Barriers and facilitators to the

Implementation of the Declaration of Istanbul (DOI)'s recommendations in transplantation policies in developing countries

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PART I: ANALYTICAL REPORT

The George Institute for Global Health

The DECLARATION of ISTANBUL on ORGAN TRAFFICKING and TRANSPLANT TOURISM

TTS THE TRANSPLANTATION SOCIETY

ISN INTERNATIONAL SOCIETY OF NEPHROLOGY

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Executive Summary

With great efforts made by global bodies such as the World Health Organization (WHO), Council for Europe; World Medical Associations and professional bodies, led by The Transplantation Society (TTS), and the International Society of Nephrology (ISN), extensive guidelines have been formulated for ethical organ transplantation laws and policies. Global guidelines supplemented by domestic regulatory framework (including national laws) have led to a decline in unethical transplant practices around the world. However, practices of transplant tourism, organ trafficking and coercion and exploitation in matters of transplantation continue to pervade. The onset of the Covid-19 crisis has further exacerbated challenges to ethical transplantation as, on one hand distress, vulnerability and poverty induced by the pandemic led to a surge in cases of organ trade and on the other hand, patients witnessed a substantial decline in transplantations owing to pressure on the health system to combat the pandemic emergency.

In such context, this study commissioned by the Declaration of Istanbul Custodia Group (DICG) and undertaken by The George Institute for Global Health, India is timely. One of the first empirical studies with a focus on the Declaration of Istanbul principles (DoI principles/guideline), this study maps empirical findings in relation to domestic regulatory framework of six countries (traditionally considered as 'hotspots') and seeks to analyse its interface with the DoI principles. An extensive review of domestic regulatory literature in 6 countries India, Egypt, Philippines, Costa Rica, Pakistan, and Colombia) has been conducted following a stepped research approach that involves policy analysis of data collected via desk review and key informant interviewees (n=24) from the 6 countries. The study presents the role of different stakeholders within the transplantation framework of each of the country under review and empirically assimilates a set of factors that influence organ trafficking, transplant tourism.

This report has two parts:

Part I with Annexures, and Part II.

Part I is the Analytical report which highlights findings across four key themes of: (i) Ethically and clinically sound organ transplantation programs (covering living and deceased donation framework and role of regulatory bodies in procurement and distribution of organ donation processes); (ii) Trafficking, Transplant tourism, Commercialisation & Financial Neutrality (covering unauthorised and coerced organ removal framework, along with trafficking regulations encompassing trafficking in persons for organ removal and organ trafficking as well as regulation of financial incentives); (iii) Equity (studied from the lens of priority listing for allocation and procurement of organs, availability of public funds to bear transplantation costs and special protection offered to vulnerable groups); and (iv) self-sufficiency (studied from the lens of giving preference to local population, financing mechanisms for transplantation and data on transplant per million population). The report synthesizes these findings and provides a list of factors that act as enablers and barriers to domestic policy organ transplant framework by highlighting the role of approximately 50 distinct factors that operate at inter-personal, intra-personal, community and public policy levels. The study concludes by highlighting issues that global bodies such as the DICG can take note of, in order to prioritise policy agenda on issues inter-alia: **supporting transplant coordinators, supporting financing mechanisms for transplants, leveraging more buy-in from religious and cultural leaders, facilitating ease of administration** and overall understanding the inherent clashes that operate at intra-personal, inter-personal, community and public policy levels which influence outcomes of ethical transplantation. The report concludes by identifying the limitations associated with the study and highlighting areas where data gaps have been experienced and avenues for future research. Part I ends with several annexures that help make this study replicable by highlighting various sources from where data has been extracted at each country level, including the keywords used for research and a detailed regulatory architecture map that provides the text of domestic regulations.

Part II follows a more in-depth narrative style of explanation wherein each country's domestic framework has been analysed and lessons on implementation drawn from the key informant interviews have been discussed. This part offers readers a more detailed explanation on how different aspects of ethical transplantation operate and contextual limitations faced within each country. Each country report has been appended with an overview of its regulatory including legal framework in a question and answer (Q&A) format.

Chapter 1 - Introduction

Organ transplantation, considered a medical miracle of the 20th century, has prolonged and improved the lives of hundreds of thousands of individuals worldwide. Organ donation and transplant rates vary across the globe, but there remains a universal shortage of organ donors. This shortage has fostered practices like financial inducement and coercion in donation. As a result, the poorest and most vulnerable sections of society often find themselves exploited. Many times, wealthy patients from developed countries travel to Low-and-Middle-Income Countries (LMIC) to purchase organs and receive transplants, resulting in illegal forms of transplant tourism. Considered unethical and illegal in most jurisdictions, transplant tourism continues to flourish, though its extent is difficult to measure. Certain regions and countries emerged as 'hotspots' for commercial transplantation, organ trafficking and transplant tourism from time to time. Hotspots are regions characterized by a capacity to perform transplantation, presence of vulnerable populations, lax regulation and some degree of collusion by transplant professionals.

The above challenges underscore the need for a regulated organ transplant framework, as the same can help prevent organ trafficking and transplant tourism, increase awareness and enable better adoption of ethical transplant practices[1] worldwide. A robust regulatory framework for transplantation may help in minimizing favoritism, exploitation, corruption, and ensures that patients receive organs solely based on medical needs rather than socio-economic status or personal connections[2]. Regulation results in credibility and trust in the transplant process, which in turn may lead to improved donation rates[3,4].

However, empirical findings on the effect of regulatory systems on countries, especially hotspots, remain sparse.

Given the transnational nature of transplant tourism, and its practices which can be classified under two different categories of legally defined crimes (i.e. trafficking in persons for organ removal (TIP for OR) and organ trafficking),[5] a need for cross-border collaboration is felt in-order to effectively enforce organ transplant regulatory framework. Furthermore, harmonizing the clinical and ethical norms across domestic organ transplant frameworks can promote self-sufficiency through elevating training standards, facilitate the adoption of cutting-edge scientific advancements, and foster the exchange of experiences among medical professionals. Recognizing the interconnected nature of organ transplant regulation, a globally inclusive perspective is essential for its development.

Evolution of global principles and bodies

International organizations led by the World Health Organization (WHO), and professional bodies, led by The Transplantation Society (TTS), and the International Society of Nephrology (ISN) have supported development of guidance to inform the development of ethical organ transplantation laws and policies.

The WHO Guiding Principles on Human Organ Transplantation, 1991 was one of the earliest global principles that urged Member states to take appropriate measures to prevent the purchase and sale of human organs for transplantation. In aftermath of these principles, the WHO Secretariat was involved in several rounds of consultations which helped refine these principles. In 2008,

1 Padilla, B., Danovitch, G. M., & Lavee, J. (2013). Impact of legal measures prevent transplant tourism: the interrelated experience of The Philippines and Israel. Medicine, health care, and philosophy, 16(4), 915–919. *https://doi.org/10.1007/s11019-013-9473-5*.

2 Tan, J., Khalil, M.A.M., Kee, T., Tiong, H.Y., Khan, T.T., Madhoun, I.E., Ishida, H., Jasuja, S., Ahmad, G., Tang, S.C.W., Vathsala, A. (2023). Deceased donor kidney transplant policies in Asia – implications on practice and recommendations for the future. Health Policy. The Lancet Regional Health - Southeast Asia. *https://doi.org/10.1016/j.lansea.2023.100*

3 Mossialos, E., Costa-Font, J., Rudisill, C. (2008). Does organ donation legislation affect individuals' willingness to donate their own or their relative's organs? Evidence from European Union survey data. BMC Health Services Research, 8(48). *https://doi.org/10.1186/1472-6963-8-48*

4 Rodgers, S.B. (1989). Legal Framework for Organ Donation and Transplantation. Nursing Clinics of North America, 24(4), 837-850. *https://doi.org/10.1016/S0029-6465(22)01548-1*

5 Toolkit on the Investigation and Prosecution of Trafficking in Persons for Organ Removal prepared by the United Nations Office on Drugs and Crime (2022) explains the nuanced differences that exist between trafficking in persons for organ removal (TIP for OR) and organ trafficking, where the former is defined in the UN Trafficking in Persons Protocol and the latter is defined as per the Council of Europe Convention on Organ Trafficking.

the TTS and ISN helped gather more than 150 representatives of scientific and medical bodies from 78 countries around the world, including government officials, social scientists and ethicists to a summit in Istanbul, Turkey, and collectively formulated a document named the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (DoI). Though not legally binding, the DoI proposed voluntary adherence and incorporation into domestic laws of nations as well as endorsement by professional and regulatory organisations of countries. The DoI aims to guide doctors, transplant centers, ministries of health, and policymakers on how to prevent organ trafficking and illegal travel for transplants.

Following this, the WHO further developed a set of Guiding Principles on Human Cell, Tissue and Organ Transplantation, which were adopted by the 63rd World Health Assembly in 2010. The Guiding principle #5 says "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." Other guiding principles provide for a framework for donor consent, criteria for living and deceased donations, prevention of conflict of interest amongst physicians, establishing a legal framework for transplantation, preventing monetary payments, promoting altruistic donation, banning advertisement and brokerage, prohibition on exploitation or coercion in matters of living donation, regulating transplantation costs, ensuring high quality care and subjecting donations and transplantation activities to transparency and scrutiny.[6]

Subsequently, in 2018, the DoI principles were also reviewed and several of the original DoI principles were updated to ensure clear and current guidance for policymakers and health professionals working in organ donation and transplantation.

With an aim to prepare strategies and implementation plans to help promote, implement and uphold the principles of the DoI, the Declaration of Istanbul Custodian Group (DICG)7 was formally established in 2010. The DICG's proposed aim is to combat organ trafficking, transplant tourism and commercialism and encourage adoption of effective and ethical transplantation practices around the world. Participants of the 2008 Istanbul summit meeting continue to play an active role in the work of the DICG, which has a formal structure of its own, including rotational leadership. The DICG offers a rich repository of policy documents, legislations in member countries and meets periodically to endorse the DoI principles and help track its implementation across the countries.

6 Human Organ and Tissue Transplantation, Report by the Secretariat, 62nd World Health Assembly, Provisional agenda item 12.10, A62/15, 26 March 2009, available at: *https://apps.who.int/gb/ebwha/pdf_files/A62/A62_15-en.pdf*

7 The Declaration of Istanbul. (n.d.). About the Custodian Group. *https://www.declarationofistanbul.org/governance*

Problem statement and focus of this study.

The development and uptake of global and ethical guidelines with involvement of transplant professionals globally[8] has led to recognition of commercial transplantation as an issue by governments[9]. While adoption of national laws in some contexts have led to a decline in unethical transplant practices around the world[10,11], they have not been eliminated completely and continue to acquire new forms in emerging contexts[12]. The onset of the Covid-19 crisis has further exacerbated challenges to ethical transplantation[13] as, on one hand distress, vulnerability and poverty induced by the pandemic led to a surge in cases of organ trade and on the other hand, patients witnessed a substantial decline in transplantations owing to pressure on the health system to combat the pandemic emergency[14].

The acceptance and incorporation of global ethics principles in the regulatory architecture and the factors influencing the regulations in various geographies have not been adequately studied. This study maps different stakeholders within the transplantation framework and empirically assimilates a set of factors that influence organ trafficking and transplant tourism. An empirical analysis of this nature will help understand how and why countries vary in their ability and interest in implementing global principles of the DoI. This in turn could help global bodies to strategise better. While global principles endorsed by various international bodies including- the WHO Guiding Principles, the Council of Europe Convention on Human Rights and Biomedicine and its Additional Protocol concerning Transplantation, World Medical Association statements, all serve great value in shaping the global framework for ethical transplantation; it is not feasible to undertake a comprehensive study on each of them. This study therefore focuses on the most recent 2018 DoI principles[15] as the point of departure in relation to which the prevalent regulatory framework in each of the countries are examined.

The current study is commissioned by the DICG and undertaken by The George Institute for Global Health, India. **The aim of the study is to understand the interplay between global principles of the DoI and the domestic regulatory frameworks of six selected LMICs.** The study's primary aim is to provide learnings for global bodies such as the DICG with regards to dissemination of the DoI principles in diverse country settings.

The core objectives of the study are:

i. mapping of the relevant organisations and policies within the selected LMICs that deal with organ transplantation issues.

ii. identification of areas where the domestic policies and the DoI principles have an interface.

iii. investigation of barriers and facilitators in the implementation of the domestic policies dealing with organ transplant.

iv. analysis of the reasons behind the barriers and facilitators to domestic policy implementation.

8 Murdie, A.M., Davis, D.R. (2012) Shaming and Blaming: Using Events Data to Assess the Impact of Human Rights INGOs. International Studies Quarterly, 56(1), 1–16. *https://doi.org/10.1111/j.1468-2478.2011.00694*

9 Imber, J.B. (2008). Trusting Doctors: The Decline of Moral Authority in American Medicine. Princeton, NJ: Princeton University Press.

10 Padilla, B., Danovitch, G. M., & Lavee, J. (2013). Impact of legal measures prevent transplant tourism: the interrelated experience of The Philippines and Israel. Medicine, health care, and philosophy, 16(4), 915–919. *https://doi.org/10.1007/s11019-013-9473-5*

11 Rizvi, S. A., Naqvi, S. A., Zafar, M. N., Hussain, Z., Hashmi, A., Hussain, M., Akhtar, S. F., Ahmed, E., Aziz, T., Sultan, G., Sultan, S., Mehdi, S. H., Lal, M., Ali, B., Mubarak, M., & Faiq, S. M. (2011). A renal transplantation model for developing countries. American journal of transplantation: official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 11(11), 2302–2307. *https://doi.org/10.1111/j.1600-6143.2011.03712.x*

12 Shroff S. (2009). Legal and ethical aspects of organ donation and transplantation. Indian journal of Urology: IJU : journal of the Urological Society of India, 25(3), 348–355. *https://doi.org/10.4103/0970-1591.56203*

13 Ritschl, P. V., Nevermann, N., Wiering, L., Wu, H. H., Moroder, P., Brandl, A., Hillebrandt, K., Tacke, F., Friedersdorff, F., Schlomm, T., Schöning, W., Öllinger, R., Schmelzle, M., & Pratschke, J. (2020). Solid organ transplantation programs facing lack of empiric evidence in the COVID-19 pandemic: A By-proxy Society Recommendation Consensus approach. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 20(7), 1826–1836. *https://doi.org/10.1111/ajt.15933*

14 Chan, E. G., Harano, T., Morrell, M. R., & Sanchez, P. G. (2021). Lung transplantation protocols during the COVID-19 pandemic: a single center experience. Journal of thoracic disease, 13(4), 2081–2086. *https://doi.org/10.21037/jtd-20-3289*

15 The Declaration of Istanbul. (n.d.). About "The Declaration of Istanbul". *https://www.declarationofistanbul.org/the-declaration*

The first and second objectives are fulfilled by conducting a broad review of the DoI principles and a desk review of written domestic laws and policies. The third and fourth objectives have been fulfilled by a detailed empirical analysis whose findings are premised on Key Informant Interviews (KIIs) of various actors, such as medical practitioners, regulators and advocacy bodies from the countries (n=24).

For this study, six countries are selected to conduct an empirical analysis. In selecting countries, a set of criteria was developed in consultation with DICG member experts. Developing countries belonging to the global south (low and lower-middle income countries as per the World Bank classification) that have been identified as hotspots for commercial transplantation and transplant tourism from time to time[16] are included for analysis as the effectiveness of health policies in LMICs continue to be a challenge.[17] The selection criteria for this study primarily included diversity of geographies which have varied socio-cultural beliefs, relatively high annual organ transplant rates, history of high transplantation rates of foreign nationals and having a significant historical incidence of organ trafficking . The selected sample of countries has also been finalised based on access to contacts within the DICG network to help recruit participants who could offer insights for the study. Based on the afore-mentioned metrics and expert opinion, the following countries were chosen for this study: India, Egypt, Philippines, Costa Rica, Pakistan, and Colombia. These countries vary extensively in their health systems, funding, insurance structures as well as socio-economic and religious cultures; all of which play a crucial role in shaping transplantation policies.

This report presents a comparative overview of all six countries and provides concrete evidence emerging from each country. This analytical report is divided into five sections. The first section provides brief introduction. The second section presents a detailed methodology for the study. The third section synthesizes findings from country-specific data and analyses them in light of the DoI guidelines. The fourth section presents a discussion which unpacks enablers and barriers that have emerged in light of this empirical exercise. The fifth section concludes by offering key takeaways from the study including learnings for global bodies such as the DICG and provides avenues for future research areas in this field.

To the best of the research team's knowledge, this is a first-of-its-kind empirical study in relation to the DoI principles, backed by an extensive literature review and interview data, analysed through credible policy frameworks applied in the health policy domain. The annexures provide a repository of legislation and policies at the individual country level, web-links of sources from where relevant policy data has been excavated at an individual country level and detailed Q&As on how domestic policies in relation to transplantation have evolved including on specific themes laid out by the DoI principles inter-alia, transplant tourism, organ trafficking, and self-sufficiency.

16 Low & Middle Income, The World Bank, *https://data.worldbank.org/country/XO*

17 Sheikh, K., Saligram, P.S., Hort, K. (2015). What explains regulatory failure? Analysing the architecture of health care regulation in two Indian states. Health Policy and Planning, 30 (1), 39–55. *https://doi.org/10.1093/heapol/czt095*

Chapter 2- Methodology

We have adopted a stepped research approach[18] involving qualitative comparative case study and used policy analysis frameworks to capture and analyse findings for the study. A detailed list of steps involved in the study has been set out below:

Step 1

A global literature review was conducted using the web database of PubMed & Google Scholar. Keywords used were: 'Organ transplantation policies'; 'implementation of organ transplantation policies'; 'implementation of organ transplantation laws'; 'implementation of organ transplantation policies in developing countries.' This exercise yielded several empirical studies highlighting the problems in implementing organ transplant policies. An overview of existing empirical studies has helped develop themes for the current study.

Step 2

We conducted a search of several global principles and guidelines on organ transplant and donation. See **Annexure 1** which has three parts: Part A and B provide the text of the DoI principles (2018 and 2008) and Part C provides for details on the WHO Guiding Principle. Note that the DoI principles are pivotal for the study and the 2018 DoI principles have been used in providing context and helping identify relevant themes for this study.

Step 3

Based on the background information obtained in Steps 1 and 2, and a discussion with DICG expert group, a list of research questions for the study was finalised (**Annexure 2**).

Step 4

Case selection was done based on findings of Step 1 and in consultation with DICG experts. 6 cases – India, Pakistan, Philippines, Colombia, Costa Rica, and Egypt were identified as relevant jurisdictions for study. The key criteria/metrics used to select countries included, inter-alia- (i) geographical representation to ensure that developing countries across diverse continents, regions and socio-cultural beliefs are included; (ii) countries with established organ transplant programs and those which have experienced high as well as declining rates of transplants on foreigners over the last 15 years; (iii) those which emerged as hotspots for organ trafficking at some stage in the last 3 decades; (iv) those with high proportion of organ transplantation from live donors.; (v) those where the DICG has contact with transplant professionals.

Step 5

Inspired by the study of Sheikh et al[19] pertaining to regulatory failures in healthcare regulation, a similar yet modified version of a "regulatory architecture map" was developed for the study. This framework aids policy review and analysis by helping map and identify: (i) the policy context, including mechanisms associated with policy implementation; (ii) the text of relevant rules, laws and policies at the national level; and (iii) the role of different regulating organisations in context of organ transplantation policies within the selected countries. The framework was chosen for its suitability to capture diverse themes of transplant landscape in different countries and provide a uniform lens to study policy developments in the six selected countries. Using this framework, policy documents were sourced at the individual country level. The term 'policy' in this study is to be understood broadly to include both laws which impose restrictions as well as regulations which may not impose restrictions but control as well as enable and facilitate activities in relation to organ transplant.[20]

The sources that we relied upon included- text of laws/regulations, including constitutional, statutory, clinical, criminal laws, and grey literature which can

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18 Harrison, H., Birks, M., Franklin, R., & Mills, J. (2017). Case study research: Foundations and methodological orientations. In Forum qualitative Sozialforschung/Forum: qualitative social research, 18 (1), 1-288.

