



Biovigilance in the process of organ and tissue donation during the pandemic: challenges for nurses

Biovigilância no processo de doação de órgãos e tecidos durante a pandemia: desafios para o enfermeiro

Biovigilancia en el proceso de donación de órganos y tejidos durante la pandemia: desafíos para el enfermero

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ABSTRACT

Objective: to identify the strategies developed by nurses capable of maintaining biovigilance in the process of organ and tissue donation in order to minimize the risk of transmission of COVID-19 among donors, recipients and health care teams. **Method:** an exploratory research, with a qualitative approach, supported by the theoretical framework on biovigilance of the Brazilian Health Regulatory Agency. Data were collected using an online form composed of open questions. Fifty-two nurses who work in the structures of the National Transplant System participated. The data was analyzed by Content Analysis. **Results:** it was identified that the monitoring and control of the donation process, based on the clinical investigation of the potential donor and on the family and community investigation, as well as the modification of the safety culture in the institution, through the development of protocols and guidelines for the care of the potential donor, were strategies developed by nurses during the pandemic in order to maintain patient safety. **Conclusion and practice implications:** the strategies developed by the nurses were the monitoring and control of possible risks related to the contamination of the potential donor by the SARS-CoV-2 virus and the modification of the safety culture through the development and implementation of protocols, in order to ensure the continuity of donation and transplantation of organs and tissues, ensuring safety and quality in this process.

Keywords: Coronavirus Infections; Patient Safety; Tissue and Organ Procurement; Transplants; Nursing.

RESUMO

Objetivo: identificar as estratégias desenvolvidas pelo enfermeiro capazes de manter a biovigilância no processo de doação de órgãos e tecidos a fim de minimizar o risco de transmissão da COVID-19 entre doadores, receptores e equipes de saúde. **Método:** pesquisa exploratória, com abordagem qualitativa, apoiada no referencial teórico sobre a biovigilância da Agência Nacional de Vigilância Sanitária. Realizou-se a coleta de dados por meio de formulário *on-line* composto por questões abertas. Participaram 52 enfermeiros atuantes nas estruturas do Sistema Nacional de Transplantes. Os dados foram analisados pela Análise de Conteúdo. **Resultados:** identificou-se que o monitoramento e o controle no processo de doação, embasados na investigação clínica do potencial doador e na investigação familiar e comunitária, bem como a modificação da cultura de segurança na instituição, por meio da elaboração de protocolos e diretrizes para o cuidado do potencial doador, foram estratégias elaboradas pelo enfermeiro durante a pandemia com o objetivo de manter a segurança do paciente. **Conclusão e implicações para a prática:** as estratégias desenvolvidas pelos enfermeiros foram o monitoramento e o controle dos possíveis riscos relacionados com a contaminação do potencial doador pelo vírus SARS-CoV-2 e a modificação da cultura de segurança a partir da elaboração e implantação de protocolos, de modo a assegurar a continuidade da doação e o transplante de órgãos e tecidos, garantindo a segurança e a qualidade nesse processo.

Palavras-chave: Infecções por Coronavírus; Segurança do Paciente; Obtenção de Tecidos e Órgãos; Transplantes; Enfermagem.

RESUMEN

Objetivo: identificar las estrategias desarrolladas por el enfermero capaces de mantener la biovigilancia en el proceso de donación de órganos y tejidos para minimizar el riesgo de transmisión de COVID-19 entre donantes, receptores y equipos de salud. **Método:** investigación exploratoria con enfoque cualitativo, sustentada en el marco teórico sobre biovigilancia de la Agencia Nacional de Vigilancia Sanitaria. Los datos se recopilaron a través de un formulario en línea compuesto por preguntas abiertas. Participaron 52 enfermeros que laboran en las estructuras del Sistema Nacional de Trasplantes. Los datos se analizaron mediante análisis de contenido. **Resultados:** se identificó que el monitoreo y control en el proceso de donación, basado en la investigación clínica del potencial donante y en la investigación familiar y comunitaria, así como la modificación de la cultura de seguridad en la institución, mediante el desarrollo de protocolos y guías de el cuidado del donante potencial, fueron estrategias desarrolladas por el enfermero durante la pandemia con el fin de mantener la seguridad del paciente. **Conclusión e implicaciones para la práctica:** las estrategias desarrolladas por los enfermeros fueron el monitoreo y control de posibles riesgos relacionados con la contaminación del potencial donante por el virus SARS-CoV-2 y la modificación de la cultura de seguridad a partir del desarrollo e implementación de protocolos, con el fin de asegurar la continuidad de la donación y trasplante de órganos y tejidos, garantizando la seguridad y calidad en este proceso.

