

#### [Special article]

Call No. 01/2018 – Publication of scientific articles in the original article and systematic and integrative review categories under the topic "Advanced Nursing Practice: Specialized care and leadership in the building of excellence in nursing".

## Integrative Review =

## Safety culture in the organ donation process: a literature review

Cultura de segurança no processo de doação de órgãos: revisão de literatura Cultura de seguridad en el proceso de donación de órganos: una revisión de la literatura

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#### **Keywords**

Organizational culture; Patient safety; Tissue and organ procurement; Transplantation

#### **Descritores**

Cultura organizacional; Segurança do paciente; Obtenção de tecidos e órgãos; Transplante

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Cultura organizacional; Seguridad del paciente; Obtención de tejidos y órganos; Trasplante

#### Submitted

August 28, 2018

#### Accepted

October 19, 2018

#### **Abstract**

Objective: To evaluate the development of a safety culture in the organ donation and transplantation process as it is available in the scientific

Methods: An integrative literature review was conducted in the CINAHL, LILACS, PubMed, Scopus, and Web of Science databases, and the electronic library, SciELO, from 2012 to 2016, using a syntax of keywords and descriptors for each database; fourteen articles were selected for analysis.

Results: One thousand six hundred and fifty nine studies were found, 33 complete articles were read, and 14 studies were selected for analysis. The information obtained was analyzed critically and grouped into two categories. Category 1 — patient safety culture for the use of medications in the post-transplant period: the involvement of the multidisciplinary team is essential in the orientation process for hospital discharge, and the main factors related to errors in the use of medicines. Category 2 - safety culture in the transplant units: issues related to patient safety of those undergoing transplantation in the pre- and intra-operative periods.

Conclusion: This study showed that the issue of a culture of safety in the donation and organ transplantation process is incipient in the literature; well-designed studies related to the culture of patient safety are necessary for all the stages of the donation and transplant process.

#### Resumo

Objetivo: Avaliar o desenvolvimento da cultura de segurança no processo de doação de órgãos e transplantes na literatura científica.

Métodos: Revisão integrativa da literatura a partir das bases de dados CINAHL, LILACS, PubMed, Scopus, Web of Science e na biblioteca

Metodos: Revisão integrativa da literatura a partir das bases de dados CINAHL, LILACS, PubMed, Scopus, Web of Science e na biblioteca eletrônica SciELO, de 2012 a 2016, com sintaxe de palavras-chaves e descritores para cada base, sendo selecionados 14 artigos para análise. Resultados: Foram detectados 1.659 estudos, desses, 33 foram lidos na integra, sendo definido para coleta dos dados 14 estudos. As informações obtidas foram analisadas criticamentre e agrupadas em duas categorias: Na Categoria 1 — Cultura de segurança no uso de medicamentos no período pós-transplante: destaca-se como fundamental o envolvimento da equipe multidisciplinar na orientação da alta hospitalar no transplante e ainda, os principais fatores de erros no uso dos fármacos. Na Categoria 2 — Cultura de segurança nas unidades transplantadoras: apresenta-se questões relacionadas à segurança dos pacientes submetidos aos transplantes nos períodos pré e intra-operatórios.

Conclusão: Por meio desse estudo, observou-se que a temática da cultura de segurança no processo de doação e transplante de órgãos está incipiente na literatura sendo necessário desenvolvimento de estudos bem delineados e relacionando à cultura de segurança do paciente em todas as etapas do processo de doação e transplantes.

#### Resumen

Objetivo: Evaluar el desarrollo de la cultura de seguridad en el proceso de donación de órganos y trasplantes en la literatura científica. Métodos: Revisión integrativa de literatura con búsquedas en bases CINAHL, LILACS, PubMed, Scopus, Web of Sciences y SciELO, entre 2012 y

2016, con sintaxis de palabras claves y descriptores para cada base, habiéndose seleccionado 14 artículos para su análisis.

