

DR. LALIT KAPOOR

- Senior General & Gastro-intestinal Surgeon
- Founder member -- Association Of Medical Consultants (AMC), Mumbai: Association of over 13000 Medical consultants now completed 50 years. Largest body of its kind. est. 1972
- Founded the first medico-legal cell in the country over 40 years ago
- Created the most unique professional indemnity scheme for AMC members
- Had the honour of being invited by the **National Judicial Academy** in December 2021 AND September 2022 to speak in workshops for High Court and District judges across the country.
- Medical Director – Shakuntala Memorial Hospital, Mumbai.



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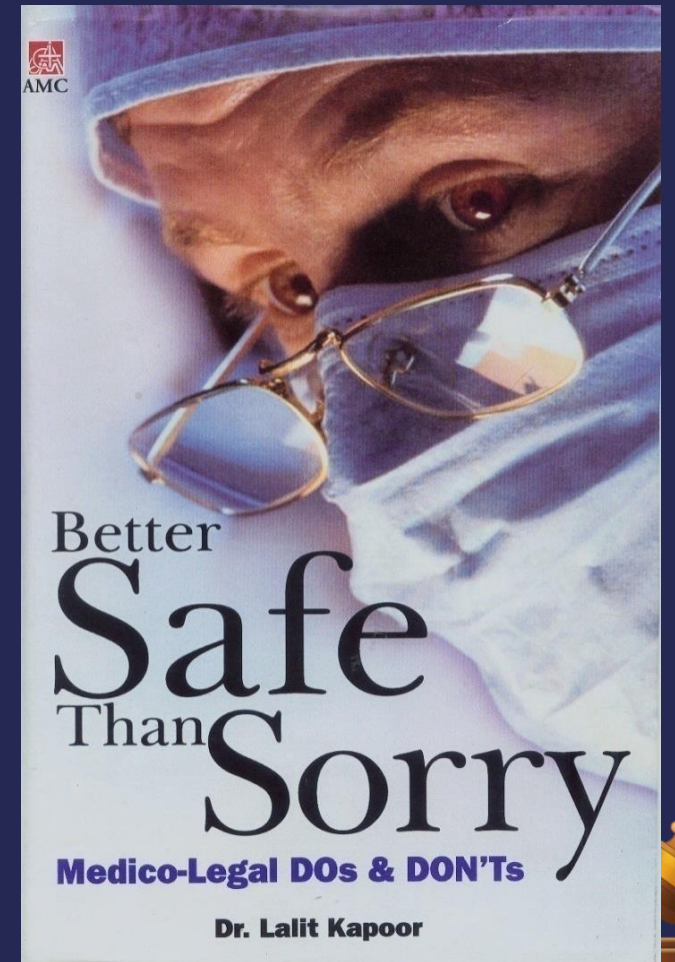
Author of Book

**BETTER SAFE THAN SORRY –
Medico - Legal Dos & Don'ts**

Released on 2nd Oct 2006 by

Mr. Narayan Murthy, Infosys Chairman

Foreword by Justice Radhakrishnan ,Bombay High
Court





DIMENSIONS OF LAW GOVERNING MEDICAL PRACTITIONERS vis-à-vis MORALITY AND ETHICS

November 2022 NJA Bhopal - DR. LALIT KAPOOR



DISCUSSION TOPICS

- Ethics and malpractice laws
- Issues related to Transplantation of Human Organs
- Data Protection and Patient confidentiality



ETHICS DEFINED

- Since the evolution of mankind, efforts have been made to regulate the behavior of individuals and groups of individuals in society by voluntarily enunciating a code of ethics for their respective members. **Ethics has been defined as a science of moral principles.**
- In fact, ethics is something that has to do with your conscience. It is a code of conduct, a way of behavior, almost a way of life. For all practical purposes, the words "ethical" and "moral" are interchangeable.
- It has been well-said that ethics begins where the law ends , or cannot reach !
- The oldest code of ethics for medical practitioners was the **Hippocrates oath** which formed the basis for a self-inflicted code of conduct.



LAW

Laws protect the welfare of society, resolve conflicts and are constantly evolving

Laws are mandatory to which all citizens must adhere or risk civil or criminal liability.



