Policy, Regulation, and Advocacy in Global Eye Banking

A BEST PRACTICE GUIDE WITH TOOLS & STRATEGIES
Foreword

The global community has made steady advances in the drive to eliminate needless blindness over the last several decades. A key driver for this progress has been to engage national and regional actors to advocate for policy, regulation, and legislation that create an environment where global health interventions can flourish. The elimination of corneal blindness is dependent on governments at the national and regional levels adopting supportive policies that ensure access to donors, access to care, and quality assurance.

Government actors, ophthalmologists, eye banking professionals, and members of civil society can leverage the best practices identified in this guidebook to begin dialogue and develop plans to address policy gaps identified at the national and regional levels. This guidebook contains a collection of evidence-based examples and methods for the development of eye banks across different countries and regions. It details the best legal policy tools and framework-providing solutions for the development of corneal donation and transplantation systems, maps the mobilization of all relevant players and stakeholders, and encourages participation and creation of the most plausible strategies and actions. These guidelines are particularly useful for countries who are developing or refining their donation policy and regulation.

Currently, there are over 12.7 million people who suffer from corneal blindness, and with fewer than 200,000 corneal transplants completed annually, more patients are added to waiting lists or suffer permanent vision loss each year. Policy change at the national and regional levels is the key to growing transplants to meet the need and beginning to address the backlog of patients.

Yours in eliminating corneal blindness,

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Introduction

According to the World Health Organization (WHO), blindness, visual impairment, and decreased vision are conditions of major public health impact that warrant imminent prioritization on the global health agenda. The International Association for the Prevention of Blindness (IAPB) alliance of The Vision Loss Expert Group (VLEG) estimates that of the 253 million visually impaired worldwide, 1.7% are blind due to corneal-related disease conditions, behind only cataract, uncorrected refractive error, glaucoma, and age-related macular degeneration (AMD). Amidst this large spectrum of blindness, it is estimated that there are more than 12.7 million corneal blind, with 98% of those living in the developing world.

To address this significant burden of global blindness, many organizations, institutions, and programs have focused on public health, epidemiological, clinical and surgical solutions. However, in many geographic locations and across many age groups, simple screening, treatment, program implementation, and planning efforts have not fully addressed the need, nor the gaps. Furthermore, as public health advocates we have the obligation to help the most vulnerable patients, including women and children, so that they can fulfill their full potential, unhindered by visual impairment. While there are limited studies on the economic cost of visual impairment (VI), data suggest that governments save billions of dollars by addressing the burden of blindness. For example, one study portends that the global economic loss due to visual impairment worldwide was 347 billion USD in 2010. This number could rise to 452 billion by 2020 if no immediate action is taken. Therefore, it is our imperative to act promptly to enhance the armory of tools to eliminate blindness with innovative and sustainable efforts.

Policy implementation can serve as a catalyst for the elimination of blindness by embedding programs into existing legal and health systems. Corneal blindness is one example of a global health issue that lends itself well to leveraging legal, regulatory, and policy avenues to move toward disease elimination. In the corneal ecosystem, legislation, regulation, and policy can establish a supportive environment to ensure that eye banks have access to donors and that patients have access to quality care. In countries that have established policies enabling eye banking and corneal transplantation, such as the United States, there are no longer waiting lists for corneal transplants. Through the creation of this guidebook, one salient gap was identified: the need for more evidence-based data and research, especially from countries with less-developed eye banking systems.

Since 1969, SightLife has been pioneering efforts towards creating an optimal corneal care ecosystem in which corneal donation and transplantation meets the demand through professionalization of eye banking. With our goal of eliminating corneal blindness by 2040, we know coupling program excellence with advocating for and implementing effective policies is necessary not only to change the existing status quo but also to transform the overall landscape.

With the breadth of experience and knowledge in this area, the goal of this guidebook is to discuss best practices, strategies, and lessons learned to advocate for effective eye bank policies and regulations worldwide.

Purpose of This Guidebook

The main purpose of this best practice guidebook is to fulfill the following objectives in eye banking:

- To provide a deeper understanding of the role of policy, advocacy, and stakeholders in strengthening eye banking systems
- To highlight and define current legal frameworks and best practices
- To showcase a roadmap and provide a toolkit for affecting change at multiple levels
This guidebook should equip you with advocacy and policy tools to help you affect lasting change in corneal blindness efforts across the globe. While all cases will not apply to all geographies or health systems, we hope that it will serve as a blueprint and effectively guide efforts.

Furthermore, our hope is that this guidebook can shed light on how these advocacy and policy tools may be utilized to further eliminate other causes of avoidable blindness.

We look forward to partnering with you to eliminate corneal blindness in our lifetime.
Stakeholder Analysis

To maximize an organization’s advocacy efforts, it is important to first identify key influencers: those who are already allies or champions of the effort, those who might be activated to join the mission, and those who may block progress toward the mission. Ensuring representation of all stakeholders who will be impacted by the advocacy is also key, with special consideration for those who typically may not have had a voice at the table historically: They are often the key link to lasting and sustainable impact.

This section will aim to help analyze key stakeholders in eye banking and strategies for how to engage them in your advocacy efforts.

Benefits of stakeholder involvement in advocacy planning:

- **Risk Awareness**
  Information about potential risks can reduce the likelihood of conflicts, which can harm the implementation and success of advocacy.

- **Transparency**
  Ongoing stakeholder involvement allows for open communication about decisions and strategy.

- **Collaboration**
  The involvement of stakeholders can possibly lead to long-term collaborative relationships that can further advocacy agendas.

- **Informed Decision-making**
  Stakeholders provide insight into the environment for corneal donation and eye banking.

A thorough stakeholder analysis allows for a bird’s-eye view of all the key players and their level of importance, ability to influence, and potential political constraints.
Types of Stakeholders

**International Stakeholders**
At the international level, actors in this arena can be a unifying force towards a combined global effort. In the case of an ideal corneal ecosystem, some of these organizations might provide a platform to access a larger global network of key influencers through global conferences on eye health and provide visibility to advocacy goals via talks, forums, or meetings. Engaging at this level opens new opportunities for partnerships.

<table>
<thead>
<tr>
<th>Type</th>
<th>Potential role and responsibility</th>
<th>Example entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intergovernmental organizations</td>
<td>• Provide best practices guidelines and direction to global blindness prevention efforts&lt;br&gt;• Act as a unifying force towards global efforts</td>
<td>World Health Organization (WHO)</td>
</tr>
<tr>
<td>International non-governmental organizations (INGO)</td>
<td>• Health-training INGOs have increased flexibility compared to government and can lead programmatic manpower, provide financing for specific needs, leverage the ability to influence policy.</td>
<td>SightLife, Orbis, International Agency for the Prevention of Blindness (IAPB), Himalayan Cataract Project, Rotary/Lions Clubs, VISION2020, GAEBAs, etc.</td>
</tr>
</tbody>
</table>

Figure 1.1 Stakeholders and their potential roles and responsibilities

When affecting eye banking policy change, even at the community level, it is important to know which bodies create policies that impact the community. These intergovernmental organizations and INGOs have a global directive with a national, state, and community impact.

