



## Review Article

# Tissue Banking and Transplantation: Role of Governments, International Organizations, and Regional Professional Associations

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## Abstract

It is crucial to complement national activities carried out by governments for the procurement, processing, sterilization, distribution, storage, and use of human tissues in specific medical treatments with activities carried out by international and regional organizations as well as professional associations in the field of tissue banking and transplantation. In the following paragraphs the reader will find a group of recommendations and suggestions for the consideration of governments, international organizations and professional associations in the field of tissue banking and transplantation to increase tissue donations and use.

## Keywords

Tissue banking, Human tissues, Tissue donors and recipient, IAEA, WHO, Tissue establishments, Tissue transplantation, Tissue sterilization, Ionizing radiation technique, Professional associations

## Introduction

Expansion of activities in many tissue establishments all over the world can be attributed to a significant increase in the aging of the population, the rising of different diseases and the application of new medical treatments in which the use of sterilized tissues is indispensable. In 2017, the global tissue banking market was valued at US\$1.056, 4 million, and it is anticipated to reach nearly US\$3.000 million by 2026. Increase in awareness for tissue donation, technological advancement, and target patient population is likely to fuel the global tissue banking market during the period 2017-2026.

An increase of government initiatives to build better facilities for tissue banking activities, nuclear facilities for the sterilization of tissues using the ionizing radiation technique, the improvement in the collaborations between tissue establishments operating in the same country and in other countries as well, and the rise in the demand of human tissues to be used in specific medical treatments, are expected to drive the global tissue banking market during the coming years.

However, stringent regulatory requirements adopted by governments to ensure that tissues transplantation is carried out safely for donors and recipients is a major factor restraining the global tissue banking market during the coming years. Without a doubt, safety for both donors and recipients are an essential factor in human tissue transplantation, and govern-

ments are responsible for ensuring that the tissue transplantation is carried out according to the best medical practices in force in the country.

For the reasons mentioned above, governments should provide the oversight of all tissue transplant activities carried out in the country, and should adopt relevant legislation, regulations, and standards to ensure the safety of donors and recipients of human tissues in specific medical treatments.

In addition to the role of governments in the field of tissue banking and transplantation, two international organizations, the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA), and several regional professional associations already established in several regions can provide also a vital support to tissue banking and transplantation activities at national, regional, and international levels.

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## The Role of Governments in the Field of Tissue Banking and Transplantation

The primary role of the government in each country in the field of tissue banking and transplantation is to establish a legal framework within which tissue transplant services can operate, monitor, and report, and to develop an appropriate mechanism for an effective tissue transplant service, and the traceability of the transplanted human tissues. The legal framework should include tissue transplant law, the circumstances in which human tissues can be retrieved, processes, and used, and the consent or authorization needed for the donation of human tissues, among others.

To improve tissue donation and the rise in the use of human tissues in specific medical treatments, governments should establish a national tissue and organ transplant office. This office aim is to coordinate all activities carried by tissue establishments operating in the country related to the procurement, processing, sterilization, storage, distribution, and use of human tissues and the transplant of tissues and organs.

Besides, national health care authorities should set up a system of authorization and inspection of tissue establishments, hospitals, and other medical facilities, to ensure that they follow the laws and regulations in force in the field of tissue banking and transplantation. The purpose of this system of authorization is to reduce to the minimum any disease transmission as a result of human tissue transplantation carried out by the hospital medical team using the human tissues processed by a tissue establishment.

Without a doubt, human tissue donation and transplantation is one of the most regulated areas of health care today in many countries. However, additional measures should be adopted to increase even further the safety of donors and recipient of human tissues.

For all the above reasons, the primary role of governments in the field of tissue banking and transplantation can be summarized as follows:

1. To establish a legal framework within which tissue transplant services can operate, monitor, and report, including the establishment of an effective mechanism for the traceability of the transplanted human tissues;
2. To put in place a mechanism for the protection of donors and recipients of human tissues. This mechanism should ensure rapid investigation of any unfortunate incidents involving human tissue transplantation services, so timely corrective and preventive actions can be taken immediately to avoid its repetition<sup>a</sup> [1];
3. To establish a national tissue and transplant office in charge of the coordination of all activities related to the procurement, processing, sterilization, storage, distribu-

