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# ORGAN TRANSPLANT LAW: ASSESSING COMPATIBILITY WITH THE RIGHT TO HEALTH

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## I. BACKGROUND AND METHODOLOGY

The development of organ transplant technologies in the 1980s led to a substantial improvement in health outcomes for people whose organs had stopped functioning properly and who were in need of new organs. Initially starting with kidney transplants, techniques and procedures to successfully transplant livers, pancreas and hearts were also developed. However, these organs were in short supply, since rates of cadaver donations (i.e. the donation of organs immediately following death) were, and continue to be low. It is also difficult to find a donor who is a match for the organ donation among the family members of the recipient. In response to this low supply and a high demand for organs of different kinds, unethical practices in organ transplants emerged. The socio-economic group most affected by these practices were those most desperately in need of money- and who were willing to part with vital organs in exchange for monetary consideration. People belonging to lower socio-economic groups were also most vulnerable to being duped or coerced into parting with their organs and were seen to not have access to the legal system as recourse.

Article 12 of the International Covenant on Economic, Social and Cultural Rights (“ICESCR”), recognises the right of everyone to “the highest attainable standard of physical and mental health”.<sup>1</sup> Further, under the General Comment 14 on the Right to the Highest Attainable Standard of Health<sup>2</sup>, there is a ‘minimum core’ obligation on states to prevent the violation of the right to health by third parties. Therefore, states would be in violation of their international obligations under the ICESCR if they fail to prevent unethical and coerced organ transplants. Additionally, as part of their obligations to progressively realise the right to health, states must also ensure that healthcare services are available, accessible, acceptable and of quality. They must thus take measures to ensure that those in need of an organ or tissue transplant, have access to a mechanism whereby they can legally seek a donor. Thus, in 2010, the World Health Assembly endorsed a set of ‘Guiding Principles on Human Cell, Tissue and Organ Transplantation’.<sup>3</sup> These were intended to provide an ‘orderly, ethical and acceptable framework’ for organ transplants, and to inform state policy in a way that ensures the realisation of the right to health.

In India, the Transplantation of Human Organs and Tissues Act, 1994 (“**the Act**”) regulates organ transplants and bans the commercial trade in organs and tissues. This legislation aims to provide a comprehensive legal framework to regulate the removal of organs from living as well as deceased persons. After approximately 23 years since it was enacted, and commercial trade in human organs and tissues was banned, instances of kidney rackets and illegal trade in organs are still being reported. Organ transplants are also out of reach for a majority of the population due to a shortage of organs, inefficient and inequitable allocation of available organs, lack of necessary infrastructure and the high costs of transplants. There is thus a need to assess the functioning of the Act and determine how successful it has been in meeting its objectives.

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<sup>1</sup> UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3.

<sup>2</sup> Committee on Economic, Social and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)

<sup>3</sup> World Health Organisation, WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, as endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA63.22

In the international human rights literature, there are benchmarks and indicators that can be used to assess the compliance of laws with human rights.<sup>4</sup> There are three kinds of indicators - (i) Structural indicators, which focus on the nature, strategy and policy framework of the law, (ii) Process indicators, which measure the ongoing efforts made by duty bearers to implement the law, and (iii) Outcome indicators, which demonstrate the extent to which the law or policy framework has been successful in achieving its intended goal.<sup>5</sup> We draw upon some of this literature to analyse the Act, measuring it against the Structural, Process and Outcome Indicators to assess its compatibility with the right to health. The objective is to evaluate the effectiveness of the law and examine the extent to which its provisions meet the requirements under the right to health.

## A. Legislative History of the Act

Prior to the implementation of the Act, several states had enacted specialised legislation with the intent of regulating organ transplants. Keeping with scientific progress at the time, this legislation often applied only to certain body parts or organs. Some examples of such legislation include the Eyes (Authority for Use for Therapeutic Purposes) Act, 1982 and the Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982 enacted in Delhi, the Maharashtra Kidney Transplantation Act, 1982 and the Bombay Corneal Grafting Act, 1957. Till the late 1980s, only three states (Maharashtra, Tamil Nadu and Karnataka) had passed legislation permitting the procurement of organs from deceased donors. Thus, the need was felt for a comprehensive legislation ‘to regulate the removal of organs from living as well as deceased persons and transplantation of such organs’.<sup>6</sup>

The Act would serve several purposes. *First*, it would provide legal sanction to the removal of organs from persons who have died, by defining ‘death’ as ‘brain-stem death’.<sup>7</sup> *Second*, even though the technology and know-how was now available, the absence of enabling legislation was impeding the ability to legally transplant organs. The Act would thus allow the transplant of human organs and later human tissues. *Finally*, the Act would seek to clamp down on the rampant trade in human organs. In several parliamentary debates, concern was expressed about the ‘blatant exploitation of

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<sup>4</sup> Paul Hunt and Gillian MacNaughton, ‘A Human Rights-Based Approach to Health Indicators’, In Mashood Baderin and Robert McCorquodale (eds.), *Economic, Social and Cultural Rights in Action*, Oxford University Press, pp. 303-330 (2007); Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, 1997, available at <[http://hrlibrary.umn.edu/instrree/Maastrichtguidelines\\_.html](http://hrlibrary.umn.edu/instrree/Maastrichtguidelines_.html)>, accessed on 17th June, 2017; Vienna Declaration and Programme of Action, adopted by the World Conference on Human Rights (1993), available at <<http://www.ohchr.org/EN/ProfessionalInterest/Pages/Vienna.aspx>>, accessed on 17th June, 2017.

<sup>5</sup> Human Rights Indicators: A Guide to Measurement and Implementation, The Office of the United Nations High Commissioner for Human Rights (OHCHR), available at [http://www.ohchr.org/Documents/Publications/Human\\_rights\\_indicators\\_en.pdf](http://www.ohchr.org/Documents/Publications/Human_rights_indicators_en.pdf) (last accessed 14 June, 2017).

<sup>6</sup> Statement of Objects and Reasons, The Transplantation of Human Organs and Tissues Act, 1994

<sup>7</sup> Prior to the enactment of the Act, ‘death’ was only defined under section 46 of the Indian Penal Code, 1860 as ‘*Death of a human being unless the contrary appears from the context*’, and section 29(b) of the Registration of Births and Deaths Act, 1969 as ‘*the permanent disappearance of all evidence of life at any time after live birth has taken place*’.

the poor by the rich' and the commodification of the human body.<sup>8</sup> The need was also felt to protect patients against contracting unnotified diseases from transplanted organs and to eliminate criminal activities involving middlemen and unethical physicians.

### 1. L.M Singhvi Committee Report

To conceptualise this legislation, a committee of medical and legal experts (headed by Dr. L.M. Singhvi) was set up. The terms of reference of this committee were to clarify: (a) the concept and definition of brain death; (b) the need to enact separate legislation to recognise brain death and the legal, medical, and social implications of such legislation; (c) the safeguards that must be adopted to prevent the misuse of the concept of brain death; and (d) the manner in which the concept of brain death should be utilized to facilitate the availability of human organs for transplantation.<sup>9</sup>

The Singhvi Committee Report was submitted in June 1991 and received Cabinet Approval in October that year. In this report, the Committee recommended that primary and subordinate legislation akin to the United Kingdom's Human Organ Transplants Act, 1989 be passed in India with appropriate modifications to account for concerns specific to the country.<sup>10</sup> This legislation should redefine 'death' as 'brain-stem death', and provide for the authorisation and accreditation of hospitals which possess the skilled manpower, equipment and associated facilities for the removal and transplantation of human organs. At any time prior to her death, a person should be able to execute in writing (in the presence of two or more witnesses) an authorisation for the removal of specified organs from her body after her death. Medical care ought to be provided to donors to promote the voluntary donation of organs from living persons. Finally, the Committee recommended that trade in human organs must be prohibited and made a punishable offence.

### 2. The Transplantation of Human Organs Act, 1994

Based on these recommendations, the Transplantation of Human Organs Bill, 1993 ("Bill") was drafted and introduced in parliament. It was passed unanimously by the Rajya Sabha on May 5, 1993 and referred to a Select Committee in December 1993. The Select Committee recommended some minor changes to the Bill, such as the inclusion of in-laws as 'near relatives' for the purpose of organ transplants and provisions for compensating living donors. However, these recommendations were rejected by the Union Cabinet and the Bill was passed in the Lok Sabha on 15 June 1994. It received presidential assent on 8 July 1994, and came into force on 4 February 1995. Rules under the Act were notified in February 1995.<sup>11</sup>

However, even after the Act came into force, several instances of illegal renal transplantations were reported. There was a popular perception that the Act had been ineffective in curbing the

<sup>8</sup> Samiran Nundy, Origin and Genesis of the Transplantation of Human Organs Act, 1994, of India, International Digest of Health Legislation, 1996, 47(1).

<sup>9</sup> Ministry of Health and Family Welfare, Constitution of a Group to examine the proposal for enactment of legislation for use of human organs and their donation for therapeutic purposes, Office Memorandum No. S. 12011/1/91-MS dated February 25, 1991.

<sup>10</sup> Report of the Group Constituted to Examine the Proposal for Enactment of Legislation for Use of Human Organs and their Donation for Therapeutic Purposes 14 (June 1991) (On file with the authors).

<sup>11</sup> Transplantation of Human Organs Rules, 1995 (G.S.R. 51(E)) dated 4 February 1995. These rules were further amended in 2008 vide GSR 571(E) dated 31 July 2008.

commercial trade in human organs, while also hindering genuine cases of organ transplants due to its onerous approval process.<sup>12</sup> Commenting on the functioning of the Act in a letter to the National Medical Journal of India, a leading Nephrologist Dr. MK Mani notes<sup>13</sup>:

*“The stalwarts of the unrelated live donor program continue to do as many transplants as they did before the Legislative Assembly of Tamil Nadu adopted the Act. What is more, they do them with the seal of approval from the Authorization Committee and are therefore a very satisfied lot. The law, which was meant to prohibit commercial dealings in human organs, now provides protection for those very commercial dealings.”*

These issues came to be addressed in a Writ Petition before the Delhi High Court titled *Balbir Singh v. The Authorisation Committee*.<sup>14</sup> In its final order, the Court ordered the setting up of a committee (“**Review Committee**”) to review the functioning of the Act.<sup>15</sup> In its Report<sup>16</sup>, the Review Committee proposed several amendments to the Act and Rules notified under it, and made recommendations which have been summarised in Table 1 below:

<sup>12</sup> Sanjay K. Agarwal, Rakesh K. Srivastava *et al*, Evolution of the Transplantation of Human Organ Act and Law in India, *Transplantation* 2012;94: 110-113.

<sup>13</sup> MK Mani, Letter from Chennai: Making an Ass of the Law, *Natl Med J India*, Vol 10 No. 5 (1997) 242 *as cited in* Sunil Shroff, Legal and Ethical Aspects of Organ Donation and Transplantation, *Indian J Urol*. 2009 Jul-Sep; 25(3): 348.

<sup>14</sup> Writ Petition (Civil) No. 813 of 2004 (Del HC).

<sup>15</sup> The Review Committee was asked to examine: the composition of Authorisation Committees, the process for certifying ‘near relatives’ under the Act, address problems faced due to procedural bottlenecks, the feasibility of setting up Organ Procurement Organisations and data banks to facilitate the dissemination of information on the availability of organs, the feasibility of the creation of a fund to provide donors social incentives and medical aid, as well as ways to prevent the exploitation of donors from lower socio-economic groups.

<sup>16</sup> Ministry of Health and Family Welfare, The Report of Transplant of Human Organs Act Review Committee, 25 May 2005, available at <http://www.prsindia.org/uploads/media/Organ%20transplantation/The%20Report%20of%20the%20transplantation%20of%20human%20organs%20act%20review%20committee.pdf> (last accessed on 19 June 2017).

### KEY RECOMMENDATIONS FROM THE REPORT OF THE REVIEW COMMITTEE

- A national organ transplant program must be set up with a special emphasis on promoting cadaver donations;
- It should be made mandatory for all the ICU/Treating Medical Staff in all hospitals to request relatives of brain dead patients to consider organ donation;
- Hospitals with adequate ICU facilities and availability of specialists to diagnose brain death should be designated as ‘cadaver donor organ harvesting centres’;
- Transplant coordinators should be assigned in hospitals with transplant activity, separate from the Transplant team, to liaise between the treating physician, the relatives of the potential brain-dead donor and the Organ Retrieval and Banking Organisation (at the All India Institute of Medical Sciences);
- The next of kin of the deceased organ donor must be given preferred status in the organ transplantation waiting list if they require organ transplantation in the future;
- Promoting ‘swap operations’ where two different but willing ‘near relative’ donors are permitted to donate their organs in exchange without monetary consideration;
- 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 customised 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;
- Any expenses or loss of income incurred due to organ donation must be compensated;
- Establishing a fund to promote Cadaver Organ Donations.

Table 1: Summary of Recommendations made by the Review Committee set up in Balbir Singh v. The Authorisation Committee

### 3. The Transplantation of Human Organs (Amendment) Act, 2011

Taking some of these recommendations into account, the government introduced the Transplantation of Human Organs (Amendment) Bill, 2009<sup>17</sup> in parliament. This amendment introduced several important changes to the Act: (i) it expanded the definition of ‘near relative’ to include grandparents and grandchildren; (ii) it expanded the ambit of the Act to include tissues; (iii) it provided for the appointment of transplant coordinators in hospitals to facilitate deceased donor donations; (iv) it placed a responsibility on medical practitioners to ascertain whether the deceased person had expressed a wish to donate their organs at any time prior to their death and if not, make the family aware of the option of authorising the donation of the person’s organs; (v) it regulated the donation of organs to foreign nationals, allowing donation only to near relatives; (vi) it provided for swap donations; (vii) it provided for the appointment of Appropriate Authorities and a National Human Organs and Tissues Removal and Storage Network with regional equivalents and (viii) it introduced

<sup>17</sup> Bill No. 136 of 2009.

new categories of offences and made the punishment for violation of the provisions of the Act more stringent.

After being referred to the Standing Committee on Health and Family Welfare<sup>18</sup>, the Transplantation of Human Organs (Amendment) Act, 2011 (“**2011 Amendment**”) was passed on 27 September 2011. However, it came into effect almost three years later in January 2014 and the Rules with respect to the amended Act were only notified in March 2014.<sup>19</sup> The Transplantation of Human Organs and Tissues Rules, 2014 (“**the Rules**”) operationalise the new entities and institutions set up by the 2011 Amendment and provide procedural and technical guidance for people carrying out transplantations under the Act. However, the basic framework of the Act i.e. Authorisation Committees to vet potential organ donors and criminal penalties for commercial trade in organs, remains unchanged. The Act has now been adopted by all states and union territories, except Andhra Pradesh<sup>20</sup> and Jammu and Kashmir<sup>21</sup>. These two states have enacted their own legislation based on the Act.

## B. Methodology

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This study adopts a mixed methodology and has two components: desk-based research and field research. For the desk-based research, the sources of information may be categorised as follows: *primary data*, for which we analysed the Act, the Rules issued under it, and the relevant Government Orders and Resolutions. These also included reports of the parliamentary standing committee, the government-established Expert Committee and Review Committee constituted by the Delhi High Court to outline and review the functioning of the Act, and the recommendations given by them.

The other category was *secondary data*, for which we reviewed all the questions asked in the Lok Sabha and Rajya Sabha on the issue of organ transplantation. We also conducted a literature review of the Act itself, and journal articles on the ethical and moral debates around organ transplantation in the country. Finally, the regulatory mechanisms governing organ transplants in the United Kingdom, the United States of America, Australia and South Africa were mapped.

Quantitative data on enforcement of the Act was acquired through the database of the National Crimes Record Bureau (“**NCRB**”), the websites of State Medical Councils, annual reports of state health departments, and through requests filed under the Right to Information Act, 2005 (“**RTI Act**”). All orders of the High Courts and the Supreme Court, between 1994 and May 2017, have also been analysed to examine trends in litigation under the Act.

To obtain information under the RTI Act, standardised requests were sent to various state authorities tasked with the implementation of the Act. These included the Ministry of Health and Family Welfare, Health Departments of all States, the National Organ and Tissue Transplant Organisation, all the

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<sup>18</sup> The Committee submitted its “Forty-Fourth Report on the Transplantation of Human Organs (Amendment) Bill, 2009” to the Rajya Sabha and Lok Sabha on 4 August 2010.

<sup>19</sup> Vide G.S.R. 218(E), dated 27 March 2014, published in the Gazette of India.

