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Biovigilance and transplantation models and initiatives: a narrative review

Modelos e iniciativas de biovigilância e transplante: uma revisão narrativa

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ABSTRACT

Introduction: Biovigilance presents a new opportunity for growth and improvement of the donation-transplantation process. Biovigilance is defined as the monitoring and control of procedures involving human cells, tissues and organs, from donation to the clinical evolution of the recipient and the living donor, in order to obtain and provide information on risks and adverse events and reactions, and to prevent its occurrence or recurrence. **Objective:** Describe biovigilance and transplant models and initiatives in Brazil and worldwide. **Method:** Narrative review of national and international literature on biovigilance and transplantation models in Brazil and worldwide. **Results:** The risk is present in all stages involving the donation-transplantation process, and implies continuous surveillance. Bio-surveillance initiatives around the world involve institutions such as the World Health Organization and Italy's National Transplant Centre, which support the sharing of surveillance information published for teaching purposes and for greater public transparency and which, together with Member States of the European Union, aim to support the development and strengthening of the capacity to monitor and control quality, safety and effectiveness in this area. The Australian Government has an initiative that collects information on serious adverse events and reactions related to organ donation and transplantation, but it does not yet have an integrated surveillance system. Brazil, through its National Sanitary Vigilance Agency, has been monitoring the adverse events and reactions analysis, but that database needs to be integrated with that of the National Transplantation System. **Conclusions:** Having National efforts to address international initiatives with the World Health Organization is urgent, thus incorporating measures to implement a culture of quality and safety in the donor-transplant process, with innovative care modelling. It is also necessary to return back to society the high investments done in an efficient and effective manner.

KEYWORDS: Biosurveillance; Tissue and Organ Procurement; Transplant; Patient Safety

RESUMO

Introdução: A biovigilância apresenta nova oportunidade de melhoria e segurança do processo doação-transplante. A biovigilância é definida como o monitoramento e o controle durante os procedimentos que envolvem células, tecidos e órgãos humanos desde a doação até a evolução clínica do receptor e do doador vivo, com o objetivo de obter e disponibilizar informações sobre riscos e eventos e reações adversas, a fim de prevenir sua ocorrência ou recorrência. **Objetivo:** Descrever acerca de modelos e iniciativas de biovigilância e transplante no Brasil e no mundo. **Método:** Revisão narrativa da literatura nacional e internacional. **Resultados:** O risco está presente em todas as etapas que envolvem a doação-transplante, e implica vigilância contínua. As iniciativas de biovigilância no mundo envolvem instituições como a Organização Mundial da Saúde e o Centro Nacional de Transplantes da Itália, que apoiam o compartilhamento de informações de vigilância publicadas para fins de ensino e para maior transparência pública e que, em conjunto com Estados-membros da União Europeia, têm o objetivo de apoiar o desenvolvimento e o fortalecimento da capacidade de monitorar e controlar a qualidade, a segurança e a eficácia nessa área. O governo australiano possui uma iniciativa que coleta informações sobre eventos adversos graves e reações relacionadas à doação e ao transplante de órgãos, mas ainda não possui um sistema de vigilância integrado. O Brasil, por meio da Agência Nacional de Vigilância Sanitária, possui acompanhamento da análise eventos e reações adversas, mas os seus bancos de dados, precisam ser integrados àqueles do Sistema Nacional de Transplantes. **Conclusões:** É premente realizar esforço nacional para atender as inciativas internacionais com a Organização Mundial de Saúde e, assim, incorporar medidas para implementar uma cultura de qualidade e segurança no processo doação-transplante com uma modelagem assistencial inovadora, e devolver à sociedade o alto investimento realizado de modo eficiente e eficaz.

PALAVRAS-CHAVE: Biovigilância; Obtenção de Tecidos e Órgãos; Transplante; Segurança do Paciente

INTRODUCTION

In February 1997, Brazil made an important leap in the area of organ and tissue procurement and transplantation. The area became more professional with the creation of the National Transplant System (SNT), the State Organ and Tissue Notification, Procurement and Distribution Centers (CNCDO) and Organ Procurement Organizations (OPO), defining the roles of these bodies and the relationships among them[1].