**INTERPLAY BETWEEN
LAWS AND ETHICS IS
VITAL – KEY
PRINCIPLES OF
BIOMEDICAL ETHICS**

- **Autonomy** : self-determination /freedom to act independently
(Paternalistic model vs patient autonomy)
- **Beneficence /Non malfeasance** :
Principles of acting in patient's best interest and avoiding harm
- **Justice** :principle that deals with fairness, equity and equality
Distributive—societal
Comparative—individual

ETHICS AND LAW



Ethical standards required of professionals often exceed those required by law.



Two illustrative examples :

**INDIAN MEDICAL COUNCIL
(Professional Conduct,
Etiquette and Ethics)
Regulations,
2002 (AMENDED UPTO 8th
OCTOBER 2016)**

1 . ADVERTISING BY DOCTORS

- 6.1 Advertising: 6.1.1 Soliciting of patients directly or indirectly, by a physician, by a group of physicians or by institutions is unethical. Any form of advertising or publicity through any mode as would ordinarily result in his self aggrandizement will be considered unethical and liable to disciplinary action.
- Thus, Advertising by doctors is unethical though not illegal !

MCI CODE OF ETHICS

2. DICHOTOMY OF FEES

- Rebates and Commission: 6.4.1 A physician shall not give, solicit, or receive nor shall he offer to give solicit or receive, any gift, gratuity, commission or bonus in consideration of or return for the referring, recommending or procuring of any patient for medical, surgical or other treatment. A physician shall not participate in any act of splitting or refunding of any fee for medical, surgical or other treatment.
- Fee-splitting though not illegal is unethical and considered professional misconduct liable for disciplinary action.

ISSUES RELATING TO NEGLIGENCE/MALPRACTICE AND LIABILITY ARISING THERE FROM.

- The term “Medical negligence” is used as an umbrella term
- In fact there are several allied terms which are often used interchangeably even though there are key differences.



MEDICAL NEGLIGENCE : TERMS WITH DIFFERING CONNOTATIONS

Malpractice

Medical Error

Medical Accident/mishap

Complications

Side-effects

Sequelae

Error of judgment

Adverse reaction/event

Simple Vs gross negligence

Professional incompetence / incapacity

Deficiency of service.

Unethical/Illegal

Unfair trade practice

COMPLICATIONS , SIDE-EFFECTS AND SEQUELAE

“Malpractice” should be distinguished from ‘complications’ , ‘side-effects’ and ‘sequelae’

Complication: refer to an unanticipated problem that arises following, and is a result of, a procedure, treatment, or illness

Side effects refer to undesirable effects that occur concomitantly with the originally intended outcome.

Sequelae refer to the symptoms that remain after an illness or to the adverse reactions occurring after an event.

These terms may not necessarily amount to negligence

MEDICAL ERROR

A medical error is a preventable adverse effect of care. This might include an inaccurate or incomplete diagnosis or treatment of a disease, injury, syndrome, infection, or other ailment

'Medical error' means the failure to observe a standard of care and skill reasonably to be expected in the circumstances.

MEDICAL ACCIDENT

An unfortunate unplanned, unintended or sometimes unavoidable event leading to injury, or such an event developing in the course of treatment of a disease.

ERROR OF JUDGMENT

An error in judgment does not amount to negligence where the physician appropriately exercises clinical judgment of a normal and prudent practitioner

LORD DENNING IN ROE VS MINISTRY OF HEALTH

“It is so easy to be wise after the event and to condemn as negligence that which was only a misadventure. We ought always to be on our guard against it. Medical science has conferred great benefits on mankind , but these benefits are attended by risks. We cannot take the benefits without taking the risks”

BOLAM TEST

BOLAM V. FRIERN HOSPITAL MANAGEMENT COMMITTEE (1957)

This is based on the principle that a doctor is not negligent if he does not breach the standard of care, which is supported by a responsible body of similar professionals.



BOLAM'S RULE IN INDIA

In India Bolam's test has been accepted as a general rule Some examples:



Achutrao Haribhau Khodwa vs. State of Maharashtra,



Poonam Verma v. Ashwin Patel and Ors.,



Dr. Suresh Gupta Vs. Government of NCT of Delhi



State of Haryana and Ors. v. Smt. Santra



Laxman Balkrishna Joshi vs. Trimbak Bapu Godbole And Anr on 2 May, 1968



BOLITHO

The Bolitho Test, which resulted from the 1996 court case of **Bolitho v City and Hackney HA**, is an amendment to the **Bolam**

