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RISK ANALYSIS OF THE TRANSPLANTATION PROCESS IN BRAZIL

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Jéssica Silva de Almeida

Risk Analysis of the transplant process in Brazil

Thesis presented to COPPEAD Graduate School of Business of the Federal University of Rio de Janeiro in partial fulfillment of the requirements for the degree of Master in Business Management.

Advising Professor: Prof. Cláudia Affonso Silva Araújo, Ph.D.

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ABSTRACT

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Organ transplant has been for years one of the best treatment options for several medical conditions. All over the world, thousands of people are in need of an organ transplant. The process through which an organ goes from a brain-dead patient to a new recipient is a complex and delicate one.

This study provides a detailed examination of the process, starting by understanding the intricacies of the activities and the mapping of the existing risks. Once identified the weaknesses within the process, this study aims to analyze and classify them using a risk analysis methodology.

As a result, a list of the main activities that compose the transplant process was obtained, and it starts at the identification of a potential donor, ending at the transplant procedure itself. Based on that list, the risks associated with each activity were determined and classified using the failure mode and effect analysis (FMEA) methodology. The scores obtained from each risk were used to elaborate a ranking comparing the impact of one risk in relation with the others.

This approach offers several insights regarding improvement opportunities for the process. It highlights the most critical weaknesses and serves as a basis for future studies to delve deeper into each one of those risks.

Keywords: risk analysis, transplant process, transplant process risks

RESUMO

ALMEIDA, Jéssica Silva de. Risk Analysis of the transplant process in Brazil. Rio de Janeiro, 2018. Master Thesis in Management – COPPEAD Business School, Federal University of Rio de Janeiro, Rio de Janeiro, 2018.

Nos últimos anos, o transplante de órgãos tem sido a melhor opção de tratamento para diversos problemas médicos. No mundo inteiro existem milhares de pessoas que necessitam de um novo órgão. O processo pelo qual um órgão passa um paciente com morte cerebral para uma outra pessoa é extremamente complexo e delicado.

Esse estudo oferece um detalhamento do processo, começando por entender e definir as minúcias de suas atividades e seguindo com o mapeamento dos riscos inerentes a elas. Uma vez identificadas as fragilidades do processo, o estudo às analisa e classifica, utilizando uma metodologia de análise de risco.

Como resultado, obtemos uma lista das principais atividades que compõem o processo de transplante de órgãos, começando pela identificação de um doador em potencial e terminando com o procedimento de transplante em si. Baseado nessa lista, os riscos associados a cada atividade foram identificados e classificados utilizando a metodologia de *failure mode and effect analysis* (FMEA). A pontuação obtida para cada risco foi utilizada para elaborar um *ranking* comparando o impacto de cada risco em relação aos demais.

Essa classificação oferece diversos *insights* em relação às oportunidades de melhoria para o processo. Ela destaca os riscos mais críticos e serve como base para estudos futuros analisarem a fundo cada um desses riscos e suas causas.

Palavras-chave: análise de risco, processo de transplante de órgãos, riscos do processo de transplante de órgãos

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1 INTRODUCTION

1.1 Problem Description

Transplant has been the best option as treatment for some medical conditions for years. The process has improved drastically from a medical point of view, with new drugs and techniques development (Caballero, 2001; Smith-Brew & Yanai, 1996; Thomson & McKeown, 2012). However, despite all these advances, transplant candidates are still dying while on the waiting list. The path along the identification of a possible donor and having that organ successfully transplanted into a recipient is extremely complex; requiring careful coordination between different people and teams (Thomson & McKeown, 2012).

Not only is the process challenging, as it holds on top of that holds an unyielding time constraint for the entire operation. Even with technological improvements, the task of keeping the potential donor stable still poses several difficulties and, as time passes, the chances of a cardiac arrest or damage to organs increase. Besides that, once retrieved from the donor's body, the organs do not stay viable for a long period of time and the transplant needs to happen as soon as possible (Fuzzati, 2005).

The 2016 report from the Brazilian Association for Organ Transplantation (ABTO - Associação Brasileira de Transplante de Órgãos), shows the existence of a considerable gap between the number of transplants performed and the estimated need of the country's population. Figure 1 demonstrates such gap.

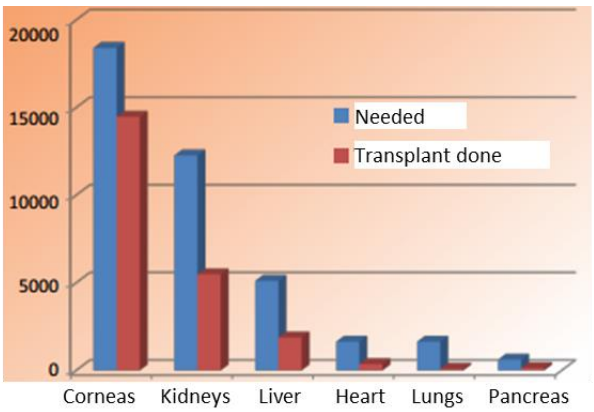


Figure 1: Estimated transplant need vs. transplants performed in Brazil
Source: ABTO Report (2016)

The report also shows that out of the 10,158 possible donor notifications (potential donors notified by the hospitals to the transplant center), only 5,939 were effectively carried out. These numbers illustrate the existing opportunity within the process in which the potential donated organs are not converted into successful transplants.

One of the causes pointed out in the report is the family refusal to donate – 2,571 cases fall under this category. Billeter et al. (2012) note that identification and recruitment of organ donors remains as one of the main problems in the organ transplant process. The authors highlight that less than one third of potential donors are identified, and a high percentage of those are not successfully recruited as donors. However, what the authors show in their study is that, while part of those refusals are related to family beliefs and conditions, some refusals are due to inappropriate protocol –, the families not being approached in a correct manner.

Besides the family refusal, there are inefficiencies within the process that lead to a sub-optimal result. Several authors point out different weaknesses throughout the process that may result in a viable donated organ failing to reach its intended destination within the appropriate time frame (Delmonico et al., 2011; Formanek & Schöffski, 2010; Mercado-Martínez, Díaz-Medina, & Hernández-Ibarra, 2013; Razdan, Degenholtz, Kahn, & Driessen, 2015; Rocon et al., 2013; Smith-Brew & Yanai, 1996).

Taking into account all those elements, it becomes possible to understand the importance of the transplant process, its complexity, and the number of people relying on its proper execution.

1.2 Objective

The objective of this study is to provide a deeper understanding in regard to the transplant process and its weaknesses in Brazil. More specifically, it seeks to map the risks involved in the process, the different events that may hinder the achievement of the desired outcomes, providing a better understanding of their impact and relevance.

Therefore, the primary objective and the main research question is:

- What are the main risks concerning the transplantation process in Brazil and what is their relative impact?

The secondary objectives aim to provide answers to the main question, as follows:

- Definition of the main activities involved in the organ transplant process and how they contribute to its success.
- Identification of how those activities are connected, and how they might fail. And how the process flows from start to finish.

1.3 Relevance of the Study

The relevance of this study is based on two different aspects, and the first, is the importance of the issue itself. While in a few cases medicine can provide alternative therapeutic options, for many people organ transplant is their only chance for quality of life, freedom from medical intervention, and long-term survival. Moreover, even though the organ transplantation process can be logistically, emotionally and ethically challenging, , it is life-changing and cost-effective, if analyzed from a socio-economic point of view (Thomson & McKeown, 2012). In addition, as the 2016 ABTO report shows, the process is not currently operating at its full potential. There is still a deficit when it comes to the number of organs available for transplant and the needed amount. At the same time, there are donation opportunities that are not successfully converted into transplants, and this is precisely the focus of this study, identifying and understanding them.

The second aspect regards this field of study, yet in development. A review of the literature shows a limited number of studies that provide an overview of the process (Caballero, 2001; Fuzzati, 2005; Miranda, Canon, & Cuende, 2001; O'Meeghan & Pedral, 2016; Pereira, Fernandes, & Soler, 2009; Peres Penteado et al., 2015; Smith-Brew & Yanai, 1996; Thomson & McKeown, 2012). Some works look into its weaknesses (Delmonico et al., 2011; Formanek & Schöffski, 2010; Mercado-Martínez, Díaz-Medina, & Hernández-Ibarra, 2013; Razdan, Degenholtz, Kahn, & Driessen, 2015; Rocon et al., 2013; Smith-Brew & Yanai, 1996). Nevertheless, there are still significant gaps and unmapped aspects, especially concerning risks and events that may lead to process failure, i.e., events that may result in the loss of a transplant opportunity. Therefore, this study has an exploratory objective: to contribute with a systemic overview in order to further the body of knowledge regarding the transplant process.

1.4 Research Delimitations

This study presents two main delimitations. The first one concerns the transplant process itself, and the second, regards the risk analysis methods considered as options to be applied to this case.

There are three main stages within the transplant process: the donation process, the transplant itself, and the follow up with the recipient. This study focuses on the two first stages, i.e., it doesn't cover the activities following the transplant surgery, and therefore, does not consider risks that appear at that stage, such as organ rejection. In addition, there are a few differences between distinct countries and regions when it concerns the transplant process and its management. This research is restricted to the Brazilian process and, more specifically, to the point of view of the ones responsible for the management – *Centrais de Notificação, Captação e Distribuição de Órgãos* (CNCDOs). For this reason, it does not get into details regarding hospital policies involved in the process.

Still regarding the transplant process, there are three different donor types: living, brain-dead, and non-heart-beating donors (Caballero, 2001; Miranda et al., 2001; Pereira et al., 2009; Thomson & McKeown, 2012). This investigation targets the second donor type –: the brain-dead.

Concerning risk analysis methods, the choice for the study was a qualitative approach due to data availability limitations. Locating reliable sources of detailed quantitative data about past failure transplant cases and those processes in Brazil wasn't possible.

Furthermore, the goal of this study is to map and classify the existing risks. It does not aim to analyze the possible causes behind each event: the focus is not investigating what causes the risks, but rather identifying their existence.

1.5 Structure of the Study

This study is organized in 6 chapters: Introduction, Literature Review, Research Method, Case Description, Case Data Analysis, and Conclusion.

The first chapter describes the study's main concern, defining the goals in a precise and clear manner. Besides that, it also delimits the research scope and the relevance of the findings to the society and the contribution to the academic literature on the subject.

In the literature review, the main subjects of the study and necessary supporting information for its development are presented. This section is structured in 3 main parts: the organ transplant process and related activities, the existing process' main risks, and the risk analysis models.

The Research Method Chapter reveals the thinking process behind the chosen method, starting with the research questions, and followed by the reasoning behind the adoption of a case study as the method to answer them. Afterwards, the employment of the method is detailed: data collection, data analysis, and the limitations of the chosen method.

Chapter 4 describes the selected case. It offers the necessary background for a better comprehension of the reality being studied, describing what the CNCDOs are and how they operate within the organ transplant management model in Brazil.

The following chapter analyzes the data obtained during the research. It displays the results found and examines these vis à vis the information gathered in the Literature Review.

The last chapter presents the conclusions for the study, highlighting the contributions, as well as opportunities and suggestions for future research.

2 LITERATURE REVIEW

The goal of this chapter is to provide a review of preexisting literature regarding the most relevant topics for the study. This section is structured in three parts: 1) the organ transplant process; 2) risk analysis structure; and 3) overview of the transplant process activities and the risks involved.

The first part introduces the organ transplant process and its key elements. It starts by introducing a macro view of the process and is followed by a more in-depth look into the main activities. In this part the expressions “organ donation process,” “organ procurement process,” and “organ transplantation process” are the key terms. The final part of the section shows what the literature has already mentioned in regard to process weaknesses and possible risks. In order to do so, the search included the expression “organ donation” combined with each one of the following terms: “critical pathways”, “difficulties”, “barriers” and “failure.”

The second part presents an overview on risk analysis, starting with a discussion on what is a risk and what it means to conduct a risk analysis. In the sequence, more details on risk analysis qualitative methods are presented, as the study approach is qualitative due to the lack of quantitative data available. For the first part, the key words used were “risk definition” and “risk analysis definition”. The goal of the second part was to focus on methods appropriate for the characteristics of the organ transplant process. First, there was an attempt to locate articles that have already approached the transplant process using the concept of risk analysis. This was performed using as key words a combination of the expressions “risk analysis” and “organ donation” or “organ procurement” or “organ transplant”. However, all articles located following those parameters focus on medical risks (diabetic patients, hypertensive recipient, etc.), and not on risks related to the process itself. Thus, in the subsequent attempt, the search was for “qualitative risk analysis” in order to find analyses of processes with similar characteristics. For the specific details on each method, the search was done using the name of the method plus the word “method” (e.g., “HAZOP method”).

The research comprised Capes, Science Direct, Risk Analysis journal, Emerald and EBSCO databases. In addition, secondary sources were used, and some articles were found in the reference lists of other articles.

2.1 The Transplant Process

In 1954 the first successful organ transplant was carried out. A group of Boston doctors effectively transferred a kidney from one twin to the other. For the past 63 years, the process has evolved in many ways. (Sayegh & Carpenter, 2004) New

immunosuppression technologies made it possible a reduction in genetic compatibility restrictions. Such improvements, along with new surgical techniques, have led to higher survival rates and larger donor pools (Linden, 2009; Sayegh & Carpenter, 2004). As medical advances bring more possibilities when it comes to transplantation (different organs, cadaveric donations, broader range of matches), the process grows in complexity, demanding procedures and standardization. Several countries have started to develop different organizational structures for managing the process (Schutt, 1998).

In Brazil, the process started in an unstructured manner. It was only in the 1980s that in Rio de Janeiro, São Paulo and Rio Grande do Sul the first organizations responsible for identifying donors and allocating available organs were created (Pereira et al., 2009).