In 2009, the Ministry of Health issued Ordinance n. 2.600 of October 21. By approving the SNT technical regulation, the document implemented important instruments for the conduction, authorization and registration of processes related to the allocation of organs and tissues, as well as for the submission of activity reports by the OPO and the Intra-Hospital Organ and Tissue Donation and Transplantation Committees (CIHDOTT)[2].

In 2017, Minister Cabinet Consolidation Ordinance (GM) n. 4, of September 28[2], gathered the rules of the Unified Health System (SUS) systems and subsystems, reiterating the previously regulated instruments and repealing Ordinance n. 2.600/2009[3]. In the same year, new Decree n. 9.175, of February 4, determined, among other rules, that the State Transplantation Center (CET), former CNCDO, define, together with the SNT central body, parameters and indicators of quality for the evaluation of transplantation services, histocompatibility laboratories, tissue banks and bodies that make up the search and donation network of organs, tissues, cells and parts of the human body. Currently, some CETs, for different reasons, are still unable to qualitatively analyze these reports or promote evidence-based improvement. The CIHDOTTs, by the same decree, also have a new name and are now called Intra-Hospital Transplantation Commissions (CIHT)[4].

Brazilian Transplantation Registry n. 4, published by the Brazilian Association of Organ Transplantation in 2018, shows that 33,454 patients were active on waiting lists waiting for an organ or tissue, 44.25% of which were adults and 58.58% were children, whereas only 23,388 organ transplantations were performed, and 2,851 patients died waiting for a transplantation. Meanwhile, in 2018, we had only 3,531 effective donors, representing 17 donors per million population (pmp).

Since the need for transplantations is greater than the supply of donors and, in this area, the donation-transplantation binomial is indivisible, the primary objective of initiatives in this area is to use these scarce assets efficiently and effectively.

With the expansion of the worldwide quality and safety movement and its impact on the Brazilian SUS, it becomes necessary to monitor and measure processes and results, on an ongoing basis, to ensure the maintenance of transplantations with equity, equality and justice for those who seek this form of treatment. This therapeutic modality, incorporated into the SUS and responsible for the conduction of health surveillance actions, now has a pressing need to monitor its processes and results with a focus on continuous improvement.

This is because the Brazilian health surveillance policy, created after GM Ordinance n. 1.660, of July 22, 2009, determines actions under the coordination of the National Health Surveillance Agency (Anvisa) for the monitoring, analysis and investigation of adverse events and technical complaints related to services and products in the post-use/post-marketing phase. The Health Surveillance Notification and Investigation System (VIGIPOS) is the system that addresses the use of cells, tissues and human organs, with the ultimate goal of promoting people's access to these products safely and in compliance with bioethical and legal principles[5].

In 2010, the 63rd World Health Assembly (WHA) of the World Health Organization (WHO) passed Resolution n. 63.22, which presents the following assumption: "appropriate information on donation, processing and transplantation of human cells, tissues and organs, including data on severe adverse events and reactions [...] must be reported and subsequently analyzed by the competent health authorities"[6].

In Brazil, since 2013, when the National Patient Safety Program (PNSP) – RDC/Anvisa n. 36 of July 25, 2013 was established, patient safety centers were created to promote a safety-oriented culture in health services. A safety-oriented culture is a structural component that favors the implementation of safe practices and the reduction of risks with the use of risk management tools, including communication[7]. In addition, the creation of this program determined that improvements in information management and monitoring, surveillance, evaluation and risk management activities be implemented. The control indicator of these actions was defined as the number of countries that have mechanisms for reporting, surveillance and management of adverse events informed to the biovigilance system implemented and coordinated by the competent authority[8].