*"A doctor will be liable for negligence in respect of diagnosis and treatment in spite of a body of professional opinion approving his conduct where it has not been established to the court's satisfaction that such opinion relied on is reasonable or responsible. If it can be demonstrated that **the professional opinion is not capable of withstanding the logical analysis, the court would be entitled to hold that the body of opinion is not reasonable or responsible**".*



BOLITHO TEST IN INDIA

The Bolitho test has been mentioned in the Indian Supreme Court in the *Samira Kohli v Prabha Manchanda* judgment, where the court clearly pointed out that "A beginning has been made in *Bolitho v City and Hackney* and *Pearce v United Bristol Healthcare*. We have however, consciously preferred the 'real consent' concept evolved in *Bolam*."



TYPES OF PATIENT CONSENT

**Implied or
Tacit consent**

**Expressed
consent
Oral / written**

Valid consent

**Informed
consent**

**Real
consent**

**Advance
consent or
directive**

**Surrogate
consent**

**Proxy
consent**

Joint consent

**Denied or
Opt-out
consent**



MEDICAL NEGLIGENCE CRITERIA

1. That there exists a normal and usual practice.

2. That this practice was not followed

3. That the course adopted is in fact , such , that no professional person of ordinary skill would have taken .

4. There is proof of the alleged negligence being the proximate cause of the purported damages .



TYPES OF NEGLIGENCE

In *Poonam Verma v. Ashwin Patel & Ors.* (1996) 4 SCC 332 where the question of medical negligence was considered in the context of treatment of a patient, it was observed as under:-

Negligence has many manifestations - it may be

Active Negligence

Collateral Negligence

Comparative Negligence

Concurrent Negligence

Continued Negligence

Criminal Negligence

Gross Negligence

Hazardous Negligence

Passive Negligence

Negligence per se

Willful/Reckless Negligence



JUDGMENTS DEFINING CRIMINALITY OF MEDICAL NEGLIGENCE AND RECOMMENDED ACTION

DR. SURESH GUPTA VS. GOVT. OF N.C.T. OF DELHI & ANR ON 4 AUGUST, 2004

Author: Dharmadhikari
Bench: Y. K. Sabharwal,
D. M. Dharmadhikari

JACOB MATHEW Vs. STATE OF PUNJAB AND ANOTHER on 5 August 2005

Justice R. C. Lahoti
Chief Justice ,
Justice G. P. Mathur, Justice
P.K. Balasubramanyam

MARTIN D'SOUZA Vs. MOHD. ISHFAQ

Justice Markandey Katju
and Justice R. M. Lodha
February 17 , 2009

V. KISHAN RAO Vs. NIKHIL SUPER SPECIALITY HOSPITAL AND ANR

Justice V. S. Singhvi and Just A. K. Ganguly March 8 , 2010

LALITA KUMARI VS. GOVT OF U.P.& ORS ON 12 NOVEMBER, 2013

Author: P.Sathasivam
Bench: P Sathasivam, B.S. Chauhan,
Ranjana Prakash Desai,
Ranjan Gogoi, S.A. Bobde



ESSENCE OF JACOB MATHEW JUDGMENT

A doctor cannot be arrested simply because a criminal charge is levied against him.

The IO will first have to obtain a credible independent and competent opinion from a doctor qualified in the same branch of medicine as the defendant preferably from a Govt hospital



SIMPLE NEGLIGENCE VS GROSS NEGLIGENCE: JACOB MATHEW JUDGMENT

- “Mere inadvertence , lack of adequate care or attention or skill does not hold a doctor to be criminally liable. The standard of negligence has to be so high as to be described as “gross negligence” or “recklessness”. It should be so grave as to show disregard for the life and safety of the patient as to amount to a crime against the State”
- “A clear distinction exists between ‘simple lack of care’ incurring civil liability and ‘very high degree of negligence’(gross) which is required in criminal cases”



**JACOB
MATHEW:
SIMPLE AND
GROSS
NEGLIGENCE**

Sec 304 A : no mention /
definition of gross
negligence

Expert committees to
declare gross or simple
negligence.

REALITY-CHECK

Pan India the directions laid down in these judgments are being violated .

In a recent case of maternal mortality , a highly experienced and competent gynecologist committed suicide , being terrorized by the slapping of Sec 302 on her for the death of the patient ,without any expert medical opinion , in clear violation of directions of the highest court in the land.