The Brazilian Ministry of Health defines transplant as the surgical procedure involving the replacement of an organ or a tissue of a sick person (the receptor) for the one from a donor (dead or alive). The Ministry also determines that, according to the law, living donors can only be used in specific cases such as: donation of one kidney, part of the liver, part of the lungs, and part of the bone marrow. The organs and tissues that can be obtained from dead donors are: kidneys, heart, lungs, pancreas, liver, intestines, corneas, valves, bones, muscles, tendons, skin, veins, and arteries. They have also defined potential dead donors as ICU patients declared brain-dead, meaning people that have death in the cells of the central nervous system, determining the interruption of blood flow to the brain in a way that is incompatible with life definitively and irreversibly (Brazilian Ministry of Health, 2008).

The entire process – from the identification of a potential donor until the organ is successfully transplanted to the recipient – is highly complex and requires the coordination of different teams and individuals (Thomson & McKeown, 2012). Some studies examined in the literature review specify and organize the activities that occur during this process. Despite having different focus and level of detail, the studies are complementary.

2.1.1 The Organ Transplant Organization Models

Before moving into the process description, it is important to notice that differences between countries' regulations and organization structures create some distinctions in some steps of the process. In the United States (US), there are more than 60 Organ Procurement Organizations (OPO), which are composed mostly of non-medical professionals (only 20% of them are based in a hospital). They each act in their respective region and collaborate with local transplant units and the United Network for Organ Sharing (UNOS). The OPOs are non-profit organizations and have their targets set by the government regarding the number of donors. In order to achieve their goals, they organize the marketing and education aspects (to attract more donors), and track the medical death records to maximize identification of donation opportunities. They also audit death cases with missed opportunities, aiming to determine the reasons. (Schutt, 1998)

In the European region, there are non-profit organizations as well; responsible for the procurement process. However, in Europe, those organizations are closely connected to hospitals. Countries have different legislations that regulate presumed consent. In some countries, the population in general is assumed to be organ donors and, if people do not want to donate, they must notify the government. In other countries it is the reverse, people must notify if they want to be donors. In the US, they adopt the latter (Schutt, 1998).

The Spanish model differs from what is generally seen in Europe. The National Organ Transplantation Organization (ONT), created in 1989, is responsible for promoting organ donation and regulating the process. They are responsible for organ retrieval and for managing the waiting list. Each hospital has one transplant coordinator, a staff member of the ICU. This person is trained by and keeps direct contact with ONT. The coordinator is responsible for detecting potential donors and for approaching their families. This model has shown donation rates considerably above the average (Schutt, 1998).

In Brazil, there is the National Transplant System (SNT), a national organization. In addition, each district has an Organ Notification, Capitation and Distribution Center (CNCDO), that works with a similar role to the OPOs. The Intra-Hospital Committee of Organ and Tissue Donation for Transplant (CIHDOTT) was created in 2001, following the Spanish model. In 1968 there was an attempt of adopting the presumed consent model as used in some European countries. However, due to the population rejection, Brazil continues to utilize the model where people are required to give consent for donation (the

deceased's family is responsible for the decision in cases of cadaveric transplant) (Pereira et al., 2009).

2.1.2 Description of the Organ Transplant Process

Looking at the overall process, Fuzzati (2005) organizes the process from a macro standpoint, dividing it in a procurement phase and a surgery phase. The medical area regards the procurement phase, the logistical and processual activities, and the surgery phase, including not only the surgery itself, but medication and post op care as well.

The author's main focus is the first phase, with special attention to data handling and systemic activities taking place in the procurement phase, not getting, therefore, into details on each step of the process. The activities mentioned are: the matching between donor and recipient, medical team scheduling, and transport routes planning.

According to his work, the matching happens when donors are identified, all their relevant information are forwarded to the responsible institution, where medical experts analyze and select the best matches among recipient candidates. After recipients are chosen, the best routing needs to be determined and a medical team must be notified and organized for the extraction surgery.

While Fuzzati (2005) process description keeps the focus on the perspective of a transplant coordination institution (such as an OPO); O'Meeghan & Pedral (2016) focus on detailed mapping from the hospital staff point of view, using a 5WH approach (who, what, when, where, why, and how). Their study takes place in the US, and for this reason a significant part of the process is specific to the relationship between the hospital and the OPO, and the bureaucratic process between both.

According to the authors, the process begins after the patient is declared brain-dead, when the physician should notify the OPO, who is responsible for determining if the patient is a candidate for organ donation (registered donor or requiring family consent). Then the process is detailed on the specific step-by-step of calling Pharmacy, changing file labels, etc., ending with the organ removal (see Appendix 2 - Workflow for organ donation US hospitals).

Pereira, Fernandes & Soler (2009) and Miranda, Canon & Cuende (2001) describe the entire process in detail, combining different points of view. According to both studies, the process starts at the detection of a potential donor, followed by the donor evaluation, and the obtention of the family consent. They also consider the legal aspects related to the process, and add the following activities: legal brain death confirmation and legal consent. Once the donation process is in motion, the subsequent activity is maintaining the donor (making sure the body remains in good conditions), and matching the organs and tissues with recipients. Once matched, the organs are harvested and properly conditioned for transport. Pereira, Fernandes & Soler (2009) in their outline of the process, also mention the distribution of the organs after the retrieval – proper storage, transplantation and follow up – even though the authors do not get into details regarding the latter activities. Figures 2 and 3 illustrate the process according to the above authors.

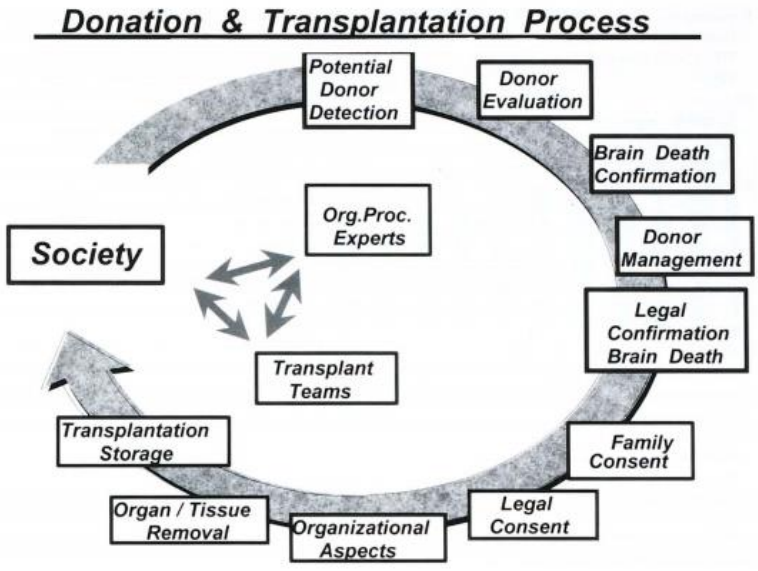


Figure 2: Donation and transplantation process 1
Source: Miranda, Canon & Cuende (2001)

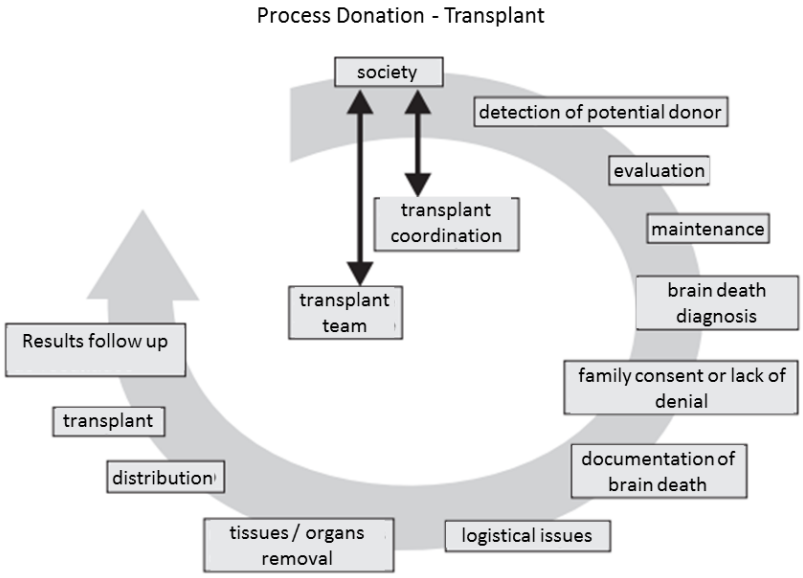


Figure 3: Donation and transplantation process 2
Source: Pereira, Fernandes & Soler (2009)

Peres Penteado et al. (2015) describe a similar process, though in less detail. They consider, however, the recipient perspective as well. Therefore, their process map starts when a new potential recipient enters the waiting list for and organs or tissue. The authors continue the process after the transportation and the transplantation, including, the follow up and notification.

2.1.3 Key Activities of the Organ Transplant Process

The following segment details each one of the previously mentioned main activities regarding the organ transplant process, explaining how they are executed and the secondary issues related to them.

2.1.3.1 Detection of Potential Donors and Brain Death Confirmation

Several authors start the description of the process with this activity (Caballero, 2001; Fuzzati, 2005; Miranda et al., 2001; O'Meeghan & Pedral, 2016; Pereira et al., 2009). There are three different types of potential donors: living donors, non-heart-

beating donor and brain-dead donors (Caballero, 2001; Miranda et al., 2001; Pereira et al., 2009; Thomson & McKeown, 2012).

Living donation is a voluntary procedure where an individual opts to donate an organ or tissue. As previously mentioned, in Brazil, living-donors can only donate a kidney, part of the liver, part of the lungs, and bone marrow (Brazilian Ministry of Health, 2008).

Non-heart-beating donors are those whose heart is no longer beating. This kind of donation, while still valid for some types of organs and tissues, present some risks as the organs may be exposed to periods of hypotension and hypoxemia. Regarding these donors it is relevant to consider how death occurred – in a controlled manner, within hospital facilities, or in an uncontrolled way (dead on arrival, unsuccessful resuscitation, and unexpected cardiac arrest). In the case of controlled cardiac death, it involves the decision that further treatment is futile and the family is contacted for authorization. The body should have proper management and medication while the heart stops beating. The acceptance of organs from uncontrolled death depends on the country's legislation. In Spain, for example, there are systems in place to allow for uncontrolled cardiac death donations (Thomson & McKeown, 2012).

Brain-dead donors are those who have a complete and irreversible interruption of activity in the brain stem and hemispheres, where cardiovascular and respiratory activities are sustained through machines and medication (Pereira et al., 2009). In Brazil the resolution n^{o} 1.480/97 of the Medical Association regulates the criteria for determining brain death. It specifies that the clinical tests need to be performed twice, in specific intervals, according to the patient's age. It also determines the parameters that need to be observed and the tests that need to be conducted for each age group.

For donors between 7 days and 2 months of life, it is necessary two encephalograms, 48 hours apart. Between 2 months and 1 year, the same test is necessary, but 24 hours apart. For the other age groups, any test can be performed as long as it is able to detect either lack of cerebral electric activity, lack of cerebral metabolic activity or lack of cerebral blood flow. For donors between 1 and 2 years old, the tests need to occur 12 hours apart, and above 2 years, 6 hours apart (Brazilian Medical Association, 1997).

In both cases of non-living donors, time is crucial and early detection of a potential donor is paramount. It is important to monitor patients with severe brain injuries that could evolve to brain death. Early identification of potential donors multiplies by five the opportunity to procure organs in an adequate manner (Caballero, 2001). In the moments following the brain stem death there is a high probability of hypertension and bradycardia, the Cushing reflex, what needs to be managed properly considering the possibility of organ donation (Thomson & McKeown, 2012).

Another important step within this activity is the notification of the transplant coordination center (OPO in the USA, CNCDO in Brazil, etc.) (O'Meeghan & Pedral, 2016).

2.1.3.2 Evaluation of Potential Donors

After a potential donor has been identified it is important to conduct a thorough clinical and laboratorial evaluation to eliminate the possibility of any conditions (viruses, cancer, etc.) that might bring risk to the recipient. The acceptance criteria has been recently expanded and there are few conditions that completely rule out the possibility of organ donation (Pereira et al., 2009).

The conditions vary by country, and in Brazil, the contraindications for donation are:

- Malignant tumors (except for skin cell carcinoma, uterus carcinoma, and some central nervous system tumors)
- Positive test for HIV, HTLV I or II
- Uncontrolled sepsis
- Active TB

The transplant team should evaluate borderline conditions i.e., those presenting some risk to the recipient, but not part of contraindications list) (Pereira et al., 2009).

2.1.3.3 Physiological Maintenance of Donors

During the entire process, physiological maintenance of the donor is essential. . It is important not only to avoid losses due to asystole, but also to ensure that the organs do not suffer any functional and structural alterations that may cause the organ to be rejected or cause complications for the recipient (Caballero, 2001).

In the case of the brain-dead donors, they present characteristics inherent to their state: hypothermia, hypotension, diabetes insipidus, hydroelectrolytic imbalance, disorders of ventilation, coagulopathy, and anemia (Caballero, 2001).

Since brain death causes impairment in self-regulation and self-modulation, donors need to be kept in Intensive Care Unit (ICU). ICU physicians and nurses can adopt proper therapies to treat loss of vegetative functions, prevent spinal shock, avoid cardiac arrest, and resume systemic homeostasis (Venettoni et al., 2004).

