WUTBA GUIDE

on how to establish tissue donation and banking.

Version 1.0

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Foreword

Access to life enhancing or lifesaving tissue transplants is denied to millions of potential waiting recipients, with the vast majority residing in lower- and middle-income countries (LMIC), where they are without routine access to tissues for transplantation.

The World Union of Tissue Banking Associations (WUTBA) was established in 2005 as a collaborative effort among the current international peak bodies in tissue and cell banking, to promote the access to safe and high quality donated human tissue grafts worldwide.

WUTBA strives to collaborate and partner with other organizations in the pursuit of ethical and clinical practice excellence in tissue donation and transplantation, such as the World Health Organization (WHO).

To that purpose, WUTBA has developed this guide on **how to establish tissue donation and banking in a given area**.

This guide is linked to a *Global action framework to advance universal access to safe, effective and quality-assured human tissues for transplantation* (GAFTT), a guide that is currently prepared by the WHO and designed to provide strategies and recommendations to Member States in overcoming identified challenges that prevent or limit autonomy and sufficiency in tissue donation and transplantation within their nation or region.

According to GAFTT, an initial step is to review capabilities with the help of targeted regional consultations, to set priorities to address identified needs, and to agree on resources and delivery of outputs. An effective and objective evaluation of cost and benefit, in the different regions, will probably show the positive impact of affording availability of transplant tissues. Often, transplant tissues, in particular eye tissues, can be produced at a lower cost than industrially produced and imported tissues, especially in LMIC.

Tissue transplantation is not always integrated in the wider health care system or not universally covered by insurance schemes. Consequent to this limitation, the 'out of pocket' cost of transplant tissue and care becomes a barrier for those awaiting transplantation.
Hence, tissue donation, tissue banking services, and transplantation must be underpinned by realistic funding and cost recovery financial models that promote self-sustainability with a patient centred approach that refrains from financial gain from donated tissues in accordance with the WHO Guiding Principles.

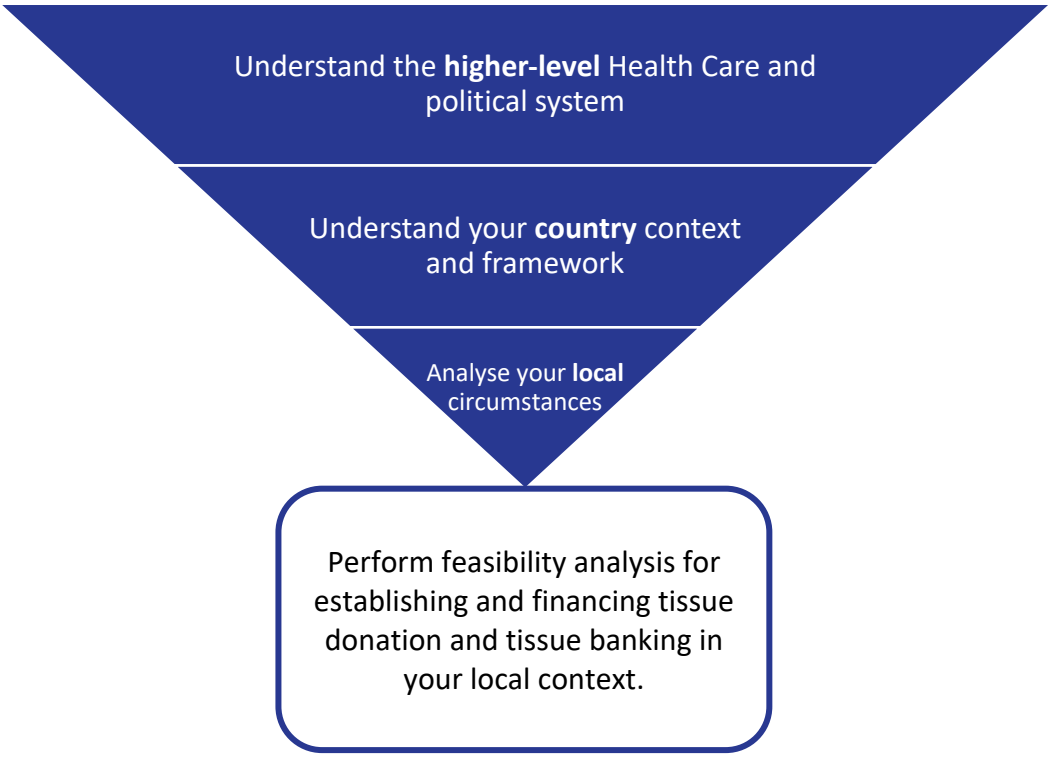
With this in mind, and in conjunction with strategic objectives of the global action framework, the purpose of this WUTBA guide is to provide a practical approach and key steps to take on the way to establish sustainable donation activities and tissue banking operating models.

