Integrative review: indicators of result process of organ donation and transplants

Authors

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ABSTRACT

Objective: Identify by integrated review the main result indicators in the process of organ donation and transplants used in Brazil and worldwide. The integrated review of this literature was performed on bibliographic database MedLine/PubMed and LILACS and governmental and non-governmental sites between 1995 and 2011. The describers/keywords used were organ donations, organ transplant and results in health, being selected 26 articles and nine sites. The evidence level classification in the articles changed from one to six. Results: The evidence level in the articles in its totality was 66.6% was four (12:18 PubMed) all the articles of LILACS database (8). The indicators showed in the articles intends to evaluate, assess, measure and control data related to the profile of the donor, clinical and hospital conditions, ischemia timing, organ size, surgical procedure and the complications that came from transplants.

Keywords: indicators; organ transplantation; transplants.

Introduction

In 2011, Brazil had more than 10 donors per million population for the first time in its history. The number of 11.4 donors per million population added up to over 23,000 transplants performed in the public health care system. The number of patients waiting for a transplant decreased by 23% in 2011 in relation to 2010. The most significant decreases were seen

in the liver (42%), cornea (39%), and pancreas (36%) waiting lists. Lesser decreases were observed in the kidney (14%), heart (13%), and lung (5%) lists, recently targeted alongside liver transplants by public policies.¹

Information on reporting rates, donations, failed overall and categorized donations broken down in terms of transplants not authorized by the subject's family, unconfirmed brain death, medical contraindication, cardiorespiratory arrest, and inadequate infrastructure is widely available. Reports have been published by non-governmental organizations based on data voluntarily provided by transplant teams and State Centers for the Procurement, Distribution, and Transplantation of Organs and Tissues, possibly introducing bias in the analyses offered by their authors.

Despite the magnitude of the job done by public transplant institutions in Brazil, the Brazilian National Transplant System is facing severe operating issues. Some have been described in a report published by the Federal Accounting Court. The report contains detailed accounts of problems in areas such as management, quality control, and technology linked to medical procedures and the provision of timely treatment in equal terms to the target audiences of the National Transplant System.²

Additionally, issues such as the precarious information systems used in state transplant coordination offices,

the lack of communication of protocols related to organ procurement and donation to medical doctors, the non-existent or barely effective intra-hospital transplant committees, and the high loss of donors and potentially transplantable organs are worthy of consideration.³ Indicators can be used in this context to help assess the performance of organ and tissue donation and transplant services.³

The purpose of indicators is to measure qualitative and quantitative aspects of variables such as the environment, structure, processes, and outcomes. Indicators cannot be construed as direct measurements of quality. Instead, they point out to what requires the attention of the assessed health care organization.

Indicators are units that allow the measurement of cases, events, and quantitative elements, and the verification of qualitative elements. Therefore, an indicator is a measurement tool used to survey the quantitative and qualitative aspects of a given phenomenon in order to assess it and substantiate the making of informed decisions. Indicators are derived from samples, and their validity depends on the good quality of the sampling process.^{4,5}

In order for an indicator to be measurable, the following attributes must be considered: validity, i.e., how much the indicator can identify situations requiring improvements; sensitivity to indicate whether a process presents problems; specificity to set apart only the cases in which problems are occurring; simplicity; possibility to calculate and analyze data; objectively defined goals; and low-cost application to allow it to be used routinely in health care institutions.^{4,5}

Indicators are designed to provide data to be used in quality improvement initiatives and to enhance the transparency and clarity of the available information.^{5,6}

The authors considered the difficulties experienced in organ and tissue donation and transplant services and the need to monitor, assess, and manage related processes, and designed a study to find the main indicators used globally in donation and transplant organizations. This study aimed to analyze the indicators used in donation and transplant services.

OBJECTIVES

- To review the outcome indicators used globally in organ donation and transplant services.
- To propose outcome indicators for the organ donation and transplant processes used in Brazil.