<sup>20</sup> The Andhra Pradesh Transplantation of Human Organs Act, 1995

<sup>21</sup> Jammu and Kashmir Transplantation of Human Organs Act, 1997

Regional Organ and Tissue Transplant Organisations<sup>22</sup>, major government hospitals in Delhi<sup>23</sup>, the State Medical Councils of Delhi and Mumbai, the Delhi Police and Mumbai Police. The replies received after filing appeals were collated to assess enforcement data. The templates for these standardised requests are appended as **Annexure A** to this report.

The second component of this report was field research. For this, semi-structured interviews were conducted to gather insights on the regulatory challenges and the best practices adopted in different states and internationally. The respondents included doctors, patient representatives and organisations working to promote organ donations. The analysis in this Report also benefits from paper presentations and panel discussions at the National Bioethics Conference, 2017 (Pune) and the 4<sup>th</sup> International Conference of the Law and Social Sciences Research Network (New Delhi).

As stated earlier, the Act has been assessed using the benchmarks and indicators developed by Vidhi to analyse the compatibility of laws with the right to health. The Structural Indicators will be used to determine whether the various institutions envisioned under the Act are in place and functional. The Process Indicators will be used to assess whether clear processes are in place for the various functions envisioned under the Act, and whether these processes are being followed. For the purposes of our analysis of the Act in this report, we have combined the Structural and Process indicators, since the assessment of both in this context is linked with each other. In the Outcome Indicators, we analyse whether the Act has been successful in meeting its objectives through criminal enforcement data and litigation under the Act. Since the Act cannot be categorised as a ‘rights-based legislation’, the indicators have been modified to assess its functioning appropriately.

The purpose of this assessment is not simply to measure the provisions, institutions and functional aspects of the Act against theoretical or abstract indicators. These indicators are intended to serve as a normative framework, and changes to improve the functioning of the Act (and health outcomes) have been recommended on this basis.

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<sup>22</sup> The ROTTOs are located at King Edward Memorial Hospital, Mumbai (West Region), the Government Medical College, Chennai (South Region), Post Graduate Medical Education and Research, Kolkata (East Region), Post Graduate Institute, Chandigarh (North Region) and the Guwahati Medical College (North-East Region).

<sup>23</sup> All India Institute of Medical Sciences, GB Pant Hospital, Institute of Liver and Biliary Sciences, Ram Manohar Lohia Hospital and Safdarjung Hospital.

## II. FRAMEWORK OF THE ACT

As stated above, the primary objectives of the Act are to prohibit the commercial trade in organs (punishing illegal transplants) and to provide a legal mechanism for organ donations by living and brain-dead donors (facilitating legal transplants). The Act does this by regulating the provision of healthcare services, and prescribing administrative and criminal penalties for failing to meet the requirements under the Act. Criminal penalties are also prescribed for certain acts outside the healthcare delivery system. Therefore, the provisions of the Act may be broadly categorised as a) those regulating the transplantation of organs and tissues, b) those regulating healthcare providers and hospitals and c) those prescribing penalties for violations of the Act. Each of these categories, and the processes under the Act, are explained in more detail below:

### A. Regulating Organ and Tissue Transplants

The Act regulates the transplantation of human organs and tissues by placing certain obligations and duties on the actors involved in the process. Not complying with these requirements may result in administrative sanctions or even criminal penalties. It envisions 4 situations that may arise when an organ is to be transplanted, and explains the procedure to be followed for each.

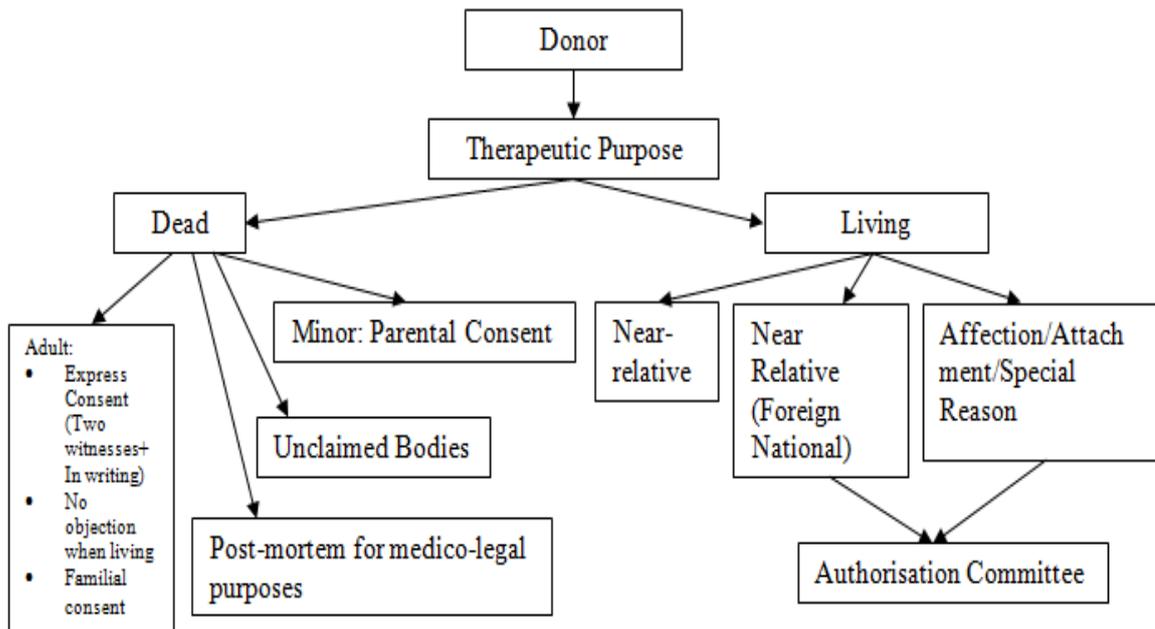


Fig 1: An Outline of the Approval Process for Organ/Tissue Transplants

## 1. Living Donor Transplants

### (a) SCENARIO 1: A living donor wants to donate her organs after her death

At any time before her death, a donor can authorise the removal of any of her organs or tissues (or both) after she has died.<sup>24</sup> Such an authorisation must be made in writing using Form 7 under the Rules, and must be in the presence of two or more witnesses (at least one of whom is a near relative<sup>25</sup> of the donor). If this authorisation has been made, and has not been revoked at any point of time before the death of the potential donor, the person in possession of the body of the person after her death is duty-bound to facilitate such donation.<sup>26</sup> 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 authorised the donation of her organs or tissues.<sup>27</sup>

The National Organ and Tissue Transplant Organisation (“**NOTTO**”) also provides the option of making a ‘donor card’, which authorises the donation of the specified organs and tissues on the death of a person. However, there is no provision in the Act which allows the creation of such cards. Further, the procedural requirements for making a donor card do not comply with the requirements prescribed under section 3(2) of the Act. The legal validity and enforceability of these cards is therefore uncertain.

If a potential donor is admitted to the Intensive Care Unit of any hospital, the registered medical practitioner (“**RMP**”)<sup>28</sup> is under a duty to ascertain from her if she has authorised the donation of her organs or tissues, and to obtain the documentation for such authorisation.<sup>29</sup> If the potential donor has not authorised donation, the RMP must make her aware that she has the option to donate her organs after her death.<sup>30</sup> If the person consents to donation, ‘brain-stem death’ is certified by a Board of medical experts upon her death.<sup>31</sup> The Human Organ Retrieval Centre<sup>32</sup> is then informed by the hospital (in writing) about the authorised donation for necessary action.<sup>33</sup>

<sup>24</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(1)

<sup>25</sup> For the purposes of the Act, the term ‘near relative’ only includes spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson and granddaughter.

<sup>26</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(2)

<sup>27</sup> The Transplantation of Human Organs and Tissues Rules, 2014, Rules 5(4)(a) and (b)

<sup>28</sup> The Transplantation of Human Organs and Tissues Act 1994, § 2(n) [defines an RMP as any medical practitioner who possesses a recognized medical qualification as defined in the Indian Medical Council Act, 1956, and is enrolled on a State Medical Register]

<sup>29</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(1A)(i)

<sup>30</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(1A)(ii)

<sup>31</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(5)

<sup>32</sup> The Transplantation of Human Organs and Tissues Act 1994, § 2(ha) [A Human Organ Retrieval Centre has been defined as a hospital (i) which has adequate facilities to treat seriously ill patients who can be potential donors of organs in the event of death and (ii) which is registered under section 14(1) of the Act]

<sup>33</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(1A)(iii)

**(b) SCENARIO 2: A living donor wants to donate her organs before her death:***(i) To a near relative*

The Act permits the transplantation of human organs and tissues if the donor and recipient are near relatives. Near relatives must seek approval from an Authorisation Committee before the organ can be transplanted.<sup>34</sup> The Authorisation Committee must be hospital-based if it conducts more than 25 transplants annually.<sup>35</sup> For institutions with less than 25 transplants a year, the State or District level Authorisation Committee can grant approval.<sup>36</sup>

This approval is also considered necessary as non-related persons may forge documents to pass off as near relatives, making it ideal that applications be vetted by the Authorisation Committee in all cases.<sup>37</sup> An application is therefore to be made to the Authorisation Committee in the format prescribed in Forms 1 and 11 of the Rules (including documentary proof specified in these forms).

Appeals against the decision of an Authorisation Committee lie before the Central and State governments.<sup>38</sup> In practice, these appeals are heard by the respective Health Department/Ministry of the State and Union governments. Further appeals also lie before the High Courts in exercise of their Writ Jurisdiction.

*(ii) To a near relative who is a foreign national*

Before an organ or tissue can be donated to a near relative who is foreign national, approval must be sought from the Authorisation Committee of the hospital, district or state.<sup>39</sup> If the Authorisation Committee is satisfied that the requirements under the Act have been met, they will grant approval for the removal and transplantation of the organ. If not, it will reject the application and record its reasons in writing. It must be noted that the donation of organs or tissues to foreign nationals who are not near relatives is not permitted under the Act.

*(iii) To a person who is not a near-relative*

The person may donate their organs or tissues to any person who is not a near-relative, only for reasons of affection or attachment towards the recipient or for any other 'special reasons'.<sup>40</sup> This

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<sup>34</sup> The Transplantation of Human Organs and Tissues Rules 2014, Rule 18

<sup>35</sup> The Transplantation of Human Organs and Tissues Rules 2014, Rule 11(4)

<sup>36</sup> The Hospital, District and State Authorisation Committees do not constitute separate tiers, but are co-equal in status. An applicant may approach the Hospital Authorisation Committee, or the District/State Authorisation Committees if one has not been set up at the hospital. [Vandana Dixit v. Visitor, Sanjay Gandhi Post-Graduate Institute of Medical Sciences 2010 SCC OnLine All 2660].

<sup>37</sup> The Transplantation of Human Organs and Tissues Rules, 2014, Rules 12&13 [These Authorisation Committees are composed of the Medical Director/Superintendent of the Hospital, two senior medical practitioners, two people of high integrity and social standing, the Secretary (Health) or their nominee and the Director (Health Services) or their nominee from the state government.]

<sup>38</sup> The Transplantation of Human Organs and Tissues Rules, 2014, Rule 33

<sup>39</sup> The Transplantation of Human Organs and Tissues Act 1994, § 9(1)(1A)

<sup>40</sup> The Transplantation of Human Organs and Tissues Act 1994, § 9(3)

affection, attachment or ‘special reason’ must be demonstrated to an Authorisation Committee, which will grant approval to the transplant if it is satisfied about the altruistic nature of the donation.

The Act also permits a special kind of arrangement known as ‘swap donations’. In this arrangement, a ‘first donor’ who is willing to donate to the ‘first recipient’ and a ‘second donor’ who is willing to donate to a ‘second recipient’ are required. If the first donor is biologically compatible as a donor for the second recipient and the second donor is biologically compatible with the first recipient, the parties can enter into an agreement whereby organs are donated and received within the group according to biological compatibility.<sup>41</sup> However, the approval of the Authorisation Committee must still be sought before the donations take place.

All donations envisioned in scenario 2 are only permitted if the donation is for therapeutic purposes and the donor is an adult who is of sound mind.<sup>42</sup>

## 2. Cadaver Transplants

### (a) SCENARIO 3: The potential donor consented to donation before her death

The RMP is duty-bound, in consultation with the transplant co-ordinator (if available) to find out from the near relatives of the donor whether she had, at any time before her death, authorised the removal of any of her organs or tissues after death.<sup>43</sup> Inspired by protocols followed in the United States of America,<sup>44</sup> this ‘required request’ has garnered support from several experts.<sup>45</sup> However, it is considered by some as unfeasible and premature, and in many cases, has not been implemented.<sup>46</sup> If such a request is made, however, RMPs must obtain the related documentation and follow the process outlined in scenario 1 above.

### (b) SCENARIO 4: The potential donor did not consent to donation before her death

#### (i) *Consent by Family*

The RMP is duty-bound to make the near relatives of the potential donor aware about the option to authorise or decline the donation of organs or tissues.<sup>47</sup> Any person lawfully in possession of the dead body can authorise the removal of any organ or tissue if a) no objection was expressed by the potential donor with respect to organ donation prior to her death<sup>48</sup> and b) no near relative objects

<sup>41</sup> The Transplantation of Human Organs and Tissues Act 1994, § 9(3A)

<sup>42</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(1)

<sup>43</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(1)(1A)(i)

<sup>44</sup> S.K. Gupta, *Drug Discovery and Clinical Research* (Jaypee Brothers, 2011) 203

<sup>45</sup> S. Shroff *et al*, *Cadaver Organ Donation and Transplantation- An Indian Perspective*, *Transplantation Proceedings*, 35, 16 (2003).

<sup>46</sup> Sanjay Nagral & J Amalorpavanathan, *Deceased Organ Donation in India: where do we go from here?*, *IJME Vol XI No 3 July-September 2014*, 164

<sup>47</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(1A)

<sup>48</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(3) [However, they cannot make such an authorisation if they have reason to believe that an inquest may have to be carried out on the body under law,

to the donation.<sup>49</sup> If the deceased person is a minor, her parents can authorise the removal of her organs or tissues for therapeutic purposes.<sup>50</sup> Before removing any organs or tissues, ‘brain-stem death’ must be certified by a Board of medical experts.<sup>51</sup> Once the donation has been authorised, the Human Organ Retrieval Centre is then informed by the hospital (in writing) for necessary action.<sup>52</sup>

If the family refuses such a donation, however, an additional problem may occur. While ‘brain death’ is sufficient for organ donation under the Act, the person is still not considered ‘dead’ until cardiac arrest or ‘cardiac death’ has occurred. This is because, while the Act defines death as ‘brain death’, the term ‘death’ has been defined differently under the Indian Penal Code, 1860 (“IPC”) and the Registration of Births and Deaths Act, 1969. Even though ‘brain death’ may have occurred, it is then legally not permissible to disconnect the patient from the ventilator and stop medication till the ‘cardiac death’ of the patient.

*(ii) 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 or prison can authorise the removal of any organ or tissue from the body.<sup>53</sup> However, they should not authorise the removal of organs if they have reason to believe that a near relative of the person is likely to claim the dead body, even though they haven’t made this claim within 48 hours.