Palabras clave: Infecciones por Coronavírus; Seguridad del Paciente; Obtención de tejidos y órganos; Trasplantes; Enfermería.

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INTRODUCTION

The world and Brazil are facing a challenging situation: since March 2020, the World Health Organization (WHO) considers COVID-19, a disease caused by SARS-CoV-2, one of the Coronavirus infections, a pandemic. Facing this scenario, health teams all over the world have been searching for effective strategies in order to minimize the contagion and the spread of this disease^{1,2}.

Even in the face of immeasurable efforts by governmental and non-governmental organizations, the disease has progressed in many countries in a devastating way, contaminating and killing many people and health professionals³⁻⁶.

Because of this, uncertainties about how to perform safe health care arise daily, especially when it comes to obtaining tissues and organs for transplantation. It has become necessary to understand all the biological mechanisms involved and the best way to ensure the safety of potential organ and tissue donors, as well as recipients. In this health scenario instituted by COVID-19, the sensitivity of the patient safety issue, especially related to the process of organ and tissue donation and transplantation, became evident from the standpoint of how to maintain safe, effective, and quality care when experiencing unique moments like this. Given this context, safety in the process of organ and tissue donation arises as a premise for the continuity of transplant procedures.

Conceptually, the WHO defines patient safety as the reduction of risk to the minimum acceptable level of unnecessary harm associated with care⁷. In relation to the process of donation and transplantation of organs, tissues and cells, the Brazilian Health Regulatory Agency (Anvisa) calls an incident the occurrence of deviation from operational procedures or safety policies related to the removal, evaluation, processing, storage and distribution of cells, tissues and organs. Such situations can be detected before or after the donation or transplant/infusion/graft/implant and may or may not lead to disease transmission, death, life-threatening, disability, prolonged illness, or hospitalization of the recipient or living donor⁸.

Anvisa's Collegiate Directive Resolution (CDR) No. 339/2020, proposes a set of monitoring and control actions that cover the entire cycle of human cells, tissues and organs, from donation to the clinical evolution of the recipient and the living donor. In addition, it aims to improve the quality of processes related to the cycle of human cells, tissues and organs, in alignment with the National Program for Patient Safety⁹.

It is noteworthy that all steps of the donation process are under the responsibility of health professionals, from the management of the evaluation and validation of the Potential Donor (PD), through the extraction of human cells, tissues and organs, to the processing, packaging, storage, transportation, availability/distribution, therapeutic use and follow-up of recipients and living donors of human cells, tissues and organs^{9,10}.

Given these concepts of monitoring and management of the stages of the organ and tissue donation process, and also considering the reality of the pandemic and the guidelines of the WHO, the Ministry of Health, the National Transplant System

(NTS) and the Brazilian Association of Organ Transplantation (BAOT), it is emphasized that, during organ and tissue donor validation, individuals can be classified as "donor with relative contraindication" or "donor with absolute contraindication", and it is not possible to classify a donor as "donor without contraindication" while the SARS-CoV-2 pandemic state lasts^{3,11,12}.