19 Sheikh, K., Saligram, P.S., Hort, K. (2015). What explains regulatory failure? Analysing the architecture of health care regulation in two Indian states. Health Policy and Planning, 30 (1), 39–55. *https://doi.org/10.1093/heapol/czt095*

20 Orbach, B. What is Regulation. (2012). 30 Yale Journal on Regulation Online 1, Arizona Legal Studies Discussion Paper No. 12-27. *https://ssrn.com/abstract=2143385*

be understood as literature which is outside of the traditional or academic publications such as reports, working papers, government documents, white papers and evaluations. This study has relied upon a wide range of instruments in the domain of grey literature including - government policies, framework devised by the state, professional bodies and non-profit organisations as well, ethical guidelines and recommendations for future reforms or pending legislative documents.

The keywords used to source documents at each country level have been described in **Annexure 3.** The list of documents relied for desk review of each country have been collated in **Annexure 4.** A collated regulatory architecture map can be found in **Annexure 5.** The first column of the regulatory architecture map enclosed in Annexure 5 reflects themes of regulatory policy as set out in the DOI. The presence or absence of the themes in each country under study has been reviewed and role of different actors have been analysed who are tasked with implementing transplantation policies.

Step 6

After information was captured and systemised under different themes and columns in the regulatory architecture map, policy analysis reports for each country was developed using the findings of the desk review. Keeping the research questions of the study in mind, and information captured under the regulatory architecture map, detailed policy review reports were prepared in Question & Answer format which **inter-alia,** provide an overview of policy evolution in relation to organ transplants including deceased and live donations, role of different regulatory actors, definitions of key terms such as transplant tourism, organ trafficking and self-sufficiency as understood in context of each country, safeguards to protect domestic citizens and vulnerable groups and presence of tools such as allocation mechanisms and registries for organ donation. Country-specific policy reports can be found enclosed along with specific country chapters in the descriptive report.

Step 8

Once the desk review policy analysis reports were generated for each country, a meeting was organised with the country- specific DICG expert. Findings were verified, and modifications made to the reports.

Step 9

Based on gaps identified in each of the reports and research questions that remained unanswered via Step 6, the Key Informants Interview **(KII)** process was designed.

Step 10

A list of possible KII was procured from each country through the DICG Network. The number of key informants received from each country was different. Table below presents the details of the key informants contacted and the number of them who consented for the interview.

Country	Number of stakeholders Contacted	Number of participants	Number of rejections/ no responses
India	18	10	8
Philippines	7	4	3
Costa Rica	20	4	16
Egypt	7	2	5
Pakistan	5	4	1
Colombia	6	0	6
Total	**63**	**24**	**39**

The list of interviewees can be found in Annexure 6

An interview guide was developed to capture data on key themes identified during the policy analysis. The interview guide was tailored to each country to fill country specific gaps that emerged from the desk review of policies. The Key Informant Interviews were conducted during the time span of 2022-2023 and interviews were analysed using Framework Analysis[21]. The KIIs were coded using predetermined categories emerging from the desk review of policies. The data was analysed in line with the objectives of the study. The transcripts were shared with each Key Informant to ensure that findings were accurately captured.

21 Gale, N.K., Heath, G., Cameron, E. et al. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology (13), 117. *https://doi.org/10.1186/1471-2288-13-117*

The findings were then integrated into the country-specific policy reports.

Step 11

The findings were shared with a larger body of experts (DICG country specific experts and other experts) and their recommendations were obtained on study findings.

Step 12

Based on triangulation of findings and synthesis of data across the above steps, the following report has been drafted. The theory of Ecological perspective used for health systems analysis has been leveraged to understand how different micro, meso and macro regulatory factors influence organ transplantation policies and their outcomes.

Chapter 3- Key Findings

Global health principles are often considered lofty and unrealistic, which stand distant from local realities.[22,23] Development and implementation of sound regulation is often considered to be challenging in LMICs due to limited regulatory capacity, regulatory service inadequacies, cultures of corruption, and a reliance on top-down oriented regulatory hierarchies.[24,25] In this light, examining the interplay between the global principles of the DoI and the domestic regulatory frameworks of organ transplant in the selected developing countries remained a challenging exercise.

In order to draw meaningful lessons from country-specific implementation of policies for bodies such as the DICG which work towards strengthening the implementation of global ethical principles of transplantation at local levels; it becomes imperative to understand in-depth the global principles of the DoI as well as the local contexts. This chapter helps conceptualise different themes emerging from the DoI principles. Further, it presents a comparative overview of countries and examines the presence and absence of domestic policies in relation to the DoI themes. It must be clarified that the domestic policies have not been formulated in light of the DoI principles as several of the policies in various countries predate the DoI guidelines (of 2008 as well as 2018). Furthermore, we acknowledge that other global principles such as the WHO Guiding Principles have influenced regulatory landscape since 1991, and therefore the findings are not meant to be attributed to the impact of DoI as such. However, mapping the interface between the domestic policies and the DoI guidelines help us understand the extent to which global ethical principles are reflected in the domestic framework of every country under review. Therefore, the synthesis keeps the DoI principles of 2018 as the point of departure for analysis, in light of which the relevant domestic policies can be mapped, examined and understood in detail.

Set out below are the different themes emerging from the DoI[26] and the nature of evidence collected from each country in relation to their domestic policies which align with the global principles of the DoI.

1. *Ethically and clinically sound organ transplantation programs*

The first and the second DoI principle envisage that governments will develop and implement ethically and clinically sound programs to prevent and treat organ failure and provide optimal care to organ donors. DoI principle 6 stipulates that designated authorities must be constituted in jurisdictions to oversee and hold accountability for organ donation, allocation and transplantation practices, with an aim to ensure standardization, traceability, transparency, quality, safety, fairness and public trust. Together, the three principles help to establish sound ethical and clinical organ transplantation programs by recognising the role of diverse actors in ensuring safe transplantation processes.

A review of the interface between the DoI principles and the domestic policies indicate that all six countries have passed statutory legislations, and regulatory guidelines (in the nature of administrative orders) that establish a framework for inter-alia:

(i) living organ donation, including regulation on foreigners receiving organs; as well as

(ii) deceased donations, and

(iii) which helps in managing the procurement and distribution process for organ donation, via committees and regulatory bodies.

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22 Nagan, W. P. (2001). Rule of Law: Lofty Ideal or Harsh Reality?. Journal of Financial Crime, 8(4), 347-355. *https://www.emerald.com/insight/content/doi/10.1108/eb025999/full/html*

23 Aginam, O. (2005). Global health governance: International law and public health in a divided world. University of Toronto Press.

24 Ndomondo-Sigonda, M., Miot, J., Naidoo, S., Dodoo, A., & Kaale, E. (2017). Medicines Regulation in Africa: Current State and Opportunities. Pharmaceutical medicine, 31(6), 383–397. *https://doi.org/10.1007/s40290-017-0210-x*

25 Williams O.D., Yung, K.C., Grépin K.A. (2021). The failure of private health services: COVID-19 induced crises in low- and middle-income country (LMIC) health systems. Global Public Health, 16(8-9),1320-1333. *https://doi.org/10.1080/17441692.2021.1874470*;

26 The Declaration of Istanbul on Organ Trafficking And Transplant Tourism (2018 Edition) available at: *https://www.declarationofistanbul.org/images/Policy_Documents/2018_Ed_Do/2018_Edition_of_the_Declaration_of_Istanbul_Final.pdf*

Each of these are discussed below:

(a) Living organ donation

Regulatory safeguards provide a consent framework for donors where consent is to be verified and regulatory bodies assess whether such donations are legitimate. Restrictions are also placed on foreigners from receiving living organs. Countries have defined broad categories of donors which include both near relatives and other persons such as - those with special reasons (India); non-relatives in case blood relations are not available (Pakistan); living non-related donors (Philippines, Egypt, Colombia) related, emotionally related, and altruistic donors (Costa Rica).

Colombia, Costa Rica and Philippines have relatively broad definitions of related donors to include categories of persons who can donate. In relation to restrictions placed on transplants of foreigners, Philippines has imposed a blanket ban on living donation of foreigners from Filipinos. For countries that allow non-citizens to receive organs, prior and strict approval from the government is followed. Laws in Colombia and Costa Rica specify that organ transplantation should not be included within the ambit of medical tourism, to prevent foreigners from visiting those countries as medical tourists and receive organs via transplantation process.

Distilled empirical evidence indicates that broad definitions of near relatives tend to create ambiguities and allow commercialisation (evidence from Costa Rica) and coerced donations (evidence from Philippines) to grow. While on the other hand, narrow definitions create impediments in organ donation as "special cases" that are not defined under the law and while the law intends altruistic donations, lack of a clear definition to this effect introduces ambiguity (evidence from India).

A review of the interface between the DoI principles and the domestic policies in relation to living organ donation framework is discussed below:

India

Hospital committees are set up to verify relationships in case of 'near relatives'[27] donation. For situations involving donations other than 'near relatives', Authorisation committees have been set up by the government that evaluate the connection between donor and recipient and detect if any illegal or commercial element may be present. Foreigners are permitted to receive donations only from Indians who are 'near relatives' after approval from the Authorisation Committees. Such relationships are verified on the basis of production of official documents and affidavits. Many transplant centres use genetic testing to establish relationships.

In order to provide optimal care to the donors, the medical practitioners are required to explain to the donor all possible side effects, hazards, and complications. The physical and mental evaluation of the donor is also required to be carried out before any donation is made.

Key Informants felt that the definition of 'near relatives' could be expanded to include stepparents and step children, and in-laws to accommodate for the cultural changes within the modern family set-up. Persons other than 'near relatives' may also donate for 'special reasons' which are not clearly defined in law. Hospital-based transplant co-ordinators highlighted the challenges they face in verifying documents submitted by donors or recipients.

Philippines

The framework in Philippines is heavily focused on kidney donation. Similar to India, both related and unrelated recipients can receive donations, and definition of related donor-recipients is slightly broad in nature.[28] An Ethics committee is set up to endorse donations amongst related recipients. Foreigners however are not permitted to receive

27 'Near relatives' defined to include spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter.

28 Relatives have been broadly defined as including parents, children, siblings, cousins, nephews, nieces, and other blood relatives.

organs from living non-related Filipino donors.

Key Informants from Philippines highlighted the power asymmetries that exist in the emotional ties of donor-recipients which may lead to coerced donations.

Costa Rica

Donation from emotionally related and unrelated living donors is permitted under law. Relatives to the fourth degree of consanguinity or third degree of kinship and spouse can donate. In case of donations from emotionally related and unrelated living donors, a sworn statement before a notary public must certify the existing relationship between donor-recipient. In the case of unrelated living donors, the hospital-based transplant coordination team applies to the hospital's clinical bioethics committee for approval. Donation to non-resident foreigners is permitted, but in case of donation to non-resident foreigners, a specific government body (i.e. Technical Executive Secretariat for Organ and Tissue Donation and Transplantation which is a unit in the National council) is required to be informed.

As part of providing optimal care, under law, health personnel in charge of the harvesting and the private/ public health establishment must guarantee the donor comprehensive health care for recovery and follow-up.

Key Informants felt that allowing 'emotionally related' donors tends to create ambiguities They also emphasized that mechanisms to certify an emotionally related donor were sub-optimal and could allow a back door for commercialization.

Colombia

Living donation is permissible only if the donor is related to the recipient.[29] Both biological and emotional (spouses, friends, partners) relationship is acceptable under the law. Such donation is required to be approved by the ethics committee. Foreigners are allowed to receive organs in donation only from related persons with prior permission of the National Authority.

As part of providing optimal care, the donor is guaranteed assistance during recovery and educated about the consequences of the procedure.

Egypt

Consent for donation from persons other than relatives is verified by the Higher Committee of Organ Transplantation; however, no analogous verification process for consent is required for a relative. Doctors are required to confirm the donor's consent verbally before the procedure, giving the donor the option to reconsider donating; they are also prohibited from carrying on with the procedure if they have knowledge of commercial dealings.

As part of providing optimal care, doctors are required to inform donors and recipients about the nature of procedure & risks.

Key Informants spoke of the challenges physicians face in ensuring that there is no commercial interest in unrelated donor transplants. One Key Informant (a transplant surgeon) said that given the tight penalties that the law prescribes, they discourage transplants from unrelated donors in their centre.

Pakistan

Consent for donation from person other than 'close blood relative'[30] is verified by Evaluation Committee; no analogous verification process for consent provided by a 'close blood relative'. Medical professionals are statutorily required to explain risks, impact & outcome of procedure to donor, to ensure informed consent is received.

29 'Related' is defined to include- being a spouse/permanent partner, relative in fourth degree of consanguinity, second of affinity or first civil.

30 'Close blood relatives' comprise of parents, children, siblings and spouse.

(b) Deceased donations

Regulatory safeguards provide for a definition of death in all countries, with the exception of Egypt where brain death is not defined but is to be diagnosed by a clinical team. Doctors other than those who are involved in transplantation are authorised in all countries to declare death, to ensure there is no foul play for seeking organs from dead persons. All countries with an exception of Colombia have an opt-in system for providing consent for donation, whereby a deceased donor may provide consent prior to death, failing which the decision for donation is taken by the family/ relative as defined by the regulations. Colombia excludes relatives from seeking consent for donation, and it is assumed that every deceased person has consented to deceased donation unless there was an express record of their opposition called opt-out.

In relation to deceased donations, evidence in Egypt, Pakistan, India and the Philippines indicate that cultural connotations of death were key barriers to deceased donation programmes. Additionally, lack of co-ordination within and among hospitals, lack of expertise in identifying deceased donors and lack of data were identified as barriers to decreased donations in Costa Rica, India, Philippines and Pakistan. In Egypt and Pakistan, the high cost of instituting a cadaveric donation system was articulated as an additional barrier. In India, the Philippines and Pakistan, poorly and unevenly developed medical infrastructure and limited resources for healthcare were articulated as additional barriers. Key Informants in the Philippines also spoke of the need for awareness programmes to build initiative among health professionals. In Egypt, key informants mentioned public education programmes involving religious leaders are being implemented to overcome public's fears and notions around deceased donations. In Pakistan, key informants spoke of the reluctance of religious leaders to participate in public education programmes to promote deceased donations.

A review of the interface between the DoI principles and the domestic policies in relation to deceased donation framework is discussed below:

India

Death is defined to mean disappearance of all evidence of life by reason of brain steam death or in a cardio-pulmonary sense. Brain-stem death occurs when all functions of the brain steam have permanently and irreversibly ceased.[31] Brain-death is required to be certified by a board of medical experts who have nothing to do with the transplant, twice. 32 A person may authorize the removal of their organs before death by providing consent in front of two witnesses. Notwithstanding such consent, the consent of near relative/ person in lawful possession of body is also required before harvesting organs.[33]

India follows an opt-in system of organ donation with legal measures in place to mandatorily ascertain brain death in potential donors, and for resources to counsel families and retrieve organs. Key Informants confirmed that this regulation is largely ignored. They also said that despite public initiatives for people to pledge their organs, there are many factors that contribute to the low rates of deceased donations, ranging from institutional, human resources and cultural barriers.

Philippines

Death has been defined to mean the irreversible cessation of circulatory and respiratory functions or of the entire brain. The Philippines follows an opt-in system of deceased donation. Donors can consent to donation through a will or other documents executed before two witnesses, and can even specify the name of the donee. In the absence of such consent, family members of the deceased (in the order of priority prescribed in law) can consent to donating his/her organs, so long as the deceased had no objections, prior to their death.

31 Section 2(d), Indian Transplant Act.

32 Section 3(6), Indian Transplant Act.

33 Rule 4(a), Indian Transplant Rules.

Costa Rica

Death is defined as irreversible cessation of circulatory and respiratory functions or irreversible cessation of the functions of the entire brain, including the brainstem. The death certificate must be signed by 3 doctors, none of whom can be part of the transplantation team. In 2015, Costa Rica moved from an opt-out to an opt-in system for deceased donation. In case donor has not provided consent for donation, their family members related in consanguinity up to the fourth degree or by affinity in the first degree can provide such consent.

Key Informants from Costa Rica were of the view that opt-out system of organ donation did not function as effectively, due to constitutional mandates that required consent from family members after death, regardless of the wishes expressed by the deceased prior to their death. Even the opt-in system of organ donation in Costa Rica requires consent from the family members of the deceased.

Colombia

The law defines a deceased donor as someone who has died either by brain death or by irreversible cessation of cardiorespiratory functions.[34] Further, brain death is defined as an irreversible absence of the functions of the brain stem, proven by clinical examination.[35] An opt-out system of deceased donation is followed, where a person may opt out of donating during their lifetime and record such intention in a notarial instrument/private document/ donation card. The consent for donation cannot be overruled by a relative. Death is to be diagnosed by two or more non-interdependent doctors (one specializing in neurology) who are not part of the transplant team. Colombia has, however, not legislated the procurement of organs from donation after cardiac death (DCD) donors.

Egypt

Death is not defined under laws. An opt-in system of deceased donation is followed and permitted only if the consent of the deceased donor has been obtained through a notarized will or other official document.[36] Death has to be diagnosed by a committee consisting of specialist doctors from neurosurgery, cardiothoracic surgery and anaesthesia, and these clinicians cannot be part of the transplant team. Organs from deceased donations can be donated to Egyptian citizens alone. Key Informants interviewed for the study advocated for an opt-out system of organ donation to increase availability of organs, but highlighted the cultural challenges associated with the same.

Pakistan

Death has been defined as cessation of brain stem functions or absence of natural respiratory and cardiac functions. Death is to be diagnosed by two clinicians (not part of the transplant team) and certified by the Evaluation Committee. No official brain death protocol has, however, been issued by the government & each hospital adopts its own criteria. Pakistan follows an opt-in system of deceased donation. Donor consent is certified by the Evaluation Committee. No provision exists for allowing the family to provide consent for deceased donation in the absence of consent from the deceased.

(c) Presence of various regulatory sites/ committees & their constitution

All six countries have set up regulatory committees which undertake responsibilities inter-alia:

(i) inspect and certify transplant centers including health facilities and hospitals.

(ii) frame rules for transplant organizations and professionals.

(iii) maintain database of donors and recipients;

(iv) help in coordination of transplant procedures.

34 (Decree Number 2493 of 2004, 2004, sec. 1)

35 (Decree Number 2493 of 2004, 2004, sec. 1)

36 Article 8, Egypt Transplant Act.

However, there is an evident data gap in understanding whether such committees showcase diversity in representation of different policy actors. While India, Philippines and Costa Rica have shown limited evidence of diversity in representation of the committees, no evidence to assess diverse representation has emerged from Colombia and Egypt. Pakistan's framework is characterized by an absence of diversity in representation as regulatory sites comprise of members from medical community & notable locals, whereas there is no representation of other stakeholder groups. Even in countries that have limited evidence of diversity, there have been challenges in relation to their work. For example, in Costa Rica, the donation and transplant secretary of the Ministry of Health is managed by general physicians who do not have formal training in donation and transplantation. The Advisory Body constituted in India has representation from bureaucrats, medical experts, social workers, legal workers and transplant specialists who are not involved in the transplant. However, similar diversity is not replicated in other regulatory bodies. Lack of lay members or patient representatives (or equal number of lay members and medical experts) also paves way for perceived conflicts of interest as professional duties of medical practitioners may potentially conflict with the fair and transparent allocation of organs in times of need.

2. Trafficking, Transplant tourism, Commercialisation & Financial Neutrality

DoI principle #3 prohibits and criminalises trafficking in human organs and trafficking in persons for the purpose of organ removal. The DoI principle #9 places the duty on health professionals and healthcare institutions to play a role in assisting in preventing and addressing three kinds of issues- organ trafficking, trafficking in persons for the purpose of organ removal, and transplant tourism. Linked to these concepts, the DoI principle #4 explicitly states that organ donation should be a financially neutral act. The 2008 DoI principles clarify the meaning of financial neutrality in relation to adherence to principle that donors and their families should neither lose nor gain financially because of organ donation.