Resultados: Fueron hallados 1.659 estudios. De ellos, 33 fueron leidos integralmente, definiéndose 14 para la recolección de datos. La información obtenida fue analizada criticamente y agrupada en dos categográs. En la Categoría 1- Cultura de seguridad para uso de medicamentos en el período postrasplante, se resalta como esencial la involucración del equipo multidisciplinario en la indicación del alta en el trasplante, y también, los principales factores de error en el uso de fármacos. En la Categoría 2- Cultura de seguridad en las unidades de trasplante, se presentan preguntas relacionadas a la seguridad de los pacientes sometificas a trasplantes en los períodos pre e intraoperatorios.

preguntas relacionadas a la seguridad de los pacientes sometidos a trasplantes en los períodos pre e intraoperatorios.

Conclusión: Este estudio observó que la cultura de seguridad en el proceso de donación y trasplante de órganos es incipiente en la literatura, requiriéndose el desarrollo de estudios bien delineados y relacionando la cultura de seguridad del paciente en todas las etapas del proceso de donación y trasplante.

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#### D0I

http://dx.doi.org/10.1590/1982-0194201800091



#### How to cite:

Cabral AS, Knihs NS, Magalhães AP, Alvarez AG, Catarina AA, Martins SR, et al. Safety culture in the organ donation process: a literature review. Acta Paul Enferm. 2018;31(6):667-73.

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## Introduction

According to the World Health Organization, patient safety is defined as the minimization of unnecessary damage associated with health care. At the national level, the Ministry of Health recently instituted the National Patient Safety Program (NPSP), which aims to improve health care in all the national health facilities.

The safety culture issue is inserted into the context of patient safety, which consists of actions by all members of an institution that are focused on the safety of professionals, patients and family members, enabling the identification, notification, and resolution of possible problems related to safety. (2)

A safety culture is often associated with the promotion of safe practices and, consequently, the quality of services provided by an individual or organization, in a prioritized manner. It aims to enable debates based on mutual trust, shared perception, confidence, and effectiveness of preventive measures, and is directed at reporting and discussing of errors or failures in the care provided. (3-5)

In this scenario, organ and tissue donation is a representative of the transplants; they are complex processes involving a multiprofessional team, as well as operational, bureaucratic, legal, and logistical issues. Such complexity demands greater cohesion, good communication, effectiveness, and above all, safety practices within the team during the execution of each stage of these processes. (6)

The donation of organs and tissues is composed of the stages: identification, assessment and validation of the potential donor; diagnosis of brain death; clinical assessment and maintenance of the potential donor; interview with the family; removal, transportation and allocation of organs. The transplant process involves these stages: recipient assessment by the multiprofessional team; placement on the waiting list; perioperative period (organ implant), and postoperative follow-up. All the stages are vital to the success of donation and transplant, and it is fundamental to establish a strong safety culture. (6-8)

Considering the increasing number of potential and effective donors in Brazil in the last seven

years (1,898 effective donors in 2010; 3,415 effective donors in 2017), in addition to the annual loss of potential donors, (over 4,000 due to cardiac arrest, family refusal, donation process logistics, and other indefinite causes), it is fundamental, relevant, and necessary to understand the safety culture reality among the teams involved in these processes. (9)

Likewise, for effective assistance in the organ donation and transplant process, professionals must consolidate their knowledge and attitudes on safety culture, with interconnection of this issue at each stage of the process. Hence, the following guiding question was developed: "How has the safety culture been developed for the process of organ donation and transplantation?"

In this sense, the objective was to evaluate the development of a safety culture in the organ donation and transplantation process, as was available in the scientific literature.