Therefore, biovigilance established, in 2019, through Anvisa public consultation n. 501, of April 2, 2018[9], a set of monitoring and control actions that address the entire cycle of therapeutic use of cells, tissues and organs, from donation to the clinical evolution of recipients and living donors, with the objective of surveying and making available information on risks, incidents and adverse events and thus prevent their occurrence or recurrence. It is a risk management tool designed to improve the safety and quality of the procedures and processes involved in the therapeutic use of cells and tissues and in the transplantation of human organs[9].

Additionally, after 22 years of enactment of Law n. 9.434, of February 4, 1997, which enabled progress and success in the area of organ and tissue donation and transplantation in Brazil, it can be considered that Brazilian institutions responsible for regulating and monitoring the donation and transplantation process are prepared to, together with European countries and other countries in the Americas, implement and promote quality and safety in this important area of Brazilian health[1].

Therefore, to fulfill its international commitment to the WHO, Brazil must adopt measures that encourage professionals working in the donation-transplantation process to implement a culture of quality and safety capable of providing information that promotes the continuous improvement of results in an ethical and responsible fashion. In this context, the objective of this study was to describe biovigilance and transplantation initiatives in Brazil and in the world.

METHOD

Narrative review study of national and international literature, following the steps of problem formulation, literature search, data collection, analysis of included studies, presentation of results and discussion.

The guiding question was defined as: what has been published about biovigilance and transplantation models and initiatives in Brazil and worldwide? Searches were done in the following databases: Pubmed, Latin American and Caribbean Literature in Health Sciences (LILACS), Embase, Scientific Electronic Library Online (SciELO), Scopus, Web of Science and Open gray, with the following descriptors: "Biovigilance"; "Procurement of Tissues and Organs"; "Transplantation"; and "Patient safety", in Portuguese and English. Searches were done from August to September 2019.

RESULTS AND DISCUSSION

The WHO has long been active in the implementation of worldwide actions and strategies aiming to reduce risks and the occurrence of incidents and adverse events. The literature points out that: "Incidents are events or circumstances that have resulted or could have resulted in unnecessary harm to the patient, whereas risk is defined as the likelihood that the incident will occur"[10].

Regarding the organ and tissue donation and transplantation process, Anvisa adopts the following definitions of incident, near miss and adverse event[11]:

Incident: deviation from the operational procedures or individual safety policies of the healthcare facility related to the harvest, assessment, processing, storage and distribution of cells, tissues and organs detected before or after the donation or the transplantation/infusion/graft/implant and that may or may not lead to the transmission of an illness, death, risk to life, deficiencies or impairment or hospitalization, or even extension of the illness or longer hospitalization, in a living recipient or donor[12,13].

Near miss: any deviation from a standard procedure or policy that, if not detected, could lead to the harvest, use or implantation of incorrect, inappropriate or useless cells, tissues or organs, but which is detected before the procedure and fixed in time[12,13].

Adverse event: any unfavorable occurrence related to donation, harvest, assessment, processing, storage, distribution and the procedure for the therapeutic use of cells, tissues and organs, in a recipient or living donor, which may or may not lead to the transmission of an illness, death, risk to life, disabilities or impairment or hospitalization or, also, the extension of the taxonomy based on the International Classification for Patient Safety (ICPS)[12,13].

The focus on safety, characterized by the concern with the magnitude of damage to the patient resulting from the provision of healthcare, highlights the urgency and the need for initiatives to mitigate risks and improve safety[14].

The healthcare sector and professionals involved in donation and transplantation are increasingly focused on promoting and establishing a safety culture. The United Network for Organ Sharing (UNOS) has made efforts to increase report comprehensiveness and, based on these data, it plans to contribute to the design of improvement strategies for the donation and transplantation process[15].

Likewise, the European Council has established quality and safety standards in the organ donation and transplantation process, involving its various stages: donation, allocation, handling, transportation and grafting of the donated organ[16]. This body also acts in the assessment and regular updating of technical requirements to ensure the quality and safety of donation and transplantation, providing technical guidance for professionals both in assistance and in the management of services and processes[17].

