfere with the quality of the final product, and so can the process of treatment of non-compliant items and corrective measures, for example. A study carried out in a Brazilian hemotherapy service reported non-compliance with the legislation in force in more than 20% of the 220 bags of red blood cells analyzed.[18]

As for the adoption of quality indicators and goals by hemotherapy services, there was a clear increase in compliance between T1 and T2 when compared to the other criteria. Nevertheless, this remains one of the most difficult components to implement. Indicators and goals are essential in any group of activities that promote continuous improvement, like improvement cycles and quality monitoring.[19]

Thus, the lack of clear indicators and goals in hemotherapy services is a sign that continuous improvement may not be part of the routine of these services, since the mere existence of procedures in established protocols does not guarantee compliance with them.[20]

It is worth considering that context-related factors play an important role in the success of any intervention to improve quality. Areas like leadership, organizational culture, and infrastructure can influence the results achieved by an institution.[21] These components, albeit not part of the assessment instruments, were noticed by the evaluators and may explain the different levels of improvement achieved by the institutions.

For example, we observed the fact that in AT3, in addition to some difficulty meeting the criteria of the initial assessment, there was a reduction in the number of criteria met in the reassessment. Factors like high staff turnover during the study period may have influenced these results by hindering the engagement of the professionals with the improvement cycle.

In UCT1, for instance, the context seemed more favorable, with more adequate facilities, less staff turnover and a 61.5% baseline fulfillment of the criteria even before the intervention.

The difficulty in adopting components of the quality management system in hemotherapy services is not exclusive to this context. A nationwide study that used the MARPSH as an assessment instrument suggested that the absence of a consolidated quality management system is one of the main non-compliant items of hemotherapy services.[9] Hence the importance of interventions that improve adherence to quality management practices recommended by health standards.

In this sense, a study by Stein et al.[22] at a transfusion agency in a capital city of southern Brazil demonstrated that improvement cycles can be valid strategies in the implementation of a quality management system. The authors reported an increase in compliance with the MARPSH criteria from 55% to 100% after the completion of the improvement cycle, with 100% compliance in other components of the assessment, like biosafety, equipment and devices, and storage.[18]

Despite corroborating with the results found in this study, it is worth noting that improvement cycles also require an assessment process of the health services, and the nature of the promoting agent may somehow influence the results.[23] While the improvement cycle promoted by Stein et al.[22] was internal, this study reported the effect of an external improvement cycle conducted by the health surveillance authority, which is a regulatory and supervising body.

In our society, especially among regulated sectors, there is still a widespread understanding of health surveillance bodies as law enforcement and punitive agencies.[24] We believe that this perception can encourage the participating services to meet the criteria for fear of punishment if there is no improvement. However, it is also worth noting that health surveillance plays an important role in improving the quality of Brazilian healthcare services and is an important driver of higher quality standards.[25,26]

Likewise, the Brazilian Ministry of Health has had the National Qualification Program for the Hemotherapy Network (PNQH) since 2008. The program intends to promote the technical qualification of the hemotherapy network, and one of its specific objectives is the implementation of quality management systems in hemotherapy services.[1] However, the PNQH works on a volunteer adhesion basis, which means the service itself should request the visit of the program's team to receive support from the Ministry of Health and improve the quality standards of the hemotherapy service.

Furthermore, it is important to consider that the present study has some limitations. The main limitation is related to the selected quality criteria, of which most are related to the structure, which measures quality only indirectly.[27] Nevertheless, the implementation of these structural components is fundamental for the development of quality management processes, like the adoption of protocols.[13]

In this sense, further studies are needed to assess compliance with quality management processes in the routine of hemotherapy services, as well as the influence of compliance with these

processes on the quality of the final product. In addition, the assessment of context-related factors, like organizational culture, can be addressed in future research to cast light on their influence on the results of similar interventions.

It is timely to consider that, because of the small sample—with data from only eight hemotherapy services in one state—the statistical tests were limited. It is therefore recommended that the methodology adopted in the present study be applied to other areas in Brazil, with the objective of corroborating the results and improving the quality of care in this context.

CONCLUSIONS

The implementation of structural components for the quality management system is still a challenge for hemotherapy services in inland municipalities of RN. This study has shown that the improvement cycle is a valid tool for achieving established health standards, with health surveillance playing an important role in the process, not only by collecting and analyzing data, but also by working to foster quality improvement. Other improvement cycles may be carried out to increase compliance with the established quality criteria.