International players also set the direction for policy on prevention of blindness and in doing so, play a key role in prioritization of focal areas. A successful policy implementation plan will identify who these bodies are, engage them, and advocate for the inclusion of eye banking in the long-term prevention efforts.
National and/or Regional Stakeholders

Those who are involved at the national and state or provincial level play a crucial role in helping create goodwill. Utilizing resources at the community level encourages collaboration among organizations and helps to align their goals with the local needs. Further, having a close relationship at the national and state level creates and empowers local champions who become community change agents.

<table>
<thead>
<tr>
<th>Type</th>
<th>Role and Responsibility</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government agencies</td>
<td>• Create national policies and ensure implementation</td>
<td>Ministry of Health, National Transportation Ministry, law enforcement, education and finance, regulatory agencies, parliamentarians</td>
</tr>
<tr>
<td></td>
<td>• Provide multisector governance and oversight</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Create, cultivate, and enforce policy change</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Comprise key opinion leaders and local representation</td>
<td></td>
</tr>
<tr>
<td>Associations and societies</td>
<td>• Represent a unified voice for their respective industries (can be at the national and state level)</td>
<td>Eye Bank Association (EBA), Ophthalmology Societies, Optometry Societies</td>
</tr>
<tr>
<td></td>
<td>• Link to the existing public health structures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can facilitate best practices and professional standards</td>
<td></td>
</tr>
<tr>
<td>Hospitals, clinics, vision centers</td>
<td>• Provide eye health care</td>
<td>Government eye hospital, Charity eye hospital</td>
</tr>
<tr>
<td></td>
<td>• Partners in implementation of initiatives, such as Hospital Cornea Retrieval Program (HCRP), may provide vision screening</td>
<td></td>
</tr>
<tr>
<td>National eye health committee</td>
<td>• National committee is a cross-sectoral committee of members working towards eye health program implementation,</td>
<td>National Prevention of Blindness Committee</td>
</tr>
<tr>
<td>Academic institutions</td>
<td>• Develop evidenced-based data</td>
<td>National or State Universities, Residency Programs</td>
</tr>
<tr>
<td></td>
<td>• Cultivate coalition building towards eye health</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Provide sources of funding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Provide clinical, surgical, and public health training</td>
<td></td>
</tr>
<tr>
<td>Local NGOs</td>
<td>• Expertise in local issues, connected resources, potential alignment in strategic goals</td>
<td>Local Lions or Rotary Clubs</td>
</tr>
<tr>
<td>Other eye banking related entities</td>
<td>• Various functions depending on region-specific needs</td>
<td>Funeral homes, mortuaries, transplant oversight committees</td>
</tr>
<tr>
<td>Organ procurement organizations</td>
<td>• Donation organizations that focus on organ procurement</td>
<td>Regional organ procurement organization</td>
</tr>
<tr>
<td>Funders</td>
<td>• Drivers of program priorities</td>
<td>private, Government, or foundations</td>
</tr>
<tr>
<td></td>
<td>• Active impact in NGO’s ability to function</td>
<td></td>
</tr>
<tr>
<td>Key opinion leaders</td>
<td>• Individuals who serve as thought leaders in the sector</td>
<td>Surgeons, association leaders</td>
</tr>
<tr>
<td></td>
<td>• May be attached to an organization (i.e., hospital or association) or independent</td>
<td></td>
</tr>
<tr>
<td>Media and public relations</td>
<td>• Potential vehicle disseminating advocacy efforts at the local, state, and national level</td>
<td>Newspapers, online media outlets, radio</td>
</tr>
</tbody>
</table>

Figure 1.3 A list of stakeholders and their potential roles and responsibilities
The examples above illustrate the multiple levels of stakeholders who plan, operate, implement, and monitor eye banking and eye health operations. Across these levels, identify champions who can build an enabling environment for “…eye banking; for example, at a political level, a minister of health, and at an operational level, hospital administration.

At the government level, it is important to first understand the governmental structure and how it impacts the flow and enforcement of policies. For example, one country’s government might enact national policies, but each state has the latitude to interpret them differently. What follows below are further details of the stakeholders and their roles.

**Defining key stakeholders within the eye banking context**

Eye Bank Associations (EBA) provide an avenue for sourcing a national level presence and leveraging policy adoption or change. Additionally, engaging ophthalmic associations and societies like the national ophthalmic or eye bank associations offer the opportunity to engage those services providers who will eventually be practicing at the primary, secondary, and tertiary levels when advocating for new policies. These services providers are eye donation counselors, recovery technicians, eye bank managers and corneal surgeons in the eye banking system.

Organ procurement organizations, hospitals, mortuaries, and funeral homes are core stakeholders to optimize eye donation. Strategic alignment with these and other stakeholders allow for streamlined integration of any new or changing policies.

Amidst all these players at the national and state level, there are some countries who have had excellent outcomes affecting change in policies. National eye health committees (NEHCs) often include all stakeholders including government, hospitals, associations, NGO/INGOs, and individuals invested in eye health.

The diagrams below demonstrate all the players involved in an entire corneal ecosystem and highlight the importance of affecting change at each one of these locations not merely one area. Policy and advocacy are the areas we are most focused on in this guidebook.
**Figure 1.4** Corneal ecosystem

**Figure 1.5** An illustration of the key issues and strategies in a corneal ecosystem

### Key Issues

- **Limited Access to Care**
- **Not Enough Donated Corneas**
- **Underperforming Eye Banks**
- **Not Enough Care Providers**

### Strategies

- **Awareness**
- **Prevention**
- **Early Intervention**
- **Advocacy**
- **Awareness**
- **Partnership**
- **Operations**
- **Training**
- **Quality**
- **Capacity Building**
- **Training**
CASE STUDY
A SPOTLIGHT ON MEXICO:

In Mexico, the prevalence of blindness in the population is 1.5% and visual deficiencies have increased to 7%, becoming the second disability of major incidence in Mexico, and corneal blindness accounts for 4.7% of the blindness in the country. Mexico historically has been heavily dependent on imported corneal tissue due to low domestic corneal donation rates (see figure 1.6).

The formation of the Eye Bank Association of Mexico (EBAM) and its partnership with the Mexican Ministry of Health Center for Transplants (MoH CENATRA) are examples of how stakeholders in Mexico have begun working together to address a key barrier to eye banking in the country: implementing policies favorable to a healthy corneal ecosystem, including donor registries, first person consent, mandatory death notification, hospital recovery programs, and donor awareness campaigns.

EBAM in collaboration with the Ministry of Health (MoH) CENATRA implemented Mexico’s inaugural training of recovery technicians to increase cornea recovery and ultimately increase the number of transplants procured locally compared to the number of transplanted imported (see figure 1.6).