POTENTIAL LIABILITIES OF HEALTH-CARE PROFESSIONALS

- Civil liability under law of Torts
 - Criminal liability – Police /Criminal Prosecution
 - Professional misconduct – Medical Councils
- } can be simultaneous

Also accessible :

- Human Rights Commission/Women's Commission/Children's court / PCPNDT Act/ POCSO /THOTA/ Lok Adalats (public utility services)

Non-judicial Sequelae

- Media (including Social media)/ Social workers / Political goons –physical violence.



IMPACT OF EXPONENTIAL RISE OF LITIGATION AGAINST DOCTORS

Undoubtedly there should be a strong disincentive for professional negligence in the medical profession. However, a balance has to be struck to avoid an undesirable impact on Society and the healthcare system.

- Doctors practice an inexact science, one that is subject to countless variables that can produce unpredictable and sometimes unfortunate results.
- Faith and trust are key ingredients in the process of healing . Increased litigation has resulted in a serious trust deficit between patients and doctors.
- Adverse or sub-optimal outcome of treatment often get equated to negligence or “deficiency in service”
- And of course there is an increased risk of doctors facing physical violence
- Hence practicing DEFENSIVE MEDICINE is considered inevitable by doctors.



WHAT IS DEFENSIVE MEDICINE ?

Doctors ordering tests and procedures, not because the patient need these but to protect themselves from any potential malpractice liability.

Reluctance to accept critical cases which are then referred to high-end tertiary centers for fear of liability.

In the USA 650 million dollars are lost by American healthcare system because of defensive medicine.

A similar effect in our country is on the way , but is something a resource-challenged country like ours cannot afford.



LIABILITIES AND OBLIGATIONS IN TRANSPLANTATION OF HUMAN ORGANS

- Human organ transplantation started in India in 1962.
- The procedure was unregulated and the shortage of donors led to organ trafficking and exploitation of the poor who were made to sell their organs.
- Transplantation of Human Organs Act (THOA) was passed in 1994
- The amendment Act –Transplantation of Human Organs and Tissues Act (THOTA) was passed in 2011 and the new rules came into force in 2014.

