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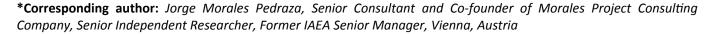
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RESEARCH ARTICLE

# Some Proposals to Strengthen the Cooperation between Tissue Banks and Organ Transplant Organizations at National, Regional, and International Levels

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#### **Abstract**

The donation of human tissues and organs increases significantly when tissue banks and organ transplant organizations work together in the procurement of human organs and tissues at donor sources (hospitals, coroners' system, organ procurement agencies, and funeral homes, among others). To achieve this vital goal, national competent health authorities should consider the establishment of a mechanism that promotes the broadest possible cooperation between tissue banks and organ transplant organizations operating in the country with all available donor sources.

One of the issues that can facilitate the above-mentioned cooperation is the adoption of all necessary laws and regulations to support the establishment of a national central office in charge of the procurement of human tissues and organs within the country, to consider the possibility of the establishment or designation of a national central office to act as regional office in charge of the coordination and cooperation among the different national offices established in different countries within a given region, and the adoption of a unified coding and traceability system that could identify all human tissues and organs used in transplant activities carried out in the country, or within the region, or at international level. The promotion of national, regional, and international cooperation between tissue banks and organ transplant organizations would enable the sharing of relevant information that could be important for medical practice and scientific studies carried out by many countries, particularly for those countries with a weak health care system.

### Keywords

Tissue banks, Organ transplant organizations, Professional associations in tissue banking, World Health Organization

(WHO), International Atomic Energy Agency (IAEA), National competent health authority, National central office, Regional central processing office, Unified coding and traceability system

#### Introduction

The need to strengthen the cooperation between tissue banks and organ transplant organizations at national, regional, and international levels has been described in detail in the document entitled "The Necessity of Strengthening the Cooperation between Tissue Banks and Organ Transplant Organizations at National, Regional, and International Levels published in 2013 [1].

It is a fact that the donation of human tissues and organs increases significantly when tissue banks and organ transplant organizations established within the country work together in the procurement of human organs and tissues at donor sources. To achieve this goal national competent health authorities should consider the establishment of a national central office for coordination of all procurements of human tissues and organs to be carried out by different tissues banks and organ transplant organizations operating in the country at donor sources, and the adoption of a unified coding and traceability system that facilitate cooperation among tissue banks and organ transplant organizations working in the country with donor sources.



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The cooperation between tissue banks and organ transplant organizations at national, regional, and international levels should include the broadest possible sharing of relevant information that could be vital for medical practice and scientific research studies in different countries. This sharing of information should also facilitate prompt action in case of an emergency affecting a country, or group of countries, during which a high amount of sterilizing human tissues is needed. "To facilitate this sharing of information at regional and international levels, national competent health authorities should promote and support all regional and international efforts related to the harmonization of different coding and traceability systems in force in different countries". This process aims to have, at the end of it, a harmonized coding and traceability system at the international level [1].

Why does the international community need urgently not only the adoption of a harmonized coding and traceability system at international level, but to strengthen the cooperation of tissue banks and organ transplant organizations at national, regional, and international levels? Worldwide there are hundreds of tissue banks and organ transplant organizations operating in different countries in all regions of the world, some of them with considerable experience in the use of sterilized tissues in specific medical treatments and the field of organ transplantation. In some countries, several tissue banks are operating in different locations and more than one organ transplant organization established. The experience has shown that in most countries there is a lack of appropriate working relationship between organ transplant organizations and tissue banks operating in them. For this reason, each of these two institutions carries out their activities independently, even in the case when human organs and tissues are procured from the same deceased person at the same donor source [1].

For organ transplantation, there is an international organization called "International Registry of Organ Donation and Transplantation" that collects information about organ donations worldwide. However, there is no similar organization dealing with human tissue donations worldwide and on the use of the processed tissues in medical practice and research activities<sup>a</sup>. This situation is not helping national, regional, and international efforts to increase human tissue donations worldwide and to promote closed cooperation between tissue banks and organ transplant organization at all levels.

The primary objective of the present paper is to review and propose some ideas and suggestions to increase further the current level of cooperation between tissue banks, organ transplant organizations, and between these two institutions operating in the same country and at regional and international levels.