EBAM and the Pan American Association of Eye Banks (APABO) continue to demonstrate engagement with key stakeholders, as they are working with SightLife and other international eye banks to develop a training conference in 2019 to continue to position Mexico as a leader in treating corneal blindness through transplants and eye banking.

EBAM and CENATRA are also actively engaging COFEPRIS (the regulatory body of Mexico) to implement standards to ensure compliance requirements are adopted at the national level. In Mexico, EBAM has made significant progress leveraging stakeholders from across sectors and regions.
Next, let’s discuss the core legal and policy concepts in eye banking that these stakeholders can mobilize around.

One way to do this is through a stakeholder analysis and affinity map, identifying the key stakeholders and deciding how ready or not they are to advocate for a cause. The Affinity map below from corneal eye banking in India can be used to map stakeholders and assign numbers to quantify their level of commitment to the cause. The stakeholders included represent government organizations, non-governmental organizations, academics, non-profits, and advocacy bodies (see figure 1.7).

### Stakeholder Affinity Map

This diagram is a tool to track stakeholder affinity: Individuals or organizations can use it to visually represent stakeholders’ affinity for a cause as supportive or non-supportive and affinity shifts over time.

#### Key messages

Identify key stakeholders across sectors; define their interest, and highlight the role they can play in effectively establishing eye banking policies.

International, national, and local stakeholders are important in assessing gaps, identifying strategies, mobilizing resources, building coalitions, and collaborating on implementation of eye banking policies and best practices.
Basic Donation Process

The Eye Donation Process
While the process may differ from country to country the following graphic illustrates a typical process of eye donation from commitment to donation, death, personal/next of kin consent, and recovery through evaluation of tissue for corneal transplantation.

The key policies/legislation methods that help frame a successful donation path in each step below will allow every donor and eye bank to fulfill conveniently and reach their potentials in eye donation:

Figure 1.8 A view of the donation process
Basic Legal Framework

Introduction

The following sections will cover specific legal concepts and policies that apply to eye banking, highlighting best practices that create an enabling corneal ecosystem for donation. Special focus is given to valuable experiences that have arisen from global legislative and judicial practices in the last decades. We understand, just as the evolvement of the practices, that the construction of a perfect legal and political framework of donation and eye banking always starts small, and it is important to take note that frameworks governing eye banking vary across countries based on the legal systems they follow and, therefore, there cannot be a one-size-fits-all approach. For example, eye donation policy is based on legislation in the United States and India, while in China it is governed by Ministry of Health regulations. Our experience working with partners in multiple countries over the years has demonstrated that certain policies are essential to access to donor tissue. These policies are discussed in detail below.

Let’s take some time to understand the difference and impact of policy, legislation, and regulations for the purposes of this guidebook.

Figure 1.9 Outline of the differences between policies, enactments, and legislation/regulation.
International Legal Framework – WHO Guiding Principles

Internationally, the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation provide the underlying basis for organ and tissue donation and transplantation for most countries. First adopted in 1991, by the World Health Assembly 44.25, the Guiding Principles provide the overarching legal and ethical framework for tissue donation and transplantation. Broadly, they lay down the framework for legal consent for donation, non-commercialization of human tissue, processing fees and reimbursements of the cost of transplantation, safety, efficacy and quality of transplantation services, and protection of donor and recipients’ anonymity and privacy. These topics are common themes that will be covered in more detail in the sections below.

Donation Law

Consent Law: Individual vs. Next of kin consent

Consent is a foundational principle of donation laws in most countries. It constitutes the legal authorization to donate. In legal systems which follow individual consent, also known as first-person consent, the autonomy of the consenting individual is paramount. Acceptable methods of consenting and revoking consent are specified.

An example of this is in the United States, where the Revised Uniform Anatomical Gift Act (Revised UAGA), (2006) recognizes individual consent in deceased donation which is actualized when intent to donate is expressed by joining a donor registry, specifying in an advance directive, completing a consent form or verbalizing intention to two witnesses. An anatomical gift not revoked by the donor before death is irrevocable and does not require the consent or concurrence of any person after the donor’s death. Such consent is valid and shall not be voided by donation programs or overridden by any individual after death. In the event of first-person consent or individual consent, there is no need to seek consent from the family as they do not have authority to make a consent decision per the Revised UAGA (2006).

It is pertinent to note that the Revised UAGA (2006) considers donation as the “right” of an individual. According to NATCO, a prominent national association of transplant professionals, not accepting the donor’s decision to be a donor is a violation of his or her autonomy and disregard for his or her wish to help those in need.

One study from the U.S. estimates that the states that adopted first-person consent showed an increased donation rate of 10–15% compared to non-adopting states.

In legal systems where next of kin consent is the law, whether or not the deceased individual has pledged/registered, the family’s consent takes precedence. In other words, even if the individual has consented to donation during his or her lifetime, at the time of death if the family refuses, the individual pledge/registration is overridden. Under India’s legislation, the Transplantation of Human Organs and Tissues Act (THOTA), 1994, while individuals may pledge organs or tissue for donation upon death, the decision and consent of the family prevails. In the United Kingdom, the law is also individual consent, which is indicated by the signing up on the organ donation registry, and family refusal does not nullify consent, but the decision is still up to medical practitioners. In Australia, family will always be asked to confirm the donation decision of the deceased before donation. Spain, Norway, Italy, and Canada allow next of kin to override the consent of registered organ donor if they personally do not concur with the donation desire of their relative.

In practice, family objection should be met with open-ended questions to better understand the family’s concerns and identify opportunities for donation staff to address concerns with respectful education.
The Revised UAGA (2006) states consent shall be obtained from any member of the highest priority classification of individual deemed reasonably available. Based on experience in the field, laws based on individual rather than next of kin consent can increase access to donor tissue. However, there is a need for more evidence-based data to support these claims. The practice of recognizing individual consent while notifying families of their loved one’s decision to donate also aligns with the legal principle of individual autonomy, i.e., the principle that all individuals have the right to decide what happens to their bodies during their lifetime and upon death.

**Opt-in vs. Opt-out (explicit consent vs. presumed consent)**

Donation legislation dictates either an opt-in or opt-out model. Opt-in legislation requires individuals complete a registration process to add their name to the donor registry. Opt-out legislation presume all individuals after a certain age are donors and they are automatically registered unless they complete a process to remove their name from the registry.

Families of potential donors should be approached regardless of the registry type, unless the registry indicates the individual has made a legal decision not to donate. Family conversations provide valuable medical social history information relevant to donor eligibility even if consent from the family is not required. Additionally, educating the family about the imminent donation process is important to the grieving process, and in regions where a donor registration is not considered legal first-person consent, then formal next of kin consent is required before donation.