How to start and how to go about it?

This guide intends to provide support and inspiration while you examine your area and existing circumstances for the feasibility of establishing tissue donation programs and tissue processing facilities.

The flow of this guide is as follows:

- Think from big to small, high-level to detail.
- Break the overall chapters down for your specific analysis (one type of tissue in one location or area).
- First understand the circumstances in your country and area, then go into detail for potential donation and tissue banking activities.
- Once your local examination is done, potentially scale-up to country and tissue donation in general in the long term.



It is important to be aware that doing the feasibility analysis will be a snap-reading method (snapshot) of your situation. It will empower you to carefully evaluate whether the advantages outweigh the foreseen challenges to establish tissue donation. It is furthermore intended to enable you to confirm that there is a critical mass of resources and possibilities available to initiate either a single or a small number of donation program(s).

Establishing tissue donation is not a linear process over time where each step would bring you forward to the same extend. Instead, it is a process where at the beginning a steep increase of activities or investments and efforts is needed, to prepare for and to establish donation activities. At a later point in time this will change into a kind of plateau, where a more constant level of activities and efforts is required to receive the same output, namely, to facilitate tissue donation in a routine manner and “pick the fruits” of what has been established and “seeded” initially.

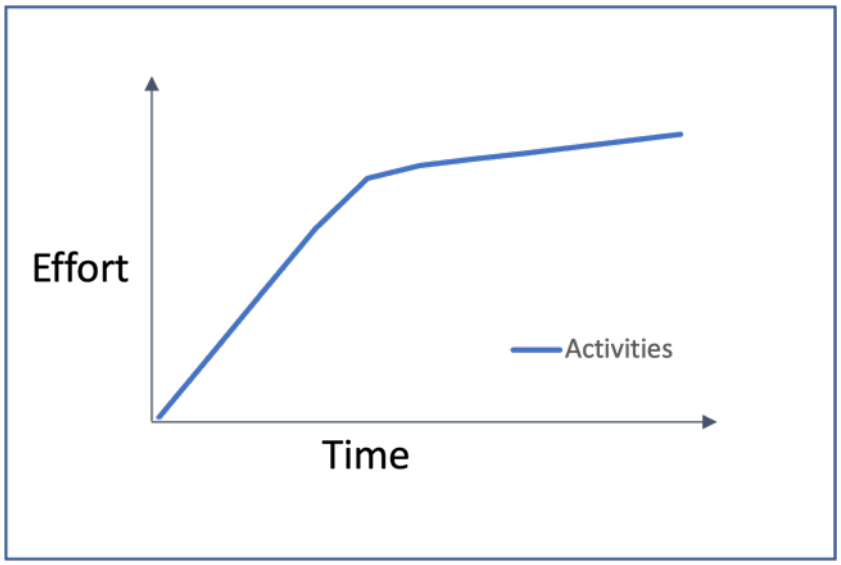


Fig.1: Non-linear course of the efforts and activities over the time to establish sustainable tissue donation; starting with a steep increase in short- or mid-time, changing into a more constant level in the long term.

1. Analysis: Health System and Political System

This chapter shall provide some key aspects and helpful questions to start analyzing the higher-level health care and political system in your region or country.

1.1. Health care

Is tissue transplantation integrated in the wider health care system or universally covered by insurance schemes?

- Understand the health care system and payment mechanisms,
- understand insurance system(s); as both will influence the demand.

1.2. Political System & Stakeholders

- Perform a stakeholder analysis on regional, national, and international level.
    - Understand structure of governmental bodies, competent authorities, and ministries in relation to tissue donation. At the government level, it is important to first understand the governmental structure and how it impacts the flow and enforcement of policies.
    - Check for associations and societies, intergovernmental organizations (like WHO)
    - Learn about non-governmental organizations and their activities in relation to tissue donation.
    - Check for potential influencers, for example surgeons that are part of committees, but also industry representatives, research and educational institutions, etc.

