

Nursing in hemotherapy services: considerations on public policies associated with blood and blood components

Enfermagem em serviços de hemoterapia: reflexões acerca das políticas públicas voltadas ao sangue e hemocomponentes
Enfermería en servicios de hemoterapia: reflexiones acerca de las políticas públicas vueltas a la sangre y hemocomponentes

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ABSTRACT

Objective: Reflect on how the evolution of legislation related to blood and blood-based products has shaped the role of nurses in hemotherapy services. **Methods:** A reflective study, carried out employing surveys in databases, about the evolution of the nurse's role in hemotherapy services. **Results:** Several legislations, published since 1950, have encouraged blood donation and shaped the work of nurses in hemotherapy services, being the most relevant Law #10.205/2001 (Lei nº 10.205/2001), about blood collection, processing, storage, distribution, and blood transfusion; and COFEN's resolution # 629/2020 (COFEN nº 629/2020), which addresses in detail the practice of these services. **Final considerations:** The evolution of legislation related to blood and blood-based products contributed to the consolidation of nurses' attributions in hemotherapy services since it guaranteed legal support and defined the practices in these services.

Descriptors: Nursing; Blood; Public Policy; Blood Donors; Hemotherapy Service.

RESUMO

Objetivo: Refletir sobre como a evolução das legislações ligadas a sangue e hemoderivados moldou a atuação do enfermeiro nos serviços de hemoterapia. **Métodos:** Estudo reflexivo, realizado mediante levantamentos em bases de dados, sobre a evolução da atuação do enfermeiro em serviços de hemoterapia. **Resultados:** Verificou-se que as diversas legislações, publicadas desde 1950, fomentaram a doação de sangue e moldaram a atuação do enfermeiro em serviços de hemoterapia, sendo as de maior relevância: a Lei nº 10.205/2001, sobre a coleta, processamento, estocagem, distribuição e aplicação do sangue; e a resolução do COFEN nº 629/2020, que aborda detalhadamente a atuação nesses serviços. **Considerações finais:** A evolução das legislações relacionadas a sangue e hemoderivados contribuiu na consolidação das atribuições dos enfermeiros em serviços de hemoterapia, pois garantiu o amparo legal e definiu as práticas a serem realizadas nesses serviços.

Descritores: Enfermagem; Sangue; Política Pública; Doadores de Sangue; Serviço de Hemoterapia.

RESUMEN

Objetivo: Reflejar sobre como la evolución de las legislaciones dirigidas a la sangre y hemoderivados moldeó la actuación del enfermero en los servicios de hemoterapia. **Métodos:** Estudio reflexivo, realizado mediante levantamientos en bases de datos, sobre la evolución de la actuación del enfermero en servicios de hemoterapia. **Resultados:** Verificado que las diversas legislaciones, publicadas desde 1950, fomentaron la donación de sangre y moldaron la actuación del enfermero en servicios de hemoterapia, siendo las de mayor relevancia: la Ley nº 10.205/2001, sobre la recolecta, procesamiento, almacenaje, distribución y aplicación de la sangre; y la resolución del COFEN n.º 629/2020, que aborda en detalles la actuación en esos servicios. **Consideraciones finales:** La evolución de las legislaciones relacionadas a la sangre y hemoderivados contribuyó en la consolidación de las atribuciones de los enfermeros en servicios de hemoterapia, pues garantizó el amparo legal y definió las prácticas a ser realizadas en esos servicios.

Descriptor: Enfermería; Sangre; Política Pública; Donantes de Sangre; Servicio de Hemoterapia.

INTRODUCTION

Hemotherapy is a segment that has stood out as a relevant field of study because it encompasses an effective use of material and human resources. However, as in any branch of health care, it is necessary to invest in procedures seeking to identify failures, increase the quality of health services provided for the population, and ensure compliance with the existing rules and regulations⁽¹⁾.

Before the 1990s, despite the existence of legislation related to blood and blood-based products, these did not contemplate strict technical, or inspection standards applied to blood therapy services. That brought low reliability to these services and often affected the population by diseases resulting from transfusion⁽²⁻³⁾.