Spain and Croatia have “opt-out” models, but family approval is still sought before proceeding with donation. France also adopted a new legislation in 2017 in which every person could become a donor upon death unless joining an official register to opt-out.14

There is no evidence to suggest a direct correlation between opt-out models and increased donation rates. Countries like Spain, Austria, and Belgium, which follow opt-out systems, have higher rates of donations; others like Bulgaria, Luxembourg, and Greece have some of the lowest rates.15

While a first-person, opt-in consent legal model has shown to have greater impact on donation rates, the benefit is likely to be more significant when supplemented through changes in infrastructure like setting up a donor registry.16
Registries are centralized databases that record the intent of individuals who have agreed to donate organs, eyes, and tissue in the event of their death (i.e., donor registry or record of wish to donate, or non-donor registry). The U.S. and European countries such as the U.K., Belgium, Denmark, France, Hungary, and Italy are examples of countries that have donation registries.

Donor registries are most often used in countries with opt-in consent for organ, eye, and tissue donation and can be used to target, measure, and evaluate awareness campaigns in support of donation. In contrast, non-donor registries are used in some opt-out consent countries as a legal means for individuals to object to being a donor and not as part of strategy to increase deceased donation. Practices across countries are different even if the approach is the same; in some countries registrations are legally binding, in others they are considered “intent” to donate, which are used in discussions with family.

Reports based in the U.S. and Europe on organ or tissue donor registries show that there is no clear evidence that organ donor registries by themselves help improve procurement rates when tested against other factors such as increased awareness prior to setting up of organ registries. More studies are required that directly compare rates of donation in countries with and without registries, including measuring the specific elements and functions the registry seeks to perform suited to the local needs (for example, a “yes” only versus a “yes, no, ask family”) and the cost-effectiveness of having such registries.

Mandatory Death Notification

Death referral is the critical first step in the process of corneal donation to ensure timely authorization and recovery. Corneas must be recovered promptly following death (typically fewer than 24 hours) to prevent tissue deterioration and reduce logistical challenges. Timely death notification is therefore key to this process. A referral is where a death is referred to a donation program to evaluate potential for donation.

Mandatory death notification systems have often led to increased donation. In most systems where donation rates are high, there exists a system of mandatory referrals.

Other examples of referral models across the globe include the U.K. and South Africa. In the U.K., a system of automatic notification for patient referrals was implemented in a particular hospital bringing the donation rate up from 3 in 2004 to 31 in 2007. Evidence from South Africa shows that required referrals work as enablers for a soft “opt-in” consent system, thereby increasing the rate of donations.

In the United States, healthcare facilities that receive government Medicare funding must comply with national conditions of participation (CoP). Medicare CoP require all deaths be referred to an Organ Procurement Organization (OPO) or designated third party organization, such as an eye bank, in a timely manner for evaluation of organ, eye, and tissue donation potential. OPOs may establish the method of referral such as electronic referral, phone call to a donor referral helpline, or face to face notification to on-site staff. In addition to 100% timely referral of deaths, the following must be met:
• The OPO or designated donation organization shall determine donor eligibility. Hospital staff are not permitted to make decisions about a patient’s medical eligibility to donate.
• Families should only be approached by OPO staff, designated donation agency staff, or trained designated requestors. This is to ensure families are provided the specialized information required to make an informed donation decision.\textsuperscript{23}

In India, a key policy intervention that has increased access to donors is through medico-legal cases. Medico-legal cases refer to those unnatural deaths that occur either by accident or suicide which fall under the jurisdiction of the local police. In practice, eye bank staff are posted at mortuaries waiting for donation opportunities, or in well-developed programs, they are notified of deaths by those managing mortuaries. However, under THOTA, specific permission of the local police and forensic department is required prior to recovery. Through successful interventions at the local level, many eye banks have obtained permission letters from the local police giving approval for recovery prior to autopsy if there is legal consent for donation, but ongoing training for forensic teams about the donation process and urgency of donation is important for program success. In recent years, police authorities at the state level have reissued circulars instructing local police to work collaboratively with eye banks to ensure timely recovery.

In the underserved Indian state of Uttar Pradesh, The KGMU UP Community Eye Bank established a successful medico-legal program in the eye bank’s first year of operations, resulting in an 83% transplant increase over their hospital ward-based donor transplant volume. The additional 334 sight-restoring corneas yielded would have otherwise been wasted in the absence of a successful medico-legal donation program. Cultivation of relationships with senior policy officials, mortuary staff, ongoing training, and professionalism played important roles.

Access to Medical Records

Access to medical records of potential donors is critical to the donation process. In practice, this operates at two levels. First, in order to determine the eligibility of the potential donor, verbal or physical access to relevant medical records is required for a preliminary screening before speaking to the family. Second, after recovery, a written request of medical records helps aid in the medical review of the tissue before it is deemed worthy for processing and distribution. Access to medical records before donation allows eye bank staff to efficiently determine eligibility before potentially giving the family false hope of donation potential. If the donor is preliminarily eligible and the next of kin consents, the consent form should also serve as a legal release of medical records, giving the donation program written access to relevant medical records.

Legally, the concerns around access to medical records relate to privacy and confidentiality of personal health information, which are protected by legislation in many countries. With respect to access to medical records for cornea donation, however, there are also exemptions provided for donor agencies. For example, in the United States, hospitals and hospices are allowed by the HIPAA exception to disclose Personal Health Information (PHI) required for the facilitation of donation without the need for authorization of patient and families.\textsuperscript{24}

In the U.S., the recommended best practice is for donation programs to provide assurance to their hospitals and transplant centers through Memorandum of Understandings (MOUs) that identifiable health information disclosed to the donation program will be maintained as confidential and used and disclosed only as necessary to coordinate the donation and transplant.\textsuperscript{25}
Legalization of Processing Fees

Legislation relating to tissue donation and transplantation prohibit commercial sale or purchase of human tissue providing criminal penalties for a violation. Most, however, allow for recovery of processing fees incurred in the procurement, processing, transfer, preservation, storage, distribution, or clinical application of these tissues and their derived products. This is consistent with Guiding Principle 5 of the 2010 WHO Guiding Principles.

In India, processing fees allow for reliable reimbursements to eye banks to meet their operational costs while allocating financial resources to improve eye bank capacity. In the U.S., cost-based reimbursements are made by Medicare under the HCPCS code V2785 - Processing, preserving, and transporting corneal tissue. These processing costs may vary from USD 2,500 to USD 3,500 per cornea. In India, the law allows for charging of processing fees to recover costs at the utilization stage. As per the current standards of reimbursement for a pair of collected corneas, eye banks are reimbursed by the National Programme for the Control of Blindness (NPCB) a small portion of the cost, i.e., Indian Rupees 2,000 (approximately USD 28); but the average processing fee for a tissue is approximately Indian Rupees 6,000 (approximately USD 86), and many eye banks do not even claim this amount because of the long payment cycles. The difference in the cost is usually transferred onto the patient in India where 70% of the costs are not covered by any type of health insurance.26 As a result, most patients in India end up paying the difference out-of-pocket. In practice, while the policy for reimbursement exists, implementation across India varies.