2.1.3.4 Family Consent

After the potential donor has been evaluated and approved, it is necessary to address the family and ask for consent regarding the donation, while the body is kept stable by the ICU staff. This stage is one that shows greater differences according to the country (Thomson & McKeown, 2012). As previously mentioned, countries may be organized in two major groups:

- Informed consent: where all individuals are presumed non-donors, unless they made their wish clear before death by registering with a national organ registry organization and/or informing family members, or if consent is obtained from a relative after death. This model is employed by several countries, such as the UK, New Zealand, and Australia. Brazil also adopts this model.
- Presumed consent: where all individuals are presumed organs and tissue donors, unless they have specifically stated prior to death their wish not to do so. Most European countries use this approach. Some countries like Spain, for example, adopt a less strict approach where relatives can refuse to donate in behalf of the deceased. Others adopt a stricter approach, such as Austria, where the relatives cannot refuse donation if the individual has not registered prior to death (Thomson & McKeown, 2012).

Talking to the family is an extremely delicate process, and it should start even before brain or cardiac death. As mentioned earlier, the ideal is that potential donors are identified as soon as possible so they can be properly managed while they undergo brain stem death or go through a controlled cardiac death. Ideally, while management occurs, the family communication process should take place simultaneously. Families should be informed regarding the high probability of death, before it occurs, and they need to receive adequate information about patients' condition. It is important that they are notified promptly that tests to determine brain death are being performed and become aware of the results as soon as they are available. Only when brain death is confirmed, the family should be inquired about the possibility of organ donation (Caballero, 2001).

Because of the delicate and emotional nature of the situation, the way families are approached make a difference on the likelihood of organ donation acceptance or refusal. It is important to consider that not everyone adopts the same definition of death and that the concept of brain death is not one easily understandable. Doctors and nurses consider those differences when talking to the relatives. It is also important to notice that the family may allow the donation of specific organs, instead of all of them, if they prefer to do so (Smith-Brew & Yanai, 1996).

2.1.3.5 Organizational Activities

Once the donation is authorized, Pereira, Fernandes & Soler (2009) and Miranda, Canon & Cuende (2001) mention that the next activity to take place is the logistical/organizational one. In their description of this stage, they both address the matching process. Fuzzati (2005), however, goes into more detail, mentioning not only the matching, but also medical team scheduling and transport route planning.

Matching organs in a highly complex process and follows a series of biological criteria – blood group, tissue characteristics, etc. The donor organs are then assigned to a recipient on the waiting list (Fuzzati, 2005). Due to the importance of transparency and fairness in the process, matching is an activity that is highly regulated. In Brazil the regulation nº 2.268/97 controls the entire transplant process and is quite specific when it comes to allocation rules (Pereira et al., 2009).

The Brazilian regulation stablishes the SNT as the national official organ control center and it holds the responsibility of managing the country's waiting list. The center also keeps all information relevant for organ or tissue matching and logistical routing. In addition, it stablishes the regional organizations (CNCDOs) as the ones responsible for promoting recipients' enrolling in a regional list, while registering all relevant biological and logistical information, as well as the date of their registration. CNCDOs should compile and send all that information to the SNT. When a donor is found, CNCDOs are responsible for the organ matching and transportation to the recipient, according to the regional waiting list. Organs not matching the regional list are notified to the SNT so they can look for a match in the national list. The matching should follow the registration chronological order, taking into consideration biological restrictions. The exceptions to that are logistical restrictions, when distance and transportation issues exist, and the time to reach a certain receptor is higher than the time the organ can survive or the receptor is in critical condition, near death (Brazil Legislation, 1997).

The survival time varies according to the organ, but under the proper storage conditions, these are the average limits, as shown is Table 1:

Organ	Time limit
Heart	4 hours
Lung	4 to 6 hours
Liver	12 hours
Pancreas	20 hours
Intestine	6 to 8 hours
Kidneys	24 hours (E. Collins solution) and 36 hours (UW solution)
Vascular	10 days (UW solution)

Table 1: Time limit of organ survival
Source: Pereira, Fernandes & Soler (2009)

2.1.3.6 Organ Retrieval

Once donation consent is obtained, as many organs as possible are matched and/or authorized, a surgical team is located and mobilized, and a transportation plan is stablished, the surgery for organs retrieval begins. There is usually more than one surgical

team and, if any surgical team is delayed, the surgery may begin with those that have arrived, especially in cases when the donor is in unstable conditions (Pereira et al., 2009).

The surgery begins with the donor's complete anesthesia, and each team retrieves the organs, following each organ survival time limit. Surgery begins by opening the thoracic cavity by heart and lungs teams who inspect these organs. After that, liver, pancreas, intestine and kidney teams open the abdominal wall and inspect the organs. Liver and pancreas teams start the dissection while repairing torn veins and arteries. Heart and lungs teams start dissecting these organs, while liver and pancreas teams finish their part of dissection. In sequence, the remaining intra-abdominal organs are retrieved, and the kidney is the last one. The procedure may change if some of the organs are not being retrieved (Pereira et al., 2009).

2.1.3.7 Organ Transportation

Once the organs have been removed, they need to be properly stored and transported to the recipient, in order to proceed with the transplant. This stage is the responsibility of regional CNCDOs. In 2016 the 2.268/97 regulation was amended so that the SNT can require transportation aid to the Brazilian Air Force when CNCDOs indicate the need. The Air Force is required to keep at least one aircraft available at all times for organ transportation purposes or for transporting the recipient patient. More aircrafts can be solicited, though this depends on the Air Force availability (Brazil Legislation, 1997).

2.1.3.7 Organ Transplantation

Once the organ has arrived at the hospital where the recipient is, the next step is the transplantation surgery. According to the Brazilian law, the transplant can only be performed with recipients' consent, after they have been briefed about possible procedure risks and probable outcomes. These steps must be documented (Brazil Legislation, 1997).

2.1.4 Process Weaknesses

Several articles point out possible areas of weakness and some risks involved in the process (Delmonico et al., 2011; Formanek & Schöffski, 2010; Mercado-Martínez, Díaz-Medina, & Hernández-Ibarra, 2013; Razdan, Degenholtz, Kahn, & Driessen, 2015; Rocon et al., 2013; Smith-Brew & Yanai, 1996).

Mercado-Martínez, Díaz-Medina, & Hernández-Ibarra (2013) and Smith-Brew & Yanai (1996) adopt a macro point of view focusing on what they perceive to be wrong with the transplant process in general. The authors do not focus on specific activities and what might go wrong. Their studies cover healthcare practitioners attitude towards organ donation and the organization model, as well as the importante of proper coordination of the entire process.

Nevertheless, a few specific weaknesses are mentioned in their articles. Mercado-Martínez, Díaz-Medina, & Hernández-Ibarra (2013) analize the discourse of transplant coordinators, their critiques to the organizational structure, and media coverage, among others, some stories regarding the process emerge. The first one is about situations where a potential donor is identified but the hospital, for a number of reasons, does not notify the transplant coordination center. The second one presents the case of the absence of a neurologist willing to diagnose brain death in time.

Smith-Brew & Yanai (1996) focus on the family interview activity and the importance of a proper way of conducting such interview. According to the authors, 80% of the families are inclined to consent to organ donation, although the delicate nature of the subject and the inadequate approach may lower that number. Organ donation inquiries need to be conducted in a proper manner, but death notification should be also be humane and clear, as they affect the family member's willingness to consent.

Rocon et al. (2013) and Formanek & Schöffski (2010), on the other hand, conduct case studies. They both cover five hospitals: the first one in Brazil, and the second, in Germany. Their studies focus on identifying reasons to understand why having potential donors did not lead to transplants.

Rocon et al. (2013) adopt a quantitative approach mapping all brain deaths during a time period and analyze what happened in each case, drawing statistics from the

information. The following table summarizes their findings. There are a few reasons that reveal weaknesses in the process, such as a cardiac arrest during maintenance, lack of equipment to conduct brain death diagnosis, and unavailability of a retrieval team.

Protocol Result	Patients n (%)	Causes of Nonconfirmation of Brain Death			
		Grouped		Detailed	n
Nonconfirmed brain death	8 (20.52)	MC	10.26	Protocol interrupted by infectious disease	3
		LEP	10.26	Cardiac arrest before finalization of the protocol	1
				Protocol interrupted by lack of transport or equipment available to perform the complementary examination	3
				Other logistical and structural problems	1
Confirmed brain death	31 (79.48)	LEP	7.69	Team capture unavailable	2
				Family did not locate the patient documents	1
		MC	10.26	Cardiac arrest after complementary examination	1
				MC (1 infectious disease, 1 cancer, 1 HIV positive)	3
		FR	33.33	Family refusal	13
		EF	28.20	Effective donation	11
Total	39 (100.00)		100.00		39

Abbreviations: MC, medical contraindications; LEP, logistical and structural problems; FR, family refusal; EF, effective donation.

Table 2: Distribution of organ donation and non-donation with reasons for failure
Source: Rocon at al. (2013)

Formanek & Schöffski (2010) adopted a different approach conducting a survey with healthcare professionals, asking them to report difficulties in the transplant process. They organize the difficulties by the activity. In regard to potential donors' identification, the authors mention two possible reasons for failure. One was already mentioned: failure to notify about the potential donors, which the authors relate to a lack of commitment to the organ donation cause. The failure to identify a potential donor is according to the authors a consequence of insufficient qualification and training of hospital personnel.

Lack of neurologists to conduct brain death diagnosis is also reported by Formanek & Schöffski (2010).. Regarding comunication with relatives, the authors' findings are aligned with Smith-Brew & Yanai (1996), though Formanek & Schöffski (2010) focusspecifically on the donation consent interview and highlight the importance of proper training.

Delmonico et al. (2011) and Razdan, Degenholtz, Kahn, & Driessen (2015) focus on the transplant process itself. Delmonico et al. (2011) focus on the reasons why a potential donor is not used, organizing those reasons in three groups: system, donor/organ and permission. In the system group, the authors include both the failure to identify a potential donor and the failure to notify the transplant center. They also mention the lack of resources and specialists to confirm brain death, and the lack of appropriate recipients

(blood type, positive serology, child, etc.). “Logistical problems” are also raised, yet on that category, the authors only bring retrieval team unavailability as an example, not getting into details about different kinds of logistical problems.

Razdan, Degenholtz, Kahn, & Driessen (2015) conducted an analysis of OPO data in the USA in order to map possible causes for the process to breakdown. They subsequently associate those causes with gender and age. Some comments are very specific to the rules of the North-American process, e.g., the person inquiring about the donation not being a trained requester. One aspect, however, applies to the process in general: failure to notify the OPO about potential donors.

Table 3 summarizes the failures reported in the studied literature:

Weakness Reported	Authors
Failure to identify potential donors	Formanek & Schöffski (2010); Delmonico et al. (2011)
Failure to notify Transplant Coordinators about potential donors	Martínez, Díaz-Medina, & Hernández-Ibarra (2013); Formanek & Schöffski (2010); Delmonico et al. (2011); Razdan, Degenholtz, Kahn, & Driessen (2015)
Lack of available neurologists to diagnose brain death	Martínez, Díaz-Medina, & Hernández-Ibarra (2013); Formanek & Schöffski (2010); Delmonico et al. (2011)
Lack of available equipment to diagnose brain death	Rocon et al. (2013); Delmonico et al. (2011)
Failure in the proper family notification about brain death	Smith-Brew & Yanai (1996)
Failure in the proper family inquiry about organ donation	Smith-Brew & Yanai (1996); Formanek & Schöffski (2010)
Cardiac arrest during physiological maintenance	Rocon et al. (2013)
Failure to find appropriate recipients (blood type, positive serology, child, etc.)	Delmonico et al. (2011)
Unavailability of retrieval team	Rocon et al. (2013); Delmonico et al. (2011)

Table 3: Summary of weaknesses mentioned in the literature and respective authors
Source: O'Meeghan & Pedral

2.2 Risk Analysis

2.2.1 Risk Analysis Definition

The concepts of risk and risk analysis have been around for centuries (Covello & Mumpower, 1985; Thompson, Deisler, & Schwing, 2005). However, modern risk analysis was stablished as a research field only in the 1970s and it has connections with a myriad of disciplines, such as toxicology, epidemiology, etc. (Hansson & Aven, 2014).

For a better understanding of risk analysis, this study starts by exploring the concept of risk. The ISO 3100 regulation defines risk as the effect of uncertainty in objectives, clarifying that the term is neutral and might refer to either a positive or a negative consequence, and that it is often expressed as a combination of the consequences of an event and the likelihood of it happening. The same regulation explains risk analysis as the process of understanding the nature of risk and determining the level of risk.

Currently, however, there is no consensus on a formal definition neither for the term risk nor for risk analysis. In addition, it is possible to find several different definitions for both terms (Aven, 2012).

Hansson & Aven (2014) define risk analysis in more detail and divide it into two major groups of risk studies. The first one refers to the awareness of risk-related events, for example studying the consequences of an oil spill in a certain region. This group of studies mixes specific discipline insights and analytical analysis, most usually statistical. The second group, concerns concepts, methods, and models, devised to understand, assess, and manage risk.

2.2.2 Risk Analysis Techniques

There are several different risk assessment techniques available in the literature and they can vary from purely qualitative to quantitative, or they can be something in between (Altenback, 1995).

Traditionally, the quantitative approach works with accident scenarios and the probabilities of each scenario are ranked according to the expected frequency of occurrence. However, it is important to notice that even the qualitative analysis deals with concepts of probability, even if not in a quantified way (Apostolakis, 2004).

Most qualitative approaches make use of quantitative scales. Traditionally, there are no rigid requirements about how these scales are chosen and, ideally, they can be adapted to the available data and the specific characteristics of the process being analyzed (Altenback, 1995).

As previously mentioned, this study focuses solely on qualitative approaches. A purely qualitative risk analysis is based on tasks and/or hazards and uses relative judgment in order to categorize the risks, usually using simple relative scales, such as Low-Medium-High. Task-based analysis focuses on each activity in a process while hazard analysis identifies potential hazards and their possible consequences (Altenback, 1995).