Among specialists, efforts to improve patient safety and to reduce incidents and adverse events have increasingly been the focus of debate, which has been encouraged by the occurrence of serious events like accidental organ disposal or process failures, disease transmission from donor to recipient, among others[18].

It is known that several incidents that did not cause damage to the patient or even those that for some reason ended up not happening (near misses), in general, are not recorded or reported, which suggests some underreporting in this regard.

Reporting makes it possible to provide information that leads to new knowledge and improves patient safety. However, since incident reporting systems are voluntary systems, they do not include a substantial amount of incidents, especially those that did not cause adverse events[15,19]. Incident reporting is valuable to all stakeholders and enables revision of processes, learning from failures and, thus, improvement of processes and care[15].

There is little information in the literature about the occurrence of incidents and adverse events, related causes and impacts for the patient, which highlights the importance of reporting. This allows the involved parties to learn from situations that have occurred, as well as to create indicators and strategies that increase safety[19].

The actual number of incidents and adverse events that occur in the donation and transplantation process is unknown. Furthermore, it is possible that less severe situations are not even reported. There are institutions that submit reports with zero incidents in annual analysis. It is unlikely that a healthcare

institution does not have any flaws in its processes nor any incidents to report, which shows their lack of practice and routine to report notifiable situations. Thus, these unequal amounts of reports of safety-related situations among transplantation institutions show that these situations are still very underreported[15].

The barriers to transparency in reporting notifiable situations involve the myth of perfectionism, the culture of guilt and shame, the fear of punishment and exposure, as well as the lack of support to deal with errors[18].

This context should be better understood and modified to emphasize principles like transparency, the non-punishment of professionals who report incidents, a culture guided by accurate data and information, giving space and recognition to work aimed at analyzing system failures and processes, and learning from incidents and failures. With that, a culture of transparency and safety can be created step by step[20,21].

Adverse events are usually unexpected and occur in association with the provision of healthcare, with impact on patients and institutions. This contributes to the increase in hospitalization and readmission rates, which, in turn, have a negative effect on the quality of life of the recipient and may interfere with transplantation results[18].

Recipients are particularly vulnerable to the consequences of incidents, errors, violations and adverse events due to the polimorbidity that leads them to need a transplant, in addition to drug treatment after graft[18,19]. These characteristics denote the importance of biovigilance and the implementation of safer measures for the patients.

The safety of living donors, of paramount and obvious importance, is of even greater concern[22]. The strategy of using *inter vivos* donations because of insufficient donors requires special attention to the donors, since these are healthy individuals and, therefore, their safety must be an absolute priority, be it in relation to clinical evaluation, surgical procedure, use of medications, perioperative assistance or post-donation follow-up[22].

There are several factors that imply the occurrence of incidents and adverse events. These range from human factors, such as fatigue, work overload, insufficient knowledge, ignorance of processes and risks, to factors that involve institutions, their processes and their workflows[15,18].

Communication failures, errors in description or data reporting are commonly identified. Communication flaws involving, for example, lack of accuracy or insufficient information about the donor, delay in the delivery of information, incomplete, erased or missing documents, communication errors (sender and/or receiver) are situations that are not rare and that jeopardize safety and imply increased risks of failure and incidents[15].

However, other factors are related to failures in the process and risks to patients, such as failure in the diagnosis of donors' serologies and infections, failure involving the surgical procedure (removal and grafting), failure in the safe surgery protocol and inadequate packaging, storage and transportation of the donated organ. These cause damage to the organ, either by contamination, injury or increased ischemia time beyond the safety limit, in addition to complications related to drug treatment or even the care and care management processes[15].