### **Methods**

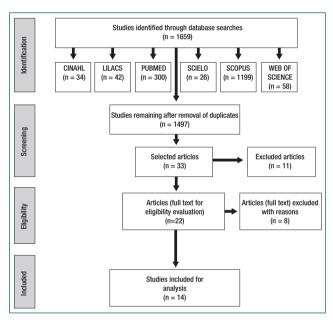
This was an integrative literature review, which allows the orderly gathering of studies on a given topic, allowing for critical analysis and a deepening of knowledge. (10) It was conducted at the Federal University of Santa Catarina, from November 2012 to November 2016, following the six steps described below:

**First step** - development of the research question considering the proposed theme, the study participants, the information to be obtained, the interventions to be evaluated, and the results to be measured. (10)

**Second step** – selection of databases, considering the subject and the largest amount of articles, using a random search with the following descriptors: safety culture, organ donation, organs donation, organ donor, organs donors, tissue and organ procurement\*, patient safety, tissue and organ procurement, tissue donors, transplantation, organ transplantation. The databases used for this study were CINAHL, LILACS, PubMed, Scopus, Web of Science, and the electronic library SciELO. The

search strategies were formulated using Boolean operators "OR" and "AND".

The inclusion criteria defined were: original articles, guidelines and experience reports related to organ donation, transplants and safety culture; publications in English, Spanish and Portuguese; available in full text. Exclusion criteria were: review articles, editorials, letters, and summaries in annals of events or periodicals. The PRISMA Diagram Model was used to facilitate the organization of study selection (Figure 1). The articles selected were exported to the Mendeley® reference management software, to identify duplicate articles and gather all publications found.



**Figure 1.** Organization of studies based on the PRISMA Diagram Model

Third step - conducted by peers, after reading all the publications in full. Where there was any doubt as to maintaining an article in the study, a discussion was conducted during a meeting with the authors. After a consensus on the inclusions, a table was developed to organize in a clear and objective manner the main information, including: title, year of publication, authors, periodical name, database, objective(s), type of study, level of evidence, results, and recommendations.

Fourth step - pairs of authors, seeking to identify the characteristics of each article, care-

fully read the information obtained. This step was developed jointly with one of the authors who has expertise in organ donation and transplantation, as well as one author with expertise in safety culture, aiming to identify greater rigor related to the method and information related to the donation process, transplantation, and safety culture, as well as the best levels of evidence.<sup>(10)</sup>

**Fifth step** - this step aimed to interpret and synthesize the information obtained, comparing the data acquired in the analysis of the articles, as well as possible gaps and research bias, presenting opportunities for the development of new studies related to this topic.

**Sixth step** - for the development of this stage, the obtained information was distributed into subgroups according to data related to the organ donation and transplantation process, with the aim of facilitating the analysis. Thereafter, two categories were constructed: 1) Culture of patient safety for the use of medicines in the post-transplant period; and 2) Culture of patient safety in the transplant units

#### Results

In the first step of the search there were 1,659 studies identified in the periodical databases: 34 in CINAHL, 42 in LILACS, 300 in PubMed, 26 in SciELO, 1199 in Scopus, and 58 in Web of Science. After removal of duplicate articles, the total obtained was 1,497 studies. Of these, 33 were selected by title, abstract and descriptors. After consensus among researchers, 14 studies were selected for use in the study. All of these articles presented a level of evidence of III or IV. (10) Chart 1 presents the information extracted from the studies included in the research.

## **Presentation of the categories**

# Category 1 - Patient safety culture for the use of medications in the post-transplant period

The information obtained indicates that the involvement of health professionals in guidelines and monitoring of medication use in all stages of the transplantation process is essential in order to pro-