DoI principles are therefore comprehensive in acknowledging different sets of crimes, i.e. TIP for OR, organ trafficking and transplant tourism. The DoI principles leverage a huge body of work from the domain of international criminal conventions which elaborate on concepts of- TIP for OR and organ trafficking. The former is governed by the United Nations TIP protocol, and the latter being governed by the Council of Europe Convention which came into force in 2018. It was felt that the TIP framework remains inadequate in certain cases, such as when organs are removed from deceased persons or when organ donor has consented to the removal of organs. To fulfil such lacunae, the Organ Trafficking Convention was evolved whose central focus is the illicit removal of an organ.[37] In such context, the DoI principles are said to contain "a more clearly structured set of principles for policymakers and health professionals working in organ donation and transplantation."[38]

Countries under review have comprehensive provisions especially under their criminal laws which provide avenues to prosecute against TIP for OR and organ trafficking. Transplant tourism as a concept however, has not been legally defined under any of the country's legal provisions; and there exists no corollary international global principle that defines transplant tourism. Some experts argue that defining transplant tourism for purposes of criminal laws may not be necessary as crimes arising out of transplant tourism such as exploitation is adequately covered under the designated crimes such as TIP for OR and organ trafficking. For purposes of this study, we use a broad lens to understand - whether a country's trafficking laws make a reference to transplant law

37 United Nations Office on Drugs and Crime, Module 2, Toolkit on the Investigation and Prosecution of Trafficking in Persons for Organ Removal, 2022.

38 Ibid, at p. 8.

and its nature and scope is examined (i.e. whether forced removal of organ is explicitly covered within the TIP laws).[39]

The findings indicate that both Costa Rica and Egypt have criminalized TIP for OR and organ trafficking. India's criminal law was also amended in 2013 where forced removal of an organ constitute a crime under human trafficking provisions. In Philippines, removal or sale of organs was included in the TIP law. In Pakistan however, the explicit reference to organ removal is lacking in the TIP legislation.

Unauthorized and coerced organ removal is criminalized in all jurisdictions under review, with sanctions against commercialization in relation to organ transplant. Similarly, in relation to financial neutrality, all countries prohibit commercialization, with some defining different categories of financial incentives for organ donation and prohibit them. We acknowledge that financial neutrality is a broad term and includes not just financial incentives. However, there is limited evidence in relation to the regulation of financial incentives under heads such as gratuity, gifts, remuneration, cash transactions etc.

Key Informants discussed whether gratitudinal gifts from recipients to donors constitute an ethical violation. Arguing from a patient perspective, one of the transplant surgeons from Egypt felt the need to draw a distinction between commercialization and gratitudinal gifts given in good faith. This sentiment was echoed in India where commercial exchange persists due to poverty and a lack of social support system. Key Informants felt that non-monetary incentives could be provided to donors. However, this view was not universal and was not echoed from the other countries. Critics also argue that permitting gratitudinal gifts may open a pandoras box of cases where a distinction between gratitudinal gifts and commercialization gets blurred. Key Informants from the Philippines have echoed such a concern. Therefore, it remains open whether gratitudinal gifts may act as a barrier or a facilitator to promote ethical transplants, even while the view of the DICG remains amply clear that gratitudinal gifts are prohibited, under global ethical policy framework.

India

Organ trafficking is not specifically defined or criminalised under the organ transplant laws. However, trafficking is criminalised under Section 370 of the Indian Penal Code (criminal law). A person is said to have committed the offence of trafficking under the Indian Penal code if he/she "for the purpose of exploitation, recruits, transports, harbours, transfers, or receives, a person or persons, by using threats, force or any other form of coercion, or by abducting, or by practising fraud or deception, or by abuse of power, or by inducement including the giving or receiving of payments or benefits, in order to achieve the consent of any person having control over the person recruited, transported, harboured, transferred or received". **The term exploitation has been defined to include the forced removal of organs.**[40] This provision also notes that the consent of the victim is immaterial in determination of the offence of trafficking.41 A person convicted under this provision is liable for rigorous imprisonment for a term that may extend from 7 to 10 years and also liable to fine.

39 In course of this report, especially in the descriptive chapters, the term 'trafficking' should be understood broadly to include both TIP for OR and organ trafficking (as has been captured in the DoI definition). The nuanced differences between the two terms as they exist under separate frameworks of international conventions have not been made as such. The interviewees were also not explicitly asked to discuss differences between these concepts under the umbrella term 'trafficking' and have provided their general views on the theme of trafficking.

40 Explanation 1, Section 370(1), Indian Penal Code.

41 Explanation 2, Section 370(1), Indian Penal Code.

This definition mirrors the definition contained in the "Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, Supplementing the United Nations Convention against Transnational Organized Crime" adopted in 2000 (**Palermo Protocol on Trafficking**). Notably, Section 370 in its present form was introduced into the Indian Penal Code in 2013, two years after India had ratified the Palermo Protocol on Trafficking. [42]

However, no specific provision exists on financial neutrality. However, there are court orders on providing compensation to donors. Commercialization of organs is penalized, though.

The Key Informants spoke of commercial dealings in organs persisting owing to many factors. Public education and public vigilance were articulated as social means of regulation.

Philippines

Anti-Trafficking in Persons Act of 2003 (Act No. 9208) (Philippine Anti-Trafficking Act) criminalizes trafficking in persons in the Philippines. The definition of trafficking under this law is similar to the definition contained in the Palermo Protocol. It has been defined to mean *"the recruitment, transportation, transfer or harboring, or receipt of persons with or without the victim's consent or knowledge, within or across national borders by means of threat or use of force, or other forms of coercion, abduction, fraud, deception, abuse of power or of position, taking advantage of the vulnerability of the person, or, the giving or receiving of payments or benefits to achieve the consent of a person having control over another person for the purpose of exploitation which includes at a minimum, the exploitation or the prostitution of others or other forms of sexual exploitation, forced labor or services, slavery, servitude or the removal or sale of organs."[43] The Act criminalizes persons who "recruit, hire, adopt, transport or abduct a person, by means of threat or use of force, fraud, deceit, violence, coercion, or intimidation for the purpose of removal or sale of organs of said person."[44]*

In addition, under this law the government is also required to provide a range of services to the victims of trafficking to ensure their recovery, rehabilitation, and reintegration into the mainstream of society, through the provision of emergency shelter, counselling, free legal services, medical or psychological services, livelihood and skills training and educational assistance to trafficked child.[45] Further, a trafficked person is also entitled to the witness protection program of the government.[46]

Key Informants felt that despite existence of a law prohibiting commercial dealings and organ trafficking, commercialisation does persist. They spoke of a lack of sufficient evidence, knowledge and understanding among law enforcement agencies as reasons for a lack of convictions in cases of organ trafficking. Efforts to strengthen investigation and conviction are underway in the Philippines. Key Informants also highlighted lacunae in witness protection programmes and the need to strengthen these.

Costa Rica

Costa Rica has agreed to enforce laws implemented by the Council of Europe Convention Against Trafficking in Human Organs, which calls on governments to establish as a crime the illegal removal of human organs from living or deceased donors. The treaty also makes it possible for victims to receive compensation.[47] Domestically, the law of Human Trafficking is used to try the accused. Article

42 United Nations Treaty Collection. Chapter XVIII. Penal Matters. Available at: *https://treaties.un.org/pages/ViewDetails.aspx?src=IND&mtdsg_no=XVIII-12-a&chapter=18&clang=_en*

43 (Anti-Trafficking in Persons Act of 2003, 2003, sec. 3(a)).

44 (Anti-Trafficking in Persons Act of 2003, 2003, sec. 4(g)).

45 (Anti-Trafficking in Persons Act of 2003, 2003, sec. 23).

46 (Anti-Trafficking in Persons Act of 2003, 2003, sec. 18).

47 (Phoebe Studdert-Kennedy, 2019).

172 of the penal code criminalizes sex trafficking, labour trafficking and trafficking for the purpose of organ removal.

Key Informants spoke of the challenges that arise from Costa Rica being a destination for medical tourism. They called for stronger regulations to prevent corruption and trafficking.

Colombia

Based on the 2000 United Nations Protocol on trafficking in persons, Colombia passed Law No. 985 of 2005 addresses trafficking for sexual exploitation, labour exploitation, servile marriage and organ transplantation. However, this law has been criticised for being restrictive in scope, as it does not technically consider organ selling illegal provided the vendor consented and cooperated.

This provision also clarifies that the consent of a victim to any form of holding will not exempt the perpetrators from criminal responsibility. Further, this law also extends protection and support to victims of trafficking through immediate assistance programs aimed at returning victims to their place of origin, security, accommodation, medical, psychological and material assistance, and legal advice regarding their rights. [48] The law also envisages the development of training programs to help victims in seeking opportunities of employment.[49]

Egypt

Law No. 64 of 2010 regarding combatting human trafficking criminalizes trafficking in persons for organ removal. The law defines the crime as *"the sale, offer for sale, purchase , or promise thereof; or the use, transport, delivery, harboring, reception, or receipt (of a natural person) ....through the use of force, violence, or threat thereof; or through abduction, fraud, deception, abuse of power , or exploitation of a position of vulnerability or need; or through a promise to give or receive payments or benefits in exchange for obtaining the consent of a person to traffic another having control over him; or if the purpose of the transaction was exploitation in any of its forms, including: .....removal of human organs, tissues or a part thereof"*[50] This definition is in line with Palmero Protocol.

In terms of implementation, Key Informants spoke of the measures instituted by the country to successfully curb commercial dealings in organ transplants by raiding networks and private clinics.

The law also prohibits the donor or any of his/her heirs from acquiring any material or in-kind benefit from the organ recipient or the recipient's relatives.[51]

Pakistan

Under the Pakistan Transplant Act, commercial dealing in organs is prohibited and any person involved in such dealings is liable to be punished with imprisonment up to 10 years and fine extending to one million rupees.[52] However the provision clarifies that payments made for commercial dealings of organs does not include within its ambit the cost of removing, transporting or preserving the organ and any expenses or loss of earnings incurred by a person that can be reasonably and directly attributed to the donation.[53] There is no protection for the sellers under this law. After this law was brought in force, it had the effect of bringing down the number of illegal transplants. [54]

Key Informants said that commercial dealings in Pakistan persist among transplants to foreign nationals and called for international cooperation to curb illegal transplants.

48 (Act 985 of 2005 - Human Trafficking, 2005, sec. 7).

49 (Act 985 of 2005 - Human Trafficking, 2005, sec. 7).

50 Article 2, Law No. 64 of 2010.

51 https://peh-med.biomedcentral.com/articles/10.1186/s13010-022-00122-4

52 (Transplantation of Human Organs and Tissues Act 2010, 2010, sec. 11).

53 (Transplantation of Human Organs and Tissues Act 2010, 2010, sec. 2(g)).

54 (Syed Ali, 2016).

3. Equity

DoI principles #7 and #8 deal with ensuring equitable access to donation and transplant services as well as organs procured from deceased donors. Equity is also understood in relation to allocation within countries in a way that is objective, non-discriminatory, externally justified and backed by transparent clinical and ethical norms.

In choosing a lens to review the interface between the DoI principles and the domestic policies in relation to equity, we study (i) priority listing for allocation and procurement of organs; (ii) management of funding and cost of transplant; and (iii) special protection offered to vulnerable groups in matters of transplant.

(a) Priority listing for allocation of organs from deceased donor

A centralized priority listing for organ allocation at a national level is present only in Philippines, and Costa Rica with a proposal underway for India. In Colombia, Egypt and Pakistan, registries are not maintained by the government and allocation is context specific. This potentially leads to variation in allocation and may adversely impact equity. Even in countries that have centralized registries, there have been reports of several irregularities in relation to their use in organ donation and allocation.

India

Presently, various states in India as well as hospitals maintain independent priority lists and criteria for allocating organs. A proposal to introduce a unified national-level transplant registry is underway. The regulatory framework provides guidelines on priority and sequencing during organ allocation, with priority being given to patients with no related living donors.

While some Key Informants spoke of the organ allocation system in India being equitable due to streamlined waiting lists allowing for organ sharing between states, others spoke of the need for developing objective scoring criteria based on MELD scores (for liver transplantation), HLA typing and patient waiting time; and a uniform national criterion to ensure equitable organ allocation.

Philippines

National Donor and Recipient registry is maintained for kidney transplants. National policies also specify that equity, justice, benevolence, etc. are the guiding principles of the organ donation and transplantation program.

Costa Rica

Costa Rica has a centralized registry and waiting list. Detailed regulations set criteria for distributing deceased donor organs and tissues based on technical standards that address the issues of equity and transparency. While the country has a registry and a waiting list of potential recipients, Key Informants reported irregularities in the implementation of waiting lists. Key Informants also called for greater transparency around criteria and management of the list to ensure orderly allocation to recipients.

Colombia

There is no registry in Colombia. The law recognizes that the criteria for the distribution and allocation of organs and tissues should be based on disease severity and compatibility. Further, in cases where 2 persons on wait list are medically compatible and have the same level of severity, the organ/tissue is to be transplanted to the person who has expressed their willingness to be a donor of organs and tissues.

Egypt

Despite references present under law, no transplant registry is maintained by the government.

Pakistan

Despite references present under the law, no transplant registry is maintained by the government.

(b) Management of funding and cost for transplant

The table below indicates the nature of universal health coverage (UHC) as provided in each of the country under review, and the extent to which it covers transplant cases. UHC can be tracked using two indicators: coverage of essential health services and catastrophic health spending (and related indicators)[55]

Country under review	UHC status indicated via UHC coverage index score[56]	Explanation	Coverage of transplant cases within the UHC framework
India	Score = 63	India does not have a UHC provision covering all of its population. However, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) was launched on 23rd September 2018, as a step towards achieving UHC.[57] The Scheme aims to cover poorest 40% of the India's population covering over 50 crore Indian population with an insurance cover of 5 lakh per family per year to protect them from catastrophic health expenditure incurred in secondary and tertiary care. By 2030, India aims to achieve full UHC, however at present, the coverage only targets poor population.	Though initially not covered, Organ and Tissue transplant was added as new package under the scheme which includes 6 procedures covering renal transplant and corneal transplant packages.[58] Transplants of other organs are not covered under the scheme.
Philippines	Score = 58	The Philippines government signed Republic Act 11223 or the Universal Health Care (UHC) Law in 2019, allowing all Filipinos, including Overseas Filipino Workers (OFWs), access to healthcare services under the Government's health insurance program (PhilHealth). The UHC aims to cover at least 50% of medical expenses to encourage Filipinos to visit specialty doctors and undergo advanced medical procedures.	No available information on whether organ transplants are covered or excluded under the 2019 law. Note however that the Philippine Health Insurance System has approved the grant of substantial subsidies for organ transplantation over the years.
Costa Rica	Score= 81	Three consecutive health reform periods mark Costa Rica's UHC development process between 1940 and 2000. The system is currently managed by La Caja and covers approx. 98% of population- Costa Rican citizens, permanent residents, temporary residents with work permits and tourists who purchase temporary health insurance.	Renal replacement therapy (RRT) is covered. The actual expenses of the living donation are further covered so that the donor is not responsible for them.
Colombia	Score = 80	Healthcare became a constitutional right in 1991 and Colombia has been moving on its UHC journey since 1991.[59] The most recent is Law 1751 of 2015, which gives practical application to the guarantee of healthcare. Approximately 95% of the population has health insurance coverage.	Organ transplant procedures are covered within the UHC system.
Egypt	Score = 70	In 2017, Egypt enacted a law (Universal Health Insurance Bill, 2017) to cover the whole Egyptian population with the quality health services they need without suffering hardship. The coverage includes most vulnerable populations, such as the elderly, disabled people, the poorest Egyptians, and those working in the informal sector. However, this law is not implemented and currently has covered only a few pilot regions.[60]	Since Egypt does not have universal health coverage, patients are supported either through insurance or through government support. Financial support from the state is also provided for post-transplant medication.
Pakistan	Score = 45	There is no UHC coverage for the entire population. However, in 2019, the Pakistan Government has launched a flagship social health insurance initiative called the "Sehat Sahulat Program" to provide free healthcare services to the underprivileged population of the country. Similarly, state specific schemes exist, e.g. for the region of Punjab, government has issued health card in January 2022 every family eligible for the treatment of about 1 million PKR (about 5650 US$) annually in government and private hospitals. It will cover all hospitalizations related to chronic conditions such as coronary heart disease (angioplasty/bypass), diabetes mellitus, arthritis, certain cancers (hepatocellular carcinoma, breast cancer, colon cancer, leukemia) and chronic infections such as tuberculosis and viral hepatitis.	The program of Sehat Sahulat extends support for kidney and liver transplantations.

Countries under review have therefore established health packages for patients. In all countries government-supported funds and insurance packages have been made available to support transplantation costs either to all populations or to poorer sections when universality has not been achieved. In countries such as Costa Rica, Colombia and the Philippines, the packages are comprehensive. In India and Egypt however, the state aid is inconsistent and usually does not cover the entire cost of the transplant. In the absence of state aid, reliance is placed on philanthropic funds to support transplants.

55 As provided by the United Nations Sustainable Development Goals, SDG 3.8.1 & 3.8.2.

56 WHO UHC indicator is measured as an index reported on a unitless scale of 0 to 100, which is computed as the geometric mean of 14 tracer indicators of health service coverage. These indicators are meant to be indicative of service coverage and should not be interpreted as a complete or exhaustive list of the health services or interventions that are required to achieve universal health coverage.

The World Bank. (2023). UHC Service Coverage Index- Philippines. *https://data.worldbank.org/indicator/SH.UHC.SRVS.CV.XD?locations=PH*

57 National Health Authority. Government of India. (2022). Concept Note on Session "Roadmap for Universal Health Coverage in India". Arogya Manthan 2022. *https://abdm.gov.in/static/media/Session%201%20Note%20-%20Universal%20Health%20Coverage.da4d39535a6227916c18.pdf*

58 National Health Authority. Government of India. (2021). National Health Benefit Package 2.2. *https://nha.gov.in/img/resources/HBP-2.2-manual.pdf*

59 The Economist. (2019). Moving Universal Health Coverage from Ambition to Practice: Focus on Colombia. *https://impact.economist.com/perspectives/sites/default/files/download/country_profile_colombia_v3.pdf*

60 Elsayed, R. (2023). The road to Universal Health Coverage in Egypt: New Expectations and Hopes. International Health Policies. *https://www.internationalhealthpolicies.org/featured-article/the-road-to-universal-health-coverage-in-egypt-new-expectations-and-hopes/*

Despite different measures, Key Informants have echoed that more needs to be done to ensure financial sustainability and support to transplantation. For example, Key Informants in India spoke of the high cost of post-transplant care. A need is felt to expand transplantation services in public hospitals and regulate costs in private hospitals to make transplantation affordable. In Pakistan, while the law envisages financial support for transplants, Key Informants highlighted the need to strengthen the implementation of these. They advocated for insurance-based systems to support patients in receiving transplants. In the Philippines, despite Universal Health Care being available for citizens for transplants, only hospitalisation costs are covered. Costs relating to pre, and post-transplant care are not covered and remain unaffordable. Key Informants in Costa Rica called for enhancing co-ordination and efficiency within the healthcare system. In Egypt, Key Informants spoke of the inequitable geographical distribution of transplant services and the challenges this poses for ensuring equitable access to transplants.

India

The 2014 regulations specify that the cost of retrieval in case of deceased donation is not to be borne by the donor, but by the recipient/ government/NGO. Regulations envisage providing benefits to Live Donors through a comprehensive healthcare scheme to provide lifelong free check-ups and medical care, and to provide a customized Life Insurance Policy worth Rs. 2 Lakhs for 3 years (with one premium to be paid by the recipient), to secure the donor against mortality risk due to organ donation (under the National Organ Transplant Program Guidelines). However, this provision is generally not implemented. The NOTP scheme valid for the period 2021-22 to 2025-26 envisages organising a robust support system to ensure optimal graft outcomes (in form of immunosuppressant drugs for ill affording and adequate timely medical support).

Essentially two types of funding are available for recipients of organ transplantation:[61]

Government Funding: Where the Prime Minister's Office provides funds of Rs. 3 lakhs to patients being treated, in both private and public hospitals. The Chief Minister's Fund and National Illness and Relief fund is offered only to patients being treated in public hospitals. These funds, however, are difficult to obtain and are often mired in a lot of bureaucracy. Only a minority of eligible subjects are able to get these.

Non-Government Funding: This comes from NGOs and corporate charities who offer funds to patients being treated at both public and private hospitals. There is no formal mechanism and much of this process is ad-hoc. There have been instances of crowdfunding, especially for paediatric transplants, through public appeals.