*(iii) Post-mortem for medico-legal purposes*

The person empowered to authorise the removal of organs under the Act can give such approval where the dead body has been sent for a post-mortem examination due to medico-legal reasons (such as the death of the person having been caused by an accident or unnatural causes) or for pathological purposes. However, the person authorising such removal of organs must ensure that the deceased person had not expressed an objection to donating their organs or tissues before their death. In practice, therefore, when a post-mortem is required after the death of a person, the RMP 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.<sup>54</sup>

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or if they have been entrusted possession of the body solely for the purposes of internment, cremation or disposal]

<sup>49</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(3)

<sup>50</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(7)

<sup>51</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(5)

<sup>52</sup> The Transplantation of Human Organs and Tissues Act 1994, § 3(1A)(iii)

<sup>53</sup> The Transplantation of Human Organs and Tissues Act 1994, § 5

<sup>54</sup> The Transplantation of Human Organs and Tissues Rules, 2014, Rule 6

## B. Regulation of Hospitals and Healthcare Providers

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In addition to regulating the grant of approval and the process of organ transplantation, the Act also regulates hospitals where organ and tissue transplants take place, as well as tissue banks. It mandates that no hospital or tissue bank shall undertake the removal, storage or transplantation of human organs or tissues unless they are registered under the Act.<sup>55</sup> For this purpose, each state must appoint one or more officers as Appropriate Authorities under the Act. These Authorities are empowered to grant, renew, suspend or cancel the registration of hospitals, and to enforce standards that have been prescribed for hospitals undertaking transplantation activities and tissue banks which test, store or distribute tissues.<sup>56</sup> They can also investigate any complaint of breach of any of the provisions of the Act and take appropriate action. Finally, they can inspect tissue banks and hospitals periodically to ensure compliance with the provisions of the Act and Rules notified under it. To carry out their functions under the Act, they have been vested with the powers of a civil court under the Code of Civil Procedure, 1908.<sup>57</sup> They can therefore summon any person in relation to a violation of any provisions of the Act, order the discovery or production of any document or material object and issue a search warrant for any place where it is suspected that unauthorised or illegal organ transplants are taking place. The Act also provides for the constitution of Advisory Committees to aid and advice the Appropriate Authorities in their functioning.<sup>58</sup>

## C. Criminal Sanctions for Commercial Dealings

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As part of its enforcement mechanism, the Act also provides for criminal penalties for committing the offences specified under the Act. These include removing a human organ or tissue without authority and indulging in any commercial or illegal dealings in human organs. The latter include making or receiving any payment for the supply of a human organ, seeking a person who is willing to supply an organ in return for payment, publishing an advertisement offering to supply, buy or sell a human organ, and forging documents to establish that a person is donating their organ as a near-relative or for reasons of affection or attachment.<sup>59</sup>

No court can take cognizance of an offence except on a complaint by an Appropriate Authority.<sup>60</sup> A complaint may also be made by a person who has given the Appropriate Authority 60 days' notice of the alleged offence and her intent to make a complaint to the court. Further, only a Metropolitan Magistrate or Judicial Magistrate can take cognizance of an offence under the Act.

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<sup>55</sup> The Transplantation of Human Organs and Tissues Act 1994, § 10

<sup>56</sup> The Transplantation of Human Organs and Tissues Act 1994, § 13

<sup>57</sup> The Transplantation of Human Organs and Tissues Act 1994, § 13B

<sup>58</sup> The Transplantation of Human Organs and Tissues Act 1994, § 13A

<sup>59</sup> The Transplantation of Human Organs and Tissues Act 1994, § 19

<sup>60</sup> The Transplantation of Human Organs and Tissues Act 1994, § 22

### III. COMPATIBILITY WITH THE RIGHT TO HEALTH

In assessing a law enacted to curb trafficking and trade in human organs, it is important that the problem is not reduced to one of the supply and demand of organs and tissues, Authorisation Committees and organised crime. In accordance with the demands of a rights -based approach, the focus must remain on the victims of organ trade and on the availability of organs to patients in need of transplants. Therefore, in this section, the provisions of the Act are assessed against human rights indicators to determine the extent to which the Act meets these objectives, and what improvements must be made to it.

This assessment employs the following colour code to indicate the degree of compatibility with the right:

	The Act is incompatible with the Right to Health in this respect
	The data available is insufficient to make an accurate assessment of this indicator
	The Act satisfies the requirements of the Right to Health in this respect

#### A. Structural and Process Indicators

The principles that the Act is assessed against are accountability, participation, non-discrimination, transparency, human dignity, rule of law and the framework of availability, accessibility, acceptability and quality (“AAAQ Framework”) identified as essential components of the international right to health under General Comment 14 of the ICESCR.

We have developed structural, process and outcome indicators that embody these principles and the AAAQ Framework, and which can be used to assess the compatibility of legislation with the right to health. Structural indicators help analyse the scheme of the legislation, process indicators attempt to assess the working of these provisions, and outcome indicators measure the extent to which the legislation is achieving its objectives.

For the purposes of this report, the structural and process indicators have been considered together, since they are integrally linked. For instance, if one of the structural indicators is ‘does the Act provide for grievance redressal mechanisms?’, this would naturally be followed by a process indicator that would analyse this with the question ‘have these mechanisms been set up and how do they function?’. Therefore, in the table presented below, ‘Indicator’ in the first column usually refers to the structural indicators, while ‘Analysis’ in the second column, in several instances, involves an assessment of the legal provision in question using process indicators. ‘Compatibility’ in the third column is determined by combining the response to the structural indicator and the analysis.

Given the manner in which the Act has been drafted, the following components are assessed separately against international human rights principles and the AAAQ Framework: institutional framework, grievance redressal, the provision of services and benefits, and resources and budget.

## 1. Accountability

Indicator	Analysis	Compatibility
<b>Institutional Framework</b>		
Does the Act set up institutions/forums for its implementation?	Instead of relying on pre-existing bodies, the Act sets up separate authorities for its implementation. These include Authorisation Committees (which grant approvals to transplants), Appropriate Authorities (to register hospitals, enforce common standards and to investigate any violations of the Act) and Advisory Committees (to assist the Appropriate Authorities in their functioning). The functions of these authorities are prescribed in the Act itself.	
Are these institutions independent/autonomous? Or do they fall within governmental control?	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.  In practice, the Authorisation Committees & appropriate authorities are government appointed and controlled. The Zonal Transplant Co-ordination Committee in Mumbai is unique in this respect as it has representatives from all stakeholders. However, it only deals with cadaveric organ allocation.	
How many institutions are required to implement the Act? Do these institutions function part-time or have they been specifically set up for the Act?	The Act sets up separate institutions to implement, or assist in implementing all its major functions. However, none of the functionaries are full-time members and are usually appointed from the government or from pools	

	of doctors working in government or private hospitals.	
Is there a time-limit under which the provisions of the Act need to be implemented?	The Act does not prescribe such a limit. This is reflected in the functioning of the Act, with the 2014 Rules, which operationalise the 2011 Amendment to the Act, being brought into force almost 3 years after the Act was amended by Parliament.	
Has the State made international commitments in relation to the subject matter covered under the Act? If yes, does the Act give effect to these commitments?	In 2010, the 63 <sup>rd</sup> World Health Assembly endorsed the 'WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation'. India has also signed and ratified the United Nations Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children- which defines 'human trafficking for organ removal'. Finally, India is bound by the United Nations' ICESCR. The enactment of the Act itself is a step towards giving effect to these international commitments. However, the Act does not facilitate or promote equity in access to organs and organ transplants. It also criminalises the victim of trafficking. In these respects, it may violate India's obligations under these international instruments.	
Are there constitutional provisions that give effect to the international commitment/s?	The Right to Health has been judicially recognised as a part of the Right to Life under article 21 of the Constitution, which includes the right to access healthcare (and by extension procedures such as organ transplants). However, so far, there have been no specific pronouncements on the right to access organs for transplants as a part of this right. Further, the criminalisation of the victims of human organ trafficking	

	also arguably constitutes a violation of their right to health, bodily autonomy and human dignity.	
Is there an enforcement mechanism under these international conventions to ensure compliance by State parties? Is this mechanism effective?	The protocols and covenants that India is party to do not provide for remedies under international law for cases of organ trafficking. Instead, they require that domestic remedies be made available for these purposes ( <i>See e.g., United Nations Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, Art. 5</i> ).	
<b>Grievance Redressal</b>		
Does the Act prescribe a forum for the resolution of grievances?	The Act provides for the appointment of an Appropriate Authority, which is empowered to investigate complaints of breach of any of the provisions of the Act. Further, appeals against the decisions of the Authorisation Committees lie before the Appellate Authority, and then the High Court of the respective state.	
Is there a pre-judicial mechanism for lodging complaints against alleged breaches?	Yes, the Appropriate Authority set up under section 13 of the Act acts as a pre-judicial authority to investigate offences, and refer them to a Metropolitan Magistrate or Judicial Magistrate for criminal prosecution.	
Does the Act have in place suitable enforcement mechanisms?	In addition to criminalising the removal of human organs or tissues without authorisation, and commercial and illegal dealings in organs, the Act also criminalises the contravention of any other provisions of the Act. These offences are cognizable by the Appropriate Authority and the Courts, and are subject to their inherent powers.	
Does the Act clearly define offences and contraventions?	As demonstrated by the judicial confusion with respect to the	

	<p>interpretation of the provisions of the Act, (<i>see infra</i> 2(b) under Outcome Indicators), the standards for non-compliance, and what constitutes a criminal offence under the Act, are vague and imprecise. There is need for legislative guidance on the burden of proof for such offences.</p> <p>However, conditions and standards for the registration of transplantation centres, organ retrieval centres and tissue banks as well as the consequences of non-compliance, are provided for under the Rules.</p>	
Is grievance redressal accessible to everyone? (for e.g., can anyone file a complaint?)	Anyone can make a complaint to the Appropriate Authority. However, criminal complaints under the Act can only be filed by the Appropriate Authority, or by any person after a one-month notice to the Appropriate Authority.	
Is the procedure for filing a complaint complicated?	Apart from the requirement to give notice to the Appropriate Authority before filing a complaint, the procedure is similar to that of any criminal complaint filed under the Criminal Procedure Code, 1973.	
Are sufficient powers bestowed upon the grievance redressal authority under the Act?	Yes. Under section 13B of the Act, the Appropriate Authority has been granted the powers of a civil court to try a suit under the Code of Civil Procedure, 1908. This includes the power to summon any person who has information related to the violation being investigated, ordering the discovery or production of any document or object, and issuing a search warrant for a place suspected to be in violation of the provisions of the Act.	
Is the reliability and credibility of information used in	Similar evidentiary standards and requirements as prescribed under	

investigation ensured through direct evidence and corroboration?	the Indian Evidence Act, 1872 are applicable to proceedings under the Act. Further, the reliability of information is ensured through informal procedures such as police verification of documents before a transplant is approved (provided for under Rule 14).	
Is decision making time-bound?	No, the Act does not prescribe time limits for the decisions taken by the various authorities set up under it. However, Rule 23 requires the Authorisation Committee to expedite its decision-making process where the patient requires the transplant on an urgent basis.	
Does the grievance redressal body assume jurisdiction <i>suo motu</i> on becoming abreast of a situation?	Under section 16, the Act explicitly grants the Appropriate Authority the power to take <i>suo motu</i> action in case the Authority is made aware of the commission of an offence under the Act. However, this is very rarely done.	
<b>Services and Benefits</b>		
Does the Act enumerate duties that ought to be complied with by service-providers?	Rule 5 contains a list of duties of RMPs under the Act. These include counselling 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.	
Does the Act ensure compliance and accountability by service providers?	Yes, the registration of service providers may be cancelled by the Appropriate Authority if they do not comply with the conditions set out under the Act and Rules. Criminal prosecution may also be initiated if it is suspected that the hospital or transplant centre has committed any of the offences under the Act. In practice, however, this power is rarely exercised. As a result, service providers often remain unaccountable and do not face	

	repercussions for non-compliance with the Act.	
Has the State framed standards/guidelines on the manner in which each health service and good is to be provided?	NOTTO has recently notified allocation policies for several organs such as Cornea, Heart, Liver and Kidneys, which includes standard operation protocols to retrieve these organs. However, these have not been uniformly adopted and currently vary from state to state. Further, the Rules specify standards and guidelines for the registration of transplant hospitals, organ retrieval centres and tissue banks.	
<b>Resources and Budget</b>		
Does the Act set up a fund for the collection of fines/penalties?	Fines and penalties are not collected under the Act.	
Does the Act envisage alternative sources of revenue (other than penalties) for improving the implementation of the Act?	No alternative source of revenue is envisaged under the Act.	
Does the Act envisage a framework for tracking out of pocket expenditure?	The Act does not provide a framework to track expenditure by the patients. While the Act prohibits any payment to a donor in return for their organ/tissue, the donor may still be reimbursed for the cost of removing, transporting or preserving the organ, and compensated for the expenses or loss of earnings due to the organ transplantation procedure.	

## 2. Participation

Indicator	Analysis	Compatibility
<b>Institutional Framework</b>		
Does the Act envisage a mode of implementation that uses public participation?	Public participation is provided for through the Advisory Committees. These Committees, set up under	

	<p>section 13A, consist of two social workers (one of whom is a representative from a women's organisation), a legal expert and a representative from non-governmental organisations ("NGOs") working in the field of organ donation or human rights.</p> <p>However, it does not provide for feedback or stakeholder input in the implementation of the Act. Further, these Advisory Committees do not exist in most states.</p>	
If yes, can all civil society groups and communities participate?	The Act explicitly allows social workers and NGO representatives on the Advisory Committees. However, patients and patient groups might not have a say in its implementation.	
Does the Act envisage participation in preliminary stages of decision-making only? Or can communities and groups participate at all levels of decision-making?	The Act does not specify at what stage the Advisory Committee can give its suggestions and recommendations to the Appropriate Authority. The Rules currently also do not specify how often it is supposed to meet, on what issues it can give recommendations to the Appropriate Authority and whether these recommendations would be binding. It is unlikely that the practice with respect to Advisory Committees is uniform across states.	
<b>Grievance Redressal</b>		
Are public hearings, where affected individuals can represent their grievances, an element of the grievance redressal machinery?	The Act does not provide for public hearings on the issue of organ trafficking.	
<b>Services and Benefits</b>		
Are the relevant stakeholders consulted while framing rules or standards under the Act?	Though the ambit of the functions of the Advisory Committee are not specified, it may be presumed that they can also advise the	

	Appropriate Authority on issues related to the provision of services.	
Does the Act specify the extent to which human resources are required for its implementation?	The Act provides for the setting up of various authorities and positions in hospitals. The composition and number of people that must serve on Authorisation Committees and Advisory Committees has been specified under the Act. Further, even though the exact manpower in hospitals is not specified, some guidance is provided under the Rules (under Rule 26 as a condition and standard for the grant of a certificate of registration for organ or tissue transplantation centres). Hospitals and transplant centres must maintain this strength to ensure that their license is not revoked.	
<b>Resources and Budget</b>		
Does the Act envisage a process through which beneficiaries can have access to funds to avail of services?	The Act does not take into account the issue of lack of access to the services that it is regulating. It is presumed that persons undergoing transplants can afford them. As a result, 95% of transplants are currently performed in the private sector. (See Press Information Bureau, Need to dispel Myths, Misconception, Superstitions surrounding Organ Donation: J P Nadda, 27 November 2015)	
Do service-providers and beneficiaries have a say in the allocation of funds under the Act?	No, the allocation of funds allocated by the Ministry of Health for the implementation of the Act is the sole purview of the executive.	

### 3. Non-Discrimination

Indicator	Analysis	Compatibility
<b>Institutional Framework</b>		
Does the Act target persons with a certain health status only? Or all persons?	Benefits under the Act are available to all Indian citizens, and foreign citizens to a limited extent.	

Does the Act identify any particular groups that are vulnerable to exploitation? If yes, is there a mechanism to account for that risk?	Yes, women are identified as a group vulnerable to be required to donate their organ owing to their socio-economic status and social hierarchies. Therefore, 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.	
Is there scope for regulatory authorities to exercise subjective discretion in the implementation of the Act?	Even though the Act does not explicitly state this, Authorisation Committees usually take into account differences in the economic status of the donor and recipient and the impact this can have on the informed consent of the donor.	
<b>Services and Benefits</b>		
Does the Act recognise discrimination by service providers as a violation?	No, the Act does not contain provisions requiring that service providers not discriminate against patients. Even in the absence of explicit discrimination, it may be argued that such discrimination is inbuilt due to the high cost of transplantation procedures.	
Is there recourse available to beneficiaries under the Act, in the instance they are denied access to services?	The denial of services does not constitute an offence or violation of any of the provisions of the Act. Therefore, no such recourse is available.	
Does the Act impose a specific duty upon service providers to adopt a fair and equitable process for accessing services?	No, the Act does not impose any obligations to ensure a fair and equitable process for accessing services.	

