

Ethics of Organ Transplantation

BY Dr. UROOJ KHAN.

Overview of Ethical Issues of Human Tissue & Organ Transplantation

A decorative graphic at the bottom of the slide consisting of several overlapping, wavy, semi-transparent shapes in shades of olive green and tan, creating a layered, wave-like effect.

Introduction

- An **organ transplant** is a surgical operation where a failing or damaged organ in the human body is removed and replaced with a new one.
- The term “organ transplant” typically refers to transplants of the solid organs: heart, lungs, kidneys, liver, pancreas and intestines.
- Animal and artificial organs may also serve as transplantable organs.

Introduction-History

- • 1954 living relating kidney transplant(Dr. Joseph Murray and Dr. David Hume Boston)
- • 1962 cadaveric kidney transplant by (Dr. Joseph Murray and Dr. David Hume Boston)
- • 1963 lung transplant (Dr. James Hardy Mississippi)
- • 1967 liver transplant(Dr. Thomas Starzl Colorado) and heart transplant(Dr. Christiaan Barnard South Africa)
- • 1981 heart/lung transplant(Dr. Norman Shumway California)

Introduction

- Although the idea of organ transplantation is an old one, successful transplantation did not occur until the Twentieth Century.
- Today the transplantation of many organs between well-matched human beings is quite successful, **with the majority of recipients living five or more years.**
- With current advances, even a human head transplant (perhaps better referred to as a body transplant) may be possible.

Introduction

- Since many people can benefit greatly from organ and tissue transplants, **the demand usually exceeds the supply.**
- The costs related to some organ transplants are very high as well.
- From the standpoint of deontological ethics, the debate over the definitions **of life, death, human, and body** is ongoing.

Introduction

- The use of cloning to produce organs with an identical genotype to the recipient has issues all its own. Cloning is still a controversial topic
- Therefore, **many questions are raised** today regarding **how best to procure more organs**, how to **fairly distribute limited resources**, and whether all transplants **should be covered by public funds**

Introduction

- The ethical and legal issues related to organ and tissue procurement and transplantation are often discussed in light of such principles as;
 - 1) Autonomy,
 - 2) Benevolence,
 - 3) Non-maleficence,
 - 4) Free and informed consent,
 - 5) Respecting the dignity, integrity and equality of human beings, fairness, and the common good.

Discussion points

Ethical Issues Regarding:

- 1) The Donor
- 2) The Recipient
- 3) Allocation of Limited Resources
- 4) Procurement of Organs and Tissues
- 5) Informed consent
- 6) Some Cases and Questions For Discussion

Ethical Issues Regarding the Donor

- 1) From the Deceased
- 2) From Living Persons (Adults, related, non-related, Mentally Disabled, Minors)
- 3) From Anencephalic Infants
- 4) From Human Fetuses

Ethical Issues Regarding the Recipient

Should individuals who have abused their bodies through smoking, drinking, or diet receive new organs, or should organs only be given to those whose organs were damaged by illness?

The recipients for the scarce organs are selected justly

Ethical Issues Regarding Allocation of Limited Resources

1) Criteria for Selection

Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent

2) Using Animals

3) Artificial Substitutes for Tissues and Organs

4) High Costs, Universality and Justice

5) Distributive justice – How to fairly divide resources –

6) Equal access –

7) Maximum benefit

Ethical Issues Regarding Procurement of Organs and Tissues

- 1) Buying and Selling Human Organs and The vicious cycle – Needs money , has organ. - Has money , needs organ Tissues;
- 2) Media Publicity
- 3) Types of Consent (Voluntary or Expressed, Family, Presumed, Required Request, Routine Inquiry)
- 4) Fears, Confusion and the Need for Education

Informed Consent

- The laws of different countries allow potential donors to permit or refuse donation, or give this choice to relatives
- Opt in (only those who have given explicit consent are donors)
- Opt out " (anyone who has not refused is a donor).
- consent required by law
- deceased person objected
- Minors and legally incompetent people

Some Questions For Discussion

- 1) Is the body a commodity? Can it be bought?
- 2) How should decisions be made on distributing scarce organs?
- 3) When several healthy organs are available, should they all go to one person or should several needy people each receive just one?
- 4) Should a person in whom a transplant has failed be given a second organ, or should a different person have a first chance?
- 5) Should individuals who have abused their bodies through smoking, drinking, or diet receive new organs, or should organs only be given to those whose organs were damaged by illness?

Some Questions For Discussion

- 6) Is it appropriate to spend money, time, and energy transplanting hands and other appendages that are not essential to life?
 - 7) Who can "donate" the organs of individuals who are unable to give consent?
 - 8) Is it possible to prevent coercion of donors?
 - 9) When should the courts get involved in organ donation decisions?
- The questions go on and on.