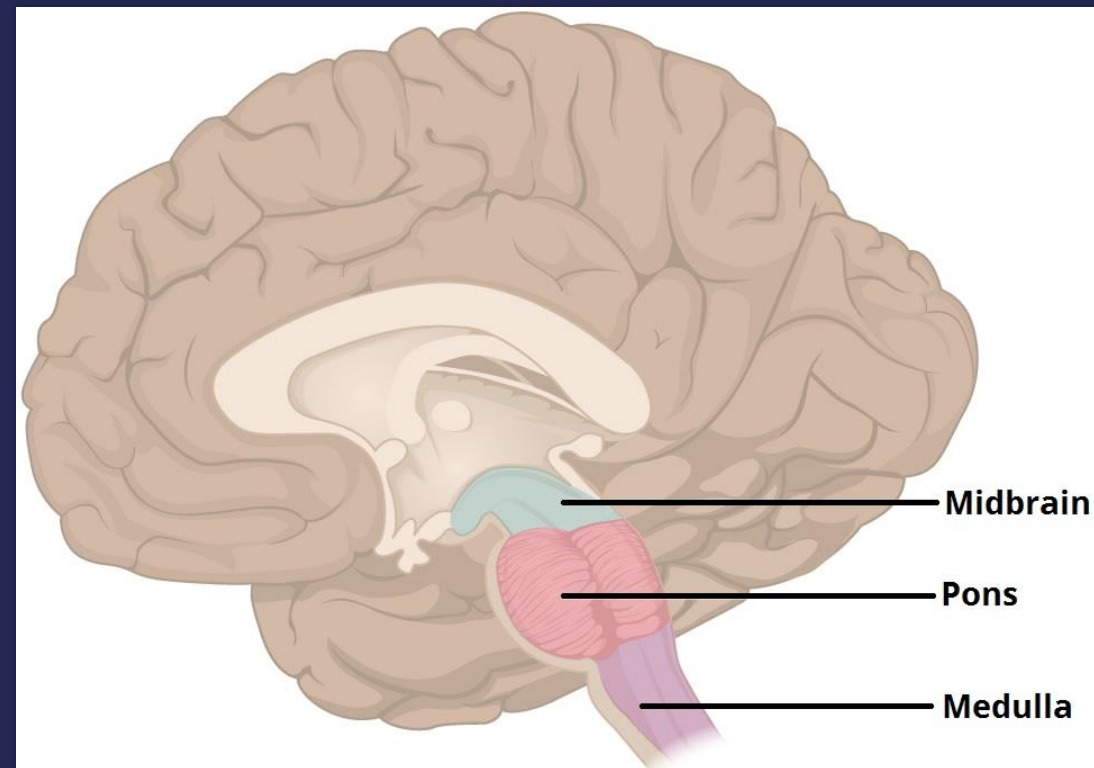


THE MOST VITAL FEATURES OF THE ACT

- It legalized brain-stem death as death ----allowing organs to be retrieved from brain dead patients
- Prevention of commercial dealings in human organs.



BRAIN



**BRAIN
DEATH**



**Brain death is legal
death**



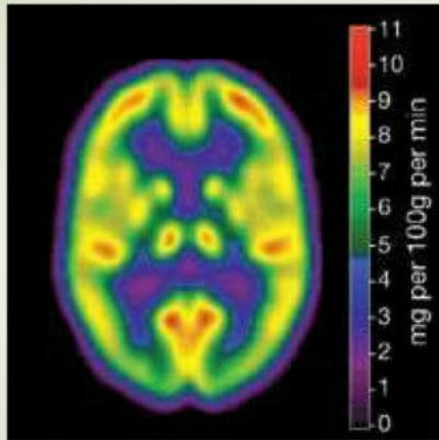
If someone is brain
dead, the damage is
irreversible and the
person has died.



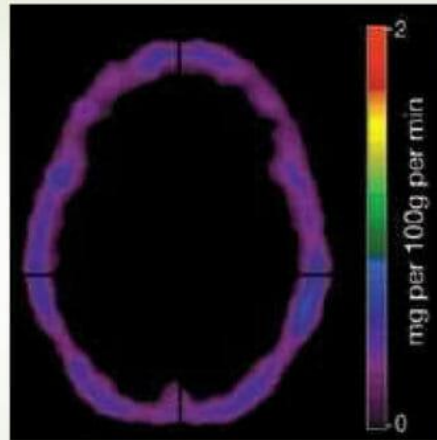
He or she will not ever
regain consciousness
or start breathing on
their own again. They
have already died.



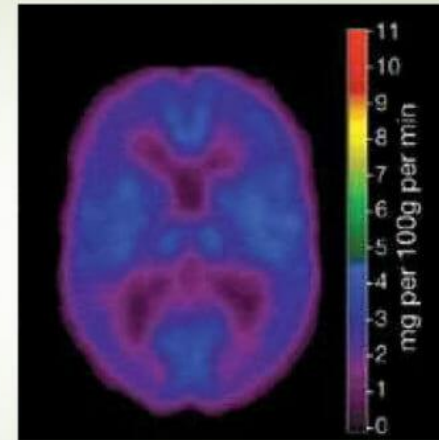
CT SCAN IMAGES



HEALTHY CONTROL



BRAIN DEAD



VEGETATIVE STATE

DIFFERENCE BETWEEN COMA, VEGETATIVE STATE AND BRAIN DEATH



DEFINITION OF DEATH

**DEATH IS BOTH A
LEGAL
&
A MEDICAL ISSUE**

In India ,presently we have 2 definitions of death

(1) Irreversible cessation of circulatory and respiratory functions(as per Registration of Births and Deaths Act of 1969.

(2) Irreversible cessation of all functions of the brain stem called Brain Death (as per THOTA 2014)

The 2nd definition of death is linked to organ donation and comes in the picture only if relatives of the patient consent for organ donation. In other circumstances , it is the first definition that is applicable.

IMPLICATIONS OF THIS DISSONANCE

In a terminally ill patient suspected of being brain-dead, the patient will be declared dead, after investigating, only if the relatives give consent for organ donation.

If the relatives refuse consent, then the first definition will apply and doctors cannot declare death (even though dead) and patient will continue to be on ventilator support unnecessarily.

In other words, the patient is dead enough to donate but not dead enough to be declared dead !!

Question that could be asked : Life-support was withdrawn because patient was dead or patient died after life support was withdrawn

RECORDING OF TIME OF DEATH

- In UK time of death is time of brain death.
- In India it is at cessation of cardiovascular system.
- ?? 2 times of death in India



NEED FOR UNIFORMITY IN DEFINITION OF DEATH

Definition of death
should be
standardised in both
Registration of Births
and Deaths Act and
THOA.

