

**HIGH COURT OF DELHI****Bench: Justice Prathiba M. Singh****Date of Decision: 4th January 2024**

W.P.(C) 3590/2020

CM APPL. 12775/2020

**AMAR SINGH BHATIA & ANR. ...PETITIONERS****VERSUS****SIR GANGA RAM HOSPITAL & ORS. ...RESPONDENTS****Legislation:**

Transplantation of Human Organs and Tissues Act, 1994

Transplantation of Human Organs and Tissues Rules, 2014

**Subject:** Writ petition challenging the delay in the approval process for kidney transplantation under the Transplantation of Human Organs and Tissues Act, 1994, and the Transplantation of Human Organs and Tissues Rules, 2014.

**Headnotes:**

Medical Law – Organ Transplantation – Delay in Authorization – Petitioners challenged delay in obtaining necessary approvals for kidney transplant – High Court emphasized need for prescribed timelines under the Transplantation of Human Organs and Tissues Rules, 2014 – Absence of such timelines caused significant delays – Court directed establishment of clear timelines for processing applications, document verification, and scheduling of interviews – Petition allowed. [Paras 1-50]

Organ Transplantation – Right to Health – Timely decision-making critical for life-saving transplants – Court emphasized that delays in authorization processes can jeopardize patients' lives – Importance of maintaining integrity and effectiveness of transplantation protocols underscored – Right to health

integral to right to life under Article 21 of the Constitution – Court called for expeditious and systematic decision-making. [Paras 38-42]

Judicial Review – Administrative Efficiency – High Court criticized administrative delays in organ transplant approval process – Directed Ministry of Health and Family Welfare to prescribe specific timelines for all steps in approval process – Recommended timely communication and documentation to prevent prolonged delays – Emphasized judicial oversight to ensure adherence to legal and ethical standards in organ transplantation. [Paras 43-50]

Decision:

Held: Writ petition allowed – Respondents directed to adhere to prescribed timelines for organ transplant approvals – Ministry of Health and Family Welfare to ensure proper communication and adherence to timelines – Petition disposed of. [Paras 48-50]

**Referred Cases:**

- Nagendra Mohan Patnaik v. The Government Of Andhra Pradesh 1997 (1) ALT 504
- Vijaykumar Hariram Sahu v. State of Maharashtra (2013) 2 Mah LJ 927
- Arup Kumar Das v. State of Orissa 2010 SCC OnLine Ori 181
- Vandana Dixit v. Visitor S.G.P.G.I MANU/UP/3515/2010
- Parveen Begum v. Appellate Authority 189 (2012) DLT 427
- C. Seshadri v. State of Telangana 2018 (5) ALT 637
- Ratnakar Peddada v. State of Telangana 2018 Indlaw HYD 294
- Radhakrishnan Pillai v. Sajeev R W.P. (C) 16216 of 2021
- Representing Advocates:
- For Petitioners: Ms. Charu Aneja
- For Respondents: Mr. Subhash Kumar (for R-1 & R-2), Mr. Saroj Bidawat (for UOI/R-3), Mr. Rishikesh Kumar (for GNCTD)

**Prathiba M. Singh, J.**

**Background**

1. The present petition brings to focus an important lacuna regarding the implementation of the Transplantation of Human Organs and Tissues Act, 1994 (*hereinafter*, '1994 Act') and the Transplantation of Human Organs and Tissues Rules, 2014 (*hereinafter*, '2014 Rules').
2. A brief background is that the present petition was filed by the Petitioners-Mr. Amar Singh Bhatia & Mukesh Kumar under Article 226 of the Constitution of India.
3. The Petitioner No. 1- Amar Singh Bhatia had retired from the Indian Air Force on 20th February, 2006. On 20<sup>th</sup> March, 2017, he was diagnosed with end stage chronic kidney disease (*hereinafter*, 'CKD') or kidney failure at the Shrinath Medicity Hospital in Bareilly, Uttar Pradesh. Thereafter, from March, 2017 to November, 2018 he obtained treatment from various hospitals such as Fortis Hospital, Noida and ECHS Polyclinic, Bareilly. In the meantime, the Shrinath Medicity hospital at Bareilly advised regular maintenance haemodialysis twice a week. The Petitioner No. 1 was additionally advised to undergo dialysis thrice a week.
4. In December, 2018, Medanta Hospital in Gurgaon recommended preemptive renal transplant. By May, 2019, Shrinath Medicity Hospital in Bareilly had also advised Petitioner No. 1 to undergo kidney transplantation. In June, 2019 the Petitioner No. 1 attempted to obtain approvals for transplantation which was, however, refused at the Army Hospital (Research & Referral) in New Delhi. The required transplant was denied due to the non-availability of a '*near relative*' donor in terms of Section 2(i) and Section 9(1) of the 1994 Act.
5. Following this, on 25<sup>th</sup> June, 2019, Petitioner No. 1 consulted Respondent No. 1-Sir Ganga Ram Hospital, where he was again diagnosed with hypertension and CKD stage V, and pre-emptive renal transplant was planned. By July 2019, the Petitioners are stated to have completed the requirements for transplant under the 1994 Act and the 2014 Rules. This included obtaining domicile verification certificates (Form No. 20) for both the donor and the recipient, which were forwarded to Respondent No. 1 by the Tehsildar of Bareilly on 23<sup>rd</sup> July, 2019. In September 2019, DNA profiling of both Petitioners was conducted by Respondent No. 1. Thereafter, on 3<sup>rd</sup> December, 2019, the Registered Medical Practitioner at Respondent No. 1

issued a 'Certification of Medical Fitness of Living Donor' (Form No. 4) for the donor i.e. Petitioner No. 2-Mukesh Kumar. On 9<sup>th</sup> December, 2019, the Army Hospital, New Delhi finally denied kidney transplantation to the Petitioner No. 1. Later, on 8<sup>th</sup> February, 2020, the Petitioner No. 1 was admitted to a hospital in Bareilly due to a kidney infection and remained hospitalized for five days.

6. According to the Petitioners, the Sir Ganga Ram Hospital raised various objections and the Petitioners continued to supply all the required documents. However, no decision was taken by Sir Ganga Ram Hospital, which ultimately led to the filing of the present petition. The prayers are extracted as under:

*“(a) To issue a writ of mandamus or any other appropriate writ, order or direction, directing the respondent No. 1/ Hospital to carry out the requisite kidney transplantation in this case; and/or (b) To issue a writ of mandamus or any other appropriate writ, order or direction, directing the respondent No. 2/ Authorisation committee to grant the necessary approval for kidney transplantation and direct the hospital to conduct the transplantation in this case henceforth; and/or (c) Pass any other further order which this Hon'ble Court may deem fit and proper in the present case.”*

### **Proceedings in the present petition**

7. Notice in the present petition was issue on 18th June, 2020 when the Sir Ganga Ram Hospital had assured that the decision on the Petitioners' application would be arrived at by 25th June, 2020. At that time, due to the outbreak of the COVID-19 pandemic, Petitioners' application under the 1994 Act continued to remain pending.

8. On 29th June 2020, the Petitioners argued that due to the COVID-19 pandemic and the short notice given, they, along with their spouses, were unable to appear in person before Respondent No. 2 - the Authorisation Committee - on 24th June 2020. Consequently, the Petitioners requested that the meeting be conducted *via* video conferencing. In contrast, Sir Ganga Ram Hospital and the Authorisation Committee insisted on the necessity of the personal presence of the Petitioners and their spouses for such matters. Thus, the Court directed Sir Ganga Ram Hospital and the Authorisation

Committee to communicate a fresh date and give the Petitioners at least a week's notice before the meeting. A further opportunity was granted to the Petitioners to approach Sir Ganga Ram Hospital and the Authorisation Committee on 28th July 2020.