Facing this scenario, the nurse, as the main manager and member of the State Transplant Centers (STC), the Organ Procurement Organization (OPO) and the Intra-hospital Organ and Tissue Donation Committee for Transplants (IHOTDCT), assumes a great challenge: to continue the identification and validation of the potential organ and tissue donor in times of pandemic, since the number of patients on the waiting list remains high and transplants cannot stop¹¹. Professionals are still required to have a proactive attitude for decision making and to continue safe nursing care in the face of so many challenges¹³.

This reality, imposed by the global health situation, challenges the professional nurse, inserted in the process of organ and tissue donation, to assume the commitment and responsibility of minimizing cross-infection among team members and patients carrying the virus, asymptomatic and not diagnosed with COVID-19⁶. Thus, it is up to the nurse to create strategies that have an impact on minimizing damage to the recipients' health, making healthy and viable organs available.

From this perspective, we understand the importance of knowing the experience of nurses, as well as the strategies used by them in the COVID-19 scenario. Considering that this is a professional who assumes many roles in the donation process, with little appreciation, visibility, and credit for the success of donation and transplantation in Brazil, it is essential to address this theme and show the contributions of this professional in the scenario of organ and tissue donation in times of pandemic, since 2020 was the year of nursing and the year in which nurses faced so many challenges.

Therefore, this study has as its guiding question, "What strategies are being developed by nurses capable of maintaining biovigilance in the organ and tissue donation process in order to minimize the risk of transmission of COVID-19 between donors and recipients?"

The objective is to identify the strategies developed by nurses capable of maintaining biovigilance in the process of organ and tissue donation in order to minimize the risk of transmission of COVID-19 among donors, recipients and health care teams. Certainly, such information can support the other colleagues of the health team, strengthen the safety in the donation and transplantation process, besides empowering and supporting the nurse as a professional active in this process.

METHOD

This is an exploratory research, with a qualitative approach, supported by the theoretical and methodological framework of Content Analysis, in which the data were coded and analyzed from the perspective of Anvisa's CDR No. 339/2020.^{9,14} This CDR was chosen because it nationally governs the process of donation and

transplantation of organs and tissues with respect to biovigilance. It is a conceptual and legal framework that imposes the analysis, reporting and monitoring of processes and procedures conducted by health professionals working in the NTS as a way to reduce risks and adverse events, contributing to patient safety.⁹

In the scope of the research, we sought to focus on the actions, procedures and processes of nurses as care managers in the donation and transplantation process, not directly exploring the notification of adverse events.

The research was carried out with 52 nurses working in the NTS structures (STC, OPO and IHOTDCT). The inclusion criterion was established as: nurses working in the care area of the NTS throughout the country. Nurses on vacation or on leave were excluded, as well as those who were temporarily replacing a professional at the time of collection.

Data collection was performed between May and June 2020 using an online form, developed by the researchers and hosted in the Google Forms® platform, consisting of sociodemographic characterization data, such as age, gender, marital status, religion, state where he/she works and academic background, as well as three open questions (Chart 1), which aimed to identify the nurses' strategies regarding the safety of the organ and tissue donation process in the context of the COVID-19 pandemic. The form was previously tested by two professionals working in the NTS, which allowed for adjustments in the open questions. They were not included in the study.

First, the researchers sent the access link, via e-mail, to the coordinators of the STCs of the Brazilian states along with an explanation of the survey. Then, the coordinators forwarded it to the other nurses linked to the STC to respond to the survey. All participants agreed to the Free and Informed Consent Term available on the first page of the data collection instrument. The participants answered the form randomly, considering their interest in the research. The sample size was not calculated.

For data analysis, we used the Content Analysis framework advocated by Laurence Bardin. This method consists of three primary steps: 1) pre-analysis: consisting of a floating reading of the responses obtained in order to perform the first recognition of the data and the formulation of category indicators; 2) exploration of the material: exhaustive reading phase, seeking to categorize the data obtained according to the indicators already identified and 3) treatment of the data obtained and interpretation, in

which, after establishing the categories, it is inferred based on the information obtained in comparison with other similar studies conducted in the thematic field¹⁴.