<sup>a</sup>An adequate system to ensure the traceability of human tissues should also be established. This would also make it possible to verify compliance with quality and safety standards. Traceability should be enforced through accurate substance, donor, recipient, tissue establishment and laboratory identification procedures, as well as record maintenance and an appropriate labelling system.

tion, and use of human tissues, and the procurement and transplantation of organs within the country. This office should also act as the focal point for the allocation and distribution of human tissues, in case of an emergency or other exceptional circumstance in which the use of sterilized tissue is indispensable, and the country involved cannot supply them;

4. To set up a system of authorization and inspection of tissue establishments, hospitals, and other medical facilities to ensure the safety of the donors and the recipients of human tissues in specific medical treatments<sup>b</sup> [2];
5. To promote the development of a system for the voluntary, non-remunerated donation of human tissues, and to increase public awareness and understanding of the benefits of the voluntary non-remunerated provision of human tissues from deceased and living donors [3];
6. To promote a system of transparency and equitable allocation of human tissues, guided by clinical criteria and ethical norms, as well as equal access to human tissue transplantation services by national capacities [3];
7. To improve the safety and efficacy of human tissue donation and transplantation services by promoting international best medical practices in all countries;
8. To strengthen national and international authorities and capacities to provide oversight, organization, and coordination of human tissue donation and transplantation in specific medical treatments and research activities. Particular attention should be given to maximizing human tissue donation from deceased donors and to the protection of the health and welfare of living donors with appropriate health care services and long-term follow-up;
9. To collaborate in collecting data, including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology, and ethics of tissue donation and transplantation, and to encourage the implementation of globally consistent coding systems for human tissues in order to facilitate national and international traceability of materials of human origin for transplantation [3];
10. To promote regional and international co-operation between tissue establishments operating in different countries and regions in the field of tissue banking and transplantation;
11. To encourage the elaboration of a global accepted unified coding system as well as common product names and definitions for unique product identification to recognize human tissues used in human tissue transplantation or research activities for traceability purposes;
12. To promote collaboration and consultation between national regulatory health care authorities and scientific and professional associations already established in each of the countries participating in this collaboration, to ensure the compatibility of the different regulatory systems in force in these countries;

<sup>b</sup>National competent health care authorities shall organize inspections and carry out control measures as appropriate whenever there is any serious adverse reaction or serious adverse event reported.

13. To promote the establishment of an international network of tissue establishments to encourage the free exchange of all relevant information related to tissue banking and transplantation activities in all countries and regions;
14. To support the establishment of a limited number of regional tissue processing centres to provide high quality sterilized human tissues in an unusual situation to specific tissue establishments operating in other countries, when necessary.

## The Role of the World Health Organization (WHO) in the Field of Tissue Banking and Transplantation

The WHO plays an essential role in the field of organ transplantation, but this role is very limited in the field of human tissue banking and transplantation.

To complement national activities carried out by governments in the field of tissue banking and transplantation, WHO should take a more active role in facilitating and supporting global and regional initiatives in both areas in all its member states.

The following paragraphs include a group of actions that WHO could promote and support in the field of tissue banking and transplantation during the coming years:

1. To encourage the use of human tissue in certain transplant services in its member states;
2. To support the establishment of a WHO Expert Advisory Panel for human tissue banking and transplantation activities. The main task of this advisory panel is to prepare a set of recommendations on how the organization could promote tissue banking and transplantation activities in its member states;
3. To facilitate, in collaboration with other relevant international and regional organizations, the development of a core of technical and ethical standards for the management of the safety, quality, and efficacy of human tissue for transplantation [2];
4. To encourage interested WHO member states to develop a legal framework on human tissue banking and transplantation and research activities involving human tissues;
5. To support all activities to be carried out by WHO member states and non-governmental organizations to eliminate trafficking of the material of human origin without observing all regulations and ethical policy and principles in force in the supplier and recipient countries;
6. To promote the establishment of an international network of tissue establishments to encourage the free exchange of all relevant information related to tissue banking and transplantation activities carried out in all countries and regions;
7. To facilitate alliances between national tissue and organ transplant offices already established in a group of WHO member states, to facilitate and promote regional and international cooperation in legal, ethical, and technical matters in the field of tissue banking and transplantation;