- Understand stakeholders' motivation and rationale to engage in tissue donation and/or tissue banking.
    - What input or support can they provide?
    - What is their freedom of action?
    - What kind of advocacy, key opinion leadership or championship can they take on?
    - Who might support, but also who might impede an engagement in tissue donation? Who might be neutral?

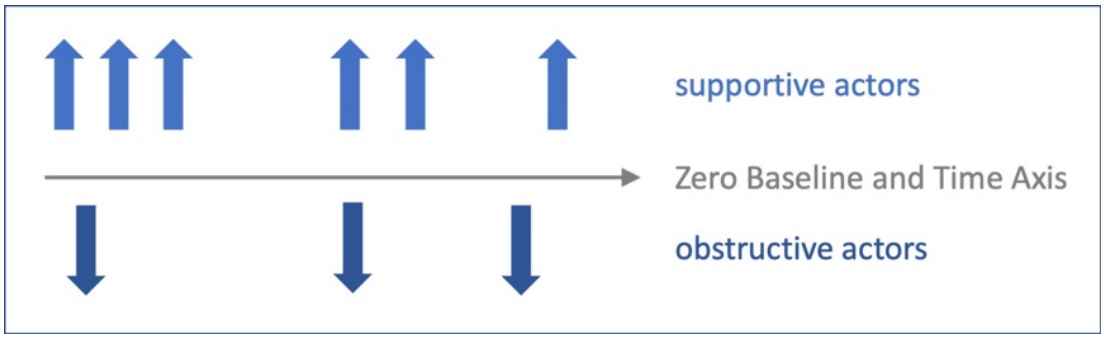


Fig.2: Schematic view of potential stakeholder attitudes. It is helpful to understand which actors within the different stakeholder types might be supportive and who might impede engagement in tissue donation over time. This evaluation can be based on a baseline representing a neutral attitude.

Supporting Material/References: **SightLife Policy Guide: Stakeholder Analysis**

1.2.1. Advocacy

To develop a strong donation program high level support is the most important – whether that's from a government hospital chief executive officer, Ministry of Health, someone who motivates the employees to make timely death notifications, or police commissioners to support donation.

Find committed supporters, champions and advocates who support and promote your efforts. Someone has to push things forward.

Supporting Material/References: **SightLife Policy Guide: advocacy guide.**

1.3. Demand of tissue

What is the estimated demand of the investigated tissue type in your region, both current and future? What are the main indications for transplantation of your tissue in scope? How many transplant centers/hospitals are there that would make use of the tissue transplants? Estimate the demand in numbers on regional and/or national level, a comparison with other countries/regions might be helpful (e.g., neighboring countries, India, USA, Europe). As sources for the estimation evidence from the literature, existing tissue banks statistical reports, country population projections and/or medical claims data may be helpful.

Supporting Material/References: **EBAA Cost-Benefit Analysis of Corneal Transplant.**

1.4. Vison & Objective

How does the implementation of tissue donation and processing fit into the national or regional context of your country? Is there a national/local health strategy or national objectives in relation to tissue donation or demand of the given health issue/demand for transplants?

For example:

- National Programme for Control of Blindness and Visual Impairment (NPCBVI): "National Campaign to eliminate corneal blindness: miracle by dream in INDIA collaborative consortium: To prepare a multicenter collaborative national action plan to achieve the target of 100,000 corneal transplants by 31st Dec 2025."

Supporting Material/References: **The Barcelona Principles, WHO Eye care in health systems: guide for action.**

This chapter should result in a good understanding of the demand of tissue in your country and lead to the conclusion that the political and stakeholder landscape provides a sufficient basis to establish tissue donation, processing, and transplantation in your country, rather than importing tissue and expertise from external countries.

2. Analysis: country context and potential way to implement tissue donation

2.1 National frameworks and conditions

- Start with the existing law on tissue transplantation and tissue donation. If no tissue specific laws exist, create team, and find consultants (lawyers, experts etc.) to draft and advocate with the Government.
    - Method of Consent (opt- in/opt-out system, who is legally allowed to provide consent, are there donor registries).
    - Is there a Legal process for medico legal cases and unclaimed bodies to obtain access to medical records for tissue banks?
    - Are there mandatory death notifications?
    - How is death declared legally?
    - Are there any legislative barriers to donation?
- Understand the billing and reimbursement system at transplantation centers and/or hospitals.