In this context, the importance of designing and using patient safety indicators based on the best available scientific evidence stands out. It is also important to adapt them to the reality of each country to ensure their feasibility in view of cultural and clinical practice variations, the availability of information systems and the capacity of hospitals and healthcare systems to implement effective quality monitoring programs. Moreover, all stakeholders should engage in the process, be they healthcare professionals, managers of health institutions, patients or professionals from regulatory bodies[23].

It is worth emphasizing the urgency and the need to record incident situations, list and validate safety strategies, mobilizing professionals and institutions to mitigate risks and improve patient safety, since the occurrence of adverse events, in addition to harm to patients and families, involves considerable social and economic costs[14].

The risk is present in all stages that involve donation-transplantation. Although it is a treatment choice that brings benefits to the recipients, the risk of incidents, adverse events and complications always exists[11,24].

Therefore, a strong safety culture favors the improvement of safer practices, with improvements in processes, communication, teamwork and knowledge sharing, since safety implies the need for continuous surveillance[14,19]. The Chart presents biovigilance initiatives in organs and tissues for transplantation in Brazil and worldwide.

The WHO Notify library is intended to be comprehensive and describe all types of reactions or events that may have educational value and support risk estimation. The objectives of the Notify Library are: 1. to provide professionals with useful information to determine the suitability of a potential donor; 2. to design common guidelines to support the implementation of effective surveillance; and 3. to give practical support to countries that are creating their surveillance systems for medical products of human origin[25].

The Notify Library uses a database that is not only a surveillance reporting program, but an instrument for collecting and reviewing identified information that is analyzed in the light of available scientific evidence and best practices from case reports of regulatory or professional surveillance programs. For each type of adverse event, at least one source of reference is cited and the international experts collaborating on the project provide a structured analysis of the event. Documents with the adopted taxonomies and the results presented by the collaborating countries are published on the website[25].

The European Union (EU) Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation

Chart. Models of biovigilance in organs and tissues for transplantation. São Paulo, SP, 2019.

Models	Institutions/ Countries	Description	Operating mechanism	Website
Notify Library, 2018[25]	World Health Organization (WHO)	The Notify Library is a joint global initiative, co-sponsored by the WHO and the National Transplant Center in Italy, which supports the sharing of published surveillance information for teaching purposes and for greater public transparency. It is the first WHO initiative to build a library of data on processes that covers the scope of human-made medical products, including human organs, blood, tissues and cells.	The Notify Library is a publicly accessible database of adverse results collected and analyzed by editorial groups formed by international specialists, regulators and clinicians.	https://www.notifylibrary.org/content/notify-project
Vistart, 2018[26]	European Union (EU)	Joint efforts to support EU Member States in developing and strengthening their ability to monitor and control the quality, safety and efficacy in the field of blood, tissues and cell transplantation.	The surveillance will be managed by the competent authorities in a consistent manner among these substances of human origin. Some types of fast alerts that are common for blood, tissue and cell sectors, such as outbreaks of epidemic infections, toxic culture media, defective laboratory instruments and preservation bags, etc. will be communicated through a common fast alert, avoiding double reporting to certification authorities.	https://vistart-ja.eu/
Australian Government Organ and Tissue Authority, 2018[27]	Australia	The structuring of the Australian Surveillance System for Organ Donation for Transplantation was completed and received formal approval in September 2016.	Australia collects limited national information and data on serious adverse events and reactions related to organ donation and transplantation and does not have a nationally integrated surveillance and vigilance system.	https://donatelife.gov.au/about-us/who-we-are
Anvisa, 2016[11]	Brazil	Biovigilance is applied to all organs, tissues, cells and derivatives of human origin to be used in humans and to all processes necessary for them to be viable for use in a recipient. The actions are implemented by the Brazilian Ministry of Health through the National Health Surveillance Agency (Anvisa).	Each health facility and body that is part of the National Transplantation System (SNT) that carries out activities related to transplantation, implants/grafts, advanced therapies and assisted human reproduction must assign a professional responsible for coordinating the work related to biovigilance for all processes to which the establishment has authorization and license to perform. There are databases, from SNT and Anvisa, which need to be integrated.	http://portal.anvisa.gov.br

WHO: World Health Organization; EU: European Union; Anvisa: National Health Surveillance Agency.