It is noteworthy that each author read and appropriated the answers from the forms. At the end, everyone shared the individually identified categories and established a joint agreement between the analyses. In case of any disagreement, an in-depth discussion was held until it was possible to reach agreement. Therefore, two categories and four subcategories were established based on Anvisa's theoretical reference.

The participants' answers are identified with the letter E followed by the order in which the answer was sent, for example: E1, E2 and so on.

It is noteworthy that the researchers have experience in the academic and assistance field regarding the process of organ and tissue donation and transplantation, four of them with about 20 years in conducting this process, which ensured the validity for the elaboration of the form and the interpretation of the data obtained.

The research respected the ethical aspects involving human beings, being guided by Resolutions No. 466/12 and 510/2016 of the National Health Council and approved by the Research Ethics Committee of the Federal University of Santa Catarina under Opinion No. 4,049,851 and Certificate of Ethical Presentation and Appreciation No. 31782620.5.0000.0121.

RESULTS

Fifty-two nursing professionals who work at the NTS (STC, OPO and IHOTDCT) participated in the research. Of these, 82.7% are female; 57.7% are married; 51.9% are catholic; 92.3% have some postgraduate degree, and 90% are graduated and have worked for more than ten years with the organ and tissue donation process.

Considering Anvisa's CDR nº 339/2020, two categories with their respective subcategories were elaborated, as shown in Figure 1.

The category "Monitoring and control in the donation process" represented the effort of professional nurses to propose adjustments in the process of organ and tissue donation, especially in the identification, validation, selection and notification of the potential donor to the STC. It also revealed the effort of the nurse and his

Chart 1. Open questions used for data collection.

- In your state, are you adopting any different routine that helps screening for SARS-CoV-2 in potential organ donors beyond the recommendation determined in Technical Note 34/2020 of the NTS? If yes, please detail some of these initiatives regarding clinical suspicion of signs and symptoms, history of hospitalization, clinical investigation with family members, investigation regarding community transmission and physical, laboratory and imaging exams.
- Is there any guidance that the care staff, who provide care to the potential donor (doctors, nurses, etc.), should not have contact, as far as possible, with other patients in the Intensive Care Unit (ICU) with a positive diagnosis for COVID-19?
- Are there any actions you would like to report/share regarding internal actions to make the donation process safer?

Source: Elaborated by the authors (2020).