Since the 1990s, due to the conception of a public blood-related program called the Blood Center Pro-Blood, and the impulse of social movements for health reform and appealing for more reliability in the services focused on blood and blood-based products, the State started to adopt effective measures aimed at inspection. In addition, it began to create specific regulations that sought to protect not only the donors but also the recipients and health professionals involved in hemotherapeutics activities⁽³⁾.

In 1997, the approved Resolution COFEN # 200/1997 (Resolução COFEN 200/1997) described which procedures nurses would perform in hemotherapy; and, in 2001, Law # 10.205/01 (Lei nº 10.205/01) was approved, establishing the National Policy of Blood, Components and Blood-based Products, guaranteeing Brazilian people access to hemocomponents, with the required quality and quantity.

According to the 7th Hemotherapy Production Bulletin⁽⁴⁾, Brazil produced, in 2018, about 7.9 million hemocomponents; this enabled the realization of approximately 1.7 million transfusions, demonstrating that this practice is essential to Brazilian public health.

In that context, there is a need for a greater understanding of how public policies shaped nurses' role in hemotherapy services since these professionals perform their activities in a multidisciplinary way, from donors' recruitment until the transfusion, including its development. Therefore, it is justifiable to develop a review on the subject in question.

OBJECTIVE

To reflect how the evolution of legislation, including laws, ordinances by the Ministry of Health (MH), and resolutions approved by the Federal Council of Nursing (COFEN), related to blood and blood-based products, has shaped nurses' jobs in hemotherapy services.

METHODS

A theoretical study based on bibliographic references consulted in April 2021 in the following databases: Virtual Health Library (VHL); Scientific Electronic Library Online (SCIELO), and Database of Nursing (BDENF), using as descriptors and keywords: "Hemotherapy Service," "Nursing," "Blood," "Public Policy" and "Blood Donors. Articles were selected by evaluating the abstracts searching for those that better suited the subject proposed and were

published in their entirety. The repeated articles were excluded, and those that provided sufficient subsidies to the argumentative framework of this review were selected.

EVOLUTION OF LEGISLATION RELATED TO BLOOD AND BLOOD-BASED PRODUCTS

The incentive to blood donation, through specific legislation, happened in 1950 with the Federal Law # 1.075/1950 (Lei Federal nº 1.075/1950), which provided for voluntary blood donation. This legislation encouraged donation guaranteeing a day off work for every public employee, civilian or military, who voluntarily donated blood⁽²⁾.

As the years went by and blood donations progressed, it became clear the need to establish a program to control the quality of hemocomponents. The purpose was to ensure compliance with the norms and procedures determined appropriately and to establish that the noncompliance would constitute a sanitary infraction and would result in applicable penalties⁽²⁾.

After the 1990s, evolutions were observed both in the blood public policies and specific regulations in the technologies associated with transfusion, promoting, in hemotherapy services, considerable improvements in "safety." Based on the pro-blood program, Brazil introduced that subject in the national political agenda, with significant investments from the federal government in hemotherapy services and inspection agencies⁽³⁾.

In 1993, with ordinance #1376/93 (Portaria nº 1376/93), which established the technical standards for the collection, processing, and distribution of blood, and ordinance #121/95 (Portaria 121/95) that addressed the need for stages in quality control during the production of hemocomponents, both issued by the Ministry of Health (MH), the legislation became more rigorous, with the gradual introduction of serological tests in the analysis of donated blood⁽²⁾.

The Brazilian National Sanitary Surveillance System (SNVS) is responsible for verifying that the norms and procedures related to blood in Brazil are decentralized, with municipal and state agencies. Its attribution is to execute sanitary inspection and supervision activities in specific localities, acting under the coordination of the Brazilian Health Regulatory Agency (ANVISA).

According to Silva Júnior et al. (2015), ANVISA plays an essential role in the Brazilian blood policy. The agency is responsible for technical support to inspections, the definition of national regulatory standards, coordination of training and continuing education programs for inspectors, coordination of the National Haemovigilance System (Sistema Nacional de Hemovigilância), development of standard inspection guides, and the usage of instruments focused on the assessment of risks inherent to the blood cycle, among other monitoring and control attributions⁽³⁾.