We can find different methods in the literature which still follow the same basic ideas of qualitatively assessing probability of occurrence and severity of the consequence. Among the most commonly used, we find the following: failure mode and effect analysis/failure mode and critical effect analysis (FMEA/FMECA); fault tree analysis (FTA); hazard and operability analysis (HAZOP) (Lopez et al., 2010); and the qualitative risk matrix.. (Altenback, 1995).

2.2.2.1 Qualitative Risk Matrix

One of the traditional methods is the qualitative risk matrix. It uses a 3 by 3 matrix where the risks are classified in comparison with the estimated likelihood of that event occurring and the severity of the consequences in case it does occur. As shown in the example in Figure 4:

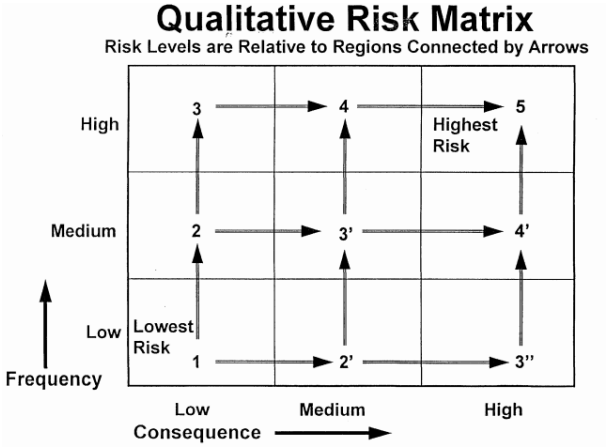


Figure 4: Example of qualitative risk matrix
Source: Altenback (1995)

The risk of a certain task or hazard is evaluated by the combination of their frequency and consequence, being the lowest risk tasks the ones in the low-low quadrant and the highest risk, those in the high-high quadrant. The quadrants in between are harder to evaluate and can be comparable in some cases. Altenback (1995) attributes them the same number in the above matrix. There are different ways to group the quadrants. For example, the USA Environmental Protection Agency (EPA) uses the following one:

Matrix Region	EPA Risk Grade	Figure 3 Risk Grade
High*High	Major Concern	5
High*Medium	Major Concern	4
Medium*High	Major Concern	4'
Medium*Medium	Concern	3'
Low*High	Concern	3''
High*Low	No Concern	3
Medium*Low	No Concern	2
Low*Medium	No Concern	2'
Low*Low	No Concern	1

Table 4: EPA risk grouping
Source: Altenback (1995)

However, Altenback (1995) points out that all of these groupings are subjective and that, even though we naturally want to organize the quadrants in groups, there is no logical foundation that indicates that every activity in a major concern area poses a greater risk than the others in the concern group (Altenback, 1995).

2.2.2.2 FMEA Method

The FMEA method is an inductive method that focuses on unwanted events that may generate a failure as an indirect way of classifying the risk of such failure , adopting a bottom-up approach that starts with the unwanted event and considers its consequences (Angel et al., 2015). It focuses on investigating how a product, process, or system might fail and, for each mode of identified failures, what the consequences are. For example, a process could fail due to employee error, equipment breakdown, faulty design, etc. The FMEA can be used to help assess possible ways in which unwanted events may occur and the impact of their consequences; uncover possible causes of failure; and understand what can be done to make a process less likely to fail.

In situations where there is historical data that registers modes of failure and their consequences, this method can also be used quantitatively. However, in many cases, this data is not available, and the method accommodates to that by using a scale of 1 to 10. The first criterion used to evaluate the risk determines the impact of the failure (where 10 is catastrophic); the second evaluates the likelihood of the event(s) that causes the said failure (where 10 is highly likely); and the third estimates the unlikelihood of detecting events that would cause a failure in time to prevent the failure from happening (where 10 is highly unlikely, meaning it is almost impossible to identify that such an event has occurred and correct it before it causes a system failure) (Snee, 2016).

These numbers are then multiplied to generate a risk priority number (RPN):

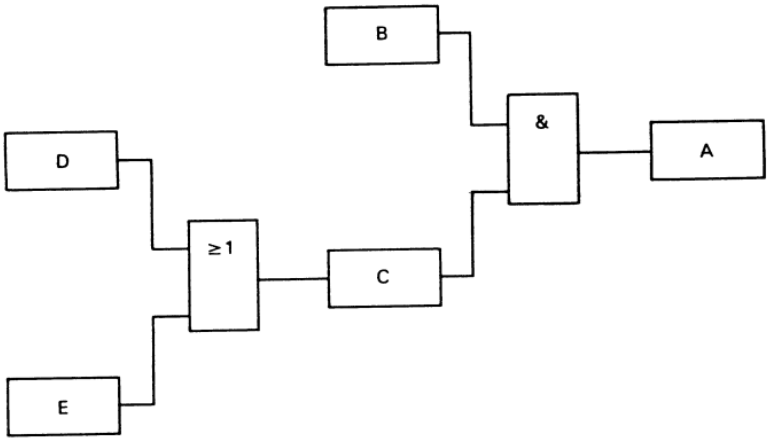
$$RPN = Severity\ (S)\ x\ Ocurrence\ (O)\ x\ Detection\ (D)$$

Source: Snee, 2016

The RPN can fall anywhere between 1 and 1,000. The higher the RPN, the more concerned the people responsible for the process should be about that particular event. They should also prioritize events with higher RPM when developing palliative and prevention measures. Once those measures are in place, it is advisable that the FMEA analysis is redone in order to assess its effectiveness (Snee, 2016).

2.2.2.3 FTA Method

Differently from the FMEA, the FTA adopts a top-down approach, starting with the failure and trying to map all possible causes for the said failure, using a deductive approach (Angel et al., 2015). This method is concerned with identifying and analyzing all events that cause or contribute to a failure. The fault tree is a graphical representation of the events leading to the failure point, referred to as the "top event." The process happens in a top-down manner and is usually qualitative in nature. The fault tree starts with the definition of the top event and, after that, it is drilled down to the definition of the causes and conditions that will lead to the occurrence of the top event. Then, those causes and conditions are drilled down in order to find their own causes and conditions (British Standard, 1991).



NOTE For each event, A, B, etc., information to be included in the event description box includes

— event code;
— probability of occurrence (if required);
— name or description of event.

Figure 1 — Example of a fault tree

Figure 5: Example of Fault tree
Source: British Standard (1991)

Different analyses can be done afterwards, both logical and numerical. Some of them rely on identifying common events (i.e., events that happen more than once in the tree and impact on several branches) and identifying independent branches. (British Standard, 1991)

2.2.2.4 HAZOP Method

While the FMEA is an inductive method and the FTA a deductive one, the HAZOP method falls somewhere in between. The method focuses on identifying deviations: it analyses system nodes (in a production unit, these are the smaller systems that compose the overall system, e.g., a gas filtration system within a bioreactor). The method qualitatively defines in what way deviations can occur in that node (the way in which parameters such as temperature, pressure etc. may oscillate). Afterwards, the method hypothesizes ways to mitigate or eliminate the effects of these variations. The HAZOP methodology focuses primarily on parameters' deviations, not only identifying them, but also their effects (Angel et al., 2015). Figure 6 shows the summary of this process:

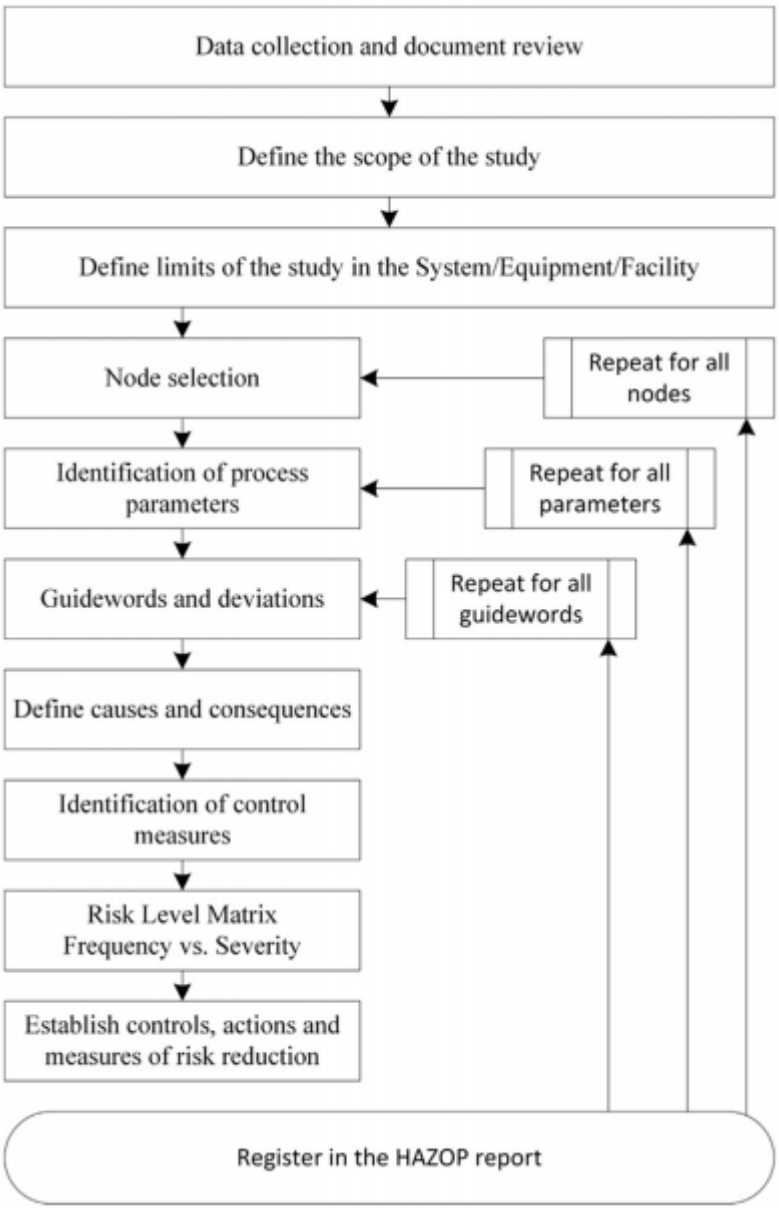


Figure 6: Application procedure of the HAZOP method
Source: Angel et al. (2015)

2.3 The Transplant Process and Main Weaknesses Overview

Table 5 shows a summary of the risks raised in the literature and their respective donors. It also contains the main activities involved in the transplant process, a brief description of each activity, and the authors who have discussed them.

Activity	Description	Authors that mention the activity	Risks Reported	Authors that mention the risk
Detection of potential donors	- Identify possible brain death - Monitor potential donors	Caballero (2001); Fuzzati (2005); Miranda, Canon, & Cuende (2001); O'Meeghan & Pedral (2016); Pereira et al. (2009); Peres Penteado et al. (2015)	Failure to identify potential donors	Formanek & Schöffski (2010); Delmonico et al. (2011)
			Failure to notify Transplant Coordinator about a potential donor	Martínez, Díaz-Medina, & Hernández-Ibarra (2013); Formanek & Schöffski (2010); Delmonico et al. (2011); Razdan, Degenholtz, Kahn, & Driessen (2015)
Brain death confirmation	- Conduct brain death confirmation tests	Caballero (2001); Miranda, Canon, & Cuende, (2001); Pereira et al. (2009); Peres Penteado et al. (2015); Smith-Brew & Yanai (1996)	Lack of available neurologist to diagnose brain death	Martínez, Díaz-Medina, & Hernández-Ibarra (2013); Formanek & Schöffski (2010); Delmonico et al. (2011)
			Lack of available equipment to diagnose brain death	Rocon et al. (2013); Delmonico et al. (2011)
Evaluation of potential donors	- Look for the presence of conditions that would make donors unsuitable	Caballero (2001); Miranda, Canon, & Cuende (2001); O'Meeghan & Pedral (2016); Pereira et al. (2009); Smith-Brew & Yanai (1996); Thomson & McKeown; (2012)		
Death notification	- Inform family of donor's death	Caballero (2001); Smith-Brew & Yanai (1996)	Failure in the proper family notification about brain death	Smith-Brew & Yanai (1996)
Family interview for consent	- Inquire family about the possibility of donation	Caballero (2001); Miranda, Canon, & Cuende (2001); Pereira et al. (2009); Smith-Brew &	Failure in the proper family inquiry about organ donation	Smith-Brew & Yanai (1996); Formanek & Schöffski (2010)

	- Determine what organs will be donated	Yanai (1996); Thomson & McKeown; (2012)		
Physiological maintenance of potential donors	- Maintain donors stable	Caballero (2001); Miranda, Canon, & Cuende, (2001); Pereira et al. (2009); Peres Penteado et al. (2015); Thomson & McKeown; (2012); Venettoni et al. (2004)	Cardiac arrest during physiological maintenance	Rocon et al. (2013)
Organ matching	- Allocate organs available for donation to recipients	Fuzzati (2005); Miranda, Canon, & Cuende, (2001); Pereira et al. (2009); Peres Penteado et al. (2015);	Failure to find appropriate recipients (blood type, positive serology, child, etc.)	Delmonico et al. (2011)
Mobilization of surgical team	- Mobilize surgical teams	Fuzzati (2005); Miranda, Canon, & Cuende, (2001); Pereira et al. (2009)	Unavailability of retrieval team	Rocon et al. (2013); Delmonico et al. (2011)
Organ retrieval	- Retrieve organs following proper procedure protocols	Miranda, Canon, & Cuende, (2001); Pereira et al. (2009); Peres Penteado et al. (2015)		
Organ transport	- Transport organs to hospitals where recipients are	Fuzzati (2005); Pereira et al. (2009); Peres Penteado et al. (2015)		
Organ transplantation	- Organ is transplanted into recipients	Peres Penteado et al. (2015)		

Table 5: Summary of transplant process' activities and risks

Analyzing the table, it is possible to observe that the literature focuses on risks up to the moment when organs are retrieved. However, there is no mention to the retrieval procedure and the activities leading to the transplantation. It is also noticeable that more authors (an average of 5 authors) focus on describing the beginning of the process, i.e., the donation, than on the end of the process, that is to say, the transplantation (an average of 3 authors).