Chart 1. Summary of results of studies included for analysis

Author/Year/Country/Level of evidence	Outcomes
Haipeng Meng, Jiayin Yang, Lunan Yan (2016) <sup>(11)</sup> China. Level IV evidence	With measures used to improve the preoperative assessment and liver surgery, the risk for liver donors is controllable and acceptable.
Lima et al. (2016) <sup>(12)</sup> Brazil. Level IV evidence	The clinical pharmacist should be part of the multiprofessional team for education of the transplant patient at the time of hospital discharge, to prevent negative results associated with pharmacotherapy, and to guarantee medication reconciliation and patient safety.
McElroy LM, et al. (2016) <sup>(13)</sup> USA. Level IV evidence	A structure for patient safety can be applied to facilitate the organization and analysis of surgical safety data. Classification instruments can be easily and consistently applied for surgeries, in a standardized manner
Fermo et al. (2015) <sup>(14)</sup> Brazil. Level IV evidence	The safety culture needs to be valued by professionals and managers aiming to achieve safe care by the professionals who work in the transplant unit. It is recommended that staff and managers discuss actions to be implemented in order to strengthen patient safety culture.
Kucirka LM, et al. (2015) <sup>(15)</sup> USA. Level IV evidence	It is critical to understand the mechanism and consequences of increased use of borderline organ donors in order to ensure a balance between patient safety and organ use.
Bonkowski et al. (2014)(16) USA. Level IV evidence	Routine adaptation of a barcode-based medicine delivery method has the potential to reduce medication administration errors in transplant patients.
Hsu et al. (2014) <sup>(17)</sup> Taiwan. Level III evidence	Implementing a team resource management program on patient safety and team member behaviors improves the culture of teamwork as well as patient safety in organ procurement and transplantation.
McElroy LM, et al. (2014) <sup>(18)</sup> USA. Level IV evidence	The use of a web-based questionnaire to increase use of an incident reporting system for assessing safety risks in renal transplants demonstrated increased information, more prospects for a single safety issue, and an increased range of participants.
Torres-Rodríguez et al.(2014) <sup>(19)</sup> Spain. Level IV evidence	Outpatient renal allograft biopsy is a safe and efficient procedure, allowing lower incidence of complications.
Gala-Lopez et al. (2013) <sup>(20)</sup> Canada. Level IV evidence	The preparation of islets prior to implantation and the administration of appropriate antibiotics prevent contamination of the patient, promote safety, and decrease possible complications in immunosuppressed patients.
Martins et al. (2013) <sup>(21)</sup> Brazil. Level IV evidence	A pharmaceutical care service enables monitoring of pharmacotherapeutic treatment and intervention in a manner that provides greater team and patient safety.
Musgrave et al. (2013) <sup>(22)</sup> USA. Level IV evidence	The involvement of pharmacists, particularly at hospital discharge, leads to improved medication safety. Future studies are needed to evaluate other possible consequences of the pharmacist's involvement
Taber et al. (2013) <sup>(23)</sup> USA. Level IV evidence	Improved safety, and reduced rates of acute rejection and infection were noted after a multidisciplinary quality improvement initiative on medication distribution.
Muñoz et al. (2012) <sup>(24)</sup> Spain. Level IV evidence	The adherence of transplant physicians to the current recommendations on antifungal and prophylaxis treatment is weak. Thus, there is a clear need for an international consensus that emphasizes patient safety in this regard.

mote the safe use of medicines, which may lead to better clinical results for the patient. (23,24)

The findings highlight the main errors related to the administration of incorrect doses and unauthorized medicines. In addition, they demonstrate the need for development of well-defined protocols, medication standardization, as well as improvement strategies related to the organization of medication administration. Furthermore, they reveal the importance of the health team guiding and educating patients on the correct use of medications. (16,24)

The findings enabled the understanding that when greater patient involvement is obtained in the manipulation of medications, a greater level of treatment adherence is achieved, leading to an improvement in the patient's clinical condition, reducing infection rates, re-admission, and graft rejection. (12,21-23)

# Category 2 - Culture of patient safety in the transplant units

The category presents questions related to the safety culture of patients undergoing renal, (18,19) hepatic, (11) abdominal, (24) pancreatic, (20) and bone marrow transplantation, (14) in the pre- and intra-operative periods.

