

**Tissue Donation Context in Portugal:
Defining a Strategy for Improvement**

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2018

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Defining a Strategy for Improvement**

**A Thesis presented in partial fulfilment of the Requirements
for the Degree of *Master* in Management**

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September 2018

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Acknowledgements

I dedicate this thesis and the conclusion of my masters to the person who I believe has the wisest and the most reasonable of personalities. His extremely simple view on life guides, to the best of my efforts, the way I face life itself. The sincerest thank you to my dear *Avô Tó* for the countless joy he brings to all of us and for the valuable insights on life which I shall carry with me forever.

To the following people I send my love and a very special thank you:

- My supervisor, for the patience, availability and valuable inputs throughout the whole process;
- My parents and 3 brothers, who shaped me to the way I am today;
- My girlfriend who, every day, gives me all the joy and support I need;
- All staff from IPST, Coordenação Nacional de Transplantação and the GCCT of the CHLC, who were always available and willing to freely provide information and specialized knowledge on the matter;
- To ISCTE, which always provided its students with every mean to successfully conclude their degrees and thesis.

Without the support of the mentioned people and institutions, the conclusion of such paper wouldn't be possible.

Resumo

A escassez de tecidos disponíveis para transplantação é um problema em todo o Mundo, nomeadamente em Portugal, pois a procura excede a oferta disponível. Neste contexto a problemática central deste trabalho consiste em saber como pode ser melhorado o contexto atual de escassez crónica de tecidos disponíveis para transplantação. Portanto, o objetivo deste trabalho é contribuir para a compreensão da problemática da doação de tecidos e definir estratégias para melhorar o contexto de escassez de tecidos disponíveis para transplantação em Portugal.

Metodologia: Neste estudo foi utilizada uma metodologia qualitativa com recurso a uma revisão sistemática e consistente da literatura, entrevistas com especialistas, reuniões informais, observações não participativas, pedidos de dados oficiais e pesquisa em *sites* institucionais, bases de dados bibliográficas e sites governamentais. Para uma análise mais objetiva dos processos de doação em Portugal, das suas lacunas e problemas, foi utilizado o método de análise de conteúdo para a análise de 6 entrevistas semiformais. Esta análise foi efetuada com o apoio do *software* TROPES® versões 8.4 e 7.2. A análise SWOT foi utilizada para integrar toda a informação de forma a facilitar a compreensão do contexto e estabelecer possíveis estratégias de melhoria.

Resultados: Os resultados da análise revelaram que as restrições económicas estão a levar a uma política de controlo de custos e a uma política institucional que limita o desenvolvimento de procedimentos novos e mais eficientes. Os resultados destacam a importância de um sistema centralizado para combater a clara falta de recursos em Portugal. O paradigma Espanhol poderá servir de para melhorar o modelo Português atual no sentido de aumentar a sua eficiência e eficácia.

Conclusões: É importante otimizar os poucos recursos alocados para a atividade e realizar atualizações de regulamentos para fornecer a base necessária para construir um sistema centralizado e mais eficiente.

Palavras-chave: Doação; Transplantação; Tecidos; Escassez.

Abstract

The scarcity of tissue available for transplantation is a problem all over the world, especially in Portugal, as demand exceeds the available supply. In this context the central problem of this work is to know how the current context of chronic shortage of tissues available for transplantation can be improved. Therefore, the objective of this work is to contribute to the understanding of the problem of tissue donation and to define strategies to improve the context of shortage of tissues available for transplantation in Portugal.

Methodology: On this research, a qualitative methodology was used with a systematic and consistent literature review, interviews with experts, informal meetings, non-participative observations, applications for official data and search in institutional websites, bibliographic databases and governmental websites. For a more objective analysis of the donation processes in Portugal, its gaps and problems, the content analysis method was used to analyze 6 semi-formal interviews. This analysis had the support of TROPES® software, versions 8.4 and 7.2. The SWOT analysis summarized all the information in order to facilitate the understanding of the context and establish possible strategies for improvement.

Results: The content analysis results showed that economic restraints are leading to a policy of cost control and an institutional-based policy limiting the development of new and more efficient procedures. Results highlight the importance of a centralized system to fight the clear lack of resources in Portugal. The Spanish paradigm may be used to improve the current Portuguese model in order to increase its efficiency and effectiveness.

Conclusions: It's very important to optimize the few resources allocated to the activity and perform regulation updates to provide the foundation necessary on which to build a centralized and more efficient system.

Key words: Donation; Transplantation; Tissue; Shortage.

Executive Summary

Portugal is currently recovering from the recent worldwide economic crisis with repercussions on healthcare, namely on the available resources for transplantation. The aim of this study is to understand the repercussions of the crisis in the context of tissue donation in Portugal and explain the gaps and strengths existing in Portugal's activity. The current context of tissue donation in Portugal as well as in the rest of the world, is of shortage of available tissues for transplantation. There is a general demand for this type of treatment that always exceeds the available supply. Therefore, the research will focus on a central problem: How can the current context of chronic shortage of available tissue be improved? The aim of this paper is to contribute for the understanding of this problem on tissue donation, explain the gaps and strengths existing in Portugal's activity and to define strategies to improve the context of shortage of available tissue for transplantation in Portugal.

Methodology: On this research, a qualitative methodology was used with a systematic and consistent literature review, interviews with experts, informal meetings, non-participative observations, applications for official data and search in institutional websites, bibliographic databases and governmental websites. For a more objective analysis of the donation processes in Portugal, its gaps and problems, the content analysis method was used to perform semantic associations through the co-occurrences analysis of 6 formal interviews to the representatives of the different stakeholders of tissue donation. This analysis had the support of TROPES® software, versions 8.4 and 7.2.

A systematic and consistent literature review together with the content analysis of 6 formal, semi-structured and recorded interviews and non-participative observations, provided a clear understanding of the context of the Tissue activity in Portugal. The SWOT analysis summarized all the information in order to facilitate the understanding of the context and establish possible strategies for improvement. A quantitative approach was not considered due to the research objectives.

Results: The content analysis results showed that economic restrains are leading to a policy of cost control and an institutional-based policy limiting the development of new and more efficient procedures. Efforts are being made in some institutions towards having a more modern tissue donation activity and increasing the number of tissues available for transplant, but always on an institutional level. Results highlight the importance of a

centralized system to fight the clear lack of resources in Portugal and to take advantage of the under-used capabilities of IPST's tissue bank.

However, the current context is also seen an extremely good opportunity to improve and reform the current legislation to provide an established, professionalized and sustainable activity. It could provide a new source of exportations, end the current tissue importations, improve Portugal's image abroad and provide a different example for other European countries to follow regarding tissue donation. The Spain's successful model can be used to build a similar one with the appropriate adaptations.

Conclusions: It's very important to optimize the few resources allocated to the activity and perform regulation updates to provide the foundation necessary on which to build a central and efficient system. Spain's results highlight the importance of efficient and smart resource allocation, which could be partially provided by IPST. Some investment is also crucial to provide the necessary means to health care professionals. Self-sustainability is at Portugal's reach, meaning that with the proper improvements, Portugal could be exporting tissue for transplantation soon.

Abbreviations List:

BTB (Banc de Teixits de Barcelona)

CHLC (Centro Hospitalar de Lisboa Central)

CHLN (Centro Hospitalar de Lisboa Norte)

CHP (Centro Hospitalar do Porto)

CHSJ (Centro Hospitalar de São João)

CHUC (Centro Hospitalar Universitário de Coimbra)

CNT (Coordenação Nacional de Transplantação)

EDQM (European Directorate for the Quality Medicines & Health Care)

EU (European Union)

EVA (Entidade de Verificação da Admissibilidade da Colheita para Transplante)

GCCT (Gabinete Coordenador de Colheita e Transplantação)

IPST (Instituto Português do Sangue e Transplantação)

OCATT (Organització Catalana de Trasplantaments)

Pmp (Per million of population)

RENDA (Registo Nacional de Não Dadores)

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1. Introduction

1.1. Choice of subject

The reason why tissue donation is the selected subject has to do with its potential for improvement. Tissue donation is extremely underexplored in Portugal and in many European countries, which provides an opportunity to set an example of an effective and efficient model (EDQM, 2017). It is believed that, since it is not yet a very established activity, small changes can bring very significant results, as recent events have demonstrated (Xavier, 2015).

Tissue donation tends to be forgotten since the most practiced donation is the organ donation because it attracts more attention and investment (Olender, 2010). This leads to an obvious lack of investment for a type of donation that has the potential of providing treatments that are more beneficial than the alternatives and significantly improve the patients' life quality (Olender, 2010).

1.2. Tissue donation context

Tissue donation contexts around the world indicate the existence of a global problem: chronic shortage of available tissues for transplantation. This means that there will always be a higher demand than the supply, due to the everyday necessity for this type of treatment (EDQM, 2017).

Tissue donation in Portugal is an institutional-based activity which relies on the work of few health professionals involved and the few resources that are available are often being miss used (CNT, 2017). This is due to a number of factors: the recent world economic crisis, the lack of experience due to the early stages of the activity which resulted in recent and meaningful technological advances (EDQM, 2017). It's an activity with which many health care professionals are not familiar with, and those who are often use outdated procedures (Olender, 2010). Recent efforts have been made to adopt modernized procedures and to become a more professionalized activity (Xavier, 2015). These problems are common in many countries, such as Portugal, which helps us to understand the current global context of chronic shortage of tissues (EDQM, 2017).

Literature review will provide a clear understanding of the situation, exploring and explaining the existing gaps and strengths of the tissue donation context in Portugal.

1.3. Definition of objectives

The definition of objectives is done from a starting definition of the problem. That is why the objectives were set to solve the main problem:

How can the current context of chronic shortage of available tissue be improved?

This problem results from the inefficient use of the available resources, the lack of investment destined to this activity and the fact that this is an activity in its early stages in Portugal. This helps to develop theories and try to understand the necessary steps that have to be taken to the achieve success in the solutions. That's why the following two objectives were set for this research: clearly understand the relevant aspects associated with the global problem: chronic shortage of available tissues; provide viable, sustainable and innovative solutions that could improve the Portuguese context.

To achieve this goals it is necessary a careful interpretation of the available literature and context, a correct application of the right methods to add and improve information and to justify and validate every assumption, conclusion and solution.

2. Literature review

When discussing donation and transplantation, it's important to have a clear idea of what is associated with the topic. Knowledge about the legislation regulating these activities is crucial to understand the complexity of the topic and analyse the ethical principles inherently related to the topic (Patrício, 2013). It is also important to highlight the uniqueness of the topic, considering the inherent need to have a donor patient, for the success of this activity (European Consensus).

A systematic review of the National and International legislation, provides a primary understanding of the process occurred in donation and transplantation (Patrício, 2013). The complexity of this process cannot be underestimated and it's important to recognize and understand the differences between the processes used for tissues and organs. It's equally important to ensure the success of the many aspects in the process to allow a successful allocation (European Consensus).

Awareness for tissue donation and transplantation is also vital to bring attention on the topic (Olender, 2010). This area, in Portugal, is currently working on very scarce resources and used to improve its results with increasingly scarce means, when compared with the rest of Europe (CNT, 2017). It's not a sustainable situation, and knowledge about tissues' potential benefits would help capture social attention (Olender, 2010).

Understanding the differences between each countries' resources and organisation allows us to draw conclusions about the disparity of their performances (EDQM, 2017).

Recent small changes in Portugal's traditional model, brought very relevant improvements in our results, which might indicate great potential for progress in this area (Xavier, 2015).

2.1. Donation and Transplantation

2.1.1. Current legislation

Law 12/1993

The current legislation in Portugal regarding retrieval and transplantation of organs, tissues and cells of human origin can be found in the 12/93 law, present in the law decree n.º 168/2015, of 21/08. This law "applies to the acts that aim the gift or retrieval of organs, tissues and cells of human origin, for therapeutic or transplant purposes, as well as to the

transplant interventions themselves.” (Assembleia da República, 2015)¹. The core of this document is divided in two parts: Chapter II - Live donation; and Chapter III - Cadaveric donation (Patrício, 2013).

In Chapter II, live donation is seen as a last resort solution. In case of donation of non-regenerable organs or tissues, the donation is only possible if there is a favourable decision by EVA (Entidade de Verificação da Admissibilidade da Colheita para Transplante) (Assembleia da República, 2015). Principles like the protection of vital integrity and the general principle of information are identifiable in the articles 6th and 7th (Patrício, 2013). The first one states that any donation that is likely to cause any serious harm to the donor is forbidden. The second applies to the donor and the transplanted patient and states that every relevant information must be appropriately given and understood by the patient (Assembleia da República, 2015).

Chapter III starts by clarifying the *opt-out* system, which states that everyone can be an organ, tissue or cells donor, unless one has been declared non-donor with the Health Ministry (Assembleia da República, 2015). All non-donors are all registered in the RENNDA (“Registo Nacional de Não Dadores”), which must always be checked in every potential donation (IPST, 2016). It is also important to mention that the main concerns regarding the donation procedures include avoiding any lacerations or mutilations of the corpse that aren’t deemed absolutely necessary, as presented in article 14 (Assembleia da República, 2015).

Law 12/2009

Another current legislation is the 12/2009 Law that regulates “the quality and safety of donation, procurement, analysis, processing, preservation, storage, distribution and application of human tissues and cells.” (ASSEMBLEIA DA REPÚBLICA, 2009)². This law does not include organs but it specifies the most important issues related to the human tissue and cell donation and application (ASSEMBLEIA DA REPÚBLICA, 2009).

¹ “*aplica-se aos actos que tenham por objecto a dádiva ou colheita de órgãos, tecidos e células de origem humana, para fins terapêuticos ou de transplante, bem como às próprias intervenções de transplante.*” Free translation of the author

² “*qualidade e segurança relativa à dádiva, colheita, análise, processamento, preservação, armazenamento, distribuição e aplicação de tecidos e células de origem humana*” Free translation of the author

It is important to highlight that it starts by defining the National tissue and cell network, stating that every authority authorized to perform this type of activities throughout through the country is regulated equally, meaning that this law is applicable to every health institution involved in such activities (Assembleia da República, 2009).

At the core of this document, we can find the requirements necessary in order to procure human tissues or cells, the provisions relating to its quality and safety as well as the consideration when selecting and evaluating donors (Assembleia da República, 2009).

This document also specifies which offenses merit sanctions and which ones apply (Patrício, 2013).

This law was updated by the 1/2015 Law and the 99/2017 Law.

Organic Laws

The relevant Organic Laws related to the main authorities are the Law Decree n°. 39/2012 regarding IPST, I.P (“Instituto Português do Sangue e da Transplantação”) – Public entity that regulates transplantation related activity (Ministério da Saúde, 2012); the Regulatory Decree n°. 14/2012 regarding DGS (“Direção-Geral da Saúde”) (Ministério da Saúde, 2012), which are both under administration of the Portuguese Health Ministry, regulated by the Law Decree n°. 124/2011 (Ministério da Saúde, 2011).

2.2. Donation Process

2.2.1. Post-mortem donation

Post-mortem donation is going to be the main focus since it is the one from which most donations occur. For many health professionals, post-mortem donation is the true meaning of life after death (EDQM, 2017). And it is understandable, since this type of treatment is often the only one possible for many patients and, in those cases, usually is the only difference between life and death (ETB-BISLIFE, 2018). However, what is truly distinctive about organ and tissue transplantation, is not technology, or cost, but its ethics since this type of treatment is always dependent on the participation of other patients (Caplan, A. 1990).

Organ and tissue donation have similar initial procedures. The common first steps for a successful donation are (EDQM, 2016, 2017):

1. Donor identification – identification of a potential donor

2. Donor screening – checking social and medical history with available documents and information provided by relatives.
3. Donor management – managing the patient’s vital signs to allow organ or tissue procurement.
4. Consent/ authorisation – relatives must be properly informed and clearly consent the donation.
5. Organ/ tissue retrieval – if organs and tissues are to be procured, organs should be retrieved first, before any tissues. All organ donors should be considered for tissue donation (European Consensus).

The next step, for organ donation, requires excellent coordination so that the organ can be allocated to a patient on the waiting list, as fast as possible, since transplantation must occur within a few hours (European Consensus). Transportation should be safe and quick to allow a successful application. It’s important to note that organs can only be donated in case of a brain death scenario (EDQM, 2016).