Brain stem death
should be de-linked
from organ donation.



AMERICAN JUDGMENT THAT NEEDS REPLICATION BY JUDICIARY IN INDIA

- Dority Vs Superior court of San Benardino County of USA:
“ Once brain death has been determined no criminal or civil liability will result from disconnecting the life-support devices”



BENEFITS

Futile life-prolonging interventions in the ICU which cause an unbearable financial burden on the family could be eliminated.

Clarity to intensive care physicians for withdrawing life-support

To the Community: Resources will not be wasted on futile treatment and diverted to patients who could benefit. (distributive justice)

Thousands of people die every year due to end-stage organ failure. Potential donor pool would increase . 1,60,000 people die in road mishaps every year . Cadaveric transplants could save many.



IMPORTANT PROVISIONS OF THE ACT

- Regulation of removal of organ/s for transplantation from cadaver donors
- Regulation of removal of organs from living donors
- Regulation of hospitals
- Regulation of medical practitioners
- Punishment for those flouting the Act



REGULATORY BODIES FOR CHECKS AND BALANCES



THOA 1994 Vs THOTA 2014

Briefly , the new Act has the following changes:

Tissues have been included

(ii) Advisory committee has been created

(ii) Hospitals doing more than 25 transplants in a year can have authorization committee

(iii) Non-transplant retrieval centres created

(v) Registration for tissue retrieval not required

(vi) Grandparents, grand children included in near relatives

(vii) Counseling for donation by critical care physicians is mandatory

(viii) Organ retrieval charges to be paid by Govt, Recipient or NGO

(ix) Penalties for violations are more severe



PUNISHMENTS UNDER THE ACT

Sec 18-
Imprisonment up to
10 years fine may
extend to 20 lakhs

Reported to SMC if
doctor for
suspension or
deregistration (3 yrs
or permanent)

For commercial
dealing jail 5 to 10
years Fine 20 lakhs
to 1 crore.

Process for getting
approval even in
genuine cases made
difficult.



CREATION AND MAINTENANCE OF REGISTRIES

National Organ and
Tissue Transplant
Organisation
(NOTTO)

Regional Organ and
Tissue Transplant
Organisation

State Organ and
Tissue transplant
Organisation

Networking and
linking of all these
registries is
requires



TYPES OF DONORS

- LIVING DONORS :
 - (i) Near related donors
 - (iii) Non-related donors
 - (iv) Swap donors
- DECEASED DONORS