3 RESEARCH METHOD

This chapter aims at presenting the methodology used in this research. Moreover, it will detail the steps taken during its conduction. It starts by showing the research questions, followed by an explanation about the choice of method and the limitations of the study.

3.1 Definition of the Research Questions

The goal of this research is to map out and analyze the risks involved in the current transplantation process in Brazil. It provides an initial overview about the main weaknesses of the process and offers insights about the major threats at present. Furthermore, it also provides a detailed and accurate mapping of the transplantation process in Brazil.

The main questions this research tries to answer are: **What are the main risks for the transplantation process in Brazil and what is their relative impact?**

In addition to the main primary questions, we address the following objectives, which can be considered as secondary. These objectives complement and give aid in the path towards finding the answers to the primary question:

- Definition of the main activities involved in the organ transplant process and how they contribute to its success.

- Identification of how those activities are connected, and how they might fail. And how the process flows from start to finish.

3.2 Research Type

According to Cresswell (2014), the research approach includes the plans and procedures chosen to carry out a specific research. Those plans and procedures will determine everything, from methods of data collection to analysis and interpretation. The choice of a specific approach should be based on the nature of the research problem and also on the researcher's previous experiences and preferences. Moreover, the researcher should take into consideration the audience for whom the research is intended.

The author divides the approaches in three groups: qualitative, quantitative, and mixed methods. As previously mentioned, the research problem (the transplant process) lacks quantitative data, therefore this study shall focus on qualitative approaches. Within this group, Creswell (2014) mentions five different research designs: narrative research, phenomenology, grounded theory, ethnographies, and case studies.

According to Yin (2001), the case study approach is ideal when the researcher wants to understand the "how" and "why" behind a certain phenomenon, and it is not necessary to exert control over behavioral aspects and focus on contemporary events. It enables the observation of events and people without the rigidity inherent to quantitative methods.

It is also relevant to observe, as Bento & Ferreira (1983) mention, that there is a natural progression to knowledge. The idea is that acquiring knowledge about a specific field is like building a staircase, where you start with assumptions and then gather exploratory information. After that, you can move on to predictive information, then to decisive information, and finally to systemic information. Also, a research project should neither take a step back nor skip a step from what has been previously built in the literature.

Taking all those elements into consideration, this study adopts a case study format, trying to understand the process and how it can fail. Although there are a few studies that address the transplant process and mention possible risks and weaknesses, none of them focuses on analyzing and classifying those risks. Keeping that in mind, this study aims at building an overview on the subject from an exploratory perspective.

3.3 Case Selection

According to Yin (2001), a case study starts with the definition of the analysis unit, called the "case." For the author, a case can traditionally be a person, an event, or an entity. That, however, is not restrictive and there are examples of case studies on decisions or even processes. Yin states that the definition of the case should be closely related to the research question.

The research object of the present study is the transplant process. However, as mentioned by Schutt (1998), the process can vary from country to country, and will also depend on the organization model adopted. In addition, the issues and specific needs can vary even within a country, according to regional characteristics.

The research question itself focuses on Brazil and its transplant process. In Brazil, the transplant management is organized by CNCDO, and there is one CNCDO for each state in the country (Pereira et al., 2009). Since the CNCDOs are responsible for the transplant process as a whole, the cases selected were the processes managed by the main CNCDOs.

Every year, the Brazilian Association for Organ Transplantation (Associação Brasileira de Transplante de Órgãos - ABTO) publishes statitistics concerning the organ transplant in the country. The 2016 report shows that during the year there were 2,981 donations in the country, and the top 10 states where the donations took place represent 91% of the total. The cases selected for this study were the processes managed by the CNCDOs of those states, namely, São Paulo, Paraná, Rio Grande do Sul, Santa Catarina, Rio de Janeiro, Ceará, Minas Gerais, Pernanbuco, Bahia, and Distrito Federal.

3.4 Data Collection and Analysis: Choosing the Risk Analysis Methodology

The aim of this study is to conduct a risk analysis. However, we must bear in mind that both the data collection process and the analysis itself depend on the specific risk analysis methodology chosen. As presented in the literature review, there are different methodologies of qualitative risk analysis that could have been used. In order to select the case studies, we took into consideration the characteristics of each process and used other risk analysis for processes with similar characteristics found in the literature as a guideline.

Lopez et al. (2010) developed a risk analysis of a cell therapy manufacturing. According to the authors, even though this is an industrial process, it is not highly standardized and automated as most processes that traditionally undergo risk analysis. It relies heavily on human intervention and it also depends on the quality of the input material (human organ, tissues, and cells), which can vary subtantially. These characteristics are also observed in the transplantation process, as are some of the reasonings behind the selection of the risk analysis method. According to the authors, regarding the methods considered at first (the ones shown in the literature review), FTA can be extremely time consuming and not conclusive when it is the single technique used. Regarding the HAZOP method, they state that since it is based on variations, it is more appropriate for highly industrialized and standardized processes, and are not entirely suitable for human intervention and manual processes.

When it comes to the FMEA, their chosen methodology, Lopez et al. (2010) explain that the method is more flexible and that it is very suitable for processes where risk analysis is being conducted for the first time. With that in mind, this case study will be conducted using the FMEA methology.

3.4.1 Data collection

Following the FMEA methodology, Lopez et al. (2010) organize the study according to the flowchart displayed in Figure 7. Before these activities take place, the FMEA team within the company must be selected. After this, a numerical analysis is performed through the use of charts and graphs used to aid in a risk management initiative.

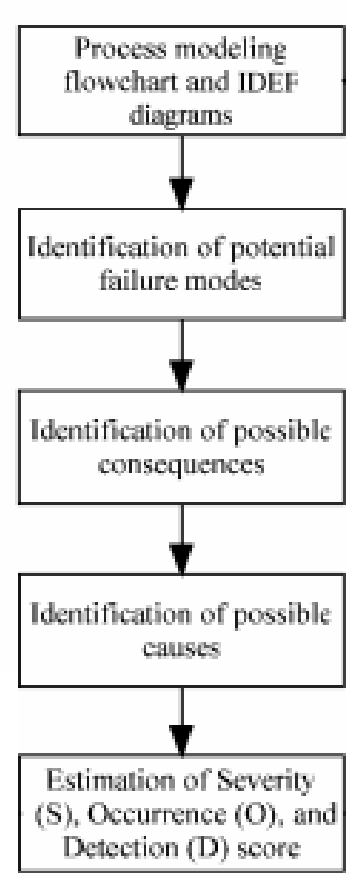


Figure 7: Flowchart of the FMEA process
Source: Lopez et al. (2010)

This study organizes the activities described in the above flowchart in two different data gathering events: validating the transplant process and causes for process failure and estimations of severity, occurrence, and detection.

3.4.1.1 Validating Transplant Process and Causes for Process Failure

It has been established, in the literature, an initial overview of the transplant process, its activities and weaknesses. During this stage, the present study aims at adjusting, if necessary, what the literature has reported by including what is the CNCDOs have to deal with in practice. Moreover, the objective is to confirm if the weaknesses reported are applicable to the cases studied and if there are other causes of failure within the process that have not been mentioned in the literature.

For this stage, open-ended interviews were conducted, based on a semi-structured script created with the use of the summary table presented on item 2.3. The purpose of these interviews was to validate the activities listed and their weaknesses. Moreover, the goal was to add information to the lists in order to obtain a complete process overview and identify possible causes of failure.

The interviewees were two coordinators from the CNCDOs and one academic researcher dedicated to studying the organ transplantation process. The two coordinators both had MBA what made them prime candidates for this interview since they not only have the medical knowledge but are also well versed in the more technical managerial point of view, understanding more precisely questions about process and risk. The more academical interviewee offered a complementary point of view, with different insights for the other two. All the interviews were face-to-face, the scrip followed was a guided conversation using the process mapped out in the literature as a guideline. During the period each interviewee reviewed the initial process making comments about both the events described and the risks associated to them. In Lopez et al. (2010) study, a working group was formed and the process was built by all the experts simultaneously. Due to schedule restrictions, for this study it was not possible to gather the experts at the same time and place. Therefore, in order to reproduce their study, the interview was organized in a way that the interviewees edited the table progressively (the table presented to the second interviewee already contained the alterations made by the first one, and so on) to construct a final, complete version. The end of this stage was marked when the interviewee no longer altered the table.

3.4.1.2 Estimating Severity, Occurrence and Detection

Once the experts had mapped all potential failure modes, the next step was to evaluate them. As shown in the literature review, the FMEA methodology assesses the possible risks by using three different dimensions: severity, occurrence, and detection. According to Lopez et al. (2010), there are two methods for collecting these scores: direct estimation and analytic hierarchy processes (AHP).

The authors explain that direct estimation is when each expert assigns a 1 to 10 grade for each risk in each category in an absolute manner (without comparing one risk to the other) using scales as guidance. In the AHP, each problem is broken down into criteria and alternatives, while comparing the grades among each risk cluster (human errors, machine failures, etc.). Between the two methods, the authors chose the direct estimation, stating that the data generated by the method was comparable to the AHP in terms of quality and the process was less time consuming. The authors also mention the possibility of using actual statistics on previous failures of the ocurrence criteria, but, as is the case of the present study, they did not have reliable quantitative data and chose to use an estimation provided by the experts. With that in mind, the present study also opted for the direct estimations approach. It is worth mentioning that the experts interviewed were the coordinators of the 10 largest CNCDOs (as previously mentioned). They all are uniquely qualified as they not only have a medical background but have also for years occupied a managerial role at the forefront of the transplantation process in Brazil. They accompany the process everyday and have to deal with the failures that occur as consequence of the the risks being evaluated.

As the experts are from different states in the country, the interviews were conducted either on skype or over the telephone. Before the interview, the coordinators received a form that specified the risks to be evaluated and included guiding tables for each criterion (See Appendix 1). During the interview each criterion and the grading system were explained and afterwards each event was evaluated, the final scores were recorded on the questionnaire with comments added when needed (in cases where there were exceptions remarked).

One important aspect of the direct estimation is the elaboration of the guiding scales. They must be clear to experts, use the appropriate jargon, and their dimensions have to consider the characteristics of the process. Some of the experts interviewed in the previous steps were asked to help elaborate the form, using the scales of the Lopez et al. (2010) study as guidelines. Tables 6 to 8 show the guiding scales:

Score (S)	Class of Severity	Description
10	Catastrophic	Process is terminated, and end result cannot be achieved
9 – 8	Critical	Very likely that the process will be terminated, and end result will not be achieved
7 – 5	Important	Likely that the process will be terminated, and end result will not be achieved
4 – 3	Average	Unlikely that the process will be terminated, and end result will not be achieved
2 – 1	Secondary	Rarely causes the process to be terminated and end result not achieved

Table 6: Severity guiding scale

Score (O)	Occurrence Classification
10 – 9	Very high
8 – 7	High
6 – 5	Moderate
4 – 3	Low
2	Very low
1	Remote

Table 7: Occurrence guiding scale

Score (D)	Detection Classification	Description
10	Remote	Very low likelihood of detecting the error

9 – 8	Very low	Low likelihood of detecting the error
7 – 5	Moderate	Moderate likelihood of detecting the error
4 – 3	High	High likelihood of detecting the error
2 – 1	Almost Certain	Very high likelihood of detecting the error

Table 8: Detection guiding scale

3.4.1 Data Analysis Method

First, the interviews were about the process and the mapping of possible risks. The initial table (Table 5) was edited alongside the experts as the interviews progressed. That approach was used as a way to minimize misinterpretation errors and to try to avoid misuse of specific medical and transplantation jargon. This first step worked as a foundation for the risk analysis, and the data itself was not analyzed in more detail at this point. It's important to keep in mind that the main objective of this study is not to analyze the process itself, but to focus on the risks and weaknesses it presents.

As an output of the second stage of this research, 10 different lists containing evaluations of risks, according to the point of view of each CNCDO, were produced. The results were compiled on an Excel document to facilitate the analysis.

As mentioned by Lopez et al. (2010), in several industries there are reference values that determine what can be considered an acceptable risk priority number (this number corresponds to the result obtained from multiplying the S, O, and D scores). Since in their study that was not the case, the authors opted for building a risk matrix using the severity and ocurrence variables, together with a chart analysis.

3.5 Method Limitations

In this study, we can observe two different types of research limitations. One is due to the nature and characteristics of a case study, and the second, to the limitations of the qualitative methods used and the FMEA for risk analysis.

Regarding the case study methodology, according to Steel, Gonnerman & Rourke (2017), there are two main concerns. The first one is the lack of generalization possibilities – even case studies with a large number of selected cases run the risk of not portraying the real situation in full. Therefore, it is important to reinforce that this study focuses on the situation in Brazil as perceived by the 10 selected CNCDOs and not in the country as a whole, nor does it necessarily describe the processes and risks of other countries. The goal at this point is not to provide an overarching theory.

The second limitation mentioned by the authors is the potential bias. They state it is not uncommon for cases to be biased when it comes to selection, emphasis, and interpretation. They also mention that both the researcher and the experts interviewed may be the ones who show bias.

When it comes to the risk analysis method chosen, Cox et al. (2005) mention that the risk rating system can be somewhat subjective both in interpretation ("very frequent", for example, can have different meanings to different people) and in bias. A risk that the experts may have recently faced could be evaluated as having a higher frequency of occurrence then it actually does.