#### 4. Transparency

<b>Institutional Framework</b>		
Do affected parties or groups have access to monitoring reports and findings relating to the implementation of services under the law?	Rule 32 requires that yearly reports must be published on the operation of the Organ Transplant Registries and shared with contributing units and other stakeholders. However, the	

	<p>Central and State Health Ministries do not release separate monitoring reports and findings with respect to the implementation of services under the law. The only information available is through the annual reports of the ministries, and the information in these reports is very limited.</p> <p>Further, there is no way for patients and the public to know about the success rates and outcomes of organ transplants carried out in the country.</p>	
Is information about services easily available under the Act?	<p>The population may ask for information under the RTI Act. However, not all the states maintain detailed information about the provision of services and functioning of the law. Importantly, however, there is (as of now) no national registry of transplants. Thus, information on the availability or organs and waiting lists is not easily accessible.</p>	
<b>Grievance Redressal</b>		
Is there transparency in the decisions rendered by authorities set up under the Act? For e.g., are their orders in writing?	<p>Both the Authorisation Committee and Appropriate Authority are required to record the reasons for the decision taken by them in writing (Rule 23), and copies are to be sent to the recipient or patient.</p>	
In case a service-provider fails to provide reasons for denying a service to a beneficiary, what is the recourse available to the beneficiaries?	<p>The Act does not provide for a remedy in case a service provider denies services to a patient, since access to such services is not recognised as a right.</p> <p>If Authorisation Committees were to be construed as a service provider (in so far as they allow or prevent transplants from taking place), appeals against their orders lie before the State and Central government.</p>	
<b>Services and Benefits</b>		

Does the State maintain centralised data on the services and goods provided under the Act? Who can access this data?	Some state governments maintain centralised data on organ and tissue transplantation. However, this is not uniform across states. Some states make this information available on their websites, but it can mostly only be accessed through a request under the RTI Act.	
<b>Resources and Budget</b>		
What is the budget as a percentage of the overall health expenditure by the State that is spent on the operationalisation of the Act?	For the states, budget expenditure on the Organ Transplant Programme varies from state to state. Under the 12 <sup>th</sup> Five Year plan, Rs. 149.5 Crore has been allocated to the National Organ Transplant Program. It started in 2009 with a budget of Rs. 149 Crores. However, further information on how these funds are utilised is not available, making it difficult to assess if this allocation is sufficient.	
Can the budget related documents, or books of accounts of service providers be accessed by members of the public?	Some information related to budget allocation may be accessed on the websites of the Union and State Ministries/Departments of Health. However, a detailed break-up of the activities to which funds have been allocated is not usually available.	

## 5. Human Dignity

<b>Institutional Framework</b>		
Does the Act envisage mechanisms to protect private data and confidentiality to ensure privacy of the individual?	The Rules prescribe Data Protection and Confidentiality as a condition for registering Tissue Banks under the Act. A unique donor identification number must be used for each donor, and access to donor records must be restricted. Under Rule 32, while determining the eligibility of the applicant to donate, the applicant must be personally interviewed by the Authorisation Committee and this process must be	

	videographed and the minutes of the interview must be recorded.	
<b>Grievance Redressal</b>		
Are there special arrangements for victims of a traumatic experience?	Apart from grievance redressal in the form of a criminal complaint, the Act does not contain special provisions for the victims of traumatic experiences such as organ trafficking.	
<b>Services and Benefits</b>		
Is there a requirement of informed consent under the Act?	Under section 12 of the Act, the RMP 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.	

## 6. Rule of Law

<b>Institutional Framework</b>		
What other Central and State Acts are relevant to the operation of the present act? Are the provisions of the present law harmonised with the provisions of other central and state laws?	<p>The various state laws regulating the retrieval and transplant of human organs that were operating at the time that the Act was enacted were repealed once it came into force. Subsequently, Andhra Pradesh and Jammu &amp; Kashmir enacted separate legislation based on the Act.</p> <p>Currently, three other laws are relevant to the operation of the Act. There is a need to harmonise the relevant provisions to ensure the smooth functioning of the Act. <i>First</i>, the term ‘death’ is defined under the Act as ‘brain-death’. However, the term is also defined under the IPC and the Registration of Births and Deaths Act, 1969 (Discussed in Part IV).</p>	

	<p><i>Second</i>, the Act defines ‘mental retardation’ as defined under the Persons with Disabilities Act, 1995, which has now been repealed. It must also be harmonised with the Mental Healthcare Act, 2017 (Discussed in Part IV).</p>	
<p>Are there versions of the law in different languages? Do the provisions of the law have the same meaning in all languages?</p>	<p>As part of standard practice, the Act is available in English and Hindi. On a plain reading comparison, the Act has the same meaning in both those languages.</p>	
<p>Can regulatory authorities under the Act frame rules/bye-laws/regulations? Can they set standards/indicators to assess compliance?</p>	<p>Under Rule 32, the Advisory Committee is required to set the norms for Data Collection Frequency and other related matters. NOTTO has also released Standard Operating Procedures with respect to organ retrieval and transplantation, and more guidance is usually provided through Government Resolutions, which are legally binding.</p>	
<b>Grievance Redressal</b>		
<p>Does the body set up under the Act follow any established rules of procedure in its investigation?</p>	<p>Rules 17-20 prescribe the procedure to be followed by the Authorisation Committee during the scrutiny of applications for transplantation with respect to near relatives (Rule 18), persons other than near-relatives (Rule 19) and foreigners (Rule 20). However, a similar procedure has not been prescribed for the Appropriate Authority and Advisory Committee.</p>	
<p>Is there a clearly set out appeals process?</p>	<p>Yes, under Rule 33, any person aggrieved by an order of an Authorisation Committee or Appropriate Authority can file an appeal before the Central Government (in case of Union Territories) or State Government (in case of States). This appeal must be filed within 30 days from the day that the order is received.</p>	

7. Availability, Accessibility, Acceptability and Quality (AAAQ)

Institutional Framework		
Are unmet healthcare needs addressed under the Act?	<p>The Act regulates the transplantation of human organs and tissues with a view to ensure the availability of these organs and tissues to patients who need transplantation. To this limited extent, it addresses unmet healthcare needs.</p> <p>In practice, however, there are large gaps between the demand for, and availability of organs for transplant. (See NDTV, In Numbers: The Status of Organ Donation in India, July 25, 2016)</p>	
Is there a provision for collection of data on the availability of health facilities, goods, services and programmes for specific demographic groups such as infants, older persons, ethnic groups etc.?	<p>Under Rule 32, the National Registry on Organ Transplants must include demographic data about the patient, donor, hospitals, recipient and donor follow up details, transplant waiting list etc.</p> <p>The collection of similar data is also prescribed for in Organ Donation Registries and Tissue Registries. However, with the exception of Tamil Nadu, Kerala and Rajasthan, these registries have not been set up.</p>	
Is there any provision for monitoring the ratio of skilled health workers to the population needs in the Act?	<p>The Act does not specifically prescribe a ratio of skilled health workers to the population needs. This is a major shortcoming, since there is a major shortage of skilled transplant surgeons in the country (See Indian Express, Surgeon shortage shows why too few transplants in India, 14 June 2016)</p>	
Does the Act provide for health promotional activities?	<p>Under Rule 31, the National/State Human Organ and Tissue Removal and Storage Networks are required to undertake Information Education and Communication (“IEC”) Activities for the promotion of deceased organ and tissue donation.</p>	

Does the Act address the rights of non-citizen populations like migrants?	Foreign citizens can seek authorisation for organ transplants under the Act. Importantly, perhaps, while the Act generally criminalises any commercial transactions in human organs, there are no special provisions addressing trans-national organ trafficking under the Act.	
<b>Grievance Redressal</b>		
Can third persons file a complaint on behalf of victims?	The Act does not explicitly state the categories of persons who can file a complaint before the Appropriate Authority. However, the Appropriate Authority is empowered to investigate any complaint of a violation of the provisions of the Act. Further, only the Appropriate Authority can file a criminal complaint against an offence committed under the Act. Any other person can only file this complaint after giving a month's notice to the Appropriate Authority. Persons and organisations working on organ donation and human rights have on numerous occasions filed public interest litigations on the issue of organ donation and trafficking.	
Does the Act envisage monitoring to ensure implementation of grievance resolution?	No, the Act does not incorporate a mechanism to systematically monitor the outcome of grievances and disputes under the Act.	
Does the Act grant sufficient jurisdiction to admit relevant disputes?	Yes, both the Appropriate Authority and courts have been granted jurisdiction to investigate and pass orders with respect to any violations of any of the provisions of the Act. The provisions outlining these offences are also broadly worded to potentially include any possible issue that may arise with respect to commercial dealings in organs or organ trafficking.	
<b>Services and Benefits</b>		

Is the State under an obligation to undertake research and development to promote technological developments in the context of the Act?	No, the Act does not place an obligation on the State or any authorities set up by it to undertake research and development activities to promote technological developments in the field of organ and tissue retrieval and transplants.	
Is there a legal obligation to inform beneficiaries and persons affected about their rights under the Act, especially for persons who are illiterate?	As stated above, the obligation to undertake IEC activities is limited to raising awareness about organ and tissue donation after death. The Act does not place a legal obligation to inform and generate awareness among vulnerable communities about the harms of organ trafficking, the offences under the Act or the remedies available to them if they are faced with commercial organ trading.	
Can persons situated in remote areas access the services?	The Act only regulates organ transplants where the service is already available. It does not account for the (lack of) availability of these services in any other areas. This is a major issue in organ transplantation, as these services are usually not available in rural and geographically inaccessible areas. Even in the cities where transplant services are available, they are largely provided in the private sector. Often, when cadaveric donations take place in the public sector, the organs end up being used in the private sector where only the financially well off can afford treatment.	
<b>Resources and Budget</b>		
Are the services financially affordable? Does the Act envisage any mechanism to ease the financial burden on the poor and vulnerable sections?	Organ transplants are prohibitively expensive in most states. However, the Act does not envisage a mechanism whereby economically weaker sections of society can access these services. In addition, currently the cost of transport, storage of the organ (in cadaver donation) is borne	

	by the recipient. So, besides the cost of the procedure these additional costs place those who can afford them at a natural advantage.	
Does the Act envisage any insurance cover that can make the service accessible?	No, the Act does not envisage any insurance cover for persons in need of organ transplants or victims of organ trafficking. However, some government insurance schemes cover certain kinds of organ transplants (see Part IV).	

The above table demonstrates that the Act, by and large meets the international human rights standards set up for structural indicators. It makes provisions for the right institutional framework, including provisions setting up the necessary authorities, enforcement mechanisms and avenues for grievance redressal. However, as the process indicators demonstrate, these provisions will remain largely hollow if State Governments fail to set up these authorities under the Act. Information that we have obtained under the Right to Information Act suggests that several of these authorities exist only on paper. The objectives of the Act, which are expressed through its legal structure, have not been translated into practice. This is made even more apparent in the second section by considering some of the outcome indicators, which test whether the Act achieves the objectives with which it was enacted.

## B. Outcome Indicators

As explained above, the Act was enacted with the primary purpose of a) preventing organ trade by criminalising the buying and selling of human organs and b) carving out an exception for, and regulating, ‘legitimate transplants’ i.e. those involving organs that have been voluntarily donated either to a near-relative or out of reasons of love and affection. The implicit reason for such an exception is the recognition that people often need organ transplants so that their bodies can function properly and sometimes so that they can survive. Assuring a legitimate process to procure such organs therefore becomes an obligation of the State, to ensure that its citizens can enjoy the ‘highest attainable standard of physical and mental health’. In this section, we undertake an analysis to measure these ‘outcomes’ of the Act, i.e. the criminal prosecutions and legitimate transplants arising from it.

To determine whether the Act has been successful in achieving its objectives, we would have to examine if instances of commercial dealings in human organs have been punished under the Act (and whether the Act has deterred people from attempting to buy or sell human organs, though this would be tougher to measure). Further, whether those who are in need of organs, are able to get them in a legitimate manner and through informed and voluntary consent. The assumption is that if everyone who needs an organ is able to acquire it legitimately, there would be no need of a ‘red market’ for the commercial trade in organs. Therefore, this illegal market will reduce considerably in volume and the exploitation of poor and vulnerable people will be avoided.

## 1. Criminalising Trade in Human Organs

As stated above, to determine whether the Act has helped in the realization of the right to health, one of the elements that would have to be examined is if the mechanisms set up through it have been successful in detecting, prosecuting and punishing trade in human organs. A simple way of doing this would be to see what proportion of actual commercial dealings in human organs is prosecuted and offenders convicted. However, we do not have reliable estimates of the denominator, i.e. the total number of commercial transactions for human organs. Therefore, we will have to rely on available data on criminal enforcement to assess the functioning of the first element listed above.

Despite the lack of data, it is widely known that there is a thriving underground market dealing with buying and selling human organs.<sup>61</sup> In the course of our research and interviews, we also came across numerous instances of people having entered into agreements for the sale and purchase of human organs. It may thus be presumed that a substantial number of such commercial transactions are currently taking place in the country. Comparing this with enforcement data under the Act, however, paints a stark picture of non-implementation.

As explained above, the Act criminalises commercial dealings in human organs and tissues. It also broadly criminalises a violation of any of the provisions of the Act. To initiate criminal action, a complaint must first be made to the Appropriate Authority, which has the power to investigate and impose administrative sanctions (such as suspending or cancelling the registration of hospitals and tissue banks). If it believes that a criminal offence has been committed, it can then make a complaint to the Metropolitan Magistrate or Judicial Magistrate of the First Class.

Based on the replies to the requests filed by us under the RTI Act, neither the States nor the Union Ministries maintain centralised data on the complaints heard and adjudicated by the Appropriate Authorities. Therefore, we have limited our analysis to the criminal proceedings taking place in the formal criminal justice system (i.e. complaints filed before the police and heard in court).

A concern that may be raised about analysing the functioning of the Act is that since the last amendment to the Act was made in 2011, and rules under the Act came into force only in 2014, it might be too early to assess whether it has met its objectives. However, it must be noted that the primary provisions of the Act, i.e. the criminal provisions, and those setting up the Authorisation Committees and Appropriate Authorities, have been a part of the Act and in effect since it was enacted in 1994. The 2011 amendment did not introduce any changes to these basic provisions that form the structural framework of the Act. We therefore study the functioning of the Act since 1994.

However, despite having been enacted in 1994, the National Crime Records Bureau (“NCRB”) did not record data on cases under the Act till 2014. Therefore, enforcement data is only available for the years 2014 and 2015, which might be inadequate to properly assess the functioning of the Act for all

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<sup>61</sup> See SCOTT CARNEY, *THE RED MARKET* 61 (2016, Hachette Pvt Ltd); Priyanka Vora, *The illegal organ trade thrives in India- and it isn't likely to end soon*, 15 August 2016 available at <<https://scroll.in/pulse/813993/the-illegal-organ-trade-thrives-in-india-and-it-isnt-likely-to-end-soon>> (last accessed on 18 August 2017); Rebecca Bundhun, *India's dire need for organs still fuels a deadly trade*, 5 June 2016 available at <<https://www.thenational.ae/world/india-s-dire-need-for-organs-still-fuels-a-deadly-trade-1.195654>> (last accessed on 18 August 2017); Scott Carney, *Indians buy Organs with Impunity*, 2 August 2008 available at <<https://www.wired.com/2007/02/indians-buy-organs-with-impunity/>> (last accessed on 18 August 2017).

years since 1994. However, even this limited data serves as an indicator of how the Act has failed to curb or even detect instances of commercial dealings in human organs and tissues.

#### (a) Enforcement by the Police

The criminal provisions under the Act constitute cognizable offences i.e. a police officer can make an arrest under the Act without a warrant.<sup>62</sup> They are also non-bailable, and therefore bail cannot be claimed as a matter of right or due procedure and a special application must be made to a court which may grant bail on a discretionary basis.

In 2014, only two cases were reported under the Act, one from Delhi and one from West Bengal. However, no arrests were made. In Punjab, a charge-sheet<sup>63</sup> was filed in one case. One person in Andhra Pradesh and one in Punjab was under trial, but they were both out on bail at the end of the year. For a detailed state wise break-down of this activity, see Annexure B.

	Male	Female	Total
Persons arrested during the year	0	0	0
Number of persons charge-sheeted	1	0	1
Persons on bail at the stage of investigation at the end of the year	0	0	0

Table 2: Disposal by Police in 2014

In 2015, there was a slight increase in activity, with 15 cases being filed across the country. The proceedings under the Act by the police are summarised in the table below:

	Male	Female	Total
Persons arrested during the year	13	1	14
Number of persons chargesheeted	10	1	11
Persons on bail at the stage of investigation at the end of the year	3	0	3

Table 3: Disposal by Police in 2015

<sup>62</sup> The Code of Criminal Procedure, 1973 sec 2(c); First Schedule

<sup>63</sup> A formal document of accusation that is presented in Court and summarises the charges framed against the accused.

**(b) Enforcement by the Courts**

Once a complaint has been filed and the chargesheet framed, the case then proceeds to the trial stage. At this stage, the accused may apply for bail, and the court (usually a magistrate of the First Class) decides whether the accused is guilty.

