

Accelerating organ donations and its effectiveness through digitization

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Foreword

Organ donation and transplantation play pivotal roles in extending human life expectancy and aiding critically ill patients, especially in the face of contemporary lifestyle-related health challenges. Rooted in the principle of voluntary donation of medically suitable organs, this practice enables life-saving procedures for those in need, provided compatibility in medical criteria is met.

Globally, the majority of nations have established frameworks to facilitate organ donation, emphasizing solidarity during crises. India's acknowledgement of the importance of organ donation is exemplified by the Prime Minister's discussion of the topic during his periodic radio program, "*Mann Ki Baat*". Furthermore, in alignment with the government's broader agenda to bolster the nation's healthcare infrastructure, particularly through digitization focusing on quality, affordability, and accessibility, organ donation has emerged as a priority. The establishment of the National Organ and Tissue Transplant Organization (NOTTO) in 2014 underscores this commitment. Despite these efforts, India trails behind the global average in organ donation and transplantation rates per capita, highlighting a significant gap between organ supply and demand. This disparity, compounded by procedural inefficiencies, results in unfortunate instances of organ wastage in a country with urgent organ needs.

This report examines the various challenges within the existing organ donation and transplantation system and provides recommendations to address them. Key challenges include manual processes, lack of public awareness, and ineffective governance mechanisms leading to coordination issues between NOTTO, SOTTO, and ROTTO. A digital transformation is imperative to streamline processes, enhance transparency, and improve accessibility in organ donation. Such a transformation would optimize organ allocation, reduce wastage, and mitigate potential unethical practices. To facilitate this shift, the policy framework needs enhancements to overcome obstacles and ensure stakeholder confidence. Additionally, public awareness campaigns are essential to dispel misconceptions and foster national pride in contributing to life-saving endeavors. We advocate for a 3P approach – Policy changes, People awareness, and Process improvements – to enhance the organ donation and transplantation system.

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Executive Summary

Organ donation and transplantation stand as crucial measures to extend human longevity and rescue critical patients, particularly amidst the prevalence of lifestyle-related health challenges in today's era. Grounded in the ethos of voluntary donation of medically viable organs, this practice facilitates life-saving transplants for individuals in need, provided there's compatibility in medical parameters.

Across the globe, the majority of nations have established frameworks to facilitate organ donation, emphasizing solidarity during times of crisis. India's recognition of the significance of organ donation is exemplified by the Prime Minister's discourse on the topic during his periodic radio program, "Mann Ki Baat". Moreover, aligning with the government's broader mission to fortify the nation's health infrastructure with a focus on quality, affordability, and accessibility through digitization, organ donation has emerged as a priority area. The establishment of the National Organ and Tissue Transplant Organization (NOTTO) in 2014 underscores this commitment.

However, despite these initiatives, India lags behind the global average in organ donation and transplantation rates per capita, highlighting a substantial disparity between organ supply and demand. This dissonance, compounded by procedural inefficiencies, contributes to the regrettable phenomenon of organ wastage in a country with pressing organ requirements.

This report analyses the various challenges in the existing organ donation and transplantation system and provides recommendations to address those challenges. The current system faces various key challenges like manual processes, lack of awareness amongst general public and inefficient governance mechanisms leading to a lack of coordination between NOTTO, SOTTO and ROTTO

A digital transformation is essential to streamline processes, enhance transparency, and boost accessibility in organ donation. This would optimize organ allocation, reducing wastage, while also addressing potential unethical practices. To facilitate this transformation, the policy framework requires enhancements to mitigate obstacles and ensure stakeholder comfort. Additionally, public awareness campaigns are needed to dispel inhibitions and foster national pride in contributing to life-saving efforts.

