Barriers and facilitators to the

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

December 20, 2023

Executive Summary

INTRODUCTION

With efforts made by bodies such as the World Health Organization (WHO), Council of Europe, and professional bodies, led by the Transplantation Society (TTS), and the International Society of Nephrology (ISN), comprehensive global ethics guidelines have been formulated for organ transplantation. These global guidelines supplemented by domestic regulatory framework (which include national laws and ethics principles) have led to a certain decline in unethical transplant practices around the world. However, such practices have not been eliminated completely and rather continue to acquire new forms in emerging contexts.[1] The onset of the Covid-19 crisis, the surge in global migration and recent conflicts have further exacerbated the challenges to ethical transplantation.[2]

One such major global ethics guidance comes from The Declaration of Istanbul on Organ trafficking and Transplant Tourism (DoI). However, DoI's impact on the actual regulation of transplantation in countries across the globe especially in the Global South has not been analysed. Given this background, the current study was commissioned by the Declaration of Istanbul Custodian Group (DICG) and undertaken by The George Institute for Global Health, India, to understand the interplay between the global principles of the DoI and the domestic regulatory frameworks of six selected Low- and Middle-Income Countries (LMICs). The study maps the relevant organisations and policies of organ transplant within the selected LMICs.

Furthermore, a deeper understanding of the domestic implementation of the organ transplant regulatory framework in each of the select LMICs is offered, by identifying the barriers and enablers to policy implementation, and through such lens, valuable lessons for bodies such as the DICG may be drawn. The study therefore aims to aid the DICG in disseminatingng the DoI principles across diverse country settings.

This may well be a first-of-its-kind empirical study in relation to the DoI principles, backed by an extensive literature review and interview data, which is analysed through credible policy frameworks applied in the health policy domain.

METHODOLOGY

This study relies on qualitative case study methodology.[3] The steps involved in conducting the research in this study are enumerated below.

(a) Identifying research areas and cases for the study

At the start of the study, the researchers conducted a global search of published empirical materials in academic literature pertaining to organ transplant policies and their implementation. A thorough review of the global ethics frameworks on organ transplantation was also done. Thereafter, upon discussion with the DICG expert group for the study, the research questions were finalised. Once the research questions and the agenda of the research was crystallised, the research team set out to select the cases for the study.

1 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*

2 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*

3 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.

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

In order to select the countries as cases for the study, the selection criteria focused on factors such as: diversity of geographies and 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. In addition to these factors, a convenient sampling criterion was also used to identify countries where the DICG network had access to, so to enable recruitment of participants during the empirical stage who could offer rich and honest insights on a sensitive topic such as organ transplantation.

The above factors enabled selection of 6 countries- India, Egypt, Philippines, Costa Rica, Pakistan, and Colombia. The selected countries would together offer thick and rich description in relation to their context that would be helpful for both individual and comparative country analysis.

(b) Data collection Step 1: Desk review of policies

In-order to collect data in relation to each of the countries under study, reliance was placed on multiple sources including text of legislations, administrative rules and guidelines, peer reviewed literature, and other grey literature such as newspaper reports and other relevant information on the web (for a detailed list of sources, **See Annexure 4**).

A framework of 'regulatory architecture map'[4] was used to conduct 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.

After information was captured and systemised under different themes and columns in the regulatory architecture map, policy analysis reports for each country was developed. 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. Thereafter, a meeting was organised with the country- specific DICG expert to discuss the findings. The desk review findings were verified, and based on DICG expert group suggestions, certain modifications were made to update the regulatory provisions in the policy review findings' chapters wherever applicable. These country-specific policy reports can be found enclosed along with specific country chapters in the descriptive report.

(c) Data collection Step 2: Key Informant Interviews

Based on gaps identified in each of the policy review reports and the research questions, the Key Informants Interview **(KII)** process was designed. KIIs were conducted across the six countries/cases (n=24). In this process, diverse set of interviewees (**See, Annexure 6** for interviewee profiles) were approached, and relevant interviews were conducted and recorded during the time period of September 2022- August 2023. The ethics approval for the study including the protocol for the interview was determined as per the terms of the Institutional Review Board (IRB) permission granted by The George Institute for Global Health, India.