In 2014, there were only two cases at the trial stage, one in Andhra Pradesh and one in Punjab. The details of the trial stage of these cases are summarised in the table below:

	Andhra Pradesh	Punjab	Total
Persons on bail during the investigation stage at the beginning of the year	0	1	1
Persons chargesheeted	0	1	1
Persons on bail during trial stage at the beginning of the year	4	0	4
Total number of persons under trial	4	1	5
Persons on bail during trial stage at the end of the year	4	1	5

Table 4: Trial stage cases in 2014

In 2015, the increase in the number of cases filed was also reflected at the trial level, with the number of persons under trial increasing from 5 in 2014 to 16 in 2015. Trial stage activity under the Act in 2015 is summarised below:

	Male	Female	Total
Persons on bail during the stage of trial at the beginning of the year	5	0	5
Number of persons under trial	15	1	16
Persons in custody during the stage of trial at the end of the year	9	1	10
Persons on bail at the end of the year	6	0	6

Table 5: Trial Stage Cases in 2015

As may be noticed from the data above, very few cases are filed under the Act and taken to trial. Though there is no reliable data on the number of commercial deals with respect to human organs taking place in the country, it may be presumed that it is much larger than reflected in the data above. Finally, for both years, there were no convictions recorded under the Act. While data for a longer time period would be necessary to draw a definitive conclusion, the data currently available indicates that the Act is failing to detect and prosecute such commercial dealings.

In addition to the criminal justice system, the Act also envisions action against erring medical practitioners. If a medical practitioner is convicted under section 18(1) of the Act for the removal of a human organ without authority, the Appropriate Authority is required to report the practitioner to the respective State Medical Council.<sup>64</sup> The State Medical Council must remove the name of the practitioner from the register of the Council for a period of three years (for the first offence) and permanently for subsequent offences.<sup>65</sup> Replies by the Maharashtra Medical Council and Delhi Medical Council to requests under the RTI Act revealed that neither State Councils have suspended any medical practitioners under this provision so far.

## 2. Regulating Legitimate Organ Transplants

As listed above, in addition to criminalising the buying and selling of human organs, the Act also provides a mechanism for the legitimate transplant of organs. According to the replies we received to the requests filed by us under the RTI Act, the states do not maintain centralised data on the number of approvals granted by Authorisation Committees. Appeals against an order of an Authorisation Committee lie before the State and Central Governments.<sup>66</sup> However, data with respect to these appeals is also not available. The next level of appeal is in the form of a writ petition before the High Court. Litigation under the Act at the level of the High Courts and Supreme Court is therefore the most reliable indicator of activity under the Act regulating legitimate transplants. It is also useful to look at this data as questions with respect to the legal interpretation of provisions under the Act can only be litigated at these fora.

### (a) Categories of Litigation

For our analysis, we looked at all the cases litigated in the High Courts and Supreme Court from 1994 to May 2017, to examine the most common litigants and categories under which cases were litigated.<sup>67</sup>

First, we looked at the categories of litigants who brought cases under the Act. For the purposes of this categorisation, cases bought by the families of the patient were clubbed with the category of cases bought by the patients themselves or by donors. The different categories of litigants and the proportion of cases are represented in figure 2 below.

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<sup>64</sup> The Transplantation of Human Organs and Tissues Act, 1994; Section 18(2).

<sup>65</sup> Id.

<sup>66</sup> The Transplantation of Human Organs and Tissues Act, 1994; Section 17

<sup>67</sup> Search was conducted using the search terms “transplantation of human organs act”, “transplantation of human organs and tissues act”, “organ trade” and “kidney racket”. Results were triangulated through inquiries on the following legal databases: sconline, manupatra and indiankanoon. We identified 122 cases, which were narrowed down to 95 cases based on relevance.

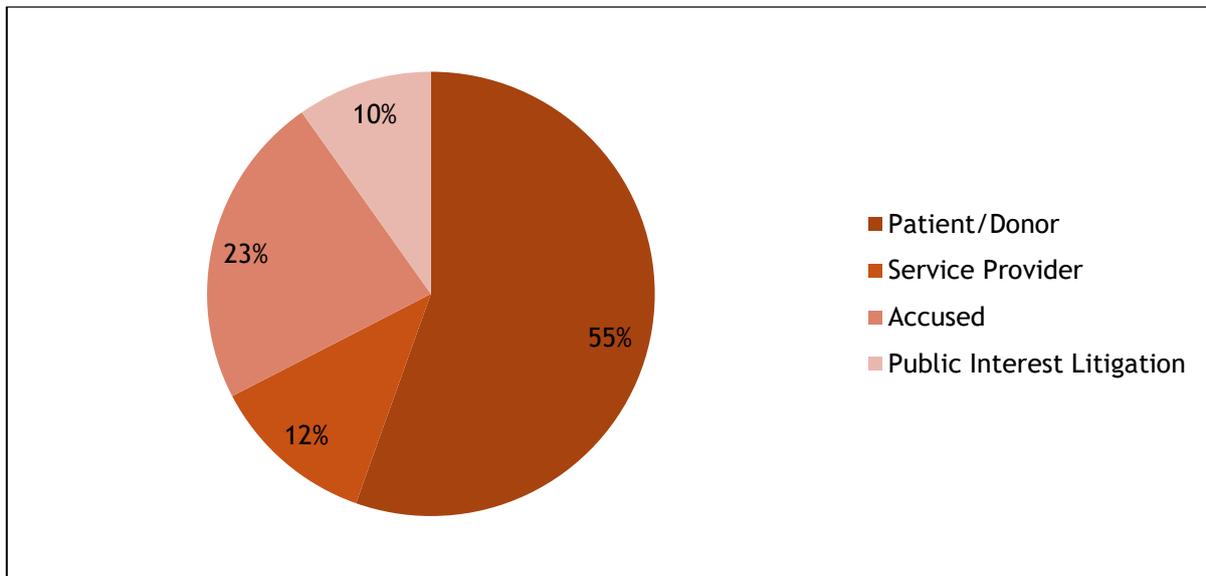


Fig 2: Categories of Litigants under the Act

From the above figure, it may be seen that more than half of the cases under the Act (55%) are brought by potential organ recipients and donors. These cases are usually appeals against inaction by, or decisions of, the Authorisation Committees. If litigation initiated by service providers is added to this, it may be seen that 67% of litigation under the Act is by actors trying to access or provide access to legitimate organ transplants. Appeals by persons accused of a criminal offence under the Act constitute only 23% of cases, by category of litigant.

Next, we looked at the grounds on which petitions were being filed under the Act. For this, the cases were split into seven categories: Ambiguity in the Act, Appeals against Orders of Authorisation Committees, Criminal Case/Bail, Petitions directing authorities to act, Public Interest Litigation, Petitions challenging the cancellation/non-renewal of hospital registrations under the Act and other petitions. Some of these categories are not necessarily mutually exclusive. For example, cases where ambiguous provisions in the Act were under question, arose out of appeals against orders of the Authorisation Committee. However, these have been categorised separately—in cases of appeal against Authorisation Committee orders, the courts decided the question of whether the transplant sought, in the given fact situation, was legitimate and allowed under the Act. A graphical representation of this categorisation is as follows:

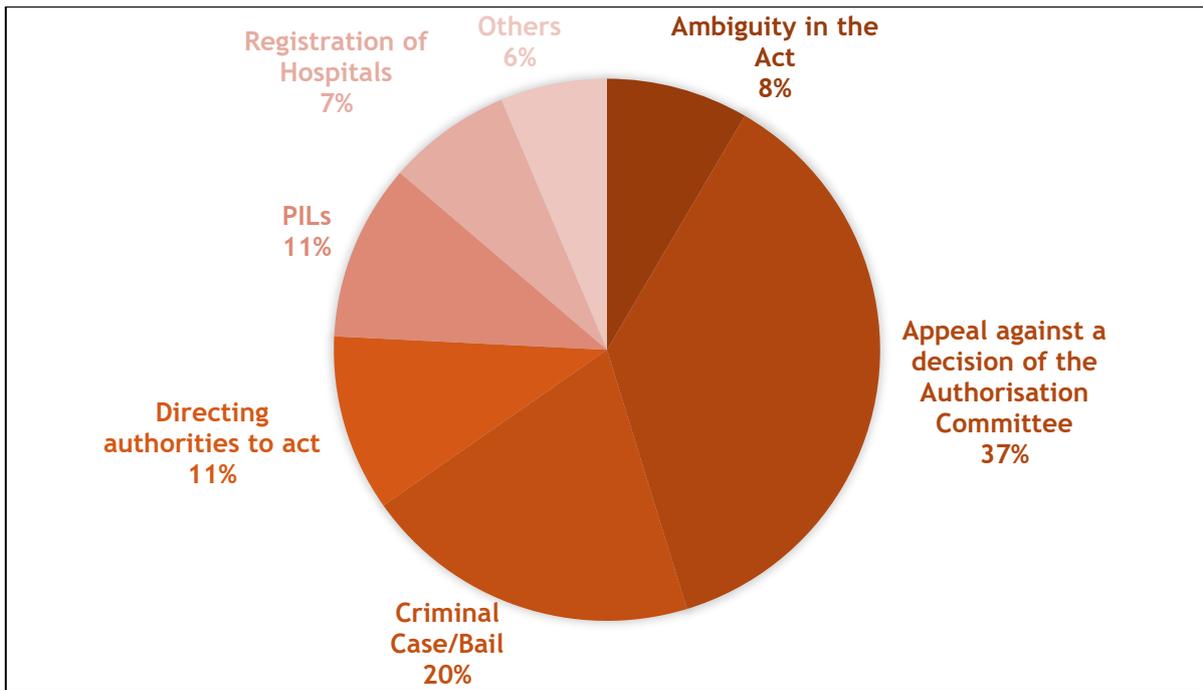


Fig 3: Grounds for Litigation under the Act

From the above figure, it can be seen that appeals against decisions of Authorisation Committees are the most common reason for litigants under the Act to approach the courts. The categories of cases under ‘ambiguity in the Act’ and ‘directing authorities to act’ are also filed to seek permission for organ transplants. If these categories are combined, it may be seen that 56% of cases litigated under the Act are by donors and their families seeking permission for organ transplants. In comparison, only 20% of cases litigated under the Act are with respect to the criminal offences under the Act. About half of these criminal cases are applications seeking the grant of bail.

It may thus be concluded that a majority of cases litigated under the Act in the High Courts and Supreme Court relate to grievances of patients seeking recourse before the courts to gain access to organs required for transplants. In comparison, cases related to arguably the primary provisions under the Act i.e. those imposing criminal sanctions constitute only a small proportion of total cases.

### (b) Trends in Litigation

An analysis of the cases identified above also demonstrate some patterns that shed light on the litigation taking place under the Act. Some of these are as follows:

#### (i) Jurisdictional Issues

There has been a degree of uncertainty with respect to the jurisdiction that is exercised by the Authorisation Committees. Disputes arising out of this area have found their way to the courts, and the Courts have clarified some of these issues.

In *Kuldeep Singh v. State of Tamil Nadu*,<sup>68</sup> the donor and recipient were from the state of Punjab, but the transplant was sought to be conducted in Tamil Nadu. The Authorisation Committee in Tamil

<sup>68</sup> (2005) 11 SCC 122.

Nadu refused to issue a No-Objection Certificate, stating that the Authorisation Committee in Punjab was the competent authority for this purpose. The Supreme Court agreed with this contention, and held that since both the donor and recipient were from Punjab, they were required to seek the approval of the Authorisation Committee in Punjab. This was because since the legislative intention under the Act was to determine the “true intent” behind the donor’s willingness to donate his or her organs, the Authorisation Committee where he or she resides would be best placed to do this.

Following this judgment, rule 6(b) was inserted in the Rules through the Transplantation of Human Organ Rules, 2008. This rule stated that the legal and residential status of the donor and recipient shall be established by state-level committees through no-objection certificates (“NOCs”). Thus, if the domicile of the donor, recipient and state of transplantation are different, NOCs would have to be sought from each state, and the approval of the Authorisation Committee is to be taken from the institution where the transplant is to take place.

This gave rise to further confusion, with some state-level committees refusing to grant these NOCs on different grounds. In *Sadhna Bhardwaj v. The Department of Health and Family Welfare*,<sup>69</sup> the petitioner’s application for the grant of an NOC from the Delhi authority to undergo a transplant in Kolkata was rejected by the authority on the grounds that there was no proven relationship between the potential donor and recipient. The Delhi High Court clarified, on a plain reading of Rule 6(b), that approval is mandatory only at the place of the intended transplant, and not at the state of domicile of the donor or recipient. The Punjab & Haryana High Court, in a case where an Authorisation Committee in Kolkata rejected an application on the grounds that the potential recipient’s domicile was in Punjab, re-iterated this position.<sup>70</sup>

A provision similar to Rule 6(b) has now been incorporated in Rule 14 of the 2014 Rules. However, this provision now states that if the donor or recipient belongs to a state different from the state where the transplant is to take place, the residential status shall be verified by the Tehsildar or any other officer authorised for this purpose in the format under Form 20.

Another issue with respect to jurisdiction arose in *Mukesh Gandhi v. Deputy Secretary (Health)*,<sup>71</sup> where the potential recipient was a resident of Ahmedabad. She sought a transplant in Delhi or Hyderabad due to higher success rates in these cities. However, her application to procure the organ in Ahmedabad and transplant it in Delhi was rejected by the State Government. This order was struck down by the Gujarat High Court, reasoning that the Act does not explicitly prohibit an organ being procured in one state and transplanted in another.

### (ii) *Burden of Proof to Approve Transplants*

Another recurring issue in litigation under the Act has been a lack of clarity with respect to the basis for approval or rejection of transplants by Authorisation Committees. In *Kuldeep Singh v. State of*

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<sup>69</sup> 184 (2011) DLT 510

<sup>70</sup> Vinay Kumar v. State of Haryana AIR 2012 P&H 160

<sup>71</sup> AIR 2009 Guj 7

Tamil Nadu,<sup>72</sup> the Court stated that the burden to prove that the donation is happening for reasons of love and affection lies on the applicants:

*“The burden is on the applicants to establish the real intent by placing relevant materials for consideration of the Authorisation Committee. Whether there exists any affection or attachment or special reason is within the special knowledge of the applicants, and a heavy burden lies on them to establish it. Several relevant factors like relationship if any (need not be near relationship for which different considerations have been provided for), period of acquaintance, degree of association, reciprocity of feelings, gratitude and similar human factors and bonds can throw light on the issue.”*

Some guidance for Authorisation Committees to make decisions with respect to grant of approval for transplants is provided under rule 7(3) of the 2014 Rules, which states that in cases where the potential donor and recipient are not near relatives, the Authorisation Committee must:

- (i) *“evaluate that there is no commercial transaction between the recipient and the donor and that no payment has been made to the donor or promised to be made to the donor or any other person;*
- (ii) *prepare an explanation of the link between them and the circumstances which led to the offer being made;*
- (iii) *examine the reasons why the donor wishes to donate;*
- (iv) *examine the documentary evidence of the link, e.g. proof that they have lived together, etc.;*
- (v) *examine old photographs showing the donor and the recipient together;*
- (vi) *evaluate that there is no middleman or tout involved;*
- (vii) *evaluate that financial status of the donor and the recipient by asking them to give appropriate evidence of their vocation and income for the previous three financial years and any gross disparity between the status of the two must be evaluated in the backdrop of the objective of preventing commercial dealing;*
- (viii) *ensure that the donor is not a drug addict;*
- (ix) *ensure that the near relative or if near relative is not available, any adult person related to donor by blood or marriage of the proposed unrelated donor is interviewed regarding awareness about his or her intention to donate an organ or tissue, the authenticity of the link between the donor and the recipient, and the reasons for donation, and any strong views or disagreement or objection of such kin shall also be recorded and taken note of.”*

Before this provision was incorporated through the 2014 Rules, the parameters on which the Authorisation Committees were expected to base their decisions to approve or reject transplant requests were not very clear. Even after some guidance has now been provided, several facets of the approval process remain unclear.

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<sup>72</sup> (2005) 11 SCC 122, at 127.

For example, the High Courts have taken different approaches to whether the Authorisation Committees are required to *conclusively establish* that a commercial transaction has taken place with respect to the organ transplantation, or if a reasonable apprehension as to the involvement of a commercial element is enough. In *Anees Ahmed v. State of U.P.*,<sup>73</sup> for example, the Allahabad High Court stated that the Authorisation Committee must give an explicit finding to the effect that there was a commercial transaction or there was a likelihood of a commercial dealing. The High Courts have ruled in a similar manner on at least five other occasions.<sup>74</sup>

In other cases, the courts have adopted a lower evidentiary standard. For example, in the case of *Mohammad Sulaiman v. Union of India*,<sup>75</sup> the Delhi High Court, in rejecting the petition to grant approval for an organ transplant, noted that the donor and recipient had only met eleven days ago, and therefore there was a high likelihood that a commercial element was involved. Similarly, in *Poonam Gupta v. State of Punjab*,<sup>76</sup> in hearing an appeal against orders of the Authorisation Committee and Appellate Authority, the Punjab & Haryana High Court noted that since the family members of the potential organ recipient hadn't come forward to offer their organs, and a clear relationship between the donor and recipient could not be established, there was a possibility of a commercial element to the transaction. In *Pawan Anand v. Director General of Health Services*,<sup>77</sup> the financial disparity between the donor and recipient was the ground for the rejection of the application to approve a transplant. In these cases, therefore, a *mere apprehension* of the involvement of a commercial element in the transplant was sufficient grounds to reject the application.