METHODS

This integrative review followed the six steps required in this type of research: 1) identification of a theme and selection of the research question; 2) definition of the study inclusion and sample selection criteria; 3) definition of the information considering all common characteristics and the representation of the selected studies; 4) assessment of the studies and critical analysis of study findings; 5) interpretation of results; and 6) presentation of a review clearly reporting the identified findings.^{6,7}

The search for papers included publications indexed on databases MedLine/PubMed and LILACS, to retrieve the references and abstracts of studies published in the Latin American and international literature. Online reports from government and non-governmental organizations were also included. The search was not limited to papers published within a specific period of time.

Studies were selected based on the following inclusion criteria: all paper types (original studies, literature reviews, update papers, research papers, case reports etc.); papers with abstracts and complete text available for analysis; papers published in Portuguese, English, or Spanish by 2011; and papers in the area of health sciences with titles and/or abstracts with the following keywords: organ donation, transplants, indicators.

Titles and abstracts were considered first in paper selection. Papers meeting the question and purposes of the study were read in full, and had their methods and relevant results analyzed.⁷

After all papers had been read, they were categorized in terms of level of evidence. Level one - evidence obtained through meta-analysis of randomized controlled trials; level two - evidence gathered from experimental studies; level three - evidence derived from quasi-experimental

studies; level four - evidence emerging from descriptive studies or qualitative approaches; level five - evidence from case or experiment reports; and level six - evidence based on expert opinions or legal documents.^{8,9}

The following data were gathered on the selected papers: author, year of publication, country of origin of the study, source, study design, method, and relevant results. Frequently found indicators that met this study's purposes were listed.

Next, indicators related to donation and transplant processes were assigned to their respective groups.

RESULTS

Nineteen papers were selected from MedLine/PubMed for their titles and abstracts, and 18 were included in the study after the entire papers were read. Eight papers from LILACS were included, along with six government and non-governmental databases.¹⁰⁻³³

The oldest paper listed on MedLine/PubMed dated from 1995. No other papers published between 1995 and 2000 were found. Thus, only this paper from 1995 with level 5 evidence was included. One paper with level 4 evidence was published in 2000, and two in 2001. 10-14,24-30 No papers were published in 2002. Two papers were listed as published in 2003, with evidence levels 4 and 5. In 2004 and 2005, only one paper was found for each year with level 4 evidence. Three papers were published in 2006, with evidence levels 4 and 6. In 2007 and 2008, two papers with level 5 evidence were published. In 2010 only two papers with evidence levels 4 and 5 were found.

Most of the papers published between 1995 and 2010 (66.6%; 12:18) were case reports or experimental studies (level 4 evidence) and 33.4% (6:18) were descriptive studies. Eighty-nine percent of the papers included in this study were published in the United States.

The earliest publication on LILACS dated from 2005, a paper with level 4 evidence. One paper with level 4 evidence was published in 2006. No records of papers published in 2007 were found.

Five papers were published between 2008 and 2010. All papers listed on LILACS and 67.0% of the studies carried out in Brazil published between 2005 and 2010 had level 4 evidence.^{3,15-18,31-33}

Two online databases were found in the United States, one in the United Kingdom, one in Canada, two in Europe, one in Spain, one in China, and one in Brazil. Five were maintained by government agencies and four by non-governmental organizations. 19-23

When indicators related to the organ donation process were grouped (Chart 1), they were found to relate mostly to donation potential, donor profile, and organ quality. The identified indicators were designed to measure the number of donors, donor characteristics, and organ quality by monitoring distribution systems, donor length of hospitalization at an intensive care unit, and cause of brain death.

Some of these indicators had been used for years in Brazil. The Brazilian Association for Organ Transplantation publishes quarterly reports featuring the data collected based on the following indicators:

- Number of processed potential donors;
- % organs offered and accepted;
- Rate of brain death reporting;
- Estimated potential number of donors (coroner's office);
- Characteristics of brain death cases per year.

Transplant indicators (Chart 2) were more related to graft survival, time on the waiting list until transplantation, survival rates, and perfusion times. These indicators monitor organ quality, patient and graft survival. In Brazil, indicators connected to survival and time on the waiting list are currently used.