The Pradhan Mantri Jan Arogya Yojana (Ayushman Bharat) which is India's health assurance scheme covers kidney transplants. In addition, many state government insurance schemes also include transplant packages. In the last few years, many state governments have brought kidney transplants into the ambit of state-sponsored insurance schemes. States like Rajasthan and Tamil Nadu also support liver transplantations. In the recent past, state government schemes are funding transplantation in the private sector. For example, there is a semi-government institute in Gujarat where transplants are provided at a subsidised rate. They also provide immunosuppressive drugs at subsidized costs for a certain period of time. Also, the government in Tamil Nadu provides for immunosuppressive drugs at a subsidized rate.

Further, help from the Prime Minister's National Relief Fund is available to people from economically weaker sections, usually with the proviso that the patient or family would arrange part of the funds.[62]

Despite the availability of the above-mentioned schemes, overall, there is not much evidence on

61 Mohan Foundation. (2014). A Study of the Deceased Organ Donation Environment in Delhi/ NCR. *www.organindia.org/wp-content/uploads/2014/11/ORGAN-Research-Report.pdf.*

62 Ramachandran R., Jha V. (2013). Kidney transplantation is associated with catastrophic out of pocket expenditure in India. PLoS One, 8(7): e67812. *https://doi.org/10.1371/journal.pone.0067812*

private hospitals accepting the state schemes. Given that more than 80% of transplant centers are in the private sector, it is symbolic of the inaccessibility to receive transplant care for the general population in India.

Philippines

The national government supports the organ donation and transplantation program through its gratuity package and provides other forms of financial support to the donor, such as postmortem care and assistance for funeral arrangements. An allocation of 20 million pesos per year has been made in support of the operations of the organ donation and transplantation program starting 2008. Other funding sources may be tapped to support the program.

Costa Rica

With a network of more than 30 hospitals, the Costa Rican Social Security Fund (La Caja) permits use of organs for transplantation in patients with end-stage organ failure. The actual expenses of the living donation are covered so that the donor is not responsible for them. Costa Ricans are said to have universal access to a health system that covers 98% of the inhabitants. It offers insurance coverage to both immigrant population and foreigners. Renal replacement therapy (RRT) is accessible to all who need it.

Colombia

Health insurance covers 97-98% of those with work pay for insurance. Poor people are paid for by the government as transplant charges remain the same for patients. A security fund exists wherein a package is paid for by the government (one month package is paid for by the government). Public funding exists through a private health company and all organ transplants are covered by this system.

Egypt

As per a 2018 article, transplantation from a live donor in a public hospital cost roughly $25,000 and the state pays $9,600, while the Egyptian Organ Transplant Association contributes another $9,600. At the same time the state covers the entire cost of kidney transplants, estimated to be around $3,800.[63] The state covers expenses for organ transplantation operations for everyone who is unable to pay. Under the law, a fund is to be established to contribute to the expenses of transporting and transplanting for those who are unable to report to the Minister of Health.

Pakistan

The Pakistan Transplant Act envisages that the federal government will establish a fund consisting of grants from the federal and provincial governments and contributions by philanthropists for the transplantation and post-operative care of indigent patients.[64] While this fund has not been constituted till date, provincial support for transplantation is provided by grant-in-aid to licensed transplant centers.

(c) Special protection offered to vulnerable groups in matters of transplant

Countries under review strive to protect vulnerable populations including women donors, minors, those with unsound mind and hold restrictions against minors and those with unsound mind to be donors. As discussed above, certain financial packages are also offered to those under financial distress or poverty. Additionally, some countries like the Philippines offer special protection to organ vendors and prevent them from being punished as it is presumed that they are subject to exploitation and should be spared from legal action. Other countries, however, do not have such provisioning for victim protection.

However, gender disparities continue to prevail. Key Informants spoke of the gender disparities in organ donors and recipients. The proportion of women donors donating to their family members was stated

63 Wilkens, K. (2018). The True Cost of Selling your Organs on Egypt's Illegal Black Market. Journal of International Business and Law, 17(2), Article 6. *https://scholarlycommons.law.hofstra.edu/cgi/viewcontent.cgi?article=1340&context=jibl*

64 (Transplantation of Human Organs and Tissues Act 2010, 2010, sec. 8(4)).

to be higher than men donating to women relatives in almost all countries. Key Informants from India and Pakistan spoke of extra counselling measures that are undertaken to ensure that consent from women donors is not coerced or influenced by pressure from their families.

India

Rules notified under transplantation law incorporate certain safeguards for vulnerable populations – requiring review of income/financial status of donor-recipient, assessment of independent identity of women donors, etc. Minors (below 18 years of age) and legally incompetent persons excluded from the ambit of living organ donation.

Philippines

Minors (below 21 years of age) and mentally unsound persons cannot be organ donors. The law also protects organ vendors and states that they are not to be punished.

Costa Rica

Minors (below 18 years of age) and mentally unsound persons have been excluded from the ambit of living donation. Doctors can oppose the transplantation if consent has not been properly obtained.

Colombia

Mentally unsound persons, minors (less than 18 years of age) and pregnant women are excluded from living donation. However, minors and pregnant women are allowed to donate stem cells.

Egypt

The legal age of consent for living organ donation in Egypt is 18 years when the recipient is a parent, otherwise it is 21 years. Persons of unsound mind are not allowed to donate.

Pakistan

Only those above 18 years of age can consent for living donation, unless it is donation of regenerative tissue to a sibling. Law does not expressly exclude mentally challenged persons from donating.

4. Self-sufficiency

While the DoI principle #11 clearly stipulate that countries should strive to achieve self-sufficiency in organ donation and transplantation; the DoI principle #10 states that governments and health professionals should implement strategies to discourage and prevent the residents of their country from engaging in transplant tourism.

The Madrid Resolution on Organ Donation and Transplantation, 2010 previously provided a broad understanding of self-sufficiency as it encompasses the following features: actions should (1) begin locally, (2) include broad public health measures both to decrease the disease burden in a population and to increase the availability of organ transplantation, (3) enhance cooperation among the stakeholders involved, and (4) be carried out based on the WHO Guiding Principles and the Declaration of Istanbul, in particular emphasizing voluntary donation, non-commercialization, maximization of donation from the deceased, support for living kidney donation, and meeting the needs of the local population in preference to "transplant tourists."

The resolution further clarified that self-sufficiency advocates national accountability for the establishment of an effective planning context for diseases treatable through organ transplantation and characterized by adequate capacity management, regulatory control, and an appropriate normative environment.

1. National capacity management involves:

- (a) development of an adequate and appropriate healthcare infrastructure and workforce consistent with the country's level of development and economic capacity;
- (b) adequate and appropriate financing of organ donation and transplantation programme; and
- (c) management of need by investment in chronic disease prevention and vaccination.

2. National regulatory control consists of

- (a) adequate legislation, covering declaration of death, organ procurement, fair and transparent allocation, consent, establishment

of transplant organizations, and penalties for organ trafficking and commercialization;

(b) regulations covering procedures for organ procurement, reimbursement, and allocation rules; and

(c) systems for monitoring and evaluation, including traceability and surveillance, and for enabling evaluation of programme performance.

3. National authorities need to lead normative change, from a perception of organ donation as a matter of the rights of donor and recipient to one of responsibility across all levels of society, through unambiguous legislation, committed support, and ongoing education and public information campaigns. Meeting needs of patients while avoiding the harms of transplant tourism and commercial donation from living persons is an ethical imperative that relies on the assumption of a collective responsibility for donation after death by all citizens and residents, thereby contributing to the common good of transplantation for all.65

Given such broad understanding of self-sufficiency, several of the enumerated factors have been discussed above such as the quality of legislation, and nature and scope of regulations including funding support from the government in transplantation cases. This section focuses on factors inter-alia: giving priority to own citizens over non-citizens or foreigners, financing mechanisms in matters of transplantation which have a bearing on affordability and access to organs, and transplant per million population data.

The regulations reviewed include restrictions on foreigners from receiving organs in countries under study, and even when it is allowed the stringency of the same to enable that the system is not unduly misused by foreigners and preference remains for a country's own citizens.

Similarly, while countries strive to provide financial assistance to transplant patients, not all countries under review have a universal health coverage to bear transplant costs. These factors combined have emerged as one of the biggest impediments in the journey towards self-sufficiency in organ donation.

For example, in India, over 80% of transplant centres are in the private sector that remain generally inaccessible to the general population in India. Similarly, transplant costs remain high and lack of universal health coverage to fund transplant cost remains a challenge. Individual states such as Gujarat have designed schemes to subsidise transplant costs in public facilities, and while the Prime Minister's relief fund for economically weaker section aims to bear part of the transplant cost, however overall costs including both the cost for transplantation and post-transplant care still remain unaffordable.[66] Similarly, in Pakistan, government efforts to increase awareness and promote organ donation have been lacking and despite the provincial governments' grant-in-aid to the licensed transplant centres, severe shortages of organ donors continue to pervade in Pakistan. Philippines' universal healthcare law covers hospital related expenses associated with transplant, but laboratory testing and ancillary expenses are excluded. Limited monetary assistance is provided to transplant patients but the same can be availed at a specific government tertiary care facility. Colombia has strong provisions for universal health coverage which also includes transplantation, however, the absence of empirical findings from KIIs indicate that the actual benefit for transplant patients have not been verified. Amongst the six countries, Costa Rica has perhaps made the most strides in universalising care for transplant patients, especially backed by the La Caja funds and strategies such as split liver transplantation.

65 The Madrid Resolution on Organ Donation and Transplantation. Transplantation 91():p S29-S31, June 15, 2011. DOI: 10.1097/01.tp.0000399131.74618.a5

66 KII8IN, Transplant Policy Maker; KII7IN, NGO (CEO); KII2IN, NGO (CEO).

Another analysis point includes transplant per million population, whose data has been extracted as below for the year 2022:

Country	Total Organ Transplant (Data presented in absolute number)	Rate per million inhabitants (pmp)
India	16,041	11.4
Philippines	591	5.25
Costa Rica	96	18.46
Colombia	1210	23.5
Egypt	Not available	Not available
Pakistan	2110	9.19

Source: Global Observatory on Donation and Transplantation

The rate of organ transplantation relative to incidence of organ failure is another lens used to ascertain self-sufficiency but data in this regard remains sparse and not very direct to ascertain self-sufficiency. Moreover, such data has been hard to obtain, and limited references have been made by country specific experts during an interaction.

Evidence in relation to countries is set out below:

India

In India, foreigners can receive organs from related or unrelated foreign donors, and from Indian donors if they are near relatives. Foreign citizens are eligible to participate in deceased donations but are ranked lowest in terms of preference for organ allocation. As per rules, priority is given to Indian citizens during allocation for deceased donor organs. However, the practice realities may differ and as echoed by Key Informants, as despite the rules, in practice there have been various media reports of instances when foreigners have been allocated organs in preference to Indian citizens.[67] Moreover, Key Informants also described that foreign recipients mainly receive lung and heart donations as surgeries for these are unaffordable to most Indians. Foreign citizens can get transplanted utilizing organs from related donors if they meet the criteria according to the Indian law. The relationship is often established on the basis of a letter from the Embassy. They have to be cleared by the state appointed Authorization Committees. There is speculation, however, that many of these are paid unrelated donors, and that the oversight from the Authorization Committee is perfunctory. Recent reports have suggested the existence of a network that brings recipients and donors from Myanmar to India with elaborate forging of documents and training of donors and recipients.[68]

As per news reports of November 2021, India ranks third in the world in terms of organ donation and transplantation, with the total number of organ transplants performed in the country increasing to 12,746 in 2019. A slightly dated study from 2009 cited that there are only 3. 25 renal transplantations done per million population from live and deceased donors, which remains grossly inadequate. ***A more recent study highlights data on transplants per million as follows:***[69]

67 Jha, V. (2018). The Seamy Underbelly of Organ Transplantation in India. The Wire. *https://thewire.in/health/underbelly-organ-transplantation-india*

68 Lovett, S., Theint, N., Smith, N. (2023). Revealed: Global private hospital group embroiled in 'cash for kidneys' racket. Telegraph. *https://www.telegraph.co.uk/global-health/science-and-disease/kidney-organ-trafficking-scandal-private-healthcare-india-myanmar/*

69 Divyaveer, S., Nagral, S., Prasad, K. T., Sharma, A., & Jha, V. (2021). Health System Building Blocks and Organ Transplantation in India. Transplantation, 105(8), 1631–1634. *https://doi.org/10.1097/TP.0000000000003685*

The current state of organ transplant in India in numbers

	Kidney	Liver	Heart	Lung	Pancreas
Estimated need	175 000	40 000–50 000	50 000	50 000	2500
Current number[a]	7936	1945	241	191	25
Number of registered centers[c]	240	125	<25	<10	35
Cost (US$)	2150–25 000	30 000–40 000	60 000–65 000	27 000–40 000	7500–30 000
Public sector	20%	<5%	<5%	<5%	<10%
Organ source[b]	L>>>D	L>>>D	D	D	D

[a]2018 data, according to NOTTO (https://notto.gov.in/, accessed 12 December 2020).
[b]D, deceased; L, living.
[c]Not all centers are active.

Source: Divyaveer et al[59]

Philippines

Under law, in case of donations from living non-related donors, Filipino recipients are to be given priority in organ allocation. In Philippines, foreigners are not permitted to receive organs from non-related Filipino donors, unless they have been married for three years. The country is in the process of formalising guidelines to tackle the issue of citizens travelling out of the Philippines to donate organs.

The data on the rate of organ transplants reveals that the annual number of foreign (mostly of Middle Eastern origin) transplant recipients fell from 531 in 2007 to two in 2011. During the same period, the number of kidney transplants with Filipino recipients also fell, from 510 to 381. This is accounted for by a significant decline in the number of transplants from unrelated donors (313–147) which could not be offset by the modest increase in transplants from deceased donors (27–88) (Philippine Renal Disease Registry 2011).

Costa Rica

Foreigners who are permanent residents and insured by Costa Rican Social Security Fund can enter the national list of recipients and obtain organs. In Costa Rica, foreign residents can come to Costa Rica to for foreign living donations provided they obtain a legal document attesting to the familial relationship and can also participate in the deceased donor programme.

As per available data, in 2021, 3.7 deceased donors per million were recorded in Costa Rica, suggesting that the road towards achieving self-sufficiency remains inadequate.

Colombia

Regulation gives priority to citizens, followed by resident and non-resident foreigners, respectively. Foreign patients can only receive donations from living related persons with permission by the government, which is hard to obtain. In addition, foreign non-resident patients can receive transplants through the deceased donation program only if there is no Colombian citizen or resident foreigner waiting on the recipient list.

With regards to the organ transplantation rates, the data reveals an overall increase in transplantations over the last decade. More than 18,000 transplants have been performed since 1966 (76% of those being kidney transplants; more than 17% of recipients received liver transplants). It is important to mention however that these numbers are based on personal information because there is currently no national registry collecting data on outcomes.

Egypt

In Egypt, foreigners are not allowed to participate in deceased donation. Foreigners are also prohibited from receiving an organ from an Egyptian national as Egyptian citizens are prohibited from donating organs to foreign citizens, unless donor-recipient have been married for at least 3 years, or in cases of implantation from children of such couples to the foreigner parent. Foreign donors and recipients possessing the same nationality can get transplanted in Egypt if they get the requisite permissions from their Embassy and the investigations have to be repeated in Egypt. No published data on organ transplantation rates have been found.

Pakistan

Under law, donation from Pakistani citizens to foreign citizens is prohibited, without exception. However, Key Informants highlighted the difficulties in ascertaining relationships between Pakistanis of foreign origin with Pakistani citizens.

Further, there is no conclusive data on the rate of transplant per incidence of organ failures. Existing information merely indicates that an estimated 50,000 people die each year in Pakistan from end stage organ failure.

SUMMARY

To sum up, the table-below provides an overview the chronology with respect to the introduction and key reforms in organ transplant landscape in each of the country under review.

Country	Year of original legislation/regulation	Year of major reform	Description of reform
Colombia	1979	2016	Presumed consent legislation
Costa Rica	1974	2015	Opt-in model to end commercialisation
Egypt	2010	2017	Increasing penalty on organ trafficking
India	1994	2014	Strengthening administrative framework & regulation of foreigners; increase in penalties
Pakistan	2007	2021	Database management for organ transplantation
Philippines	1991	2022	Trafficking related amendments

Additionally, the below table provides a high-level summary in relation to the presence / absence of key regulatory provisions and the nature of safeguards present within the organ transplantation framework of the countries reviewed.

Overview of regulatory Provisions	India	Philippines	Costa Rica	Colombia	Egypt	Pakistan
Is (brain) death defined?	Yes	Yes	Yes	Yes	No	Yes
Criminalisation of trafficking	Yes (under criminal laws)	Yes (under anti-trafficking legislation)	Yes (under criminal laws)	Yes (under anti-trafficking legislation)	Yes (under anti-trafficking legislation)	Yes (but organ trafficking is not included in TIP legislation)
Can foreigners receive organ transplants?	Yes, with high restrictions	Yes, with lower restrictions	Yes, with high restrictions	Yes, with high restrictions	Yes, with high restrictions	No
Consent framework process	Opt-in	Opt-in	Opt-in	Opt-out	Opt-in	Opt-in
Maintenance of waiting list for receiving transplants	Yes	Yes (but limited, to kidney alone)	Yes	Yes	Yes	Yes
Maintenance of national registries to record transplantation activities	Yes	Yes	Yes	Yes	No clear evidence	No clear evidence
Availability of national level or universally available public funds to make transplants affordable	No	Somewhat	Yes	Yes	No	No
Existence of regulations to recognise and safeguard vulnerable persons[70] in the organ donation framework	Yes	Yes	Yes	Yes	Yes	Yes
Presence of regulatory committee to monitor transplant process	Yes	Yes	Yes	Yes	Yes	Yes
Diversity of actors in the regulatory bodies managing transplants	Yes, but to a limited extent	Yes	Yes	No clear evidence	No clear evidence	No

70 Based on criteria, inter-alia: income group, gender, mental soundness, minority status.

Chapter 4- Discussion

In light of the findings discussed in the previous section, this section of the report has three parts. First, we discuss the interface between the DoI principles and domestic policies. Second, we discuss various contextual factors and their role as either an enabler or a barrier to effective and ethical organ transplantation in countries. An ecological framework of analysis is used to examine various barriers and enablers and understand the role of context within which the diverse factors work. Lastly, we identify areas where future policy actions are needed in-order to strengthen the existing landscape within the countries, as well as lessons that global bodies including the DICG may draw. Together, each of the sections help in fulfilling the aims that were set for this study, i.e. to understand the interface between DoI and local regulations and understand the implementation of organ transplant regulatory framework empirically at a local level.

1. Interface between the DoI principles and domestic organ transplant framework

A review of the 6 countries indicates that organ transplantation and donation policies have pre-existed both the DoI guidelines of 2008 and 2018 in all countries with the exception of Egypt whose legal framework was finalised after the DoI guidelines of 2008.

Since its inception, the DICG has played a critical role in policy enforcement within the countries by reporting incidents of illegal transplants. For example, evidence from Philippines indicates that DICG reported cases of unrelated living donations, which led to cases being initiated within the country.[71] Another interviewee from Costa Rica remarked on the role of DICG in helping investigate and prosecute a case of illegal cross-border transplant of a Palestinian resident of Israel who got a transplant done in Costa Rica and compensated the donor. The case was exposed by a US based DICG member as the patient came to California for post operative health complication. The advocacy efforts of the DICG member led to a trigger of chain of evidence being unearthed in Costa Rica which ultimately led to a senior nephrologist being prosecuted for conducting illegal transplant. The incident also led to fear of scrutiny amongst all hospitals as given a small country and close network of professionals, such prosecution gave a strong message against unethical practices of transplant. [72] From time to time, DICG has flagged reports of transplant tourism and commercialization in India to law enforcement officials and national professional societies.