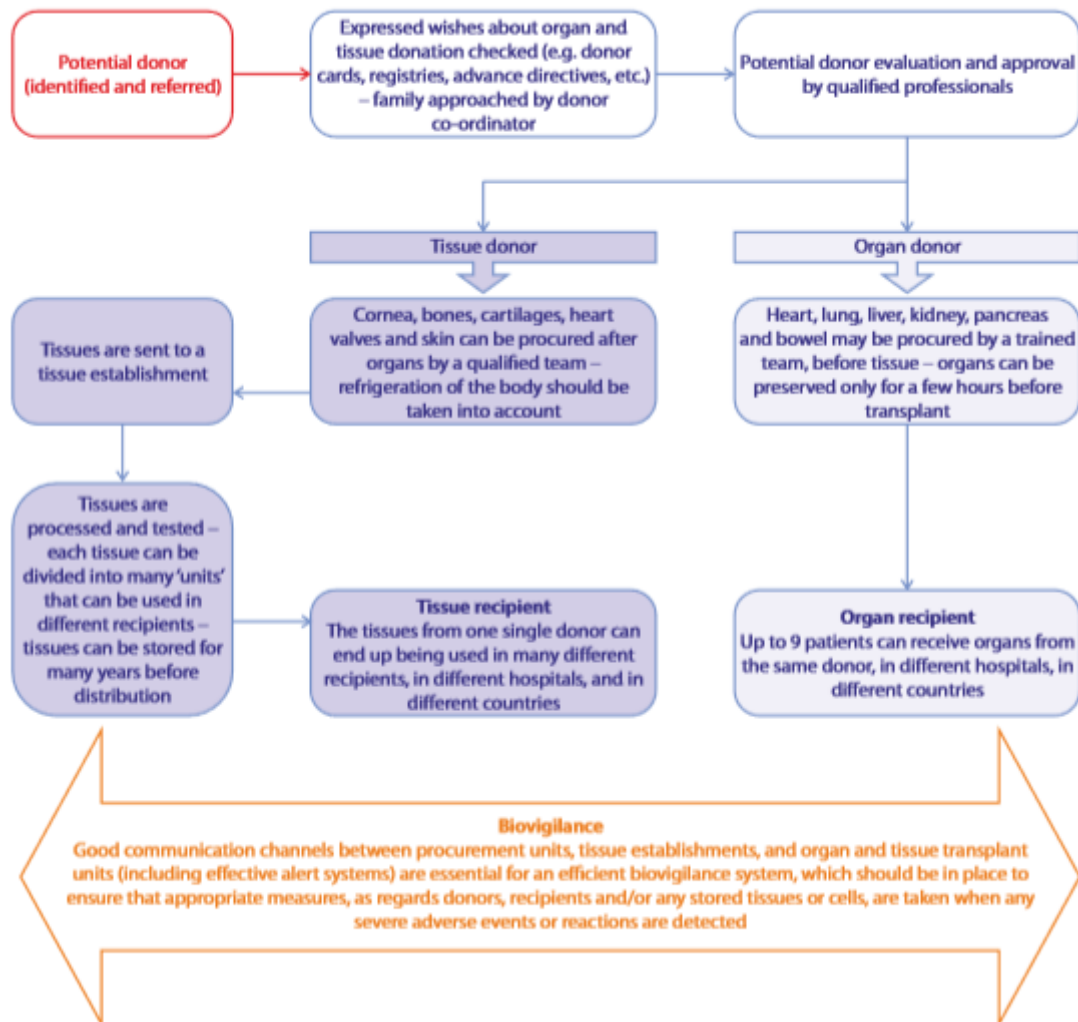
When considering tissues, these are usually sent to a tissue bank to be tested, processed, preserved, stored and later transported to the allocation site, when and where transplantation is scheduled to take place. Tissue donation can occur in cardiac death cases (European Consensus).

These processes are long and complex and require great coordination between all parties (Malm, 2016), and every operation should be registered (European Consensus). The process is outlined in figure 1 and there should be established protocols and partnerships for every step to ensure traceability of all procedures, patients, tissues and organs (EDQM, 2017).

Challenges can be found throughout the whole process (Villapalos, 2010). They include controlling of all crucial technical activities and services such as procurement, transportation, processing, preservation, quality control and storage, which will enable tissues and cells to be successfully donated to a needing patient (IPST). Reimbursement of expenses and service charges, safeguards from exploitation or misuse (e.g. formal requirements for consent from the potential donor before procurement of tissues or cells) and the complex chain of intermediaries (people and institutions) in the process of donation and human application are also complex factors to be considered in the tissue donation and human application process (Visser, 2010). How these complex links are

formed throughout the process, can also be understood by examining the following figure 1 (EDQM, 2017).

Figure 1 - Complex links from donors to recipients in the context of donation after death



(adapted from EDQM, 2017)

Although Portugal is currently performing well in the transplantation area compared to other developed countries, mainly when it comes to organs (EDQM, 2017), there is still a lot that can be done in tissue donation, and many more patients could benefit from this type of treatment (Silva, 2016). But due to the chronic shortage of organs and tissues available, most transplant clinicians must be extremely selective about those who get to enter a waiting list (European Consensus).

Regarding tissues, Portugal is not very far behind, when compared to most of the European countries (EDQM, 2017) and is close to achieving self-dependence (no necessity to import) (CNT, 2016). However, it's important to continue to improve our results such as in collecting as many different types of tissues as possible (CNT, 2017). Although, Portugal managed to achieve self-dependence in certain types of tissues (amniotic membrane) (Xavier, 2017), it doesn't mean that our goals should be limited by achieving it, increasing tissue procurement beyond that, will bring many benefits, not just financial, due to the possibility to export. It also contributes for international recognition, foreign relations, and will help far from our borders, approaching the problem of Chronic Shortage as a global issue, rather than a national or local one (EDQM, 2016).

2.3. The importance of tissue donation

2.3.1. Benefits and risks of tissue transplantation

There are two types of risks associated with tissue transplantation: Process related risks and donor-related disease transmission risks, which is why, when assessing the risk of human application of tissues, both donor and recipient must be considered. The potential benefits should always prevail over the risks. The benefits of tissue transplantation for the recipient depend on the type of tissue allocated, as can be verified on the following table 1 (EDQM, 2017).

Table 1 - Most used tissues and their potential benefits for the recipient (adapted from EDQM, 2017)

Type of tissue	Potential benefits for the recipient
Corneas/ eyes	Indicated for visual problems caused by damage or deterioration of the front part of the ocular globe; if the eyes as a whole are donated, the corneas can be used in transplants for corneal blindness and the sclera can be used for reconstructive and glaucoma surgery
Musculoskeletal Tissue	Used to repair or stabilise the spine and other bones and cartilage damaged by degeneration, trauma, cancer or birth defects; as well as in oral surgery and filling bone cavities or other areas where

	bone mass has been lost and to repair tendons, muscle, ligaments, joint injuries and deformities.
Cardiac Tissue	Used for patients with valve defects, especially in children, to replace blood vessels that are damaged by disease, trauma or prolonged dialysis treatment. Also used in bypass surgery to re-route blood flow.
Skin	Used for the treatment of burn patients, certain types of ulcers, abdominal wall repairs and reconstructive or plastic surgery.
Amniotic Membrane	Used in burns and wound healing (to reduce surface inflammation, scarring and pain in surgical applications), in certain types of ulcers and in oral, maxillofacial and ocular surface surgery.

New developments in the area are increasingly allowing many forms of tissue banking, which highlights the increasingly complicated and interconnected ways in which a person's tissues and cells may be used to help others or themselves (IPST).

2.3.2. Awareness for tissue transplantation

Repeated campaigns promoting organ donation and the frequent mention of topics related to organ donation and transplantation in the mass media have increased public awareness of this issue (Domingos, 2015). What is quite striking here is that the idea of transplantation seems to be commonly identified only with transplantation of vascularized organs like kidney, liver or heart whereas, in practice, transplantation should never be limited to organs alone (Villapalos, 2010). The complexity and drama of life-saving organ transplantation tend to overshadow the existence and importance of tissue transplantation, which not only contributes to the healing process and improves the recipients' quality of life but can also be life-saving procedures in cases of severe burns or heart valve failure (Olender, 2010).

Studies have revealed that knowledge about the topic of transplantation usually generates a positive attitude towards the issue (Conesa, 2004). This premise suggests that low awareness of tissue donation and transplantation means that the attitude towards it won't, at least compared to organ donation (Conesa, 2004; Gross, 2001).

A Polish study confirmed it, stating that people tend to support organ transplantation (94%) more than they do regarding tissues (82%). People tend to be least supportive

towards skin allocation (77%), probably because it's the most difficult to understand (Olender, 2010). Moreover, the physician involved in the process should be motivated to promote this activity, in order to improve coordination in the different steps of the process (Olender, 2010).

In Portugal, the improving results in tissue donation are mainly due to the commitment, effort and proactivity of its health professionals (Xavier, 2017), even though, due to the recent economic crisis, the resources allocated toward this area were cut significantly (around 50%) and are exponentially lower when compared to organs and hematopoietic cells (Despacho n. ° 7215/2015, 2015).

2.4. Tissue donation in Portugal: analysis and relevant comparisons

2.4.1. Activity results: Portugal and Europe

The resources have been increasingly scarce over the years but Portugal has managed to improve its results consistently (EDQM, 2015, 2016, 2017). In 2016, both the number of donors and the number of tissues procured have both improved 1% compared to the previous year (Xavier, 2017). In terms of imported tissues, Portugal has been reducing its need to import, although Portugal had to import three times more skin in 2016, than in 2015. The need to import skin tissue for transplantation is due to the fact that Portugal isn't procuring skin tissue currently. Although, it is expected that Portugal will start to procure skin tissue as well in 2018 (Xavier, 2017). Cornea importation has been reduced by 14% in the last two years and musculoskeletal tissue was imported 51% less in 2016, than in 2015 (EDQM, 2016, 2017). Overall, in 2016, Portugal had 579 tissue donors, from which 1393 tissues have been retrieved (74% of those were corneas and 21% musculoskeletal tissue) (EDQM, 2017). The number of transplanted units also experienced a growth of 2% in 2016, from 1569 to 1613, and were applied in 1400 patients (CNT, 2017). In 2016, 337 patients donated organs for transplantation, from whom 864 organs were procured, benefiting 814 transplanted patients (CNT, 2017). Based on these results, we can conclude that that tissues benefited much more patients, when compared to organs, as expected.

The Spanish model seems to be performing above the average (OCATT, 2017). For this reason, it is relevant to make a comparison between the two countries. The best way to do so, when analysing and comparing international results, is using the per million of population (pmp) rate which allows to establish comparable values across countries (EDQM, 2017).

Portugal's pmp rate for corneal donation in 2016 was 51.1, which is the 8th best rate in the European Union (EU) (EDQM, 2017). The donation of this tissue is the most popular in Portugal, due to the less demanding conditions in which a donation can occur (European Consensus). Spain occupied the 4th place in this type of donation with 82.4 cornea donations pmp, after Luxemburg (222.1), Netherlands (86.9) and France (83.9) (EDQM, 2017). The second most procured tissue in Portugal is the musculoskeletal, with 5.4 donations pmp (IPST, 2017). This type of donation may be today's most important type of tissue, since one donor has the potential to help a wide variety of patients and it

can be used in many ways (see table 1) (EDQM, 2017). Portugal's musculoskeletal tissue donation pmp rate is considerably low, compared to Spain's and to the rest of the European countries (EDQM, 2017). Spain's pmp rate for this type of tissue donations is 54 (ten times Portugal's rate) and all 22.515 tissues retrieved from 2649 donations contrast with Portugal's 299 tissues retrieved from 56 donations (EDQM, 2017). However, many countries have pmp rates higher than Spain's and some with rates well above 100 tissue donations pmp (EDQM, 2017).

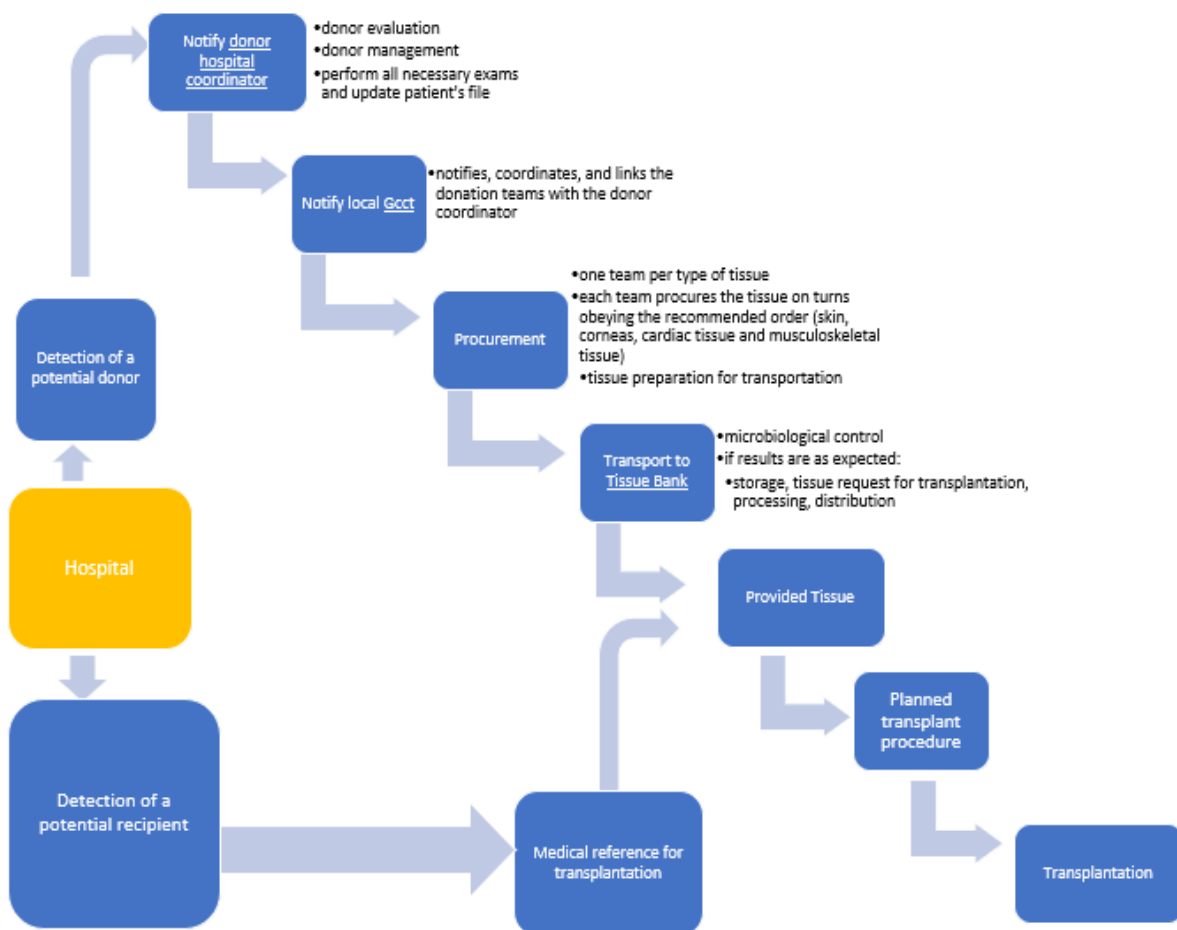
The rest of the tissues – cardiac tissue, skin and amniotic membrane – aren't procured nowhere near as much (CNT, 2017). Regarding cardiac tissue, only a few countries in Europe achieve a pmp rate above 10. In 2016, Portugal had 2.8 donations pmp, while Spain managed 5.4 (EDQM, 2107). As for skin, since Portugal isn't procuring this tissue, the rate is 0. Also in 2016, seven donations of amniotic membrane were made. In the EU, only two countries achieved a pmp skin donation rate above 10 – Netherlands and Bulgaria – and only a few countries had 2 or more amniotic membrane donations pmp (EDQM. 2017).

After analysing Portugal's performance in comparison to the rest of the European countries, it's important to understand the causes of these differences. Besides the lack of resources available, when compared to Spain, there are other aspects that relevantly influence the countries' results, such as the model in which the activity operates (IPST, 2016; Xavier, 2015).

2.4.2. A comparison between the Spanish and Portuguese models: Bringing the Portuguese model closer to its Spanish counterpart

Portugal's traditional model is similar to others in Europe. The procurement of tissues, in Portugal, is done by tissue-specific teams, which means that if a donor donates more than one type of tissue, it's likely that multiple teams will be present at the donation, making it more difficult to coordinate all the activities and retrieve the tissues in a pre-established order (CNT, 2014). A simplified process of tissue donation and allocation can be observed in figure 2 (EDQM, 2017; CNT, 2017; IPST) and it demonstrates Portugal's way of operating.

Figure 2 - Portuguese model: tissue donation and allocation process



(adapted from EDQM, 2017; CNT, 2017; IPST)

Any donation process starts in a hospital (IPST). Health care professionals that are not directly related to donation should have the necessary awareness to spot a potential donor,

in case such situation presents itself (EDQM, 2017). The next step requires the notification of the hospital donation coordinator, which every hospital, authorized to procure organs, tissues or cells, must have (CNT, 2015). The coordinator will later contact the local Gcct³ (Gabinete de coordenação de colheita e transplantação), which will contact the procurement teams and act as the link between the teams and the Hospital in which the donation shall happen (CNT, 2017). This is a crucial step in the whole process due to the stressful environment that can be created (Visser, 2010). The timing of the arrival of the teams to the Hospital needs to be as practical as possible (the greater the number of procurement teams, the more difficult will be to coordinate) and there are often last-minute requests for medical exams that the Gcct will have to provide, linking the Hospital and its coordinator to the team(s) in question (CNT, 2017).

With the procurement teams in place, the procurement process may begin (EDQM, 2017). An important aspect of this step, which is not detailed in figure 2, is that, in Portugal, most tissues are only procured when there is also organ donation. In Portugal, the only tissue that can be procured without organ donation, except for the amniotic membrane (live donation) is the cornea (Xavier, 2017). Since the contamination risk is lower, the conditions of the operating room are less demanding (European Consensus). Regarding musculoskeletal tissue, cardiac tissue and skin, the operating room must have certain conditions of temperature, air quality and asepsis, to prevent cross-contamination (EDQM, 2017). In Portugal, rooms with those conditions only exist with advanced life support, which are exclusively allocated for brain dead patients (organ donors) (EDQM, 2017).

