MAKING AFTER - LIFE
A REALITY IN INDIA:

EXECUTIVE SUMMARY OF
THE NATIONAL ROUND TABLE ON ORGAN DONATION FROM DECEASED DONORS

October 18th 2014

King George Medical University, Lucknow

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Secretary, Department of Health & Director General, ICMR

It is a pleasure to be here at this meeting. Organ donation awareness in India is low, and faces multiple challenges such as low social acceptance and the formidable logistics of organ allocation and distribution.

There are three primary drivers that can take organ donation to the next level. Firstly, we should focus on creating a social movement to increase awareness for organ donation in the community. All sections of civil society- physicians, media, NGOs and the government –must play their part.

Secondly we should recognize the important role played by the physicians that manage patients with critical illness. Critical care and emergency doctors play an important role in encouraging and counselling bereaved families, optimising donors for organ donation. There should be every effort made to impart these skills to critical care and emergency physicians.

Thirdly, we need to identify mechanisms to increase the pace of organ donation in our government. We will need to involve politicians and bureaucracy with constant inputs from the medical fraternity to create a just, viable and appropriate system for organ donation after brain death.

It is very appropriate that this round table is held in partnership with the conference on Emergency medicine. One the one hand, lives are lost in traffic accidents, while patients with organ failure perish due to lack of available organs. Hopefully this round table can provide solutions to this challenge.

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Contents

Foreword

Organ transplantation saves lives.

In India, the Transplantation of Human Organs Act of 1994 defined paradigm shifts for the landscape of organ donation and transplant in the country and there has been no looking back from then.

In 2011, we performed 5482 transplants from living donors; second only to the United States of America at 6020. However, comparative figures for transplants from deceased donors for the USA in the same year were a staggering 23,368 while less than 1000 Indians were this fortunate1.

These paradoxical numbers for a country three times the geographic size of India, but with a quarter of its population bring forth the premise of what follows ahead.

It is not the "how to transplant" but the "what to transplant" that India needs to focus on - to change the numbers in the larger picture.

It is making the transition from living to deceased donor transplant, consequently reorganizing the organ donation to common pooling, sound matching and safe and rapid transport with cost sharing for organ recovery that would go a long way in making organ reception truly equitable.

There are challenges in developing the deceased donor program on a national scale in India; but none of which are insurmountable.

This strategy paper starts with defining where we want to scale the transplant program to in this country, starting with the first two years and outlines what we need to put in place to get there.

It takes realistic stock of the challenges in view of the demand for organ transplants; a review of what has worked so far for India and for more successful models worldwide and how we can work around these issues to set in a growth plan to develop the National Organ Transplant Program for India.

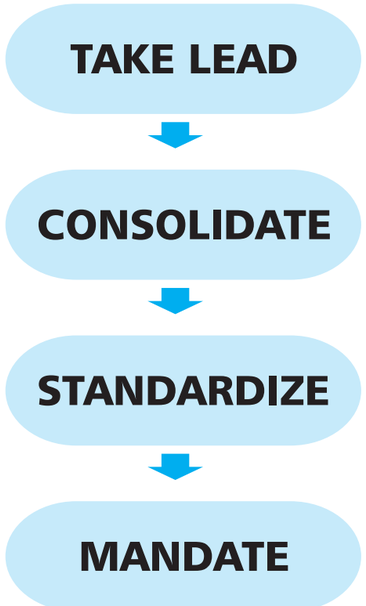
1. Sarah White et al. The global diffusion of organ transplantation: trends, drivers and policy implications. Publication: Bulletin of the World Health Organization; Type: Policy and practice Article ID: BLT.14.137653

THE JOURNEY TO BECOMING NUMBER ONE

STARTS WITH **1**

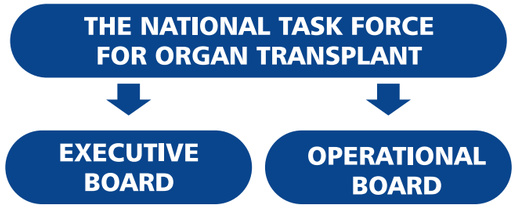
Increasing organ donations from deceased donors from 0.25 to 1 per million – In 2 years

HOW DO WE GET THERE



Take Lead

The first step towards redefining organ transplant in India is setting up a National Task Force with the responsibility for taking the deceased donation rates from 0.25 to 1 per million population in the next two years. All states would need to have atleast one identified center for facilitating deceased donor organ recovery/transplant.



Executive Board

The Executive board will include key members from the government at central levels and at least two medical professionals responsible for policy-based decisions and driving the Task Force towards meeting its 2017 goals. The MCI and NABH should be represented for statutory execution of the policy across public and private hospitals. The decisions of this board would be binding on state and independent.

The Operational board

The Operational board will involve a broader team of:

- Medical professionals spanning across Transplant surgeons and physicians, Intensivists, Pathologists, Emergency Medicine Specialists & Hospital Administrators/Deans
- Representatives from organizations involved in promoting organ transplant specializing in public awareness and training of transplant coordinators
- Heads of support teams for software, public outreach and data collection with hospital surveys.