8. To encourage and support the highest possible collaboration between different professional associations already established in the field of tissue banking and transplantation in different regions;
9. To facilitate communication between regulatory health care authorities and providers on the international circulation of human tissues for transplantation and research purposes;
10. To establish a database of the known infectious risks and the safety measures that should be applied to donors and tissue donations in different countries and regions;
11. To assist WHO member states to develop the necessary capacity for national regulatory approaches to quality and safety in the field of human tissue transplantation and research activities involving human tissues;
12. To elaborate regional educational strategies for hospital coordinators and health care professionals in the field of human tissue procurement and transplantation;
13. To encourage and improve research, education, training, and clinical use of human tissues in specific medical treatments;
14. To identify and disseminate relevant information on successful models of human tissue transplantation that use local resources and cultural norms;
15. To promote the elaboration of an international accepted unified coding system to identify human tissues used in tissue transplantation for traceability purposes;
16. To encourage the development of a global network of vigilance and surveillance to ensure the use of the best medical practice in the field of tissue banking and transplantation;
17. To support the establishment of a limited number of regional tissue processing centres to provide high quality sterilized human tissues in an unusual situation to specific tissue establishments located in other countries, when necessary;
18. To promote closed cooperation between national tissue and organ transplant offices established in all WHO member states.

## The Role of the International Atomic Energy Agency (IAEA) in the Field of Tissue Banking

The IAEA was the leading international organization within the United Nations system in the promotion of the use of the ionizing radiation technique for tissue sterilization during the period 1971- 2005. The IAEA provided technical and financial assistance to 33 of its member states from four regions to implement 36 projects at national, regional, and interregional levels in the field of tissue banking. For the entire IAEA program on radiation and tissue banking, the organization allocated, during the period 1971-2005, a total of US\$7.285.422, distributed in the following manner:

- For the implementation of 31 national projects: US\$3.420.757;
- For the implementation of three regional projects in Asia

and the Pacific and Latin America and the Caribbean regions: US\$2.239.504;

- For the implementation of two interregional projects: US\$1.625.161<sup>c</sup> [4].

At the same time, the IAEA's program facilitated the training of 284 tissue establishment operators and medical doctors in the international, regional, and national training centres established in Singapore, Buenos Aires, and Seoul under the program mentioned above [5].

Considering the outcome of the IAEA program on radiation and tissue banking, the following are a group of recommendations and suggestions that the IAEA should support in the field of tissue banking in the future:

1. To develop, support, and improve the quality of the research, education, and training activities carried out in different countries regarding the use of the ionizing radiation technique for the sterilization of human tissues;
2. To set up a group of international experts with the task of reviewing the IAEA Radiation Sterilization of Tissue Allografts: Requirements for Validation and Routine Control. A Code of Practice, adopted by the IAEA in 2007 [6]. The purpose of the review is to include the experience in the use of this code for tissue sterilization in different IAEA member states in the last 12 years and the results obtained;
3. To support the implementation of an interregional project within its technical cooperation program to strengthen the capacity of the national regulatory health care authorities in the field of quality and safety in a select group of countries in Asia and the Pacific and the Latin America and the Caribbean regions;
4. To promote and support the establishment of an international network of tissue establishments to collect relevant information related to the use of the ionizing radiation technique for human tissue sterilization;
5. To promote and support the highest possible cooperation, in the use of the ionizing radiation technique for the sterilization of human tissues, among different regional and national professional associations already established in different regions and interested tissue establishments;
6. To support the establishment of a limited number of regional tissue processing centres to provide high quality sterilized human tissues using the ionizing radiation technique in an unusual situation to specific tissue establishments located in other countries, when necessary;

## The Role of Regional Professional Associations in the Field of Tissue Banking

There are several professional associations already established in four regions in the field of tissue banking, two of them found with the direct support of the IAEA. These four

<sup>c</sup>For a comprehensive information on the role played by the IAEA in the field of tissue banking see the book entitled "The Use of the Ionizing Radiation Technique for Tissue Sterilization: The International Atomic Energy Agency Experience" [5].

professional associations are the following:

- Asia-Pacific Association of Surgical Tissue Banking (APASTB);
- Latin American Association of Tissue Banks (ALABAT);
- European Association of Tissue Banks (EATB);
- American Association of Tissue Banks (AATB) [7].