(d) Data analysis

In order to analyse the data and obtain a better understand how different micro, meso and macro regulatory factors influence organ transplantation policies and their outcomes, this study leverages the theory of ecological perspective,[5] which is generally used in health systems analysis. Based on triangulation of findings from different sources and synthesis of data, two reports- analytical and descriptive have been drafted.

The Analytical report (Part 1) highlights the findings, key discussion points regarding the study and concludes with limitations associated with this study. Our descriptive report (Part II) follows a more in-

4 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*

5 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*

depth narrative style of explanation wherein each country's domestic framework has been analyzed and lessons on implementation drawn from the key informant interviews have been discussed. This report offers readers a more detailed explanation on how different aspects of ethical transplantation operate and contextual limitations faced within each country. The annexures to this study provide a repository of legislations and policies within each country, as well as web-links of sources from where relevant policy data has been excavated at an individual country level.

FINDINGS

In relation to the analysis of the domestic implementation framework of organ transplant policies, the findings are presented across four broad themes as follows:

1. **Ethically and clinically sound organ transplantation programs**

   The DoI principles #1, #2, #5 and #6 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 (administrative orders) that establish a framework for inter-alia: (i) living organ donation, including regulation on foreigners receiving organs; (ii) deceased donations; and, (iii) have set up committees and regulatory bodies which manage the procurement and distribution process for organ donation. Each of these issues are discussed below:

   (a) Living organ donation- Countries under review have defined broad categories of donors which include both near relatives and other category of persons such as - those with special reasons (India);[6] 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 donations from Filipinos to foreigners. 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.

   Distilled empirical evidence from the interviews indicates that broad definitions of near relatives often tend to create ambiguities and this may allow commercialisation (as the evidence shows from Costa Rica) and coerced donations (evidence from Philippines) to grow. While on the other hand, narrow definitions tend to create impediments in organ donation. For example, while the Indian law recognises affection, attachment or any other 'special reason';[7] however by not defining what these special reasons are, the law tends to create some ambiguity although the ostensible intention may well be to promote altruistic donation.

   (b) Deceased donations 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 or /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, a process 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 emerged as barriers to decreased donations in

6 The term "special reason" is not defined in the Indian law; however, the Authorization Committee generally considers a wide range of altruistic donation cases under this category.

7 Section 9(3), Indian Transplant Act.

Costa Rica, India, Philippines, and Pakistan. In Egypt and Pakistan especially, the interviewees echoed that high cost of instituting a cadaveric donation system was an additional barrier, given that retrieval of organs in a timely manner is an expensive procedure. Further, in India, the Philippines and Pakistan, poorly and unevenly developed medical infrastructure and limited resources for healthcare were articulated as additional key barriers by the interviewees.

Key Informants in the Philippines referred to the need for awareness programmes to sensitize 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.

(c) Presence of various regulatory sites/committees & their constitution- All six countries have set up regulatory committees which undertake responsibilities of inspecting and certifying transplant centers including health facilities and hospitals; framing rules for transplant organizations and professionals; maintaining database of donors and recipients; and helping in coordination of transplant procedures.

Whether such committees showcase diversity in representing members who are part of both medical community as well as those that represent the interest of patients, and are in the nature of advocacy groups is another lens used for analysis in the study. Based on this lens, the findings indicate that evident gap exists in understanding if such diverse representation exists in Colombia and Egypt. Pakistan's framework is characterized by an absence of diversity in representation as regulatory sites often comprise of members from medical community and notable local elites, whereas other stakeholder groups are not represented at all. 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 Committee constituted in India has representation from bureaucrats, medical experts, social workers, legal workers and transplant specialists who are not involved in the transplant. However, such Advisory Committees are not present across all Indian states and such rich diversity is not at all replicated in other regulatory bodies present in India as well as their counterpart in Costa Rica.

Overall, inadequate representation characterized by lack of parity in lay members and medical experts who constitute these regulatory committees often paves way for perceived conflicts of interest as there are no checks and balances on medical practitioners whose professional duties to save patient's lives may conflict with the overall fairness and transparency that is needed in allocation of organs.