Consolidate

There is significant work ongoing in fragmented pockets around the country for transplant varying across or even within states. However, there is no unified system or database that can assimilate this at national levels.

So the first step would be online interfacing to consolidate:

- all centers performing transplant and/or recovery with their capacity and performance
- a national organ-wise waiting list
- a national transplant registry
- a uniform donor pledge card incorporated on a national identity document

Standardize

In line with the aforementioned, the next step for the Task force would involve standardizing each skill and process involved in organ transplant.

Standard clinical operating protocols to be instituted for:

- brain/circulatory death testing and declaration
- tissue HLA matching and use of virtual cross-match
- organ-wise protocols for recovery, storage and transport media

Specific training and credentialing for:

- how, when and who should test for brain death
- who can surgically recover and transplant organs
- paraclinical surgical and intensive care teams
- role and early incorporation of trained transplant coordinators

Guidelines for organ-sharing and transport:

- organ-viability based national guidelines for organ sharing
- organ-viability based transport logistics

Formal and uniform process for organ pledging:

- explaining the concept of brain-death and its repercussions on organ donation
- inclusion of family members in informing the decision of organ pledging
- documented records of brain deaths – pledge/consent – actual donation chain
- charting of reasons of refusal in the ICU/ER

Mandate

The Task Force would have to lay down certain mandates in view of ensuring compliance to the protocols outlined for standardizing and thus expanding the organ transplant program.

Some essential statutes would include:

- brain death testing and declaration audits across all recovery/transplant centers
- review of consent-donation records and reasons for refusal
- performance review of registered hospitals based on rate of actual organ utilization

Background

A review of the present day scene for organ transplantation in India

A lot of commendable work has been done over the years in various aspects of organ transplant, albeit in scattered pockets. Nonetheless, the relentless efforts of those select few have set important precedents and generated crucial primary data on the ground figures, clinical outcomes and social perspectives on this multidisciplinary specialty. Particularly notable is the steadily increasing government initiative driving the eradication of organ trafficking in the country.

Factsheet:

- Organ statistics: 0.25 per million and rising
- Changes in the law & establishment of NOTTO
- Public & private hospitals - ranging from free to unaffordable options
- Present waiting lists and projected trends in need for organs
- Implications of the opt-in type pledging for organ donation

Understanding real-life challenges to organ transplantation in India

Organ transplantation is unarguably one of the most complex surgical procedures to accomplish end-to-end; additionally so if involving organ transport. It is also one of the most expensive clinical interventions with distinct costs of organ recovery and actual transplant. Time is pivotal and often dictates transplant decisions in addition to clinical outcomes. Above all, actual organ donation is a choice - often an emotional one - to be made at the death bed of a loved one.

It is obvious then that organ transplant would work smoothly in a scenario equipped with appropriate surgical and intensive care infrastructure, highly skilled teams working on preset algorithms, fluidic transport arrangements, independently funded organ recovery & finally a well informed, rationally emotional family willingly consenting to donation irrespective of whether previously pledged. Ideally the future; but certainly far from the present reality of Indian healthcare.

Organ donation is a human rights issue, and its acceptance in the community is dependent on how much the community trusts the healthcare system. Improving emergency and intensive care for the critically ill or injured will benefit our population, and increased organ donation rates will be a secondary gain.

Key Sensitive issues:

- Parallels the adhoc status of emergency care
- Medical fraternity ambivalent and often uninformed on brain death declaration and transplant protocols
- Inadequate understanding of brain death in the eyes of Indian public & its impact on organ donation; especially scarred by what has been heard/ seen in the past

- Logistic challenges for deceased donor organ transport
- Variable regulatory powers shared between the center/state with limited role of law
- Costs of common organ pooling for equitable sharing

What has worked for India and successful models around the world

- The Tamil Nadu model
- The Regional Organ and Tissue Transplant Organization (ROTTO)
- Indian Armed Forces Organ Retrieval and Transplantation Authority (AORTA)
- The Spanish opt-out model
- The USA: UNOS and OPTN
- The UK : NHSBT-ODT

Closing the living-versus-deceased donor debate

The first step well before the DDOT program should even be worked into; is establishing a consensus within the government and medical fraternity on prioritization of deceased donation over living.

Considering the fact that pushing the DDOT on a national level will take sustained serious efforts to string together all the right pieces in place, the program will stand on crutches if not preceded by this undiluted acceptance.

Key concerns in living donor transplantation:

- ethical dilemma of primum non nocere
- actual morbidity/mortality risk ratios for living donors
- propensity for commercialization and subtle gender based exploitation of women as donors

Why the Government needs to take lead

The government forms the backbone of any initiative with nationwide implications especially involving health care where the larger common good is at stake. The organ transplant program is trying hard to resurrect itself in the eyes of public as well as the medical field and needs to start growing comprehensively.

In the absence of governmental leadership, the program will eventually fade back into the fragmented private sector where transplants will be available to only those who can easily afford them.