Supporting Material/References: **WHO Aid-Memoire for national health authorities, The Barcelona Principles, WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.**

2.2 Tissue Donation: Process analysis and potential course of actions

Create a potential course of actions and/or workflows for tissue donation and retrieval, processing, and distribution. Focus on donation activities and infrastructure because the set-up of a tissue bank will be a logic consequence of tissue being available for processing.

Analyze potential processes for a best-case and worst-case scenario, include analysis of gaps and bottle necks.

The intention is to perform a **feasibility analysis** of processes and/or workflows to arrive at a go/no-go.

2.2.1 Donation

- Analyze your area for potential donors and locations of hospitals, mortuaries, funeral homes.
- Understand the infrastructure of large high mortality hospitals, other hospitals and forensic services to get access to potential donors.
- Helpful questions:
    - How many deaths per year occurred in the last 10 years?
    - How many people die per hospital?
    - How many post-mortem cases are handled by the forensics department every year (where death occurs outside of hospital)?
    - What are the main causes of death?
    - What will be needed to enable death notifications?
- Is any donation activities or voluntary donation already ongoing in your area?
- Is trained staff for counseling and tissue recovery available? If not, create a training plan.
- Are there any barriers to donation from cultural or religious perspective?

Supporting Material/References: **WHO Aid-Memoire on key safety requirements.**

2.2.2 Processing and Tissue Banking

- Find potential space for the tissue bank. Decide on a new construction versus reusing an existing space.
- Create standard operating procedures, forms and templates for the tissue banks using existing ones from other tissue banks.
- Is laboratory infrastructure available in the area?
- List all required equipment and supplies, look for suppliers and create a procurement plan. Talk to other tissue banks to avoid unnecessary spent on equipment that is not really needed and to make sure you invest on high quality equipment that will work for the long-run.
- Is a tissue bank registration or accreditation required?

Supporting Material/References: **EDQM, Standards of Eye Banking in India 2020, WHO Aid-Memoire on key safety requirements.**

2.2.3 Distribution/Transplantation

- Create estimation of demand for tissue and given indications in your area. What area could be covered by the potential donation program? For example, this could be a capital city and surrounding area.
- Analyze hospital and transplantation center infrastructure in your area (how many centers, structure of primary/secondary/tertiary care centers)? How many surgeons?
- Is there potential to implement a central registry of wait listed patients?

3. Analysis: Costs and Financial aspects

An effective and objective evaluation of cost and benefit, in the given country, will probably show the positive impact of affordability of transplant tissues.

Perform a feasibility analysis on economic aspects and financing options to arrive at a go/no-go.

Is any calculation of cost already available of disease or impairment (e.g., vision loss) and potential savings from tissue transplantation (e.g., cornea)?

Supporting Material/References: **EBAA Cost-Benefit Analysis of Corneal Transplant.**

3.1 Process cost driven analysis.

- Determine the financial efforts that need to be made in relation to the processes and activities of donation, processing, storage and distribution. Determine cost categories, *for example:*
  - Human resources and labor costs (create a manpower plan), infrastructure (IT, facilities, equipment etc.), depreciation of tangible fixed assets, consumables.
  - Allocate costs in categories of fixed-costs, process-driven costs, investment costs.
- Estimate and focus on the main cost drivers in your foreseen processes.
- Estimate a forecast for the next few years, regarding numbers of donations, processed tissue and distributed transplants and the related costs.
- Estimate potential reimbursement costs per distributed tissue transplant. Consider potential discard in this calculation in dependence of the time point during the process flow (early or late in process).
- Questions to ask: What activity has which effect? Are there dependencies or connections of process steps?

Process module	Sub-process	Cost driving material or (flat) charge	Quantity unit		Personnel	Quantity unit		Devices/ infrastructure	Potential Discard Rate
Donation	**1 Determination of a donation**								
	Donor notification				counsellor, hospital staff		minutes	access to hospital information system	
	Donor criteria/medical history check				counsellor, treating physician		minutes	clarification for medico-legal case, as appl.	non-release of body by police?
	Next of kin interview				counsellor		minutes		percentage of interview leading to non-consent
	Internal planning, retrieval team				counsellor, recovery technician		minutes		
	2 Retrieval								
	2.1 Retrieval preparation								
	Preparation of material and documentation				counsellor, recovery technician		minutes	forms	
	Travel of retrieval team	km dependent charges		currency	counsellor, recovery technician		minutes	car(s)	
	Examination and preparation of body	consumables and disposable material		pieces	counsellor, recovery technician, tissue bank medical director for consultation as appl.		minutes	forms	percentage of stop of recovery due to body examination
	2.2 Retrieval								
	Collection of blood samples	consumables and disposable material		pieces	recovery technician		minutes	hospital or mortuary facility	stop of process if no blood sample available?
	Retrieval of tissue(s)	packaging material		pieces	recovery technician		minutes	hospital or mortuary facility	
		recovery intruments		pieces					
		reconstruction material		pieces					
		charge use of infrastructure		currency					