9. Vide order dated 25<sup>th</sup> November, 2020, this Court granted a last opportunity to the Petitioners to supply the required documents to the Authorisation Committee. Thus, repeatedly documents were called for and meetings were also held. However, on 24th February, 2021, finally, two more weeks were granted for taking a decision, and the said decision was directed to be placed on record. On the said date the following order was passed:

*“2. Petitioner No.1 is a kidney patient who has been waiting for his kidney transplant since 2017. It is submitted that in March, 2017, he was diagnosed with chronic kidney disease and is presently in urgent need of a kidney transplant.*

*3. A perusal of orders shows that some documents were being demanded from the Petitioners. Ld. counsel for the Petitioners submits that all documents have been submitted, however, no decision has been taken by the Authorisation Committee.*

*4. Considering the facts and circumstances of the case, it is directed that the **Authorisation***

***Committee shall take a decision on the Petitioner's application for his kidney transplant within two weeks. The said decision shall also be placed on record before this Court. The Authorisation Committee shall take into consideration all the documents which have been submitted by the Petitioners and also consider the medical condition of Petitioner No.1 while taking a decision.** If any clarifications are needed by the Authorisation Committee, they are permitted to call the Petitioners once again before taking their decision. If the decision is not taken within two weeks, the Petitioners are permitted to approach this Court.*

*5. Ld. counsel for the Petitioners to serve Ld. Counsels for the GNCTD and Union of India, who shall file a short affidavit in*

*respect of the timelines that are to be followed under Rule 23 of The Transplantation of Human Organs and Tissues Rules, 2014.”*

10. By the time the matter was again listed on 11th October 2021, Petitioner No. 1 had unfortunately passed away. However, this Court has continued with the present petition in order to obtain the stand of Respondent No. 4 - Union of India, and Respondent No. 5 - Government of National Capital Territory of Delhi (*hereinafter, 'GNCTD'*), regarding the issues raised by the Id. Counsel. It is her submission that timelines within which the Authorisation Committee constituted under Section 9(4) of the 1994 Act is to conduct interviews, make decisions therein, and handle the appeal procedure are not prescribed which is the reason for such delays. 11. On 13<sup>th</sup> September, 2022, Id. Counsel appearing for the Sir Ganga Ram Hospital and the Authorisation Committee, referred to Rule 23 of the 2014 Rules. He emphasized that sub-rules (2) and (3) of said Rule 23 mandated the Authorisation Committee to act urgently and make a final decision within 24 hours. *Per contra*, the Petitioners argued that significant time is lost between the start of the screening process and the final presentation of the matter to the Authorisation Committee. Consequently, on the said date, Id. Counsel for the Petitioners' suggested that additional guidelines need to be framed to address the said issue. Thus, the Court, acknowledging the need for more information to address this issue, directed that the following details be provided, including:

- Information about the admission of the original Petitioner No. 1,
- Commencement date of the screening process, and,
- the date when the proposal was sent to the Authorisation Committee.

These details were directed to be submitted to the Court in the form of an additional affidavit by the Sir Ganga Ram Hospital and the Authorisation Committee.

12. On 15th February 2023, it was noticed that no affidavit, as directed vide order dated 13th September 2022, had been filed by Sir Ganga Ram Hospital and the Authorisation Committee. Subsequently, in an affidavit dated 12th April 2023, Dr. Satendra Katoch deposed that the guidelines under the 1994 Act and the 2014 Rules are being adhered to in decisions relating to the Petitioners. The key points from the said affidavit are as follows:

- Meetings of the Authorisation Committee were scheduled on several occasions and but were either not attended by the Petitioners or resulted in requests for rescheduling.
  - Vide Authorisation Committee's Decision dated 9<sup>th</sup> March, 2021, the said Committee was not persuaded by the evidence presented to demonstrate a long-term association and love & affection between the Petitioner No. 1 and the Petitioner No. 2. Thus, the Authorisation Committee did not approve the transplant.
  - The affidavit emphasizes the Sir Ganga Ram Hospital's compliance with 1994 Act, the 2014 Rules and the due diligence applied by the Authorisation Committee to ensure no commercial transaction was involved in the transplant proposal.
13. In the said affidavit, the timeline of the Petitioners' case is provided, which is summarised as follows:
- **18th June 2020:** The Authorisation Committee committed to deciding on the Petitioner No. 1's application by 25th June 2020.
  - **23rd June 2020:** The Petitioner No. 1 was advised to attend the Authorisation Committee meeting scheduled for 24th June 2020.
  - **24th June 2020:** The Authorisation Committee meeting was held, but the Petitioner No. 1 did not attend.
  - **29th June 2020:** The Petitioner No. 1 cited the COVID-19 pandemic as the reason for not attending the meeting on 24th June 2020.
  - **17th July 2020:** A reminder was sent to the Petitioners to attend the meeting scheduled for 24th July 2020, which he did not attend.
  - **28th July 2020:** The Petitioners requested another opportunity for the meeting, citing the Petitioner No. 2's inability to attend due to COVID-19 related professional commitments.
  - **25th August 2020:** The Petitioners attended the Authorisation Committee meeting. However, the Authorisation Committee was not convinced of their long-term association.
  - **6th October 2020:** An email was sent to the Petitioner No. 1 requesting more evidence of the long-term association.
  - **9th November 2020 & 19th February 2021:** The Petitioner No. 1 submitted documents, which the Authorisation Committee found unsatisfactory in establishing a long-term association.
  - **24th February 2021:** The High Court directed a decision within two weeks.



- **9th March 2021:** Authorisation Committee meeting was convened; the transplant was not approved due to insufficient evidence of a longterm association.
  - **10th March 2021:** The decision was uploaded on the hospital website, in compliance with the High Court's directions.
14. Thus, according to the Respondent Nos. 1&2, the COVID-19 pandemic and subsequent lockdowns played a significant role in causing delays and difficulties in scheduling and attending meetings, as well as in interstate travel, which was crucial for both the Petitioner No. 1 and the Petitioner No. 2. Further, Authorisation Committee's requirement for the Petitioners to provide sufficient evidence of a long-term association and love & affection with the unrelated donor caused considerable delays in the decision making. Despite multiple opportunities and submissions of documents, the Committee was not convinced of the relationship's nature and depth.
15. Thereafter, on 28th April 2023, the Court noticed the 1994 Act and the 2014 Rules and called for a specific affidavit from the Respondent No. 4. The said order reads as follows:

*"2. The present petition is an unfortunate case where the Petitioner was seeking organ donation and had challenged the Respondent No. 1-Sir Ganga Ram Hospital's indecision and delay in taking a decision on the kidney transplant which the Petitioner required.*

**3. In the present petition, the issue that has been raised is that, once the requisite documentation is submitted, there are no prescribed timelines for holding of the interview by the Authorisation Committee under the Transplantation of Human Organs and Tissues Rules, 2014 ('2014 Rules').**

**4. Ld. counsel for the Petitioner submits that when the petition itself was filed, the Petitioner had sought approval for kidney transplantation at the Respondent No. 1-Hospital on an expedited basis. However, while the present petition was pending, the Petitioner has passed away in March-April, 2021. The submission of Id. Counsel for the Petitioner is that the Hospitals do not follow any timelines between the submission of documents and for fixing the date of interview.**