DISCUSSION

This integrative review showed that database keyword-based searches identified the largest number of papers connected to donation and transplant. However, after titles and abstracts were read the number fell to 18 on MedLine/PubMed and eight on LILACS.

CHART 1 MAIN INDICATORS IDENTIFIED ON MEDLINE/PUBMED, LILACS, GOVERNMENT AND NON-GOVERNMENTAL ORGANIZATION DATABASES CONCERNING THE DONATION PROCESS PubMed • Number of donors: Number of potential donors successfully processed; Shehv E et al.:10 Donor profile: Rithalia A:11 • Donor clinical status: Barber K et al.;12 Organ quality; Hernandez et al.;13 • Distribution time; Zheng et al.14 • % offered and accepted organs; • Causes for brain death. LILACS • Donor ICU hospitalization length; Causes for impeded organ donation: Brain-death reporting rates; Marinho A:3 • Estimated potential donors (coroner's office); Mattia NL de et al.;15 • Estimated yearly availability of organs and tissues; Reis, DJFdos;16 • Potential brain-death cases per institution; Solar P et al.;17 • Donor age (% and mean); Mesa et al.18 • Cause of death; Occupation and family income; • Donor family satisfaction. Government and non-governmental organizations • Number of organs per age; • Number of organs per blood type; • Organ origin; Organización Nacional de Transplantes;19,20 • Number of organs per center; Registro Brasileiro de Transplantes.²¹⁻²³ Number of cases of brain death per institution; Death characteristics per year; • Death characteristics per age.

CHART 2 MAIN INDICATORS IDENTIFIED ON MEDLINE/PUBMED, LILACS, GOVERNMENT AND NON-GOVERNMENTAL ORGANIZATION DATABASES CONCERNING THE TRANSPLANT PROCESS

PubMed	
Pacheco Z et al.; ²⁴ Moreno A et al.; ²⁵ Carbajal H, Cabriales H; ²⁶ Atlés et al.; ²⁷ Reese et al.; ²⁸ Svyeder et al.; ²⁹ Werterm et al. ³⁰	 Perfusion time; Cost of transplantation; Individual surgical risk; Time on waiting list; Risk of graft failure; Organ characteristics; Risk of infection; MELD score for liver transplant recipients.
LILACS	
Lima FET <i>et al.;</i> ³¹ Freire MP; ³² Fusco CC <i>et al.</i> ³³	 Time on waiting list; Death rate of patients on the waiting list; Survival rate; Risk of infection; MELD score for liver transplant recipients.
Government and non-governmental orga	nizations
Organización Nacional do Transplantos: 19,20	Time on waiting list;

• Survival rate;

· Rate of infection.

Two thirds (66.6%) of the papers on MedLine/PubMed and LILACS had level 4 evidence, and none had evidence levels 1, 2, 3, or 6.

Organización Nacional de Transplantes; 19,20

Registro Brasileiro de Transplantes.²¹⁻²³

Significant development is needed in the organ donation and transplant services in Brazil, particularly in what concerns the quality of the

return over the funds invested through health care public policies.³⁴⁻³⁹

Nonetheless, this fact is not an excuse for the lack of studies on quality indicators, nor for the published literature's low levels of evidence. One might infer that the Brazilian culture is not very appreciative of assessment processes, in an attitude that affects the willingness of officials and managers to establish indicators to measure the correlations between funds invested and the quality of processes and their outcomes.

Indicators are measurement tools used to survey the quantitative and qualitative aspects of a given phenomenon in order to assess it and substantiate the making of informed decisions.⁴⁰⁻⁴³

The use of indicators allows the capturing of trustworthy data connected to the phenomenon targeted in the assessment, and the identification of factors and situations impacting the process. And there lies the importance of employing indicators in the organ donation and transplant services to aid in the identification of improvement opportunities. However, this review found a very limited number of studies in which valid indicators were used to assess organ donation and transplant services.