We recommend a 3P approach— Policy changes, People awareness, and Process improvements to enhance the organ donation and transplantation system

Policy changes

Health is a state subject and each state is entitled to run its process independently. The present role of NOTTO does not give it the necessary powers it needs to coordinate effectively with the SOTTO, ROTTO, and transplant centers which leads to a complex and weak process. The biggest policy change we recommend is –

1. *Give NOTTO executive powers* that allow it to have a role larger than just coordination and data collection:
 - a. Short to medium-term: Integrate "appropriate authorities" into the national digital platform for hospital/center registration. NOTTO can also be designated as an "appropriate authority" over time.
Long-term: Empower NOTTO to allocate funds to ROTTO and SOTTO, elevating it to the apex body.
2. *Introducing a state waitlist payback system:* Prioritize patients based on a state-centric point system to ensure fair organ distribution and save lives efficiently.

People awareness

The next big issue to be tackled is a lack of awareness regarding organ donation. This can be solved through multiple angles.

1. A *grassroots program* that educates the wider public on the ground via various mass campaigns and in some form, also becomes a part of the school curriculum thereby educating future generations.
2. *Seminars* regarding brain death and transplantation should be held by the medical fraternity
3. *Adored public figures and mediums* can be leveraged to spread awareness.
4. The government can look into *peak hours advertising* similar to anti-smoking advertisement campaigns.

Process improvement

Finally, the process improvements need assistance from the policy framework and awareness programs but even within the current situation, it can function much better.

1. *Technology players* can be included to support the development of the national platform
2. *Interoperability of data* should be ensured so that data is easily accessible by the authorized people across the country
3. *Robust data storage and security protocols* should be established, ensuring compliance with regulatory standards and safeguarding sensitive information

By undertaking these concerted efforts, India can rejuvenate its organ donation ecosystem, fostering a culture of generosity and compassion while significantly enhancing the prospects for individuals in dire need of life-saving transplants.

Our analysis shows us that process improvements, policy updates and public awareness are key to enhancing India's organ donation system. India's success with its CoWIN infrastructure is a testament to its potential in healthcare. The key steps needed to help India excel are –

- Short term: Launch NHA's organ donation platform, phasing out legacy systems gradually, coinciding with extensive awareness campaigns.
- Medium term: Integrate non-medical stakeholders (police, transport authorities) into the digital platform, refining it based on collected feedback
- Long term: Implement key policy actions post-stakeholder discussions, enhancing the process to maximize the legal framework's potential

Current State of Organ Donation

Introduction

The Indian organ donation system was legally formalized with the enactment of the Transplantation of Human Organs Act (THOA) in 1994. However, the amendment in 2011 and guidelines released in 2014 provided the required impetus to improve the system. Nonetheless, multiple observations indicate that India still has a long way to go.

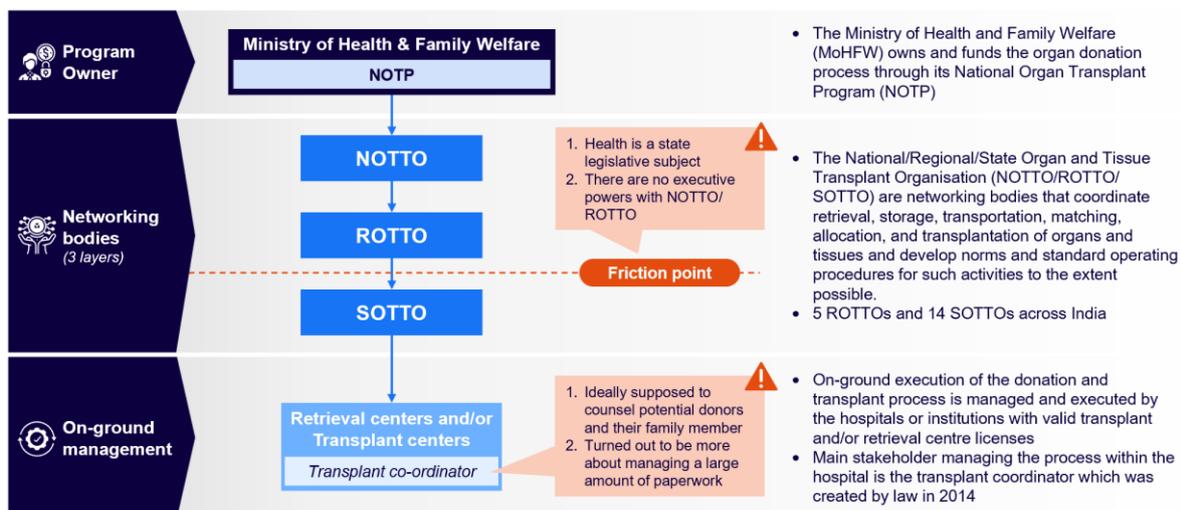
- **Significantly lower donations and transplants vs global average** – India had 5.39 organ transplants per million population in 2020 as compared to the global average of 26.77 as per GODT data. The deceased donor rate in India is also very low with 0.25 deceased donations per million population in 2020 relative to the global average of 8.1.
- **Non-homogenous organ donation behavior in the country** - There is a significant divide in organ donations between north and south India with 80% of all cadaver organs donated by the southern states.
- **Large gap between supply and demand** - India requires 1.5 lakh kidneys per year but only observes ~3,500 transplants annually. Similarly, there are ~2.8 lakh liver failure cases in India per year but only ~28,000 patients get a healthy liver transplant. The situation is worse for a critical organ like the heart with only 50-60 heart transplants per year even though there is a requirement of more than 50,000 annually.