### **Expected Achievements**

The main expected achievements with the adoption of the different ideas and proposals on the main subject of this paper can be found in [1] and [2]. However, it is relevant to stress, once again, the following ideas and proposals on the same subject:

- To support the gradual harmonization at national, regional, and international levels of all laws and regulations in force in different countries, particularly in the case of codes of ethics, codes of practice, coding and traceability systems, Standard Operational Procedures (SOPs), among others in force in different countries. The gradual harmonization of these laws and regulations will allow the strengthening of the cooperation between tissue banks and organ transplant organizations already established in different countries at all levels.
- 2. To support the establishment of a National Tissue and Organ Transplant Office<sup>b</sup>. or equivalent competent authority in interested countries with the responsibility of carrying out the transplant coordination process of human tissues and organs at the national level<sup>c</sup>.
- 3. To promote the establishment of an effective donor referral system by which tissue banks and organ transplant organizations are informed or notified by the National Tissue and Organ Transplant Office, or equivalent competent authority in the country, of potential tissue and organ donors when a death occurs at donor sources.
- 4. To consider the possibility of establishing Regional Tissue Processing Centers in interested regions of the world, with the aim of assisting countries within the region to increase human tissues donations or to provide human tissues in an emergency.
- The adoption of a joint program for the training of staff working in different tissue banks and organ transplant organizations or donor sources in the same country, or in different countries within the region as well.
- 6. To promote the establishment of a quality management system to reduce the risk and maximize the benefits of the tissue and organ transplantation

<sup>&</sup>lt;sup>a</sup>In the paper entitled "The Importance of Establishing an International Network of Tissue Banks and the Creation of Regional Tissue Processing Centers in Different Regions of the World" published in 2013, the necessity of establishing a regional network of tissue banks has been proposed in order to increase further the current level of cooperation among established tissue banks operating in several countries in different regions of the world.

<sup>&</sup>lt;sup>b</sup>This office could be also called "National Transplant Coordination Office".

<sup>&</sup>lt;sup>c</sup>This office should also act as a focal point for the country and should be responsible for human tissues and organs transplantation coordination.

processes. The main elements of the quality management system could be found in [3] and [4].

### The Need for Establishing a National Tissue and Organ Transplant Office and Its Main Responsibilities

This office aims to act as the focal point for the country for tissue banking and organ transplantation activities<sup>d</sup>. The central role and responsibilities of this office should be the following:

- To coordinate and to support all activities carried out by tissue banks and organ transplant organizations during the procurement of human tissues and organs within the country.
- To promote the broadest possible sharing of information and experience in human tissue and organ transplantation activities among all tissue banks and organ transplant organizations operating within the country.
- To promote closed cooperation among tissue banks and organ transplant organizations with donor sources within the country.
- 4. To develop new technologies for the procurement, processing, sterilization, and storage of human tissues.
- 5. To act as the focal point for the implementation of human tissues and organs transplant activities at regional and international levels.
- To promote the establishment of a quality management system to reduce the risk and maximize the benefits of the tissue and organ transplantation processes.

The primary responsibilities of the National Tissue and Organ Transplant Office or equivalent competent authority propose to be established in a country are well described in [2]. However, to carry out the responsibilities mentioned above the following activities should be implemented:

 The National Tissue and Organ Transplant Office should inform appropriate tissue bank and organ transplant organization of possible tissues and organs donor to allow these two institutions to assembly their procurement teams as quick as possible. These teams should be ready to initiate the

dIn Argentina, the regulatory and controlling office for organ and tissue transplant activity is the National Central Unique Coordinating Institute for Ablation and Implant (INCUCAI). In Brazil, a National Transplant Organization has been established but this office does not deal with tissue donation. In Spain, there are two organizations, the Organització Catalana de Transplantaments (OCATT) and the Organización Nacional de Transplantes (ONT), with the responsibilities of organizing the exchange between generating and transplanting centers. Other countries have Organ Transplant Offices, but the donation of tissues is excluded from the responsibilities of these offices.