Strengths of a government led national program:

- A national body executing the program with uniform policy guidelines
- Credibility of the program in the eyes of the public as being fair and transparent
- Increased options for cost-sharing with a good chance of making transplants truly equitable, affordable and accessible

Paying for organ transplant

Traditionally, except for a few public hospitals, living donor transplants have been funded nearly entirely by the recipient, making it an economically exclusive therapeutic intervention for those who can afford. Organ transplant is a multi-step event with two fundamental cost components – recovery & transplant – which have different operational repercussions especially within the deceased donor organ transplant program.

Organizing the cost of organ recovery in particular is crucial to the expansion of the DDOT on a national scale because it acutely depends on common organ pooling. Both parts however need addressal in view of the overall affordability of organ transplant.

Part 1 - Organ recovery:

- cost of (deceased) donor maintenance in the intensive care unit
- surgical cost of organ recovery
- cost of storage and transport (deceased) donated organ

Part 2 - Organ transplant:

- surgical cost of organ transplant
- cost of immunosuppressant therapy

We will need to keep in mind that the cost-sharing of transplant can significantly limit the expansion of an Indian transplant program. The already strained federal budget on health has many parallel priorities to satisfy; so although government funding for organ transplant is important, it is also important to also think of out-of-the-box solutions for tapping in alternate resources.

Some suggestions for cost sharing could include:

- Using the Make-in-India strategy for indigenous production of pharmaceutical and surgical supplies to bring down the bare cost of both surgeries
- Using media and social platforms to push for donations and CSR activities to fund transplant
- Skill based public-private partnerships where surgeons operate in public settings for basic honorariums – also boosting the training of transplant teams in public hospitals

How this strategy paper has evolved

The National Program for Deceased Donor Organ Transplant is an idea whose time has come.There have been similar efforts in the past to push for the same and the National Policy Round Table on DDOT in India – Converting Challenges into Opportunities held on the 18th of October 2014; eventually was a culmination.

What distinguished the meeting was the proactive participation of the government; presided by Dr. V.M. Katoch and represented via the NOTTO with Drs. Anil Kumar and Harsha Jauhari. The government took lead and engaged in dialogue, welcoming inputs on how we could take this initiative forward.

This day-long session of interactive deliberation convened by the Vice Chancellor Professor Dr. Ravi Kant of KGMU Lucknow and Dr. Sagar Galwankar under the aegis of INDUSEM 2014; conducted and chaired by Dr. Sonal Asthana and Dr OP Kalra created the primary structure on which this summary has evolved.

The participants included Dr R.K. Sharma, who set the tone for what had been done in the field so far and shifted focus to a national program. Dr. Ajai Khanna relayed live from the Cleveland Clinic outlining what India could use from the UNOS experience for national organ sharing, as well as the opportunities that tissue banking could provide.

Professor Dr. OV Nandimath brought in legal aspects of the THOTA and its role in facilitating organ sharing. The barriers to access and cultural biases were extensively discussed by Drs. Vivekanand Jha and Lalitha Raghuram respectively.

Drs. Praveen Aggarwal, Abhijeet Chandra and Shridhar N. specified role of training with special attention to that of the Critical Care & Emergency Room Physician. Dr. AG Gokhale emphasized on the specific challenges encountered in developing heart-lung transplant programs.

The success story of the organ transplant program in the Indian Army presented by Col. Sanjay Sharma set the precedent for what the model had already done to conquer the herculean task of organ transport logistics.

Drs. Christopher Barry and Suresh Menon illuminated the important roles that corporate India and the pharmaceutical industry could play in cost sharing for the program on a national scale.

A comprehensive policy document is now underway to expand in detail all the aspects involved with scaling the program at a National Level involving the Task Force focused on achieving the 2017 target of 1.0 donation (deceased donor organs) per million population.

Conclusion :

- Organ Donation from deceased donors is in its infancy in India. Concerted efforts need to be made at a National and Local level to meet the demand for transplantation.
- A panel of experts should be constituted at a National Level to empower and advise the current decision making authority (NOTTO and develop a strong and transparent National organ donation program.

Abbreviations

MCI	:	Medical Council of India
NABH	:	National Accreditation Board for Hospitals and Healthcare Providers
HLA	:	Human Leukocyte Antigen
ICU	:	Intensive Care Unit
ER	:	Emergency Room
CSR	:	Corporate Social Responsibility
NOTTO	:	National Organ and Tissue Transplant Organization
UNOS	:	United Network for Organ Sharing
OPTN	:	Organ Procurement and Transplantation Network
NHSBT-ODT	:	National Health Services Blood Transfusion – Organ Donation and Transplant
INDUSEM	:	Indo-US Emergency Medicine Summit 2014
KGMU	:	King George Medical University
THOTA	:	The Transplantation of Human Organs and Tissues Act
DDOT	:	Deceased Donor Organ Transplantation

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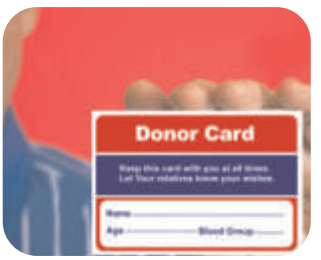

Partner Organizations

Indo US Emergency and Trauma

Indian Society of Organ Transplantation

Indian Society of Nephrology

Indian Society of Critical Care medicine

The Integrated Liver Care foundation