These observations indicate a deficiency in the current system primarily due to policy roadblocks, process inefficiencies, lack of awareness, and donor consent. It therefore becomes imperative to first understand the current governance and processes and consequently identify key challenges to improve the overall organ donation system based on best practices.

Governance

As stated before, the regulatory framework for organ donation in India arises from the Transplantation of Human Organs Act (THOA) 1994, which was amended in 2011, and the Transplantation of Human Organs and Tissues Rules of 2014 providing additional guidelines to all stakeholders. The organ donation governance structure in India has 5 layers across the Union ministry to hospitals as shown in Figure 1.

Figure 1: Governance structure



Source: NHA

Although the governance structure efficiently covers the coverage cascade, there are two key issues which exist. Firstly, the governance structure faces a friction point between SOTTO and ROTTO/NOTTO since health is a state legislative subject as per the Indian constitution. Therefore, in reality, the SOTTOs enjoy a high degree of autonomy in deciding and sending organ alerts to other states than NOTTO. Secondly, while the main aim of creating the role of transplant coordinator was to counsel potential donors and their family members, the role has turned out to be more about managing a large amount of paperwork which hampers process efficiency and reduces family consent.

Types Of Organ Donation

Two types of organ donation and transplantation are practiced in India:

- **Donations from living donors** - The living donor process applies only to a few organs, like - liver and kidney and the transplantation is generally approved for close family members with adequate medical parameter matching (blood group, medical score, etc.). Although the law allows transplantation between non-family members for living donor cases, the approval rate is very low due to a much more stringent verification of the transplantation case which seeks to avoid malpractice.
- **Donations from brain-stem deceased donors** - The deceased donor process can be done for multiple organs, like – the heart, lungs, intestine, liver, kidney, pancreas, and other tissues. However, there are organ-specific time limits within which it needs to be harvested, transported and transplanted which acts as a key constraint in the process. Although, Albeit, donations from brain-dead donors are conceptually understood and socially acceptable in other parts of the world, in India, this is not the case. Apart from the socio-religious beliefs in the country, Indians have a hard time accepting brain-stem death while the heart is still beating

Donation from deceased donors after cardiac arrest is non-existent in India although it is practiced in a few international systems, like –there have been few cases in Spain, France, and Italy. Donations from donors post-cardiac arrest is limited as medical research is still underway in this field.

Process

The process includes multiple steps – registration, availability alert, allocation, transportation and transplantation as shown in Figure 2.



Figure 2: Broad process flow of organ donation and transplantation

The government has provided guidelines for the allocation cascade from the local to the national level. The hospital/center harvesting the organ gets the first chance to use the organ for recipients registered through them, post which the organ comes into the SOTTO pool for use by hospitals in the state. Once the organ remains unutilized by the harvesting state's hospitals, it goes into the ROTTO pool followed by the NOTTO pool. If the organ is not used at the national level within the ischemic time limit of the organ, it gets wasted.