- procurement process immediately that the family or the legal representative of the potential donor gives their consent or authorization for human tissues and organs donation.
- 2. The National Tissue and Organ Transplant Office staff, or the staff of any other designated competent authority, should work closely with the tissue and organ procurement teams and hospital staff in requesting family donor or legal representative their consent or authorization for organ or/and tissue donation. This request should be carried out in the order of priority established by the national competent health authority.
- 3. The National Tissue and Organ Transplant Office, or any other equivalent designated competent authority, should support the harmonization of all codes of ethics, codes of practice, and the adoption of a unique coding and traceability system by all tissue banks and organ transplant organizations operating within the country. This harmonization should be carried out taking into account any other systems adopted at regional and international levels by the competent regional and international organizations such as the WHO, and professional associations established in different regions in the field of tissue banking and organ transplant activities.

### The Need for Adopting a Common Coding and Traceability System at Regional and International Levels<sup>e</sup>

According to [1], one of the most important responsibilities of a tissue bank and organ transplant organization is the traceability of all human tissues and organs procured and processed by them, and used by hospitals and other medical facilities in specific medical treatments. There is an increasing global circulation of human tissues and, in some cases of human organs, and an expanding role played by commercial markets in many of these cases. Any of these human tissues could not be adequately sterilized or handled and, for this reason, the recipients of such tissues could be contaminated. Due to this complicated situation, tissue banks and organ transplant organizations should know where their procured human organs and procured and processed human tissues were transplanted and to whom, in case of a rejection of these human tissues and organs is reported. The system should allow clarifying if the tissue bank or organ transplant organization involved in the supply of the human tissues and organs have any responsibility in this situation.

The National Tissue and Organ Transplant Office, or

<sup>&</sup>lt;sup>e</sup>A coding system provides the necessary standards and control in order to ensure that each donation, and each product prepared from that donation is uniquely identified, and that a common terminology is used. A traceability system maintains records on the activities associated with donated material from the time of procurement to the point of implantation.

any other designated competent authority established in the country, should promote and support, in consultation with professional associations of tissue banks and organ transplantation, the WHO, the IAEA, and any other relevant regional and international organizations, the adoption of an appropriate coding system for the full traceability of human tissues and organs for transplantation. This system should be used most effectively, independently of the place and country in which the human tissue or organ was procured and processed, and the location and country in which was definitively used."The introduction of a standardized coding system for donation identification numbers for all donated human products should ensure the global traceability for all tissues and organs used in medical treatments and research activities" [1].

## Role of the Professional Associations in the Promotion of the Broadest Possible Cooperation between Tissue Banks and Organ Transplant Organizations

There are several regional professional associations [5]<sup>f</sup> that have been established with the aim of promoting tissue banking among its members, such as European Association of Tissue Banks (EATB), the American Association of Tissue Banks (AATB), the Latin American Association of Tissue Banks (ALABAT), and the Asian and the Pacific Association of Surgical Tissue Banking (APASTB). There are also several organizations involved in the donation of human organs operating in different countries and at the international level.

According to [1], several activities could be supported by these two groups of organizations in the future [5]<sup>g</sup>. Some of these activities are the following:

- The promotion of the broadest possible sharing of information among its members about the transplant of human tissues and organs worldwide.
- The identification of problems presented in the field of transplantation of human tissues and organs, and the solutions that are given to overcome these problems.
- 3. The harmonization of laws, regulations, rules, and other guiding documents in force in each member countries to facilitate the cooperation between tissue banks and organ transplant organizations operating in different member countries, including codes of ethics, codes of practice, and SOPs, among others.

In the paper entitled "The Future Role of the Professional Associations in the Promotion of Tissue Banking Activities in Asia and the Pacific and in the Latin America Regions", published in 2011 by Cell Tissue Banking journal [5], a group of actions that these professional associations could be supported on this issue in the future are included.

<sup>9</sup>For a detailed description of the activities that these professional associations can carry out in the field of tissue banking see [5].

- 4. The need to have a harmonized coding system for the identification and traceability of human tissues and organs that are used at regional and international levels.
- To promote the establishment of a quality management system to reduce the risk and maximize the benefits of the tissue and organ transplantation processes.
- 6. The establishment of Regional Tissue Processing Centers in interested regions of the world. The purpose of these centers is to increase human tissue donations and used, to support tissue banks in an emergency in any country of the region, and the training of the staff working in tissue banks in any of the states within the region.