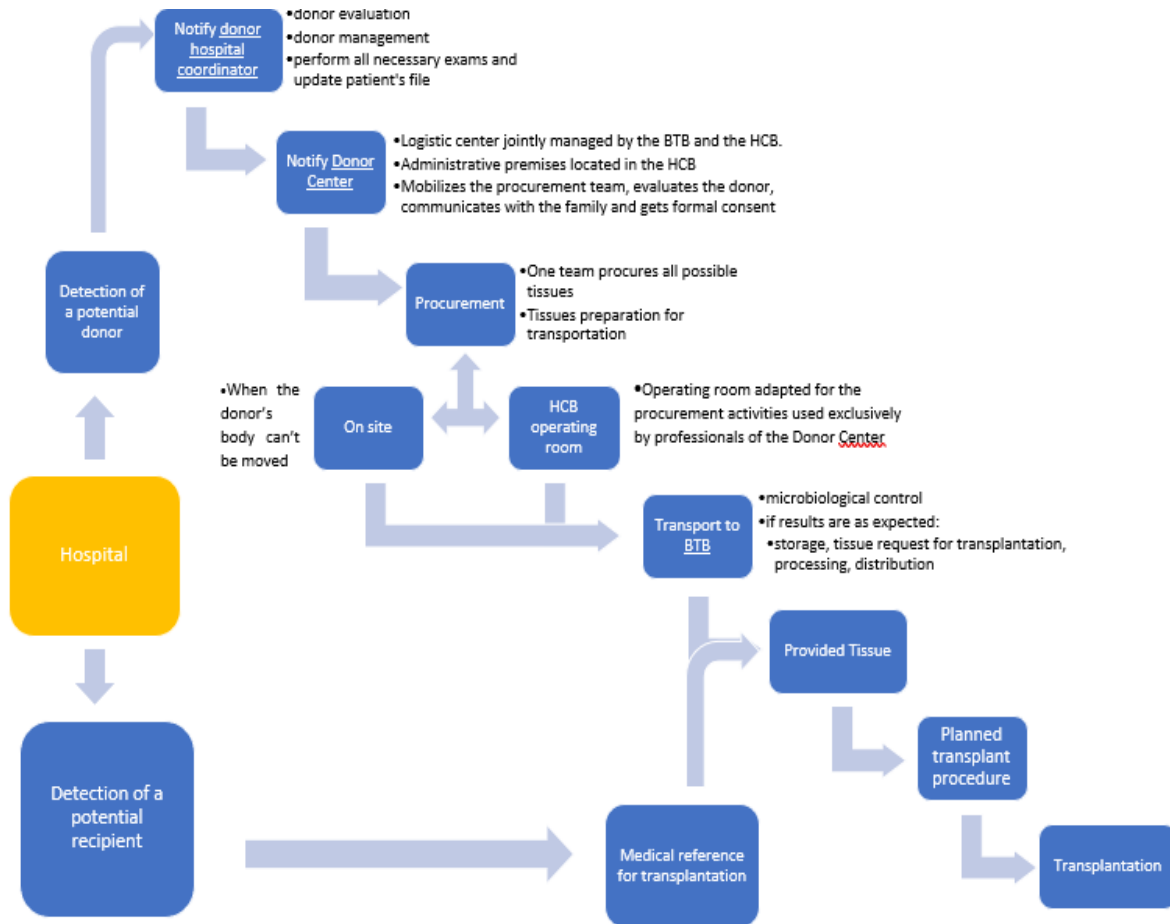
The tissue is prepared for transplantation in a Tissue Bank, where it can be processed and stored in many ways, depending on the form of application intended (IPST). The Tissue Bank must also ensure its packaging, labelling and storage (EDQM, 2017).

The rest of the process is related to the allocation of the tissue, where, if there is a suitable patient referenced to receive a transplant, the responsible doctor requests, with the local Tissue Bank, the tissue(s) intended and plans the operation in coordination with the Bank (European Consensus). The Spanish model is not entirely different from the others, but certain differences originate great performance disparities (EDQM, 2017). Those differences can be verified in the following figure 3 (EDQM, 2017; CNT, 2017; IPST).

³ There are 5 Gcct's: two in Lisbon, two in Oporto and one in Coimbra

Probably the greater difference between the two models, is that the BTB (Barcelona Tissue Bank) has much more resources than the Tissue Banks in Portugal (BTB, 2017). Right away, it allows the BTB to own their own operating room in the HCB (Clinical

Figure 3 - Spanish model: tissue donation and allocation process



(adapted from EDQM, 2017; CNT, 2017; IPST)

Hospital of Barcelona) which is adapted to have the necessary conditions to procure all types of tissues, and only the Donor Center professionals can work on it (BTB, 2017). The BTB has also built a similar room at the Legal Institute of Catalonia. Thanks to these premises, procurement teams can procure tissue from non-organ donors (OCATT, 2017). The procurement teams also belong to the BTB, and, in the Spanish model, only one procurement team is present at the donation, despite the number of types of tissue to be procured, since these teams receive special group training for that (OCATT, 2017).

The fact that Spain has premises that allow them to procure tissue from any potential tissue donor, and that their procurement teams collect all types of tissue, mark the main major differences between the two models (OCATT, 2017). In addition, it allows them to consistently be an international benchmark of tissue donation (EDQM, 2017).

With Portugal's resources and organisational structure, it's impossible for a Tissue Bank to have that kind of financial autonomy, which makes the Spanish model very hard to replicate (IPST, 2015). There are, however, other alternatives. In 2015, there was an attempt to adopt some features of the Spanish model. With the cooperation of the BTB, the first Portuguese multi-tissue procurement teams were created (Xavier, 2015). However, only one multi-tissue procurement team is currently functioning, at São José Hospital in Lisbon, which allowed immediate and relevant performance improvements at the Hospital's tissue donation activities (Xavier, 2015). In their first year of activity, donations improved 17,6%, which raised the number of tissues procures by 26,1%. The musculoskeletal tissue was the most affected one, with just one graft being procured in 2014, and a total of 93 in the following year (Xavier, 2015).

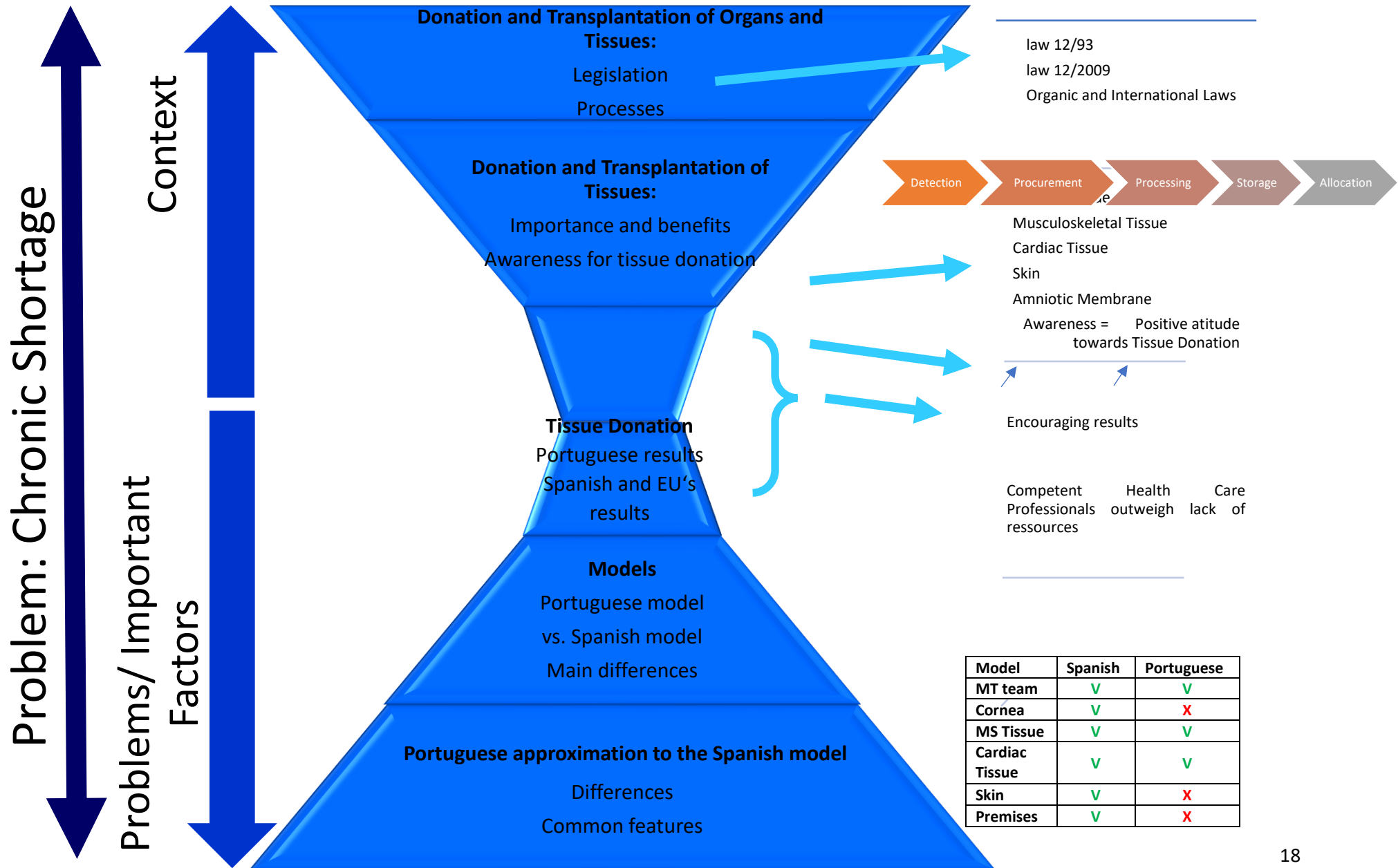
Since this is a new working format, very recently acquired by the São José Hospital, it's expected to be a learning curve, with continuously improving results and processes (CNT, 2015). Nowadays, the multi-tissue procurement team is not procuring cornea (the hospital already procured cornea in donors after cardiac death, since the operating room, for cornea donation, have less demanding requirements than for other tissue donations) neither skin, although it's expected that skin donation will occur at the São José Hospital in 2018 (Xavier, 2015). Another difference lies on the fact that the procurement team only procures tissues on donors expected to donate organs as well (brain dead donors), due to the lack of premises with the needed requirements to procure tissues (Xavier, 2016).

Even though São José's procurement team is only doing part of what a typical Spanish procurement team does, the results show that the few changes that were made, brought very relevant results, which indicates that this is an area with great potential (Xavier, 2015).

If Portugal manages to adapt its model to become more similar to its Spanish counterpart, it will be possible to increase significantly our performance with a few strategic changes (CNT, 2015).

3. Conceptual reference framework

Figure 419 - Portuguese tissue donation context



There are many and important topics to approach, when studying Tissue Transplantation. But, firstly, it's important to understand that the goal is to improve the current situation: Chronic shortage of available tissues. So, it's appropriate to approach it from the management point of view in order to improve results and being able to help more people (EDQM, 2017). From the literature review, it can also be concluded that much of the current situation is due to management related issues.

The conceptual reference framework demonstrates how the literature review's topics link between each other, starting with an understanding of the context to conclude which are the characteristics/factors that are responsible for the activity's status.

3.1. Context

There are concepts related to Donation and Transplantation that very important to consider when discussing the theme. The Legislation that regulates these activities and its Processes are concepts that are always relevant, regardless of the matter in discussion. A general knowledge about these concepts is the first step to be able to have an educated discussion on the problem (Patrício, 2013). The relevant legislations are the ones that regulate the activities nationally (Law 12/93 and 12/2009), internationally and the legislation concerning the public agencies responsible for the areas (Patrício, 2013). Regarding the activities' processes, it's relevant to understand the steps that are common to both organs and tissues, and what are its' main characteristics (European Consensus). However, tissues have certain characteristics that require a different process. After procurement, tissues must be processed and stored to ensure its quality and be packaged and labelled appropriately to ensure its traceability. To have a successful allocation, all the previous steps must be fulfilled without problems (EDQM, 2017).

Focusing on the Tissues, its potential benefits and importance, it can be concluded that despite the complex process necessary, tissues have a real potential to help a lot of people, improving their life quality and even saving lives (EDQM, 2017). This is something that surprisingly have very little awareness, which harms the activity. A general knowledge on subject, especially among health professionals would smooth the whole process and turn it more effective (Olender, 2010).

The activity's results are the last piece that completes the context. A careful and comparative analysis of the results, allow us to understand that certain types of tissues are more available and procured than others in Portugal, but Portugal's performance

internationally is consistent and with room for improvement (CNT, 2017). A deep analysis on the results can give clues of the final important factors that need attention when discussing the improvement of Portugal's performance.

3.2. Problems/Important factors

Some authors considered that the Spanish way of working it's close to the optimal (OCATT, 2017), it's important to study it and understand what makes it successful. The answer to improve the performance may lie in the Spanish Model, and there might be some underlying characteristics in the model that can overweigh the current lack of resources (Xavier, 2015). The Portuguese approximation to the Spanish model, which happened at the São José Hospital in 2015, is proof that adopting some of their characteristics can have a great positive impact. The adoption of the multi-tissue procurement team was a great success and a great step towards relevant improvement (Xavier, 2015).

Currently, the structural factors that differentiate the Spanish model and the São José Hospital's way of working are: at São José, the multi tissue procurement team is not procuring cornea (corneal tissue is procured separately) nor skin (skin procurement expected to begin in 2018) and in Portugal there are no premises adapted for tissue procurement (tissue procurement must occur only after organ donation) (CNT, 2017).

Despite the natural gap between Europe's main countries and Portugal, there is a desire to improve and work is being made to close this gap.

4. Methodology

A qualitative approach was used during this research. The resources were 6 interviews, informal meetings with experts, non-participative observations, applications for official data, search in institutional websites, bibliographic databases and governmental and institutional websites. Moreover, a systematic and consistent literature review provided a clear understanding of the context of the Tissue activity in Portugal, which was facilitated by a formal application to gain access to official and relevant information (ANNEX I). Finally, a non-participative observation of processing a Tissue (musculoskeletal) in the public Tissue bank of IPST, allowed a better understanding of the requirements and processes involved in such an important operation.

A quantitative approach was not considered since the aim of this study is to understand the context of the Tissue activity in Portugal and if it is possible to apply and implement strategic measures.

Throughout the investigation, some meetings with experts led occurred and their insights were used to guide the investigation and clarify many doubts and questions. Semi-structured interviews were conducted, since Tissue donation is still an under-developed area in Portugal, there wouldn't be a big or relevant enough sample to perform surveys. The 6 interviews were tape recorded, transcribed to word and translated in order to do content analysis method. Anonymity was assured through a declaration of consent and the analysis was subjected to the interviewees' approval.

Content analysis is a research methodology used to describe and interpret the content of a text. To Bardin (2009), content analysis, as a method, is a set of techniques of analysis of communications that uses systematic and objective procedures of description of messages' content. Categorization, description and interpretation are the essential steps in this methodology of analysis. Systematic, quantitative or qualitative analysis help the reinterpretation of the text and allows an understanding that a simple read wouldn't. The goal is to perform a qualitative interpretation of a text, supported by quantitative data, excluding any subjectivity of the researcher from the research (Bardin, 2009). Current applications of content analysis show three distinct approaches: conventional, directed, or summative (Hsieh, 2005). The researcher used the summative content analysis because besides counting and comparisons of keywords he did the interpretation of the underlying context. Accordingly, 3 types of analysis were made: frequency analysis, where the

frequency of certain keywords were analysed; evaluative analysis, where the attitude of the interviewees towards the subjects were analysed; and associative analysis where the relations between certain keywords were analysed.

In a content analysis is important to set the objectives to help set boundaries to the research (Heish, 2005). This analysis aims to draw conclusions on: Why is Portugal in this current context? Which areas have the most potential for improvement? What are the biggest challenges? Therefore, questions were made in an attempt that interviewees would freely approach these subjects and the text was edited and interpreted in a way that the objectives would be the main focus.

Data from the interviews was categorized into pre-defined dimensions. The initial dimensions that are considered in the process of Tissue donations are as follows:

1. Activity context/ results in Portugal;
2. Challenges in Tissue donation;
3. Gaps in the Tissue donation area;
4. Innovation in the Tissue donation process;
5. Awareness about Tissue donation;
6. Legal and ethical issues in Tissue donation and transplantation.

Six interviews were conducted, tape recorded and transcribed to word between June and July of 2018. The interviews were later translated to English and edited to an appropriate format to be run in the Tropes software. The interviews had an average duration of 24 minutes of recorded text, with a minimum of 12 minutes and a maximum of 43 minutes, as can be seen in table 2.

Table 2 - Description of the participants and duration of the interviews

INTERVIEWEES	DURATION
COORDENAÇÃO NACIONAL DE TRANSPLANTAÇÃO (POLITICAL DECISOR)	42 minutes
COORDENAÇÃO NACIONAL DE TRANSPLANTAÇÃO (POLITICAL DECISOR)	18 minutes
COORDENAÇÃO NACIONAL DE TRANSPLANTAÇÃO – TISSUE SPECIALIST (POLITICAL DECISOR)	12 minutes

GCCT OF CHLC – MULTI-TISSUE TEAM	31 minutes
GCCT OF CHLC – MULTI-TISSUE TEAM (POLITICAL DECISOR)	23 minutes
BARCELONA’S TISSUE BANK – DONATION SPECIALIST (FORMER MEMBER OF IPST)	20 minutes

It was used a convenient sample to target different stakeholders involved in the Tissue donation and transplantation in Portugal.