**5. Under the 2014 Rules, Rule 23(4) requires the decision to be displayed on the website within 24 hours and Rule**



**23(3) requires that the decision has to be taken within 24 hours. Insofar as the Rule 23(1) of the 2014 Rules is concerned, from the filing of the forms there is no timeline fixed for holding of the interviews. The said Rules are reproduced below:**

***“23. Decision of Authorisation Committee.— (1) The Authorisation Committee (which is applicable only for living organ or tissue donor) should state in writing its reason for rejecting or approving the application of the proposed living donor in the prescribed Form 18 and all such approvals should be subject to the following conditions, namely:-***

***(i) the approved proposed donor would be subjected to all such medical tests as required at the relevant stages to determine his or her biological capacity and compatibility to donate the organ in question;***

***(ii) the physical and mental evaluation of the donor has been done to know whether he or she is in proper state of health and it has been certified by the registered medical practitioner in Form 4 that he or she is not mentally challenged and is fit to donate the organ or tissue:***

***Provided that in case of doubt for mentally challenged status of the donor the registered medical practitioner or Authorisation Committee may get the donor examined by psychiatrist;***

***(iii) all prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation;***

***(iv) all interviews to be video recorded. (2) The Authorisation Committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where the patient requires transplantation on urgent basis.***

***(3) Every authorised transplantation centre must have its own website and the Authorisation Committee is required to take final decision within twenty four hours of holding the meeting for grant of permission or rejection for transplant.***

- (4) *The decision of the Authorisation Committee should be displayed on the notice board of the hospital or Institution immediately and should reflect on the website of the hospital or Institution within twenty four hours of taking the decision, while keeping the identity of the recipient and donor hidden.”*
6. *The said 2014 Rules have been enacted by the Central Government under Section 24 of the Transplantation of Human Organs & Tissues Act (THOTA), 1994. Let an affidavit be filed by the Respondent No. 3-Ministry of Health and Family Welfare, Union of India on this issue. This issue shall be considered on the next date of hearing.*
7. **If there are no timelines, for calling the interview, the Respondent No. 3-Union of India shall also state in its affidavit as to what is the reasonable period that should be followed by the Hospitals, Authorisation Committees and for the screening process for holding interviews and conveying the decisions to the applicants under the 2014 Rules.**
8. *The Union of India through the Secretary, Ministry of Health and Family Welfare is impleaded as Respondent No.3 in the matter.”*
16. In terms of the above order, an affidavit dated 25<sup>th</sup> September, 2023 has been placed on record by the Under Secretary, Ministry of Health and Family Welfare, Government of India stating that the timelines under the 1994 Act and 2014 Rules have already been communicated vide communication dated 24<sup>th</sup> January, 2022, and the said communication has also been circulated amongst all the States. The relevant portion of the said affidavit reads as follows:
- “As you are aware the Government of India enacted Transplantation of Human Organs and Tissues Act, 1994 to provide for the regulation of removal, storage and transplantation of human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in human organs and tissues and for matters connected therewith or incidental thereto. 2. As per provisions of Transplantation of Human Organs and Tissues Act, 1994 (as amended in 2011) for purposes of live donation,*

*permission of the Competent Authority (in case of Indian near relative defined under Section 2(i) of the Act) and Authorisation committee (in case when the donor is other than near relative) is required.*

*3. It has been observed that in many cases the process to grant approval for organ donation from a living donor gets substantially delayed, at times leading to demise of the recipient. The matter is of grave concern and as such has also been raised in the Parliament. To streamline the process for timely outcomes the matter has been considered in this Ministry in consultation with Directorate General of Health Services (Dte. GHS) and the following is advised to the States/Union Territories for implementation:*

- i. Authorisation Committee/Competent Authority should decide the case of a transplant from a living donor within 7 working days after the receipt of all required documents, as per THOTA, 1994 and rules thereunder, in respect of proposed transplant. As per Rule 23(3) of Transplantation of Human Organs and Tissues Rules, 2014 “Every authorized transplantation centre must have its own website and the Authorisation Committee is required to take final decision within twenty-four hours of holding the meeting for grant of permission or rejection for transplant.”***
- ii. Appeal preferred under Section 17 of the Act in respect of case of rejected donor must be heard within 7 working days after the receipt of all required documents, as per THOTA, 1994 and rules thereunder in respect of proposed transplant”.***

### **Submissions**

17. The Respondent No. 4 submits that in terms of the said affidavit, the decision by the Authorisation Committee has to be taken within seven working days after the receipt of all the required documents. The Respondent No. 4-Central Government is the Appellate Authority, only if the application from a living donor has been rejected by the Authorisation Committee and even in

case of such appeals the same is to be decided within seven working days after receipt of all the required documents.

18. *Per contra*, the Id. Counsel for the Petitioners, who appears solely to assist the Court, submits that no timelines exist for the Authorisation Committee to hold the interview under the 2014 Rules, consequently leading to delays in deciding cases of transplants from living donors.
19. She specifically drew the Court's attention to Rule 7 of the 2014 Rules, which outlines the procedure to be followed by the Authorisation Committee. She argues that if timelines are not prescribed and the Authorisation Committee indefinitely adjourns hearings without meeting with the donor and their family, as well as the recipient and their family, the applications remain in suspended animation, causing prolonged suffering for the patient. Therefore, she suggests that specific timelines should be established under the 2014 Rules and communicated to the Authorisation Committees and all hospitals nationwide where such committees operate.
20. Furthermore, she submits that to facilitate the processing of documents, proper arrangements should be made accessible on the respective hospital's website. This would allow for the handling of organ transplant cases through online submission of forms and documents, rather than requiring in-person filing.

#### **An overview of the 1994 Act and 2014 Rules**

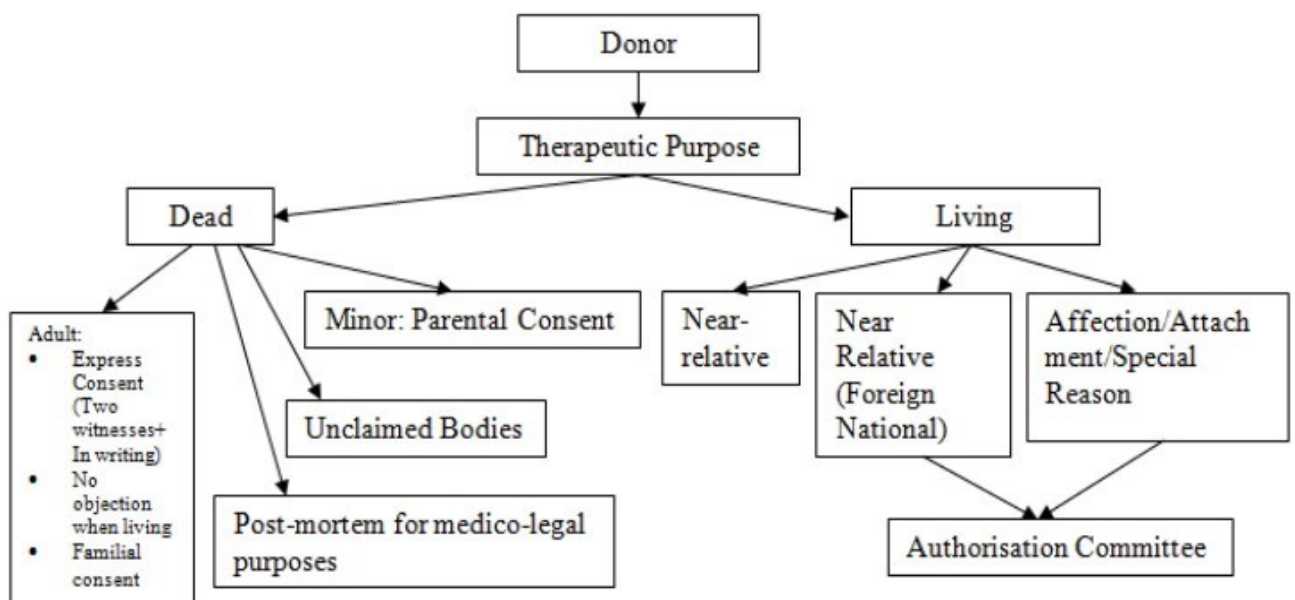
21. In the present petition, the primary issue for the Court's consideration is whether there is a need for prescribing specific timelines under the 2014 Rules for the Authorisation Committee's interviews and decision-making processes in organ transplant cases.
22. Before considering the issue that has arisen in the present petition, an overview of the 1994 Act and 2014 Rules is essential. The 1994 Act represents a significant step in establishing a regulated and ethical environment for organ and tissue transplantation in India, prioritizing the health and rights of individuals while addressing the critical need for organs for therapeutic use. According to the Preamble of the 1994, the objectives of the 1994 Act are as follows:
  - Regulation of Organ and Tissue Transplantation: To provide a legal framework for the procedures involved in the removal, storage, and transplantation of human organs and tissues, ensuring that these activities are conducted for therapeutic purposes.