In 2001, it was sanctioned Law #10.205 (Lei nº 10.205), also called Blood Law, whose purpose was to regulate paragraph #4 of Article 199 of the Federal Constitution, which deals with the collection, processing, storage, distribution, and application of blood. This law establishes the institutional order for the proper performance of these activities and disposes blood recruitment as the first activity performed in a hemotherapy service. It is worth mentioning that the principles and guidelines of the National Policy on Blood, Components, and Blood-based Products include:

voluntary donation, with the public authorities stimulating it as a relevant act of human solidarity and social commitment; protection of the donor's and recipient's health through information; encouragement of educational drives to stimulate regular blood donation and donors' recruitment; and implementation of the discipline of hemotherapy in undergraduate medical courses⁽⁵⁾.

We can establish that the detailing of the technical activities to be performed by hemotherapy services, associated with protecting donors, recipients, and professionals involved in hemotherapy activities, demonstrates the Brazilian legislator's concern with this matter. Moreover, the Blood Law describes a complex system organized in a network, including services aimed at producing blood products and transfusion procedures. This system is called the Brazilian National Blood System (SINASAN), coordinated by the Ministry of Health, and comprising state and municipal blood services⁽³⁾.

The Blood Law also recognizes the regulatory agencies as a support structure: they are responsible for supervising hemotherapy services to guarantee the distribution of hemocomponents throughout the country⁽³⁾.

In 2004, the Collegiate Directive Resolution (RDC) #153, issued by the Ministry of Health, determined that health professionals working in the hemotherapy field must perform their actions pursuing compliance with the hemotherapy procedures described therein. That RDC outlined the procedures for collecting, processing, testing, storage, transportation, quality control, and application of blood components in humans obtained from venous blood, umbilical cord, placenta, and bone marrow⁽²⁾.

Ordinance # 253 (Portaria n° 253), of February 11, 2009, established the Technical Advisory Committee for Recruiting Voluntary Blood Donors, whose competencies are: to conduct studies and research with different segments of the population; to establish guidelines and proposals for the implementation of actions to recruit voluntary blood donors, and to provide technical contributions to the Coordination of National Policy on Blood and Blood Derivatives (Coordenação da Política Nacional de Sangue e Hemoderivados).

Ordinance # 2712, of November 12, 2013, altered by Ordinance # 3. 158, of February 4, 2016, both from the MH, brought the detailing of the procedures affected to hemotherapy, addressing the following topics: blood and its components; blood donation; the collection of donor blood; preparation of blood components; qualification tests on donor blood; labeling the donor's blood; conservation of blood and components; donation of components by apheresis; release of blood for transfusion; transfusion; transfusion reactions; autologous blood; registrations and quality assurance.

Currently, it is worth mentioning that Consolidation Ordinance # 5/2017 (Portaria de Consolidação n° 5/2017), issued by the Ministry of Health, regulates hemotherapy activity. After further analysis of numerous ordinances, the Ministry of Health decided that some ordinances would have criteria for consolidation, i.e., they presented normative content and permanent and lasting effects. That fact occurred with Ordinance # 158/2016, which stipulates how hemotherapy procedures should be performed; the ordinance was withdrawn but had its content consolidated and inserted in the Consolidation Ordinance # 5/2017 (Portaria de Consolidação n° 5/2017) of the MH.

RESOLUTIONS OF THE FEDERAL NURSING COUNCIL REGARDING HEMOTHERAPY SERVICES

In 1997, was approved the Resolution COFEN # 200, which listed in detail the procedures that nurses should perform both in hemotherapy and in activities involving bone marrow transplant, and this resolution was the initial regulatory framework for the activities of nurses in hemotherapy services. In that resolution were listed the nurses' competencies and guidelines on how to plan, coordinate, execute, evaluate, and supervise every procedure in the hemotherapy service. The goal was to ensure the quality of the blood and hemocomponents, provide donors comprehensive care, perform clinical screening, participate in donor recruitment programs, and develop and participate in research related to hematology and hemotherapy, among other things.