### Role of Governments in the Promotion of the Broadest Possible Cooperation between Tissue Banks and Organ Transplant Organizations

One of the main tasks to be carried out by governments interested in increasing human tissue and organ transplantation at the national level should be the promotion of the broadest possible cooperation among tissue banks and organ transplant organizations operating in the country and other countries as well. To achieve this goal interested governments should:

- Support the establishment of a National Tissue and Organ Transplant Office, or equivalent competent authority, to coordinate all human tissues and organ transplant activities to be carried out within the country.
- To support regional and international efforts currently carried out by different international and regional organizations for the elaboration of an appropriate harmonized coding and traceability system of human tissues and organs procured and used at all levels.
- To promote the establishment of a quality management system to reduce the risk and maximize the benefits of the tissue and organ transplantation processes.
- 4. To support the establishment of Regional Tissue Processing Centers in interested regions of the world. The purpose of these centers is to increase human tissue donations and used in all interested countries within the region, to support tissue banks in an emergency in any country of the region, and the training of staff working in tissue banks at the national level.
- To support the establishment of an "International Registry of Tissue Donation and Transplantation" that collects information about tissue donations worldwide.

### Role of the WHO, IAEA, and Other Relevant Regional and International Organizations in the Promotion of the Broadest Possible Cooperation between Tissue Banks and Organ Transplant Organizations

Some of the main tasks that the WHO, the IAEA, and any other relevant regional and international organizations in the field of tissue banking and organ transplantation should carry out in the future are the following:

- The harmonization of all laws and regulations in force in different countries.
- The promotion of the establishment of a quality management system to reduce the risk and maximize the benefits of the tissue and organ transplantation processes.
- The adoption of a harmonized coding and traceability system [1,6]<sup>h</sup>.

Professor Glyn O Phillips, in a lecture gave in the 5<sup>th</sup> World Congress on Tissue Banking, held in Kuala Lumpur, Malaysia on June 5, 2008, entitled "Global Role and Future of Tissue Banking", expressed the following: "The IAEA has gained more experience and success than any other international organization in establishing tissue banks in developing countries and applying ionizing radiation for sterilizing tissue grafts, used in transplant surgery (in orthopedic reconstruction, treatment for cancer, trauma and high velocity impact damage), the treatment of burns, leprosy and intractable skin wounds and pressure sore ulcers".

On the other hand, WHO has concentrated their assistance in the promotion of activities associated primarily to the donations of human organs, and had participated in some events in the field of tissue banking organized by the IAEA in the past. The adoption of a joint program by both organizations for the promotion and support of human tissue and organ transplantation at regional and international levels will have a significant impact in the number of human tissue and organ donations in many countries. However, until today the establishment of a joint program by these two international organizations has not yet been included in their respective plans for the coming years.

For this reason, perhaps the following ideas could be considered by the Secretariat of the IAEA and WHO in the future:

 The establishment of a working group with a staff of the IAEA, the WHO, and a limited number of selected experts in the field of tissue banking and organ transplantation. This group aims to increase human

- tissue and organ donations at the world level, and to identify the main activities that both organizations should carry out in the future to achieve this goal.
- 2. The promotion of the establishment of a unified and harmonized coding and traceability system at international level for human tissues and organs transplantation.
- 3. To support the establishment of a National Tissue and Organ Transplant Office, or equivalent competent authority in interested IAEA and WHO member states
- 4. To consider the possibility of the establishment of Regional Tissue Processing Centers in different interested regions of the world.
- To promote the establishment of a quality management system to reduce the risk and maximize the benefits of the tissue and organ transplantation processes.

#### **Conclusion**

The promotion of the broadest possible cooperation between tissue banks, organ transplant organizations, and between these two institutions with hospitals, and other donors sources in the country, the establishment of a National Tissue and Organ Transplant Office, the establishment of a Regional Tissue Processing Centers, the harmonization of laws and regulations in the field of human tissue and organ transplantation, and the adoption of a unique coding and traceability system, among others, are concrete proposals that deserves the attention of the national competent health authorities of the different countries, as well as by the relevant regional and international organizations and professional associations in the field of tissues and organs donations.

The aim of implementing these activities is to increase human and tissue donations at national, regional, and international levels, and to increase the quality of life of those patients that need the transplant of human tissues and organs.

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<sup>&</sup>lt;sup>h</sup>The main responsibilities of the IAEA, WHO, and other relevant regional and international organizations in the promotion of the broadest possible cooperation between tissue banks and organ transplant organizations are described in detail in [6] and [1].

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