- Prevention of Commercial Dealings: A crucial aspect is to prevent commercial dealings in human organs and tissues. It aims to curb any form of illegal trade or exploitation related to organ and tissue transplantation.
  - Ethical and Legal Oversight: The 1994 Act ensures that the process of organ and tissue transplantation is carried out in an ethical and legally compliant manner, safeguarding the rights and welfare of both donors and recipients.
  - Therapeutic Purposes: The 1994 Act emphasizes that the removal and transplantation of organs and tissues should be strictly for therapeutic purposes, aligning with medical and ethical standards.
23. The key provisions of the 1994 Act include the following aspects:
- Scope and Definitions: Section 2 of the 1994 Act defines critical terms such as "donor," "recipient," "hospital," and "brain death." It outlines its applicability, covering aspects of organ and tissue transplantation, including conditions under which organs can be removed from living or deceased individuals.
  - Authority for Removal of Human Organs: Specific provisions, such as Sections 3-9 of the 1994 Act, provide for the removal of organs or tissues from both living and deceased donors. This includes scenarios where the donor is brain dead, a minor, or an unclaimed body in a hospital. Consent procedures are detailed, emphasizing the need for voluntary and informed consent.
  - Regulation of Hospitals and Transplant Centres: The 1994 Act under Sections 10-12 mandates that hospitals performing organ or tissue removal, storage, or transplantation must be registered. It specifies conditions for registration, including necessary infrastructure, facilities, and qualified personnel.
  - Appropriate Authority: Under Sections 13-13D of the 1994 Act, an Appropriate Authority has been established for each State or Union Territory. The said Authority is responsible for granting registrations to hospitals, enforcing the 1994 Act's provisions, and conducting inspections.
  - Advisory Committees: Section 13A of the 1994 Act provides for the establishment of Advisory Committees to assist the Appropriate Authority. These committees, comprising medical and legal experts, advise on technical, ethical, and legal issues related to transplantation.
  - Prohibition of Commercial Dealings: One of the crucial aspects of the 1994 Act is its strict prohibition of commercial dealings in human organs as provided in Section 19 and 19A of the 1994 Act. It criminalizes the buying and

selling of human organs, including advertising for organ sale. Violations are punishable by imprisonment and fines.

- Appeals: Provisions are made for appeals under Section 17 of the 1994 Act against the decisions of the Authorisation Committee and Appropriate Authority.
- Section 24 of the 1994 Act empowers the Central Government to make rules for the implementation of its provisions. As empowered by this provision, the Central Government has framed the 2014 Rules. Thus, it can be seen that the provisions of the 1994 Act can be generally grouped into three main categories:
  - Regulations overseeing the transplantation of organs and tissues,
  - Rules governing healthcare providers and hospitals, and,
  - Stipulations of penalties for any infractions of the 1994 Act.

The approval process under the 1994 Act has been diagrammatically explained by the *Vidhi Centre for Legal Policy* in one of its reports, in the following flowchart<sup>1</sup>:



25. Under Section 9 of the 1994 Act, the Authorisation Committee plays a critical role in the transplantation process. In terms of Section 9(3) of the 1994 Act, the Committee's primary responsibility is to oversee and approve organ transplant procedures involving donors and recipients who are not near relatives. This approval is crucial, especially in cases where organs are

<sup>1</sup> Vidhi Centre for Legal Policy, 'Report on Organ Transplant Law: Assessing Compatibility with the Right to Health' pp. 8, available here [https://vidhilegalpolicy.in/wpcontent/uploads/2020/06/171003\\_OrganTransplantsReportFinal.pdf](https://vidhilegalpolicy.in/wpcontent/uploads/2020/06/171003_OrganTransplantsReportFinal.pdf) .



donated for reasons of affection, attachment, or other special circumstances, to ensure ethical compliance and prevent illegal practices. Under Section

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9(5) of the 1994 Act, the Committee is expected to conduct a thorough inquiry while reviewing applications for transplant approval. The most crucial aspect of such an inquiry to be conducted by the Authorisation Committee is to verify the authenticity and genuinity of the donor and the recipient, as also to ensure that the donation is not due to any commercial motives.

26. The provisions relating to the working of the Authorisation Committee under the 2014 Rules are:

- Rule 7: It provides for the constitution of the Authorisation Committee as also the nature of enquiry and evaluation to be conducted by the Committee. Under Rule 7(3), in cases where the donor and recipient are not near relatives, the Committee must ensure there is no commercial transaction involved, evaluate the relationship between the donor and recipient, and verify the authenticity and motivation for the donation. Under Rule 7(5), if the recipient is in a critical condition and needs transplantation within a week, the hospital can be approached for expedited evaluation.
- Rule 10: Details the application process for living donor transplantation, requiring joint applications by donor and recipient.
- Rule 11: Describes the composition of Authorisation Committees at state and hospital levels, including medical professionals, a medical director and two senior medical practitioners not part of the transplant team.
- Rule 17: Details the scrutiny process for applications by the Authorisation Committee, including the verification of documents and information.
- Rule 19: In case of transplant between persons who are not near relatives or in cases where either the donor or the recipient is a foreign national, the approval can be granted only by the Authorisation Committee of the hospital and in its absence, the District or State level Authorisation Committee. This is meant to ensure that proper certifications in terms of Rule 20 in case of foreigners can also be obtained and greater caution is exercised in such cases.
- Rule 23: This rule prescribes the manner in which the Authorisation Committee is to convey its decisions. This requires that the reasons have to be given in writing for either approving or rejecting the application. Every approval would require all medical tests for determining biological capacity



as also compatibility. The physical and mental evaluation of the donor is also required. The interviews to be conducted would also have to be video recorded. It is expected that the decision shall be taken within 24 hours after the holding of the meeting.