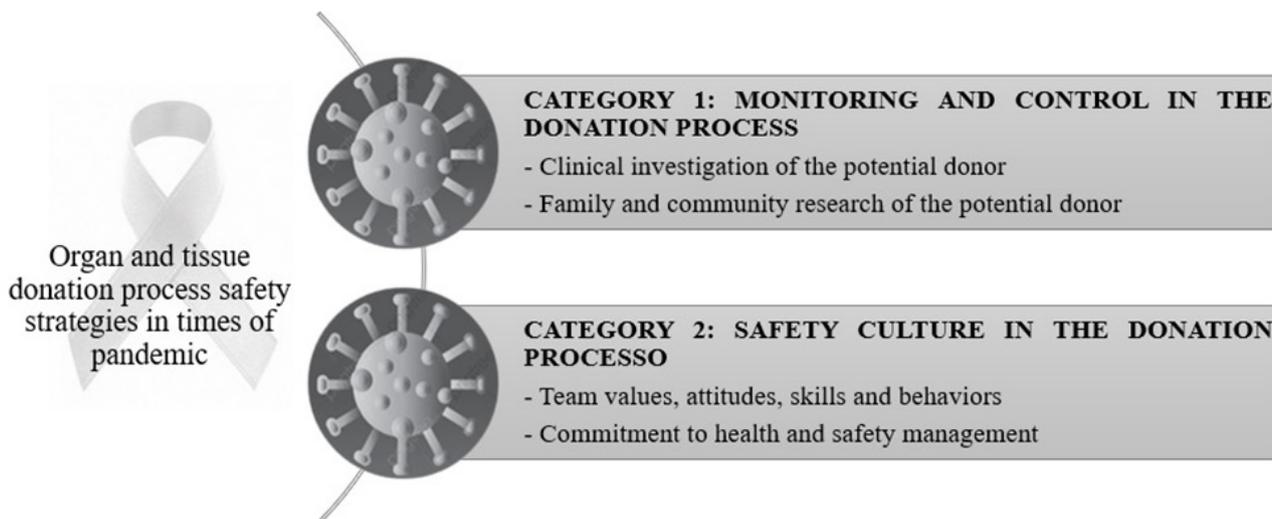


Figure 1. Graphic representation of the categories and subcategories.
 Source: Elaborated by the authors, 2020.

team as to the tracking and monitoring involving clinical, social, physical and laboratory issues in order to monitor, control and investigate the factors that may indicate a possible contact of the potential donor with the COVID-19.

In the subcategory “Clinical investigation of the potential donor”, nurses used their clinical competence in care practice to evaluate the potential donor, focusing on detailed physical examination and evaluation of laboratory and imaging tests to ensure safety in the selection process of this patient. Below are some examples of answers, provided by nurses, that subsidized the construction of this subcategory.

We test all potential donors, even without clinical and/or epidemiological data (sic) for COVID-19. It doesn't matter, we want to have a safe process. (E35)

The collection for the PCR exam is performed by tracheal aspirate and the operationalization of this (sic) collection has proven to be safer for the nursing professionals than the swab, since the patients use a closed suction system. (E27)

We perform fever monitoring with daily chart and saturation (correlating with images and medical team assistance. (E24)

We investigated fever, low saturation, signs of arrhythmias, tachycardia, and skin lesions. (E43)

Mainly, the fever. We track the temperature curve. But we also evaluate cardiac and pulmonary changes. (E45)

Mainly, the respiratory part (secretion, pulmonary auscultation, peripheral perfusion, saturation). (E52)

In the subcategory “Family and community investigation of the potential donor”, we identify the nurse’s concern in understanding

the patient’s path to becoming a donor. The attention to this detail stems from the attempt to be sure or to minimize the risk of the patient having had contact with other individuals contaminated by SARS-CoV-2.

The professional nurse has created, as a strategy, the traceability and verification with family members and health professionals of the path until the final care. For this, a detailed investigation of the therapeutic itinerary of the PD through the health institutions is carried out, seeking to identify the existence of previous hospitalizations and the length of stay in the health units.

Requested to (sic) the health team that, in all contacts with the family, develop (sic) the clinical investigation, specifically (sic) about COVID-19. (E1)

We investigate whether the patient has had any previous hospitalizations in the past few days. (E12)

We follow the history of the hospitalization, together with the history of another institution, if there has been a transfer, as well as following up daily after being in active search. (E25)

We sought to know where the patient went through before arriving at the Intensive Care Unit where he is hospitalized, if he went through health units that may have had contact with confirmed or suspected cases of COVID-19. How long he/she was hospitalized in the places he/she went through before arriving at the Intensive Care Unit. (E34)

Before notifying the PD, we developed a discussion of the case between the physician of the Hospital Transplant Committee and the State Transplant Center. (E31)

We investigate with the team that has cared for the patient until that moment, if there are any alterations or any indications of signs of COVID-19. A search is also made in the patient's medical record, identifying everything that has been registered by the team, so far, about the patient. (E53)

Also, as a strategy to support the selection of the potential donor before notifying the STC, nurses investigate with family members the routine home and social care for the prevention of COVID-19.

The question was asked about what measures the family members and the PD have taken and are taking for the prevention of COVID-19, as well as what the PD's routine was, how they are doing in quarantine, in addition to assessing how many people live in the household [and] if there are suspected cases in the family or community. (E7)

We asked how the PD was doing before hospitalization. If he was keeping social distance, how many people lived together and if any of them got sick or had a symptom or (sic) COVID-19 in the last few days. (E19)

The "Safety culture in the donation process" is the second category and represents the involvement of the health team regarding the need for changes facing the pandemic of COVID-19. It also highlights the need for changes in norms, procedures and behaviors related to the safety of the organ and tissue donation process.