The domestic framework of countries under review indicates several areas of interface between the principles of the DoI and domestic policies and their implementation. Having a clear framework for organ donation for both living & deceased donors with explicit consent requirements, provisions which explain risks of transplant to donors, definition of brain death, verification of records for deceased donation, Prohibition on financial considerations as part of organ transplants, criminalization of commercial dealings and trafficking (either via TIP for OR or organ trafficking approach), maintenance of priority lists for organ allocation, giving priority to own citizens over foreign nationals in organ allocation, protection of those minors, those with unsound mind from participating in donation, and preventing conflict of interest amongst physicians involved in donation processes are some examples where the countries under review show-case an alignment with the global principle of DoI. It is noteworthy that several of these principles were also enshrined in the WHO Guiding Document, and the countries offer alignment with those principles as well; however, since the current study is focused on the DoI, we have conducted an in-depth study in relation to the DoI principles alone.

71 KII1PH, Policy Maker

72 KII3CR, Transplant Surgeon

Besides issues of alignment, the areas where countries need to focus more efforts include, **inter-alia** building sustainable self-sufficient practices to support local populations, providing more support to cadaveric organ donations, strengthening infrastructure and finance mechanism to overcome concerns of equity, protecting victims of organ trafficking and ensuring complete prohibition of gratitudinal gifts and payments in relation to donations. Absence of concrete efforts or poor implementation in these areas create conditions amongst countries which undermine the global principles set by the DoI.

Mapping issues of convergence or conflict between the DoI and the domestic policies narrates only one side of the story. In order to truly understand whether convergence leads to optimal and ethical outcomes, and how to overcome areas of conflict, one needs to examine in detail all the enablers and barriers to policy implementation that have emerged. An assessment of barriers can help pave the path for future reforms and help DICG identify areas where it should focus upon.

The next section of this report highlights the barriers and enablers to domestic policy implementation, which can be useful for DICG's strategy.

2. Identifying Enablers & Barriers to domestic policy organ transplant implementation

Findings from the review of six countries help reveal a set of different barriers and facilitators to implementation of the DoI principles via domestic enforcement. Relying on the ecological framework,[73] a multi-level, interactive approach has been leveraged to analyse various factors that are said to influence organ donation practice (positively as an enabler or negatively as a barrier) across the six countries.

As per the ecological perspective, a study of the interaction and interdependence of factors within and across all levels of a health problem is vital. Based on the five levels of influence for health-related behaviors and conditions as set out in the ecological framework, the table below distills different factors that impact organ donation across countries, and their potential classification as an enabler or a barrier.

While a comparative study of this nature can be useful in drawing common lessons of success and failures and provide an opportunity to learn from each other's failures; such comparisons are subject to appreciation of country specific context. Each country represents a diverse context in terms of size, geography, culture, religion, socio-economic empowerment and so on. This diversity is accentuated by the fact that organ donation/ transplant is not just influenced by public policy or institutional factors (which are easy to compare and learn from), but from several intra and inter-personal factors which are diverse and cross-country learnings may not work in such contexts. Therefore, it is imperative to understand the factors which are enablers or barriers, or both depending upon the context and identify potential for clashes at different levels/factors which influence organ donation/ transplant. An appreciation of these factors and inherent limitations or clashes among these factors will help us to draw useful lessons to understand the limits of law, and what can be done in terms of future reforms. An analysis of this nature further helps explain questions such as 'why a country becomes a hotspot in organ transplantation' which does not have a clear-cut answer.

73 McLeroy, K. R., Bibeau, D., Steckler, A., & Glanz, K. (1988). An ecological perspective on health promotion programs. Health Education Quarterly, 15(4), 351–377. *https://doi.org/10.1177/109019818801500401*

The table below lists the different levels of influences and various factors of domestic policy implementation that have been uncovered from the desk and empirical review of 6 countries and is classified and explained.

Levels of influence	Factors emerging from domestic policy implementation	Explanation as a barrier/facilitator
Intrapersonal Level[74]	Cultural beliefs	Is often considered a barrier. Illustratively, an interviewee in this study revealed that donors approach hospitals with staunch beliefs such as a vegetarian persons would prefer to donate organs to vegetarian persons only. Such beliefs often act as impediments in widespread uptake for organ donations.
	Religious beliefs	Is often a barrier as interviewees revealed that regardless of the type of religion, there are set notions on life after death, bodily integrity etc., all of which come in way of organ donation after death as inflicting pain even on dead body is not considered in alignment with certain religious beliefs especially those pertaining to after-life. Overall, there often seems to be a belief in certain communities that their religious practices prohibit organ donation, especially after death. On asking the source for such beliefs, clear answers are usually not forthcoming.
	Knowledge & Awareness	Is an enabler, as increased knowledge and awareness regarding the donation process helps form a valid consent for donation and can even help in voluntary sign up as a deceased donor. Knowledge and awareness at any level- as an individual member of the public or as an official tasked with discharge of organ transplant policy, helps in improving ethical outcomes.
	Gender	Is often a barrier, as it creates disparities. Most interviewees revealed that if a husband is a recipient, wife or his sister, or wives' relatives may act as donors, but if a wife is a recipient, she has to rely on her own family or brother for donation. There are notable exceptions, however.
	Type of relationship or Family structure	Certain relationships have an inherently unequal negotiation power (based on gender, earning capacity etc.) which end up acting as a barrier to ethical donation. The most widely prevalent example is that of a wife donating to her husband. On one hand, it is easily explained as this is the strongest relationship but on the other hand, power discrepancies can prevent a wife from expressing her wishes, especially if she is unwilling to donate.
	Age	Is an enabler as younger persons are more likely to recover during post transplantation processes, and often older persons are restricted by law to donate.
	Fitness	Is an enabler as being generally fit and free of ailments such as diabetes or other lifestyle diseases make individuals more acceptable as donors.
	Socio-economic condition	Poverty make people prone to inducement to donate, but this is a barrier in ethical transplant processes.
Interpersonal Level[75]	Presence of emotionally related donors	Is an enabler as it provides broad criteria for donations but may turn into a barrier, if relationships with inherently adverse negotiating powers (such as driver – master) come under the garb of being emotionally related and hence creating potential for misuse.
	Presence of unrelated donors	Is an enabler, as altruistic donors present in a country can help meet the transplantation burden; but may act as a barrier as potential for misuse may arise.
	Cultural belief of family/ community	An individual may be willing to sign up for deceased donation or participate as a living donor, however, if there is an opposition from relatives or family members or larger groups to which an individual affiliates with (e.g. the key informants' views on the case of transgender donation),[76] the same may become a barrier.
	Affiliation to religious organisations	Fear of fatwas 'edicts' maybe a better word act a barrier as affiliation to religious organisations influence personal decisions.
	Financial condition & offerings	Beliefs that gratitudinal gifts or offerings made to help the donor (e.g. take care or funeral expenses, funding education of donor's children etc.) can act as both a barrier or an enabler depending on the context.
Community Level: Institutional Factors[77]	Consent framework	Is an enabler, as a clearly defined framework for consent shields against unethical practices, and especially protects vulnerable groups (such as women, minors etc.)

74 Individual characteristics that influence behaviour, such as one's knowledge, attitudes, beliefs, and personality traits.

75 Interpersonal processes and primary groups, including family, friends, and peers that provide social identity, support, and role definition.

76 KII10IN, Transplant Coordinator

77 Rules, regulations, policies, and informal structures, which may constrain or promote recommended behaviours.

Levels of influence	Factors emerging from domestic policy implementation	Explanation as a barrier/facilitator
	Presumed consent framework	No evidence emerges indicating that presumed consent models are better enablers vis-à-vis opt-in models. For example, Costa Rica has moved from an opt-out model to an opt-in model subsequently as even under the presumed consent approach, consent of family was needed which was equally time consuming as in case of an opt-in model. Both models can face barriers depending on the context in which they function.
	Presence and role of ethics committees	Is an enabler, as they scrutinize ethical practices; however, if they become bureaucratic in structure or have members who hold conflicting interests, their presence may become a barrier.
	Role of transplant coordinators including resources available to them	Is an enabler as they help conduct interviews with donors, validate documents, help bring in organs; but given their extensive responsibilities (such as doing domicile checks), their functioning may become a barrier if they are not adequately backed with financial resources, training and administrative support from the hospital or allied institutions involved in transplants.
	Coordination amongst hospitals and institutions providing healthcare	Is an enabler and especially helps in the uptake of cadaveric donations once brain stem death is declared and deceased donation has been approved. Even for living donations, coordination enables sharing of information and timely provisioning of organs which can save lives.
	Awareness amongst healthcare professionals	Is an enabler, but lack of it may act as a barrier as ultimately ethical transplantation is in the hands of healthcare professionals and transplant surgeons who may have conflicts of interest. More awareness, especially in treatment of patients with severe brain injury has a direct linkage with helping cadaveric transplants. However, many a times medical practitioners who are tasked with the duty to provide care and save lives of patients, turn a blind eye to illegal or unethical practices. Such attitude potentially creates a barrier to ethical processes.
	Requirement of documentary proof	Is an enabler as more proof helps in ascertaining relationships and preventing foul play. For example, asking for childhood photos, income tax and bank account disclosures in case of unrelated donors are some checks that have helped keep check on malpractices. However, the same can also become a barrier as it is time-consuming and breeds corruption. For example, in India, even genetically related donor and recipient pair, if they live in different states, need to get permission from each state health authority. This leads to significant delays, often adversely affecting the health of the potential recipient.
	Dedicated organization or regulatory tool for allocating organs	Is an enabler as it provides requisite infrastructure support in helping in organ allocation as diverse bodies (hospitals, care providers, coordinators, donors-recipients) are present and may make the process convoluted if left on their own.
	Dedicated organization for harvesting organs and promoting cadaveric transplants	Is an enabler, as sole reliance on hospitals to help harvest organs and promote cadaveric transplants has seen a limitation as hospitals are over-worked and under-staffed and have missed instances where transplants could have taken place after instances of brain stem death.
	Pre-transplant orientation	Is an enabler as it helps shape consent which is a significant pillar for ethical transplant.
	Medical tourism landscape & presence of foreigners competing for treatment within the medical set up	Can act as a barrier as hospitals end up servicing foreign patients more as they bring more revenue to the hospitals and preference may be given to them as opposed to own citizens. Weak or poor oversight can also promote transplant tourism. However, exclusion of organ transplant from medical tourism can be an enabler (as practiced in Philippines and Colombia).
	Definition of death	Clear definition of brain stem death including clarity of rules around mandatory declaration of the same can be an enabler to promote cadaveric transplants.
	Expertise in identifying and declaring brain stem death	Is an enabler, and lack of expertise has proven to be an impediment in certain cases as precious time gets lost between declaration of death and harvesting of organs for transplant.
	Definition of near relatives	A broad definition can be an enabler if it provides more clarity and covers modern relationships (such as step relationships) but can also be a barrier as it may hold potential for misuse on account of broad terms such as 'emotionally connected' or 'special reasons' for transplant, which remain vague in interpretation.
	Post transplant monitoring of donors	Is an enabler, as it helps build more trust in the transplant system. Supporting this process by regular monitoring and providing funds help in a long way to ensure success in transplantation process. Putting in place mechanism to ensure this, however, is difficult because of inherent weaknesses in the healthcare systems
	Criteria for organ allocation including donor allocation score	Is an enabler, in the absence of which organ allocation may be done randomly (e.g. based on alphabetical order of hospital's name) rather than based on needs of the patient. Clear criteria such as reliance on MELD score is an enabler.
	Victim/Witness protection	Is an enabler, as blanket ban on commercialization and punishment may inflict more harm on the victims.

Levels of influence	Factors emerging from domestic policy implementation	Explanation as a barrier/facilitator
	Real time reporting of transplant	Is an enabler, as it can help track cases of commercialization or organ trafficking more swiftly. However, non-reporting or misreporting (e.g. undertaking transplant in the garb of some other operational procedure) may act as a barrier.
Community factors[78]	News reports, social media forums & TV expose	Is an enabler, as public vigilance helps expose incidents and spread awareness regarding ethical practices. However, may also act as a barrier as people use such platforms to generate advertisements to sell-purchase organs.
	Donation drives or pledges	Is an enabler, but pledges or donor cards alone are not said to be effective unless backed by adequate infrastructure.
	Registry or priority listing to manage organ allocation	Is an enabler, as they help in equitable organ allocation process.
	Counseling sessions especially for women	Is an enabler, as they help in equitable organ allocation process.
	Reporting and public availability of data on factors inter-alia: donor and recipient morbidity, mortality	Is an enabler, as they create transparency in knowledge regarding position in the waiting list and overall help increase trust in the transplantation process.
Public policy[79]	Legislation, Financing & Subsidies, Health insurance coverage.	Laws and mandatory rules provide clear deterrence and act as enablers.
	Constitution, Administrative Orders	Act as an enabler, in supporting legislation and offering wider protection to vulnerable groups. They also offer more immediate relief as regulations or administrative orders can be passed more efficiently in less time. However, despite their presence in several jurisdictions, they have excluded specific vulnerable groups such as migrants, refugees etc. which is a barrier.
	Investigation & Prosecution framework	Their presence is an enabler, but they have often been perceived as a barrier as it takes time to initiate complaints. The framework requires relevant committees to refer to the police to begin investigation, and complex bureaucracy around investigation-prosecution has led to lower instances of deterrence. There is sometimes a perception that this framework can be manipulated and influenced by players with vested interests, such as large hospitals.
	Knowledge of law enforcement authorities	Is an enabler as it helps with timely intervention and better prosecution.
	Infrastructure to protect dead bodies & conduct timely organ excavation	Is an enabler, but often such infrastructure is expensive to build and hence it has emerged as a case of barrier.
	Funds for organ procurement	Is an enabler, but countries have experienced lack of such funds which has acted as a barrier.
	Funding structure including health insurance, subsidies, access to philanthropic funds	Is an enabler, but countries have experienced wide disparities across regions in accessing funds/insurance schemes, and philanthropic funds which results in a barrier (evidence from India, Pakistan). Furthermore, even in regions backed by state funding, disparities have existed between access of patients to such funds who are present in public v private setting (evidence from Colombia and Costa Rica).
	Federal structure within a country	Is an enabler as it helps in consolidation of regulations; however, giving wide powers to states and local authorities also ends up creating national level disparities which is a barrier.
	Privatized healthcare	Has emerged as a barrier as it shoots up transplantation expenses and calls have been made to strengthen the public/government system. However, it has also been an enabler as the private sector has pioneered transplants owing to more sophisticated resources at its disposal.
	Culture of corruption	Forgery or tampering of documents by families, staff, hospitals, embassy level act as impediments in ethical transplant practices.
	International/Cross border cooperation	Is an enabler as helps disseminate information across authorities of different regions which help combat cases of transplant tourism, TIP for OR and organ trafficking.

78 Social networks and norms, or standards, which exist as formal or informal among individuals, groups, and organizations.

79 Local, state, and federal policies and laws that regulate or support healthy actions and practices for disease prevention, early detection, control, and management.

Future lessons to further strengthen ethical transplantation.

Despite several barriers in implementation, all countries under review have taken affirmative steps to improve transplantation realities and some of the measures have been more successful than the others. For example, the Philippines has offered victim protection and linked trafficking to its organ transplant framework directly. In Costa Rica, La Caja manages the centralized funding process for transplants, and it has worked towards more international cooperation in combating organ trafficking. Colombia has adopted a presumed consent model to increase uptake of cadaveric donations, has a policy on real time reporting of transplants and excluded organ transplant from its scope of medical tourism. Pakistan has worked towards reducing inflow of foreign patients and Egypt has conducted some strong raids against private clinics to prosecute and enforce against trafficking cases. India has consolidated its regulatory framework and states have taken individual steps in subsiding transplantation costs.

The implementation measures, however, has been uneven and the outcomes not well described. For example, after the success of transplant coordinators in Latin America countries, countries like Costa Rica also provided for such coordinators within their regulatory framework. Under the Indian laws as well, transplant coordinators have been tasked with extensive responsibilities from ascertaining domicile to verifying consents. However, their uptake has been limited in both Costa Rica and India, as not all hospitals involve transplant coordinators in the procurement and allocation processes.

The section below further discusses potential areas for future reforms that countries may explore. These also point towards setting up a more actionable policy agenda for global bodies such as the DICG.

Supporting transplant coordinators- Regulations in almost all countries place a huge reliance on transplant coordinators. While it is important to give them autonomy and enhanced powers (to validate donors, and conduct domicile checks) etc., such powers must be supplemented by resources, training, and funds. Coordinators have proven to play a vital role in improving hospital administration and making transplantations successful. Therefore, policy focus on these individuals to improve their condition help prevent frailties of coordinators from coming in way of successful transplant stories.

Supporting financing mechanisms for transplants- Management of a deceased donor involves both financial and cultural implications, and none of the countries under study indicated that the programs are supported more via better finance mechanism in-order to increase their uptake. Similarly, given high costs, the health insurance coverage ought to be more for cadaveric transplants, but insurance packages offered by the government barely ever makes such distinction. Therefore, issues of financing at the public policy level must consider the role of interpersonal factors. However, governments alone may not be able to fulfill the financial deficit. Therefore, in countries with large poor populations such as India, Pakistan and Egypt, adequate focus must be made on philanthropic funds to help meet transplant success. While in some instances crowdsourcing has helped patients as echoed by some interviews, these processes should be more integrated with institutions to support their uptake. Philanthropy is a poor substitute, especially for large countries.

Leveraging more buy in from religious and cultural leaders- Countries where religious leaders have emerged in support of organ transplant policies have seen a positive attitude towards organ donation. Therefore, religious, cultural, and social groups can be leveraged by countries to support in their transplantation process.

Facilitating ease of administration- Transplantation and donation processes require diverse actors who work in a web of convoluted regulations, disparities in social and economic contexts etc. This results in long wait lists, multi-level bureaucracy involved in consent, several permissions to be granted for confirming donation; all of which is vital to ensure patient safety and ethical transplant process. However, efforts must be made to streamline several of these processes through organizational tweaks such as better coordination amongst hospitals, easing steps to initiate investigations in case of foul play detection.

Chapter 5- Conclusion

This study was premised on four objectives:

(i) to map the relevant organisations and policies within the 6 select countries under review;

(ii) to identify areas of intersection as well as potential conflicts between global ethics principles (DoI principles) and the domestic policies;

(iii) to investigate factors which act as barriers and facilitators in implementing transplant policies within the countries; and finally,

(iv) to analyse reasons that make a factor a context or an enabler. Synthesizing findings across these four areas, the broad aim was to assess direction of future reforms for countries under review as well as for global bodies such as the DICG that help implement the DoI principles. In fulfilling the aims and objectives, an extensive set of research questions were developed, to probe into the presence of different actors and laws/ policies across health systems and clinical care and identify the interface between domestic policies and DoI principles.

The country specific Q&A enclosed within the descriptive report and the regulatory architecture map (Annexure 5) provide a detailed mapping of the actors within the relevant organisations and text of relevant laws and policies within the regulatory framework. The findings in Chapter 3 help identify areas of intersection and potential conflicts between the DoI principles and domestic policies across four primary themes of: Ethical and clinical organ transplantation programs; Trafficking, Transplant tourism, Commercialisation & Financial Neutrality; Equity and Self-sufficiency. Chapter 4- Discussion has shed light on investigation of different factors and their role as barriers and facilitators and helps assess policy areas where future reforms or strengthening can improve the policy landscape of organ transplantation. This concluding section remarks on the key takeaways from the study, that bodies such as the DICG can take note of. The limitations of this research, as well as data gaps in the study which pave pay for future empirical inquiry are also presented.

Key take aways from the study

Assessing unique set of wicked problems- It is vital to understand the inter-relation of different factors at play in order to understand and influence the organ transplantation policy landscape in different countries. Regulation or policy or even global guidelines which set standards do not work in isolation but are subject to the context in which they operate. Every country has a unique set of wicked policy problems that must be addressed. In some countries such as Pakistan and Egypt, governance is linked to religious beliefs. In a large diverse country like India, credibility or trust in the fragmented system needs to be worked upon. Countries such as Costa Rica and India should work on regulating medical tourism, which opens avenues for commercialization in transplant. Colombia can provide more clarity in its framework on donation after cardiac death and the Philippines can clarify some of its rules regarding gratitudinal incentives and enhance focus of transplantation on other organs apart from just kidneys.