Fig.3: Exemplary table to determine potential processes and to define the main cost drivers related to the respective process steps (timewise, material-wise, infrastructure-wise). Source: DGFG

Designation	Unit Description (*e.g. week/month/etc.*)	No. of Units	Unit cost per given year	Total Cost (given currency)
Managing Director	Reflects 20% time	12		
Medical Director	Months	12		
Manager	Months	12		
Eye Donation Counsellor (EDC)	Months	12		
HCRP Coordinator	Months	12		
Eye Donation Counsellor	Months	12		
Admin Assistant	Months	12		
Training Manager	Months	12		
Tissue Evaluation Technician	Months	12		
EDC cum Eye Recovery Technician (ERT)	months	12		
Pt. Care Coordinator	Months	12		
Quality coordinator	Months	12		
Night counsellor	Months	12		
Driver	Months	12		
Office Assitant	Months	12		
Finance and Accounting Specialist (20% time)	Months	12		
HR Manager (20% time)	Months	12		
Other	Months	0		
Total Salaries				
EDC Incentives	Monthly	4		
Incentives for all others	Monthly	4		
Staff Benefits	Monthly	12		
Total Incentives				
Designation	**No. of Visits**	**No. of Staff**	**Unit cost per given year**	**next year(s) Contribution**
Travel				
No of activity	**Unit Description**	**Number of Units**	**Unit cost per given year**	**next year(s) Contribution**
5	Training cost	3		
2	SME Visits	2		
5	Awareness Events	1		
1	Brading, IEC, IT	1		
12	Disposable supplies	1100		
500	Tissue Transport	1000		
1	Storage Media	1500		
300	Serology tests	1500		
12	Laundry	12		
12	Car insurance	12		
12	Fuel	12		
	EB insurance	12		
1	Training curriculum	1		
Total Activites				
Used for	**Unit Description**	**Number of Units**	**Unit cost per given year**	**next year(s) Contribution**
Nodal center refrigerator	Number of Equipment	1		
Nodal center autoclave	Number of Equipment	0		
Retrieval kit	Number of Equipment	5		
Microscope for Preparation	Number of Equipment	0		
trays, bowls, disposal bins	Number of Equipment	2		
Computers	Number of Equipment	4		
Printers & scanners	Number of Equipment	1		
Dymo label printer	Number of Equipment	1		
Tablet for field staff	Number of Equipment	1		
Phone,router	Number of Equipment	1		
Total Capex	**0**			
Used for	**Unit Description**	**Number of Units**	**Unit cost per given year**	**next year(s) Contribution**
Office supplies	Monthly	12		
Two cell phones usage/ bills	Monthly	12		
MS office and Zoom	Monthly	12		
Clic Trac	Monthly	12		
Total Runnig Cost	**0**			
Used for	**Unit Description**	**No of Units**	**Unit cost per given year**	**next year(s) Contribution**
Quarterly fee for int audit	Quarterly	4		
Public launch event	One time cost	0		
Equipment Calibration	Annually	6		
Monthly maintenane	Monthly @ Rs. 1/ sq ft	12		
Total Indirect cost	**0**			

PLEASE SPECIFY SOURCES OF FUNDING FOR THE PROJECT BUDGET				

Fig.4: Exemplary table to determine costs for human resources, equipment and facility and infrastructure. Note that you don't need all of these positions at the beginning - you can start with far fewer people and build capacity over time. Source: SightLife.