In other regions of the world the reimbursement policies vary. For example, in the Taiwan region, the processing fee for tissue is set by the National Health Insurance Administration (NHIA). Hospitals performing corneal transplants pay processing fees to the eye banks, which supply tissue and thereafter claim reimbursement from the NHIA.

Globally, the best practice is for eye banks to operate on a cost recovery model that promotes eye bank sustainability. Reliable and efficient reimbursement is critical to their continued operations. In countries that have established mature eye banking systems, a reimbursement policy that incentivizes utilization rather than recovery is more desirable as it leads to quality optical grade corneal tissue for patients in need of transplants.
Non-physician recovery of corneal tissue is typically performed by eye recovery technicians, who are employees or volunteers with eye banks. Many countries require cornea recoveries be performed by medical doctors; however, studies show highly trained recovery technicians who routinely perform the procedure can achieve industry leading cornea recovery technique while also reducing death to preservation times due to increased availability for timely recovery.

Recovery of corneal tissue by trained recovery technicians is now standard practice across many countries with supportive government policies. In India, this was enabled by an amendment in 2011 to THOTA allowing qualified and trained recovery technicians to carry out cornea recovery that earlier was restricting to only clinicians. In Mexico, CENATRA moved to allow certified technician recovery in December 2016.
The table below shows a summary of the presence or absence of key policies across countries/regions that impact eye banking.

*Table 1 Key issues adopted by select countries*

<table>
<thead>
<tr>
<th>Country</th>
<th>Opt-in or Opt-out</th>
<th>Eye Donation Law</th>
<th>National Donor Registry/First-Person Consent</th>
<th>Mandatory Death Notification</th>
<th>Access to Medical Records Before Consent</th>
<th>Non-Physician Recovery</th>
<th>Processing Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>In – only for living donors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>In</td>
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<tr>
<td>Hong Kong</td>
<td>In</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Taiwan</td>
<td>In</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td>Ethiopia</td>
<td>In and Out</td>
<td>✓</td>
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<tr>
<td>India</td>
<td>In</td>
<td>✓</td>
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<tr>
<td>Japan</td>
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<tr>
<td>Philippines</td>
<td>In and Out</td>
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<tr>
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<tr>
<td>Singapore</td>
<td>In and Out</td>
<td>✓</td>
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<tr>
<td>Spain</td>
<td>Out</td>
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<td>Sri Lanka</td>
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<tr>
<td>United Kingdom</td>
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<td>✓</td>
<td>✓</td>
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<td></td>
</tr>
<tr>
<td>United States of America</td>
<td>In</td>
<td>✓</td>
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<td>✓</td>
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<td></td>
</tr>
</tbody>
</table>
Advocacy Guide

Now that we have had the opportunity to take a deep dive into identifying key stakeholders and learning about the legal framework for eye banking, the next step is analyzing, planning, and implementing an advocacy strategy to affect change via the local, state, and national levels. The ultimate goal is to ensure mobilization of the tools necessary to implement best practices, policies, and strategies to eliminate corneal blindness.

**Initial questions to consider before beginning eye banking advocacy efforts include:**

- What are the challenges or key barriers toward increasing access to donor tissue?
- What key policies at the local, state, and national levels relate to these problems, and how are they implemented?
- How can policy changes, regulations, and legislation help resolve these problems?
- Who are the stakeholders associated with the policy change?
  - Who are the key advocates and supporters of optimizing eye banking operations?
  - Who are the key opponents?
  - Who are the key decision makers?
- What are the channels to reach policy makers?

There are many methods for determining the best strategy for putting your advocacy efforts into action. The International Agency for the Prevention of Blindness (IAPB) presents us with a model that informs much of what this guide aims to cover. The Advocacy Cycle consists of five phases of planning.

![The Advocacy Cycle](image_url)

**Figure 3.1 The Advocacy Cycle**
Know What You Want to Change

The first step is knowing exactly what to change. Having a clear objective of what policy to change will be the foundation on which to build an advocacy plan. Ensuring that this is focused and specific will be crucial for its success. For example, a clear goal might to be to make a national donor registry a legal requirement. This has now set the stage for moving efforts forward and sets a clear end-goal for the next stage of planning.

IAPB’s Advocacy Guide outlines a few basic steps in first knowing what to change (Figure 3.2).

![Figure 3.2 Steps for starting an advocacy campaign](image)

Once the lack of a national donor registry is identified as the problem, the underlying reasons should be identified. The ability to recover tissue might be hindered by an eye bank’s inability to identify those who have consented to donate. In your problem identification process, you find that there is a version of a donor registry but it has not been implemented at the state level. You then determine your position is to push for implementation at the state level. Through this exercise, you have successfully walked through an issue and picked your aim and objective.

Identify Best Influencing Strategy

Second, once the objective is clear and understandable, determining what strategy you will employ will be the road map for the coming weeks, months, or even years in policy change. An organization might think that a clear, simple objective may be enough to achieve your advocacy goals. However, ensuring a clear and structured influencing strategy is a driver for pushing activities forward with a common framework for why your activities are occurring and to what end.

It is important to note that at many stages, your policy position may be challenged. This is both expected and a healthy part of the advocacy process. Disagreement also helps inform you of where different priorities, values, perspectives, and interests lie.

While there are many ways to determine your influencing strategy, we will only broadly cover the concepts for establishing your direction. In policy, it is important to know where, who, how, and when the decision is made. Who influences this decision?

Assess your ability to make the change. Do you have financial resources? Human resources? Knowledge and skills? These are important to know before you enter a strategy, as it might first identify some gaps that you will need to fill before starting your strategy. It might also trigger a change in the policy objective. This step is crucial in knowing how you can influence a certain policy change.
Next, you will select who will be your audience to target. In a centralized donor registry, is it the Ministry of Health (MoH) who would administer this? Would the government delegate to a certain NGO or a hospital play a role? Is the Ministry of Transportation (MoT) a key player? Or all the above? Knowing the answers to some or all of these questions guides the target selection.

Finally, you will want to develop a unified message or collective argument.

Devise Action Plan

With both an objective and a strategy for how you will obtain your policy change, you can enter the third step of planning. Here is where you want to devise the most effective ways of engaging the target audiences that you identified in the influencing strategies. While the objective and influencing strategies should remain constant, in this phase you can adjust your action plan to suit the changing environment you want to influence. When devising an action plan, it is paramount that all individuals are unified on the overall goals, objectives, and their specific tasks.

**Here is a suggested model for creating an ideal action plan:**

1) Plan activities to engage each audience.
2) Compile integrated action plan.
3) Finalize M&E and risk management plans.
4) Agree on strategy and coordination mechanism.