This category is supported by the subcategory "Values, attitudes, skills and behaviors of the team". The findings of this subcategory reveal the need for nurses to show that changes in attitudes and behaviors, combined with the competence of the team, can ensure the continuity of organ donation, even in the face of the critical global health situation.

By developing strategies that promote the confidence of the ICU team and the STC, the nurse strengthens the system, promotes the accountability of peers, to follow what was proposed, and provides new learning. The strategies for change are related to the routine of care to the PD and the development of protocols to minimize the risks of transmission of COVID-19 to the potential donor while waiting for the completion or completion of the brain death (BD) protocol or the extraction of organs from the PD.

We promote the change of the care routine, [from] the identification of the PD, this patient is cared for by a single team member after the result of the PCR exam until the removal of the organs. (E28)

A questionnaire to be filled out with family members to secure information, such as whether the patient has had contact with someone with COVID-19, whether they have

traveled out of [the] state and out of their city in less than [21] days, among other questions that are asked. (E40)

A protocol was created with the tests and care to be followed by the team while this patient awaits the BD protocol and organ removal to minimize the risk of transmission of the SARS-CoV-2 virus to the PD. (E13)

We have a protocol for requesting PD exams in COVID-19; generally, it is CBC and CT scan, we keep the same in all PDs, however, if there is need, we request other specific exams. (E22)

Guidelines and routines were developed in the service that I work in to develop any assistance with the patient, actually. Care in moving in areas with COVID-19, use all the Personal Protection Equipment necessary for [the] individual protection, care in the use of elevators (so there is no exposure), training in dressing and how to remove the PPE without contamination, careful use of mask, using properly the mask indicated to the place you are, and even how to behave outside the hospital environment, the care in each, (sic) with our family members. (E18)

The other subcategory, entitled "Commitment to health and safety management", exposes the nurses' search to make this process as transparent and safe as possible in times of pandemic. Through the information obtained, it is possible to understand that this professional transcends the walls of his institution to seek information in other health settings in an attempt to strengthen the safety of the donation process.

In addition, the nurse understands that this is a complex process that involves many people, both in the donation and explantation stages, especially the recipients. Thus, it is essential to seek information in all instances to ensure that this patient was not contaminated by the SARS-CoV-2 virus, either by making contact with the municipality's epidemiological surveillance, or with the professionals who took care of the PD.

The importance of the leadership of this professional in the incorporation of new institutional protocols is emphasized, aiming at the safety of the process. The speeches reveal the path of this nurse.

We try to make contact with the epidemiological surveillance team, identifying if the region of the patient is considered an endemic area and if there are cases close to the patient's home or workplace. (E16)

We contact all the professionals who have seen the patient in the places where he has been. If the patient was in more than one institution, we contacted all of them. (E44)

We designed an instrument to develop information that could form a detailed clinical history (sic). (E37)

DISCUSSION

In times of the pandemic of COVID-19, the nurse, as a health professional, faces numerous challenges, which are directed to working conditions, personal safety, changes in workflows, adjustments in health policies, new professionals in institutions, pressures from increased demand, and the complexity of care for patients affected by the disease. In this scenario of fear, doubts, insecurity, and new challenges, the nurse begins to face the need for continuity of health care, having to ensure the speed of processes, safety, and effectiveness^{15,16}.

Still in the scenario of high complexity institutions, this professional tries to give continuity to the process of organ and tissue donation, since, for the patients who remain on the waiting list, this is the only treatment. Both the WHO and governmental and non-governmental organizations have pointed out ways to ensure the safety of this process during the pandemic through technical notes, resolutions and recommendations^{3,11,12}.