Ongoing performance assessment of organ donation and transplant services favors the establishment of strategies conducive to process improvements. And improvements lead to better quality organ and tissue donation processes. 44-46 Quality can be gauged by monitoring process outcomes and assessing indicators. 47-50

Countries such as Spain, Portugal, and the United States have given significant strides to develop this area and have seen increases on the number of donors. Conversely, catastrophic results have been reported in countries such as India, China, and others. 19,51-56

In 2009, 6,490 reports of potential donors were made (34.2 pmp/year), but only 1,658 came through and 4,832 were missed. In 2010, 6,842 potential donations were reported (36.4 pmp/year), only 1,920 were processed, and 4,922 were missed. In 2011, 7,233 reports were made, only 2,048 donors came through, and 5,185 were missed. This data supports the information published in this study, as 67.0% of the papers

included in the LILACS database described matters pertaining to the Brazilian organ donation and transplant scene. However, the indicators referred to in these studies were not properly validated, and cannot be used to effectively assess donation and transplant processes.

Brazil, as many other countries, ^{34,36,38,57,58} has not implemented valid indicators to assess organ donation and transplant processes, which often prevents the identification of possible flaws and implementation of process improvements. However, some of the presented indicators (Charts 1 and 2) have been used for years in Brazil. In the United States, organ procurement organizations (OPOs) monitor the steps of the organ and tissue donation processes and donor loss causes through performance indicators. ^{34,38,59-61}

PubMed had more publications (Charts 1 and 2) on indicators for organ donation and transplant services. When donations were considered separately, the papers on LILACS had more indicators described. Thus, it is possible to realize the effort being made in Brazil to develop and validate indicators for organ donation and transplant processes.

Most transplant indicators have been described in papers published on MedLine/PubMed, with 89% of them being proposed in papers written in the United States, reinforcing the efforts to develop and validate indicators to monitor not only the donation process, but also the quality of the transplants performed.

The scarce donor populations, the low rates of successfully processed potential donors, and the increasing number of patients entering transplant waiting lists every year call for decisive action by government and non-governmental organizations and health care workers in the search for new strategies and tools to enhance the management of the organ and tissue donation system. Each of the steps involved in this complex process has to be exhaustively and systematically assessed on an ongoing basis so that possible shortcomings are identified and proper corrective action is taken. ^{62,63}

Following this perspective (Chart 1), it was clear on PubMed that organ donation indicators were mostly geared towards potential donor profiles and their clinical statuses (length of hospitalization, intubation, and others). In addition to these factors, the papers on LILACS included social, demographic, cultural, religious, and patient family satisfaction levels with the process.

Government and non-governmental organization databases had indicators concerned with territorial factors and patient death. The issues faced by many countries in the donation process, particularly Brazil, include underreporting (varying depending on the region of the country considered), and loss of potential donors due to poor organ management or families refusing to authorize the donation. 1,21,64-67

Thus, it may be suggested that once the indicators (Charts 1 and 2) found in the reference databases included in this integrative review have been validated, they may help decision-makers monitor and assess organ donation processes.⁶⁸⁻⁷⁰

The use of these indicators would make it possible to identify which health care institution is underreporting potential donors and which has been more effective at generating potential donors. Additionally, the assessment of donor clinical conditions could lead to more effective donor management procedures and more viable organs for transplantation.

Transplant indicators found on PubMed (Chart 1) took into account organ variables such as time of ischemia, size, and organ characteristics. Factors connected to surgical procedures and complications were also identified by these indicators.

The indicators on LILACS revolved around waiting time management, survival, and complications related to the process.

In order to improve the donation and transplant process success rates, the authors of the studies included in this review recommended reporting as many potential donors as possible, identifying the reporting potential of health care units with significant numbers of cases of brain death, and perform proper potential donor management.⁷⁰⁻⁷³

By their turn, distribution systems have to be designed to take into account time, organ ischemia, and the satisfaction of the family as the donor is returned to them after the organ donation has been completed.