**Plan activities to engage each audience**

Now that you have established your case of support, audience, and influencing strategy, plan what activities will propel your advocacy efforts forward. Certainly, ensuring that you are engaging with the important stakeholders, creating a consistent preparation, execution, and follow up for all your activities will have the most impact.

Throughout your planning, it is important to know that you cannot predict with any certainty the outcome of your advocacy efforts and enter each activity with this understanding. Although your influencing strategies are established, your action plans need to be flexible. The action plan can then be updated on a regular basis depending on responses from your target audiences. For example, with an end goal to establish a national donor registry, your first plan is to get an audience with the ministry of health. However, you soon find that it is quite difficult to get an audience with them due to other priorities. You pivot your plan to first establish your full proposal, with the end to obtain a meeting. In this example, your goal to influence the ministry of health remains constant but your activities change, perhaps you first approach other organizations who focus on promoting organ donation and approach the ministry together.

**Compile Integrated Action Plan:**

You will soon find that with a diverse group of activities serving different needs and objectives comes the need to organize your activities in a way that allows you the best ability to map out the activities, intended outcome, who is responsible, and when they should be completed.

A simple example like Figure 3.3 can help you plan out activities for the year, present it to stakeholders, seek funding if needed, and move on to the next step.
Finalize monitoring and evaluation, risk management plans

While every region or market is distinct from one another, advocacy in eye banking can face a few hurdles. For example, you might face ministry officials who deprioritize corneal blindness amidst other health or blindness issues. Understanding the landscape, what the other priorities are, and the government’s stance allows you to contingency-plan for the counter voice in your case of support. It is important to do this very early in your activity planning.

Agree on strategy and coordination mechanism

You plan is complete and ready to be approved. Generally, your plan should include the following elements for a complete strategy:

1. Aim
2. Objectives
3. Audiences
4. Proposition
5. Risks & assumptions
6. Monitoring & evaluation plan
7. Organizational structure and decision-making
8. Budget
9. Action plans & timetable

The plan should be regarded as a working document and so should be as concise as possible. Other supporting information such as descriptions of the problem, evidence gathered, or consultations undertaken should be in other documents.

Let’s review the first three steps in summary. While this is only a hypothetical example, it helps illustrate how to walk through the steps to create a plan (Figure 3.4).
Step 1 - What do you want to change?

There is a large waiting list of corneal transplant patients in your country and a donor registry does not exist. Establishing one would likely increase access to donors, improve donation rates, and help with a backlog of patients waiting for care. The objective is to influence the ministry of health through your eye bank’s network of hospitals and community health workers.

Step 2 - Identify your best influencing strategy

To increase influence, you first assess eye banks’ contacts within government agencies. Do you have the financial resources to take this on? Yes, you have budget set aside to support these efforts. Do you have a dedicated staff to do the job? You determine that you have a team member who could spend 50% of her time focused on advocacy efforts without impact to operations. Therefore, you rework the team member’s roles and responsibilities to ensure 50% of her time is set aside to work on policy issues for your eye bank and work on building confidence at the state government level. Through your stakeholder analysis, you decide to bring together other eye banks and hospitals for a unified advocacy voice.

Step 3 – Devise an action plan

First, you decide that you will build confidence at the government level through your network. Using the template in Figure 3.1, your activities will include advocacy meetings with community health workers, local government officials, ophthalmologists, and potentially other eye banks. You identify that other eye banks or eye health professionals may not prioritize a donor registry and plan contingency messages and actions. Finally, you set forth a budget that is agreed upon by your governing committee.

Figure 3.4 Step-by-step guide for advocacy planning

Now that we have walked through the steps of putting together an advocacy plan, it is time to put the plan into motion.

Implement Action Plan

Time for action! This step is where your planning all comes into motion. All the action owners should be clear on meeting their respective targets and do so in a cohesive fashion.

The example below discusses influencing a ministry of health to conduct a national study of avoidable blindness in Ecuador, including post-advocacy effort debrief.
**CASE STUDY**

*A repeat RAAB (Rapid Assessment of Avoidable Blindness) needs to be repeated to measure progress*

**The objective of the advocacy initiative**

Ecuador last did their RAAB in 2009 to measure the national prevalence of avoidable blindness. In order to measure progress towards WHO Global Action Plan, a measure of change needs to happen via a repeated national study.

**Who is the target audience? Who are the key stakeholders?**

The Ministry of Health of the Ecuador is the primary target. Without its approval and buy-in, the study would lack government buy-in—a crucial step towards ensuring necessary human resources and publishing results. Others targeted are the National Eye Health Committee, state and national ophthalmic associations, and INGOs/NGOs.

**Determining the best influencing strategy**

The National Eye Health committee was previously actively engaged with WHO at the regional level with PAHO (Pan-American Health Organization). It was determined that through their close relationships with MoHs across the continent, leveraging that relationship was going to be key. Equally as important was utilizing the national eye health committee to convene all other key stakeholders to a RAAB planning session. Finally, ensuring the NGOs who might fund the study was the final piece.

**What were the outcomes?**

1. A national RAAB planning meeting was convened but was poorly attended.
2. While an agreement to advance the RAAB study was agreed upon, a change in government soon after affected continuity of the plan.
3. While the ultimate goal was not obtained, valuable lessons were learned and risk management tactics implemented.

**What were the lessons learned?**

- Even though there was a strong push and elevated interested from the outset, follow-up and evaluation is crucial towards pivoting towards new short and long-term objectives.
- A lack of risk management, by identifying the change in government via elections, was an oversight and should have been planned early on to forecast this change.
- Regardless of not reaching the ultimate objective, the key stakeholders committed and remain engaged in the topic for further realignment.

*Figure 3.5 An advocacy case study from Ecuador*
Monitoring and Evaluation Process (M&E)

As comprehensive as an eye banking advocacy strategy might be, it is never enough to simply enact your plan and not actively measure your impact and course-adjust. When planning for an M&E framework for your campaign, it is worth determining why you are undertaking this endeavor:

1. To provide you with the information you need to manage your advocacy campaign and determine the next steps, updating your work plan and revising your strategy as appropriate.
2. To help you learn which approaches are most effective so you can improve your planning in the future and share your learning with other organizations.
3. To motivate yourselves and those doing the advocacy with you, so that you continue your efforts and achieve your objectives.
4. To hold yourselves accountable to the various stakeholders in the advocacy, including communities affected by the issue, your partners and colleagues, your managers, and your funders.

These are the basic leading principles on which you will be able to see the true impact of your campaign and then report out to stakeholders. The basic flow for a strong M&E plan might follow this suggested flow, as suggested by IAPB’s Advocacy Guide:

![Figure 3.6 Steps towards a complete M&E plan and action]

In this format, you are now building a framework around which all of those in who are advocating are aligned in the same direction. Being honest with the efforts, evaluating the lessons learned, and acting to steer to a new, more effective activity or event afford the chance to adapt to the ever-changing advocacy environment.