The process has multiple manual procedures with repetitive paperwork at every stage and a severe lack of data consolidation. The process is coordinated primarily through state-wise WhatsApp groups which include all medical superintendents and transplant coordinators of registered hospitals/centers in the state.

While the process stated above is broadly applicable across the country, state-level nuances exist. For example, Tamil Nadu, a leader in organ donations in India, has recently transitioned from WhatsApp to a mobile application called Vidiyal which has digitized many steps in the process. Delhi NCR on the other hand operates on WhatsApp and follows a rotation/round-robin format for organ allocation where a hospital being allocated an organ in the current allotment round is moved to a lower priority during the future rounds. Meanwhile, Telangana and Maharashtra follow a medical and chronological prioritization approach to organ allocation.

Key Challenges In The Current System

Challenges faced by various stakeholders

The complex and manual process stated above involves multiple stakeholders which interact at different steps of the process and therefore it is imperative to understand the challenges faced by them to improve the process.

The key challenges faced by the various stakeholders in the value chain are stated below.

1. General public

- Lack of awareness, infrastructure and information about how, why and where the donation processes run
- Absence of uniformity in the process. E.g. A patient might get an organ from hospital A within days while another patient admitted in hospital B (next door to hospital A) might have to wait for months and years for an organ

2. NOTTO/ROTTTO/SOTTO

- No executive powers to veto a change and exercise control over quality and transparency
- No consultation and process involvement by the states with the National body
- None of the transplants are recorded on a universal portal. All of it is done manually over WhatsApp
- The medical fraternity seems to be at odds with the parameters to be verified before the transplantation
- For hospital registration, which is a time-consuming process, self-certified license copies are submitted to NOTTO in physical format

3. NHA and ABDM

- Lack of integration of patients' health records through ABHA, HPR ID, HFR ID integration. Name registration on many platforms and hospital lists creates a disorganised ecosystem
- Recipient details get outdated over time and the latest health information is not available

4. MEA, DGHS and MofW

- Lack of availability of data for foreign patients
- Lack of availability of statistics on the nation's organ donation system

5. Patients

- Lack of a proper waitlisting system (currently done through WhatsApp) and no real-time status available
- Need to submit documents independently to different stakeholders
- Lack of awareness about information on the process of donating an organ
- Need the body to be returned as soon as possible after organ harvest

6. Transplant surgeons

- Lack of a single platform for collection and retrieval of patient medical records
- Long waiting time due for organ receipt before the transplantation process begins
- Misinformation and misconception about brain death in patients
- Lack of awareness of the importance of organ donation in the nation hampers doctors' approach to patients with the idea of donating an organ

7. Transplant centers and hospitals

- Lack of a central database for hospitals to share data when the organ is being transported to a different state
- Delayed and unclear communication from transplant coordinators
- Lack of transparency from NOTTO regarding waitlists for inter-state organ logistics
- Lack of transparency and information about the incoming patient's pledge status

8. Authorisation committee

- Untimely information from the transplant co-ordinator puts unnecessary pressure on the decision-making of a case
- Gathering the members physically within a short time and recording the activities of the meet is a hassle

9. Transplant co-ordinator

- Difficulty in coordination with multiple stakeholders under time pressure as a single point of contact
- Manual processes for data entry and sharing make it difficult to update lists
- Lack of availability of tools and technology to save time and make the processes smoother
- Lack of authorisation tool to verify identification documents especially while establishing a relation

10. Harvesting team

- Logistical issues can creep up every time an interstate transport is made on the radar
- Possibility of delays from transplant co-ordinator
- Possibility of errors (although rarely) during the execution of surgery due to immense time pressure

Need For Change

1. The goal of the entire organ donation and transplantation effort is to save people from unfortunate health circumstances and help the larger society to live a longer and more fruitful life. A digital transformation is necessary to make the process smoother, increase transparency and improve accessibility. It would also help in optimal allotment of organs in the country thereby reducing organ wastage. Improvement in transparency would also help in tackling unethical practices that may exist in the current process. Additionally, the existing policy framework needs enhancement to remove potential roadblocks to a digital transformation of the process and make the stakeholders more comfortable in this sensitive field. Finally, the population needs to be aware of this noble process, relieve inhibitions and instill a sense of national pride in helping save the lives of fellow citizens. Together these actions would help patients receive organs during their critical time in a transparent and seamless process and help save lives and improve the longevity of citizens thereby indirectly improving the national productivity levels of the country.