Apostolakis (2004) also points out that the final analysis of qualitative methods may also be highly subjective. There is no formal definition of what is an "acceptable risk" and what is not, therefore, classifying risks can also pose a challenge.

4 CASE DESCRIPTION

This study identifies and analyses risks within organ transplantation processes from the point of view of the 10 CNCDOs in Brazil with the highest number of organ transplants. In order to provide a context for the case studied here and properly understand the results, this chapter explains the functioning and structure of the CNCDOs and how they operate within the Brazilian organ transplantation management model.

4.1 The Brazilian Organ Transplantation Model

As mentioned in the literature review, the SNT in Brazil is a national organization responsible for the organ transplant process in the country. According to the Brazilian Ministry of Health website (2017), the SNT is responsible for the control and monitoring of the entire process of organ donation and transplantation. The SNT goal is to develop and improve the process and, in order to do so, they are expected to be accountable for all the stages involved in the process, from the organ donation until the follow up with the recipients. They have to deal with the political management of all issues related to the process, promote organ donation, develop the required logistics, sanction teams and hospitals, and define the financing and structure of the organizations needed to help manage the process.

The Health Ministry coordinates the SNT and the CNCDOs manage activities on a regional level. There is one CNCDO for each state and they answer to the respective Local Health Secretariat. In 2000, the National Transplantation Center (CNT) was created to serve as a link between the CNCDOs and the other institutions belonging to the SNT. Their objective is to make the entire process more transparent, especially as organ allocation is regarded, and make transportation and distribution more efficient.

There are two organizations that give assistance to the CNCDOs operations: the Comissão Intra-Hospitalar de Doação de Órgãos e Tecidos para Transplante (CIHDOTT) and the Organização de Procura de Órgãos e Tecidos (OPO). The CIHDOTTs are located in the hospitals. They are formed by the hospital board and answer to the hospital administration. They are responsible for organizing hospital activities in such a way that the identification of potential donors is made viable. The CNCDOs train the commissions and give them a formal certification. The OPOs regulate the activities involved in the process of organ donation and donor management. They work in partnership with the CIHDOTTs and one of their goals is to improve the process and aid in communication.

4.2 The CNCDOs

As established in regulation 2.268/97, each CNCDO is responsible for coordinating all organ donation and transplant actions in its assigned region. Among their main duties, they must do the following:

- Register potential recipients, including all relevant information for a fast warning, in case an organ is made available (contact information, address, etc.), and all the necessary data to evaluate organ compatibility;
- Update recipient information within the SNT;
- Notify SNT center in case there is an organ or tissue available, that is in good conditions, and there is no match within the region;
- Control and inspect all donation and transplant activities in the region.

To that end, the CNCDOs have specialized teams to diagnose brain death (done at authorized sites) and retrieve organs and tissues. The hospitals are responsible for notifying the center whenever a potential donor is identified (Brazilian Ministry of Health, 2017).

5 CASE DATA ANALISYS

This chapter analyses the data obtained in the risk mapping interviews and the questionnaires filled by the coordinators of the top 10 CNCDOs, ranked by transplant volume. First, we analyzed the mapped risks and the ones that were added to or removed from the literature. With the data obtained from the risk evaluation, as determined by the risk analysis method chosen, the risks mapped were ranked. In order to do so, the average score for each criterion was used, multiplied by one another, then they were analyzed with the use of charts and graphs, and, after that, a risk matrix was built based on the severity and occurrence data to facilitate the analysis.

5.1 Risk Mapping

Using the summary table presented on item 2.3 as a base, open-ended interviews with experts from the CNCDOs were conducted. The goal was to complete the table, mapping the risks not mentioned in the literature and validating those that were mentioned, and checking if the latter are applicable to the actual circumstances in Brazil. This segment is organized in the same fashion as the interviews took place, presenting the results found for each activity.

5.1.1 Potential Donor Identification

At this stage, we found out that the literature focuses on issues concerning the unfamiliarity with donor criterion and staff engagement, which leads, for example, to failure in identifying (Delmonico et al., 2011; Formanek & Schöffski, 2010) or in reporting (Delmonico et al., 2011; Formanek & Schöffski, 2010; Mercado-Martínez et al., 2013; Razdan et al., 2015) a potential donor. During the mapping process, both issues were confirmed. Technical difficulties regarding communication were also brought up – currently, some centers use phones as the main form of contact and there have been reports of situations when the hospital tried to call the CNCDO and could not reach it.

5.1.2 Brain Death Confirmation

The issues initially mapped were either lack of equipment (Delmonico et al., 2011; Rocon et al., 2013) and/or lack of necessary staff (Delmonico et al., 2011; Formanek & Schöffski, 2010; Mercado-Martínez et al., 2013). Both those issues were validated, and no other was added.

5.1.3 Potential Donor Evaluation

It was not possible to find in the literature review any mentions of potential risks at this stage. However, during the interviews, several weaknesses were mentioned. The first one was the possibility of evaluation errors – either approving an organ that should not have been approved or rejecting an organ that should have been approved.

The possibility of laboratory errors was also brought up, more specifically regarding serology. Another risk mentioned was the possibility that the staff was not properly qualified to run the tests required at this stage.

The last risk mentioned was the lack of resources. Occasionally, it is necessary to seek the opinion of a specialist for a specific issue, or to run more detailed tests (a biopsy, for example), and it may occur that the region does not have those resources available.

5.1.4 Potential Donor Clinical Management

Rocon et al. (2013) mention the risk of cardiac arrest during this stage and the experts confirmed that this may become an issue in the process. They also added another issue concerning the lack of resources in some regions – hospitals that do not have ICU beds available to maintain the donor, or do not have the necessary medication, among other problems.

5.1.5 Family Notification of Brain Death and Family Consent Interview

The literature covers the importance of proper training of staff to notify the family of the potential donor's death and to appropriately approach the family to inquire about the possibility of organ donation. Both moments are extremely delicate and may increase the chance of a denial when improperly conducted (Smith-Brew & Yanai, 1996). Those risks were validated for these stages and no others were added.

5.1.6 Organ Matching

A possible risk is that the matching time may take longer than the ischemia time, that is to say, the organ becomes improper for use before a matching recipient can be identified (Delmonico et al., 2011). The interviews brought up another risk: the possibility that the first match found presents a clinical condition that makes them ineligible to receive the organ.

5.1.7 Mobilization of Surgical Team

The first risk identified for this activity is that the retrieval team may not be available to retrieve the organ (Delmonico et al., 2011; Rocon et al., 2013). During the mapping interviews, other risks were mentioned: the retrieval team may arrive late; the transplant team may not be available; either team may not have the necessary means of transport to arrive at the location. They also mentioned that a specific license is required in order to retrieve an organ, and that, sometimes, the team's certification is out of date.

5.1.8 Organ Retrieval

From this point forward, no mention of risks was found in the literature, so the interviews did not have the initial table (from chapter 2.3) as a guideline. The risks revealed in this stage were the following: the possibility of errors when sectioning the organ from the donor; the unavailability of an operation room to perform the surgery; and errors made when preparing the organ for transport, for example, using a recipient that is not sterile.

5.1.9 Organ Transportation

The risks mapped during this activity were: mixing organ containers (sending an organ to the wrong location), delays, major accidents (car or plane crashes), transport unavailability, and bad weather when air transport is necessary.

5.1.10 Organ Transplantation

Concerning the transplant activity, the risks mentioned were: lack of resources for transplant surgery (operation room unavailability, no space in the ICU for post-op, etc.), detection of incompatibility (delayed detection of serology mistakes), or a refusal (the patient or the transplant team refuse to accept the organ).

5.2 Risk Mapping Overview

Table 9 shows the result of the activity mapping. It combines the events found in the literature (presented in segment 2.3) and adds the risks mentioned by the experts during the first stage of the data collection. This table served as the base for the questionnaires used to score the risks according to the FMEA methodology.

Process Activity	Event	Literature
Potential donor identification	Not identifying a potential donor (ICU, ER, and post-op teams unfamiliar with donor criteria)	x
Potential donor identification	Not notifying the CNCDO of a potential donor (once they have been identified)	x
Potential donor identification	Communication failure between hospital and CNCDO	

Brain death confirmation	Lack of specific equipment to properly diagnose brain death	x
Brain death confirmation	Lack of specific staff (neurologist or neurosurgeon) to properly diagnose brain death	x
Potential donor evaluation	Evaluation error - approving donor that should not have been approved	
Potential donor evaluation	Evaluation error - rejecting donor that could have been approved	
Potential donor evaluation	Laboratorial errors (serology)	
Potential donor evaluation	Undertrained staff for the process	
Potential donor evaluation	Lack of resources (specialists and equipment: biopsies) to conclude the evaluation	
Potential donor clinical management	Cardiac arrest	x
Potential donor clinical management	Lack of resources to properly maintain donor (antibiotics, medication, infrastructure)	
Family notification of brain death	Failure to properly communicate brain death (lack of properly trained staff)	x
Family consent interview	Failure to properly inquire about donation (lack of properly trained staff)	x
Organ matching	First recipient presenting clinical conditions that renders transplant surgery unacceptable	
Organ matching	Matching time exceeding organ ischemia time	x
Mobilization of surgical team	Retrieval team unavailability	x
Mobilization of surgical team	Retrieval team delay	
Mobilization of surgical team	Transplant team unavailability	
Mobilization of surgical team	Lack of transport for teams' displacement	
Mobilization of surgical team	Bureaucratic issues (expired license)	

Organ retrieval	Improper organ conditioning (contact with ice, contamination exposure, etc.)	
Organ retrieval	Errors when sectioning organ from donor	
Organ retrieval	Unavailability of operation rooms	
Organ transportation	Weather (preventing air delivery)	
Organ transportation	Mixing organ containers (sending organ to wrong location)	
Organ transportation	Delays	
Organ transportation	Major accidents (crashes)	
Organ transportation	Transport unavailability	
Organ transplantation	Refusal (patient or surgical team refuse to accept the organ)	
Organ transplantation	Incompatibility (delayed identification)	
Organ transplantation	Lack of resources for transplant surgery	

Table 9: Risk map overview

5.3 Risks Ranking and Graphical Analysis

The first step for the analysis is to find the risk priority number (RPN) for each of the risks mapped. As shown in the literature review, the RPN is calculated through the formula:

$$RPN = Severity\ (S)\ x\ Ocurrence\ (O)\ x\ Detection\ (D)$$

Source: Snee, 2016

The result of the case analysis was a data set of 10 scores for each criterion for every risk, obtained by filling the questionnaire together with the CNCDO coordinators

in the 10 selected states. In order to apply the formula, the 10 scores were averaged into one number.

The maximum score of acceptable risk varies according to the industry. In many industries, it is possible to find reference values for acceptable risks and for the ones that require immediate action (Lopez et al., 2010). As previously mentioned, there is not enough research on process risk in the area of organ transplant; therefore, those values have yet to be established.

On account of that, the present research has opted to adopt a descriptive approach and show a ranking of the events along with a graphical analysis. Table 10 shows the complete table with the total score for each event:

Process Activity	Event	S	O	D	Score
Potential donor identification	Not identifying a potential donor (ICU, ER, and post-op teams unfamiliar with donor criteria)	10	5	6	300
Potential donor clinical management	Cardiac arrest	10	5	6	300
Family notification of brain death	Failure to properly communicate brain death (lack of properly trained staff)	9	6	5	270
Organ transplantation	Refusal (patient or surgical team refuse to accept the organ)	6	5	7	210
Potential donor identification	Lack of notification to the CNCDO of a potential donor (once they have been identified)	10	4	5	200
Family consent interview	Failure to properly inquire about donation (lack of properly trained staff)	9	5	4	180
Organ transportation	Delays	6	5	5	150
Potential donor identification	Communication failure between hospital and CNCDO	9	4	4	144
Organ retrieval	Errors when sectioning organ from donor	8	2	9	144
Organ transportation	Weather (preventing air delivery)	9	2	8	144

Potential donor evaluation	Evaluation error - approving donor that should not have been approved	9	2	7	126
Potential donor evaluation	Evaluation error - rejecting donor that could have been approved	10	2	6	120
Organ retrieval	Unavailability of operation rooms	8	2	7	112
Brain death confirmation	Lack of specific staff (neurologist or neurosurgeon) to properly diagnose brain death	9	3	4	108
Potential donor evaluation	Lack of resources (specialists and equipment: biopsies) to conclude the evaluation	9	4	3	108
Potential donor clinical management	Lack of resources to properly maintain donor (antibiotics, medication, infrastructure)	7	5	3	105
Organ matching	First recipient presenting clinical conditions that renders transplant surgery unacceptable	4	5	5	100
Brain death confirmation	Lack of specific equipment to properly diagnose brain death	10	3	3	90
Organ transportation	Transport unavailability	9	2	5	90
Organ transplantation	Lack of resources for transplant surgery	9	2	5	90
Organ transportation	Mixing organ containers (sending organ to wrong location)	9	1	9	81
Mobilization of surgical team	Retrieval team delay	4	4	5	80
Mobilization of surgical team	Transplant team unavailability	8	2	5	80
Organ retrieval	Improper organ conditioning (contact with ice, contamination exposure, etc.)	10	1	8	80
Organ transportation	Major accidents (crashes)	8	1	10	80
Organ transplantation	Incompatibility (delayed identification)	10	1	8	80
Potential donor evaluation	Laboratorial errors (serology)	9	1	7	63
Potential donor evaluation	Undertrained Staff for the process	7	3	3	63

Organ matching	Matching time exceeding organ ischemia time	9	2	3	54
Mobilization of surgical team	Retrieval team unavailability	9	2	3	54
Mobilization of surgical team	Lack of transport for teams' displacement	7	2	3	42
Mobilization of surgical team	Bureaucratic issues (expired license)	5	2	2	20

Table 10: RPN scores

5.3.1 Scores and Ranking Insights

5.3.1.1 Potential Donor Identification

Table 10 shows that all the risks mapped for donor identification are within the top 10 highest RPN scores, illustrating what a high impact this stage has on the process as a whole and how fragile it is. These events are highly severe as they prevent the beginning of the process, and they occur more often than other risks. This indicates a major weakness in the process, since people who could be potential donors are not even identified or notified to the CNCODs.