In the last category of cases, on the other hand, the courts have been very liberal in approving organ transplants. They have thus not considered discrepancies in the evidence presented to establish a relationship between the donor and recipient as sufficient ground to reject applications to approve transplants.<sup>78</sup>

While the law is sufficiently lucid about the documentary and evidentiary requirements that must be met by applicants seeking approval for an organ transplant, it does not clearly specify the grounds on which an Authorisation Committee ought to approve or reject an application for an organ transplant. The result is a diversity of judicial opinion, as set out above.

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<sup>73</sup> 2012 SCC OnLine All 4427

<sup>74</sup> *Belson Baby v. State of Kerala* W.P.(C) No. 23868 of 2015 (Ker HC)(Unreported); *Latheefa E. v. State of Kerala* W.P.(C) No. 8339 of 2013 (Ker HC)(Unreported); *S. Samson v Authorisation Committee* AIR 2008 Mad 227; *Jaswinder Singh v. State of Punjab* 2008 SCC OnLine P&H 576; *Rajinder Kumar v. State of Punjab* AIR 2005 P&H 172

<sup>75</sup> 2016 SCC OnLine Del 5197

<sup>76</sup> 2009 SCC OnLine P&H 4572

<sup>77</sup> 2012 SCC OnLine Del 4145

<sup>78</sup> *S Malligamma v. State of Karnataka* ILR 2004 Kar 5078; *Noushad KK v. Chairman* W.P.(C) No. 31925 of 2010(M); *Mohammed Sali v. State of Kerala* 2012 SCC OnLine Ker 30178

## IV. RECOMMENDATIONS

Based on our assessment of the provisions of the Act against the Right to Health indicators, and its functioning, we recommend the following legislative and policy changes:

### 1. The definition of ‘death’ should be harmonized across different laws

Section 2(d) of the Act defines ‘brain-stem death’ as ‘the stage at which all functions of the brain-stem have permanently and irreversibly ceased’. Brain-stem death is a pre-condition for cadaver organ donation, and must be certified in accordance with section 3(6) of the Act.<sup>79</sup> The Board for certifying brain death must consist of the registered medical practitioner in charge of the hospital in which the brain-stem death has occurred, an independent registered medical practitioner and a neurologist/neurosurgeon.<sup>80</sup> However, the term ‘death’ is also defined under other legislation in different contexts. Section 2(b) of the Registration of Births and Deaths Act, 1969 defines ‘death’ as the ‘permanent disappearance of all evidence of life at any time after live-birth has taken place’. The term is also defined under section 46 of the IPC as ‘the death of a human being, unless the contrary appears from the context’.

In practical terms, there is a difference between how the term ‘death’ is defined under the Act, and how it is defined under both the Registration of Births and Deaths Act, 1969 and the IPC. Brain-stem death may have occurred in a person, even though there has not yet been a ‘permanent disappearance of all evidence of life’. A common manifestation of this inconsistency is patients in whom brain-stem death has occurred, but who are plugged to a ventilator or other forms of life support. They may, therefore, continue to show signs of ‘life’, such as a heartbeat, a pulse, and in some cases even involuntary movement.

As a result of this inconsistency, a person may be certified “brain dead” for the purposes of the Act, but are not yet “dead” for the purposes of the Registration of Births and Deaths Act, 1969 and the IPC. Thus, while the Act may permit the organs of such a person to be removed, such a removal may constitute an offence under the IPC since the person is still alive for the purpose of the IPC. Even though there have not been reports of cases having been filed on this basis, this inconsistency in the law has led to uncertainty about when organs can legitimately be retrieved from a cadaver. There is therefore a need to harmonise the definition of ‘death’ across these laws, to ensure the smooth functioning of the Act.

In 2017, a public interest litigation was filed in the Kerala High Court asking for directions to curb the alleged widespread malpractice of declaring a patient ‘brain-dead’ incorrectly with the intention of harvesting their organs for transplantation.<sup>81</sup> The petitioner submitted that instead of using an EEG test to determine brain-death, hospitals were relying on apnea tests instead, which are less reliable. The Court noted that compared to apnea tests, EEG tests were easily available. Apnea tests were also considered to be last-stage confirmatory tests. It therefore recommended that the Central and State Governments should consider issuing directives on the subject.

<sup>79</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 2(d).

<sup>80</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 3(6)

<sup>81</sup> Dr. S. Ganapathy v. State of Kerala W.P.(C) No. 5552 of 2017 (Ker HC).

Reference may also be made to the ‘Clinical Criteria for the Determination of Death’ issued by the World Health Organisation.<sup>82</sup> It recommends that a ‘brain-death’ algorithm should be formulated to explain how death ought to be determined in cases of neurological arrest, where the traditional cardiocirculatory criteria of death cannot be applied. This algorithm should include “(1) the basic requirements that must exist for triggering the algorithm, (2) the clinical examination and diagnosis; and (3) confirmatory testing to ensure irreversibility.”

Based on these guidelines, and after consultation with subject-matter experts, the following steps should be taken:

- Comprehensive national rules for the uniform definition of death should be drafted. The Central Government should exercise its power to make rules under Section 24(2)(b) of the Act to provide for “the form and the manner in which a brain-stem death is to be certified and the conditions and requirements which are to be satisfied for that purpose under sub-section (6) of section 3.”
- On the basis of this consultation, Form 10 (For Certification of Brain Stem Death) under the Transplantation of Human Organs and Tissues Rules, 2014, should also be appropriately modified.
- An easy first step towards ensuring that there is no confusion about the definition of death under the Act would be to amend Section 2(d) of the Act to clarify that its provisions apply irrespective of anything contained in the Indian Penal Code 1860 and the Registration of Births and Deaths Act 1969.

Existing Provision	Revised Provision after Amendment
Section 2(d): “brain-stem death” means the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified under sub-section (6) of section 3”	Section (d): brain-stem death” means the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified under sub-section (6) of section 3. <b><i>This definition will have effect despite anything inconsistent in the Indian Penal Code, 1860 and the Registration of Births and Deaths Act, 1969.</i></b> ”

## 2. Victims of organ trafficking should not be treated as offenders under the Act

As explained in part II, the Act criminalises any commercial dealing in human organs.<sup>83</sup> This includes not only the person buying or facilitating the sale of organs, but also the donor. Thus, anyone who receives payment for the supply of human organs<sup>84</sup>, or offers to supply a human organ in exchange for payment<sup>85</sup> has committed an offence. As a result, whenever instances of commercial dealings in

<sup>82</sup> World Health Organisation, *Clinical Criteria for the Determination of Death: WHO Technical Expert Consultation 7* (2017) available at <<http://apps.who.int/iris/bitstream/10665/254737/1/WHO-HIS-SDS-2017.5-eng.pdf>> (last accessed on 13 August 2017)

<sup>83</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 19

<sup>84</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 19(a)

<sup>85</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 19(b)

organs are detected, criminal charges are also framed against the victim of trafficking, further punishing a vulnerable person who has undergone a difficult ordeal and in many instances, may require immediate medical attention.

In most cases of trafficking in human organs, the donor (or the victim) belongs to poor and marginalized sections of society who may have been coerced (through threats of harm or due to financial constraints) to sell their organ.<sup>86</sup> Since these organs can be quite expensive, the buyer and facilitator of the transaction will usually be financially better off. In such a situation, the victim cannot be treated on the same footing as the buyer of the organ. A human rights-based approach to organ trafficking also requires that the victim be placed at the center of any initiatives to combat the practice.<sup>87</sup> This would involve taking into consideration the socio-economic conditions and lack of agency of the donor.

A recent such incident was highlighted as a case study at the National Bioethics Conference held in Pune.<sup>88</sup> In the case of the ‘kidney racket’ detected at a large private hospital in Mumbai, the victim, a 42-year-old domestic worker from rural Gujarat, was sent to jail after the racket was detected.<sup>89</sup> Ironically, while all the other accused were granted bail, the victim in this case was unable to secure a guarantor and had to remain in jail for a period longer than the other accused. She was also unable to access basic medical help to recover from the retrieval of her kidney, and had to depend on non-governmental organizations and benevolent doctors to apply for bail and receive treatment.

In the context of surrogacy<sup>90</sup>, sex-work<sup>91</sup> and HIV<sup>92</sup>, it has been well documented that criminalising certain acts only drives them underground. In turn, this makes the people involved in these acts, who often belong to vulnerable groups, at risk of exploitation and imperils their health. A similar phenomenon may also be occurring with respect to organ trafficking. As has been highlighted in Part

<sup>86</sup> Debra Budiani-Saberi et al, *Human trafficking for organ removal in India: a victim-centered, evidence-based report*, *Transplantation*. 2014 Feb 27; 97(4):380-4

<sup>87</sup> Debra Budiani-Saberi & Sean Columb, *A human rights approach to Human Trafficking for Organ Removal*, *Med Health Care and Philos* 2013 Nov; 16(4):897-914

<sup>88</sup> Nehal Shah, *Kidney Transplantation: Ethical Issues in Law and Medical Profession* paper presented at the 6<sup>th</sup> National Bioethics Conference, Pune (13-15 January 2017) available at <<http://ijme.in/nbc-20140321/pdf/nbc6/nehah-shah-kidney-transplant.pdf>> (last accessed on 13 August 2017)

<sup>89</sup> Malathy Iyer & V Narayan, *Kidney ‘donor’ fails to find guarantor, back in jail*, *Times of India* (15 April, 2015) available at <<http://timesofindia.indiatimes.com/city/mumbai/kidney-donor-fails-to-find-guarantor-back-in-jail/articleshow/58189049.cms>> (last accessed on 13 August 2017).

<sup>90</sup> Nishtha Gautam, *Banning Surrogacy in India Will Drive it Underground*, *The Quint* (24 August 2016) available at <<https://www.thequint.com/india/2015/11/10/banning-surrogacy-in-india-will-drive-it-underground>> (last accessed on 13 August 2017); *But see* Madhuri Karak, *Surrogacy bill does not address risks faced by surrogate mothers, says researcher Daisy Deomampo*, *Scroll* (31 July 2017) available at <<https://scroll.in/pulse/844254/interview-the-surrogacy-bill-does-not-address-medical-social-and-health-risks-of-surrogate-mothers>> (last accessed on 13 August 2017).

<sup>91</sup> Krüsi A, Pacey K, Bird L *et al*, *Criminalisation of clients: reproducing vulnerabilities for violence and poor health among street-based sex workers in Canada—a qualitative study* *BMJ Open* 2014;4: e005191

<sup>92</sup> UNAIDS, *Criminalisation of HIV Non-Disclosure, Exposure and Transmission: Background and Current Landscape*, Background Paper 22 (February 2012) available at <[http://files.unaids.org/en/media/unaids/contentassets/documents/document/2012/BackgroundCurrentLandscapeCriminalisationHIV\\_Final.pdf](http://files.unaids.org/en/media/unaids/contentassets/documents/document/2012/BackgroundCurrentLandscapeCriminalisationHIV_Final.pdf)> (last accessed on 13 August 2017).

IV, the current framework relies completely on the police or state authorities ‘discovering’ a commercial transaction, and has therefore failed. Decriminalising the victims of organ trade rackets will enable them to come forward and approach the authorities, without fear of prosecution.

Incidences like these show the need for a “victim-centric” approach to addressing commercial dealings in human organs. The first step, therefore, must be to amend section 19 of the Act so that receiving payment for or offering to supply organs for sale is not a criminal act.

Decriminalising the victims of organ trafficking, and introducing mandatory reporting requirements, will be crucial steps towards empowering these victims of organ trafficking. Once a case has been filed, or charges framed alleging that the full informed consent of a live donor was not obtained and they were forced to undergo an organ transplant under coercion, the state should provide them free medical treatment to ensure that their life is not in danger. The state should also introduce compensation schemes for persons who suffer from long-term illnesses or disability as a result of such trafficking.

Decriminalising the victims of organ trafficking, and introducing mandatory reporting requirements, will be crucial steps towards empowering these victims of organ trafficking. Once a case has been filed, or charges framed alleging that the full informed consent of a live donor was not obtained and they were forced to undergo an organ transplant under coercion, the state should provide them free medical treatment to ensure that their life is not in danger. The state should also introduce compensation schemes for persons who suffer from long-term illnesses or disability as a result of such trafficking.

Under Rule 26 of the Transplantation of Human Organs and Tissues Rules, 2014, hospitals seeking registration are required to ‘maintain documentation and records including reporting of adverse events.’ This information is required to be assessed by the Appropriate Authority before granting registration. Adverse events include deaths that occur during living transplant procedures. Since Appropriate Authorities already have access to this information, they should conduct an independent inquiry into all cases of deaths of unrelated live donors during organ transplants to ascertain if the full informed consent of the person was taken before the procedure. If irregularities are detected, the Advisory Committee may make recommendations on the compensation to be paid by the state to the next of kin of the victim.

The legislative changes that these recommendations will require are as follows:

- Amendment of Section 19 of the Act so that receiving payment for or offering to supply organs for sale, except by middlemen, is not a criminal act.
- Insertion of provision requiring investigating authorities to refer victims of organ trafficking to the Advisory Committee within their jurisdiction.
- Insertion of provision requiring Advisory Committee to make recommendations to the State Government for the medical treatment and rehabilitation of victims of organ trafficking and to require an action-taken report from the State Government.
- Amendment of Section 13 of the Act to confer powers on the Appropriate Authority to conduct independent inquiries into the deaths of unrelated live donors during organ transplants.
- Amendment of Section 24 of the Act to confer power on the Central Government to make rules to prescribe the manner in which the Appropriate Authority will conduct this independent inquiry.

Existing Provision	Revised Provision after Amendment
<p><b>Section 19. Punishment for commercial dealings in human organs.</b> “Whoever—</p> <p>(a) makes or receives any payment for the supply of, or for an offer to supply, any human organ;”</p> <p>(b) seeks to find a person willing to supply for payment any human organ;</p> <p>(c) offers to supply any human organ for payment;</p> <p>(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;”</p>	<p><b>Section 19. Punishment for commercial dealings in human organs.</b> “Whoever—</p> <p>(a) makes any payment for the supply of, or for an offer to supply, any human organ; [the words ‘or receives’ have been deleted]</p> <p>(b) seeks to find a person willing to supply for payment any human organ;</p> <p>(c) offers to supply for payment any human organ of a person other than himself or herself;</p> <p>(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;”</p>

Existing Provision	Revised Provision after Amendment
<p><b>Section 13. Appropriate Authority.—</b></p> <p>“(1) The Central Government shall appoint, by notification, one or more officers as Appropriate Authorities for each of the Union territories for the purposes of this Act.</p> <p>(2) The State Government shall appoint, by notification, one or more officers as Appropriate Authorities for the purposes of this Act.</p> <p>(3) The Appropriate Authority shall perform the following functions, namely:—(i)to grant registration under sub-section (1) of section 15 or renew registration under sub-section (3) of that section;</p> <p>(ii)to suspend or cancel registration under sub-section (2) of section 16;</p> <p>(iii)to enforce such standards, as may be prescribed,—</p> <p>(A)for hospitals engaged in the removal, storage or transplantation of any human organ;</p> <p>(B)for Tissue Banks engaged in recovery, screening, testing, processing, storage and distribution of tissues;</p> <p>(iv)to investigate any complaint of breach of any of the provisions of this Act or any of the</p>	<p><b>Section 13. Appropriate Authority.—</b></p> <p>“(1) The Central Government shall appoint, by notification, one or more officers as Appropriate Authorities for each of the Union territories for the purposes of this Act.</p> <p>(2) The State Government shall appoint, by notification, one or more officers as Appropriate Authorities for the purposes of this Act.</p> <p>(3) The Appropriate Authority shall perform the following functions, namely:—(i)to grant registration under sub-section (1) of section 15 or renew registration under sub-section (3) of that section;</p> <p>(ii)to suspend or cancel registration under sub-section (2) of section 16;</p> <p>(iii)to enforce such standards, as may be prescribed,—</p> <p>(A)for hospitals engaged in the removal, storage or transplantation of any human organ;</p> <p>(B)for Tissue Banks engaged in recovery, screening, testing, processing, storage and distribution of tissues;</p> <p>(iv)to investigate any complaint of breach of any of the provisions of this Act or any of the</p>

<p>rules made thereunder and take appropriate action;</p> <p>(iva)to inspect Tissue Banks periodically;</p> <p>(v)to inspect hospitals periodically for examination of the quality of transplantation and the follow-up medical care to persons who have undergone transplantation and persons from whom organs are removed; and</p> <p>(vi)to undertake such other measures as may be prescribed.”</p>	<p>rules made thereunder and take appropriate action;</p> <p>(iva)to inspect Tissue Banks periodically;</p> <p><b>(ivaa) to conduct an inquiry into all reports of deaths of donors during or reasonably attributable to a transplantation, where the donor was not a near relative of the recipient, to determine whether the donor was coerced into supplying his or her organs;</b></p> <p>(v)to inspect hospitals periodically for examination of the quality of transplantation and the follow-up medical care to persons who have undergone transplantation and persons from whom organs are removed; and</p> <p>(vi)to undertake such other measures as may be prescribed.”</p>
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#### Insertion of Section 22A

##### **Section 22A. Referral of victims of organ trafficking to the Advisory Committee**

If:

- (1) the relevant authority investigating an offence under the Act; or
- (2) the Appropriate Authority conducting an inquiry under Section 13(3)(ivaa) of the Act have reason to believe that any person has been coerced into offering to supply or supplying his or her organs, whether or not for payment, such investigating authority or Appropriate Authority, as the case may be shall make a referral to the relevant Advisory Committee for the purposes set out in Section 22B.