The macro, meso and micro levels of decision in healthcare are considered in this study. The macro level comprises the health system at a central level such as the National Transplantation Coordination as part of the IPST. The meso level comprises the health system at both the local and the organizational level, such as the Donation and Transplantation Coordination Office. The micro level includes the health professionals that are part of the Multi-Tissue Team. Inclusion of the three groups was considered relevant to obtain multiple perceptions and relate information on different organizational levels. However, the underdevelopment of the specific area of Tissue donation, limited the number of interviews that were made and tape recorded.

Interviewees were chosen based on their influence in the area, experience and role in Tissue donation and years in strategic positions. 1 Interview was impossible to conduct due to bureaucratic issues, with a IPST bank professional – specialist in tissue processing – hence the non-participative observation that helped to clear notions about Tissue processing.

The majority of the questions were open in order to limit as less as possible the interviewees’ answers but still directing them to a relevant topic of discussion (i.e. “What do you think about...”) (Farago & Fofonca). Occasionally closed questions had to be made to confirm or deny certain aspects (i.e. “Do you think...is enough?”).

The main questions and common to all interviewees were the following:

1. What do you think about Portugal’s results in the Tissue area, considering Portugal’s resources and comparing with the other countries in the European Union?
2. What are the biggest challenges for Portugal in this area, in your opinion?

3. What is the most urgent aspect to be changed in this area, in your opinion?
4. The introduction of the Multi-Tissue team in Portugal's model brought immediate and relevant results. What do you think about the creation of other teams like this and how much room for improvement is there for this team?
5. How adequate do you think is the legislation regarding the financial incentives destined to this area? Are there other aspects that you would consider relevant, related to legislation?
6. Considering that the donation process starts with the identification of a potential donor, which can happen anywhere, how important is to have a general knowledge of the subject?

Content analysis of interviews was performed with Tropes® software in order to identify the main problems in the Tissue donation activity. Semantic associations through word frequency were used as support for content analysis. Tropes software proposed numerous Semantic Analysis tools since it has been intentionally designed to analyse the semantic structure and to identify the references found in various texts. Only the essential information is retained (Tropes, 2012).

The data was compared and some information was removed in order to obtain only the relevant information for the research question. It was also possible to extract the words that influence or are influenced by each category and to establish relationships between the different categories. The different kinds of relationships can be represented in several kinds of charts. The selection of the charts was done considering the aim, the dimensions of the research and their readability. In each chart, it's possible to identify the frequency of each word in the interviews and, in the charts with spheres, it's possible to also visualize the words more related with a category or the relationship between categories, according to the dimension of the spheres and the distance from the middle of the chart. This allowed an understanding of the importance of some words and the different relationships between the studied categories.

After the extraction of information and analysis of the semantic relationships, conclusions were drawn to develop theories which might eventually influence strategic decisions. This method was used to understand not only the context and problems of the Tissue donation in Portugal but also to learn possible ways of action to improve the current situation.

5. Results

The applied qualitative methodology was mainly inductive, based on the literature review, non-participative observations, tape recorded interviews and on the content analysis method. A SWOT analysis was done to facilitate the interpretation.

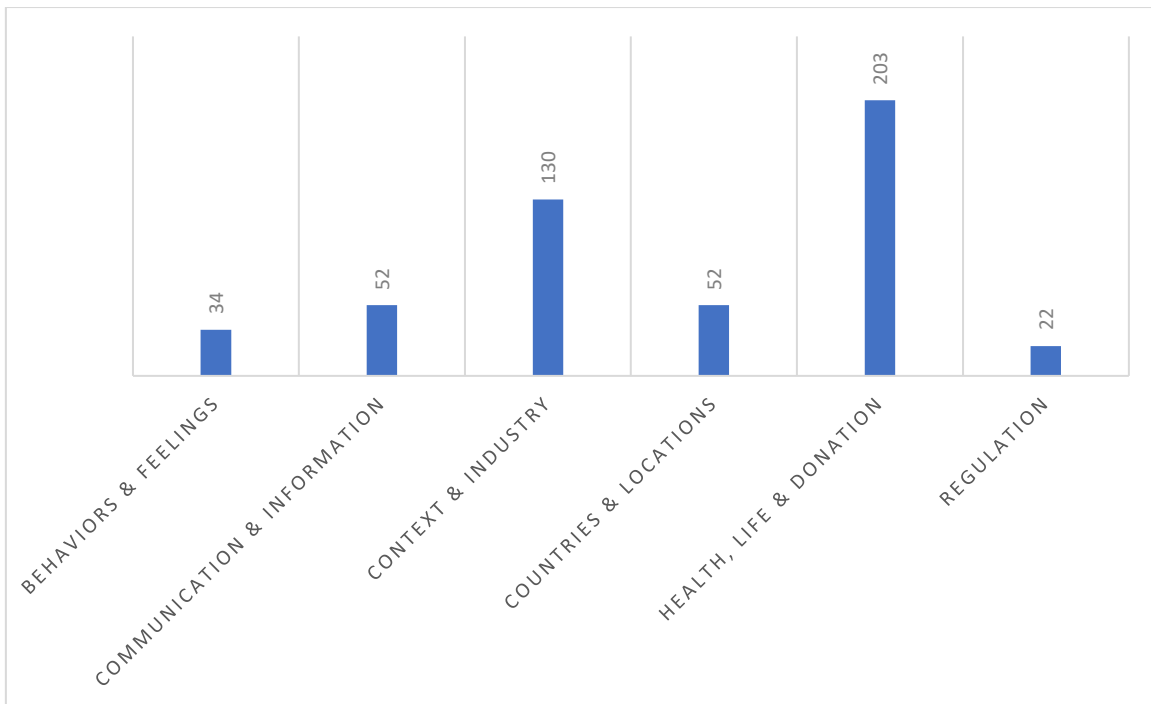
From the observation of the processing procedures to perform on musculoskeletal tissue, some conclusions were drawn. A team of 3 health professionals adapted the musculoskeletal tissue to be suited for application in a several hours' operation. These bank employees know before-hand how the tissue is expected to turn and need to have many demanding cares regarding hygienic and safety issues. A successful achievement of all the requirements and steps, results in a Tissue ready for a specific application with internationally recognizable quality. The IPST bank has the human resources and means necessary to process every tissue according to European recommendations, which highlights the importance of this public institution. This means include the recommended medical tools and the facilities with all the technical requirements recommended by European guidelines.

From the content analysis provided by Tropes® many conclusions were drawn, which data was edited and filtered by the researcher in order to obtain only the most relevant information.

5.1. Content analysis results – Categorization

The content analysis results are provided by Tropes® which generated the following categories, represented in figure 5.

Figure 5 - Categories generated by Tropes®



The figure 5 indicates that 6 categories were obtained and that the one that was more discussed throughout the interviews was Health, Life & Donation. The different categories were obtained from the semantic analysis and, in spite of the different frequencies, all of them are important according to the objectives and methodology of the research.

The categories were codified and defined. Each category's code, examples representing each category, their definitions and the frequencies of the words were obtained with TROPES® support and are represented in table 3. The categories had different frequencies (table 3) with "Health, Life & Donation" being the most representative followed by "Context & Industry", "Countries & Locations", "Communication & Information", "Behaviors & Feelings", "Related Work" and "Regulation", as we can observe in figure 5 and table 3.

Table 3 - List and description of the categories

CATEGORIZATION	CODE	DEFINITION	EXAMPLE	FREQUENCY
BEHAVIORS & FEELINGS	Behavior	Relation with people's	"This was based on an initiative of the IPST,	34

		behaviors and feelings	together with the Tissue Bank of Barcelona...”	
COMMUNICATION & INFORMATION	Communication	Relation with different ways to communicate informative content	“...and together with the communication office we have prepared a poster with the characteristics required by...”	52
CONTEXT & INDUSTRY	Context	Relation with context and state of the industry	“...generating end products in a centralized way, it is possible to optimize the surgical times in a better way.”	130
COUNTRIES & LOCATIONS	Locations	Relation with countries, locations and areas	“ Portugal will achieve (...) in the first phase. It should not be forgotten that the Barcelona model (...) meets the needs of all of Catalonia. ”	52
HEALTH, LIFE & DONATION	Donation	Relation with medicine, health, death and donation	“...it is possible to optimize the surgical times in a better way.	203

		What happens in particular in the example of the corneas... ”
REGULATION	Regulation	“...done and is within the law, respects all principles, the 22 more easily the activity is done. “

5.2. Content analysis results – Scenario

The 6 categories were divided into subcategories, each of one with different frequencies. The subcategories obtained from the analysis of interviews with Tropes® are presented in the following tables according to the frequency of words. Each subcategory is represented by some examples and is considered to be relevant according the objectives and methodology of the research (tables 4 to 9).

Table 4 - Description of the category Health, Life & Donation

<u>Health, Life and Donation (227)</u>	
Donation (122)	<p>“What happens in particular in the example of the corneas, formerly only the whole cornea transplant was done, therefore total keratoplasty.”</p> <p>“...but in the context of a brain death donor where the organ harvesting team will be there...”</p> <p>“Regarding the skin, we do not have at the moment because we do not yet have technical conditions for harvesting skin.”</p>

<p>Medicine and Health (105)</p>	<p>“It all starts with a part of individual initiative of the hospitals in order to respond to an individual need of each institution”</p> <p>“...generating end products in a centralized way, it is possible to optimize the surgical times in a better way.”</p> <p>“In relation to the musculoskeletal system, to the valves, all this, the Institute has at the moment the technical conditions, of rooms, of equipment, of human resources, necessary...”</p> <p>“...and transplantation) of the hospital of San José, is made up of nurses and technicians and is supervised by a medical surgeon.”</p> <p>“...but we could harvest in the hospitals around us, namely Beatriz Ângelo, Garcia da Horta...”</p>

Table 5 - Description of the category Context & Industry

<p><u>Context & Industry (130)</u></p>	
<p>Amounts (14)</p>	<p>“To move from one phase to another there are always a number of obstacles.”</p> <p>“Regarding the corneas we have to know exactly the number of patients we have on waiting lists...”</p> <p>“...is in a position to harvests in more places, thanks to the number of large</p>

	<p>hospitals in the south and the geographic area involved.”</p> <p>“...not only of transmission, of having a sufficient number of abnormal situations...”</p> <p>“It is necessary to consider the number of professionals involved, the times of occupation, the techniques developed...”</p> <p>“...they send a sms with the number of the process”.</p>
<p>Costs (15)</p>	<p>“...which involve high costs and allow the use for other patients to be operated.”</p> <p>“Here in Portugal nothing works without money. So we need to start there. Maybe associate the Money factor with the evaluation of hospital activity. For hospitals is all that matters: Money and nice results in terms of evaluation.”</p> <p>“...because part of the compensation has to go to pay for the necessary materials. Then there is not much left...”</p>
<p>Investment (4)</p>	<p>“That's a more personal investment. But what happens is...”</p> <p>“...what we could do without an extraordinary investment is the allocation of an exclusive operative block for tissue procurement.”</p>
<p>Labor & Work (26)</p>	

	<p>“...where it's not welcome an outside team perform work that insiders do or could do.”</p> <p>“...let's work little by little maybe something can be done. The team of St. José is a great example...”</p> <p>“...because in the work of health professionals this is an issue that rarely appears and the more people think about it”</p> <p>“...the units of harvest can work with a collaboration agreement and I think it is an advantage...”</p> <p>“But someone who is sensitized can probably do extra work even without the necessary or desirable conditions.”</p>
<p>Potential (16)</p>	<p>“We have the potential to do more, because we have donors from which no tissues are harvested...”</p> <p>“...and that we can optimize the full potential of donation in the deceased that meet the selection criteria.”</p>
<p>Supply & Demand (11)</p>	<p>“Because IPST is the only entity that can import tissue...”</p> <p>“...this capacity of tissue distributor, is implemented already.”</p> <p>“If we have tissue bank that can supply products with just as high or higher</p>

	<p>quality than those that come from outside...”</p> <p>“...it’s easier to find suppliers from the United States or ask for a part especially from the Barcelona bank than to ask IPST to start developing new products...”</p>
Tissue Banks (47)	<p>“Centralizing these operations in the tissue bank of the IPST, was the great objective, similar to...”</p> <p>“This was based on an initiative of the IPST, together with the Tissue Bank Of Barcelona, to carry out practical training...”</p>

Table 6 - Description of the category Countries & Locations

<u>Countries & Locations (52)</u>	
Countries (46)	<p>“So that Portugal becomes self-sufficient in relation to the corneas. In a first step is to respond to internal needs...”</p> <p>“At the moment, at European Union level, we have between 80 and 90 transplants per million inhabitants (pmp)...”</p> <p>“In Catalonia, despite having a population of 8 million, they have managed to centralize tissue banks in the last 10 years.”</p>
Locations (6)	

	<p>“Maybe if we got one team in the north and another in the south would be enough for these needs.”</p> <p>“In the case of the southern zone, where this training was carried already out by IPST in collaboration with the tissue bank of Barcelona...”</p>
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Table 7 - Description of the category Communication & Information

<u>Communication & Information (52)</u>	
Communication & Information (38)	<p>“...and they have a number of hospitals in their network. They have in Faro, in Funchal, in Beja, etc.</p> <p>“...and together with the communication office we have prepared a poster with the characteristics required by the process of accreditation in...”</p> <p>“Many of the protocols are still initial protocols and have not yet been reviewed. In addition, the national coordination has sent just a draft for the revision of the protocols...”</p> <p>“...namely the University of Trás-os-montes and Minho, have organized several seminars and workshops, which gave rise to relevant results...”</p> <p>“For example we have a lot of data, we have a lot of information, but it is not treated.</p>

News & Media (4)	<p>“...where organ donation has a more media impact and is characterized by being life-saving and therefore there is a greater investment of governments and the state.”</p>
Train (10)	<p>“...and we are at this moment training people to have technicians capable of developing this activity...”</p> <p>“But we have to train more people, even because it is important to pass, at this stage, all that has been learned.“</p> <p>“...to be able to train them. Because we do not have so many opportunities to form practically...”</p>

Table 8 - Description of the category Behaviours & Feelings

<u>Behaviours & Feelings (34)</u>	
Advantages & Privileges (7)	<p>“...to take more advantage of and to profit from the corneas that are harvested. And this is going to take up block time...”</p> <p>“So there is still a lot of work to be done to take advantage of the potential there is.”</p>
Behaviours (12)	

	<p>“This was based on an initiative of the IPST, together with the Tissue Bank Of Barcelona, to carry out practical training for the acquisition of the technique of collecting various tissues.”</p> <p>“But even this whole area still lives much of the goodwill of professionals, which in my opinion is absolutely unjustified.”</p>
Feelings (3)	<p>“And I think that the legislation should encourage the harvest because it doesn't encourage at all...”</p>
Opinion & Guess (12)	<p>“As things evolve and, from an organizational point of view, the country is structured, we create the need for a cost...”</p> <p>“Because people can sense that they are being looked aside for something they are doing well”</p>

Table 9 - Description of the category Regulation

Regulation (22)	
Attitude (3)	<p>“...is within the law, respects all principles, the more easily the activity is done.”</p>
Control & Regulation (3)	

	<p>“...when not evaluated, can transmit diseases. And this must be taken into account. But if the donors are scrutinized well...”</p>
<p>Criteria (7)</p>	<p>“In this hospital, all those who meet criteria for harvesting corneas are triggered...”</p> <p>“...and we already know that the tissues have a much narrower collection and selection criteria than the organs...”</p>
<p>Law (9)</p>	<p>“Legally the law is interpreted in a certain way that limits the harvest, but which in fact can be interpreted in a broader way so as to limit the harvest less.”</p> <p>“I find it more important to be in the law the minimum constituent elements of the cabinets...”</p>

5.3. Content analysis results – most important phrases/ sentences

The style of the interviews was rather argumentative, involving the researcher and the interviewees and the staging is active, dynamic and based in reality. The TROPES® software allowed to extract the most important sentences from each one of the interviews.

Some interviewees agree that the current context of tissue donation in Portugal depends on “(...) a part of individual initiative of the hospitals in order to respond to an individual need of each institution”. Such happens because there is a “(...) need to have available tissue to the development of bone and corneal banks in several hospitals” to enable a “(...) direct application (...)” (Source: CNT decision maker).

However, “(...) there are many new techniques that can be performed without spending time in the operative block, which involves high costs (...)” and are much more efficient, since it allows tissues to be useful to more people in need. Such techniques need a centralized system to be performed. In relation “(...) to the musculoskeletal system, to the valves, and the rest of the tissues, the IPST has at the moment the technical conditions, of rooms, of equipment, of human resources, necessary (...)” to distribute processed tissues with internationally recognized quality (Source: CNT decision maker).

According to this political decision maker “The biggest problem right now is the transition phases. We have gone from a stage in which hospitals harvest the corneas for application in the hospitals themselves, now we are going to a second phase (...)” in which the tissues are shared with IPST for processing and can be multiplied to be applied in multiple patients. “In relation to the tissue bank of IPST (...)”, the “(...) capacity of tissue distributor, is already implemented” meaning that IPST is able to distribute processed tissue to any health institution in the country, working as a processing and distribution center (Source: CNT decision maker).