2. Trafficking, Transplant tourism, Commercialisation & Financial Neutrality

DoI principles #3, #4 and #9 together prohibit and criminalises trafficking in human organs and trafficking in persons for the purpose of organ removal (TIP for OR) and place a duty on health professionals to prevent such acts including transplant tourism. The DoI principle #4 proposes that organ donation should be a financially neutral act, meaning that donors and their families should neither lose nor gain financially because of organ donation.

Countries we reviewed allow for prosecution against TIP for OR and organ trafficking. The findings in this study 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 is 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. Besides high penalties that each country under review has formulated, countries have prosecuted illegal cases. In-fact the

interviewees echoed that DICG has played a critical role in some instances of policy enforcement 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.8Another 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.

However, a related concept of transplant tourism is missing from the policy texts of countries we reviewed. There is a lack of definition or conceptual clarity regarding transplant tourism within all six jurisdictions. This is despite the concept being defined under the global principles, i.e. the DoI (2018 edition). The DoI defines transplant tourism as travel for transplantation that involves TIP for OR or trafficking in organs or undermine country's ability to provide transplants to own citizens by diverting resources to non-resident patients.

Additionally, all countries prohibit commercialization, with some defining different categories of financial incentives for organ donation and prohibiting them. However, we acknowledge that financial neutrality is a broad term and may go both beyond financial and non-financial incentives. Data in this regard remains limited from the countries reviewed. The regulatory framework in each country does not specify how different heads of financial incentives such as gifts, remuneration, cash transactions are treated. Similarly, there is lack of data on how other forms of biases creep into the system and how non-financial incentives are dealt with such as if patient's waiting lists are tampered and if some patients are accorded more favorable treatment than others.

Whether gratitudinal gifts from recipients to donors constitute an ethical violation, has emerged as another key issue during the empirical findings. 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 Pandora's box of cases, especially in countries where organ markets are rampant as the distinction between gratitudinal gifts and commercialization may get blurred.[9] Key Informants from the Philippines have further echoed such a concern. Therefore, it remains open whether gratitudinal gifts may act as a barrier or a facilitator to increase donations, even while the DoI interprets financial neutrality in a way to ensure that gratitudinal gifts which enrich the donor or the family in any form remains prohibited.

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. The findings on equity in this study focuses upon:

(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.

(b) Management of funding and cost for transplant- This has been studied in relation to a country's score on the UHC (Universal Health Care) index.

8 KII1PH, Policy Maker

9 Danovitch, G. M., Capron, A. M., & Delmonico, F. L. (2021). The true meaning of financial neutrality in organ donation. American Journal of Kidney Diseases, 77(6), 967-968.

10 The findings show that 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.11 Though initially not covered, Organ and Tissue transplant was added as new package under the scheme which includes 6 procedures covering only renal transplant and corneal transplant packages.12 However, coverage of hospitals under the AB PM-JAY scheme remains limited. This leads to an anomalous situation where private hospitals that have the capacity to offer transplantation remain outside the purview of the AB PM-JAY scheme, and those covered under the scheme do not have adequate capacity to offer transplantation.

In Philippines, the 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). However, the interviewees stated that the UHC law is not fully operational yet and the covered packages under PhilHealth remain inadequate to cover all pre and post transplantation costs such as laboratory tests.

In Costa Rica, three consecutive health reform periods mark the country's UHC development process between 1940 and 2000. Renal replacement therapy (RRT) is covered under the UHC scheme. The actual expenses of the living donation are further covered so that the donor is not responsible for them.

In Colombia, healthcare became a constitutional right in 1991 and the country has been moving on its UHC journey since 1991.13 The most recent is Law 1751 of 2015, which gives practical application to the guarantee of healthcare. Organ transplant procedures are covered within the UHC system.

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. 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.

In Pakistan, 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. The program of Sehat Sahulat extends support for kidney and liver transplantations.

Despite the aforesaid measures, the Key Informants informed 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 and expanding transplantation services in public hospitals whilst regulating costs in private hospitals. In Pakistan, while the law envisages financial support for transplants, Key Informants highlighted the need to strengthen the implementation of these. They advocated 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.