REFERENCES

1. Ministério da Saúde (BR). Guia para implementar avaliações nos serviços de hematologia e hemoterapia na perspectiva do programa nacional de qualificação da hemorrede. Brasília: Ministério da Saúde; 2016.
2. Campos CO. Importância das boas práticas de fabricação no ciclo do sangue: análise comparativa das legislações referentes aos serviços de hemoterapia no Brasil com outros países [monografia]. Rio de Janeiro: Fundação Oswaldo Cruz; 2016.
3. Vuk T, Qiu Y, Bust L, Strengers P, Seidl C. Quality monitoring and risk management in blood transfusion services. ISBT Sci Ser. 2018;13(3):284-9. https://doi.org/10.1111/voxs.12418
4. Silva Júnior JB, Costa CS, Baccara JPA. Regulação de sangue no Brasil: contextualização para o aperfeiçoamento. Rev Panam Salud Publica. 2015;38(4):333-8.
5. Bastos MS, Souza MK. Agências transfusionais e conformidades com a legislação hemoterapia. Vigil Sanit Debate. 2016;4(2):27-34. https://doi.org/10.3395/2317-269x.00697
6. Takakura V. *Benchmarking* nos processos de gestão de qualidade entre dois serviços de hemoterapia [dissertação]. Botucatu: Universidade Estadual Paulista; 2011.
7. Agência Nacional de Vigilância Sanitária – Anvisa. Marco conceitual e operacional de hemovigilância: guia para a hemovigilância no Brasil. Brasília: Agência Nacional de Vigilância Sanitária; 2015.
8. Silva Junior JB, Rattner D. Segurança transfusional: um método de vigilância sanitária para avaliação de riscos potenciais em serviços de hemoterapia. Vig Sanit Debate. 2014;2(2):43-52. https://doi.org/10.3395/vd.v2i2.126.
9. Silva JB, Rattner D, Martins RCA. Controle de riscos potenciais em serviços de hemoterapia no Brasil: uma abordagem para autoridades reguladoras. Rev Panam Salud Publica. 2016;40(1):1-8.
10. Figueiredo FM, Gama ZAS. Melhoria da proteção radiológica mediante um ciclo de avaliação interna da qualidade. Radiol Bras. 2012;45(2):87-92. https://doi.org/10.1590/S0100-39842012000200005
11. Cecagno S, Castro JL, Soares MC, Gama ZAS, Cecagno D. Gestión de calidad en el prenatal: atención a las infecciones urinarias en un municipio de la Amazonia legal. Enferm Glob. 2019;18(3):377-420. https://doi.org/10.6018/eglobal.18.3.344971
12. Portela MC, Pronovost PJ, Woodcock T, Carter P, Dixon-Woods M. How to study improvement interventions: a brief overview of possible study types. BMJ Qual Saf. 2015;24(5):325-36. https://doi.org/10.1136/bmjqs-2014-003620
13. Saturno-Hernández P. Métodos y herramientas para la realización de ciclos de mejora de la calidad en servicios de salud. Cidade do México: Instituto Nacional de Salud Pública; 2015.
14. Secretaria de Estado da Saúde Pública do Rio Grande do Norte – Sesap-RN. Plano diretor da política de sangue do estado do Rio Grande do Norte. Natal: Secretaria de Estado da Saúde Pública do Rio Grande do Norte; 2015.
15. Juran JM, Godfrey AB, Hoogstoel RE, Schilling EG. Juran's quality handbook. New York: McGraw-Hill; 1999.
16. Hansen E, Bechmann V, Altmeppen J, Last M, Roth G. Quality management in blood salvage: implementation of quality assurance and variables affecting product quality. Transfus Med Hem. 2004;31(4):221-7. https://doi.org/10.1159/000080405
17. Heymann C, Pruß A, Kastrup M, Marz S, Braun J, Kiesewetter H et al. Quality management regarding the use of blood products with special respect to the self-inspection program: a report from a university hospital. Transfus Med Hem. 2003;30(2):78-85. https://doi.org/10.1159/000070548
18. Menezes AN, Santos CA, Santos RDL, Santana JVF, Santos CN, Teles WS. Análise da qualidade dos concentrados de hemácias em um hemocentro de Sergipe. In: Anais da 19ª Semana de Pesquisa da Universidade Tiradentes; Aracaju, Brasil. Aracaju: Universidade Tiradentes; 2017.
19. Saturno-Hernández P. Métodos y herramientas para la monitorización de la calidad en servicios de salud. Cidad do México: Instituto Nacional de Salud Pública; 2015.
20. Deitrick LM, Baker K, Paxton H, Flores M, Swavely D. Hourly rounding: challenges with implementation of an evidence-based process. J Nurs Care Qual. 2012;27(1):13-9. https://doi.org/10.1097/NCQ.0b013e318227d7dd

21. Kaplan HC, Brady PW, Dritz MC, Hooper DK, Linam WM, Froehle CM et al. The influence of context on quality improvement success in health care: a systematic review of the literature. Milbank Q. 2010;88(4):500-59. https://doi.org/10.1111/j.1468-0009.2010.00611.x

22. Stein BP, Imeton TS, Geraldo A, Bueno ED, Stringari FB, Martinello F. Avaliação da gestão da qualidade de uma agência transfusional. R Bras Cienc Saude. 2017;21(3):203-10. https://doi.org/10.22478/ufpb.2317-6032.2017v21n3.26439

23. Silva LMV. Avaliação do processo de descentralização das ações de saúde. Cienc Saude Colet. 1999;4(2):331-9. https://doi.org/10.1590/S1413-81231999000200008

24. Oliveira AMC, Ianni AMZ. Caminhos para a vigilância sanitária: o desafio da fiscalização nos serviços de saúde. Vig Sanit Debate. 2018;6(3):4-11. https://doi.org/10.22239/2317-269x.01114

25. Agência Nacional de Vigilância Sanitária – Anvisa. Assistência segura: uma reflexão teórica aplicada à prática. Brasília: Agência Nacional de Vigilância Sanitária; 2013.

26. Gama ZAS, Saturno-Hernández PJ. Inspeção de boas práticas de gestão de riscos em serviços de saúde. Natal: Universidade Federal do Rio Grande do Norte; 2017.

27. Donabedian A. The quality of care: how can it be assessed? Jama. 1989;261(8):1151. https://doi.org/10.1001/jama.1989.03420080065026

Authors' Contribution

Medeiros AVC, Piuvezam G, Pimenta IDSF, Alves TPS, Rodrigues JM - Conception, planning (study design), data acquisition, analysis, and interpretation, and writing of the manuscript. Bezerra INM, Mata ANS, Medeiros WR, Santos VEP, Macedo LOL - Data interpretation and writing of the manuscript. All authors approved the final draft of the manuscript.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.