It is important to understand also that in Portugal “(...) institutional donation is an asset to hospitals and a factor of differentiation (...)” and “(...) with the current legislation hospitals are receiving funding so the Institute could not be also a center for harvesting” (Source: CNT decision maker).

Focusing on hospitals, it’s mentioned that the role of “(...) the donor coordinators’ role (...)” in the hospitals is to evaluate and be “responsible for identifying the potential donors (...) and here the scrutiny of the donor has to be very large (...)” since “(...) the initial restriction is the fear of disease transmission”. Also the presence of an “hospital team that can harvest all the tissues possible from a certain donor, is crucial” and “(...) decreases the need for Portugal to import” since it brought an “(...) exponential increase in the number of tissue donations” (Source: CNT decision maker).

According to another CNT member, “This whole area still lives much of the goodwill of professionals, which in my opinion is absolutely unjustified”. The donation area “(...) should already be an established activity and be part of the normal operation of a hospital”. In relation to the multi-tissue team, the interviewee explains that “The initial idea was to implement a thing more similar to the Barcelona model (...)” where the team

would belong to the tissue bank or would have members from the tissue bank (Source: CNT member).

However, in the last few years, have been witnessed some important developments since that in the beginning “Tissue donation wasn't financed (...)” and now they are, although still very much underfinanced. That’s why the interviewee considers that the most important thing to change is the financing destined to this area, “(...) as nothing gets done without money” and even the “(...) hospitals complain that they don’t have the necessary resources(...)”. It is also considered that “The introduction of tissue bank members in the multi-tissue procurement team is crucial (...)”, since the hospitals need resources that the bank can offer and “The bank is interested in having tissue to process and distribute (...)” (Source: CNT member).

Another important problem in the Portuguese system is that “There is no operating room exclusive to tissue donors (...)”, meaning that tissue procurement is only being done after organ donation, and cardiac failure donors are not donating tissues (“most tissue donors are heart-stopped donors that actually die in the nurseries and are sent to the morgues, where a nurse could evaluate all hospital casualties and select those fit for tissue donation” which must occur in a suitable operating room) (Source: CNT member).

The awareness for this issue is also considered to be “(...) extremely important, so people can understand, once and for all, that the placement of non-human prostheses is much more expensive and long-term results are not as good as the ones with the application of tissues”. It’s also explained that “(...) there’s also the issue of disease transmission, but with today’s technology, that risk is becoming much more reduced and controllable” (Source: CNT member).

For a CNT member responsible for the tissue donation area, “The law is interpreted in a certain way that limits the procurement (...)” since it’s being interpreted as being mandatory that a doctor is always present throughout the whole process. “But which in fact can be interpreted in a broader way so as to limit the harvest less (...)” since that it is not specifically written (“it only refers the medical responsibility, which is obvious”) and this could allow nurses and technicians to do most of the work and, therefore, increase the procurement team’s flexibility (Source: CNT tissue specialist).

Another problem has to do with the “(...) fact that there are always many other activities that are exercised by these professionals and we have realized also that it is only with

very good will that things can get done” in this area. The fact that in Spain there are professionals exclusively dedicated to this area was mentioned as a factor that concedes a lot of flexibility to the procurement teams. Another factor that could help with the team’s flexibility is the introduction of “new members to the team from different institutions, like the IPST”, as previously referred (Source: CNT tissue specialist).

It is also mentioned that since “There is a major concern for detecting organ donors (...)”, it becomes easier to neglect the detection of “(...) other types of donation, strengthening the idea that this area still has lots of room to be improved” (Source: CNT tissue specialist).

A nurse member of the São José’s multi-tissue team and the CHLC GCCT explains that at São José’s “(...) hospital, all those who meet criteria for harvesting corneas are triggered, and the processing, evaluation and all activity is managed by the GCCT, while the harvest is conducted by the cornea application unit”. Regarding skin explains that “(...) we still don’t have the necessary technical conditions (...)” but “(...) the equipment is already in acquisition phase”. That creates “(...) the need to import when a skin transplant is necessary. (...) As for musculoskeletal tissue, it’s harvested when there are organ donors that meet the criteria (...)” and there are procedures in place in order to allow this team to “(...) harvest in the hospitals in the Lisbon area when these types of donors are detected” (Source: GCCT and MT team member).

In the interviewee’s opinion, the biggest challenge lies in “(...) the formation, to have tissue harvesting there must be training” and it’s not easy to “(...) train each person that is allocated to a service (...)” and then must perform procurement procedures “(...) out of their normal working schedule”. To overcome this challenge “We have proposed to organize trainings in collaboration with the hospitals regarding these organ and tissue donation and transplantation programs” because it is extremely important to “(...) the activity of harvesting and transplantation to be a continuous activity, so is the awareness.” (Source: GCCT and MT team member).

Regarding the financial incentives destined to the area, is believed that the “(...) area is underfinanced (...)” which is “(...) a great limitation to attract health professionals to the activity” and explains that “(...) the law is interpreted in a way that the incentives are destined to the whole activity, so all the costs it carries have to be deducted from that financing” (Source: GCCT and MT team member).

Another member of the São José's multi-tissue team and the CHLC GCCT believes that our results "(...) are still insufficient to respond to all the situations that we know of from the tissue bank." Although an effort is made to "(...) try somehow to cover all the situations that appear to us. Even in at least two situations, we had to stop collecting due shortage of staff available" (Source: GCCT decision maker).

The interviewee also points out the difficulty of "(...) distributing the funding to a team that participated in a harvest that has elements from two institutions (...)" regarding the possibility of adding members from other institutions to increase flexibility. The fact that "This activity has its costs, not only the value that is attributed to the team but also the consumables (...)" contribute to the precarious state of the activity (Source: GCCT decision maker).

Regarding formation, the interviewee alerts to the fact that "We do not have so many opportunities to form in practice, because there are not so many donors per year" due to the fact that "(...) donors with a stopped heart have a much lower age limit than brain death donors" (Source: GCCT decision maker).

However, the success of the GCCT CHLC lies in the fact that "(...) it is possible here to have always at least 3 people who dedicate themselves full time (...)" to the activity. It is also referred that "This GCCT is lucky" for that and is doubted "(...) that the others GCCT have so many people fully dedicated" to the activity (Source: GCCT decision maker).

A tissue specialist working at the Barcelona's Donor Center believes that everything is in place to have better results "(...) the law is designed in a way that everyone can donate"; "People are aware of the importance of donation and transplantation (...)" so it's all a "(...) matter of optimizing the resources that we have at the level of tissue activity (...)". However, it's always positive to invest in awareness, specially "(...) within hospitals so that doctors do not just look for the classic donor who will donate organs (...)" but also look for tissue potential donors (Source: BTB member).

"In Spain the difference is that the donor center is part of the tissue bank. The bank is allocated physically elsewhere (...)" but the staff belongs to the bank, so "(...) the extraction is be part of their normal activities and we do not have to pay incentives (...)". It is also believed that for a country like Portugal "(...) it's always easier to find an

American supplier or ask for a part especially from the Barcelona bank than to ask IPST to start developing new products” (Source: BTB member).

“The centralization is the major factor for Spain’s success, without a doubt” because the only way to really tackle the chronic available tissue shortage is by approaching it as global problem. By having tissue bank staff on a procurement team “(...) means that the team will know exactly the amounts, shapes and technicalities the tissues to harvest must have”. Another big difference “(...) from the procedure point of view, is the fact that nurses, technicians and biologists are capable to perform many of the procurement procedure”, which allows to “(...) attract health professionals at much lower costs (...)” and the fact that “We have operating rooms dedicated exclusively for tissue procurement (...)” allowing the “(...) procedures to be performed at day time (...)” (Source: BTB member).

The most discussed topics were the lack of funding and the necessity for regulation updates. It is considered that the area needs more investment and there’s a big need to update many aspects about the regulation, which is clearly outdated.

Other important topics discussed by some of the interviewees was the necessity to centralize de activity and, therefore, the possibility of adding bank staff members to the São José’s procurement team. When discussing the centralization of the activity every interviewee agreed that having hospital tissue banks is an outdated practice that compromises the scientific, technological and technical developments the activity needs to provide this type of treatment to more people in need. When discussing adding IPST staff members to the procurement team, many agreed that it is an important step towards the centralization and it would benefit the efficiency of the activity. One interviewee alerted to the fact that it would be tough to figure out the financial and regulative details needed for such operation to happen.

Topics related to the development of the activity such as the possibility of having an operating room dedicated to the tissue procurement activity, the necessity of having more health professionals exclusively dedicated to this activity and the need to raise awareness to tissue donation among health professionals, were topics popular among the interviewees. All of them considered that these are aspects that need to be implemented in order to have a professional, good and internationally recognized tissue donation service.

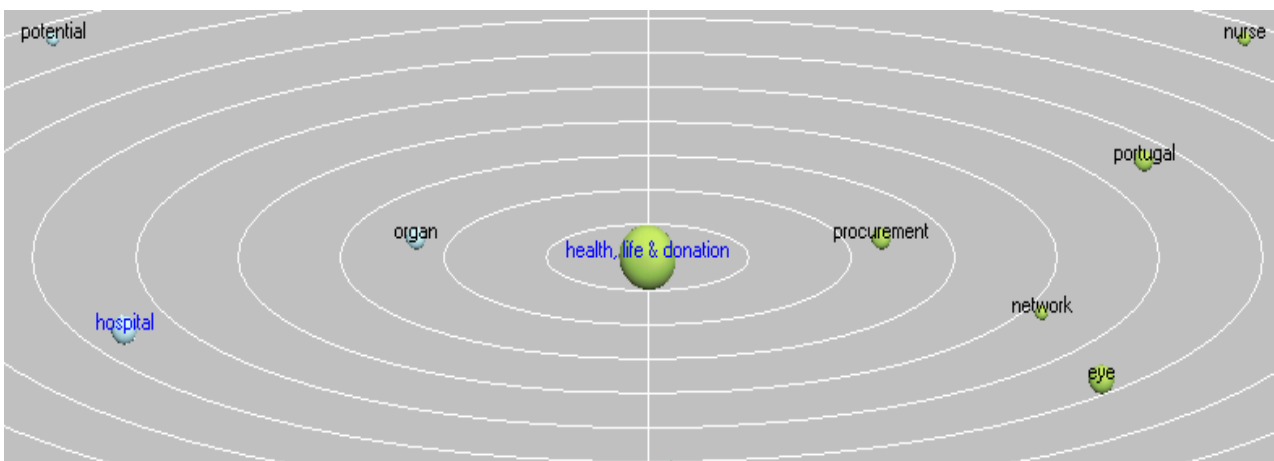
Only a few interviewees mentioned a need to attract more health professionals to the area, through training and practical formation. It is considered a very important subject to the medium/ long term future of the activity and essential to have a sustainable practice.

5.4. Content analysis results – Semantic associations and relationships

When analysing the different types of graphics and their representation of the semantic associations and relationships in figures 6 to 17 obtained through TROPES® software, it's possible to draw some relevant conclusions on the relevant terms and topics and its' relations with other words/ terms/ topics.

The relevant relations with the category “Health, life & donation” can be seen on the figure 6. The sizes of the balls indicate the topic's frequency and the proximity indicates the level of dependency (close = higher; distant = lower). This category is mainly influenced and affected by organ donation but also by the conditions of each hospital, which makes sense since Portugal's results regarding donation are very dependent of the organs and the specific conditions of each hospital.

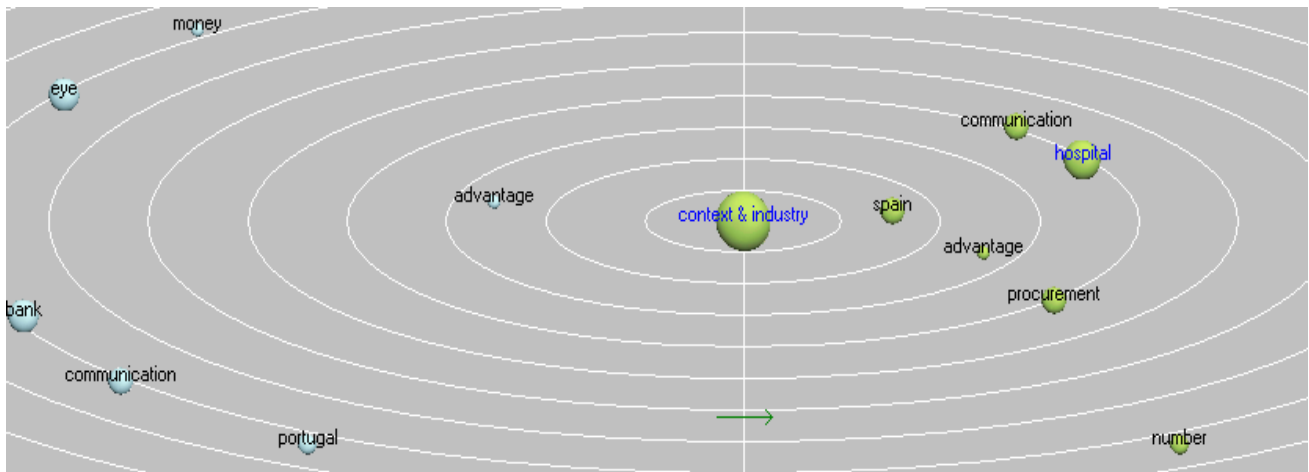
Figure 6 - Graphical representation of the category Health, Life & Donation and its relations



It's also possible to conclude that this category influences mainly the procurement since it is entirely dependent on the number of potential donors there is in a society. “Health, life & donation” also influences the results of the network of hospitals involved in donation in Portugal.

In figure 7, factors like the available funding, number of corneal donations, subjects related to the tissue banks, awareness related efforts and Portugal’s performance have a great influence on the Portuguese tissue donation context. But according to figure 7, the factor that influences more this category are actions that bring advantages to the activity.

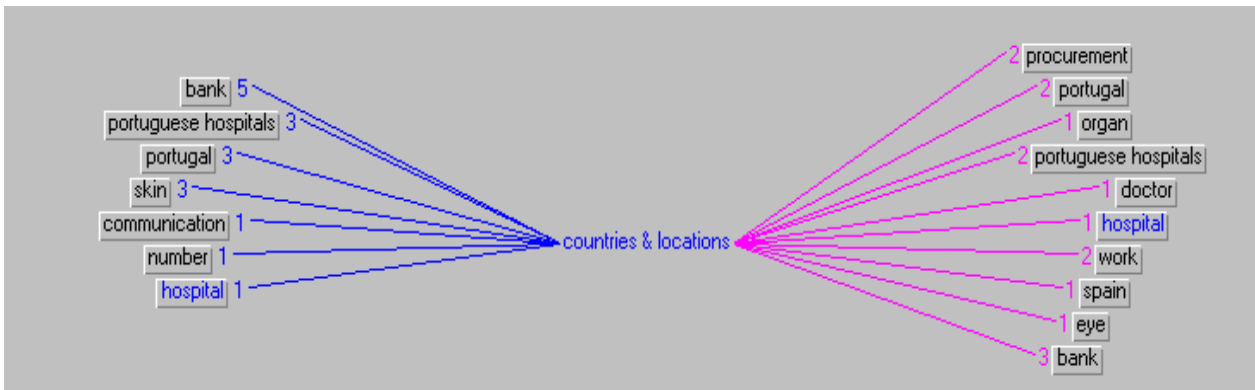
Figure 7 - Graphical representation of the category Context & Industry and its relations



According to Tropes, it is also shown that Spain is greatly influenced by the Portuguese context since there are many institutional relations between the two countries and many financial trades are made. The constant comparison of the two countries’ contexts brings advantages due to their exemplary performance in the tissue donation activity. Figure 7 also shows that the context also influences communication within hospitals, the tissue procurement, and therefore the results of tissue donation in Portugal.

Figure 8 presents a different type of graphic, in which the frequency is located next to each topic related with the category “countries and location” and their position in the graphic indicates the relevancy of each relation (higher position = more relevant relation; lower position = less relevant relation). It’s clear that the countries’ infrastructures, and the characteristics inherent to Portugal (11) influence this category the most.