(c) Special protection offered to vulnerable groups in matters of transplant- Countries under review strive to protect vulnerable populations including women donors, those with unsound mind and maintain restrictions against minors to be donors. As discussed, certain financial packages are also offered to those under financial distress or poverty. Additionally, some countries like

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

11 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*

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

13 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*

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.

Despite the laws make an attempt to protect different categories of the aforesaid vulnerable groups, overall, gender disparities continue to prevail. For example, key Informants spoke of the gender disparities in both organ donors and recipients. The proportion of women donors donating to their family members was stated 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.

4. Self-sufficiency

While the DoI principle #11 clearly recommends 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 has been leveraged to further understand the concept of self-sufficiency in this study.

Overall, countries face challenges in achieving self-sufficiency in transplantation. Some efforts have been made in placing restrictions on foreigners from receiving organs in the six countries. When foreigners receive organs, stringent regulations are devised to ensure that the system does not favor them over own citizens.

Another lens to study self-sufficiency is accessibility and affordability of organs. Deceased donation has not received adequate uptake in the countries reviewed. 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[14] 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 National 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.[15] 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.

Besides funding, the gap in provisioning of services and infrastructure for transplants outside of big cities have also emerged as a challenge to achieve self-sufficiency, as indicated through evidence from Egypt. Another analysis point for self-sufficiency includes transplant per million population which still remains low in each of the cases under review. The extracted data from 2022 evidences the low rate of pmp, where the figures for the countries under review can be contrasted with some developed countries in North America and Europe.

14 Nundy S. (2022). Why Are So Few Liver Transplants Done in the Public Sector in India and How Can We Improve the Numbers?. Journal of clinical and experimental hepatology, 12(4), 1029–1030. https://doi.org/10.1016/j.jceh.2022.04.019

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

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
USA	43743	130.65
Spain	5385	115.31
Portugal	798	79.01

Source: Global Observatory on Donation and Transplantation, 2022

To sum up, the table below 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	No	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[16] 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

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

DISCUSSION

The countries we reviewed showcase that their domestic policy implementation is reflective of several global principles that are enshrined in the DoI. For example, 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 (stem) 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), maintenance of priority lists for organ allocation, giving priority to own citizens over foreign nationals in organ allocation, protection of those who are minors, those with unsound mind from participating in donation, are some examples where the countries under review show-case an alignment with the global principles of the DoI.

In-fact, several key regulatory provisions such as the incorporation of presumed consent legislation in Colombia, increasing penalty on organ trafficking in Egypt, strengthening trafficking laws in Philippines, placing restriction on foreigners in India, establishing organ transplantation database in Pakistan have in place even before the enactment of the DoI principles of 2008. This indicates that regulating organ transplantation has been on the policy agenda of the countries under study. Such an agenda has further been honed and strengthened with several amendments that took place in the aftermath of the DoI principles of both 2008 and 2018.

However, despite presence of several regulations, and role of diverse policy actors and organisations in the transplant ecosystem; all countries under review continue to face challenges in achieving self-sufficiency. Making transplants accessible and affordable to a large segment of population, and ensuring that transplantation services are delivered in an equitable manner also remains a challenge.

Overall, the study contributes to the larger discourse on organ transplant regulatory framework in two ways: First, the study helps to uncover the set of enablers and barriers that have emerged from the empirical data in context of the six countries. And, Second, the study demonstrates how organ transplantation management is a wicked problem that needs a multi-level action framework. Each of the two issues are set out below.

Enablers and Barriers to Implementation of Organ Transplant Regulations

The synthesized findings help uncover a list of factors that have emerged as enablers and barriers to domestic policy organ transplant framework in context of the six countries that have been reviewed. The role of approximately 50 distinct factors that are said to influence the organ donation practices (positively as an enabler or negatively as a barrier) across the six countries have been distilled from Key Informant Interviews data. A summary of the such enablers and barriers is presented below and its detailed explanation follows in the Analytical report.