3.2 Financing scenarios and Funding

- Determine potential reimbursement mechanisms to recover the costs.
    - Is there enough available finance and will to commit to quality systems?
- Create a best-case and a worst-case reimbursement scenario.
- Estimate the period to reach return of investments and break even.
- Define the legal status of your tissue bank (Non-profit, public, private, limited liability company, foundation, etc.)
- Estimate best workload and capacity utilization for donation and processing activities.
    - How many hospitals/wards/mortuaries could one counselor cover in an area?
    - How many tissues can a technician process?
    - How many transplants are needed per year to be financial sustainable? It will be a few donations in the first months or year but have an idea on expected increase of the numbers in the mid and long term.
- Search for funding opportunities in different sectors. “The private sector (business) is good at developing products and services, while the public sector (government) is good at delivering solutions to all the people who need them.”
    - For example, programs between high-income countries and low- and middle-income countries (LMIC).
    - Grants by Philanthropic Foundations

Supporting Material/References: **GIZ Hospital Partnerships Global Program, Bill and Melinda Gates Foundation, Lions Clubs International Foundation (LCIF).**

4. Chances and Risks

We believe that the opportunities and benefits outweigh the risk when thinking about establishing tissue donation in your area. One should keep in mind that in general there is no lack of donors but lack of organization of donation.

The **potential and benefits** of implementing local tissue donation programs are:

- Becoming independent from imports from other countries.
- The local level of expenses and reimbursement costs will make tissue medicine affordable on the long term.
- Creating added value within the country
    - Know-how
    - Jobs and infrastructures

Implementing local donation activities and infrastructure is a contribution to national economy.

Networking opportunities: A tissue bank does not necessarily have to be at the location where donation takes place. Cooperation with existing tissue banks in other regions or cities is conceivable when initiating donation programs.

It is possible also in a non-for-profit environment to generate reimbursement of investment and process costs that generates a level of surplus which can be re-invested in expansion of tissue donation and/or research & development activities. This in turn, will generate knowledge and expertise in the country or region.

Hiring donation counselors, recovery technicians and tissue bank technicians will create jobs that generate income for people to cover their living expenses and be independent.
When a tissue bank is established, it means that a facility must be build or hired and equipped sourced. For this, local suppliers and/or contractors will be utilized. Thus, direct and indirect involvement in establishing tissue donation activities will support the national infrastructure and economy.

Training of people becoming specialists increases know-how in the field of tissue donation and transplantation medicine, and in the places or regions where people work. It creates opportunities for personal development and careers and becoming role models and consultants for other regions or countries.

If the expenses and investments are made on a national pricing-level, the total costs will be affordable.

On the other hand, there are **risks** that could harm the implementation and success of tissue donation. It is therefore important to objectively and honestly consider information about potential risks and so reduce the likelihood of conflicts.

- Lack of support by ministries, administration, regulatory bodies, e.g., officials who deprioritize the given health challenge amidst other health issues.
- Advocacy, awareness, objections by the stakeholders and/or communities.
- Time-consuming policy making.
- Challenges in obtaining funding.

Supporting Material/References: **SightLife Policy Guide.**

5. Management and coordination

It is important to have a strong management structure and coordination of the plan, actions, and objectives.
Strong leadership, clear and effective decision-making, communication, and effective resource mobilizations are all key topics to keep in mind when making sure that the driving force behind your advocacy efforts is not hindered by constant disagreement, poor communication, or lack of interest.

- Create a mid to long term strategy, short term activity plan, targets and evaluate it regularly.
- Initiate admin processes- HR, finance, accounting, and compliance.
- Develop a system of regular oversight and improvement (committees/board).

6. Long term perspective → Upscaling

If your feasibility analysis based on the previous chapters arrives at a "GO" on the local level and a single tissue type, you might consider it useful to start thinking bigger. This could be:

- Network structures, hub and spokes models, centralized oversight, and quality management structures
- Influence policy as a long-term strategy
- Check options to optimize each donation through multi-tissue donation by one donor, creating synergies and opportunities for collaboration with other banks.

7. First Steps – Start Somewhere

While you are doing your analyses you can start activities in parallel. Especially policy making will take time and years, but that should not hold you from starting tissue donation efforts.

- Partner with one or more large high mortality hospitals and/or mortuary to get access to potential donors.
- Implement hospital corneal retrieval programs (HCRP), other tissue donation programs.
- Check if any hospital structure can be utilized/linked to receive death notifications.
- Learn from existing structures, e.g., for blood donation.
- Start cooperation and awareness work with clinics:
    - Inform clinical doctors about tissue donation.
    - Ask surgeons who need tissue transplants to be proactive.
    - Win hospital staff as multipliers.
    - Convince hospital management about the economic profile linked to tissue donation and the reimbursement plan.
    - Assess if surgeons need training and create a plan for it.