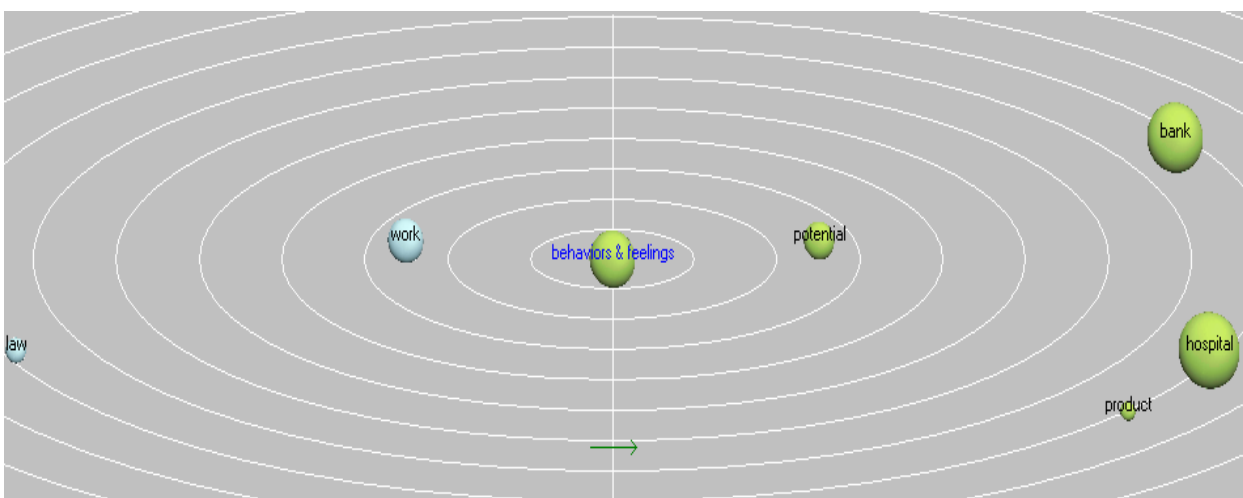
Figure 8 - Graphical representation of the category Countries & Location and its relations



Each location's characteristics have influence on the tissue procured in Portugal and the Portuguese hospitals (6), on the organ donation and on the work of the doctors and the tissue banks (8). This analysis seems to agree with previous indications of high dependency of each location on the centralized infrastructures, which has influence on the countries' outcomes and inherent characteristics.

In figure 9 it's interesting to see that health care professional's behaviours and feelings are mainly dependent on the work conditions. This category is also slightly influenced by the characteristics of the Portuguese law.

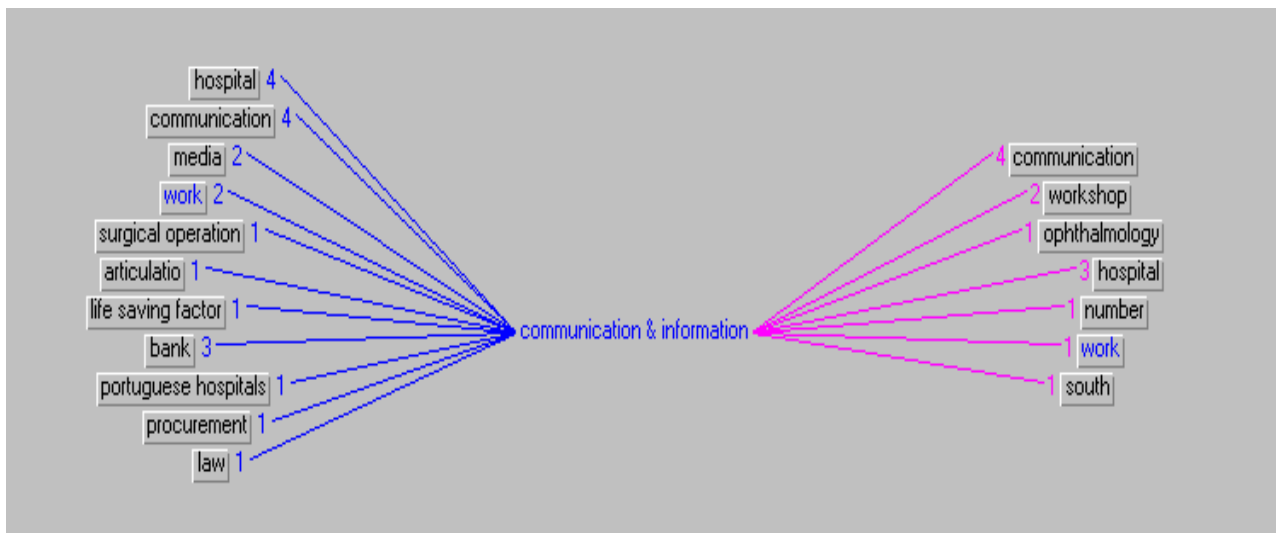
Figure 9 - Graphical representation of the category Behaviours & Feelings and its relations



Health care professional's behaviours and feelings have a great influence on the potential of tissue donation in Portugal, and some influence on the products generated by tissue banks and hospitals. This analysis was also made on the most important phrases/sentences of many interviewees, which highlights this category's and its relations' importance.

Analysing figure 10, the category "communication & information" is mainly influenced by the hospital's efforts to raise awareness to tissue donation (12). Other relevant factors influencing this category are the life-saving factor (1) and the cooperation between organizations (5).

Figure 10 - Graphical representation of the category Communication & Information and its relations

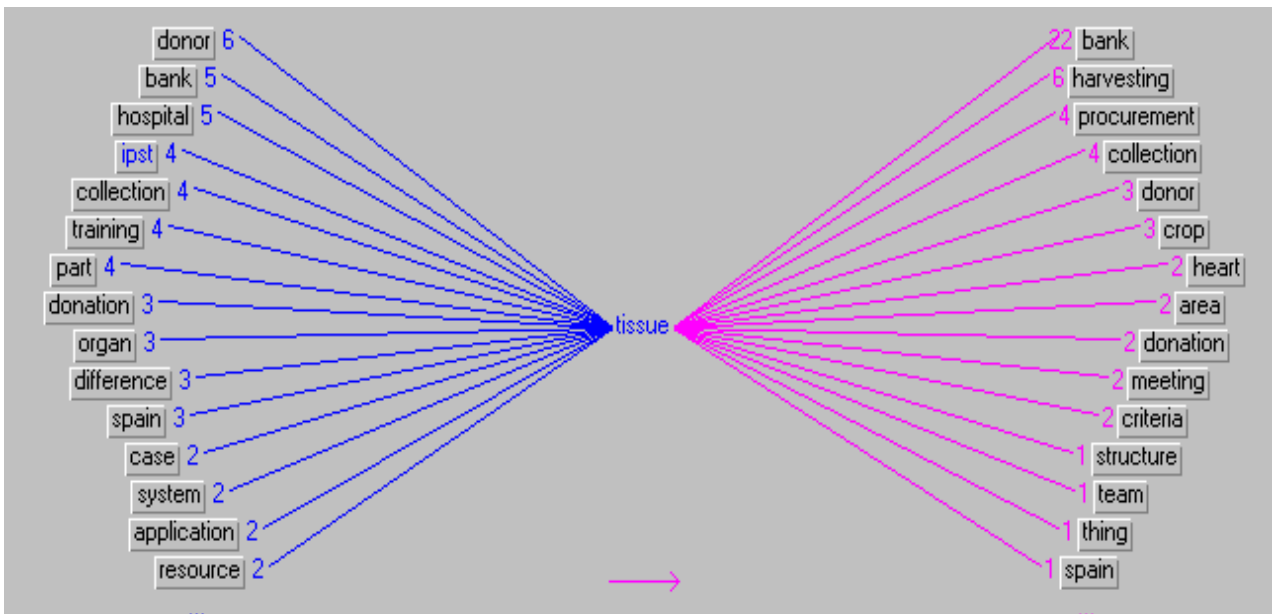


Different types of communication (6) and the coordination between units within the hospital (4) are the main factors influenced by this category. Communication also influences the professional's efforts (1) and the organizational results (1).

Analyzing the main references (words/ topics more discussed and referred throughout the interviews) is also relevant since their relations may help to draw new conclusions or confirm previous analysis.

The reference tissue is referred 112 times and is mainly influenced by the number of donors (6) and organizational resources (14), as already seen in previous figures. Figure 11 also indicates that factors like professional training (4), organ donation (6) and donation related processes (6) have a relevant influence on the number of tissue available.

Figure 11 - Graphical representation of the reference Tissue and its relations

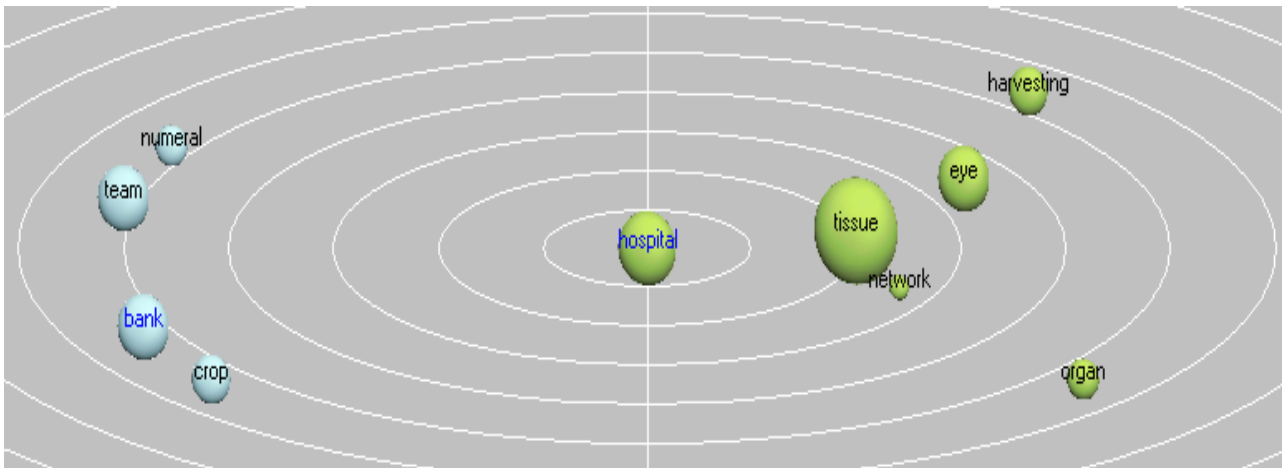


This reference has a great impact on the tissue banks, as is easy to understand since their work is totally dependent on the tissues available. Procurement procedures (14) are also dependent on the number of potential tissue donors (3).

Figure 12 shows the relevant relations with the reference hospital (56).

The factors that influence more deeply, regarding tissue donation, are the inherent characteristics of a hospital are their results and medical performance, if it has an operating multi-tissue procurement team and its tissue bank policy.

Figure 12 - Graphical representation of the reference Hospital and its relations

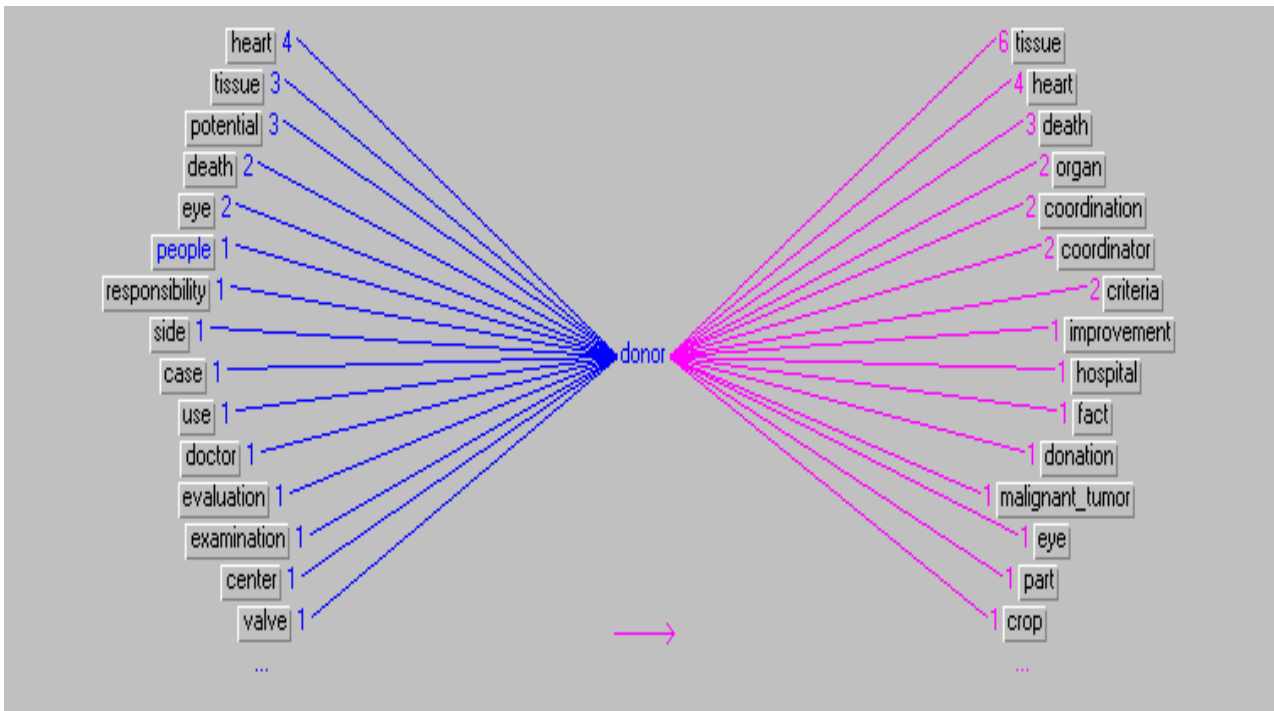


The hospitals have a great impact on the available tissues and on the network in which it belongs to. The procurement of corneal tissue and organs is highly influenced by the hospital's resources and capabilities. Here only corneal and organ donation are referred due to their importance in Portugal's and its hospitals results.

In figure 13, are presented the reference donor (55) and its relations.

In Figure 13, according to Tropes semantic analysis, the non-use of potential cardiac failure donors (7) is the main influencing factor for the detection of tissue donors. The number and types of deaths (3), logically have a great impact on the reference.

Figure 13 - Graphical representation of the reference Donor and its relations

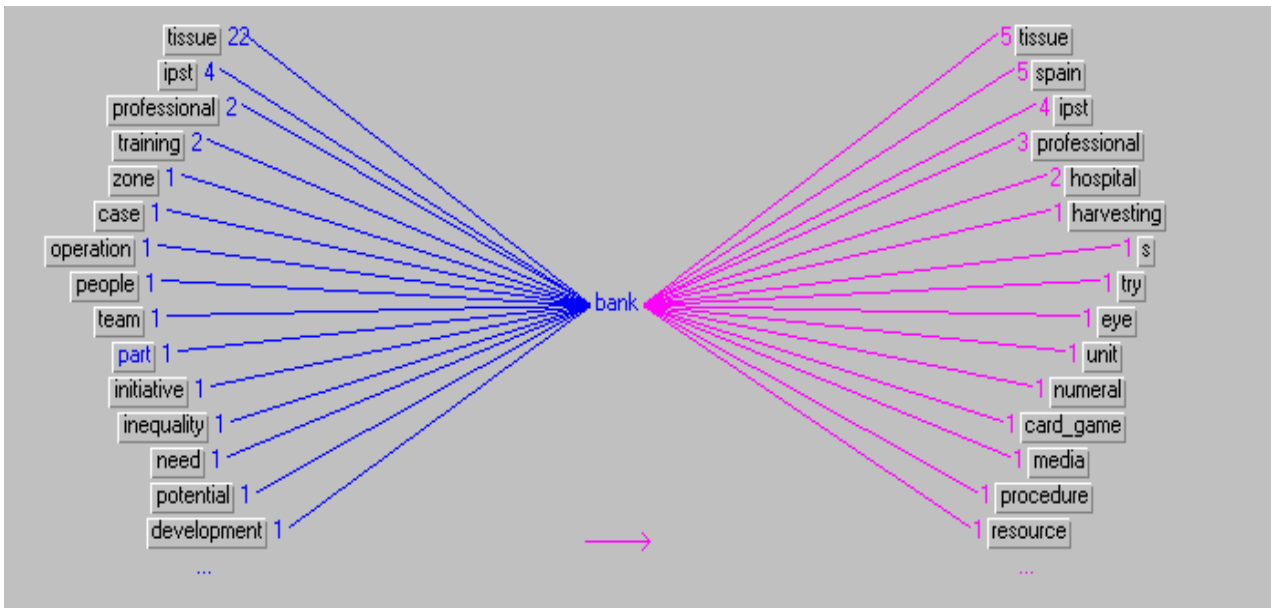


The existence of donors, obviously influences greatly the tissues and organs available for donation. The use or non-use of cardiac failure donors is also dependent on the occurrence of those types of death (7). The use of all potential donor influences the organ availability (2) and the work of hospital donation coordination and its coordinator (4).

In figure 14, are presented the reference bank (47) and its relations.

The main factor influencing the bank and its work is the availability of tissue (22) to process. Ipst's professionalism and the presence of trained professionals also has a great impact on the tissue bank system.