In the context of safety in organ and tissue donation, before the WHO confirmed the pandemic, Anvisa, through CDR No. 339/2020, made public the principles and guidelines to health professionals on biovigilance, in order to ensure the continuity of transparent steps from the identification of the PD until the implantation of the organ, with the prospect of improving the quality of processes related to the cycle of cells, tissues and human organs, in alignment with the National Program for Patient Safety⁹.

Thus, in the face of the pandemic and the new Anvisa guidelines, it is understood that the professional nurse, as the manager of this process, is facing complex moments to ensure continuity and safety in organ and tissue donation. The challenges in the context of the pandemic are numerous, from the identification, selection, and notification of the potential donor to the STC, to the logistics, organization, and evaluation of the patient who will receive the donated organ. The statements of the nursing professionals make clear the challenges of continuing organ donation in times of pandemic of COVID-19, pointing out the need and importance of each clinical sign and symptom being tracked and investigated with great tact and care.

In this perspective, it is necessary that the professional starts, from the active search for the possible organ and tissue donor, a rigorous clinical investigation of the patient, as well as a family and community investigation, in addition to tracking, together with the health team, clinical situations, hemodynamic alterations, signs and symptoms, and other findings that may lead to clinical signs of COVID-19^{3,11,12}.

In this study, the actions of nurses to promote safe steps in organ donation in the face of the pandemic are evidenced, since this professional seeks to follow the recommendations for monitoring and controlling the possible risks related to the contamination of the PD by SARS-CoV-2. In the speeches, the participating nurses mention care actions directed to map, track

and monitor any clinical findings that may indicate a possible contamination by the virus.

It is noteworthy that these professionals enhance surveillance through clinical information with family members and the community in an attempt to identify what information may indicate the contact of the PD with COVID-19. There is a real pilgrimage of the nurse between evaluating the record in the medical records, evaluating the hemodynamic alterations and tracing and mapping each path taken by the patient until the arrival at the Critical Care Unit (CCU). At all times, this investigation is clear in the statements collected, evidencing the strategies used to ensure quality and safety in this process.

Monitoring patients with clinical signs that may indicate COVID-19 is one of the fundamental tools in Brazil's current pandemic situation. The donation process must follow strict and cautious care. The potential donor can only be validated for organ and tissue donation after a detailed clinical and epidemiological investigation¹⁷.

Thus, it is understood that among the strategies used by the professional are the monitoring and the clinical and epidemiological investigation combined with clinical reasoning. Clinical reasoning proved to be one of the indispensable strategies used by nurses in the organ donation process during the severe pandemic situation, since it reflects and articulates the information and evidence obtained that may indicate to them and other team members whether the patient may or may not be infected by the SARS-CoV-2 virus¹⁸.

Clinical reasoning is developed by nurses through the recognition of evidence about the situation they are investigating, differentiating it from similar ones, and concluding their thinking through clinical skills and competencies. For nurses to develop this health strategy and ensure safe and effective care, it is crucial that they are supported by knowledge, skills, and attitudes for the clinical evaluation of the PD, as well as knowledge of the work process in which they are working. Clinical reasoning provides opportunities for quick and safe decision making, contributing to the nurse's autonomy, leadership, and management^{18,19}. This was one of the unique strategies acquired by nurses to face this new reality in face of the pandemic. In the speeches, the discussion held with the transplant donation team of the institution and the STC is made clear.

Furthermore, this study reveals that clinical reasoning is also being used as a tool and strategy by nurses, and not only as an investigative tool. But, above all, it is used as an instrument capable of guiding, orienting, and ensuring effective decision making, considering the technical notes, resolutions, and recommendations in force in Brazil regarding the process of organ and tissue donation during the pandemic^{3,11,12}, by pondering that the signs and symptoms of COVID-19 may generate doubts and insecurity for the nursing professional, since many of the hemodynamic alterations presented by the severe patient contaminated by the SARS-CoV-2 virus are also

common alterations in the possible and potential donor due to the irreversible neurological lesion²⁰.