Strengthening domestic framework to prevent cross-border issues- Besides dealing with their unique challenges, a common lesson from all countries is that commercialisation, TIP for OR and organ trafficking can be combated only when the domestic regulatory system on transplant is strengthened, and transplantation is made more accessible to own patients. The focus must be on both living donation whose cornerstone is a strong consent framework and deceased organ donation which is a result of broader awareness, knowledge and requisite funding and infrastructure.

Role of population & their cultures- Even after identifying specific areas for reforms, implementing them is challenging as the transplantation landscape offers some inherent clashes. For example, regulations that seek obtaining consent from several family members in case of deceased donation may be crafted with an aim to safeguard and respect the dead. However, each individual, family or community has a different notion of bodily integrity. Some countries such as Costa Rica recognize personhood even after death as per their

constitutional mandate. Therefore, it remains hard to develop a consensus on such thorny issues. Similarly, enabling clarity around brain stem death is a step in the right direction to improve deceased donations. However, it remains challenging to educate especially rural and uneducated population around highly technical concepts such as brain death and what ramifications these legal provisions have with their inherent beliefs on inflicting pain on human body even upon death. These are some examples of inherent clashes in interests amongst different actors in policy making such as medical profession, government and public at large.

Infrastructure & Funding- Practices such as pledges or donation drives can help increase the uptake of willing individuals who can sign up to become organ donors. But translating such pledges into reality further requires investment in infrastructure and funding by the state to support timely excavation of organs and linking deceased with the recipients. The countries surveyed in this study all have relatively weak healthcare systems, which are unable to provide timely care for populations that form the donor pool. ICU beds remain scarce and timely transport of trauma victims to hospitals does not take place. As a result, a large proportion of the potential donors remain un-utilized. These factors explain why cadaveric donations have been extremely slow to develop as opposed to live donations.

Inherent clashes amongst various health policies- There may be inherent clashes between different health policies which adversely affect the transplantation regime. For example, while a ban on foreigners or reducing the inflow of foreigners help in combating commercialization or unethical organ donation practices; such prohibitions may have a direct bearing on medical tourism policies which are said bring revenues for countries. Similarly, the lack of reforms in post-mortem related legislation often conflicts with transplantation timelines and impedes cases of deceased donation especially in situations of motor vehicles or related accidents where police is involved. Offering a middle path is difficult to achieve in such scenarios.

Ascertaining personal ties- Laws have their own limitations even when they are crafted meticulously. For example, related donors are regulated in almost all the jurisdictions under study. Some jurisdictions go on to regulate emotionally related donors as well. While such a level of regulation indicates an extra level of safeguard, but a pertinent issue for analysis remains, whether it adds anything to prevent the exploitation of donors. Regulations may impose an emotional dependency test and regulate ethical practices by doing extensive scrutiny of documents, but there are evident clashes with factors at play at an intra and inter-personal level. For example, the relationship dynamic as husband-wife, or long-standing employee and employer, is complex to understand. As a result, several donors may pass the 'informed consent' test even when authorities have sensed foul play but there is no way to identify or act upon the same. Even the healthcare professionals and the transplantation actors of countries that provide for emotional dependency tests have expressed concerns in ascertaining genuineness of relationships when persons are said to be unrelated but emotionally connected.

Low enforcement capacity- While criminal laws comprehensively cover a broad definition of trafficking (TIP for OR and in some cases even organ trafficking), prosecution of cases may still remain difficult owing to factors such as: lack of evidence trail to meet the threshold under criminal law, limited capacity of police personnel to ascertain evidence of commercialization from clinical records, tendency of victims to blame themselves, socio-economic vulnerabilities and deprivations of victims who are not powerful enough to withstand lengthy proceedings before police and the court, and lack of culture towards whistle-blowing against criminal acts in settings such as hospitals.

Therefore, global principles such as the DoI are not reflective of only ideals but have played a significant role in altering the transplantation policy landscape in several countries; it still remains hard to draw

an inventory on specific issues where clear global consensus may emerge. This study has revealed that domestic policy implementation would remain contextual and policy lessons for global bodies would have to emanate from unique and local context-driven factors.

Limitations of this study

(i) A key challenge was to find the most updated position of regulation in a country. As a result, several of the initial findings for countries turned out to be dated or based on an older position of law. Since much information on when the legal/regulatory position altered did not exist in public domain, a lot of findings had to be verified by experts, after which the findings were modified accordingly.

(ii) Availability of grey literature was not uniform. While several commentaries existed for India and Pakistan from internal scholars and reporters, for countries such as Egypt, a lot of commentaries were from external audience. For countries such as Colombia, Costa Rica, grey literature remained sparse, and language remained a barrier as English translated copies of regulations were not readily available for analysis.

(iii) Empirical stage of data collection remained challenging as it was hard to approach participants. The email addresses of relevant stakeholders as available in public domain data was incorrect and they could not be reached. There were several unwilling participants who did not respond even when approached via telephonic channels, thereby signalling reluctance to share findings with respect to the given issue. Because the issue is perceived as controversial and sensitive, individuals were hesitant to converse or provide frank opinions. There was also a perceived sense of hostility and anxiety in discussing sensitive issues of practice with an external researcher, perceived as an 'outsider' to the system, whose affiliations are linked with a 'global body' such as the DICG.

Data gaps and avenues for future studies

Some research questions could not be answered as data gaps emerged on issues inter-alia. These areas are open for future research based on additional empirical inquiry.

1. The effect of diversity (or lack of it) in representation at different regulatory sites and committees associated with transplant approval.
2. How deceased donation can be promoted in a country taking into account the unique contextual challenge that a country faces is an area ripe for future study.
3. How educational campaigns can be defined effectively tackling the social and cultural barriers such as gender dominance in a family set-up, higher bargaining powers of certain classes of individuals, religious views on bodily integrity.
4. Whether and how are transplant cases prioritized in the overall clinical system remains unclear. Even though some interviewees did mention that the general perception is to focus more on cases such as diabetes or cardiovascular treatment as they are more commonly prevalent than transplant. However, how does the government and other actors perceive and allocate resources towards prioritizing transplant is an issue that the current study intended to inquire upon but could not gather sufficient data. It opens room for further research.
5. Financial neutrality can further be examined as this research could probe into only limited aspects such as the role of gifts and incentives which remain a grey area of regulation.
6. Different scenarios in which duty of healthcare professionals may conflict with their responsibilities towards organ donor also remain to be inquired. This area is ripe for further research as it sits at the interface between sociology of medical profession, law and regulation as well as ethics.

Conclusion

A review of the six countries in this study indicate that the organ transplantation regime is highly prone to the process of regulatory capture in each of the countries under review, i.e. the regulatory regime often ends up favouring certain interest groups rather than protect wider public interest. As a result, it is witnessed that most often than not, stakeholders including transplant professionals, transplant coordinators, regulatory committees and intermediaries who are set up to protect ethics, end up resorting to illegal or unethical practices. Even patients and their families who are in need of organs in dire straits and donors who are induced by poverty or other forms of distress end up entering into commercial dealings with respect to organ facilitation.

Given the evident lack of lay and civil society representation in regulatory bodies, predominance of medical practitioners who often step into regulatory roles to decide on issues of ethics and permit transplantation especially because they are equipped to understand clinical problems and time-window for transplantation remains extremely short; conflict of interest remains an inevitable reality of contemporary transplantation landscape. Coupled with this, a predominant culture of corruption amidst socio-economic challenges continue to influence how healthcare is managed in these countries. As a result, regulatory capture breeds amongst the countries, and several rampant malpractices of illegal and unethical organ donations pervade despite presence of laws and policies.

Given that patient safety is one of the primary goals, ubiquitous laws at different levels exist in the transplantation regulatory landscape. However, the complexity of the system paves way for several leakages. This study has identified that leakages may exist due to constraints and barriers operating at different levels across inter-intra-personal, community and public policy factors.

While text of laws and policies may remain comprehensive, for example all countries under review have detailed regulations on living and deceased donations, have set up ethics review committees, provide for health coverage and insurance schemes, especially protect poor and vulnerable populations, place restrictions on foreigners, criminalise trafficking (either via TIP for OR which includes removal of organ or express framework on organ trafficking); the underlying problem lies in their effective implementation. Implementation occurs at various levels involving an individual's ethics (determined by own personal, social or financial circumstances and identities such as gender); hospital's management; transplant professional's expertise; state's financial and infrastructure support; presence of support groups including NGOs, patient advocacy organisations and philanthropists etc. Role of other ancillary regulations such as the criminal enforcement system which deals with TIP for OR or organ trafficking, laws defining and declaring death, post-mortem and transfer or dead bodies, medical tourism which attracts foreigners, and religious laws - all remain very proximal to organ donation framework and play a significant role in determining success of organ transplant policies in a country.

This study has identified potential areas of conflict and interface between DoI and local principles and a set of common and unique issues that act as barriers or facilitators in domestic policy implementation. Global bodies such as the DICG can take note of the unique circumstance of each country in light of which some policies within organ transplant regulatory framework are more successful vis. Others. There may not emerge a common blue print of an effective implementation of organ transplant framework but focus on specific issues such as supporting actors who can emerge as champions of ethical transplants (such as NGOs, transplant coordinators, religious and cultural leaders); focusing on strengthening state infrastructure including funding and insurance coverage; and sensitising general population over ethical transplant practices can go a long way in combating transplant tourism, TIP for OR and organ trafficking.

Annexures

ANNEXURE 1: DOI AND WHO PRINCIPLES

Annexure 1 is informative and provides embeds the actual text of the DoI principles of 2018 as well as 2008 along with the WHO Guiding Principles.

Part A: The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018 Edition)

Part B: The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2008 Edition)

Part C: WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation (2010 with commentary)

ANNEXURE 2: LIST OF RESEARCH QUESTIONS

Actors:

I. Who are the key policy actors in the country and how empowered are they to discharge responsibilities of transplantation policies?

i. Do the policy actors represent a fair interest of diverse bodies and stakeholders (such as healthcare institutions, healthcare professionals, government, professional bodies, patient rights groups, health & human rights organisations, and advocacy groups such as women's groups)?

ii. At various regulatory sites (such as constitution of ethics committee to approve transplantations), is diversity of actors represented?

iii. Are there potential challenges associated with conflict of principles amongst various actors involved in transplantation?

For example:

a) do challenges arise due to skewed representation of actors in ethics approval committees and related sites?

b) does the duty of healthcare professionals, conflict with their responsibilities towards organ donors e.g. if healthcare providers are discharging their duties to extend care/save life of their patients even in situations where accessing organs may be in the context of trafficking.

Laws & Policies:

II. What are the contours of legal and ethical policy principles within a country and how do they address specific transplantation related challenges?

i. How do the current laws and policies (in text and implementation) deal with issues, inter-alia:

Legislation related:

a) How are concepts such as perpetrators of organ trafficking, legitimate travel for transplantation, transplant tourism, and trafficking defined?

b) What measures are put in place by domestic laws and policies (e.g. promoting deceased donation) in-order to combat the challenge of trafficking.

c) Whether citizens have priority in organ allocation from deceased donors?

d) What are the provisions envisaging a strengthened role of local capacity to prevent harms from transplant tourism.

e) Are penalties for organ trafficking offences proportionate to the role of individuals in trafficking activities?

f) Are there protections for organ sellers in the penalty provisions?

Health systems related:

g) Are public funds available for transplant care?

h) What is the rate of organ transplantation relative to incidence of organ failure? How do actors perceive self-sufficiency within their countries?

i) Are transplantation cases prioritised in the overall clinical care system?

j) Whether allocation of organs from deceased donors is perceived as equitable?

k) Whether similar or differential treatment of citizens and non-citizens exist under the transplantation policies. Whether such treatment tends to be disadvantageous to any specific group.

Transplantation activity/Clinical care related:

l) What safeguards exist to evaluate cases of international travel or domestic living donation that may involve trafficking?

m) What are the key challenges faced in implementing organ transplantation policies?

III. How do the international principles intersect with domestic policies?

i. How do the global principles (including the WHO principles and DOI (2008/2018) account for local contexts, and advocate the role of local voices?

ii. To what extent do domestic guidelines overlap or conflict with the core global principles? How are the global actors recognised within the domestic networks of implementation?

iii. Are potential conflicts observed when global principles are interpreted and translated into realities within the developing countries/LMICs?

iv. Are there domestic lessons of policy implementation that may inform the global community in its call for ethical organ transplantation?

V. With what measures of success or failures have the legal and ethical organ transplantation been implemented by the government, healthcare providers and experienced by the healthcare consumer groups.

ANNEXURE 3: KEYWORDS FOR DESK REVIEW

The following keywords have been utilized for conducting the desk research review of this project. These keywords are carefully chosen bearing in mind the scope and objective of this research project.

1. General Research:

Organ transplant, organ transplantations, organ trafficking, organ donation, organ transplantation programs, living donors, deceased donation, laws on organ transplantation, brain death, cadaveric organ donation, commercial dealings in organs, illegal organ transplants, medical tourism for organ transplants, organ trafficking

2. India

organ transplant laws, organ transplantation act, consent requirements, living organ donation in India, deceased donation, foreign organ transplants, number of organ transplants, organ trafficking in India, NOTTO, SOTTO, trafficking laws in India, brain death definition, medical tourism for organ transplants, availability of organs, national registry for organs.

3. Colombia

organ donation in Colombia, organ transplant laws, organ allocation framework in Colombia, living organ donation, deceased organ donation, foreign organ transplants, organ trafficking in Colombia, news on organ trafficking, organ trade in Colombia, brain death, foreign organ transplants in Colombia, medical tourism.

4. Costa Rica

organ transplantation in Costa Rica, organ transplant laws, organ donation in Costa Rica, la caja Costa Rica, living organ donation, deceased donation, Costa Rica 1994 Act, brain death, medical tourism for organ transplants, national registry for organ donation, organ trafficking in Costa Rica, organ trafficking laws, foreign organ transplants in Costa Rica, medical tourism

5. Egypt

organ transplantation in Egypt, organ donation in Egypt, organ transplant laws, Egypt transplantation act, the Higher Committee for Organ Transplants, organ trafficking in Egypt, living organ donation, deceased organ donation, brain death definition, foreign organ transplants in Egypt, religion and organ donation, organ trafficking in Egypt, medical tourism

6. Pakistan

organ transplantation in Pakistan, organ donation in Pakistan, organ transplant laws, foreign organ transplants, Transplantation of Human Organs and Tissues Ordinance 2007, living organ donation, deceased organ donation, transplantation society of Pakistan, Pakistan Transplant Act, organ trafficking in Pakistan, brain death definition, medical tourism

7. Philippines

organ transplantation in Philippines, organ donation in Philippines, organ transplant laws, foreign organ transplants, Philippines organ transplant act, living organ donation, foreign organ transplants, deceased donation, national transplantation ethics committee, organ trafficking, witness protection.

ANNEXURE 4- LIST OF SOURCES COUNTRY WISE

INDIA

Articles

- Organ Transplant Law : Assessing Compatibility with the Right to Health - Vidhi Center for Legal Policy
- Organ Transplantation: Compassion & Commerce - Selected Readings from IJME
- Health System Building Blocks & Organ Transplantation in India : Wolters Kluwer
- How Deceased Organ Donation is Saving Lives in Pakistan : The Wire
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- Basics and beyond: Manjula Yadav
- Evolution of the Transplantation of Human Organ Act and Law in India: 94(2):p 110-113, July 27, 2012.
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- Towards achieving national self-sufficiency in organ donation in India – A call to action: Indian J Nephrol. 2014 Sep-Oct; 24(5): 271–275.
- Liver Transplantation in India: At the Crossroads: https://doi.org/10.1016/j.jceh.2015.11.001
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- A narrative review of the empirical evidence on public attitudes on brain death and vital organ transplantation: the need for better data to inform policy Journal of Medical Ethics 2015;41:291-296.
- Singh P. What Ails Cadaveric Transplant Programs in India: Perspectives of a Transplant Coordinator. Progress in Transplantation. 2002;12(1):49-51.
- On the Way to Self-sufficiency: Improving Deceased Organ Donation in India. Transplantation 105(8):p 1625-1630, August 2021.

Laws & Regulations

- National Organ Transplant Programme Guidelines, 2022
- The Transplantation of Human Organs (Amendment) Act, 2011
- The Transplantation of Human Organs & Tissue Rules, 2014

Press & Media

- *https://www.mohanfoundation.org/press_release/press_release.asp*
- *https://www.mohanfoundation.org/transplant_organ_donation_news.asp*
- *https://isot.co.in/new_hota_amendment*
- *https://health.economictimes.indiatimes.com/news/policy/transplantation-laws-time-to-get-our-act-together/86242201*
- *https://onlinelibrary.wiley.com/doi/10.1111/ajt.16537*
- *https://sites.ndtv.com/moretogive/indias-organ-transplant-law-requires-better-implementation-as-some-recommendations-remain-unimplemented-2177/*
- *https://www.mohanfoundation.org/organ-donation-transplant-resources/organ-commerce-issues-challenges-ethics-organ-transplantation.asp*
- *https://www.mohanfoundation.org/organ-donation-transplant-resources/organ-donation-in-india.asp*
- *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779960/*
- *https://science.thewire.in/health/change-post-mortem-protocols-missed-chance-tackle-organ-donation-problems/*

EGYPT

Articles

- Trafficking of Human Beings for the Purpose of Organ Removal in North & West Africa: Interpol 2021
- Egypt debates transplant law, hopes to cut organ trade-*https://www.reuters.com/article/us-egypt-transplant-idUSTRE5BR29X20091228*
- After announcing "Health" its activation.. Learn about the law of transplantation and transplantation of organs in Egypt
- Egyptians still hesitant on organ donation: *https://www.al-monitor.com/originals/2021/10/egyptians-still-hesitant-organ-donation#ixzz7lfwOG1YB*
- Parliament committee approves harsher penalties in Organ Transplant Law
- The gift of life: Organ donation after death; a law yet to be implemented
- Egypt organ transplant bill welcomed by WHO
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ANNEXURE 5- REGULATORY ARCHITECTURE MAP

INDIA

Target of Transplantation Regulatory Policy	Mechanisms for policy implementation	Groups tasked with relevant functions	Relevant laws, rules, policies	Type of law/rule/policy	Relevant activities expected of groups
Trafficking	**Act 1994** - No court can entertain an offense except on a complaint by an Appropriate Authority. - A complaint may also be made by a person who has given the Appropriate Authority 60 days' notice of the alleged offense and her intent to make a complaint to the court. Further, only a Metropolitan Magistrate or Judicial Magistrate can take cognizance of an offense under the Act. - Appeals against the decisions of the Authorisation Committees lie before the Appellate Authority, and then the High Court of the respective state.	Appropriate Authority, Hospitals, Medical practioners	**Act 1994** - Regulation of hospitals conducting the removal, storage, or transplantation of human organs - Punishment for commercial dealings in human organs - Offences by companies - Punishment for illegal dealings in human tissues	Laws - THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994	The authorities set up under the Act (such as Authorisation Committees, Appropriate Authorities, and Advisory Committees) are not envisaged as independent bodies and include government representatives. The funding for all these bodies is allotted from the health budget of the government itself. - No prescribed time limits for the decisions taken by the various authorities set up under it. - Authorisation Committees (which grant approvals to transplants) | Expedite the process if the patient requires urgent transplantation - Appropriate Authorities (to register hospitals, enforce common standards, and to investigate any violations of the Act | S.13B - has all powers of a Civil Court) - Advisory Committees (to assist the Appropriate Authorities in their functioning). The functions of these authorities are prescribed in the Act itself.
Clinical care	**Act 1994** Criminalizes the contravention of any other provisions of the Act. These offenses are apprehended by the Appropriate Authority and the Courts and are subject to their inherent powers.	Appropriate Authority, Hospitals, Medical practioners NOTTO | ROTTO | SOTTO	**National Organ Transplant Guidelines** - To establish new and strengthen the existing organ and tissue retrieval and transplant -infrastructure facilities, especially in public sector hospitals/ institutions. - To train required manpower for Organ & Tissue Donation, Retrieval & Transplant. - To identify/establish skill centers for training of transplant & retrieval surgeons, physicians, Anaesthetists, immunologists, Nurses, Transplant Coordinators, etc. in NOTTO/ ROTTO/SOTTO/ Medical Colleges/ Institutions as applicable. - To monitor organ and tissue transplant services and bring about policy and program corrections/ changes whenever needed. Rule 26 (2014 Rules) provides detailed guidelines for when a hospital will be allowed registration under the Act- when it has adequate and ready/available staff and experts (Provision meant to safeguard or minimize complicated cases); NOTTO website- SOP for organ retrieval. - Enhancement of training capacities for undertaking transplantation - Increasing Awareness	National Organ Transplant Programme guidelines	
			- Enhancement of training capacities for undertaking transplantation - Increasing Awareness	National Organ Transplant Programme guidelines	
Financial incentives	No specific provision on financial neutrality		**Rules 2014** - Deceased donation: 2014 Rules specify that cost of retrieval is not to be borne by the donor but by the recipient/government/NGO - Providing benefits to Live Donors through a comprehensive healthcare scheme to provide lifelong free renal/liver check-ups, and medical care, and to provide a customized Life Insurance Policy (NOTP Guidelines) worth Rs. 2 Lakhs for 3 years (with one premium to be paid by the recipient) to secure the donor against mortality risk due to organ donation;	Regulation	