Figure 14 - Graphical representation of the reference Bank and its relations

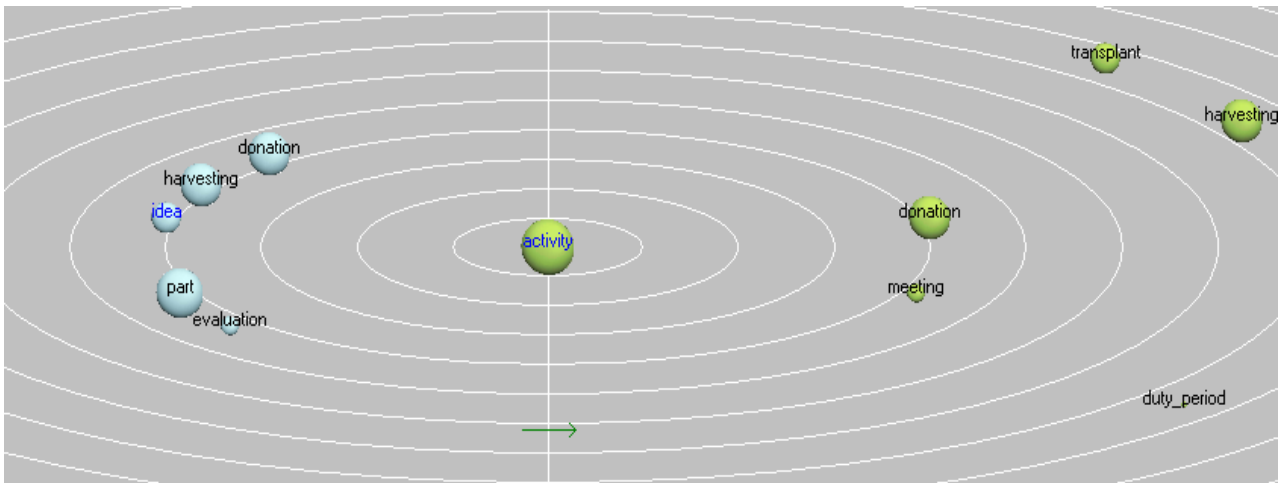


The tissue banks' performance have a great influence on the tissues available for transplanted (5) and on Spain's activity (5), which has to provide us processed tissue depending on the Portuguese banks' needs. The presence and capabilities of other tissue banks also have a big impact on Ipst's results (9).

In figure 15 are presented the reference activity (44) and its relations.

The factors that are influencing the most the activity of tissue donation is Portugal's ability to perform procurement procedures on many tissue donors as possible, and the ability to come up with new ideas/ innovative methods to improve the tissue chronic shortage. The evaluation of hospitals' activity also has a relevant influence on the tissue donation activity.

Figure 15 - Graphical representation of the reference Activity and its relations

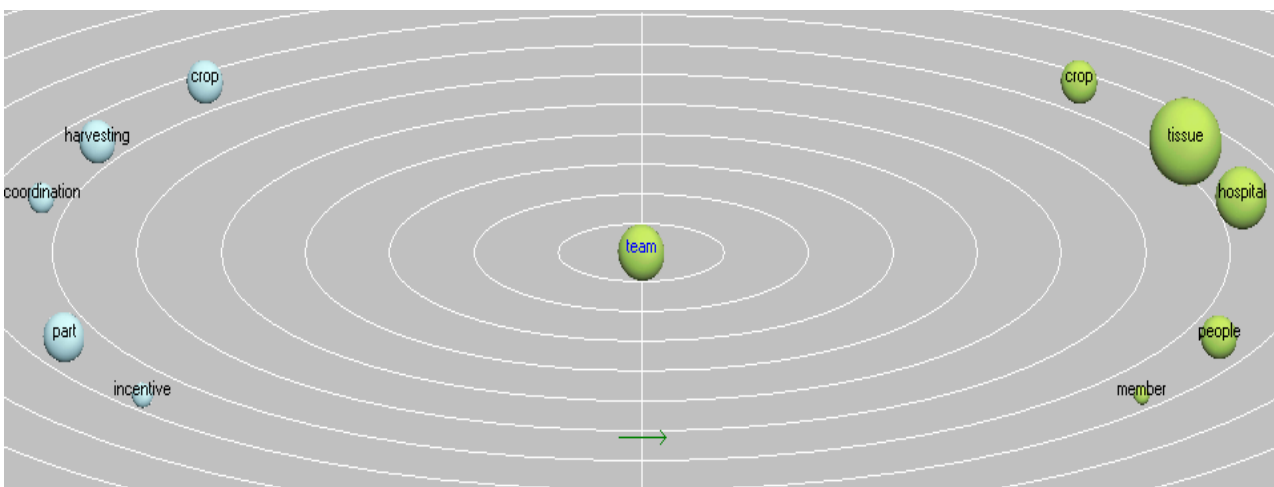


The activity has a big impact on the Portuguese donation and transplantation context and creates the need for new institutional relationships.

In figure 16, are presented the reference team (44) and its relations.

The main factors impacting the work of the multi-tissue team are their procurement capabilities, their ability to coordinate with the necessarily different parties and the amount of financial incentives destined to tissue donation.

Figure 16 - Graphical representation of the reference Team and its relations

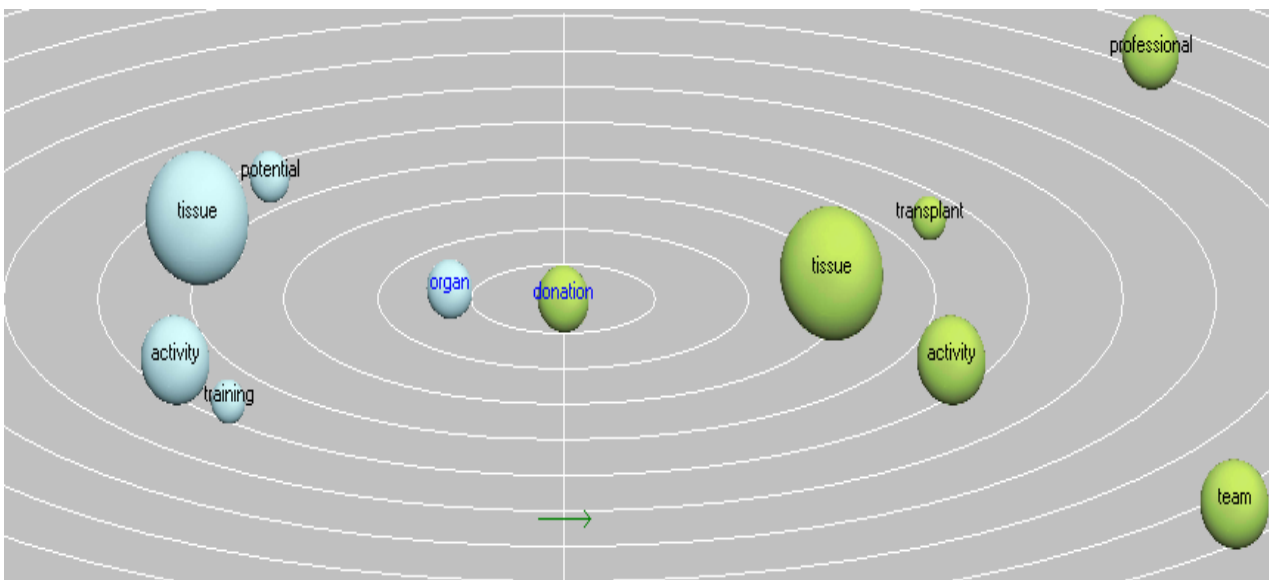


On the other hand, the work of multi tissue teams have a great impact on the number of tissue procured in a hospital. Such analysis strengthens the importance of the presence of more teams that can efficiently harvest more tissues and the necessity of always improve and innovate the teams' capabilities.

In figure 17, are presented the reference donation (24) and its relations.

The Portuguese donation context is mainly influenced by organ donation as was previously seen in the Portuguese results. The potential present in tissue donation also has great implications on the Portuguese donation context. Donation is also greatly influenced by how the activity and the training is conducted and professionalized.

Figure 17 - Graphical representation of the reference Donation and its relations

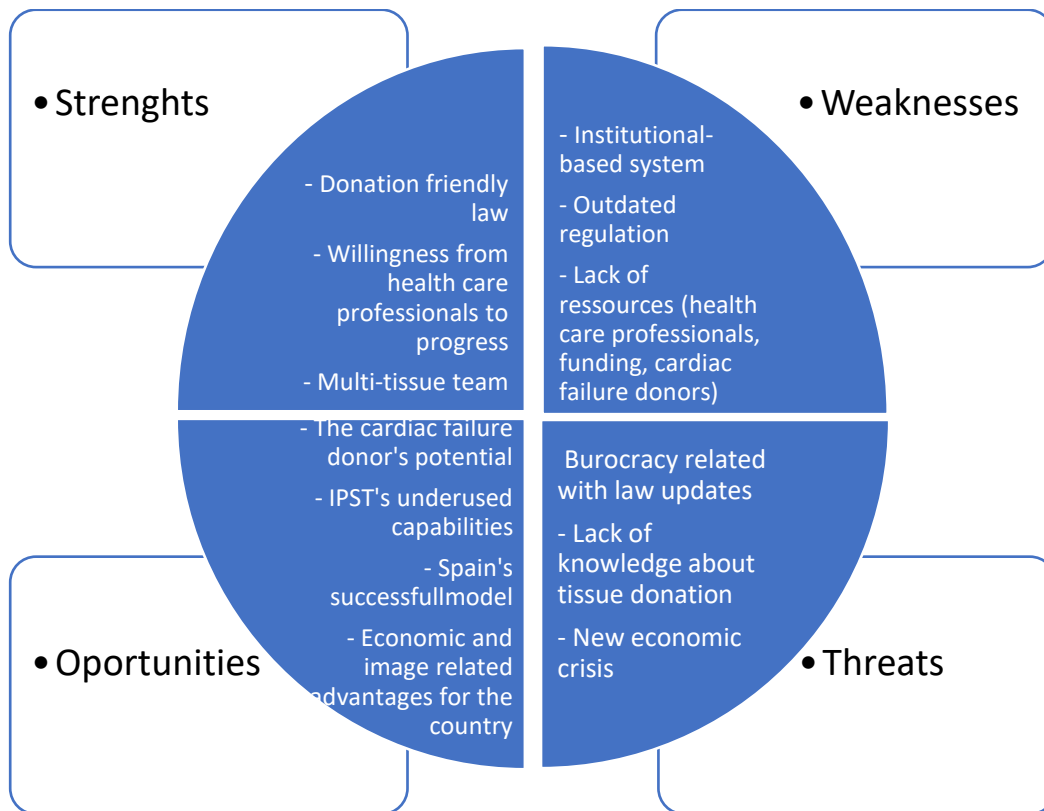


A country's context and culture regarding the donation activity have an important impact on the country's results regarding tissue activity. The level of professionalism and the existence of multi-tissue procurement teams also have a high dependency on a country's context and culture regarding the donation activity.

5.5. SWOT analysis

From the literature review analysis and from the content analysis it was possible to build a SWOT analysis (figure 18), which can help summarize the relevant information, used for strategical decision making.

Figure 18 - SWOT analysis



Strategy will be built upon mitigating the weaknesses and defining strategies around solving these problems. In order to build a strong foundation to fully establish a sustainable and efficient system of tissue procurement, it's necessary to end or mitigate the weaknesses and threats (Gurel, 2017). To take advantages on the opportunities that the context provides is crucial to be an exemplary European model.

6. Discussion

When discussing tissue donation, as previously referred, it's important to understand that the global context in this area is of a chronic shortage of this type of treatment. Being a global problem, it seems that it needs to be approached in a global, centralized, efficient and optimized manner. In Portugal it is approached in an institutional style, since tissue donation is a recent, different and very special type of medicine. Recent efforts have been made in order to optimize resources and develop the activity, however Portugal's dependency on the individual performance and initiative of each institution combined with Portugal's evident lack of the necessary resources limits greatly this development, hence the need for a global resource optimization.

The main problems and their implications will be discussed, solutions will be proposed and explained with detail and their expected future implications and results will be explained and justified.

6.1. Problems:

The most important problems/ factors that limit the tissue donation activity are:

1. Need for a centralized system;
2. Lack of resources;
3. Lack of awareness to the subject/ outdated ways of thinking

1. The main problem is considered to be the system in which this activity is inserted. In Portugal, each institution manages its policy and practices regarding tissue donation, which limits greatly the level of professionalism, efficiency and potential of tissue donation. It is considered to be the main problem since every subject is inherently related to the system in which it is inserted. This is a macro level issue that partially predefines Portugal's performance in the tissue donation activity.

In this macro level there's a big reluctance about the hospital tissue banks. Even if they manage to fulfil all the necessary minimum technical requirements a tissue bank must have, the tissues are not being optimized, since a public tissue bank has the means to process, multiply and optimize tissues for transplantation that a hospital tissue bank

cannot have. IPST's processed tissues are guaranteed to be optimized at the best possible level and have the best possible quality (IPST). Limiting IPST's activity means to limit the available tissues for transplantation, their quality and the number of patients that would benefit from this type of treatment.

2. The lack of resources is a problem that occurs in many different areas throughout the country and in tissue donation and transplantation this can also be verified. This, combined with new technological developments, creates the need to optimize such scarce resources and is forcing the industry to create new and better methods of operation, techniques and procedures (Silva, 2016).

2.1. One of the major limitations is the unavailability of an operating room with the technical conditions necessary, according to European recommendations, to perform tissue procurement on cardiac failure donors. The fact that cardiac failure deaths are potential tissue donors is, when comparing with organ donation, one of the few facts that increases the pool of potential tissue donors. All the other criteria for donation is favourable to organ donation, due to the life-saving factor.

2.2. Another obvious limitation as to do with the difficulty of attracting new health professionals to this area. Despite the efforts made to raise sensibility to this subject, the activity, in Portugal, is not yet very established which always leaves room for having a wrong idea about tissue donation (Olender, 2010). Also, there's another factor limiting the dedicated health professionals to this area as to do with the interpretation of the regulation regarding medical responsibility and the need of the presence of a doctor throughout the whole process or just in the most important moments. The last factor limiting the attraction of health professionals is the obvious lack of funding destined to the activity. This is a matter that has to do with the need for deep updates in the tissue donation regulation.

2.3. The current legislation lacks the clarification of certain details important to allow the full establishment of the activity as a successful service in health care. Most of these lacking details are operational and regarding the GCCTs, IPST, hospital donation coordination and the multi tissue team. Some details need updates and serious reflection, like the funding destined to the activity that, as can be seen in *Despacho* n.º 7215/2015 (ANNEX II) which defines the current funding destined to donation and transplantation and states: "To the institutions (...) authorized to perform such activities, will be

attributed the following funding: (...) b) harvest of one type of tissue for transplant (until 2 grafts) – €350,00 with a supplement of €50 for each additional graft; (...)”⁴. This activity is clearly underfinanced when compared to the funding destined to the harvest of organs that can go up to €7500,00 per procurement procedure. When presenting the solutions these gaps will be thoroughly examined.

3. The last limiting factor as to do with the idea that each health care professional has of tissue donation and their daily contact with the reality. As it is something that is not yet fully established in Portugal’s health care, it’s easy to understand that only a few health care professionals have contact with or are dedicated to tissue donation on their daily work. The inability to attract professionals to the activity brings unawareness and poor results, which leads to, in most cases, low investment on the activity limiting its potential (Olender, 2010). The fact that tissue donation is strange to some health care professionals and institutional pride/ individuality encourage the inefficiency of the current institutional-based system.

6.2. Possible solutions:

1) In order to turn this institutional-based system into a more centralized one, it would benefit the activity to end the tissue banks in each hospital and allocate all tissues for processing to the public, internationally certified and more capable tissue bank of IPST. It would allow tissues to be optimized and help more people since IPST has means to produce more and with better quality tissues for transplantation. The management of the distribution would be handled nationally by IPST who would impartially manage the distribution of the tissues and their processing nationally. This way IPST would have more responsibility, and could function more efficiently, allowing a better use of the hospitals’ and IPST’s resources. The main factor of Spain’s success is considered to be the crucial work done by the tissue bank that plays a much more important part in the activity than Portugal’s. Increasing IPST’s influence in the activity will partially

⁴ “às instituições autorizadas a realizar atos de colheita e transplante (...) serão atribuídas as seguintes verbas: (...) b) Colheita de um tipo de tecido para transplante (até 2 peças) – €350,00, cabendo acréscimo de €50,00 por cada peça suplementar; (...)”

centralize the activity, optimize Portugal's chronic scarce resources and multiply the available tissue for transplantation.

2) To fight the lack of resources destined to this activity, the solution has to act on 3 different dimensions in order to be effective: use of potential cardiac failures donors; perform regulation updates and changes; and developing the multi-tissue team.

2.1) The availability of an operating room dedicated to tissue procurement procedures, has an extreme importance because it is the only way to take advantage of cardiac failure donors. This is believed that, if properly optimized, it would bring very relevant improvements in Portugal's results, since this is the only kind of donation that can occur in this type of death and it has not been taken advantage of, to this day. However, efforts are being made to make this a reality and the possibility of creating this operating room is currently being analyzed.

2.2) It's considered that the current regulation does not encourage the development of the activity and it could be a great instrument to boost the professionalization of tissue donation. There are 5 different areas in which regulation regarding tissue donation could be improved: Funding mechanism and issues related with multi-tissue teams, IPST, the GCCTs and hospital donation coordination.

2.2.1) The first step is to change the funding system for tissue donation. This incentives destined for tissue donation are not enough and contrast with the ones destined for organ donation and transplantation as can be seen in *Despacho* n.º 7215/2015 (ANNEX II). The current system could even remain active, but it should be created and would be appropriate, for the multi-tissue procurement team, a different system, that could be similar with the one created for the hospital donation coordinators. When the law requiring all hospitals to have a donation coordinator was implemented, a salary supplement was created for the coordinators, which had great success to attract professionals to perform these tasks. Meaning that a similar supplement could be created to fund and attract health care professionals to the multi-tissue procurement team, which would be properly divided for the members of the multi-tissue procurement team. To the supplement it could be added a bonus for the members that participate in successful procurement procedures after achieving a certain annual goal.