Factors influencing the organ transplantation framework

Intra-personal level factors	**Enablers**	One's own knowledge & awareness, age, fitness
	Barriers	One's own cultural, religious beliefs, gender, socio-economic condition
Inter-personal level factors	**Enablers**	Presence of emotionally related, unrelated donors
	Barriers	Cultural belief of family, affiliation to religious group
Institutional factors	**Enablers**	Consent framework, presence of ethics committees, role of transplant coordinator, coordination amongst hospitals, awareness amongst healthcare professionals, requirement of documentary proof, pre-transplant orientation, clear definitions in regulation, victim protection, real time reporting of transplant
	Barriers	Medical tourism
Community factors	**Enablers**	News reports, donation pledges, registry, counseling session
	Barriers	-
Public policy	**Enablers**	Legislation, financing, subsidies, constitution, administrative orders, knowledge of law enforcement authorities, infrastructure to protect dead bodies, funds for organ procurement, country's federal structure, cross-border cooperation
	Barriers	Privatized healthcare, culture of corruption
Financial condition & offering which is an inter-personal factor; Investigation and prosecution framework which is a public policy related condition have emerged as both a barrier and a facilitator/enabler depending upon the context of operation.		

Source: Author's compilation based on the KII data

Organ Transplantation: A Wicked Problem

Given that organ transplantation is influenced by many interdependent factors (as discussed above), managing such complex landscape becomes challenging for regulators and medical practitioners. In such complex scenarios, innovative solutions are often needed to tackle the 'wickedness' of the problem at hand, that often involve multiple stakeholders.[17] However, the analysis of the stakeholders involved and the overall complexity of the system showcase inherent clashes that exist amongst these different stakeholders and policy goals.

For example, organ donation is integrally linked to religious beliefs, therefore religious leaders tend to play a key role in making the organ transplant program a success or a failure. Similarly, while the legislation universally recognizes both family members and even emotionally regulated donors in some countries; the question remains: does this prevent the exploitation of donors? Regulations may well impose an emotional dependency test and regulate ethical practices by doing an 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 the authenticity of relationships when persons are said to be unrelated but emotionally connected.

Similarly, 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, especially when the window to conduct deceased donor transplants remain extremely short.

Another issue is enabling clarity around brain stem death. It remains challenging to educate rural and less educated populations 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. Additionally, the lack of reforms in post-mortem related legislation is another area that directly often conflicts with transplantation timelines and impedes cases of deceased donation especially in situations of deaths where the police is involved who have their own view of the legal formalities. These are some examples of inherent clashes in interests amongst different actors in policy making such as medical profession, government and public at large.

Apart from clashes within the transplantation landscape, there exist inherent clashes between different health policy domains 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. In order to balance interests across the two fields, the nuanced differences between legitimate travel for transplantation and transplant tourism (a distinction recognized by the DoI principles),[18] needs to be more formalized in country specific contexts. The former is imperative when transplantation facilities are not available in a country, and therefore its citizens have to move as 'foreigners' into another country to avail transplants -- yet, the latter remains prohibited as it involves unethical practices. Such realities are currently not factored into legislation and administrative guidelines given that policy actors deal with these issues in specific life-and-death nature of scenarios.

While offering a middle path is difficult to achieve in such scenarios; but tackling these reforms are likely go a long way in improving transplant realities. In the concluding section, we discuss some of the areas where reforms may be strengthened.

17 Conklin, J. (2006). Wicked problems & social complexity (Vol. 11). Napa, USA: CogNexus Institute.

18 Martin, D. E., Van Assche, K., Domínguez-Gil, B., López-Fraga, M., Gallont, R. G., Muller, E., ... & Capron, A. M. (2019). A new edition of the Declaration of Istanbul: updated guidance to combat organ trafficking and transplant tourism worldwide. Kidney international, 95(4), 757-759.

Limitations of the study and future research avenues

The challenge in finding most updated position of regulation in the countries we studied, which necessitated heavy reliance on grey literature during desk review stage especially because the English translated versions of regulations were not readily available; remain some limitations of this study. Furthermore, the KII numbers in the study remains small (n) especially because of several unwilling participants who did not respond to multiple emails, or telephonic requests to participate as interviewees, given the sensitive nature of the topic of study though the participants were assured anonymity.