Management and Coordination

An internal influence that drives all of these steps involves having a strong structure of management 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, just to name a few.
Conclusion

We hope the advocacy and policy tools embedded in this guidebook will help you affect lasting change in corneal blindness elimination efforts in your region. Based on the case studies and best practices included in the guide, we know that countries that have successfully eliminated corneal blindness have leveraged policy and regulation to do so.

Having read the guidebook, we hope you are able to:

- Discuss the role of policy, advocacy, and stakeholders in strengthening eye banking systems
- Define current legal frameworks and best practices
- Leverage the toolkit for affecting change at multiple levels

As you begin to leverage this guidebook in your respective region, please let us know about your progress, including what additional information or resources you need to affect change and how SightLife and other organizations can partner with you to support your efforts. As discussed earlier, the need for more evidence-based data and research, especially from countries with less-developed eye banking systems, is evident.

Advocacy efforts require time and commitment from a diverse group of stakeholders. Change may take many years to realize; however, advocating for a supportive policy environment is critical to ensuring that corneal blindness is eliminated by 2040.
APPENDIX

2010 WHO GUIDING PRINCIPLES ON HUMAN CELL, TISSUE, AND ORGAN TRANSPLANTATION (WHO GUIDING PRINCIPLES):

Guiding Principle 1- Cells, tissues and organs may be removed from the bodies of deceased persons for the purpose of transplantation if: (a) any consent required by law is obtained, and (b) there is no reason to believe that the deceased person objected to such removal.

Commentary on Guiding Principle 1
National authorities are responsible for defining the process of obtaining and recording consent for cell, tissue and organ donation in the light of international ethical standards, the manner in which organ procurement is organized in their country, and the practical role of consent as a safeguard against abuses and safety breaches.

Under a regime of explicit consent – sometimes referred to as “opting in” – cells, tissues or organs may be removed from a deceased person if the person had expressly consented to such removal during his or her lifetime; depending upon domestic law, such consent may be made orally or recorded on a donor card, driver’s license or identity card or in the medical record or a donor registry. When the deceased has neither consented nor clearly expressed opposition to organ removal, permission should be obtained from a legally specified surrogate, usually a family member.

The alternative, presumed consent system – termed “opting (or contracting) out” – permits material to be removed from the body of a deceased person for transplantation and, in some countries, for anatomical study or research, unless the person had expressed his or her opposition before death by filing an objection with an identified office, or an informed party reports that the deceased definitely voiced an objection to donation.

Although expressed consent is not required in an opting-out system before removal of the cells, tissues or organs of a deceased person who had not objected while still alive, procurement programmes may be reluctant to proceed if the relatives personally oppose the donation; likewise, in opting-in systems, programmes typically seek permission from the family even when the deceased gave pre-mortem consent. Programmes are more able to rely on the deceased’s explicit or presumed consent, without seeking further permission from family members, when the public’s understanding and acceptance of the process of donating cells, tissues and organs is deep-seated and unambiguous.


SECTION 4. WHO MAY MAKE ANATOMICAL GIFT BEFORE DONOR’S DEATH. Subject to Section 8, an anatomical gift of a donor’s body or part may be made during the life of the donor for the purpose of transplantation, therapy, research, or education in the manner provided in Section 5 by: (1) the donor, if the donor is an adult or if the donor is a minor and is: (A) emancipated; or 18 (B) authorized under state law to apply for a driver’s license because the donor is at least [insert the youngest age at which an individual may apply for any type of driver’s license] years of age; (2) an agent of the donor, unless the power of attorney for health care or other record prohibits the agent from making an anatomical gift; (3) a parent of the donor, if the donor is an unemancipated minor; or (4) the donor’s guardian.

SECTION 5. MANNER OF MAKING ANATOMICAL GIFT BEFORE DONOR’S DEATH. (a) A donor may make an anatomical gift: (1) by authorizing a statement or symbol indicating that the donor has made an anatomical gift to be imprinted on the donor’s driver’s license or identification card; (2) in a will; (3) during a terminal illness or injury of the donor, by any form of communication addressed to at least two adults, at least one of whom is a disinterested witness; or (4) as provided in subsection (b). (b) A donor or other person authorized to make an anatomical gift under Section 4 may make a gift by a donor card or other record signed by the donor or other person making the gift or by authorizing that a statement or symbol indicating that the donor has made an anatomical gift be included on a donor registry. If the donor or other person is physically
unable to sign a record, the record may be signed by another individual at the direction of the donor or other person and must: (1) be witnessed by at least two adults, at least one of whom is a disinterested witness, who have signed at the request of the donor or the other person; and (2) state that it has been signed and witnessed as provided in paragraph (1). (c) Revocation, suspension, expiration, or cancellation of a driver’s license or identification card upon which an anatomical gift is indicated does not invalidate the gift. (d) An anatomical gift made by will takes effect upon the donor’s death whether or not the will is probated. Invalidation of the will after the donor’s death does not invalidate the gift.

SECTION 6. AMENDING OR REVOKING ANATOMICAL GIFT BEFORE DONOR’S DEATH. (a) Subject to Section 8, a donor or other person authorized to make an anatomical gift under Section 4 may amend or revoke an anatomical gift by: (1) a record signed by: (A) the donor; (B) the other person; or (C) subject to subsection (b), another individual acting at the direction of the donor or the other person if the donor or other person is physically unable to sign; or (2) a later-executed document of gift that amends or revokes a previous anatomical gift or portion of an anatomical gift, either expressly or by inconsistency. (b) A record signed pursuant to subsection (a)(1)(C) must: (1) be witnessed by at least two adults, at least one of whom is a disinterested witness, who have signed at the request of the donor or the other person; and (2) state that it has been signed and witnessed as provided in paragraph (1). (c) Subject to Section 8, a donor or other person authorized to make an anatomical gift under Section 4 may revoke an anatomical gift by the destruction or cancellation of the document of gift, or the portion of the document of gift used to make the gift, with the intent to revoke the gift. (d) A donor may amend or revoke an anatomical gift that was not made in a will by any form of communication during a terminal illness or injury addressed to at least two adults, at least one of whom is a disinterested witness. (e) A donor who makes an anatomical gift in a will may amend or revoke the gift in the manner provided for amendment or revocation of wills or as provided in subsection (a).

SECTION 8. PRECLUSIVE EFFECT OF ANATOMICAL GIFT, AMENDMENT, OR REVOCATION. 29 (a) Except as otherwise provided in subsection (g) and subject to subsection (f), in the absence of an express, contrary indication by the donor, a person other than the donor is barred from making, amending, or revoking an anatomical gift of a donor’s body or part if the donor made an anatomical gift of the donor’s body or part under Section 5 or an amendment to an anatomical gift of the donor’s body or part under Section 6.