- Start awareness & communication activities on tissue donation in your communities.
- Create publicity and tell success stories.
- Networking:
    - Connect with your local Lions Club, via global unions like WUTBA or GAEBA (Global Alliance of Eye Bank Associations), or via international NGOs like Sightlife, HCP Cureblindness, Eversight, Miracles in Sight etc.
    - Join tissue bank associations or connect through them, for example:
      American Association of Tissue Banks (AATB)
      Asia Pacific Association of Surgical Tissue Banking (APASTB)
      Biotherapeutics Association of Australasia (BAA),
      European Association of Tissue and Cell Banks (EATCB)
      Latin American Association of Tissue Banks (ALABAT)
      South African Association of Tissue Banks (SATiBA)

Look for training opportunities for profiles of donation coordinators/counselors, tissue bank managers, recovery and banking technicians, and surgeons.

- Training and practice can be obtained in other countries or other tissue banks.
- It may be advantageous to learn from a country or institution that has or had similar circumstances. For example, the Indian Dr. Shroff's Charity Eye Hospital (SCEH) training academy is open to international trainees, or the Eye Bank of Ethiopia.
- Start work shadowing exchanges.
- Utilize workshops and wet labs on (inter)national conferences, e.g., held by the above-mentioned tissue bank associations. Tissue bank associations may offer travel grants to attend their (annual) meetings.
- Perform (online) training courses, like for example the Tissue Banking & Advanced Therapies Training Program by the Donation and Transplantation Institute (DTI), Spain

Supporting Material/References: **SCEH training academy, DTI Foundation courses and programs, EEBA Annual Meeting Andrew Tullo Travel Grant Scheme.**

8. Resources, Supporting Material and References

- AATB (American Association of Tissue Banks) https://www.aatb.org/
- ALABAT (Latin American Association of Tissue Banks) https://en.alabat.net/
- APASTB (Asia Pacific Association of Surgical Tissue Banking) https://apastb.org/
- BAA (Biotherapeutics Association of Australasia)
- Bill and Melinda Gates Foundation https://www.gatesfoundation.org/
- Cost-Benefit Analysis of Corneal Transplant, Eye bank association of America (EBAA), 2013
- DTI (Donation and Transplantation Institute) Foundation https://tpm-dti.com/ and https://tpm-dti.com/en-training/
- EATCB (European Association of Tissue and Cell Banks) https://www.eatcb.eu/
- EDQM (European Directorate for the Quality of Medicines & HealthCare): Guide to the quality and safety of tissues and cells for human application, 5th Ed.
- GAEBA (Global Alliance of Eye Bank Associations) http://www.gaeba.org/publications/
- GIZ (Gesellschaft für Internationale Zusammenarbeit) https://hospitalpartnerships.org/
- LCIF (Lions Clubs International Foundation) https://www.lionsclubs.org/ and https://www.lionsclubs.org/en/start-our-approach/grant-types
- National Campaign To eliminate corneal blindness: MIRACLE by DREAM in INDIA COLLABORATIVE CONSORTIUM
- SATiBA (South African Association of Tissue Banks) https://satiba.org.za/
- SCEH (Dr. Shroff's Charity Eye Hospital and eye bank) https://sceh.net/best-charity-dr-shroff-charity-eye-hospital-academy-in-north-asia/
- SightLife Policy Guide v3
- Standards of Eye Banking in India 2020
- The Barcelona Principles: An Agreement on the use of human donated tissue for ocular transplantation, research, and future technologies, 2018
- WHO Aid-Memoire for National Health Authorities, Access to safe and effective cells and tissues for transplantation, WHO/HTP/EHT/CPR/2006.03
- WHO Aid-Memoire on key safety requirements for essential minimally processed human cells and tissues for transplantation, WHO-HTP-EHT-CPR-2006.02
- WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, WHO-HTP-EHT-CPR-2010.01
- WHO Eye care in health systems: guide for action, 2022, ISBN 978-92-4-005006-8 (electronic version), ISBN 978-92-4-005007-5 (print version)
- WUTBA (World Union of Tissue Banking Associations) https://www.wutba.org/news and https://www.wutba.org/education-training-1

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SightLife International (SightLife International and HCP Cureblindness have joined forces as one organization to make a greater impact in eye care worldwide.)