Deceased donation	**Rules 2014** For living donation - Using Form 7 with 2 or more witnesses | However, the consent of the near relative, or person in lawful possession of the body, is required before donation irrespective of whether the donor has authorized the donation of her organs or tissues; 'donor card', which authorizes the donation of the specified organs and tissues on the death of a person.	Authorization Committee, Medical Practitioners - counseling the donor and family for donation, ensuring the informed consent of the donor, and ensuring that the donor is a near relative of the recipient before going ahead with the transplantation.	**Rules 2014** specify that (i) consent prior to death has not been revoked; (ii) brain stem death has been certified (simplified procedure post-2011 amendment); (iii) presence of witnesses (at least 1 near relative); (iv) relative needs to sign a declaration; (iv) post-mortem officials' permission needed (as applicable in specified cases) - appointment of transplant coordinators in hospitals to facilitate deceased donor donations; Amendment Act 2011	Regulation	
Access & Equity in donation/ to donated organs	Does not exist	NOTTO	**Rule 31, Rules 2014** Role of networking organization to prioritize those in need; principles for organ allocation by State; 2011- Storage networks, National registry established; NOTTO- helpline, allocation policy, registry, website.	Regulation	
Transplant tourism	**Act 1994** - Living Donor- Before an organ or tissue can be donated to a near relative who is a foreign national, approval must be sought from the Authorisation Committee of the hospital, district, or state. - The Act criminalizes the contravention of any other provisions of the Act. These offenses are cognizable by the Appropriate Authority and the Courts and are subject to their inherent powers.	Authorization Committee	**Rules 2014** - Special provisions in case donor/ recipient is foreign national- scrutiny by Authorisation comm; marriage validation etc. Indian living donors wanting to donate to a foreigner other than near relatives shall not be considered. - If the recipient is a foreigner but near relative, it may be considered rarely case to a case basis & a certificate from Embassy/foreign govt needed - regulation of the donation of organs to foreign nationals (Amendment Act 2011)	Law	
Protecting vulnerable groups	Does not exist		**Rules 2014** Detailed protocol for Authorisation committee including reviewing income/financial status of donor-recipient; Prohibition of organ removal (live) of mentally challenged persons; Special provisions where the donor is a woman to ascertain her independent identity | Rule 22 requires that greater precaution should be taken for women and their identity and independent consent must be confirmed by a person other than the recipient. **2011 Amendment Act** Higher penalty for trading in organs	Review Committee - Pointer for Discussion but no conclusion	
Approach on Consent/ Consent Model	**"Rules 2014** - Rule 5: Unclaimed Bodies - If a dead body (with certified brain death) is lying unclaimed in a hospital or prison, and is not claimed by a near relative within 48 hours of the death of the deceased person, the person in charge of the management or control of the hospital. - Rule 6: Post-mortem for medico-legal purposes - Medical Practioner will ascertain the consent of the donor/family, and then make a request to the Station House Officer, Superintendent of Police or Deputy Inspector General of the area to facilitate the timely retrieval of organs or tissues from the donor. **Act 1994** - Medical Practioner cannot undertake the removal or transplantation of a human organ or tissue unless she has explained all possible effects, complications, and hazards connected to the removal and transplantation to the donor and the recipient. Further, this process is required to be videographed to ensure that only legitimate transplants are allowed.		**Rules 2014** - Deceased Donation: Adult - Express consent in writing | no objection when living | familial consent; - Minor - Parental consent; unclaimed bodies; post mortem for medico-legal purposes - Living Donation: near relative | foreign national - near relative | for affection, attachment/special reason - 13D - National Registry - Any contravention will attract a penalty | No data collection or maintenance regulations; Documentation of records & creation of unique donor identification no.	**Laws - The Transplantation of Human Organs Amendment Act, 2011 & Rules 2014**	
Self-sufficiency			**NOTP Guidelines 2022** Organ registry; Network System; Reducing demand for transplant recognized in 2021 guideline doc by reducing the burden of NCDs, promoting live donation, etc.		

PHILLIPINES

Target of Transplantation Regulatory Policy	Mechanisms for policy implementation	Groups tasked with relevant functions	Relevant laws, rules, policies	Type of law/ rule/policy
Trafficking	Organ Donation Act, 1991 - The main purpose of the Act is to authorize the legacy or donation of all or part of a human body after death for specified purposes. This Act however only regulates posthumous organ donation. Revised National Policy on Living Non-Related Organ Donation and Transplantation and its Implementing Structures Amending | Administrative Order No. 2008-0004 - Focus on Kidney donors Anti Trafficking of Persons Act, Republic act no 9208/2003 |	1991 ACT | Department of Health - in cooperation with institutions, such as the National Kidney Institute, civic and non-government health organizations and other health related agencies, involved in the donation and transplantation of human organs, shall undertake a public information program. 2008 Order - Philippine Board for Organ Donation and Transplantation	Presently, under the 2021 AO organ sale (of any kind) is strictly prohibited.[Annex A, 2021 AO.] The 2021 AO also notes that "organ commodification/commercialism (wherein the giving of the organ is conditioned on the financial or material gain for the donor) violates human dignity, and has no place in organ donation." Anti-Trafficking in Persons Act of 2003 (Act No. 9208) (Philippine Anti-Trafficking Act) criminalizes trafficking in persons in the Philippines. The definition of trafficking under this law is similar to the definition contained in the Palermo Protocol. The crime is punishable with imprisonment of twenty years and a fine ranging from one million pesos to two million pesos. This law also criminalizes anyone who commits other acts in order to aid or promote trafficking in persons. Under Filipino law, trafficked persons are recognized as victims of trafficking and cannot be penalized for any crimes committed in relation to the act of trafficking, irrespective of consent provided.	Law
Clinical Care	The pre-transplant orientation (AO 2021) is meant to be comprehensive and includes an overview of the organ donation and transplantation procedure, importance of informed consent, benefits and risks to the donor and recipient, recognition and management of adverse effects, policies and guidelines related to the procedure, responsibilities of donors, recipients, transplant team and hospital, long term follow-up requirements, previous outcomes and alternatives to transplantation. A certificate of attendance issued for attending this orientation is also included in the documents submitted to the HTEC for its approval prior to the procedure.	In terms of long-term follow-up care, the Hospital Transplant Ethics Committee is required to ensure that there is a monitoring system within the institution to follow-up on the donor over a lifetime. Each accredited transplant facility is also required to maintain a "Kidney Donor Monitoring Unit" which can ensure donor protection and long-term monitoring of donors.	The AO 2021 mandates that the potential donor and recipient, and his/her spouse or a family member (in case unmarried) to attend a pre-transplant orientation in a licensed transplant hospital.	Regulation
Financial Incentives				Law
Deceased Donation	Under the Organ Donation Act, a person can express his willingness to donate (a) through his will or (b) any other document signed in the presence of two witnesses. The term death has been defined as the "irreversible cessation of circulatory and respiratory functions or the irreversible cessation of all functions of the entire brain, including the brain stem". The Organ Donation Act allows directed deceased donation, i.e., the donor has the option to specify the donee, at the time of recording his consent to donate.	Transplant Co-ordinators | Human Organ Preservation Effort (HOPE), a unit of the National Kidney and Transplant Institute and government organ procurement organization, plays in deceased and living organ donation. HOPE acts as an organ procurement organization for deceased donors. But at the same time it also has a function in our hospital of evaluating all our living unrelated donors.	Organ Donation Act, 1991	Law
Access & Equity in donation/ to donated organs	Under 2008 Kidney order, Under the new Order, Filipino recipients were to be given priority in donor allocation as a majority of organs that were sold at that time were to foreigners to the detriment of Filipinos who needed organs for transplantation. Concept of Equity, justice explained.	The 'Philippine Network for Organ Sharing' (PHILNOS) was established based on the 2010-0019 AO. PHILNOS serves as the coordinating body for allocation of organs harvested from deceased donors. At the level of the transplant hospitals, the "Hospital Transplant Coordinating Office" maintains the registry with the aforesaid data and coordinates with the PHILNOS.[(Revised National Policy on Living Non-Related Donation and Transplantation and Its Implementing Structure Amending for the Purpose Administrative Order No. 2008-0004-A, 2010, para. VI.8)] Any recipient seeking an organ donation through the deceased donation program is required to register with the Philippine Organ Donor and Recipient Registry System	Revised National Policy on Living Non-Related Donation and Transplantation and Its Implementing Structure Amending for the Purpose Administrative Order No. 2008- 0004-A,	Regulation
Transplant Tourism	1991 ACT - International Sharing of human organs or tissues shall be made only through exchange programs duly approved by the Department of Health: Provided, That foreign organ or tissue bank storage facilities and similar establishments grant reciprocal rights to their Philippine counterparts to draw organs or tissues at any time. Order 2008 - Kidney cannot be exported or transported abroad. For the first time, the national policy had provisions dealing directly with transplant tourism. The Order tried to exclude kidney transplantation from medical tourism and forbade the exportation or transportation of kidneys abroad. Order No. 2008-0004-A | foreigners are not eligible to receive organs from Filipino living non-related donors.	Any approval granted to a foreign donor-recipient pair is also to be communicated to the National Transplant Ethics Committee (NTEC), allowing it the opportunity to review and overrule the decision of the HTEC within 24 hours of the receipt of the information, if required.	AO 2021 - foreigners can receive organ transplantation in the Philippines from a living related donor (up to the fourth degree of consanguinity) or a spouse (having been legally married at least 3 years). Filipino law also allows a foreign recipient to identify and bring a foreign related donor for the procedure.	Law
Protecting vulnerable groups				

Target of Transplantation Regulatory Policy	Mechanisms for policy implementation	Groups tasked with relevant functions	Relevant laws, rules, policies	Type of law/ rule/policy
Approach on Consent/ Consent Model	**1991 ACT -** Deceased Donation - Irrespective of the authorization/consent of the deceased individual, the donation of all or parts of his/ her organs can be made by a spouse, adult son or daughter, parent, adult siblings or guardian, in that order. Any individual, at least eighteen (18) years of age and of sound mind, may give by way of legacy, to take effect after his death, all or part of his body for any purpose. Living Donation - The 2021 AO presently governs living organ donation to Filipino citizens, Filipino dual citizens, as well as foreign citizens. In Philippines, only those that are 21 years of age or older and mentally sound are legally permitted to be living organ donors.	A transplant procedure from a related or unrelated living donor can proceed only with the approval of the Hospital Transplant Ethics Committee (HTEC). The HTEC is a multi-sectoral representative body appointed by the Hospital Director/ Medical Centre Chief. The HTEC is tasked with the function of assessing whether the proposed organ transplant is ethical, free of commercial intent and based on voluntary and informed consent. In addition to evaluating the submitted documents, the HTEC also conducts separate interviews with the donor and recipient, to understand their motive for donation and to also once again apprise them of the risks involved	Organ Donation Act, 1991 & Administrative Order 2021.	Law & Regulation
Self-sufficiency	**Under the guidelines listed in the 2010** AO, the national government is required to allocate 20 million pesos per year in support of the operations of the organ donation and transplantation program starting 2010.	In addition, the Department of Health is also obligated to undertake public information program to raise awareness about organ donation.	Philippine Health Insurance System has approved the grant of substantial subsidies for organ transplantation over the years.	Regulation

COSTA RICA

Target of Transplantation Regulatory Policy	Mechanisms for policy implementation	Groups tasked with relevant functions	Relevant laws, rules, policies	Type of law/rule/policy	Relevant activities expected of groups
Trafficking	**LAW 9222 of 2014 | Article 59** - Anyone who sells or buys organs, tissues, and/or human fluids or possesses or transports them illegally will be punished with a prison sentence of eight to sixteen years. - **Article 60 -** Anyone who carries out the extraction of organs, tissues and/ or human fluids without the prior informed consent of the living donor, in accordance with the provisions of articles 15 and 16 of the Law on Donation and Transplantation of Human Organs and Tissues, or misleading it through the concealment of information or the use of false information or any other form of deception or manipulation. - Whoever extracts organs, tissues and/or human fluids from a deceased person without the latter having expressed their consent in life or without the authorization of their relatives or representatives, shall be punished with a sentence of three to ten years in prison, in accordance with the law."	Ministry of Health | Technical Executive Secretariat for Donation and Organ and Tissue Transplantation (Article 44 - 53)	Regulates activities related to the procurement and clinical use of human organs and tissues, including donation, evisceration, preparation, transport, distribution, transplantation and follow-up for therapeutic purposes. - Covers Deceased donor & Living donor - Respect and protection for the donor and recipient - Prohibition to receive gratuity, remuneration, gift, in cash or in kind, social conditioning, psychological or of any other nature.	Law on Donation and Transplantation of Human Organs and Tissues, 2014	responsible for expressly authorizing health establishments, both public and private, to carry out the process of organ and tissue donation and transplantation. - authorization given by the Minisry of health may be revoked or suspended by the when the requirements established by this institution are not met. - any type of substantial modification that occurs in the structure, processes and results of donation and transplantation in the health establishment must be notified to the Ministry of health - may suspend or revoke the authorization to carry out organ or tissue donation and transplant processes at health establishments that do not meet any of the requirements established in this law. - sanctions established in the internal regulations, those who, through intent or gross negligence, violate confidentiality or disclose or alter the content of the information related to donors and recipients of human organs or tissues, will be subject to disciplinary sanctions, with dismissal without employer responsibility. which they have access in the exercise of their functions.
Clinical care	**Law 9222 of 2014** **Article 19** - Prior to the extraction of organs and tissues, health personnel must ensure, in a reasonable manner, the viability and success of the transplant, by carrying out all the necessary studies. **Article 20 -** The health personnel in charge of the extraction and the private or public health establishment where the extraction will take place must guarantee the living donor all comprehensive health care for their recovery and follow-up in relation to this specific procedure.	Ministry of Health		Law on Donation and Transplantation of Human Organs and Tissues, 2014	
Financial incentives	No Mention | Article 4 The donation, extraction and transplantation of human organs and tissues from living or deceased donors and their transplantation will be carried out for therapeutic purposes. Its main purpose will be to promote the health or living conditions of its recipient.			Law on Donation and Transplantation of Human Organs and Tissues, 2014	

Deceased donation	Law 9222 of 2014 Deceased donor: corpse from which it is intended to extract organs and tissues, fulfilling the requirements established by law. There are: ventilated corpse (brain death), corpse in cardiac arrest.	Health establishment that removes organs or tissues from deceased donors: health establishment that, in compliance with the requirements established in the law and its regulations, has the corresponding authorization issued by the Ministry of Health for the development of organ har-vesting activities. or tissues in deceased donors.	**Article 11 -** The economic cost or any other type of medical procedures related to the donation, extraction and transplantation of organs may not be attributed to the living donor or to the family of the deceased donor. **Article 23 -** Obtaining organs and tissues from deceased donors for therapeutic purposes may be carried out as long as the deceased person, from whom it is intended to extract organs and tissues, has expressed his/her consent in life. | or consanguinity up to the fourth degree, or by affinity in first degree of the deceased | or case of deceased minors or deceased declared in a state of interdiction, the donation will be requested from those who have been their legal representatives in life, whether they are their parents, guardians or curators. **Article 27 -** The diagnosis and certification of the death of a person will be based on the confirmation of the irreversible cessation of brain or cardiorespiratory functions, in accordance with the provisions of subsection c) of article 3 of this law.	Law on Donation and Transplantation of Human Organs and Tissues, 2014	
Access & Equity in donation/ to donated organs	Executive Decree No. 39895-S | Article 101.- The equitable distribution of donated paired organs is based on the prioritization criteria established for the single national list of the National Registry of Information of the processes of Donation and Transplantation of Organs and Tissues Human, where benefit will be given to a patient on the waiting list of the health facility where the extraction was performed and the other organ was placed on the list only national waiting. If there is no potential beneficiary in the establishment extractor both peer bodies will become part of the national list.		**Article 98 -** The Registry of recipients of the National Information Registry of Human Organ and Tissue Donation and Transplantation processes will have sub-records according to the organ and/or tissue(s) whose transplant is required, and they will include both Costa Ricans and foreigners who meet the requirements established in the national legislation, according to the information provided by establishments authorized to carry out transplants. The prioritization for Reception of organs and/or tissues from corpses will be carried out in strict order according to the single national list of the National Information Registry of Human Organ and Tissue Donation and Transplantation processes. **Article 99.-** Every receiver must be registered in the unique waiting list of the National Registry of Information on the Donation and Transplantation processes of Human Organs and Tissues. **Article 100.-** The distribution and allocation of organs and/or tissues will be determined according to criteria established and agreed by the transplant specialists of the authorized health establishments. These criteria will be in the National Registry of Information of the processes of Donation and Transplantation of Organs and Tissues Human Rights in charge of the Secretary of the Ministry of Health and will be reviewed every two years in order to maintain equity in the distribution, or when so establish the Secretary.	Executive Decree No. 39895-S	

COLOMBIA

Target of Transplantation Regulatory Policy	Mechanisms for policy implementation	Groups tasked with relevant functions	Relevant laws, rules, policies	Type of law/rule/policy
Trafficking	Legislation prohibiting organ transplantation for non citizens has been introduced in 2004. Article 2 | 2016 - Donations do not generate any type of family, legal, or economic link. Article 20 | 2016 - Who will bring, buy, sell or market human anatomical components, will incur three (3) to six (6) years in prison. On the same penalty it incurs who subtract an anatomical component of a corpse or a person without the corresponding authorization, who participates as an intermediary in the purchase, sale or placing on the market of the component or making publicity about the need for an organ or tissue on its availability, offering or seeking some kind of gratification or remuneration. When the behavior is performed in order to commercialize the human anatomical components on the outside, the penalty will be increased from half to double the penalty.	Article 7 | 2016 - The National Institute of Health (INS) assumes from this law functions of the highest administrative authority in relation to the structure and organization of the Organ Donation And Transplantation Network. The National Health Institute (Instituto Nacional de Salud) is in charge of the organ and tissue transplant network that has been established in 2004. There is a mandatory reporting of every donor (both live and deceased) and every transplant. Although transplant activities are well reported, there is only limited information available on long-term transplant outcomes. The Art 16 | 2016 - National Registry of Donors will be in charge of the National Institute of Health (INS), which should keep it updated and open to the consultation of all medical institutions instantly to verify the quality of the person's donor. The consultation of the National Registry of Donors, prior to any action for donation, is mandatory for the medical entity. The rules shall lay down penalties for this infringement. **Art 3 | 2004 -** The Donation and Transplantation Network will be structured in two (2) levels: National and Regional.	**LAW 1805 OF 2016 -** By means of which Act 73 of 1988 and Law 919 of 2004 are amended on the donation of anatomical components and other provisions are dictated. **DECREE NUMBER 2493 OF 2004 -** purpose of this decree is to regulate the obtaining, donation, preservation, storage, transport, destination and final disposal of anatomical components and the procedures for their transplantation or implantation in human beings.	Law
Clinical care	Article 13 | 2004 - Deceased donor maintenance. When brain death has been diagnosed subject to the provisions of this decree, procedures for maintenance and support of the deceased donor may be carried out by artificial means in order to maintain optimal viability of the anatomical components that are intended for transplants, which which does not invalidate the diagnosis of brain death.			Law
Financial incentives	Article 15 | 2004 - Remuneration or any type of compensation or compensation for the donation or supply of an organ or tissue to which refers to the present decree, particularly it is prohibited: 1. Gratification or payment to the living donor, the family of the deceased donor, the Tissue or Bone Marrow Bank, the IPS, the EPS, or any other natural or legal person for the donation or supply of human organs or tissues. 2. The payment to the recipient for the transplanted organ. 3. Publicity about the need for an organ or tissue or about its availability, offering or seeking some type of gratification or remuneration. Paragraph 1. Excepted from this article are the costs caused by the detection and maintenance of the donor, the diagnosis, the extraction, the preservation, the tests or examinations previously required for the donation or the supply, the transportation, the transplant, the supply of medicines and controls subsequent to said procedure. Paragraph 2. The extraction and related costs may not be charged in any case to the living donor or the family of the deceased donor, but may be included as part of the costs of the transplant			Law
Deceased donation	Colombia's transplant activity is mainly based on deceased donations. Art 2 | 2004 - It is one who has died either due to brain death or irreversible cessation of cardiorespiratory functions and who is intended to extract anatomical components for the purpose of transplants or implants.		Article 16 | 2004 - anatomical components for transplant or implant purposes, the following may be performed: Use of anatomical components. The use ofIn the case of a deceased donor: a) Provided that the informed consent process of the donor has been guaranteed and ensured and, in the absence of the latter, that of the relatives; b) That the donor or relatives responsible for the donation, at the time of expressing their will, are of legal age and civilly capable;	Law