27. The scheme of the 1994 Act and the 2014 Rules shows that there is a sense of urgency underlying the process of granting approvals for organ donation. The processing of forms, the conduct of interviews and the decision making itself is expected to be within fixed timelines and not in an expanded or elastic manner. The 1994 Act and the 2014 Rules definitely do not contemplate months together of deliberation in such cases. The reason is obvious - if a particular application is to be approved then the same has to be done in a timebound manner so that the patients do not continue to suffer. If the approval is to be rejected then the decision has to be taken quickly so as to enable the recipient to explore other options of the donor in terms of the 1994 Act and the 2014 Rules.
28. The state of suspended animation, wherein neither approval nor rejection is conveyed, is contrary to the letter and spirit of the 1994 Act and the 2014 Rules. In fact, urgency and alacrity ought to be shown by the Authorisation Committee, as is reflected in, for example, Rule 23(3) which requires a final decision within 24 hours of holding of the meeting. If the process was not one of such urgency, the time period of 24 hours would not have been prescribed under the 2014 Rules.
29. The time-sensitive nature of the functioning of the Authorisation Committee first came under consideration before the Andhra Pradesh High Court in ***Nagendra Mohan Patnaik v. The Government Of Andhra Pradesh, [1997 (1) ALT 504]***, wherein the constitutional validity of some provisions of the Andhra Pradesh Transplantation of Human Organs Act, 1995, was questioned. The Court upheld the vires of the said Act and observed that time is of the essence in treatments involving organ transplants. Delays in such cases can have life-threatening consequences. In the Court's opinion, the Committee is expected to conduct its inquiries efficiently and without unnecessary delays. The process should not be prolonged over days and months, as this can jeopardize the health and survival of patients awaiting transplants. The relevant portions from the above decision are as follows:  
  
**"17. Time, we are fully convinced, shall always be the essence in treatment of ailments in which transplant of organ is needed for therapeutic purposes. No one in such cases**

**can afford to make delay. Authorisation Committee or the appellate authority for that reason cannot embark on a lengthy inquiry spread over days and months. We are of the clear view and good reasons to believe that the Authorisation Committee and the appellate authority shall act with the quickest dispatch and deliver their orders within such period of time, which the hospital, Doctor or medical practitioner would indicate for the purpose of removal of the organ and transplantation.**”

30. As recognised by the Andhra Pradesh High Court in ***Nagendra Mohan Patnaik (supra)***, it operates as a quasi-judicial authority, tasked with the responsibility of approving or rejecting applications for organ removal and transplantation. The Authorisation Committee, in the context of organ transplantation, holds a time-sensitive and a critical role as mandated by the 1994 Act and the 2014 Rules. The said quasi-judicial body is responsible for the swift and judicious approval or rejection of organ transplant applications, a process steeped in urgency due to the life-saving nature of such medical procedures. The Committee must ensure all applications align with the 1994 Act, particularly emphasizing the voluntary and well-informed consent of the donor. Recognizing the delicate balance between thorough inquiry and the pressing need for prompt decisions, the Committee's operations are marked by a sense of urgency. Delays in decision-making can have dire consequences for recipients awaiting transplantation. Hence, the Committee is expected to act with expediency, adhering to a stringent timeline that respects the critical medical timelines dictated by the nature of organ transplants.
31. In the above context, the Bombay High Court in ***Vijaykumar Hariram Sahu v. State of Maharashtra [(2013) 2 Mah LJ 927 (Bom)]*** observed that the 2014 Act balances the autonomy of the individual as a decision maker with the societal interest in protecting the concerns of the family. Both the 2014 Act and the 1994 Rules, seek to bring about a healthy balance between the need for transplantation of human organs and tissues in order to save lives on the one hand and the public interest in ensuring that this does not become a facade for exploitation or for trafficking in human organs and tissues. The relevant paragraphs of the said decision are as follows:

“8. The Transplantation of Human Organs and Tissues Act, 1994 is an Act “to provide for the regulation of removal, storage and” transplantation of human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in human organs and tissues and for matters connected therewith.” The Statement of Objects and Reasons accompanying the Bill in Parliament notes that there was a need for a comprehensive legislation for regulating the removal of organs from cadavers and living persons and prohibiting commercial dealings in human organs. In the absence of legislation, transplantation of organs had been impeded and there was a persistent demand for regulatory legislation on the subject. In enacting the legislation, Parliament **has borne in mind two principles of public interest. First, there is a need to allow transplantation as an instrument of saving lives. Transplantation has an important element in the protection of public health. Second, there was a need to ensure that trafficking in human organs does not take place by exploiting poverty, illiteracy and ignorance of a large section of Indian Society. In its regulatory provisions, the Act seeks to bring about a balance between the two competing principles.**

...

11. [...] The object and purpose of the Act is to prohibit commercial dealings in the transplantation of human organs and tissues. Parliament was cognizant of the fact that unless the process was regulated, human beings in our society which suffers from poverty, illiteracy and ignorance, could be subjected to exploitation for the purposes of transplantation. Where the proposed transplantation is not between near relatives, the Authorisation Committee is specifically under a mandate under Rule 6F(d) to evaluate and ascertain that there is no commercial transaction between the donor and the recipient. The Authorisation Committee has, therefore, to consider the explanation which is furnished of the link between the donor and the donee, of the circumstances which led to the offer being made, documentary evidence of the link, reasons why the donor wishes to donate and can even look at old photographs to show

*the link between the donor and the donee. The Authorisation Committee has to ascertain that no middleman or tout is involved. The financial status of the donor and the recipient has to be probed and in the case of a gross disparity, that has to be taken note of having regard to the object of preventing commercial dealings. Where there is a gross disparity in the financial status of the donor and donee, the legislature was cognizant of the need to ensure that this had not been used to suborn the will of the donor. The views of the next of kin of the proposed unrelated donor are required to be ascertained in order to ensure that such persons are aware about the intention of the donor to donate an organ. Their views are also significant for assessing the authenticity of the link between the donor and the recipient and the reasons for the donation. Any strong views, disagreement or objection of such kin is to be recorded and taken note of. At this point it is necessary to clarify that the Rules do not confer an overriding veto on the next to kin of the donor. **The Act balances the autonomy of the individual as a decision maker with the societal interest in protecting the concerns of the family. Both the Act and the Rules, seek to bring about a healthy balance between the need for transplantation of human organs and tissues in order to save lives on the one hand and the public interest in ensuring that this does not become a facade for exploitation or for trafficking in human organs and tissues.** The views of the next of kin are entitled to deference but this is not to suggest that the Authorisation Committee, once a disagreement is expressed, would have no power to take an independent decision based on the best interest of the donor and the donee. Ultimately, the Authorisation Committee has to take a judicious decision after considering all the facts and circumstances. ”*

32. In ***Arup Kumar Das v. State of Orissa, (2010 SCC OnLine Ori 181)***, the Petitioners' application for kidney donation was initially rejected by the Authorisation Committee and the appellate authority, mainly due to poor HLA (Human Leukocyte Antigen) matching and doubts over the emotional

connection between the donor and recipient. The Court noted the advancements in medical science, particularly in immunosuppressive drugs, which reduce the significance of HLA matching in kidney transplants. Further, according to the Court, expert opinions suggested that HLA matching should be a secondary consideration, especially for unrelated donor-recipient pairs. It also criticized the functioning of the Authorisation Committee for not adequately considering medical advancements and for being overly stringent in their interpretation of the 1994 Act. In addition, the Orissa High Court directed the State Government to issue necessary directions for fixing time limits for dealing with applications under Chapters III and IV of the 1994 Act. The relevant portions of the said decision are set out below:

*“11. It is by now well settled in law that TOHO Act, 1994 was enacted as a comprehensive legislation for regulating the removal of organs from cadavers and living persons and prohibiting commercial dealings in human organs. It is a well accepted principle incorporated in the said Act which recognizes the technology by which it is possible to remove organs from living and deceased person and transplant such organs to save life of suffering human beings. This advancement of science, medicine and technology has also brought with it the evil of mal-practices and commercial dealings in human organs keeping in view the economic reality of huge part of our population living below poverty line and the danger of exploitation by sale of organs due to compelling economic necessity in our country. It is in this background that TOHO Act, 1994 was enacted. Various procedural requirements/safeguards have been created both in Act and Rules for ensuring that there is no exploitation and no commercial dealing in human organs. Even then, under the enactment of TOHO Act, a donor may be a relative or a non-relative and may even be an outsider for 9 which approval of transplantation is required to be given by the Authorisation Committee under Section 9 for the reason of affection and attachment with the recipient.*

...