The main recommendations related to transplants were connected to assessing organ conditions, time of organ ischemia, factors related to the transplant recipient, graft survival, and recipient quality-of-life.^{3,24-33} Studies on transplant indicators considered the need to minimize time of organ ischemia and the importance of producing better graft survival. These indicators may lead to improvements on surgical procedures, but focused more specifically on conditions connected to organ status and organ management until the transplantation.

The need to increase the number of donors is a global issue.⁷⁴ One million people need transplants, and fewer than enough donors are available. Indicators are therefore needed to identify opportunities for improvement in the donation and transplant processes. Countries such as Spain, Portugal, Italy, the United States, to name a few, have significantly changed this scenario.^{36-38,41,42,58-62}

Waiting lists mirror the need for transplants, and donation statistics show the losses of potential donors and the transplant opportunities missed every year. Indicators need to be validated so that quality programs can be implemented in the Brazilian organ donation and transplant services.

Countries such as the United States already count on effective indicator-based performance monitoring programs. Interestingly, 67.0% of the papers on performance indicators found in this study were published in the USA. In the United States, the information collected by the Organ Procurement and Transplantation Network (OPTN) is turned into indicators that are followed and assessed to aid in the development of process improvement strategies. The OPTN is a public-private partnership whose primary goals are to increase the effectiveness of the organ procurement process, foster principles of equality in the national organ allocation system, and augment the supply or organs for transplantation. 36,38,59-62

Spain, also a leading country when it comes to organ donation services with a rate of 34 pmp, installed quality assurance programs

in all potential donor generating health care institutions, after carefully analyzing their performance through indicators. 57,74-77

Considering the significant number of indicators published in the literature, it was clear that organ donation and transplant process improvement initiatives have recently grown to offer methods, tools, and indicators to help government officials, non-governmental organizations, and society identify opportunities for improvement.

CLOSING REMARKS

This study listed the main indicators used globally in organ donation and transplant services published on MedLine/PubMed, LILACS, government and non-governmental databases.

As the papers were read, it became clear that most indicators had been published by authors in the USA (MedLine/PubMed), followed by their Brazilian counterparts publishing on LILACS. However, most papers published on either of the databases had level 4 evidence (descriptive or qualitative studies). Additionally, the authors did not mention whether the indicators had been properly validated. However, these indicators were developed to assess, measure, and manage data related to the donor's profile, clinical status, time of hospitalization, time of intubation, and other factors. Indicators were also used to assess organ characteristics, time of ischemia, organ size, surgical procedure, and transplant complications. Ultimately, these indicators were developed to improve donation and transplant processes.

It is thus recommended that other indicators be used in Brazil in addition to the ones in use today, so as to improve the organ donation and transplant processes currently in effect. However, given the level of evidence of the papers published in the literature and the fact that none of the indicators were validated, in order for those indicators to be used, they must be first validated.

The use of indicators in organ donation and transplant services is supported by the need to monitor and improve processes. Indicators can help identify issues directly impacting potential donor reporting and, considering the estimated rate of 70 pmp potential donors in Brazil and the

goal set by the Brazilian Association for Organ Transplantation of achieving a rate of 15 pmp in successful transplants by 2015, increase the number of transplants performed.

Thus, the following indicators were recommended for Brazil:

DONATION PROCESS

- Brain-dead donor potential per health care institution;
- Process distribution times;
- Donor clinical status;
- Time of ICU hospitalization;
- Patient family satisfaction;
- Perfusion time;
- Cost of transplantation;
- Individual surgical risk;
- Time on waiting list;
- Risk of graft failure;
- Organ characteristics;
- MELD score to assess severity of transplant patient.

The adoption of these indicators will certainly facilitate the monitoring of organ donation and transplant processes in Brazil, in addition to allowing each individual step to be further scrutinized. It will also improve the management of health care institutions with greater potential for donor generation and shed light on the factors impeding increases on the number of donors.

Transplant indicators will also reveal the reality faced by patients in the waiting list and help determine how severely ill they are and their surgical risk, thus helping health care teams assess the conditions of these patients and how likely they are to survive after transplantation.

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