#### Insertion of Section 22B

##### **Section 22B. Rehabilitation of victims of organ trafficking**

- (1) When a referral under Section 22A has been made to the Advisory Committee by the relevant authority investigating an offence under the Act, the Committee shall:
  - (a) determine whether the person coerced into supplying his or her organs is in need of medical treatment and rehabilitation;
  - (b) recommend that the State Government take appropriate measures to ensure that such treatment and rehabilitation is provided.
  
- (2) When a referral under Section 22A has been made to the Advisory Committee by the Appropriate Authority conducting an inquiry under Section 13(3)(ivaa) of the Act, the Committee shall make a recommendation to the State Government regarding the amount of compensation to be paid to the next of kin of the donor;

(3) *Within three months of a recommendation having been made to the State Government under this section, the State Government shall submit a report to the relevant Advisory Committee on the action taken in response to such recommendation.*

#### **Insertion of Section 24(iaa)**

**Section 24. Power to make rules.**—(1) *The Central Government may, by notification, make rules for carrying out the purposes of this Act.*

(2) *In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—*

*(iaa) the manner in which the Appropriate Authority shall conduct an inquiry under Section 13(3)(ivaa).*

### 3. Provisions related to mental illness should be harmonized with the Mental Healthcare Act, 2017

Under the Act, any person can authorize the removal of her organs or tissues for therapeutic purposes.<sup>93</sup> However, an exception has been made to this rule for ‘mentally challenged persons’. For the purpose of the Act, this includes all persons with mental illnesses and mental retardation.<sup>94</sup> Here, ‘mental illness’ has been defined to include dementia, schizophrenia and any mental condition which makes a person ‘intellectually disabled’.<sup>95</sup> However, the terms ‘mentally challenged persons’ and ‘intellectually disabled’ have not been defined in any law, and their use is considered outdated.

Since the Act does not clearly define ‘mental illness’, reference must be made to section 2(1)(s) of the Mental Healthcare Act, 2017 to understand its application. In this provision, the phrase ‘mental illness’ has been defined broadly as “a substantial disorder of thinking, mood, perception, orientation or memory that grossly impairs judgment, behavior, capacity to recognize reality or ability to meet the ordinary demands of life, mental conditions associated with the abuse of alcohol and drugs”. Further, the Mental Healthcare Act, 2017 also recognises the right of every person with a mental illness to equality and non-discrimination in the provision of all healthcare.<sup>96</sup>

Given this recognition of the right of persons with mental illness to equality and non-discrimination, their exclusion from the ability to donate their organs for therapeutic purposes may constitute discrimination on the grounds of mental disability. There is also no sound scientific evidence which suggests that persons with mental illnesses are either incapable of making an informed decision to donate their organs or are vulnerable to exploitation. These provisions in the Act must therefore be amended to recognise the legal capacity of persons with mental illnesses and to allow them to donate their organs before or after their death. Further, the terminology and definitions must be updated and harmonised with the Mental Healthcare Act, 2017.

<sup>93</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 3(1)

<sup>94</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 9(1)(1C)(i)

<sup>95</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 9(1)(1C)(ii)

<sup>96</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 21(1)(e)

Finally, section 9(1)(1C)(iii) of the Act also defines ‘mental retardation’ with reference to the Persons with Disabilities (Equal Opportunities, Protection of Right and Full Participation) Act, 1995. However, this legislation has now been repealed. The provision must therefore be amended to refer to the Mental Healthcare Act, 2017 where this phrase has been defined in section 2(1)(s) as “a condition of arrested or incomplete development of mind of a person, specially characterised by sub-normality of intelligence”.

We therefore recommend:

- An amendment to section 9(1)(1C) of the Act to replace references to “mentally challenged person(s)” with “persons with mental retardation”.
- The deletion of Explanations (i) and (ii) to sub-section (1) of section 9.
- An amendment to Explanation (iii) to sub-section (1) of section 9 to harmonise the definition of “mental retardation” with the Mental Healthcare Act, 2017.

Existing Provision	Revised Provision after Amendment
<p><b>Section 9. Restrictions on removal and transplantation of human organs or tissues or both.—</b></p> <p>(1) <i>Save as otherwise provided in sub-section (3), no human organ or tissue or both removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.</i></p> <p>(1C) <i>No human organs or tissues or both shall be removed from the body of a mentally challenged person before his death for the purpose of transplantation.</i></p>	<p><b>Section 9. Restrictions on removal and transplantation of human organs or tissues or both.—</b></p> <p>(1) <i>Save as otherwise provided in sub-section (3), no human organ or tissue or both removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.</i></p> <p>(1C) <i>No human organs or tissues or both shall be removed from the body of <b>persons with mental retardation</b> before their death for the purpose of transplantation.</i></p>
<p><b>Section 9: Restrictions on removal and transplantation of human organs or tissues or both.—</b></p> <p>(1) <i>Save as otherwise provided in sub-section (3), no human organ or tissue or both removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.</i></p> <p><i>Explanation.—For the purpose of this sub-section,—</i></p> <p>(i) <i>the expression “mentally challenged person” includes a person with mental illness or mental retardation, as the case may be;</i></p> <p>(ii) <i>the expression “mental illness” includes dementia, schizophrenia and such other</i></p>	<p><b>Section 9: Restrictions on removal and transplantation of human organs or tissues or both.—</b></p> <p>(1) <i>Save as otherwise provided in sub-section (3), no human organ or tissue or both removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.</i></p> <p><i>Explanation.—For the purpose of this sub-section,—</i></p> <p>(i) <b>[deleted]</b></p> <p>(ii) <b>[deleted]</b></p>

<p><i>mental condition that makes a person intellectually disabled;</i></p>	
<p><b>Section 9: Restrictions on removal and transplantation of human organs or tissues or both.—</b></p> <p>(1) <i>Save as otherwise provided in sub-section (3), no human organ or tissue or both removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.</i></p> <p><i>Explanation.—For the purpose of this sub-section,—</i></p> <p>(iii) <i>the expression “mental retardation” shall have the same meaning as assigned to it in clause (r) of section 2 of the Persons With Disabilities (Equal Opportunities, Protection of Right and Full Participation) Act, 1995 (1 of 1996).</i></p>	<p><b>Section 9: Restrictions on removal and transplantation of human organs or tissues or both.—</b></p> <p>(2) <i>Save as otherwise provided in sub-section (3), no human organ or tissue or both removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.</i></p> <p><i>Explanation.—For the purpose of this sub-section,—</i></p> <p>(iii) <i>the expression “mental retardation” shall have the same meaning as assigned to it in clause (s) of sub-section (1) of section 2 of the Mental Healthcare Act, 2017 (10 of 2017).</i></p>

#### 4. Remove the Requirement for Permission from the Appropriate Authority for Courts to take cognizance of an offence

The Act states that no court can take cognizance of an offence (committed under the Act) till a complaint is made to it by the Appropriate Authority. If anyone else wants to make a complaint, they must first give notice to the Appropriate Authority of not less than 60 days. This makes filing a complaint under the Act a long and cumbersome procedure, and the courts have in the past rejected complaints that were brought directly to it instead of through an Appropriate Authority. The Act does not specify whether, once a complaint has been made to it, an Appropriate Authority is obligated to file the complaint before a competent court, or if this power is discretionary. Further, the Act also does not specify a time period within which the Appropriate Authority must process a complaint, and file it before a court.

When persons are charged for offences under the Act, charges are brought not only under the provisions of the Act, but usually also under the provisions of the Indian Penal Code, 1860. In fact, it may be easier to just bring charges under the IPC, and eschew the provisions of the Act altogether, given the cumbersome procedure to be followed before a court can take cognizance of an offence under the Act. Given all these issues, there is an urgent need to simplify the process of bringing a complaint under the Act. To increase access to the court system, we recommend:

- Amendment of Section 22 of the Act to remove the requirement for filing a complaint through an Appropriate Authority to allow persons affected by organ trafficking to bring complaints to the courts directly.
- Amendment of Section 24 of the Act to remove prescriptions on the manner in which persons may give notice of their intention to make a complaint to the Appropriate Authority.

Existing Provision	Revised Provision after Amendment
<p><b>Section 22. Cognizance of offence.</b>  “(1) No court shall take cognizance of an offence under this Act except on a complaint made by—</p> <p>(a) the Appropriate Authority concerned, or any officer authorised in this behalf by the Central Government or the State Government or, as the case may be, the Appropriate Authority; or</p> <p>(b) a person who has given notice of not less than sixty days, in such manner as may be prescribed, to the Appropriate Authority concerned, of the alleged offence and of his intention to make a complaint to the court.”</p>	<p><b>Section 22. Cognizance of offence.</b>  “Courts shall take cognizance of an offence under this Act on complaints made by—</p> <p>(a) any person; or</p> <p>(b) the Appropriate Authority concerned, or any officer authorised in this behalf by the Central Government or the State Government or, as the case may be, the Appropriate Authority.”</p>

Existing Provision	Revised Provision after Amendment
<p><b>Section 24. Power to make rules.—</b>  “(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely.—</p> <p>(o) the manner in which a person is required to give notice to the Appropriate Authority of the alleged offence and of his intention to make a complaint to the court under clause(b) of sub-section(1) of section 22</p>	<p><b>Section 24. Power to make rules.—</b>  “(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely.—</p> <p>(o) the manner in which a person is required to make a complaint to the court under section 22.</p>

## 5. Introduce proper protocols for the removal of organs from bodies that have been sent for post-mortem examinations

The Code of Criminal Procedure, 1973 (“CrPC”) makes its mandatory in all cases of unnatural death (i.e. possible suicides, death due to an animal, machinery or accident, or a death which raises a reasonable suspicion that another person has committed an offence), for the officer in charge of a police station to send the body to the nearest Civil Surgeon or medical practitioner appointed by the State to carry out post-mortems.<sup>97</sup>

Further, according to section 6 of the Act, in cases where a cadaver has been sent for post-mortem examination for medico-legal (i.e. if the death of the person was unnaturally caused) or for pathological purposes, the removal of the organs and tissues of the person may be authorized.

<sup>97</sup> The Code of Criminal Procedure, 1973, § 174(3).

However, the person making such an authorization must be satisfied that the deceased person had not expressed an objection, or revoked previously granted permission, to donate their organs or tissues after death.

Rule 6 of the Transplantation of Human Organs and Tissues Rules 2014 provides for some degree of coordination between the organ retrieval centre and post-mortem centre. If a private organ retrieval centre is not doing the post-mortem, it should arrange for the transportation of the body along with medical records to the designated postmortem centre. The registered medical practitioner doing the postmortem should take on record the medical report with respect to organ retrieval in his or her postmortem notes.<sup>98</sup>

However, due to a lack of synchronization between the protocols prescribed under the Act and the CrPC, the procedures for the removal of organs, and then the post-mortems are carried out separately. This is an inhumane process, and only serves to worsen the misery of the family that has agreed to donate the organs of their loved one.

To frame these protocols, reference may be made to Government Order (Ms) No. 86 of 2011 issued by the Government of Tamil Nadu. This Government Order allows for the post-mortem and organ retrieval to be carried out simultaneously, and permits post-mortems to be carried out by: (i) a medical officer from the forensic medicine department of a Government Medical College, (ii) a forensic medicine expert, government medical officer or pathologist posted in the Forensic Medicine department, (iii) any government medical officer (current or retired) who has experience in post mortem work.

To ensure that the retrieval of organs and post-mortems can be carried out simultaneously, we recommend that:

- An additional sub-rule be inserted in Rule 6, which allows the post-mortem and organ retrieval to be carried out simultaneously in medico-legal cases.

#### Insertion of Rule 6(6)

Sub-rule (6), Rule (6)-

*As far as possible, the post-mortem and organ retrieval shall take place one after the other, before the body is handed over to the relatives of the deceased.*

### 6. Ensure the proper institution and functioning of Advisory Committees

Section 13A of the Act was incorporated through the 2011 Amendment Act, which provides for Advisory Committees to advise the Appropriate Authority. This Advisory Committee includes senior representatives from the State Government, the Ministry of Health and Family Welfare, eminent social workers, a legal expert, a representative from non-governmental organizations and a specialist from the field of human organ transplantation. In addition to having representatives from the different stakeholders involved in the field of human organ transplantation, the Act also provides for

<sup>98</sup> The Transplantation of Human Organs and Tissues Rules 2014, Rule 6(3)

the terms and conditions for appointment to the Advisory Committee to be prescribed by the Central Government.<sup>99</sup>

However, six years after the provision was introduced in the Act, it isn't clear how many State Governments have actually appointed Advisory Committees. This information is not available with the State Transplant Coordination Centers or Health Departments, and was not provided by the different states in their replies to our requests under the RTI Act. This fact forced a Public Interest Litigation<sup>100</sup> to be filed in the Bombay High Court, where the Court directed the State Government of Maharashtra to constitute an Advisory Committee and discharge its statutory duty.

It is therefore recommended that:

- Advisory Committees be set up in all states on an urgent basis.
- The functions and powers of these Committees be clearly outlined through an amendment to the Act, or under the Rules.

#### Insertion of Section 13AA

##### **Section 13AA. Powers and Functions of Advisory Committees**

*(1) In addition to the powers and functions set out under Section 22B, Advisory Committees shall advise Appropriate Authorities on the discharge of their functions under the Act. This includes, but is not limited to:*

- (a) Advising the Appropriate Authorities regarding the conditions for registration of hospitals and Tissue Banks under Chapter V, taking into account medical and technological advancements and the existing geographical distribution and need for such hospitals and Tissue Banks;*
- (b) Advising the Appropriate Authorities on making the process of investigating complaints of the breach of any of the provisions of the Act or rules made thereunder speedier and more accessible to complainants, especially those who have suffered medical harm as a result of such breach.*
- (c) Advising the Appropriate Authorities on the action to be taken on complaints under the Act. This could include recommendations, where appropriate, to:*
  - (i) Prosecute complaints as offences under the Act;*
  - (ii) Refer complaints to the relevant State Medical Council for disciplinary action against registered medical practitioners committing a breach of the provisions of the Act;*
  - (iii) Refer complaints to the authority in charge in that State for the registration of clinical establishments to consider the suspension or cancellation of the registration of a hospital or a Tissue Bank for a breach of the standards prescribed under the Act;*
  - (iv) Refer complaints to the District Forum under the Consumer Protection Act, 1986 to determine the compensation to be granted for a breach of the provisions of the Act.*

<sup>99</sup> The Transplantation of Human Organs and Tissues Act, 1994, § 13A(3)

<sup>100</sup> Sampat Shetty v. State of Maharashtra PIL No. 126 of 2009 (Bom HC) (Unreported).