2.2.2) There isn't any legislation regarding the possibility of existing multi-tissue procurement teams, which is essential to enable the activity to achieve the necessary level

of professionalism. Certain aspects should be revised, changed or added, such as a minimum and a maximum of members necessary to form such a team, the type of professionals it must have (doctors, nurses and technicians) and their main roles, clarification of the meaning of medical responsibility and in which moments is necessary the presence of a doctor, determination of an annual minimum participation on tissue procurement procedures necessary to be part of such team, a clarification of the types of partnerships possible to be established and add the possibility of a team having members from different institutions, clarifying the conditions in which it could occur. This would allow health care professionals to perform such activities without having to give up their current tasks (part-time dedication according to availability) and assuring a minimum level of equality with the minimum service required to be a part of the team. Health care professionals would have the possibility of performing extra work and being properly paid for it.

2.2.3) Regulation regarding IPST would be improved if there was a better explanation on the duties, roles and capabilities, namely regarding tissue procurement. It would be beneficial if there was the possibility of IPST's staff to perform procurement procedures (be a part of the multi-tissue procurement team). This would implicate additional clarification on the possible agreements and relationships to be made and established. Having IPST's staff as part of a multi-tissue procurement team is believed that can improve efficiency, since it would allow a specialized knowledge on how the tissue should be procured to optimize the following processing and the types of tissue needed at a certain date. It's also recommended that IPST should start programs of medical advertisement of the tissues it can provide for treatments and do it sending professionals to hospitals and health care facilities that might need this type of treatment to explain its advantages.

2.2.4) Regarding GCCTs' regulation, it would only need a clarification on the minimum amount of fully dedicated staff needed to maintain a working and effective GCCT. This would force the hospitals to assign more professionals to the area and therefore encourage the full establishment of tissue donation on the daily activity of a hospital.

2.2.5) Regarding the regulation of hospital donation coordination, it would need to allow the creation of a team around the coordinator or establish a minimum of at least 2 health care professionals to perform all the tasks necessary to coordinate the donation activity of a hospital. The definition of minimum results to be achieved by the hospital donation

coordination and the establishment of bonus to distribute after achieving certain goals would assure a higher level of equality in the supplements currently paid to all coordinators.

3) All the previous solutions would facilitate this last proposal: the creation of a Lisbon multi-tissue procurement team. The first step would be to add 3 new members to the São José's team. One from the hospital of Santa Maria, one from the Fernando Fonseca's and another from IPST. The choice of these 3 institutions relies on the fact that all of them participated on the program that started São José's team, so they all should have capable staff to join the team. These would increase the team's flexibility and, with an efficient donor detection system, provide the team the capability of procuring tissues in every donor in Lisbon's hospitals. Also, the hospitals that are more connected with this activity will still be able to be a part of the system without reducing its efficiency. The second topic that needs to be attended to is the medical responsibility and it would have to be assigned to the doctors of the hospital of São José, due to their already acquired experience in the procedures. This team would have to be able to procure every type of tissue and respond to every situation. The third topic that needs to be attended to is the assembly of the team. The assembly of the team for each procurement procedure would result from the coordination between the two GCCTs that would evaluate which members are available at the time. In the procurement procedure there should always be present two of the three new members in order to assure their minimum service and practical training. A salary supplement destined to this team and a minimum of procurement procedures for all the members would assure the attraction of professionals, a certain level of equality and sustainability and response capabilities.

All the previous proposed solutions facilitate the creation of this team and the sustainability of the activity, but those that are truly crucial for it to be possible are the creation of an operating room dedicated for tissue procurement procedures (2.1) and the redefinition of the funding system (2.2.1). The researcher believes that these are the only factors that really determine the success of the Lisbon's multi-tissue procurement team.

The following table 10 represents a summary of the proposed solutions and expected outcomes:

Table 10 Proposed Solutions and Expected Outcomes

Proposed Solution	Expected Outcomes
End Hospital Tissue Banks + Give IPST responsibility of managing distribution and processing procedures nationally	<ul style="list-style-type: none"> • More power to a Public Institution; • Increase efficiency by a better use of hospitals' and IPST's resources
Create an operating room exclusive to tissue procurement procedures	<ul style="list-style-type: none"> • Use of cardiac failure donors increasing pool of potential donors
Change funding system (create a salary supplement destined to the MT teams' members and a bonus for any additional procurement procedure after achieving a pre-determined goal)	<ul style="list-style-type: none"> • Attraction of professionals; • Incentive to productivity
Change MT team regulation (Determine a minimum and a maximum of members a team can have; the type of professionals the team must have; define medical responsibility; determine minimal service for each member; clarify partnership situations)	<ul style="list-style-type: none"> • Possibility of having part-time dedicated members of the MT team(s); • Create room for a more flexible team; • Assurance of a certain level of equality in the service provided by each of the team members
Clarify the possibility of IPST having staff in a MT team and other partnership situations	<ul style="list-style-type: none"> • Allow specialized knowledge on the tissues to be procured
Determine a minimum amount of fully dedicated staff to the GCCT's	<ul style="list-style-type: none"> • Contribute to the professionalization and establishment of the activity
Create a Lisbon MT team (add 3 members to the São José's Team – one from the Hospital Santa Maria, one from the Hospital Fernando Fonseca and other from IPST; assign medical responsibility to São José's doctors; assembly of the team determined by the coordination between the two GCCTs;	<ul style="list-style-type: none"> • Assurance of a qualified and multi-institutional team; • Increase the team's flexibility; • With an effective donor detection system, allows the team to procure tissues from every potential tissue donor in the Lisbon's hospitals;

<p>in the initial procurement procedures there should always be present 2 of the 3 new members)</p>	<ul style="list-style-type: none">• Allow hospitals to remain connected to the tissue donation activity;• Assurance of minimum service and practical training;• Assurance of a certain level of equality, response capabilities, and sustainability
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7. Conclusions

To build a strategy that intends to improve the tissue donation context in Portugal is a difficult but appealing challenge.

The appealing part is due to its already mentioned potential. It appears to be consensual that much more could be done in this area and its proven that small, smart changes can have a relevant impact.

The difficult part is related with some inevitable limitations. Due to the lack of professionalization, there isn't enough information available related with technical details, such as financial and activity reports. Only the medical institutions more professionalized in the matter provide such information, which limits the possible scope of investigation.

The strategy was built as much as possible based on procedures known to be applicable and the interpretation of the Portuguese regulation related with tissue donation. Recent efforts in the area provide the confidence on the success of this solutions because it indicates that an update on our system is the key to achieve better results.

An inherent limitation of this type of research is that many measures assume their successful implementation which can be proven otherwise. The government's or the institutions' will to invest in this area may not be enough to create an operating room dedicated to tissue procurements and allocate more resources to the tissue donation activity.

The regulation changes needed, most are simple note changes, but others require a more careful reflection like the changes necessary on the funding system. That's why the financial system proposed had to be similar with some other that is already established like the supplement destined to hospital donation coordinators.

Another important change in the regulation would be the ones related with the multi-tissue procurement teams, which is a subject that currently is not mentioned in the Portuguese law. Conservative thinking may consider that the creation of the Lisbon's multi-tissue procurement team is too complicated to implement and/or unnecessary.

The proposed strategy assume a dynamic National Health System built on an institutional network used to institutional cooperation. The Portuguese National Health System

appears to have such capabilities, but such is threatened by governmental changes and bureaucracy and it is also believed that this type of donation will always be disregarded in an economic crisis context.

It is considered that if the measures turn out successful and if there is transparency and the publication of reports is constant, it will inevitably lead to the end of unawareness and show everyone that Portugal can in a different model be an example in the European community.

Such assumptions rely on the fact that a certain foundation is already established, by merit of the organ donation, on which the foundation for tissue donation can be built upon. Spain's success in this area can provide a meaningful help to build our own model.

It is believed that from the difficulties found and the assumptions made, none is disabling enough to not be confident in the success of the proposed solutions. However, this study has several limitations, and is extremely important that more detailed researches can be made in this area in order to contribute to the mitigation of the shortage of tissues available for transplantation.

8. Bibliography

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ANNEX I

Declaração de consentimento

Ao assinar este documento declaro que irei voluntariamente participar numa entrevista relacionada com a atividade de Doação e Transplantação de Tecidos em Portugal, e que me foram prestadas todas as informações relacionadas com os objetivos e as finalidades do estudo, e que todas as minhas questões e dúvidas foram esclarecidas. Além disso, fui informado que as informações recolhidas apenas serão utilizadas no âmbito da Tese de Mestrado a ser desenvolvida, podendo algumas frases ser transcritas para o trabalho. Fui também informado que será sempre mantido o anonimato do entrevistado, sendo que as gravações e a transcrição da entrevista ficarão apenas na posse do investigador.

O investigador compromete-se ainda a disponibilizar a toda análise que for feita, antes da submissão da Tese de Mestrado em desenvolvimento, e tal submissão será sujeita a aprovação do entrevistado.

Aceito participar neste estudo e autorizo a gravação da entrevista.

Entrevistado:

Nome (Maiúsculas) _____

Assinatura _____

Data ____/____/____

Investigador que apresentou e solicitou Consentimento:

Nome (Maiúsculas) _____

Assinatura _____

Data ____/____/____

ANNEX II

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Despacho n.º 7215/2015

O despacho n.º 1886/2014, publicado no *Diário da República*, 2.ª série, n.º 26, de 6 de fevereiro de 2014, procedeu à revisão dos montantes de financiamento a atribuir aos serviços e instituições do Serviço Nacional de Saúde (SNS) e do Serviço Regional de Saúde dos Açores e da Madeira que praticam atos de colheita e transplantação de órgãos, e estendeu a sua aplicação às instituições privadas e em regime de Parceria Público Privada que realizem atos de colheita de órgãos e tecidos.

Pretendeu -se, com tal revisão, ajustar a política de financiamento à necessidade de reforçar a verba referente à doação de órgãos, de forma a incluir os custos com a deteção, referenciação e manutenção de dadores, e a incentivar os hospitais com potencial de doação a realizarem estas atividades. De igual modo, os montantes de financiamento previstos para a colheita foram também revistos com vista a suportar a totalidade dos custos de cada colheita com o material, os solutos de preservação dos órgãos, o funcionamento dos gabinetes coordenadores de colheita e transplantação, responsáveis por toda a logística necessária à realização da colheita e distribuição dos órgãos às unidades de transplantação, e com os complementos remuneratórios devidos aos profissionais que integram as equipas de colheita para assegurar a necessária disponibilidade para esta atividade, a qual, pela sua natureza não programável, exige que seja permanente.

Decorrido pouco mais de um ano sobre a aplicação do despacho n.º 1886/2014, publicado no *Diário da República*, 2.ª série, n.º 26, de 6 de fevereiro de 2014, e tendo em conta o índice de doação obtido, justifica- se o reforço dos montantes de financiamento para a colheita e a necessidade de introduzir alguns ajustamentos no que respeita ao modelo de distribuição das verbas referentes ao transplante, tendo em vista a sua uniformização a nível nacional.

Esta política de adequação do financiamento à atividade de doação justifica -se pela necessidade de aumentar o número de órgãos disponíveis para transplante, encontrando- se alinhada com a Resolução do Parlamento Europeu, de 22 de abril de 2008, sobre a transplantação e a dívida de órgãos: ações políticas a nível da UE, que salienta a importância do financiamento da atividade de colheita e transplantação como incentivo à realização destas atividades pelos hospitais.

Assim, determino:

1 — Aos estabelecimentos públicos ou privados autorizados a realizarem atos de colheita e transplante, incluindo as entidades localizadas nas Regiões Autónomas dos Açores e da Madeira, serão atribuídas, pela prática dos atos identificados, as seguintes verbas:

- a) Exame de histocompatibilidade (por órgão transplantado) — € 548,68;
- b) Colheita de um tipo de tecido para transplante (até 2 peças) — € 350,00, cabendo acréscimo de € 50 por cada peça suplementar;
- c) Colheita de um tipo de órgão para transplante (inclui a deteção e manutenção do potencial dador) — € 5 000,00;
- d) Colheita multiorgânica (inclui a deteção e manutenção do potencial dador) — € 6700,00;
- e) Colheita de órgãos em dadores falecidos em paragem cardiocirculatória — € 7500,00;
- f) Transplante renal — € 6 239,97;
- g) Transplante pancreático — € 7 481,97;
- h) Transplante cardíaco — € 12 469,94;
- i) Transplante hepático — € 27 433,88;
- j) Transplante pulmonar — € 27 433,88;
- k) Transplante do intestino — € 27 433,88;
- l) Transplante de células hematopoiéticas (inclui colheita):
 - 1) Com dador alogénico não relacionado — €27 433, 88;
 - 2) Com dador alogénico relacionado — €19 951,91;
 - 3) Com células de origem autóloga — € 14 963, 93;
- m) Transplante de córnea — € 798,07.

2 — Os montantes referidos nos números anteriores serão concedidos às instituições, a título de subsídio extraordinário, pela Administração Central do Sistema de Saúde, I.P. (ACSS, I.P.), nos moldes seguintes:

- 2.1 — Por órgão colhido será atribuído o valor de € 500,00 aos estabelecimentos hospitalares em que exista gabinete coordenador de colheita e transplantação (GCCT), desde que este tenha coordenado a colheita, individualmente ou em articulação com outro gabinete;

2.2 — Os valores referidos no número anterior destinam-se a suportar os custos de cada colheita com o material, os solutos de preservação dos órgãos, e o funcionamento dos gabinetes coordenadores de colheita e transplantação;

2.3 — Os valores referentes aos exames de histocompatibilidade serão atribuídos ao Instituto Português do Sangue e da Transplantação, I.P.

(IPST, I.P.);

2.4 — Os valores referidos nas alíneas b), c) e d) do n.º 1 serão atribuídos à instituição dadora, onde se efetuou a colheita;

2.5 — Nos casos em que a colheita de órgão/tecido se processe por equipa pertencente a instituição diferente daquela onde ocorra a colheita, o valor do financiamento referido no número anterior será atribuído em:

2.5.1 — 85 % para a instituição onde se efetuou a colheita;

2.5.2 — 15 % para a instituição a que pertence a equipa que procedeu à colheita;

2.6 — Os valores atribuídos à instituição dadora em resultado da colheita devem ser afetos à constituição de uma reserva financeira destinada a suportar os custos do suplemento remuneratório devido ao coordenador hospitalar de doação e os custos resultantes da afetação extraordinária de profissionais de forma a garantir a manutenção do dador, a realização do diagnóstico de morte cerebral e a efetivação da colheita, bem como a garantir a melhoria das condições técnicas e científicas dos serviços envolvidos;

2.7 — O valor referido na alínea e) do n.º 1 será atribuído às instituições que integrem o programa de colheita de órgãos em dador em paragem cardiocirculatória, onde tenha sido realizada a colheita;

2.7.1 — O valor referido no número anterior deve ser afeto à constituição de uma reserva financeira destinada a suportar os custos do suplemento remuneratório devido ao coordenador hospitalar de doação e os custos resultantes da afetação extraordinária de profissionais diretamente envolvidos no programa de colheita de órgãos em dador em paragem cardiocirculatória.

2.8 — As verbas referentes aos transplantes de órgãos sólidos, de células hematopoiéticas e de córnea são atribuídos às instituições onde se efetuou o transplante devendo ser aplicada na melhoria das condições técnicas e científicas necessárias à continuidade dos programas de transplantação, seu desenvolvimento e atualização e para suportar os complementos remuneratórios devidos aos profissionais

diretamente envolvidos nos programas, e incentivar a sua disponibilidade permanente para esta atividade;

2.9 — A distribuição pelos profissionais do montante referido no número anterior

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será feita segundo critérios a estabelecer por cada conselho de administração ouvido o IPST, I.P., tendo em vista a sua uniformização a nível nacional e respeitando as normas legais em vigor no que ao pagamento por trabalho extraordinário disser respeito;

2.10 — O IPST, I.P., divulgará no seu sítio da internet os critérios de distribuição seguidos em cada centro de transplantação.

3 — As instituições que pretendam beneficiar do subsídio extraordinário previsto no presente despacho deverão enviar para aprovação, anualmente e até ao final do primeiro trimestre, ao IPST, I.P., o plano de atividades da coordenação hospitalar de doação, tendo em conta a avaliação do potencial de doação de cada instituição, bem como o plano de atividades da área da transplantação.

4 — As instituições que realizem atos ao abrigo deste despacho devem manter atualizado o reporte de atividade para fins de verificação por parte do IPST, I.P., que, após análise, os remeterá à ACSS, I.P.

5 — O financiamento às unidades que efetuem transplantações é assegurado pela ACSS, I.P., da seguinte forma:

5.1 — 90 % com a realização do transplante;

5.2 — 10% com o cumprimento integral dos objetivos estabelecidos no plano de atividades.

6 — São objeto de financiamento específico os transplantes realizados a doentes do SNS e dos subsistemas de saúde.

7 — Caso seja necessário proceder ao transporte de órgãos ou tecidos colhidos na Região Autónoma dos Açores e Madeira, assim como no território internacional, o custo daquele será suportado pela ACSS, I.P.

8 — O presente despacho produz efeitos a partir do primeiro dia do mês seguinte ao da sua publicação, devendo os valores previstos ser revistos anualmente.

9 — É revogado o despacho n.º 1886/2014, publicado no *Diário da República*, 2.ª série, n.º 26, de 6 de fevereiro de 2014.

23 de junho de 2015. — O Secretário de Estado Adjunto do Ministro da Saúde, *Fernando Serra Leal da Costa*.