14. We also feel it essential to point out herein that the various objectives of TOHO Act, 1994 and the intention of the Parliament in enacting the present legislation appears to have not been properly understood by the statutory authorities who have been vested with

the responsibility of enforcing the said Act. What must not be lost sight of is that, transplantation of human organs has not been prohibited but regulated in terms of the said statute. What has been prohibited under the statute is commercial dealings in human organs and prevention and exploitation of humans for financial benefits. The Authorisation Committee as well as the appellate body must endeavour to ensure that while exploitation must be prevented and commercialization dealing in human organ is prohibited, yet bona fide applicants may not be viewed in a suspicious manner since the TOHO Act, 1994 itself permits not only the donors from within the family but also permits non-relative donors. We are of the considered view that the TOHO Act, 1994 should not be interpreted in a manner which effectively amounts to prohibiting transplantation of human organs. In conclusion, we may state that the TOHO Act, 1994 is enacted by the Parliament for regulating transplantation of human organs and only prohibits commercial dealings in human organs.

15. In course of hearing of the present writ application, this Court found that even though the TOHO Act, 1994 has come into existence for more than years, yet the aims and objectives of the said statute remain largely unfulfilled. We are, therefore, of the view that the following directions are necessary in order to attain the objectives behind the legislation:-

(i) ....

(ii) ....

(iii)

(iv) The State Government is directed to issue necessary Notifications fixing time limits within which period the applications for transplantation of human organs may be processed by the Authorisation Committee and time limit also be fixed for disposal of the statutory appeals. (v) The State Government is directed to issue necessary direction fixing time limits for dealing with the applications under Chapters-III and IV of TOHO Act, 1994.”



33. In *Vandana Dixit v. Visitor S.G.P.G.I, [MANU/UP/3515/2010]*, the Petitioner, a housewife, had been suffering from renal failure since 2004. She was advised to undergo dialysis and a renal transplant and was on regular dialysis. Her relatives, though willing, were medically unsuitable to donate a kidney. One person, who was not a near relative but was emotionally attached to the Petitioner, volunteered to donate his kidney. They jointly applied to the Authorisation Committee for permission to proceed with the transplant. On 21st November, 2009, the Committee granted Authorisation, albeit with a caution about a blood group mismatch. Despite the state-level Authorisation, two hospitals – Fortis Hospital in Noida and the Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) – refused to perform the transplant. The said hospitals cited extraneous policy decisions and the absence of approval from their Hospital Based Authorisation Committees as reasons for their refusal. The Court made it clear that the authorisation by the State-level Committee overrides individual hospital policies or the absence of approval from Hospital Based Authorisation Committees. The Court emphasized the urgent responsibility of doctors, hospitals, and Authorisation Committees to expedite organ transplant processes in critical cases, adhering to the legal provisions of the 1994 Act and 2014 Rules. It highlighted the potential fatality of delays in such treatments and asserts the patient's right to a prolonged, comfortable life. The Court observed as follows:

*“57. The Authorisation Committee may be the State Level Authorisation Committee or the District Level Authorisation Committee or Hospital Based*

*Authorisation Committee has to judge the application moved by the donor and recipient on the basis of guidelines, parameters and conditions which have been mentioned in the Act and the Rules. Once the Authorisation Committee duly constituted by the State Government or Central Government as the case may be, gives such approval/Authorisation after being satisfied that all the conditions stand fulfilled, there would be no occasion for such person namely; the donor and the recipient to have another*

*Authorisation from any other Authorisation Committee for the transplant.*



58. No Hospital and registered Doctor, can refuse to undertake the transplant of any human organ on the ground that despite approval being given by one duly constituted Authorisation Committee, additional Authorisation from any other Authorisation Committee will be needed, **unless it is found that the Authorisation has not been given in accordance with the rules but even in such a case, the matter has to be referred to the Authorisation Committee for reconsideration within the shortest possible time.**

...

65. We, therefore, conclude with a note that it is the responsibility of all the doctors and hospitals to facilitate the treatment in a deserving case to the patient **who is in emergent need of transplantation of human organs by following the provisions of the Act and the Rules at the earliest and the Authorisation Committees so formed have the responsibility to give permission only when they are satisfied about the statutory requirements having been fulfilled with promptitude. The delay in giving such treatment sometimes may prove fatal, for the ailing who has a right to live a longer life which life should be as comfortable as it could be.** Transplant of human organ can not be refused for the reasons which do not flow from the Act aforesaid. We, therefore, dispose of this petition finally with the direction that the petitioner may approach the Fortis Hospital or SGPGI as per her liking and discretion, where she would be provided the necessary treatment/operation, as may be medically advisable, with immediate promptness as she is waiting for the transplant for the last six years or so, by following the instructions given in Rule 6F(c)(xi).”

34. Following ***Arup Kumar Das (supra)***, a Id. Single Judge of this Court in ***Parveen Begum v. Appellate Authority [189 (2012) DLT 427]*** held that the Authorisation Committee’s approach in matters under the 2014 Rules ought to be pragmatic and its discretion should be judiciously used, particularly in cases requiring immediate transplantation. In the said case, the timeline of events pertaining to the Petitioner is as follows:

- **August 2011:** Petitioners submitted their application for necessary tests.

- September 2011: Petitioners submitted necessary documents.
- 8<sup>th</sup> February, 2012: The State Authorisation Committee approved the petition
- 17<sup>th</sup> February, 2012: An enquiry was conducted by the Authorisation Committee.
- 21<sup>st</sup> March, 2012: A further meeting of the Authorisation Committee was held.
- 14<sup>th</sup> February, 2012, 2<sup>nd</sup> March, 2012, 15<sup>th</sup> March, 2012, 3<sup>rd</sup> April, 2012: Interviews were conducted by the Authorisation Committee on these dates.
- 5<sup>th</sup> April, 2012: The Petitioners' case was rejected.
- 24<sup>th</sup> April, 2012: Petitioners appeared before the Appellate Authority. Appellate Authority rejected the Petitioners' case.
- 15<sup>th</sup> May, 2012: Judgment delivered in the Petitioners' favour.