- (2) *Advisory Committees shall monitor and evaluate the implementation of the Act in their respective States, taking into account yearly reports published in respect of the National Registry under Rule 32 of the Transplantation of Human Organs and Tissues Rules, 2014.*
- (3) *On the basis of this monitoring and implementation, Advisory Committees shall submit an annual report to their respective State Governments, making recommendations to improve the implementation of the Act.*
- (4) *Within three months of receiving the report under sub-section (3), each State Government shall publish details of action taken on the recommendations contained in the report.*

### 7. Making Organ Transplants accessible and affordable

The recommendations listed above are limited to changes that would require amendments to the Act. Meeting its obligations under the Right to Health also requires that the State take measures to ensure that organ transplants, which may often constitute life-saving procedures, are made available and accessible for all people.

This would require, first, a major upgrade of the physical infrastructure available not just in healthcare facilities, but also the implementation of “green corridors” to ensure the smooth availability of organs. It has been reported that these corridors, which provide a well-defined passage-way for the transport of organs from the donor to the potential recipient, have been implemented in Chennai, Delhi, Pune, Mumbai and Kolkata.<sup>101</sup> There is also a need for greater transparency in organ transplant registries- currently reports say that it is easier to procure organs in private hospitals<sup>102</sup>, and 95% of transplants still happen in the private sector.<sup>103</sup> There are also stark geographic disparities among states as to the availability of organ transplants. For example, from replies received by us to requests filed under the RTI Act, we found that there are no authorized centers for carrying out organ transplants in the north-eastern states, except at the Guwahati Medical College.

The affordability of these procedures is also a problem. It is estimated that private hospitals currently charge between Rs. 10 lakhs and Rs. 30 lakhs for a heart transplant, Rs 5 lakhs to Rs 20 lakhs for a

<sup>101</sup> Roli Srivastava, *Green corridors make inter-State organ transplants a success*, The Hindu (4 January 2016) available at <<http://www.thehindu.com/news/cities/mumbai/news/Green-corridors-make-inter-State-organ-transplants-a-success/article13980700.ece>> (last accessed on 13 August 2017); Express News Service, *Kolkata Police form ‘green corridor’ to help organ transplant*, Indian Express (5 November, 2016) available at <<http://indianexpress.com/article/india/india-news-india/kolkata-police-form-green-corridor-to-help-organ-transplant-3738073/>> (last accessed on 13 August 2017).

<sup>102</sup> K.P. Narayana Kumar, *How cadaver organ donation could turn government hospitals into donor bases that cater to the affluent*, The Economic Times (5 June 2016) available at <<http://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/how-cadaver-organ-donation-could-turn-government-hospitals-into-donor-bases-that-cater-to-the-affluent/articleshow/52591608.cms>> (last accessed on 13 August 2017).

<sup>103</sup> Press Information Bureau, *Nationwide Registry for Organ and Tissue Donation launched*, 27 November 2015 available at <<http://pib.nic.in/newsite/PrintRelease.aspx?relid=131941>> (last accessed on 13 August 2017).

kidney transplant and Rs. 15 lakhs to Rs. 35 lakhs for a liver transplant.<sup>104</sup> These prohibitive costs put organ transplants out of reach for almost everyone except people in the highest socio-economic category, or those with access to health insurance.

Some states have attempted to increase the affordability of organ transplant procedures through state health insurance schemes and special financial assistance programmes. In Tamil Nadu, for example, kidney, liver and heart transplants are available for free in government hospitals.<sup>105</sup> A corpus of Rs. 35 crores has also been created for surgeries with costs exceeding the Rs. 1.5 lakh limit. Similarly, organ transplants in Goa are financed by the government, and are covered under state insurance schemes in Karnataka, Andhra Pradesh, Maharashtra (under the Rajiv Gandhi Jeevandayee Arogya Yojana, economically backward patients can claim up to Rs. 3.9 lakhs, which includes Rs. 90,000 for immunosuppressants) and Kerala (under the Karunya Benevolent Fund, economically backward people are provided financial aid for serious health and kidney ailments through the state lottery). However, the numbers of people who can benefit under these schemes constitute a very small percentage of those who need them.

There is therefore a need to expand the mandate of the National Organ Transplant Programme under the Directorate General of Health Services, so that these issues may be addressed comprehensively.

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<sup>104</sup> Preetu Nair, *Organ is Free, Transplant Cost is Problem*, Times of India (5 September 2016) available at <<http://timesofindia.indiatimes.com/life-style/health-fitness/health-news/Organ-is-free-transplant-cost-is-problem/articleshow/54014378.cms>> (last accessed on 13 August 2017).

<sup>105</sup> TNN, *Financing organ transplant still a patient's headache across India*, Economic Times (11 August 2017) available at <<http://health.economictimes.indiatimes.com/news/diagnostics/financing-organ-transplant-still-a-patients-headache-across-india/60014003>> (last accessed on 13 August 2017).

## V. ANNEXURES

### A. RTI Questions for the Transplantation of Human Organs and Tissues Act, 1994

#### Ministry of Health and Family Welfare

1. Please provide details of the programs/schemes run by the Ministry of Health to encourage cadaver donations
2. Please provide a copy of all the notifications/orders appointing Appropriate Authorities for the Union Territories under section 13 of the Transplantation of Human Organs and Tissues Act, 1994 ('THOTA').
3. What is the information available in the National Registry required to be set up under section 13D of the THOTA?
  - (i) Please provide demographic data with respect to the patient, donor, hospitals, recipient and donor follow up details, and transplant waiting list with respect to the NCT of Delhi for the period 2013-16 as required under rule 32(1) of the Transplantation of Human Organs and Tissues Rules, 2014 ('Rules').
  - (ii) Please provide a copy of norms decided by the Advisory Committee for data collection frequency. As required under Rule 32(2), is this information maintained both specific organ wise and in consolidated format?
4. How many hospitals have been registered by the Appropriate Authority for the NCT of Delhi under section 14 of the THOTA? Please provide a complete list of hospitals.
5. Please provide a complete list of Tissue Banks that have been registered for the NCT of Delhi under section 14A of the THOTA along with year of registration.
6. Please provide a complete list of Human Organ Retrieval Centres that have been registered for the NCT of Delhi under section 14(1) of the THOTA.
7. Please provide complete details of notices that have been issued by Appropriate Authorities to hospitals and Tissue Banks in Delhi under section 16 of the THOTA. For each of these, please specify if they were issued *suo motu* or on complaint.
8. How many suspensions/cancellations of licenses by the Appropriate Authority in Delhi? Please provide a year-wise break up.
9. Please provide a copy of all the notifications issued since 2011 under Section 13A constituting Advisory Committees for the NCT of Delhi.
10. Please provide complete data on the number of appeals made to the Central government under section 17 of the THOTA for the NCT of Delhi. Please specify whether these appeals were accepted or rejected.
11. Rule 5(3)(g): In how many instances have living organ or tissue donations by minors been authorised for the NCT of Delhi? Please provide year-wise data.
12. Rule 9: What decision about cost-bearing has been made for the NCT of Delhi? Who has been designated to bear the costs of maintenance of the cadaver, retrieval of organs, their transport and preservation?
13. As permitted under Rule 10(3), has the NCT of Delhi merged Form 11 with Forms 1, 2 or 3 under THOTA?

14. As required under Rule 14, in how many instances have Authorisation Committees in Delhi informed the police department for investigation and action because of a doubt of organ trafficking? Please provide complete data.
15. As required under Rule 16, has a uniform format for approval of Authorisation Committees been notified for the NCT of Delhi as per Form 18? If so, please provide a copy of the notification.
16. As permitted under Rule 25(3), in how many instances has renewal of hospital/tissue bank registration been refused by the Appropriate Authority? Please provide details.
17. As required under Rule 28A(1) have standards and guidelines been laid down for Tissue Banks in Delhi? If yes, please provide copies of the same.
18. As required under Rule 28A(2), has the Union Government constituted an expert committee to advise on matters related to tissue-specific standards?
19. As required under Rule 31(4)(f), has a State organ sharing and networking policy been framed for the NCT of Delhi?
20. Please provide a year-wise break up of cadaver transplants from unclaimed bodies in prisons and hospitals in Delhi

### State Health Ministries

1. Please provide details of the programs/schemes run by the Ministry of Health to encourage cadaver donations.
2. Has the application of the Transplantation of Human Organs and Tissues Act, 1994 ('THOTA') been extended to your State? If so, please provide a copy of the government order/notification to this effect.
3. Please provide a copy of all the notifications/orders appointing Appropriate Authorities for your State under section 13 of the THOTA.
4. Have State and District level Authorisation Committees been constituted for your State under Rule 11 of the THOTA Rules? If so, please provide a copy of all the relevant notifications/orders.
5. How many hospitals have been registered by the Appropriate Authority for the State under section 14 of the THOTA? Please provide a complete list of hospitals.
6. Please provide a complete list of Tissue Banks that have been registered under section 14A of the THOTA along with year of registration.
7. Please provide a complete list of Human Organ Retrieval Centres that have been registered under section 14(1) of the THOTA.
8. Please provide complete details of notices that have been issued by Appropriate Authorities to hospitals and Tissue Banks under section 16 of the THOTA. For each of these, please specify if they were issued *suo motu* or on complaint.
9. How many hospital/tissue bank licenses have been suspended/cancelled by the Appropriate Authority? Please provide a year-wise break up.
10. Please provide a copy of all the notifications issued since 2011 under Section 13A of the THOTA constituting Advisory Committees.
11. Please provide complete data on the number of appeals made to the State government under section 17 of the THOTA. Please specify whether these appeals were accepted or rejected.

12. Rule 5(3)(g): In how many instances have living organ or tissue donations by minors been authorised? Please provide year-wise data.
13. Rule 9: What decision about cost-bearing has been made by the State Government or Union Territory? Who has been designated to bear the costs of maintenance of the cadaver, retrieval of organs, their transport and preservation?
14. As permitted under Rule 10(3), has your State merged Form 11 with Forms 1, 2 or 3 under THOTA?
15. As required under Rule 14, in how many instances have Authorisation Committees informed the police department for investigation and action because of a doubt of organ trafficking? Please provide complete data.
16. As required under Rule 16, has a uniform format for approval of Authorisation Committees been notified by the State Government as per Form 18? If so, please provide a copy of the notification.
17. As permitted under Rule 25(3), in how many instances has renewal of hospital/tissue bank registration been refused by the Appropriate Authority? Please provide details.
18. As required under Rule 28A(1) have standards and guidelines been laid down for Tissue Banks? If yes, please provide copies of the same.
19. As required under Rule 28A(2), has the State Government constituted an expert committee to advise on matters related to tissue-specific standards?
20. As required under Rule 31(4)(f), has a State organ sharing and networking policy been framed?
21. Please provide a year-wise break up of cadaver transplants from unclaimed bodies in prisons and hospitals.
22. Please provide complete information on the authorisation committees set up in the State.
23. For each authorisation committee, please provide year-wise break-up of
  - (i) the number of requests for approval of human organ/tissue transplants
  - (ii) the total number of human organ/tissue transplants approved

## NOTTO

1. Please provide the organ and tissue donation information for the period 2013-2016, for the Union Territory of Delhi and State of Maharashtra:
  - (i) Details of all organ donations, categorised by organ type and year
  - (ii) Gender-disaggregated data for number of organ donors each year
  - (iii) Break-up of living/cadaver donations year-wise.
  - (iv) Total number of human organ and tissue transplants done per year
  - (v) Break-up of 'near related' transplants and 'other' transplants year wise.
2. As required under Rule 31(7), have organ and tissue retrieval teams been designated/constituted?
3. As required under Rule 31(9), is there a dedicated website for organ networking?
4. As required under Rule 31(10), have reference or allocation criteria been developed by the networking organisation?
5. What IEC activities have been undertaken by the networking organisation for the promotion of deceased organ and tissue donation?

**ROTTTO**

1. Please provide state-wise organ and tissue donation information for the time period 2013-2016:
  - (i) Total number of organ/tissue donations year wise
  - (ii) Gender-disaggregated data for number of organ donors each year
  - (iii) Break-up of living/cadaver donations year-wise.
  - (iv) Total number of human organ and tissue transplants done per year
  - (v) Break-up of 'near related' transplants and 'other' transplants year wise.
2. As required under Rule 31(7), have organ and tissue retrieval teams been designated/constituted?
3. As required under Rule 31(9), is there a dedicated website for organ networking?
4. As required under Rule 31(10), have reference or allocation criteria been developed by the networking organisation?
5. What IEC activities have been undertaken by the networking organisation for the promotion of deceased organ and tissue donation?

**Government Hospitals in Delhi and Mumbai**

1. For the period 2013-2016, please provide year wise data of the number of human organ transplants done for:
  - (i) Kidney
  - (ii) Heart
  - (iii) Liver
  - (iv) Lungs
2. Please provide a copy of the office order and details of the authorisation committee set up in your hospital
3. We should also ask for details of the transplant coordinator appointed, unless this information is already available on the hospital website. Perhaps also details of the Board of medical experts required to be set up by the hospital to certify brain-stem death? We could also ask the Appropriate Authority whether it maintains a panel of experts as required under Rule 4 in order to ensure the efficient functioning of the Board of Medical Experts.
4. For each authorisation committee, please provide year-wise break-up of
  - (i) the number of requests for approval of human organ/tissue transplants
  - (ii) For each request, please provide anonymised information with respect to kind of organ/tissue, gender and nationality.
  - (iii) Please provide details of the number of requests for organ/tissue swaps under section 9(3A) and approvals granted by the authorisation committee year wise.
  - (iv) the total number of human organ/tissue transplants approved
5. Please provide the organ and tissue donation information for the time period 2013-2016, for your hospital:
  - (i) Break-up of living/cadaver donations year-wise.
  - (ii) Break-up of 'near related' transplants and 'other' transplants year wise.
6. As required under Rule 32(3) of the Transplantation of Human Organs and Tissues Rules, 2014 ('Rules'), does the hospital website contain information with respect to the total number of transplantations done and details of each transplantation?

7. Please provide a copy of the Yearly Reports required to be published under Rule 32(4).
8. Are monthly reports on key events (new patients, deaths and transplants):
  - (i) Notified as soon as they occur on the hospital?
  - (ii) Information sent to the networking organisation monthly?
9. Rule 5(1)(c): have coordinating organisations been authorised to inform the authorised Human Organ Retrieval Centre? If so, please provide a complete list.
10. As required under Rule 6 (1), has a post-mortem doctor for the hospital been designated?
11. As required under Rule 6(5) has a post-mortem centre been designated?
12. As provided under Rule 7(5), in how many instances has a request been made to expedite evaluation by the Authorisation Committee? Please provide year wise data.
13. Rule 8: What 'current and accepted scientific methods' have been prescribed to retrieval centres or hospitals for the preservation of removed organs and tissues?
14. Rule 18(8): In how many instances has the competent authority asked for the assistance of the Authorisation Committee in its decision-making?
15. Rule 28H: How many adverse events have been reported during transplants? Please provide year wise data.
16. As required under Rule 29(2), has the hospital made arrangements for initial induction and retraining of transplant coordinators at periodic intervals?

#### **Delhi and Maharashtra Medical Council**

1. In how many instances have names been reported by the Appropriate Authority to the State Medical Council to take necessary action?
2. What action has been taken by each State Medical Council in response to these reports?

#### **Delhi and Mumbai Police**

What measures have been taken to sensitise the police on the issue of organ donation? Have standard protocols been drafted for the police?

#### **Additional Information (Through Interviews)**

Rule 17(2): In how many instances has an explanation been sought from the applicant and in how many instances has its veracity been ordered to be confirmed?

Rule 28A(3): What written guidelines and SOPs have been put in place for Tissue Banks?

## B. State-wise cases filed in 2014 (Pre-Trial Stage)

	Andhra Pradesh	Delhi	Punjab	West Bengal	India
Cases pending investigation from the previous year	0	0	1	0	1
Cases reported in police stations during the year	0	0	0	1	1
Cases reported during the year	0	1	0	1	2
Male victims	0	0	0	1	1
Female victims	0	1	0	0	1
Number of victims in registered cases	0	1	0	1	2
Cases chargesheeted out of cases from previous year	0	0	1	0	1
Cases chargesheeted	0	0	1	0	1
Total cases investigated	0	0	1	0	1
Cases sent for trial during the year	1	0	1	0	2
Cases pending investigation at the end of the year	1	0	0	1	2
Cases pending trial from the previous year	1	0	0	0	1
Cases pending trial at the end of the year	0	0	1	0	1
Cases reported under section 156(3) during the year	0	1	0	0	1



# Vidhi

Centre For Legal Policy

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