International Best Practices

Different countries have different governance systems for organ donation

- US System - The U.S. transplantation system works by having a significant involvement of the private sector via the United Network for Organ Sharing (UNOS) and Organ Procurement Organizations (OPOs). This system receives support from the government but at the same time enjoys autonomy.
- UK System - The organ donation process in the UK is managed by the National Health Service Blood and Transplant (NHSBT), the blood and transplant body of the National Health Service (NHS). The British system considers several unique factors such as life expectancy, drug abuse, etc. at the time of organ allocation.
- Spanish System –Widely recognized as one of the best-run systems, organ donation in Spain is managed by the National Transplant Organization (ONT). It takes advantage of robust fundamentals in the form of presumed consent for organ donation and strong awareness among the masses, resulting in a seamless process for stakeholders.
- French System - France works similarly to the U.S. and ensures high participation rates from private players. It has an exclusive performance-based contract with its Ministry of Health thereby ensuring high process efficiency.

- Australian System - Organ and Tissue Authority, an independent statutory agency, manages the process in Australia. The payback/state balancing system is a key feature of the Australian system that has resulted in lives being saved urgently with respective states getting their due return for sharing organs.
- KSA System - Saudi Center for Organ Transplantation enjoys a strong open channel of communication with other governmental agencies resulting in process efficiency.

USA	Spain	UK	France	Australia	KSA
Central body with extensive powers avoids delays in decision making.	Opt-out system is a good start but trained teams that have tough conversations before the death are more helpful in identifying donors and easing family consent.	Use of unique lifestyle parameters such as increase in life expectancy, alcohol use, drug use etc. in allocation.	Performance based tracking of all coordination bodies ensure accountability.	Mandatory updates on patient, communication in ICU to gain the family's consent and system all ensure transparency.	Central coordination and funding role provides greater control leading to improved efficiency.
Regular educational and marketing campaigns in favor of organ donation increases awareness and consequently donations.	Awareness and pride about organ donation and pride through constant national awareness programs improves organ donations.	Super-urgent and urgent waiting list helps in finding the critical patients accurately but requires checks to avoid malpractice.	Pledge transparency ensures less contradiction by deceased donor's family member.	Providing plenty of portals/opportunities and infrastructure to the Australian citizens pushes them to donate.	Close coordination and assistance across governmental departments crucial for success.
Participation by private organizations in different aspects of the process especially logistics improves accountability and efficiency.	Outsourcing the process of logistics allows the national body to focus on its core competencies.	Consistent audits and iterations of patient status and patient details brings transparency to the system.	Private player participation at important process steps ensures efficiency.	Equality among states and efficiency in the system is brought via short timeframes to accept/reject under the rotation system.	Zonal priority in allocation is a good step to avoid organ wastage.

Figure 4: Key success factors across international systems

Based on the assessment of the nations depicted in Figure 4, the top 5 learnings relevant for India are:

1. **Default Opt-Out system:** While the assumed consent/default opt-out system (in which the citizens have to specifically opt-out as organ donors when they are alive) is a great measure to increase organ and tissue donations, it needs other actions to realize the true potential.
2. **Increased coordination through public-private partnership (PPP):** In the USA, private players have key roles in the organ donation process, especially concerning logistics via a network of Organ Procurement Organizations (OPOs). Whereas in India, important aspects of the donation process occur in a silo and vary between hospitals with the inter-hospital interactions coordinated by the hospitals themselves which can be improved through PPP
3. **Transparent process:** Data transparency and accessibility are common in successful nations with all stakeholders having digital access to the lists of donors and recipients in different forms. However in India, data transparency, reporting and accessibility remain an issue with critical steps of the process being done manually over social media applications, NHA is building a national digital portal for NOTTO and bringing in a unified, uniform, and transparent practice to an otherwise divided process.
4. **Regular awareness drives:** The prominent factor across the best organ donor systems in the world is the constant awareness programs promoting the concept of 'organs being the nation's resources' once the person passes away. This duty of national service is lacking in the common Indian citizen and needs to be inculcated. Of course, there are multiple social and religious factors at play in a diverse country such as India, but the message needs to be regular, clear, and such that it guides Indians to donate, while not hurting their socio-religious beliefs
5. **Independent logistics body:** Nations with strong organ transplantation systems run an independent body or outsource the process of transportation to an independent body making resource utilization in hospitals more efficient. In India, the recipient hospital is responsible for the logistics of the organs and that derails the medical staff from the crucial tasks at hand.

Use Of Digital Transformation To Address The Challenges In The Current Organ Donation System In India

Introducing new technology and updating the existing systems can address the challenges weakening the entire donation and transplantation process which are highlighted in Figure 5.

Challenge: Multiple data entry points and manual actions make it challenging for transplant coordinators and hospital staff

Potential solution:

1. **Central notification system** – Relevant stakeholders in the process would get notified when certain events are triggered. (like – prospective donor ID, organ available, etc.)
2. **Evolving system** – Administrators should collect bi-annual feedback through the system post-rollout to enhance its efficiency and smooth operation

Challenge: Lack of knowledge of deceased donor pledge by the stakeholders (especially family and hospital staff) due to the absence of a reliable publicly accessible repository.

Potential solution:

1. **Selective public access** – The pledged donor list with selected fields can be provided on the authority websites.
2. **API and ABHA Integration with hospital systems** – APIs can be built for hospitals/centers to retrieve donor pledge status from the central repository or through ABHA ID during registration

Challenge: Manual process of informing the police and other logistics support partners. Once informed, there is a lack of awareness within the police force about the organ donation processes

Potential solution:

1. **Dashboard/approval portal:** Analyze current police systems, and create a **dashboard/approval portal** for them and SPOCs, allowing tracking and approval of organ extraction requests, accompanied by DIY videos for guidance
2. **Automation of notifications:** Post understanding the current systems of relevant logistic stakeholders, a decision needs to be taken to automate notifications on the national platform to inform relevant contacts like the DCP office (for green corridors) and airport authorities about transportation details

Key Imperatives To Drive The Change

Comparing India's performance to other nations, a stark difference in the levels of organ and tissue donation is emphasized. The comparison highlights the inadequacies of the present Indian way of working. The current system needs to take advantage of the best practices known to deliver results worldwide and the learnings from their COVID digital infrastructure and needs a major transformation on several fronts. The nation needs to enhance its organ donation system through a 3P approach – Policy changes, People awareness, and Process improvements.