Thus, it can be seen that it took **approximately 288 days** to get the necessary approval under the 1994 Act, starting from August 2011 and concluding with the judgment delivered in favour of the Petitioner on 15th May 2012. Noting the delay caused due to multiple rounds of interviews and other procedures under the 1994 Act, the Court held as follows:

*“85. The Supreme Court in **Comptroller and Auditor General of India Gian Prakash, New Delhi (supra)** held in para 20 that in an appropriate case, in order to prevent injustice resulting to the concerned parties, the Court may itself pass an order or give directions which the Government or a public authority should have passed or exercised its discretion at a proper level.*

*86. In the present case, the petitioner no.1 has been in need of a kidney replacement since June 2011. The joint application for seeking the approval of the Authorisation Committee was submitted by the petitioners in August 2011. Over this period of time, the condition of the petitioner no.1 has only deteriorated and she requires dialysis thrice a week. Even from the interviews of petitioner no.1 conducted on different dates, her deteriorating condition of her health is evident.*

*87. **Considering these facts and circumstances, and the urgency of the matter, I am inclined to require the Authorisation Committee to forthwith grant its approval to the case of the petitioners for donation of one kidney by petitioner no.2 to petitioner no.1 in terms of their application. The formal approval should be granted within two days.***

**failing which it shall be deemed that the said formal approval stands granted.**

**88. Upon the grant of the said formal approval/deemed formal approval, the petitioners shall be entitled to undergo the required medical procedures and operation for the purpose of carrying out the transplantation, as aforesaid.”**

35. In ***C. Seshadri v. State of Telangana [2018 (5) ALT 637]***, the Petitioner, suffering from renal failure for an extended period and being a diabetic patient for about 25 years, had been receiving dialysis three times a week since August 2017 at Century Hospital, Hyderabad. The doctors interviewed the Petitioners on 26th April 2018. However, the Authorisation Committee, vide order dated 18th May 2018, rejected the application, doubting the altruistic nature of the donation and without considering the submitted evidence. Aggrieved, an appeal was filed on 20th May 2018 before the Appellate Authority, which remained undecided. The Telangana High Court subsequently overturned the Authorisation Committee's decision, approving the necessary transplant. The Court stressed that mere suspicion or economic disparity should not be reasons to deny approval, and noted the significant delay in decision-making, including the Appellate Authority's failure to address the Petitioner's case.

36. In ***Ratnakar Peddada v. State of Telangana (2018 Indlaw HYD 294)***, the Petitioner No. 1 was diagnosed with Tuberous Sclerosis, a chronic kidney disease. His right kidney was removed in 2007 due to internal bleeding, and he had been undergoing dialysis three times a week since November 2016. The timeline of events in the present case in relation to the Petitioner is as follows:

- On 11<sup>th</sup> November, 2017, the doctors conducted an interview with both Petitioners to assess their suitability for kidney transplant.
- On 29<sup>th</sup> November, 2017, the State Authorization Committee for Organ Transplant, Telangana State conducts another interview with the Petitioners.
- On 11<sup>th</sup> December, 2017, the State Authorization Committee for Organ Transplant, Telangana State conducts another interview.

- Following the interviews, the State Authorization Committee for Organ Transplant, Telangana State issues communication dated 12<sup>th</sup> December, 2017, rejecting the application for kidney transplant.

Keeping in mind the delicate health situation of the Petitioner, following ***Parveen Begum (supra)***, Telangana High Court allowed the writ petition and directed the Authorization Committee to grant the approval to the case of the Petitioners for donation of one kidney by Petitioner No.2 to Petitioner No.1.

37. In ***Radhakrishnan Pillai v. Sajeev R, [W.P. (C) 16216 of 2021, decision dated 27<sup>th</sup> August, 2021]***, the Petitioner No. 1, was a kidney patient undergoing treatment at Medical Trust Hospital, Ernakulam, who urgently needed a kidney transplant. His driver, volunteered to donate his kidney due to their close relationship, as evidenced by certificates from local authorities. Despite legal consent and an earlier Court direction for authorities to consider their application, the Authorisation Committee rejected the petition due to the donor's involvement in criminal offenses. The Petitioners had submitted their application for permission under the 1994 Act and 2014 Rules on 18th March, 2021. However, the final decision in respect of the application was not issued until 8th July, 2021, and that too following the filing of a contempt case in the Court. The Kerala High Court criticized such delays and emphasized the need for swifter action in the future. It also observed that the Authorisation Committee had to follow a pragmatic approach while deciding applications under Rule 23 of the 2014 Rules. The relevant extract from the said judgment is as follows:

*“8. Therefore, a great care is necessary while considering an application by an Authorisation Committee constituted as per the Act 1994. Of course, it is a divine duty also. The main duty of the Committee is to see that there are no commercial dealings in human organs. It is the subjective satisfaction of the Committee. A pragmatic approach is necessary from the side of the Committee. Rule 23(2) of Rule 2014 says that, the committee shall use its discretion judiciously and pragmatically while taking decisions. The intention of the legislature while enacting the Act 1994 is only to prevent commercial dealing in human organs. If there is no evidence for the same, the Authorisation Committee should take a human approach. If there is no evidence to show that there is no commercial dealing, pragmatism*

**should overtake technicalities, because a man is on death bed. The decisions of the Authorisation Committee should inspire people to donate their organs to needy people.**

Awareness is necessary to increase the organ donation ratio in India. Some studies in the internet show that, India remains a country with one of the lowest organ donation rates in the world. Some statistics says that, organ donation in India is very poor around 0.3/million population, as compared to some western countries where it is as high as 36/million. It also shows that in the US, it is around 26/million population. So, the motivation and inspiration for organ donation are necessary from all sides.

...

13. Moreover, **delay in convening meetings and taking decisions by the Authorisation Committee in applications for organ donation is also to be deprecated.** Exts.P6 is the application submitted by the petitioners for getting permission as per the provisions of Act 1994 and Rule 2014. Exts.P6 is dated 18.03.2021. The final order in Exts.P6 was passed by the respondent only on 08.07.2021 and that also after filing a contempt case before this court. This should not be allowed to continue in the future. **The Chief Secretary of the State should issue appropriate orders directing all the authorities concerned to convene meetings to consider the applications submitted as per Act 1994 and Rule 2014, as expeditiously as possible, at any rate, within one week from the date of receipt of such applications. In urgent cases, the authority concerned should convene the meeting and consider the applications forthwith.** It is to be noted that, in Rule 23(3), it is stated that the final decision in an application is to be taken within 24 hours of holding the meeting by the Authorising committee. **A time limit is necessary for convening the meeting also. If there is any delay happened beyond 1 week for convening the meeting from the date of receipt of the application by the Authorisation Committee, the Committee concerned should mention the reason for the delay in the order.** The Registry will send a copy of this judgment to the Chief Secretary forthwith for issuing appropriate common directions in this regard to all the

*Authorisation Committees constituted as per Act 1994 and Rule 2014.”*

### **Analysis**

38. From the perusal of the above decisions, the following position emerges:

- Absence of timelines under Rules 21 and 23 of the 2014 Rules for holding of the pre-transplantation interviews by the Authorisation Committee has led to delays. In some cases, as in the present case, the recipient has in fact passed away awaiting the decision of the Authorisation Committee.
- Under the 1994 Act and the 2014 Rules, pre-transplant assessment of potential donors is a critical component of the organ transplantation process.
- However, significant delays in the interview process hamper the ability of the recipient to receive timely transplantation of the required organ under the 1994 Act.
- Sometimes the Courts have felt the need to direct formal approval failing which deemed approval has also been granted. Further, the Courts have often intervened to ensure that the transplantation process is completed within specified timelines. For instance, in ***Parveen Begum (supra)***, the Court directed that formal approval for the transplant must be granted within two days; otherwise, it would be considered that the said formal approval had been granted.

39. Furthermore, the purpose of conducting the pre-transplant interview as outlined in the 2014 Rules needs to be appreciated. Under Rule 7 of the 2014 Rules, when the proposed donor and the recipient are not near relatives, an interview with a near relative or an adult person related to the donor by blood or marriage must be conducted to ascertain awareness of the donation intention, the authenticity of the link, and the reasons for donation. Any strong views or objections from such individuals should be documented. Further, as required by Rule 21 of the 2014 Rules, in determining the eligibility of an applicant to donate, the Authorisation Committee must personally interview the applicant.