(VISTART) initiative aims to encourage and enable the standardization of inspections, systems for the authorization and surveillance of blood, tissues and cells for human use and increase collaboration between Member States and their confidence in each other's inspection and surveillance, with particular attention to the implementation of the Single European Code for Tissues and Cells in accordance with relevant legislation. In total, 17 centers from 13 European countries participate (Italy, Hungary, Romania, Portugal, France, Croatia, Ireland, Greece, Austria, Belgium, Lithuania, Norway and Poland)[26].

In addition, the common treatment of incidents and adverse events favors efficient and uniform solutions, as well as the formation of an agreed content of communication and alert messages for healthcare professionals, health institutions and patients. New risks associated with emerging diseases will be considered using the extensive historical experience of the blood transfusion field to make tissue and cell applications safer. Competent safety and quality authorities will share principles about their expectations for patient follow-up when new processing methods are introduced. The WHO library on adverse events in transfusion, transplantation and assisted reproduction will be enhanced with didactic cases provided by the competent EU authorities. It currently operates in an integrated manner with the Notify Library[26].

Australia has a national surveillance system for organ donation and transplantation, which is essential to support quality systems in the donation and transplantation sectors; monitor, record and analyze adverse events and the impact of interventions; improve patient outcomes; and inform future organ donations for transplant management and health policies. The next step is the establishment of a surveillance specialist and a surveillance Advisory Committee to monitor the performance of the surveillance and vigilance system; evaluate adverse events and reactions according to international reporting criteria; retrospectively analyze adverse events and reactions; identify and recommend best practices; identify the potential need for strategic intervention; and provide long-term policies. The association will be formed by specialists with experience in surveillance

and vigilance, infectious diseases, epidemiology, oncology, communicable diseases, donation and transplantation activities[27].

In Brazil, in cases that are related to human cells or tissues intended for the production of medicines or combined with health products, biovigilance should only be applied to the donation, harvest/collection and assessment process; the other processes must be regulated by pharmacovigilance or technovigilance. Thus, the set of actions to control and monitor risks related to the entire blood cycle, from donation to the use of blood and its components for transfusion purposes, is regulated by hemovigilance[11].

The basic tools for the operation of the reporting system are available on the website of the Coordination of the Biovigilance System (http://portal.anvisa.gov.br/), in which there are reporting forms for adverse reactions and incidents and a guide with instructions on how to fill out the forms[11].

In Brazil, we have found that the reporting flows have been mapped, but an analysis process and measures to improve the process still need to be implemented. Additionally, the data should be made available in an accessible library.

CONCLUSIONS

Quality and safety results in the donation-transplantation process can be improved by the adoption of goals and indicators to guide better care practices. For this, surveillance models already implemented in other countries must be investigated and their adaptation to our reality must be considered. If this is not possible, Brazil should build process improvements based on its own evidence. An example of these improvements is the disclosure of Brazilian results to the society, offering transparency to the public and enabling more informed decisions by all those involved in the donation-transplantation process.

Considering that transplantation is often the only possibility of survival for many patients, investments in results and indicators are needed to enable the construction of databases for the donation and transplantation processes and to give further insight into necessary improvements.

It is also necessary to build the National Program for Quality and Safety in Donation-Transplantation, to monitor processes, results and indicators related to care outcomes.

We also emphasize the need to make the world's largest public transplantation program an integral part of the Brazilian Unified Health System, ensuring that patients go through the entire SUS healthcare network safely. This can be achieved with the design and implementation of the Donor or Receiver Patient Care Line for organs and tissues. Thus, new directions are needed in the area of organ and tissue donation-transplantation. This means measuring Brazilian results with large-scale data and building, based on the analysis of the indicators, an innovative assistance model that warrants the high financial investment and is efficient and effective.

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Conflict of Interest

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