In 2006, COFEN, through Resolution # 306, revoked Resolution # 200/1997 and altered the nurse's role in hemotherapy. However, these amendments brought few changes when we observed the content in Resolution # 200/1997. The main change was the inclusion of the attributions of planning, coordinating, executing, evaluating, and supervising the activities destined to recruit donors, internships, training, and development of nurses in different levels of education, bringing up their responsibility and participation in blood recruitment and training of personnel working with hemotherapy.

Resolution # 511 of 2016, approved by COFEN in replacement of # 306 of 2006, presents in its appendix a technical note that addresses the performance of nurses and nursing technicians in hemotherapy. That technical note is structured to describe the nurses' competencies in hemotherapy and the general rules to be followed in blood recruitment and hemotransfusion. When compared to Resolution # 306/2006, it demonstrates a significant advance in detailing information about nurse's activities who works in hemotherapy, providing a substantial gain both legislative, legally supporting the nursing professionals in hemotherapy, and technical, because it details the duties and attributions of nurses, based on established references.

The COFEN Resolution # 629/2020⁽⁶⁾ updated regulations and procedures related to the nurses' role in hemotherapy, addressing, among other issues, the competencies of these professionals: in screening and donors' recruitment, hemotransfusion, and emergency transfusion assistance. There are described, in detail, all the nurses' attributions in several areas related to hemotherapy, the blood cycle, and hemotransfusion.

However, the evolution of those resolutions did not clearly contemplate the importance of dimensioning the teams working in hemotherapy services. This fact should be a point for improvement in future COFEN resolutions that deal with this subject, as it would provide legal support for those professionals to fight for the right to have a correctly sized team for the activities to be performed by the most diverse hemotherapy services.

STATE POLICIES AND DONORS' RECRUITMENT

As established in the Federal Constitution of 1988, health is a right of all and a duty of the State. Therefore, the State is responsible for developing public policies to ensure access to basic healthcare services to reduce the risk of contracting the most diverse diseases⁽²⁾.

The need to increase the number of donors, aiming to ensure that the stocks supply the demand for hemocomponents for transfusions, should be met by adopting policies that involve health professionals and institutions, establishing a relationship of trust and safety with the donor in the blood donation procedures⁽¹⁾.

This fact is in line with the World Health Organization's position. It recognizes that blood and its components are essential medicines for national health care systems, recommending countries to establish regulatory systems that should operate with a strict policy to supervise the services that produce hemocomponents⁽³⁾.

In Brazil, it is necessary to execute an educational work aimed at raising awareness and sensitization of the general population, since the act of blood donation is still seen with prejudice and shrouded in taboos: it should be understood as an act of citizenship, solidarity, and preservation of human life and not as something that can bring harm. The recruitment of donors plays an essential role in this demystification because educating the population about blood donation is a way to win them over and guarantee retention. After all, there is no substitute for blood⁽²⁾.

Therefore, the role of the State in recruiting blood donors through public policies and awareness drives for the population is essential for the successful availability of hemocomponents for those in need. Creating specific drives for each Brazilian region, aimed at recruiting active donors, is one of the decisive actions that the State adopts and must be improved and intensified.

THE ROLE OF NURSES IN HEMOTHERAPY SERVICES

In their daily activities, nurses act directly with patient care and organize all the variables involved in the aid process. Therefore, it is necessary to develop their management skills for correct interaction with the entire organizational environment, enabling them to contribute more to assistance⁽⁷⁾.

In the most varied health services, the nurse's management performance has been presented as primordial to contribute to the synergy among the professionals of the most varied backgrounds that compose the teams and the organization of the work process. Their management performance is continuously transforming due to the ongoing studies and theories that scientifically support nursing management. That is because these professionals must be skilled in providing care and deal with the human and material resources employed, seeking to achieve a set of knowledge, skills, practices, and attitudes capable of ensuring quality in the patient's care⁽⁸⁻⁹⁾.