40. On the issue of pre-transplantation interviews, in the Directive bearing ***no. 2010/45/EU*** passed by the European Parliament and of the



Council titled ‘*On Standards of Quality and Safety of Human Organs Intended for*

*Transplantation*’ dated 7<sup>th</sup> July, 2010, one of the Preambles to the Directive notes as follows:

*“Pre-transplant evaluation of potential donors is an essential part of organ transplantation. That evaluation has to provide enough information for the transplantation centre to undertake a proper riskbenefit analysis. **It is necessary to identify and document the risks and characteristics of the organ in order to allow its allocation to a suitable recipient.** Information from a potential donor’s medical history, physical examination and complementary tests should be collected for the adequate characterisation of the organ and the donor. To obtain an accurate, reliable and objective history, the medical team should perform an interview with the living donor or, where necessary and appropriate, with the relatives of the deceased donor, during which the team should properly inform them about the potential risks and consequences of donation and transplantation. Such an interview is particularly important due to the time constraints in the process of deceased donation which reduce the ability to rule out potentially serious transmissible diseases.”*

41. It need not be emphasised that the pre-transplantation interviews play a crucial role as the Authorisation Committee has to ascertain that there are no commercial considerations in the donor donating the organ to the donee. However, the said process of interview and documentation requires to be done in a timebound manner failing which the purpose of the process itself could be defeated. The requirement of the interview, the video graphing of the same, counselling during the said process, all play a crucial role. But considering the condition of the donee, without timelines being adhered to, the object and purpose of the 1994 Act is likely to be defeated. Quick decision making is crucial not just for the donor or the recipient, but also for their respective families. The complex nature of the process, in fact, tends to deter organ donation which would also not be in the overall interest of the society as a whole, in terms of the object sought to be achieved by the Act. The intention of the Act and Rules is to regulate organ donation and not to completely dissuade the same.



42. Thus, considering the critical importance of such interviews, this Court finds it necessary to establish timelines under the 2014 Rules. Such a time-bound approach is crucial to maintain the integrity and effectiveness of organ transplantation protocols. This would also be in furtherance of the right to health under Article 21 of the Constitution. The Supreme Court in ***Association of Medical Super Speciality Aspirants & Residents v. Union of India [(2019) 12 S.C.R. 1011]*** held that right to health is fundamental to the right to life under Article 21 of the Constitution of India. The right to life extends beyond mere survival to include living with dignity, encompassing basic necessities like nutrition, clothing, shelter, and the freedom to express, move, and interact. Every act that undermines human dignity amounts to a partial deprivation of the right to life. Such restrictions must align with a reasonable, fair, and just legal procedure that upholds other fundamental rights. To truly live is to live with dignity. The relevant portions of the decision are as follows:

*“26. Right to health is integral to the right to life. Government has a constitutional obligation to provide health facilities. The fundamental right to life which is the most precious human right and which forms the ark of all other rights **must therefore be interpreted in a broad and expansive spirit so as to invest it with significance and vitality which may endure for years to come and enhance the dignity of the individual and the worth of the human person.** The right to life enshrined in Article 21 cannot be restricted to mere animal existence. **It means something much more than just physical survival. The right to life includes the right to live with human dignity and all that goes along with it, namely, the bare necessities of life such as adequate nutrition, clothing and shelter, and facilities for reading, writing and expressing oneself in diverse forms, freely moving about and mixing and commingling with fellow human beings. Every act which offends against or impairs human dignity would constitute deprivation pro tanto of this right to live and the restriction would have to be in accordance with reasonable, fair and just procedure established by law which stands the test of other fundamental rights.***

27. *To live is to live with dignity. The draftsmen of the Constitution defined their vision of the society in which constitutional values would be attained by emphasizing, among other freedoms, liberty and dignity. So fundamental is dignity that it permeates the core of the rights guaranteed to the individual by Part III of the Constitution. Dignity is the core which unites the fundamental rights because the fundamental rights seek to achieve for each individual the dignity of existence.*

28. **The State's obligations are not satisfied solely by refraining from imposing limitations on the right to human dignity. The State must also take action to protect human dignity and to facilitate its realization. The constitutional right to dignity is intended to ensure human beings' political and civil liberties as well as their social and economic freedoms**".

43. An organised and timely transplantation decision making process which is contemplated under the 1994 Act and the 2014 Rules would be nullified if timelines are not prescribed for various steps. While the satisfaction of the Authorisation Committee is absolutely crucial in this process, internal timelines will still have to be fixed to ensure that the said Committee's functioning is systematic.

44. Further, repeated opportunities given for submission of the required documents without any outer time limit is also not in the spirit of the 1994 Act and the 1994 Rules as there ought to be a maximum limit for the number of opportunities that can be granted. If the requisite documentation cannot be completed within the outer time limit, the application ought to be rejected with liberty to move afresh. However, if the documentation is complete, the Authorisation Committee cannot continue to delay the decision, either way prescribing of time limits is essential.

45. This Court is of the opinion that even the timelines fixed vide communication dated 24<sup>th</sup> January, 2022 are insufficient due to the uncertainties in the same. The said communication, in fact, dilutes the timelines fixed under Rule 23 of the 2014 Rules. The communication also does not lay down any timeline for scheduling interviews for proposed donor by the Authorisation Committee and, therefore, there can be several delays at that stage. In view of the above background and considering that there

are several similar cases which are arising across the Courts, timelines ought to be fixed at each of these following steps:

<b>Steps</b>	<b>Timeline for consideration</b>
Processing of application under Rule 11 of the 2014 Rules	Maximum 10 days from the date of the application.
Verification of documents as per Form 20 of the 2014 Rules	Maximum 14 days

46. In addition, timelines also ought to be fixed for the following steps:-

**Documentation Completion:**

- Within the prescribed timeline under the 2014 Rules, any opportunity given to the donor or recipient to complete the required documentation must be communicated.
- The donor or recipient should be given a maximum of one week to respond.
- If further opportunities need to be given, the same ought to be given after due consideration, with a strict deadline.
- Upon expiry of this timeline, the case should be presented to the Authorisation Committee.

**Scheduling Interviews by the Authorisation Committee:**

- After 4 to 6 weeks from receiving the application, the interview ought to be scheduled within a 2-week period.
- During the above 2-week window the Authorisation Committee ought to:
  - Conduct the interview of the donor/recipient on one or two occasions.
  - Facilitate a meeting of family members of both the donor and the recipient.
  - Convey the decision as per Rule 23 of the 2014 Rules.
- The entire process, from submission to decision, ought not to ideally exceed 6 to 8 weeks.

**Appeal Process:**

- Under Rule 33, any appeal against an order should be decided within a maximum of 30 days.

47. The non-adherence to timelines has resulted in extended waiting periods of 2 to 3 years in some cases before a decision is made, which contradicts the intent as also the letter and spirit of the 1994 Act and the 2014 Rules. Such prolonged delays can cause significant mental and physical anguish for both the donor and recipient as also their families. Therefore, clear and prompt communication regarding the application is essential, whether it be oral or written, to enable the donor/recipient and their respective families to proceed with the decision-making process.

48. The Petitioner, in the present case, has passed away. However, the fact that the Petitioner's demise occurred during the pendency of the petition, prompted the Court to hear submissions and make the aforementioned observations. The suggested timelines above are provided as a reference for the competent authority, enabling them to take an informed decision in this matter. Furthermore, the competent authority is expected to issue a proper communication to all stakeholders, prescribing timelines and ensuring their adherence.

49. Let the present judgment be placed before the Secretary, Ministry of Health and Family Welfare so as to ensure that timelines under the 1994 Act and 2014 Rules are prescribed for all the steps in the process of consideration of applications for organ donation, after consultation with the relevant stakeholders.

50. The present writ is, accordingly, disposed of in the above terms. All pending applications are also disposed of.

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