Given this reality, the study shows another strategy adopted by nurses: the change / adjustment of the safety culture in institutions. Professionals working in the process of organ and tissue donation need to understand this moment, considering the pandemic of COVID-19 and making room for new learning and changes. Even if they are professionals with significant time working in the donation process, the moment needs specific skills in each step of this process. The study also reveals that the nursing professionals used the support of management to ensure the continuity of the process, ensuring safety and quality.

According to Anvisa, patient safety culture is defined as a product of group and individual values, attitudes, perceptions and skills that determines the standard of behavior and safety commitment of the institution, replacing blame and punishment with the opportunity to learn from failures²⁰. Facing the organ and tissue donation process during the pandemic of COVID-19, the nurse is faced with the need to create strategies to strengthen the safety of the whole process, which is the patient's right, as well as the ethical commitment of the multiprofessional team and the health institution¹⁰.

The speeches of the study made it clear that the strategy to help change the safety culture was the development and implementation of new protocols, guidelines and care tools to support nurses in the investigation with family members and health professionals, as well as tools that ensure the continuity of care to the potential donor, even at the risk of contamination by the SARS-CoV-2 virus. The strategy of using patient safety protocols is a stimulus for safe care practice and for strengthening the safety culture in care settings^{21,22}.

In the context of the pandemic of COVID-19, it is essential that the team adjust their goals and conducts to continue safe care. As established by Decree No. 9,175, of October 18, 2017, the multiprofessional team needs to have coherent conducts, hold regular meetings, and maintain continuous contact in order to align objectives and achieve the proposed goals. It is also worth noting that the CDR No. 339/2020 supports the implementation of protocols, guides and manuals of good practice in the processing of cells, tissues and human organs for transplantation, aiming to ensure the quality and safety of the procedures provided^{9,23}.

The serious public health problem established by the pandemic reflected in the practice of professionals so that, to maintain qualified and safe assistance, nurses needed to adjust their care. One of the nurse's competences in the process of organ and tissue donation is directed to the management of care, involving values, knowledge, skills and actions consistent with the nature of the work²⁴.

Thus, it is understood that health and safety management is directly related to risk management described in the CDR No. 339/2020, which calls for the application of policies, procedures,

conducts and resources in the identification, analysis, evaluation, communication, control of risks and adverse events that affect, among others, safety⁹.

In the context of the pandemic, nurses needed to reorganize their conducts to investigate the possible contamination of PD by the SARS-CoV-2 virus, having as a main challenge to ensure the continuity of care in each step of the organ and tissue donation process. Added to this, there is the responsibility to ensure that each step is developed following all ethical and safety parameters considered in the current legislation. Finally, it is emphasized that the institution of protocols, standards and routines assists this important task, making the work processes safer for professionals and patients³.

CONCLUSION AND IMPLICATIONS FOR PRACTICE

The strategies developed by nurses working in the NTS, capable of maintaining biovigilance in the process of organ and tissue donation in times of pandemic, include the monitoring and control of possible risks related to the contamination of the PD by the SARS-CoV-2 virus, using detailed clinical and epidemiological investigation articulated to clinical reasoning.

Another strategy implemented was the modification of the safety culture, starting with the development and implementation of protocols, in order to ensure the continuity of donation and transplantation of organs and tissues, ensuring safety and quality in the process, since the number of people on the waiting list waiting for a transplant has not decreased.

The impossibility of a debate and the little depth of the answers are understood as limitations of this study. This situation is intrinsically related to the context experienced in the pandemic, especially regarding health professionals, who are overloaded with the increase of work and workload. However, the results denote the concern with the safety and quality of the work performed by these professionals on behalf of the patient and the process of donation and transplantation.

The results presented highlight the activities performed by nurses that aim to ensure biovigilance in the context of the pandemic of COVID-19. The nurses' statements show a change in attitudes and behaviors, as well as the commitment of these professionals to ensure the continuity of the organ and tissue donation process for transplants in a safe and quality way. It is noteworthy that the presence of nurses in this context proved to be important for the promotion of patient safety culture.

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