ORGANS AND TISSUES THAT CAN BE DONATED

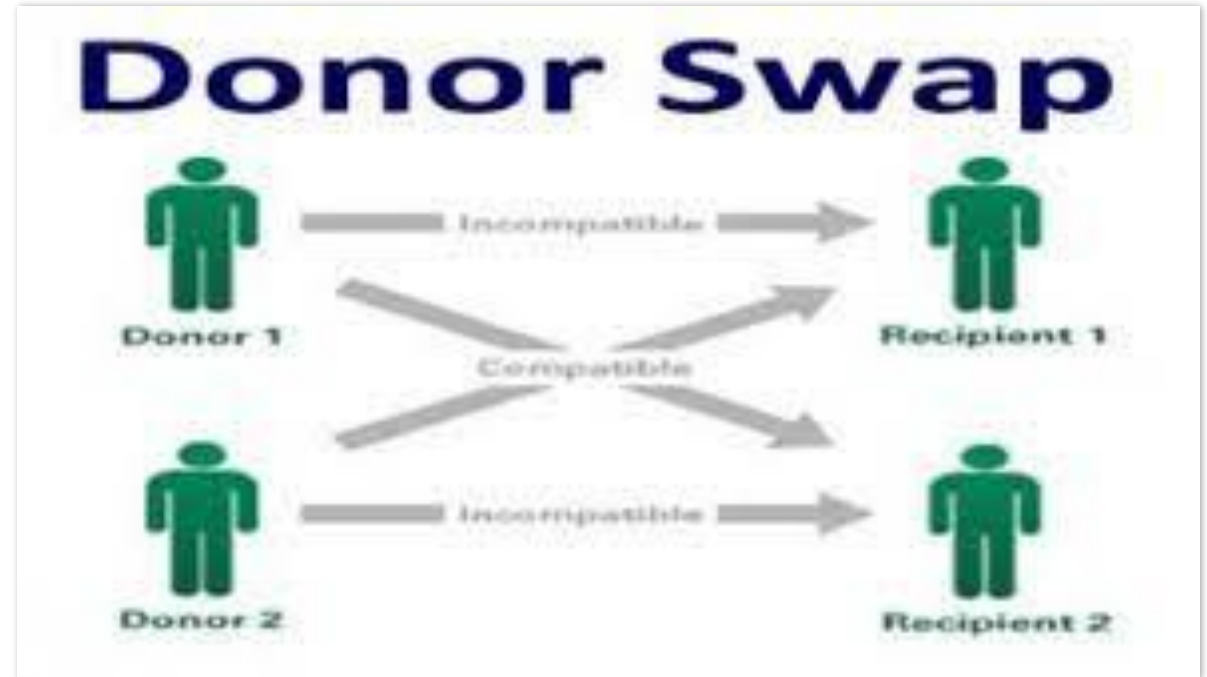
CADAVERIC TRANSPLANTS

- **ORGANS:** Liver, Kidney, Pancreas, heart, lung intestines.
- **TISSUES:** Cornea, Bone, Skin, heart valves, blood vessels, nerves, tendons, ear drum & ear bones.

LIVING DONOR can donate 1 kidney, portion of pancreas and part of the liver , uterus



SWAP TRANSPLANT



SOME PAIN-POINTS



Minors as Live donors

Medico-legal and
Police formalities in
Accident cases

Swap transplants

NOC for interstate
related transplants

Transportation issues
.After retrieval Heart
(6 hours) Liver,Kidney
12 hours.

High cost 15 -20 lakhs



LIVE DONATION BY MINOR

17 year old boy moved high court seeking permission to donate liver to ailing father

Urgent hearing before bench of CJI Justice U.U.Lalit , Justice Ravindra Bhat and Justice P.S.Narsimha (SEP 22)



MAGNITUDE OF THE DEMAND

1

50,000 people in
need of heart
transplant

2

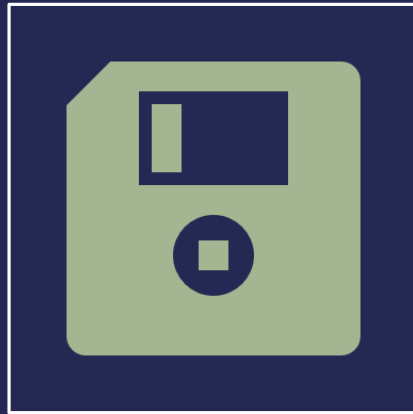
3,00,000 –Kidney
transplant

3

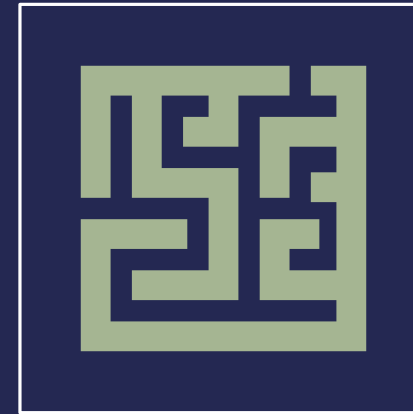
1,00,000 for Liver
and cornea



THE WAY FORWARD



Many lives can be saved.



Lacunae have to be filled up and we have to connect the dots.

State, Law Makers, Law Implementers, Medical Profession & Civil Society must collaborate to save precious lives.

DATA PROTECTION AND CONFIDENTIALITY OF MEDICAL RECORDS

Confidentiality has been a central feature of the doctor-patient relationship for centuries.

As early as 430 BC confidentiality was codified in the Hippocratic oath:
“Whatever I see or hear professionally which ought not to be divulged I will keep secret and tell no one “

This principle remains an important ethical , legal and professional practice in clinical medicine.

ELECTRONIC HEALTH RECORDS --EHR

- Given the sensitive nature of health care information, the issues of integrity, security, privacy, and confidentiality are of particular significance have to be clearly and effectively addressed by medical professionals.
- Privacy and confidentiality of individual health information is now vital and can become a subject of litigation.
- In the past ethical more than legal concerns were of paramount importance ,as I will illustrate.



A HISTORICAL EXAMPLE OF MEDICAL CONFIDENTIALITY

Partition of India in
1947

FINAL QUESTION



Does Ethics Drive the Law or
Does the Law Drive Ethics?



THANK YOU