5.3.1.2 Cardiac Arrest Risk

The high risk of cardiac arrest, that comes second in the ranking, also reinforces the importance of speed and efficiency within the process as mentioned by Caballero (2001) – the less time is spent on maintaining the donor, the lesser the risk of losing a donor due to cardiac arrest during the waiting period.

5.3.1.3 Communication with the Family

The results also illustrate the importance of appropriate communication with the family. Both communication problems are in the top 10 events, and the impact that a poorly conducted consent interview might generate on the process, as mentioned by Smith-Brew & Yanai (1996), is high. This can be reflected on the percentage of refusal to donate organs. In Brazil, this percentage was 43% in 2016 (ABTO, 2016), while in Spain, for example, in 2000, that percentage was 21,5% (Miranda et al., 2001).

5.3.2 Impact Percentage Graph Analysis

In figure 8, the graph helps to illustrate the impact of the top 10 risks, by comparing their magnitudes against each other. The graph was built as follows: failure events were ordered according to decreasing RPN scores; percentage values were calculated; and a column of cumulative correspondent values was added from their cumulative sum. RPN% values were then plotted against RPN% cumulative values on a bar chart.

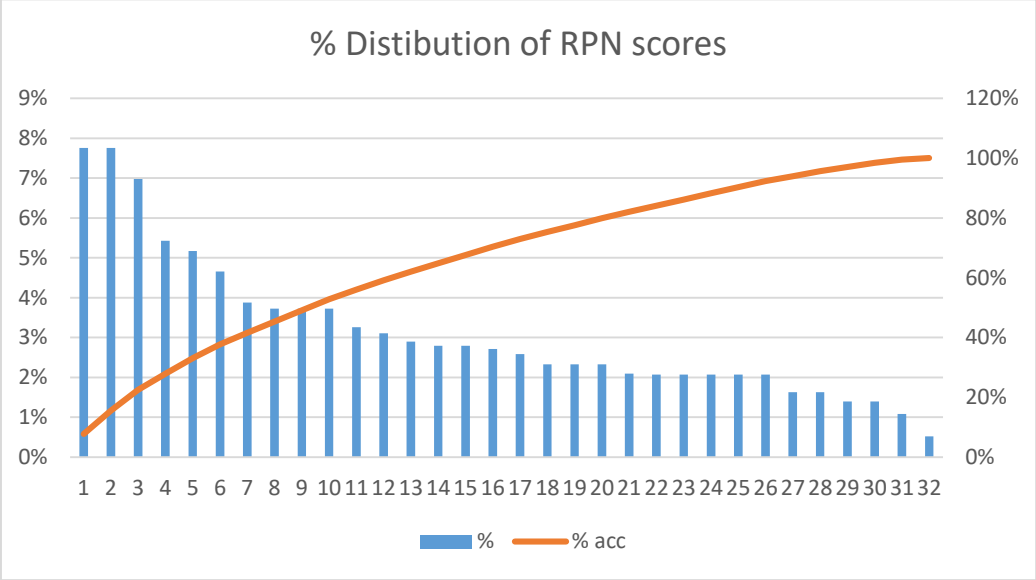


Figure 8: Percentage graph analysis of the distribution on RPN scores

The graph shows that the top 10 risks represent more than half (53%) of total RPN score points. It also shows that the lower end of the table has a significantly smaller impact on the total RPN sum (almost all present near values). An analysis of the table demonstrates that while some of these risks have a high severity score, for example the matching time exceeding the organ isquemia time, they do not happen as frequently. Moreover, it is relatively easy to detect that this event might happen before it actually does, therefore, while the severity score is high, the other two are comparatively low.

5.4 Severity-Occurrence Matrix

This matrix was devised to help in the analysis of the RPN results since there are no established industry acceptable range values for this industry. This study has opted to use the same approach adopted by Lopez et al. (2010) and build a risk matrix to complement the ranking and graph analysis made on 5.3. It is possible to observe that the risk matrix follows the model found in the literature review. Figure 9 shows the plotted matrix. The y axis is based on the occurrence scores and the x on the severity scores.

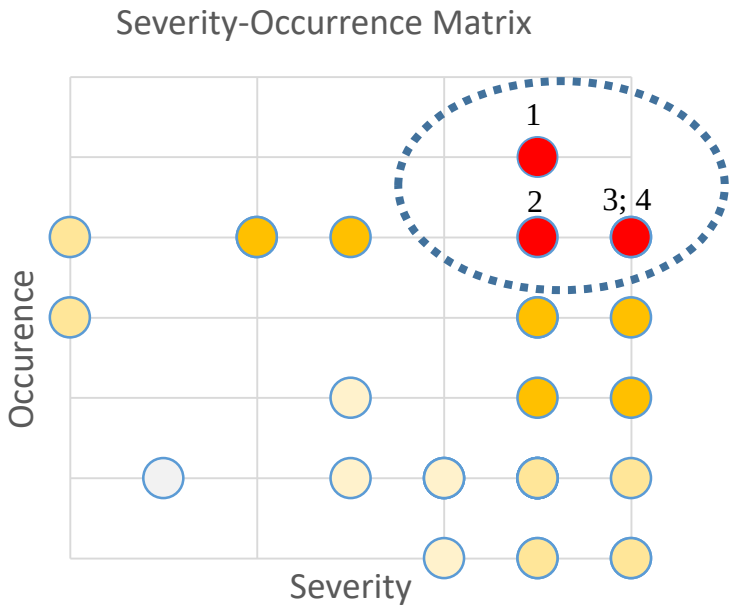


Figure 9: Severity-Occurrence Matrix

The points shown within the dotted circle in figure 9 represent:

1- Failure to properly communicate brain death
2- Failure to properly inquire about donation
3- Lack of identification of potential donor (unfamiliarity with donor criteria)
4- Cardiac arrest

It is possible to observe that 3 out of the 4 items above are among the top 5 in the RPN ranking, and 3 of them are among the top 3. However, failure to properly enquire about donation is not among the top 5, and failure to properly communicate brain death in the lowest in rank out of the 3 that are among the top 5. Considering that the matrix does not account for the detection score, that can be easily understood. Both errors in communication represent grave risks. However, it is possible to foresee when and where they might occur since they might represent gaps in training or adherence to the instructions received.

6.2 Conclusions

The case analysis along with the review of the literature made it possible for this study to answer the proposed research questions. The structure of this segment is organized starting with the secondary objectives:

- Definition of the main activities involved in the organ transplant process and how they contribute to its success.

The main activities were mapped combining different articles that focused on specific parts of the process and insights obtained in the first round of interviews.

The first activity is identifying the potential donor. For that hospital staff to identify a brain injury that might evolve into brain death it is necessary to monitor the patient. Early identification is important to avoid complications that could hinder a possible organ donation. This activity includes not only properly identification and monitoring of a potential donor, but also making sure the CNCDO is notified.

The second main activity is brain death confirmation. This step is highly regulated by law and needs to follow the specified requirements to fully confirm brain death. Once brain death has been confirmed, the subsequent activity is to evaluate the potential donor. This stage ensures that the organs are in good condition and that the donor has no health issue that might cause severe complications for the recipient. This step relies on the CNCDOs judgement when it involves the evaluation of borderline cases.

The fourth step is the clinical management of the potential donor. Actually, this activity initiates when the potential donor is first identified and ends when the organs are retrieved. This activity ensures that the organs stay in good condition to be transplanted through the maintenance of the donor's stability.

The next activity is the obtaining of family consent. First the family is notified of the brain death, and afterwards, they are questioned regarding the possibility of organ donation. This is an extremely delicate activity and several of the coordinators interviewed have described it as one of the most difficult steps of the process.

The sixth activity is matching the available organs to potential recipients. The matching takes into consideration the region, the position in the waiting line, biological characteristics, transportation distance, among others. This activity is managed by the CNCDO. Once matches are found, the retrieval and transplant teams are mobilized.

The following activity is the retrieval surgery, when the organs are harvested and conditioned, so they can be transported to the transplantation location where the transplant surgery and the last activity will take place.

There are other activities after the transplant surgery, but those are outside the scope of this study.

- Identification of how those activities are connected, and how they might fail. And how the process flows from start to finish.

This question concerns the weaknesses of the process, the risks that were mapped on the first round of interviews and found in the literature.

Regarding the potential donor identification, there is the possibility of a potential not being identified, be it for unfamiliarity of the hospital staff with the donor criteria, or lack of specific control and monitoring. Another possibility is that a potential donor is identified but nothing is done about it: the CDCDO isn't notified and the hospital opts not to follow through with the donation process. During the interviews several possible reasons for this to happen were pointed out. However, as previously mentioned, the mapping of the possible causes for the task failure is outside the scope of this research. Still concerning the notification, another way this specific task can fail is due to technical issues with the telephone lines.

Regarding the brain death confirmation activity, according to the regulations, the presence of neurologist or a neurosurgeon to confirm the diagnosis is mandatory. If those professionals are unavailable, the legal confirmation might not be possible, potentially blocking the process. The same happens regarding the necessary tests: if the equipment is not available at the hospital, this may cause complications for the development of the task.

The main risks related to the potential donor evaluation concern laboratory errors or evaluation errors. The risk of lack of resources was also mentioned and it might include the need for a specific test or specialist and the inability to fulfill these needs.

Concerning the clinical management, one of the main risks is the potential donor going through an irreversible cardiac arrest. There is also the possibility of lack of

resources, such as hospitals that don't have beds in the ICU available to keep a potential donor or don't have the necessary medicines.

When notifying the family of the potential donor about the brain death and inquiring about the possibility of organ donation, there is the risk that the conversations aren't carried out in the most ideal way (in the middle of hallways, or in a hurry, without giving the family time to process, etc.). This may cause a negative impact and the family unwillingness to donate.

At the matching stage, there is the risk of finding a match, but for some reason the person the organ was assigned to, couldn't receive it or the matching took longer than the organ ischemia time.

At the stage of mobilizing the surgical teams, the main risks mentioned were either the unavailability of a team or possible issues with transportation and/or delays.

During the organ retrieval procedure, the first risk is lack of an operating room available to perform the surgery. As previously mentioned, the clinical management of the potential donor is a very delicate activity and the time wasted due to lack of resources adds to the difficulties. The second risk would be surgical mistakes during the procedure. The third would be the preparation of the organ for transportation, when mistakes might happen, such as the use of inappropriate containers.

Regarding the transportation of the organs, the possibilities are destination errors, sending the organ to the wrong location, unavailability of resources, and delays. Concerning the transplant surgery itself, there is the possibility that the patient or the transplant team refuses to accept the organ or lack the resources for the surgery.

Having addressed the secondary objectives, it is possible to focus on the main one:

- What are the main risks for the transplantation process in Brazil and what is their relative impact?

In order to answer the question, we start with a list of the risks mentioned on the previous question and by using the FMAE risk analysis methodology to score each risk, in order to assess their impact comparatively.

Using Table 10 as a reference and the matrix on Figure 9, it is possible to observe that all the risks within the top critical quadrant are part of the top 10 risks on the RPN ranking. It's also noticeable in the graph displayed in Figure 8 that they represent 53% of the total RPN.

Those top 10 risks are in order: Not identifying a potential donor; cardiac arrest during clinical maintenance; failure to properly communicate the brain death to the family; patient or surgical team refusing to accept the organ; not notifying the CNCDO of a potential donor; failure to properly inquire family about donation; organ transportation delays; communication failure between hospital and CNCDO; errors when sectioning organ from donor; bad weather (preventing air flight delivery).

It is possible to observe in this list the importance of the detection stage, i.e. identifying a potential donor (all the weaknesses regarding this activity are found on the top 10 list). A great opportunity lies in improving this stage and managing these risks, setting policies in place in order to strengthen these weak points.

It is also important to highlight another aspect within the top 10 risks: the communication with the deceased's family members and how it poses a risk to the entire process.

6.3 Contributions

This study provides an exploratory overview concerning the risks that exist in the current transplant process. As a result, we have compiled a list of the main risks, as well as a ranking to classify their impact. This provides a clear perspective on the challenges of each activity and their impact on the overall process.

From an academic point of view, it offers a foundation to further develop the body of knowledge regarding the organ transplantation process risks. This work presents the existing weaknesses in a systemic and objective manner, describing and classifying them. Those can be of great value for future studies that may focus on more in-depth information about each of these weaknesses and investigation of the possible causes.

The results here presented also have managerial implications. They provide a clear indication of the major risks faced in the process, what can help managers to focus and

allocate resources for a careful development of those tasks. It also provides guidance as to where risk mitigation initiatives should be implemented to maximize their impact.

6.4 Future Research Suggestions

As previously mentioned, this study offers an initial outline concerning the organ transplantation process and risks. The next step would be to delve further into those risks. This research aims to build a foundation showing the points of weaknesses in the process, although it doesn't get into the details of each risk event. Understanding their causes and their variation over time, would lay an important ground work to start thinking of risk management.

Another study could be the investigation of the best approach to mitigate each one of those risks and what is the acceptable risk range for this specific process.

A quantitative research could also be designed in order to stablish quantifiable parameters for the risks mapped in this study and to precisely estimate the numeric impact each risk has on the number of transplants.