Access & Equity in donation/ to donated organs	Article 7 | 2016 - The unique national criteria for the distribution and allocation of organs and tissues should be defined by the National Institute of Health (INS) based on the severity scale of the patient's disease and compatibility. List of People Waiting for Donation (LED). For each anatomical component there will be a List of People Waiting for Donation (LED) that will be administered and monitored by the National Institute of Health (INS). Article 14 | 2016 - In cases where two (2) persons on an organ or tissue transplant waiting list are medically compatible and have the same level of severity, the organ or tissue will be transplanted to the person who expressed their willingness to be a donor of organs and tissues and is identified as such. Article 25 | 2004 - Distribution.The anatomical components will be distributed throughout the national territory in such a way as to guarantee equity in the allocation of the anatomical components without any discrimination, for reasons of family origin, socioeconomic status, sex, race, language, religion, political or philosophical opinion,	**Art 13 | 2016 -** Within twelve (12) months following the enactment of this law, create a Quality Intersectoral Commission whose object will be to update the current regulations on donation of organs and tissues, differentiating according to: potential donor to organs, potential donor to tissues, living donor, deceased donor, effective donor, implant or graft, organ or tissue, anatomical component; with special attention to the results and the quality of the services provided by the institutions Health Prders (IPS). This Commission will be made up of representatives of the Organ Donation and Transplant Network, the insurance sector, the academy, the Health Care Institutions (IPS), and the other members. the Government considers relevant.		Law
Transplant tourism	The 2004 law allows deceased donor transplants in foreign patients only if there is not a Colombian citizen waiting for an available organ. Moreover, non-Columbian citizens can only receive living related transplants with permission by the government. **Article 10 | 2016 -** The provision of organ and tissue transplant services to foreign non-residents in the national territory is prohibited, unless the recipient is a spouse or permanent partner, relative in fourth degree of consanguinity, second of affinity or first civil, of the donor. The Ministry of Health may temporarily authorize transplants to non-resident foreigners when it is duly established that the available tissues are sufficient to cover domestic demand. In any case, nationals and resident foreigners will have priority. **Article 40 | 2004 -** Provision of transplant or implant services to non-resident foreigners in Colombia.The provision of organ transplant or tissue implant services to foreigners who do not reside in the national territory may be carried out as long as there are no national or foreign recipients residing in Colombia on the regional and national waiting list, taking into account the unique technical criteria. - Assignment and selection scientists and prior signing of the institution's contract with the recipient or the entity that will assume the cost of care. In 2016, only 10 foreign patients have been transplanted in Colombia,all having received living donor kidney transplants with the permission by the health authorities of both, their home country and Colombia's National Health Institute. In 2017, only 5 foreign patients (4 livers and 1 kidney) were transplanted, all with living related donors			Law
Protecting vulnerable groups				Law
Approach on Consent/ Consent Model	In Colombia, a law passed in 2016 (Article 2) abolished explicit consent, and starting in 2017, established presumed consent for organ donation. The will of donation expressed in life by a person can only be revoked by itself and cannot be replaced by their bereaved and/or family members. **Art 15 | 2016 -** Children may be organ and tissue donors, as long as their legal representatives express their informed consent for organ and/or tissue donation within eight years. (8) hours after the occurrence of brain death. **Article 2 | 2004 -** Informed consent for donation, transplant or implant:It is the manifestation of will coming from that person who has the quality of donor or recipient of an anatomical component, which has been issued freely and expressly, after having received and understood the information related to the procedure to be performed.	**Article 4 | 2016 -** Everyone can object to the legal presumption of donation by expressing his will not to be a donor of organs and tissues, by means of a written document that must be authenticated before Notario Público and the National Institute of Health (INS). You will also be able to oppose the moment of affiliation to the Health Promoter Company (EPS), which will be required to report to the National Institute of Health (INS).		Law
Self-sufficiency	Organ transplantation in Colombia has increased over the last decade and more than 18000 transplants have been performed since 1966 (76% of those being kidney transplants; more than 17% of recipients received liver transplants. It is important to mention that those numbers are based on personal information because there is currently no national registry collecting data on outcomes. Article 6 | 2016 - At least a proportion equal to fifteen percent (15%) of the budget allocated to the official guideline of those entities in the Health Sector of both the Executive Branch of the National Order, Departmental and Municipal; as of the Decentralized Sector for Services, it will be used to promote the donation of organs and tissues and to explain the scope and nature of the legal presumption of donation. **Article 41 | 2004 -** Donation Promotion.The Ministry of Social Protection and the territorial health entities, in coordination with the National Donation and Transplant Network, will carry out public campaigns to promote donation, through information, education and communication strategies for the entire population, in order to promote awareness of solidarity that increases donations in favor of patients who need organs and tissues for transplants. These campaigns will be financed with State resources through public health actions, without prejudice to the fact that private campaigns can be carried out.			

EGYPT

Target of Transplantation Regulatory Policy	Mechanisms for policy implementation	Mechanisms for policy implementation	Groups tasked with relevant functions	Relevant laws, rules, policies	Type of law/ rule/ policy	Potential list of interviewees (regional diversity, and representation from diff stakeholders, mainstream professionals)
Trafficking	For North and West Africa, data reveals that criminal actors involved in this type of crime are most often individuals with strong connections to the medical sector. These networks are often transnational and frequently connected with organ recipients through the Internet. Key actors identified for THBOR cases in North and West Africa are: 1. Brokers/coordinators have connections with the healthcare sector (clinics, analytical laboratories, doctors) and their role is to connect organ recipients (buyers) with victim-donors. 2. Local recruiters are responsible for detecting and approaching potential organ suppliers (victim-donors). 3. Most often, commercial transplantations are performed in the same facilities where legal transplantations are conducted, but medical/health professionals are not always aware of the illicit aspect of the organ transplant. 4. Health facilities/laboratories play a key role in the THBOR chain providing services (tissue typing) for various brokers. From North and West Africa, information suggested that Egypt appears to be among the countries with a higher number of transplants for foreign patients. For example, a report from 2019 depicted Egypt as a destination country with the highest number of kidney transplants performed for patients from the United States that were on transplant waiting list for the period 2010 - 2016. The study suggests that patients who travelled abroad for kidney transplants were most likely socioeconomically advantaged men with a high level of education. The Transplantation of Human Organs and Tissues Act (2010) prohibits foreign patients to receive a transplant in Egypt, unless the donor and the recipient have been married for at least three years. Despite national regulations, Egypt has been reported as a destination for wealthy organ recipients from Saudi Arabia who travel to the country to allegedly buy an organ from impoverished Egyptians.	Following the Declaration of Istanbul, Egypt adopted the Transplantation of Human Organs and Tissues Act (2010) and established "The Higher Committee for Organ Transplants", responsible for regulating and supervising all organ and tissue transplant procedures in the country. The law criminalizes organ trafficking and sets strict penalties for physicians, hospitals and medical facilities performing illegal organ transplant procedures. Also comprised regulatory rules for living organ donation to fight commercialism and transplant tourism. In 2017, the Egyptian Parliament's Legislative Committee approved amendments to the Transplantation of Human Organs and Tissues Act with the aim to increase penalties for organ trafficking and minimize the risks of Trafficking in Human Beings for the Purpose of Organ Removal. In Egypt, the first live kidney transplantation was performed in 1976 with more than 7500 cases performed so far (2022).	**Article 9(2010) -** A supreme committee shall be established called (the Supreme Committee for Human Organ Transplantation). The Minister of Health shall chair the committee and appoint a technical secretariat for it. The committee shall manage and organize the operations of transplanting organs, their parts, and tissues, identifying the facilities that are licensed for transplantation, as well as supervising and controlling them in accordance with the provisions of this law, its executive regulations, and the decisions implementing it. The Minister of Justice, in agreement with the Minister of Health, issues a decision granting the status of judicial officers to the workers who undertake the supervision and control of the aforementioned facilities, within the limits of the competencies entrusted to them in this law, its executive regulations, and the decisions implementing it	**Article 2 (2010)-** It is not permissible to transfer any organ or part of an organ or tissue from the body of a living person with the intention of transplanting it into the body of another human being except for a necessity necessitated by preserving the life of the recipient or treating a serious disease, and provided that the transfer is the only means to meet this necessity and not be Transfer would expose the donor to serious danger to his life or health. It is prohibited to transplant organs or their parts, tissues or reproductive cells, which may lead to mixing of lineages. Article 4 (2010) - It is not permissible to transfer any organ or part of an organ or tissue from the body of a living human being for transplantation into the body of another human being, unless it is by way of a donation among Egyptian relatives. . It is permissible to donate to non-relatives if the patient is in urgent and urgent need for a transplant, provided the approval of the special committee formed for this purpose by a decision of the Minister of Health in accordance with the controls and procedures specified by the executive regulations of this law. **Article 6 (2010) -** It is prohibited to deal in any organ of the human body, part of it, or one of its tissues by means of sale or purchase for consideration, whatever its nature. In all cases, the transplantation of the organ, part of it, or one of its tissues may not result in the donor or any of his heirs acquiring any material or in-kind benefit from the recipient or his relatives because of or on the occasion of the transfer. It is also prohibited for the specialist doctor to start performing the implantation process when he learns of a violation of any of the provisions of the two previous paragraphs. Article (17): Imprisonment and a fine of not less than twenty thousand pounds and not exceeding one hundred thousand pounds shall be the penalty inflicted on whoever transports a human organ or part thereof for the purpose of transplantation in violation of any of the provisions of Articles 2, 4, 3, 7 of this law. A living human being, the penalty shall be imprisonment for a period not exceeding seven years. If the act referred to in the preceding paragraph results in the death of the donor, the penalty shall be temporary hard labor and a fine of not less than one hundred thousand pounds and not exceeding two hundred thousand pounds. Article (18): Without prejudice to the penalties prescribed in Articles 17 and 19 of this law, whoever performs a transfer or implantation operation in other than licensed medical facilities with his knowledge of that shall be punished by imprisonment and a fine of not less than two hundred thousand pounds and not exceeding three hundred thousand pounds. If the act results in the death of the donor or recipient, the penalty shall be life imprisonment. The same penalty stipulated in the preceding paragraph shall be imposed on the director responsible for the actual management of the medical facility in unauthorized places where any operation of transferring human organs or part thereof or human tissue is carried out with his knowledge of that.	Law	
Clinical Care				**Article (11)** The state shall take care of the expenses of conducting organ transplantation operations in licensed medical facilities, with regard to everyone who is unable to pay, who has the turn, in accordance with the controls issued by a decision of the Minister of Health. A fund shall be established to contribute to the expenses of transporting and transplanting organs and tissues for those who are unable to report to the Minister of Health. Its resources consist of what the state allocates in the general budget. The proceeds of fines imposed on violators of the provisions of this law. Fees collected according to this law.	Law	

Financial Incentives				**Article 6(2010) -** It is prohibited to deal in any organ of the human body, part of it, or one of its tissues by means of sale or purchase for consideration, whatever its nature. In all cases, the transplantation of the organ, part of it, or one of its tissues may not result in the donor or any of his heirs acquiring any material or in-kind benefit from the recipient or his relatives because of or on the occasion of the transfer. It is also prohibited for the specialist doctor to start performing the implantation process when he learns of a violation of any of the provisions of the two previous paragraphs.	Law	
Deceased Donation				**Article (8) -** It is permissible, out of necessity to preserve the life of a living person, treat him from a serious disease, or complete a vital deficiency in his body, to transplant an organ and part of an organ or tissue from the body of a dead person, among Egyptians, if the dead person recommended that before his death. By a notarized will, or proven in any official paper, or he acknowledged that in accordance with the procedures specified by the executive regulations of this law.	Law	
Access & Equity in donation/ to donated organs						

PAKISTAN

Target of Transplantation Regulatory Policy	Context	Mechanisms for policy implementation	Groups tasked with relevant functions	Relevant laws, rules, policies	Relevant activities expected of groups	Perspectives/ Debates
Trafficking	Frail national economy and status of health care infrastructure restricts access of the local population to both dialysisand transplantation in Pakistan. Foreign nationals share the marketplace. There are current attempts from the government to stop organ trade by strictly enforcing a recently sanctioned law on organ transplantation. Scarcity of comprehensive reliable data has hampered plausible assessments and indispensable modifications to facilitate designs for the future health care. Ninety percent of organs transplanted to family members are donated by the mothers, daughters, sisters, or wives of the patients in Pakistan. This is consistent with the ubiquitous global trend. Most females take care of the household. An emotional bond, better health status among females alongside a perception that there are better chancesof a close match are the motivations in traditional families of lower and middle socioeconomic strata.	In July 2006, the Supreme Court of Pakistan issued a directive to the federal health ministry to accord high priority to formulate and implement a law.The apex court on a later date underlinedinherent ambiguities and limitations (specificallydealing with monetary transfer) in the proposed law,and instructed the authorities to remedy the situationexpeditiously. The federal cabinet revised the originaldraft in August 2007 taking into consideration theobservations of the judicial body. Transplantation of Human Organs and Tissues Ordinance 2007(THOT 2007) was promulgated on September 3,2007. Further revisions (with patient representation)may be needed for the legislative framework to takefinal shape. Concerns expressed by various quartersthus far could be addressed during the ratificationprocess pending a debate on the transplantation bill,which was forwarded to the parliament in May 2007 for the sixth time in the last 15 years.	A federal monitoring authority has been convened. The Human Organ Transplant Authority(HOTA) is its implementing arm. Only institutions accredited by HOTA will be allowed to carry out organ transplantation. They will have to undergo clinical audits, quality assurance, and performance assessments.	President Pervez Musharraf issued the Transplantation of Human Organs and Tissues Ordinance (hereinafter, the transplantation ordinance or the ordinance) in September 2007. The ordinance included aprohibition on unrelated living organ donation, a prohibition on transplanting organs from Pakistani donors to foreigners; prohibitions on commercial dealings in human organs, severe penalties for violations; provisions addressing deceased donation;and establishment of a federal monitoring authority to oversee the country's transplant activity and investigate violations. With support from the media, the two chambers of Pakistan parliament passed thel egislation unanimously and, in March 2010, the Transplantation of Human Organs and Tissues Act. The transplantation ordinance and the act thereafter replaced the regulatory vacuum with strict rules and prohibitions enforced by the Human Organs Transplantation Authority (HOTA). On Feb 14, 2022, Upper House of Parliament on Monday passed the Transplantation of Human Organs and Tissues (Amendment) Bill, 2021 with the aim to set a requirement as the National Database and Registration Authority (NADRA) to display the consent of potential donor on the National Identity Card for identification and apt management of transplantation of organs and tissues. https://senate.gov.pk/ uploads/ documents/1582101388_863.pdf	https:// joshandmakinternational. com/resources/ laws-of-pakistan/ health-and-food-laws/ the-transplantation-of- human-organs-and- tissues-act-2010/	People are poor, some have to marry their daughters off... they work at brick kilns. Theywork in such a hot weather but they don't receive the wages they deserve. People remainhungry, some fall ill. As people came to know about selling [a] kidney, they presentedthemselves. Here people don't have sufficient land for agriculture... and there is no business.They are all uneducated and ignorant and know nothing. They take loans ... if they don't workthey don't get food. If they are in tension and there is no solution then people have to dosomething for their children. They sacrifice their bodies for their children. People do it due topoverty; nobody does it happily. All the men had to repay loans ... their wives are abused andhumiliated, they can't go anywhere ... they can do anything to protect their honor
Clinical Care	According to the Human Organs Transplant Authority (HOTA) , there were 20 registered institutions across the country, which were doing organ transplants, but public sector institutions were hardly doing transplants.	A welfare fund would be set up for patients with End Stage Renal Disease, unable to afford renal rehabilitation, and for organizing donor care and follow-up.		Fund established for 2010 ACT, that will aid in post-transplant care and medicines.		
Financial Incentives				No financial incentives, permitted under the 2010 ACT.		
Deceased Donation				Permitted under the 2010 ACT.		
Access & Equity in donation/ to donated organs				The new 2021 Act, establishes a national database & registration authority		
Transplant Tourism	According to the Pakistan Society of Nephrology, 98% of transplant activities in the twin cities of Rawalpindi-Islamabad are performed in private medical centers. Advertisements imploring kidney donors are regularly featured in our newspapers. The most glaring example was a want ad in a daily newspaper on August 10, 2006, by a premier public-private hybrid transplant institution.			Punishment of 10 years and a fine of 1 million Rupees under the 2010 ACT for transplantation without any authority and commercial delaying of organs. Any other contravention of the 2010 ACT, is punishable with 3 years &/or 3k fine. Offences by Companies are also covered. https://joshandmakinternational.com/ resources/laws-of-pakistan/health-and-food-laws/the-transplantation-of-human-organs-and-tissues-act-2010/		
Protecting vulnerable groups						
Approach on Consent/ Consent Model	The voluntary nature of most Liver unrelated donors that implicate females is debatable. Most of these cases are not divulged by the victims, who are under pressure from their families or authorities. Economic deprivation, coercion, and deceit have been recounted. No remedial measures have been prescribed in the law for putting an end to the exploitation of females.					
Self-sufficiency						

ANNEXURE 6- DETAILS OF THE KIIS INTERVIEWED

Country	Codes	Professional Background	Gender
India	KII1IN	Researcher (Previously transplant Coordinator)	Female
	KII2IN	NGO (CEO)	Female
	KII3IN	Policy Maker/Regulator & Transplant surgeon	Male
	KII4IN	NGO Founder	Male
	KII5IN	Hospital Transplant Coordinator	Female
	KII6IN	Journalist and a potential donor	Female
	KII7IN	NGO (CEO)	Female
	KII8IN	Transplant Policy Maker	Male
	KII9IN	Transplant Coordinator	Female
	KII10IN	Transplant Coordinator	Female
Philippines	KII1PH	Policy Maker	Male
	KII2PH	Lawyer	Female
	KII3PH	Nephrologist and Advocate	Female
	KII4PH	Transplant Surgeon	Male
Costa Rica	KII1CR	NGO Representative	Female
	KII2CR	NGO Founder	Female
	KII3CR	Transplant Surgeon	Female
	KII4CR	Enforcer/Regulator	Male
Egypt	KII1EY	Transplant Surgeon	Male
	KII2EY	Transplant Surgeon	Male
Pakistan	KII1PK	Policymaker	Male
	KII2PK	Transplant Surgeon	Male
	KII3PK	Bioethicist	Male
	KII4PK	Lawyer in Provincial administrative agency	Male

The George Institute for Global Health

The DECLARATION of ISTANBUL on ORGAN TRAFFICKING and TRANSPLANT TOURISM

TTS THE TRANSPLANTATION SOCIETY

ISN INTERNATIONAL SOCIETY OF NEPHROLOGY