Studies emphasize the importance of the health team in focusing on the transmission of diseases, and it is important that the professionals ensure, by means of examination and clinical history, the absence of any signs that may indicate that the organ donor has any transmissible disease. (13-15,17,18)

In addition, they point out that the organization and analysis of surgical data, as far as the donor and the recipient are concerned, are strategies for promoting a culture of patient safety. With regard to the prevention of possible irregularities and complications, it was noted that the use of prophylactic antibiotics, as well as biopsies, was strategies that could minimize the risk of infections and prevent other health events, such as early rejection. (11,19,20)

### **Discussion**

The recommendations identified in this study show that the development of a safety culture during the process of organ donation and transplantation is directly related to transplantation. Most of the studies are related to safety in the transplantation process, involving the use of medication, the participation

of the multiprofessional team at hospital discharge, as well as actions aimed toward the intraoperative period. In addition, the level of evidence from the studies was identified as levels III and IV, showing the need for stronger studies, with level of evidence I and II, which can subsidize strategies for safety improvements in the process of organ donation and transplantation.

The safety culture scenario in donation and organ transplantation presents itself as an extremely complex process, involving the participation of several professionals who act in different stages, requiring synchrony, organization, and knowledge of the team in the development of each stage.<sup>(8)</sup>

Therefore, we understand the need for a strict look by the authorities at the process of organ donation and transplantation, in order to enable healthy organs which are feasible to be transplanted using efficient and effective logistics, which can ensure a higher survival rate for the patient undergoing transplantation. Therefore, the development of new studies that can provide quality and safety in this area is relevant, prudent, and essential. (6,8,25)

Although practically all the studies were categorized as level IV evidence, relevant information was obtained, especially regarding the participation of the multiprofessional team, as well as the cohesion of these professionals in the thorough evaluation of the potential donor, in order to obtain quality organs and tissues, avoiding the transmission of infectious diseases or neoplasias to the transplant recipient. (7,15)

Conducting an in-depth physical examination for potential donors was rated as effective in reducing risks and adverse events in transplants. (13-15) In addition, evidence from these studies indicates the use of tools (protocols, guidelines and directives) by the health team is important for safety in the donation and transplantation process, to investigate possible changes presented by the donor as well as by the transplant recipient. (13,14,17)

The findings also point the way to the safety process, contributing to the safety of the organ donor validation stage, minimizing the risk of *loss* of organ *donors owing to cardiac arrest*, and ensuring viable organs for transplant. It is important to note

that transplantation only occurs through the availability of a donor of viable organs and tissues. (9,26-28)

At the same time, the use of tools (protocols, guides and guidelines) promotes team synchronization and cohesion, effective communication, rapid making-decision, time and process management. The safety culture emerges as a proposal for discussion, enhancement, growth, and improvement in the quality of care provided by health professionals throughout the donation and transplant scenario; after all, more satisfied professionals provide better and safer care. (29,30-32)

Also, regarding the evidence of the study, the applicability of safety programs and instruments as effective strategies for transplant safety is highlighted, especially regarding the participation of the multiprofessional team at hospital discharge. In addition, the findings indicate the need to promote strategies that influence the improvement of patient adherence to medication use, which is one of the factors related to the development of organ rejection.

In the transplantation process, teamwork must take place from the first contact of the individual with the health service until the post-transplantation period, for a better result in the professionals' performance and in the treatment of the patient, as well as promoting safety in the process. (33,34) In the daily life of transplanted patients, medications are essential and provide a better quality of life, protection, and safety regarding rejection of the transplanted organ. (30-33)

The findings also point to the need for managers and professionals to work in an integrated manner, in order to develop a strengthened safety culture, guaranteeing the provision of quality, safe, and effective care in the organ and tissue donation process. In the donation process, the safety culture provides a reduction of errors in all stages, from the diagnosis of brain death and maintenance of the potential donor, to the procurement and implantation of the organs, as well as during the postoperative care. (34,35)

#### Conclusion

Only one study related to a safety culture for transplantation was identified. The other studies focused

on donor safety and transplantation safety, especially with the use of medications. Regarding the development of a safety culture, the studies guide the participation of a cohesive multiprofessional team, in-depth physical examinations with the potential donor, as well as the use of tools (protocols, guides, and guidelines) to support the team in providing care. Further studies related to the patient safety culture at all stages of the donation and transplantation process need to be conducted to deepen this theme, especially related to each step of the donation process, given the amount of donor losses in Brazil.

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