AORN GLOBAL SURGICAL CONFERENCE & EXPO
April 1 - 4, 2023 • San Antonio, TX

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1933

NOTIFICATION OF ADVERSE EVENTS IN ORGAN DONATION AND TRANSPLANTATION

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INTRODUCTION

The concern with patient safety and with the quality of processes involving health care has mobilized teams and institutions regarding greater vigilance in processes. In the area of donation and transplantation, this movement is called biovigilance and aims at greater safety in procedures involving the therapeutic use of human cells, tissues and organs for transplantation, from donation to the clinical evolution of the recipient and the living donor.(1) In order to contribute to the prevention of risks and adverse events, biovigilance aims to obtain and make available information on risks and adverse events and to implement monitoring and process control measures[2].

PURPOSE

To synthesize the scientific evidence on the reporting of adverse events (AE) in organ donation and transplantation.

Continuation method

METHOD

Systematic review of observational studies following the recommendations of the Methodological Guidelines and Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA). Primary studies on biosurveillance and/or AE in organ donation and/or transplantation were included, without restriction of publication date or language. The search strategy was performed according to the PRISMA checklist. Six electronic databases were used to search the scientific literature: MEDLINE, Embase, Web of Science, LILACS, Scopus and the Scielo electronic library. A data search was also carried out in the following secondary databases: Notify - World Health Organization, Pan-American Health Organization and Google Scholar. To assess the quality of the studies, the MINORS tool was used. The research project was registered with PROSPERO/NHS.

RESULTS

The analysis corpus of the study consisted of eight studies. The results show AEs that occurred at some stage of the donation and transplantation process, such as adverse drug reactions, neurotoxicity, increased hospitalization time, surgical reinterventions, fall, coma, death, graft failure or loss. However, it is noteworthy that the AE notification data is possibly still underreported.

Findings related to outcomes, processes and strategies for preventing adverse events

RESULTS	FAILURES IN PROCESSES	PREVENTIONS STRATEGIES
Adverse drug-related reactions Neurotoxicity	Underreporting	Plan adverse events prevention and risk mitigation strategies Perform risk management
Increased hospitalization time Reinterventions	Communication failures	Implement a communication system to support professionals in decision-making
Death	Failure in information systems and/or documents	Implement a portal to support family members
Graft failure or loss falls	Compliance errors	Create a database of adverse events situations for analysis and to support prevention and decision-making
	Errors in decision making	Standardize processes
	Errors in the selection and management of the waiting list	
	Labeling errors	
	Failure in the transcription of laboratory and immunology information and results	

Study data

FINAL CONSIDERATIONS

The results point to the occurrence of AE occurring at some stage of the organ and tissue donation and transplantation process, such as: adverse drug-related reactions; neurotoxicity; increased length of hospital stay; surgical reinterventions; fall; with the; death; graft failure or loss. It is noteworthy that the AEs are possibly still underreported.

PERIOPERATIVE NURSING IMPLICATIONS

In this context, the data from the present study present scientific evidence about systems of biovigilance and notification of adverse events in the process of donation and transplantation of organs and tissues, showing consequences of the occurrence of AE and related causes, in addition to presenting strategies to mitigate risks, prevent the occurrence of errors and make the team more prepared and qualified to act with greater safety and quality in the process of organ and tissue donation and transplantation.

Bibliographic references:

•Roza B, Kusahara D, Pessoa J, Treviso P, Oliveira P, Leite R et al. Modelos e iniciativas de biovigilância e transplante: uma revisão narrativa. Vigilância Sanitária Em Debate: Sociedade, Ciência & Tecnologia, 2019; 7(4):10-16. DOI: https://doi.org/10.22239/2317-269x.01403

•2. Brasil. Anvisa. Agência Nacional de Vigilância Sanitária. Resolução de Diretoria Colegiada RDC Nº 339. Dispõe sobre a instituição do Sistema Nacional de Biovigilância. 2020 fev 20 [citado em: 2020 mai 25] Disponível em: http://portal.anvisa.gov.br/documents/10181/3146460/RDC_339_2020_.pdf/b7b60dd9-ba54-4d91-b6db-8d3a2d369afb