Nonetheless, the study has identified various avenues for future researchers especially at the confluence of sociology of medical profession, law and regulation as well as ethics. Future research must focus on the empirical analysis of issues such as the effect of representation in different regulatory committees with a focus on the issues surrounding conflicts of interest in more detail. The role of factors such as educational campaigns in boosting deceased donation or how transplant cases are prioritised in the overall clinical systems of the country are other areas ripe for study. The study further shows that money matters: and therefore, the scope of financial neutrality and the grey areas between legitimate compensation to donors and one which paves room for commercialisation are other fecund avenues for scholars and policy-makers to examine.

CONCLUSION

Countries reviewed in this study have enacted strong regulations for organ transplantation and are striving to strengthen their enforcement but despite decades of these regulations being in place, implementation falls short due to the uneven impact of such regulations and conflicts of interest in the stakeholders. The complexity of the transplantation landscape and its inherent clashes with other regulatory frameworks alsocreates problems for implementation. Such problems are exacerbated given the multiple cconstraints and barriers operating at different levels across inter-intra-personal, community and public policy factors. This study therefore remains first of its kind in drawing empirical evidence of policy implementation from the six select countries through rich interview data from diverse stakeholders and has studied transplantation regulations from a broad lens of issues.

Candor demands the recognition that global principles such as the DoI are not reflective of only ideals but have played a role in impacting the transplantation policy landscape in the countries we reviewed. While it is hard to draw an inventory on specific issues where clear global consensus may emerge, in relation to the implementation of principles set out in the DoI, the study has revealed that several context rooted policy lessons emerge from the domestic policy implementation. These policy lessons can be leveraged by global bodies such as the DICG to promote dissemination on organ transplant regulation, especially as the current empirical study shows that unique and local context-driven factors remain vital.

A review of these different context-driven factors further indicate that the organ transplantation regime is highly prone to the process of regulatory capture, i.e. the regulatory regime often ends up favouring certain interest groups rather than protect wider public interest. More often than not, stakeholders including transplant professionals, transplant coordinators, regulatory committees and intermediaries who are set up to protect ethics, end up resorting to or being bystanders in 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. Corruption influences how healthcare is managed in these countries, which influences the management of wait lists, permissions for confirming donations etc. As a result, regulatory capture breeds amongst the countries, and several rampant malpractices of illegal and unethical organ donations persist despite the presence of laws and policies.

Based on the study, we have identified the following areas where future reforms must focus:

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.

Strengthening 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 the lack of evidence trail to meet the threshold under criminal law, the limited capacity of police personnel to ascertain evidence of commercialization from clinical records, the 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 an indifferent, apathetic or hostile culture towards whistle-blowing against criminal acts in settings such as hospitals.

Focusing on 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 lag behind in cadaveric donations especially given the weakness in healthcare systems such as lack of ICU beds, inadequate and timely support for trauma victims, high insurance costs and lack of universal coverage for transplants. Besides governmental support, adequate focus on philanthropic funds is another vital avenue for transplant success.

Similarly, the study shows that the autonomous and enhanced powers granted to the transplant coordinators must be supplemented by resources, training, and funds, as they remain a vital component of the transplant ecosystem.

Managing conflict of interest to prevent regulatory capture- Physicians inevitably perform the dual role of managing their duty of care, protecting the interests of dying patients, and fulfilling best practices for organ and tissue donation. The need for strong ethics guidelines to mitigate these interprofessional conflicts including both real and perceived conflicts of interest remains imperative in country specific context. Similarly, regulatory committees should represent diverse interest (both clinical as well as lay persons) so as to ensure that conflict of interest circumstances are kept in check. Medical associations of some countries[19] have issued ethics guidelines to manage conflict of interest, that can be scaled across more countries.

19 Shemie, Sam D. MD1,2,3; Simpson, Christy PhD4; Blackmer, Jeff MD5,6,7; MacDonald, Shavaun MD8; Dhanani, Sonny MD7,9,10; Torrance, Sylvia MD11; Byrne, Paul MD12,13 on behalf of the Donation Physician Ethics Guide Meeting Participants. Ethics Guide Recommendations for Organ-Donation–Focused Physicians: Endorsed by the Canadian Medical Association. Transplantation 101(5S):p S41-S47, May 2017. | DOI: 10.1097/TP.0000000000001694