The nurses' role in hemotherapy services occurs in providing hemotherapy and/or hematological assistance and in almost all stages of the blood cycle, including apheresis, which aims to collect hemocomponents individually.

In blood recruitment, the nurse is responsible for planning, coordinating, and supervising blood donation drives and seeking blood donor retention. Thus, it is the task of all professionals in hemotherapy, particularly the nurse, to find alternatives to the classic models of donors' recruitment, such as the blood donated when a family member needed it the most. There must be a shift towards adopting models aiming at donor retention, showing them that blood donation is safe and letting them be satisfied during the service process.

In screening blood donors, nurses, due to their generalist characteristics and holistic vision, are the most suitable professionals to perform this function because they combine fundamental professional knowledge and experience. They evaluate potential donors and guide the candidates to donate blood or when they cannot donate guide and direct them to the appropriate health professional to assist them, if necessary.

In the cycle stage called "collection," the nurse supervises the nursing team and helps the donors in clinical complications during the procedure.

If the donation is apheresis, which collects only one blood component, such as red blood cells, plasma, platelets, or progenitor cells for bone marrow transplantation, the nurse has a significant role because it is a complex procedure that requires theoretical and practical knowledge.

In the "serologic screening" stage, the nurse does not work directly in the serological tests for the several diseases tested, aiming to avoid transfusion with possibly contaminated blood. Instead, the nurse works in the orientation of unfit donors in the serological screening, regarding the mode of transmission, clinical manifestations, and treatments of the pathologies that classified them as unfit, referring them to the appropriate health professionals for assistance.

In processing - the stage of the blood cycle that, through physical centrifugation methods, breaks blood down into specific hemocomponents to be transfused according to each patient's needs - the nurse must know all the operating stages to be able to manage hemocomponents stocks appropriately.

Transfusion therapy is a procedure of a complex nature that requires the intervention of specialized professionals and with remarkable knowledge not only of the matters related to blood quality and safety but also in the identification of complications that can occur during transfusion - most common reactions, such as allergic and febrile; and uncommon, such as transfusion-associated acute lung injury⁽¹⁰⁾.

It is noteworthy that, in the blood cycle, the haemovigilance is also the nurse's function because this task consists in actively seeking patients who have undergone blood transfusion with adverse events so that they do not become underreported and serve as subsidies to establish individual protocols for future transfusions in patients who presented such events. In this sense, the nursing professional and the hemotherapy doctor are responsible for investigating and inserting data in the Brazilian Health Surveillance Notification System (NOTIVISA).

Given the above, it is noted that nurses integrally perform their duties in the stages of the blood cycle, aiming at the integrity of the donor and recipient. Furthermore, they actively participate by caring for complications related to transfusion reactions, haemovigilance, management of teams, and organization of the work process. This performance aligns with the current legislation recommendation that deals with this matter.

FINAL CONSIDERATIONS

The purpose of nursing is to care for patients in various types of health assistance. The nurse working in hemotherapy services is responsible for the continuous supply of blood and

hemocomponents required to attend to patients needing various treatments and procedures.

With the increased demand for hemocomponents, changes in the legislation were necessary, such as laws, ordinances, and resolutions that regulate various activities related to this subject and guide the professionals working in hemotherapy services in the country.

These changes in the legislation aimed to offer patients a quality service in an appropriate quantity and were only possible, for the most part, thanks to the search both by society and by the professionals who work in these services to ensure safety in transfusion procedures minimizing health risks.

With this in mind, we observe the considerable relevance of public policies and COFEN's resolutions, both in support of nursing

professionals and in the definition of hemotherapy activities that will be performed by these professionals, since they not only act as an integral part of the process but also act to manage an extensive sequence of events and procedures involved in the entire blood cycle.

SUPPLEMENTARY MATERIAL

This article originated from questions and considerations during the elaboration of the master's thesis "The Management Functions of Nurses in the Professional Practice with Hemotherapy Service at a University Hospital," which is available in the Repository of the Library at the Federal University of the State of Rio de Janeiro (UNIRIO).

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