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APPENDIX

Appendix 1

INTRODUÇÃO
Essa pesquisa faz parte de um estudo sendo realizado como dissertação de conclusão do curso de mestrado em administração da COPPEAD/UFRJ. O Estudo em questão visa realizar uma análise de risco em relação ao processo de doação-transplante de órgãos no Brasil. Por meio de entrevistas iniciais junto a profissionais envolvidos no processo foi mapeada uma lista de possíveis eventos que colocam em risco o processo. Esse questionário tem como objetivo avaliar esses eventos segundo os critérios da metodologia de análise de risco chamada Failure Mode and Effect Analysis (FMEA). Abaixo segue a descrição de cada um dos 3 critérios

INSTRUÇÕES

Cada evento a ser avaliado deverá receber uma nota de 1 a 10 para cada um dos 3 critérios, seguindo como guia as tabelas auxiliares.

Preencher as áreas marcadas em amarelo com número inteiro de 1 a 10.
Por favor usar apenas um único número e não um intervalo e preencher sob o ponto de vista de sua região.

SEVERIDADE

Avalia o impacto das consequências do evento para o processo.

Ex: Um evento com severidade 10 significa que o processo não pode continuar, ou seja, não haverá transplante. Um evento com severidade 1 apenas em casos raros levará o processo a ser interrompido.

Pontuação (S)	Classificação de severidade	Descrição
10	Catastrófico	O processo é interrompido e o resultado final não é atingido
9 – 8	Critico	Muito provável que o processo seja interrompido e o resultado final não seja atingido
7 – 5	Importante	Provável que o processo seja interrompido e o resultado final não seja atingido
4 – 3	Mediano	Pouco provável que o processo seja interrompido e o resultado final não seja atingido
2 – 1	Secundário	Raramente ocasionará que o processo seja interrompido e o resultado final não seja atingido

Etapa do Processo	Evento	S
Identificação do doador em potencial	Não identificação do doador em potencial (equipe dos departamentos de emergência não treinadas para detecção)	
	Identificação do doador em potencial, mas não notificação do mesmo para a CNCDO	

	Falha na comunicação entre hospital e a CNCDO	
Confirmação da morte encefálica	Equipamento necessário para o diagnóstico indisponível	
	Nenhum neurologista ou neurocirurgião disponível para realizar o diagnóstico	
Avaliação do doador em potencial	Validar um doador que não deveria ser validado	
	Rejeitar um doador que deveria ser aprovado	
	Erro laboratorial (sorologia)	
	Equipe não treinado para o procedimento	
	Indisponibilidade de recursos (equipamentos e/ou especialistas)	
Manutenção clínica do doador em potencial	Parada cardíaca	
	Falta dos recursos necessários (leito, medicamento, etc.)	
Notificação familiar da morte	Falha em comunicar a morte do paciente à família de forma apropriada	
Entrevista familiar de doação	Falha em solicitar o consentimento para doação de forma apropriada	
Alocação do órgão	Primeiro receptor selecionado apresentar alguma condição clínica que impossibilite o transplante naquele momento	
	Tempo de alocação ultrapassar o tempo de isquemia do órgão	
Mobilizar equipes cirúrgicas	Equipe de captação indisponível	
	Atraso da equipe de coleta captação	
	Equipe de transplante indisponível	
	Falta de transporte disponível para deslocamento das equipes	
	Questões burocráticas (equipe com licença expirada)	
Captação do órgão	Acondicionamento inapropriado do órgão (contato com gelo, recipiente não estéril, etc.)	
	Erros ao extrair (amputação vascular) órgão	
	Indisponibilidade de centro cirúrgico	
Transporte do órgão	Meteorologia ruim (quando em viagens aéreas)	
	Troca de caixa de órgãos (enviar o órgão para o local errado)	
	Atrasos	
	Acidentes graves (batidas)	
	Indisponibilidade de veículo/aeronave	

Transplante do órgão	Recusa do órgão por parte do receptor ou equipe de transplante	
	Incompatibilidade (identificação tardia de erro de classificação de tipo sanguíneo)	
	Indisponibilidade de recursos necessários para realizar a cirurgia.	

FREQUENCIA

Avalia com quanta frequência o evento ocorre.

Ex: Um evento com frequência 10 significa que ele ocorre com uma alta frequência. Um evento com frequência 1 pode ocorrer, mas é bem raro que ocorra.

Pontuação (O)	Classificação de frequência
10 – 9	Muito alta
8 – 7	Alta
6 – 5	Moderada
4 – 3	Baixa
2	Muito Baixa
1	Remota

Etapa do Processo	Evento	F
Identificação do doador em potencial	Não identificação do doador em potencial (equipe dos departamentos de emergência não treinadas para detecção)	
	Identificação do doador em potencial, mas não notificação do mesmo para a CNCDO	
	Falha na comunicação entre hospital e a CNCDO	
Confirmação da morte encefálica	Equipamento necessário para o diagnóstico indisponível	
	Nenhum neurologista ou neurocirurgião disponível para realizar o diagnóstico	
Avaliação do doador em potencial	Validar um doador que não deveria ser validado	
	Rejeitar um doador que deveria ser aprovado	
	Erro laboratorial (sorologia)	
	Equipe não treinado para o procedimento	
	Indisponibilidade de recursos (equipamentos e/ou especialistas)	
	Parada cardíaca	

Manutenção clínica do doador em potencial	Falta dos recursos necessários (leito, medicamento, etc.)	
Notificação familiar da morte	Falha em comunicar a morte do paciente à família de forma apropriada	
Entrevista familiar de doação	Falha em solicitar o consentimento para doação de forma apropriada	
Alocação do órgão	Primeiro receptor selecionado apresentar alguma condição clínica que impossibilite o transplante naquele momento	
	Tempo de alocação ultrapassar o tempo de isquemia do órgão	
Mobilizar equipes cirúrgicas	Equipe de captação indisponível	
	Atraso da equipe de coleta captação	
	Equipe de transplante indisponível	
	Falta de transporte disponível para deslocamento das equipes	
	Questões burocráticas (equipe com licença expirada)	
Captação do órgão	Acondicionamento inapropriado do órgão (contato com gelo, recipiente não estéril, etc.)	
	Erros ao extrair (amputação vascular) órgão	
	Indisponibilidade de centro cirúrgico	
Transporte do órgão	Meteorologia ruim (quando em viagens aéreas)	
	Troca de caixa de órgãos (enviar o órgão para o local errado)	
	Atrasos	
	Acidentes graves (batidas)	
	Indisponibilidade de veículo/aeronave	
Transplante do órgão	Recusa do órgão por parte do receptor ou equipe de transplante	
	Incompatibilidade (identificação tardia de erro de classificação de tipo sanguíneo)	
	Indisponibilidade de recursos necessários para realizar a cirurgia.	

DETECÇÃO

Avalia o quanto **improvável** é que seja identificado que o evento irá ocorrer antes que ele ocorra.

Ex: Um evento com detecção 10 significa que é praticamente impossível saber o evento irá ocorrer antes que ele ocorra. Um evento com detecção 1 significa que é muito provável que existam indicativos e alertas que o evento irá ocorrer antes que ele ocorra.

Pontuação (D)	Classificação de detecção	Descrição
10	Remota	Muito pouco provável que o erro seja detectado antecipadamente
9 - 8	Muito baixa	Pouco provável que o erro seja detectado antecipadamente
7 - 5	Moderada	Probabilidade moderada que o erro seja detectado antecipadamente
4 - 3	Alta	Provável que o erro seja detectado antecipadamente
2 - 1	Quase certa	Muito provável que o erro seja detectado antecipadamente

Etapa do Processo	Evento	D
Identificação do doador em potencial	Não identificação do doador em potencial (equipe dos departamentos de emergência não treinadas para detecção)	
	Identificação do doador em potencial, mas não notificação do mesmo para a CNCDO	
	Falha na comunicação entre hospital e a CNCDO	
Confirmação da morte encefálica	Equipamento necessário para o diagnóstico indisponível	
	Nenhum neurologista ou neurocirurgião disponível para realizar o diagnóstico	
Avaliação do doador em potencial	Validar um doador que não deveria ser validado	
	Rejeitar um doador que deveria ser aprovado	
	Erro laboratorial (sorologia)	
	Equipe não treinado para o procedimento	
	Indisponibilidade de recursos (equipamentos e/ou especialistas)	
Manutenção clínica do doador em potencial	Parada cardíaca	
	Falta dos recursos necessários (leito, medicamento, etc.)	

Notificação familiar da morte	Falha em comunicar a morte do paciente à família de forma apropriada	
Entrevista familiar de doação	Falha em solicitar o consentimento para doação de forma apropriada	
Alocação do órgão	Primeiro receptor selecionado apresentar alguma condição clínica que impossibilite o transplante naquele momento	
	Tempo de alocação ultrapassar o tempo de isquemia do órgão	
Mobilizar equipes cirúrgicas	Equipe de captação indisponível	
	Atraso da equipe de coleta captação	
	Equipe de transplante indisponível	
	Falta de transporte disponível para deslocamento das equipes	
	Questões burocráticas (equipe com licença expirada)	
Captação do órgão	Acondicionamento inapropriado do órgão (contato com gelo, recipiente não estéril, etc.)	
	Erros ao extrair (amputação vascular) órgão	
	Indisponibilidade de centro cirúrgico	
Transporte do órgão	Meteorologia ruim (quando em viagens aéreas)	
	Troca de caixa de órgãos (enviar o órgão para o local errado)	
	Atrasos	
	Acidentes graves (batidas)	
	Indisponibilidade de veículo/aeronave	
Transplante do órgão	Recusa do órgão por parte do receptor ou equipe de transplante	
	Incompatibilidade (identificação tardia de erro de classificação de tipo sanguíneo)	
	Indisponibilidade de recursos necessários para realizar a cirurgia.	

Table 11: Questionnaire used as guidance to CNCDO's coordinators interviews

Appendix 2

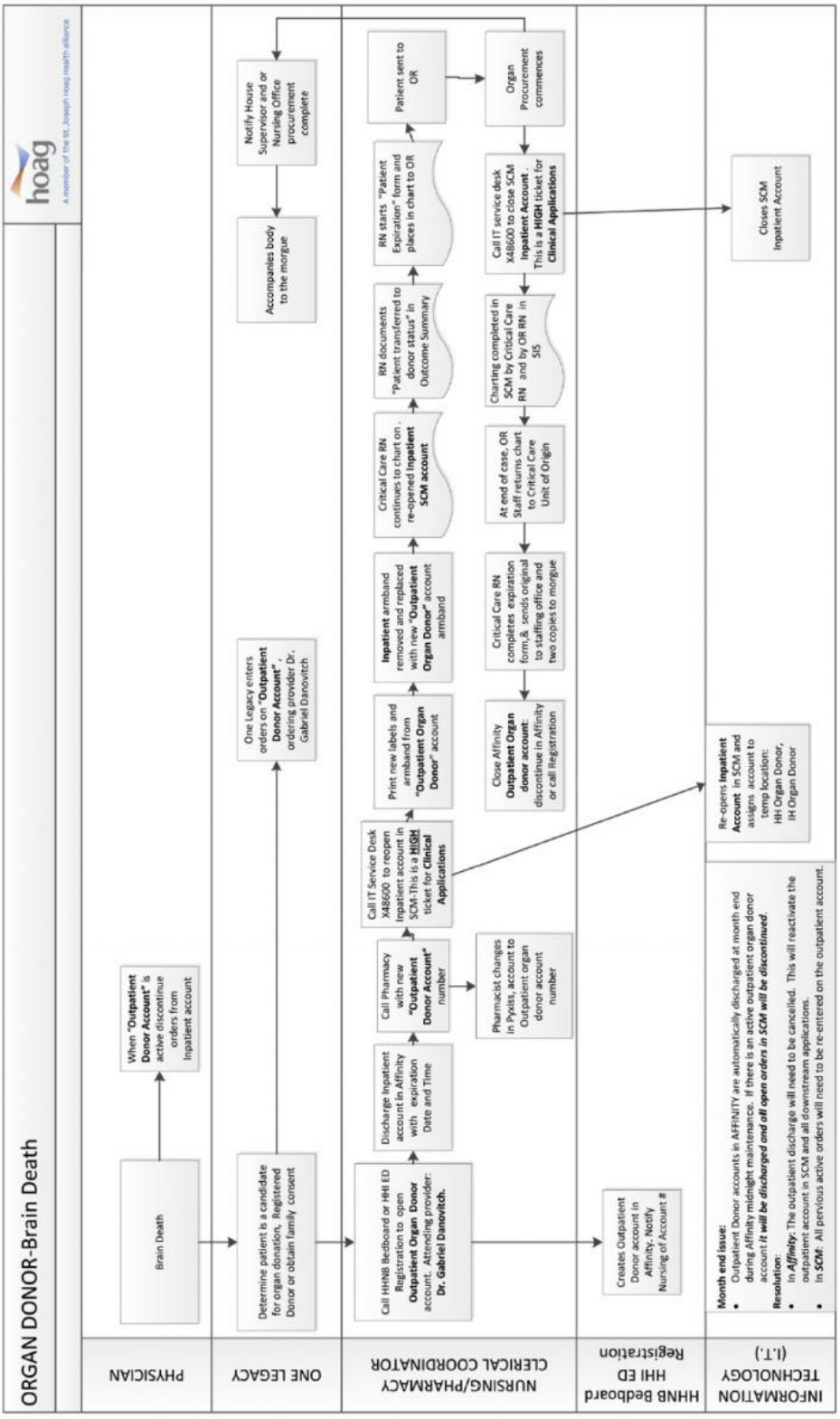

Figure 10: Workflow for organ donation in US hospitals

Source: O'Meeghan & Pedral