All of the above professional associations play an essential role in the promotion of tissue banking activities in their respective regions. The objective to be achieved by these regional professional associations is to improve the quality of the activities carried out by the tissue establishments and nuclear facilities in charge of the sterilization of human tissues, as well as to increase tissue donations in all countries.

The following is a group of actions that the above-mentioned professional associations can carry out in the field of tissue banking during the coming years:

1. To promote research, education, and training activities in the use of the different techniques for the sterilization of human tissues, particularly the use of the ionizing radiation technique for this specific purpose;
2. To disseminate new technologies for processing of human tissues, and to promote the application of new methods of processing and conservation of human tissues;
3. To encourage the implementation of new techniques such as the principles of engineering regeneration of skeletal tissue and cell culture, among its members;
4. To promote the development of a core of technical and ethical standards for the management of safety, quality, and efficacy in the processing of human tissue for transplantation purpose that can be used as a model for tissue establishments;
5. To encourage tissue establishments to develop and adopt a legal framework on human tissue banking activities that reflect the particularities of each country and region;
6. To promote and support the adoption of a quality manual to ensure the highest possible quality in the procurement, processing, and sterilization of human tissue by the tissue establishments;
7. To promote and support the creation of an international network of tissue establishments to collect relevant information related to human tissue procurement, processing, sterilization, storage, distribution, and use of human tissue carried out in all tissue establishments located in different countries;
8. To encourage the alliances between national tissue and organ transplant offices to promote the cooperation in legal, ethical, and technical matters in the field of tissue banking and transplantation;
9. To promote the highest possible collaboration between different regional and national professional associations already established in the field of tissue banking, and between these associations and the various regulatory and national health care authorities in different countries;

10. To elaborate regional educational strategies for hospital coordinators and health care professionals to be applied to increase tissue donations;
11. To identify and disseminate relevant information on successful models of human tissue banking activities that use local resources and cultural norms;
12. To promote and support the elaboration of an international accepted unified coding system to identify human tissues used in transplantation or research activities for traceability purposes;
13. To encourage the development of global networks of vigilance and surveillance to ensuring optimal medical and research practices in the field of tissue banking and transplantation;
14. To support the establishment of a limited number of regional tissue processing centres to provide high quality sterilized human tissues in an unusual situation to specific tissue establishments located in other countries, when necessary;
15. To support the implementation of a public awareness strategy for tissue establishments, to increase public and professional awareness of the activities carried out by the tissue establishments, and to enhance tissue donation;
16. To promote the establishment of individual agreements between national competent health care authorities in interested countries and the relevant authorities in charge of national, regional, and international tissue banking training centres established by the IAEA to promote the cost sharing of training activities carried out in these centres;
17. To support the adoption of an agreement with public national competent health care authorities, to collaborate in achieving sustainability of the tissue banking activities carried out at national, regional, and interregional levels in the benefit of the population of the different countries;

## Conclusion

The fast development of tissue establishment in several countries all over the world in the last decades and the increase in tissue banking and transplantation activities in these states made necessary the adoption of a group of measures to ensure the safety of the donors and recipient of human tissues processed by the tissue establishments. The experience has shown that the measures already adopted were not enough and, for this reason, new actions need to be considered and approved by governments, regional and international organizations and professional associations in the field of tissue banking and transplantation to ensure the safety of the donors and recipients of human tissues.

Besides, there is a need to consider new actions in several areas to increase tissue donations and the safety of donors

and recipient. Among these actions are the following:

- To qualify new tissue bank operators and medical doctors to improve the activities in some tissue establishments in all regions;
- To prepare the regulatory national health care authorities to audit a select group of tissue establishments to identify problems and difficulties that are affecting their activities and are preventing the correct processing of the tissues;
- To promote the use of the ionizing radiation technique for the sterilization of tissues to produce free-contaminated tissues;
- To harmonize norms and regulations as well as standards now in force in several countries to promote cooperation among them, among others.

The above group of recommendations and suggestions included in this paper could be used as reference to prepare a set of actions that should be implemented by governments, regional and international organizations, and professional associations to improve the safety of donors and recipient of human tissues, and to increase tissue donations, procurement, and use of sterilized human tissue in certain transplant activities.

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