SECTION 9. WHO MAY MAKE ANATOMICAL GIFT OF DECEDENT’S BODY OR PART. (a) Subject to subsections (b) and (c) and unless barred by Section 7 or 8, an anatomical gift of a decedent’s body or part for purpose of transplantation, therapy, research, or education may be made by any member of the following classes of persons who is reasonably available, in the order of priority listed: (1) an agent of the decedent at the time of death who could have made an anatomical gift under Section 4(2) immediately before the decedent’s death; (2) the spouse of the decedent; (3) adult children of the decedent; (4) parents of the decedent; (5) adult siblings of the decedent; (6) adult grandchildren of the decedent; (7) grandparents of the decedent; (8) an adult who exhibited special care and concern for the decedent; (9) the persons who were acting as the [guardians] of the person of the decedent at the time of death; and (10) any other person having the authority to dispose of the decedent’s body. (b) If there is more than one member of a class listed in subsection (a)(1), (3), (4), (5), (6), (7), or (9) entitled to make an anatomical gift, an anatomical gift may be made by a member of the class unless that member or a person to which the gift may pass under Section 11 knows of an objection by another member of the class. If an objection is known, the gift may be made only by a majority of the members of the class who are reasonably available. (c) A person may not make an anatomical gift if, at the time of the decedent’s death, a person in a prior class under subsection (a) is reasonably available to make or to object to the making of an anatomical gift.

Donor Registry:

WHO GUIDING PRINCIPLES ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION:
“...Depending upon domestic law, such consent may be made orally or recorded on a donor card, driver’s license or identity card or in the medical record or a donor registry.”

INDIA- THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994- as amended in 2011

Section 13D National registry. -The Central Government shall maintain a national registry of the donors and recipients of human organs and tissues and such registry shall have such information as may be prescribed to an ongoing evaluation of the scientific and clinical status of human organs and tissues.

Rule 32 The Transplantation of Human Organs and Tissue Rules 2014- Information to be included in National Registry regarding donors and recipients of human organ and tissue.—

The national registry shall be based on the following, namely:-.....

**Tissue Registry:**
(6) The Tissue Registry shall include demographic information on the tissue donor, site of tissue retrieval or donation, primary cause of death in case of deceased donor, donor maintenance details in case of brain stem dead donor, associated medical illnesses, relevant laboratory tests, driving license or any other document pledging donation, donation requested by whom, identity of counsellors, tissue(s) or organ(s) retrieved, demographic data about the tissue recipient, hospital conducting transplantation, transplant waiting list and priority list for critical patients, if these exist, indication(s) for transplant, outcome of transplanted tissue, etc.
(7) Yearly reports in respect of National Registry shall be published and also shared with the contributing units and other stakeholders.

MANDATORY DEATH NOTIFICATION

INDIA- THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994- as amended in 2011

Section 6: Authority for removal of human organs or tissues or both from bodies sent for post-mortem examination for medico-legal or pathological purposes

Where the body of a person has been sent for post-mortem examination-
(a) for medico-legal purposes by reason of the death of such person having been caused by accident or any other unnatural cause; or
(b) for pathological purposes, the person competent under this Act to give authority for the removal of any [human organ or tissue or both] from such dead body may, if he has reason to believe that such [human organ or tissue or both] will not be required for the purpose for which such body has been sent for post-mortem examination, authorise the removal, for therapeutic purposes, of that [human organ or tissue or both] of the deceased person provided that he is satisfied that the deceased person had not expressed, before his death, any objection to any of his [human organs or tissues or both] being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his [human organs or tissues or both] for therapeutic purposes after his death, such authority had not been revoked by him before his death.

ACCESS TO MEDICAL RECORDS

WHO Guiding Principles- Guiding Principle 11

The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

US Code of Federal Regulations § 164.512 (h)

“**Uses and disclosures for which an authorization or opportunity to agree or object is not required.**
A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in§ 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to,
a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally….”

“….Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes. A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.”

Legalization of Processing Fees

WHO GUIDING PRINCIPLES - Guiding Principle 5

Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

Commentary on Guiding Principle 5

This Principle permits compensation for the costs of making donations (including medical expenses and lost earnings for live donors), lest they operate as a disincentive to donation. The need to cover legitimate costs of procurement and of ensuring the safety, quality and efficacy of human cell and tissue products and organs for transplantation is also accepted as long as the human body and its parts as such are not a source of financial gain.

Guiding Principle 8

All health care facilities and professionals involved in cell, tissue or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.

Commentary on Guiding Principle 8

This provision reinforces Guiding Principles 5 and 7 by forbidding profiteering in cell, tissue and organ recovery and implantation. Health authorities should monitor the fees charged for transplantation services to ensure that they are not disguised charges for the cells, tissues or organs themselves. All persons and facilities involved should be accountable for all payments for transplantation services. A medical or other health care practitioner uncertain whether a fee is justifiable should seek the opinion of an appropriate licensing or disciplinary authority before proposing or levying the fee. Fees charged for similar services may be used as a reference.

UK Human Tissue Act 2004

The Act makes it clear that reimbursement for the costs of retrieval is acceptable.

References in subsections (1) and (2) to reward, in relation to the supply of any controlled material, do not include payment in money or money’s worth for defraying or reimbursing— (a) any expenses incurred in, or in connection with, transporting, removing, preparing, preserving or storing the material, (b) any liability incurred in respect of— (i) expenses incurred by a third party in, or in connection with, any of the activities mentioned in paragraph (a), or (ii) a payment in relation to which subsection (6) has effect, or (c) any expenses or loss of earnings incurred by the person from whose body the material comes so far as reasonably and directly attributable to his supplying the material from his body.

INDIA- THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994- as amended in 2011

Rule 9 – Transplantation of Human Organs and Tissue Rules, 2014
Cost for maintenance of cadaver or retrieval or transportation or preservation of organs or tissues.— The

cost for maintenance of the cadaver (brain-stem dead declared person), retrieval of organs or tissues, their

transportation and preservation, shall not be borne by the donor family and may be borne by the recipient or

institution or Government or non-Government organisation or society as decided by the respective State

Government or Union territory Administration.

NON-PHYSICIAN RECOVERY

INDIA- THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994- as amended in 2011

Section 3 (1A)- “For the purpose of removal, storage or transplantation of such human organs or tissues or

both, as may be prescribed, it shall be the duty of the registered medical practitioner working in a hospital, in

consultation with transplant co-ordinator, if such transplant co-ordinator is available…..”

“(4) The authority given under sub-section (1) or sub-section (2) or, as the case may be, sub-section (3)

shall be sufficient warrant for the removal, for therapeutic purposes, of the 1 [human organ or tissue or both]

but no such removal shall be made by any person other than the registered medical practitioner: [Provided

that a technician possessing such qualifications and experience, as may be prescribed, may

enucleate a cornea.]


18. Ibid, Rosenblum. CITATION NEEDED


23. Section 6, THOTA, please see Appendix at page 33,

24. [Regulation §164.512 (h)], See Appendix at page 34.


27. Please see Section 3 of THOTA at Appendix, pages 32–33.