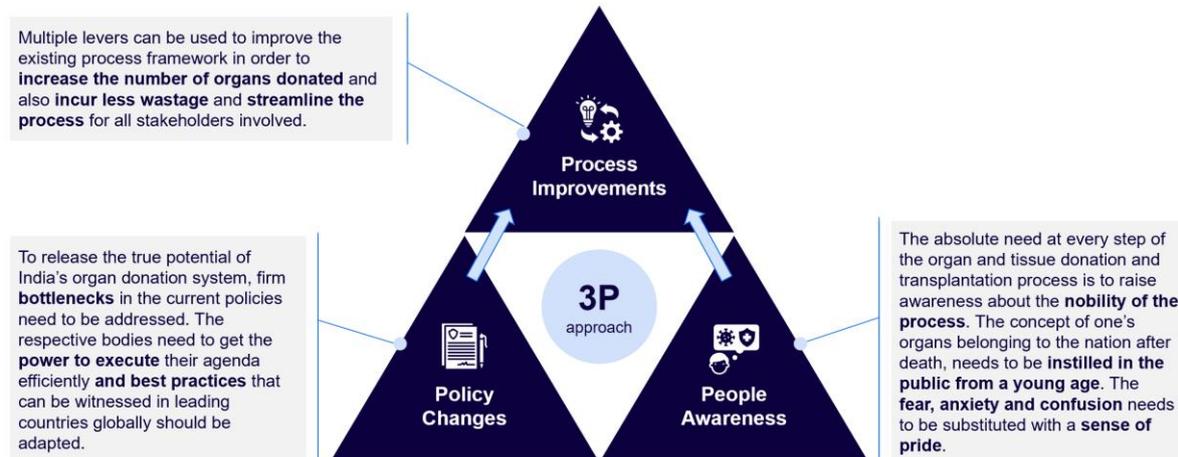


Figure 1: Recommended 3P approach

India's real donor growth potential lies in implementing new and updated policy reforms and spreading awareness to counter socio-religious biases. The donation rates are low because of the sheer lack of donors owing to tepid levels of awareness regarding the importance of organ donation and transplantation. In the rare scenario that the family of a patient wants to donate the organs, the policy constraints that guide the regulations and shape the process framework allow inefficiencies to creep in. Such policies at key steps need to be reconsidered and a revamped set of regulations need to be introduced. These alterations will allow the system to bring in changes to update the process, function smoothly, increase the number of harvested organs, and reduce organ wastage.

Policy changes

Health is a state subject and each state is entitled to run its process independently. The present role of NOTTO does not give it the necessary powers it needs to coordinate effectively with the SOTTO, ROTTO, and transplant centers which leads to a complex and weak process. The biggest policy change we recommend is –

3. *Give NOTTO executive powers* that allow it to have a role larger than just coordination and data collection:
 - a. In the short and medium term, we recommend onboarding “appropriate authorities” on the national digital platform and routing the hospital/center registration and renewal process through the platform. Eventually, NOTTO can also be made an additional “appropriate authority” by law.
 - b. In the long run, the administration can extend NOTTO's powers to include tangible executive powers like – the allocation of funds to ROTTO and SOTTO to make NOTTO the ultimate apex body.
4. *Introducing a state waitlist payback system* can make the process fair. As of today, a patient might get an organ in a particular hospital within days while another patient in the hospital next door may have to wait months or years. Involving states in a priority points-based payback system can save the lives of the neediest appropriately.

People awareness

The next big issue to be tackled is a lack of awareness regarding organ donation. This can be solved through multiple angles.

5. A *grassroots program* that educates the wider public on the ground via various mass campaigns and in some form, also becomes a part of the school curriculum thereby educating future generations.
6. *Seminars* regarding brain death and transplantation should be held by the medical fraternity for the citizens frequently, not only inside the hospital arena but also as public events.
7. *Adored public figures and mediums* can be leveraged to spread awareness. The government can request and convince influential personalities, politicians, movie stars, and national athletes to pledge their organs to motivate the citizens to do the same. This awareness and sensitization can be spread via movies and cinema as well.
8. The government can look into *peak-hours advertising* similar to anti-smoking advertisement campaigns.

Process improvement

Finally, the process improvements need assistance from the policy framework and awareness programs but even within the current situation, it can function much better.

4. *Technology players* can be included to support the development of the national platform
5. *Interoperability of data* should be ensured so that data is easily accessible by authorized people across the country
6. *Robust data storage and security protocols* should be established, ensuring compliance with regulatory standards and safeguarding sensitive information

Way Forward

Our analysis shows us that process improvements, policy updates and public awareness are key to enhancing India's organ donation system. India's success with its CoWIN infrastructure is a testament to its potential in healthcare. The key steps needed to help India excel are –

- Short term – The first iteration of NHA's organ donation platform should be launched with a gradual phase-out of legacy systems. The launch of the platform should coincide with large-scale awareness campaigns.
- Medium-term – Non-medical stakeholders (police, transport authorities) should be integrated into the digital platform, while continuously improving it by collecting and incorporating feedback.
- Long-term – Key policy actions should be undertaken after discussions with stakeholders while enhancing the process to achieve full potential of the legal framework.

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