Human Organ & Transplant Act(HOTA)

Transplantation of Human Organs and Tissues Act 2010

THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT 2010

(Act VI of 2010)

C O N T E N T S

Section	Heading
1.	Short title, extent and commencement.
2.	Definitions.
3.	Donation of organ or tissue by a living person.
4.	Donation of human organs or tissues after death.
5.	Evaluation Committee.
6.	Transplantation to be carried out by the team of transplant surgeons and physicians, etc.
7.	Effects etc., to the donor and the recipient.
8.	Monitoring Authority.
9.	Prohibition of removal or transplantation of human organs for any purpose other than therapeutic purpose.

10. Punishment for removal of human organ without authority.
11. Punishment for commercial dealings in human organ.
12. Punishment for contravention of any other provision of this Act.
13. Offences by companies.
14. Cognizance of offences.
15. Savings.
16. Protection of actions taken in good faith.
17. Power to make rules.
18. Removal of difficulties.

**[1] THE TRANSPLANTATION OF HUMAN ORGANS AND
TISSUES ACT 2010**

(Act VI of 2010)

[18 March 2010]

*An Act to provide for removal, storage and transplantation
of
human organs and tissues for therapeutic purposes.*

WHEREAS it is expedient to provide for the regulation, removal, storage and transplantation of human organs and tissues for therapeutic purposes and for matters connected therewith or ancillary thereto;

It is hereby enacted as follows:-

1. Short title, extent and commencement.— (1) This Act may be called the Transplantation of Human Organs and Tissues Act, 2010.

(2) It extends to the whole of [2][the Punjab].

(3) It shall come into force at once.

2. Definitions.— In this Act, unless there is anything repugnant in the subject or context,—

(a) “brain dead” means irreversible loss of brain and brain-stem functions simultaneously;

(b) “death” means an irreversible cessation of the entire function of brainstem;

(c) “donor” means a person who donates any part of his body, organ, tissue or cell;

(d) “Evaluation Committee” means a committee appointed under section 5;

[3][(dd) “Government” means Government of the Punjab;]

(e) “human organ” mean any part of a human body, organ or tissue;

(f) “Monitoring Authority” means an authority constituted under section 8 to monitor the process of transplantation of human organs or tissues and matters relating thereto;

(g) “payment” means payment in money or money’s worth but does not include any payment for defraying or reimbursing,—

(i) the cost of removing, transporting or preserving the human organ to be supplied; or

(ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any organ from his body;

(h) "prescribed" means prescribed by rules made under this Act;

(i) "recognized institution" means a medical institution or hospital for practice of operative surgery in transplantation of human organs or tissues to be recognized by the Monitoring Authority;

(j) "recognized transplant surgeon or physician" means Surgeons or Physicians possessing appropriate qualifications, experience, and trained in the relevant field, to investigate, examine and carry out transplantation surgery of human organs or tissues; and

(k) "transplantation" means the grafting of any human organ or tissue of any living or deceased person to some other living person for therapeutic purposes.

3. Donation of organ or tissue by a living person. – (1) Notwithstanding anything contained in any other law for the time being in force, a living donor who is not less than eighteen years of age, may, during his lifetime, voluntarily donate any organ or tissue of his body to any other living person genetically and legally related, who is a close blood relative and the donation of organ or part or tissue by such person for therapeutic purpose shall be regulated in the manner as may be prescribed. In the case of regenerative tissue, i.e. stem cells, there is no restriction of age between siblings.

Explanation. – For the purpose of this section, the expression "close blood relative" means parent, son, daughter, sister, brother and includes spouse:

Provided that transplantation shall be voluntary, genuinely motivated and without any duress or coercion.

(2) In case of non-availability of a donor as explained under subsection (1), the Evaluation Committee may allow donation by a non-close blood relative, after satisfying itself that such donation is voluntary.

4. Donation of human organs or tissues after death.— (1) Any person who is not less than eighteen years of age may before his death, in writing duly signed and verified by the respective Evaluation Committee, donate any of his organ or tissue for transplantation and for this purpose may authorize any medical institution or hospital duly recognized by the Monitoring Authority. The cases of unclaimed brain dead hospitalized patients shall be presented to an Evaluation Committee for transplantation after an intense search for their relatives within twenty-four hours.

(2) On the death of a donor referred to in sub-section (1), any close relative of the deceased shall inform the Evaluation Committee about the deceased and cause the removal of the human organ or tissue in accordance with the authorization.

(3) A donation under this section may be executed in such form and manner as may be prescribed and may be revoked at any time during the lifetime of the donor in the presence of two witnesses.

5. Evaluation Committee.— (1) As soon as may be after the commencement of this Act the [4][Government] may, by notification in the official Gazette, appoint as many Evaluation Committees as may be necessary which shall consist of a surgical specialist, a medical specialist, a transplant specialist, a nephrologist, and a neurophysician and an intensivist where available and two local notables having a good record of social service. The Evaluation Committee shall be established for every medical institution and hospital where at least twenty-five transplants are being carried out annually.

(2) The Evaluation Committee shall—

(a) ensure that no organ or tissue is retrieved from non-related living donors without the prior approval of the Evaluation Committee;

(b) determine brain death of a person;

(c) determine propriety of removal of a human organ from any living person using brain death protocol to be formulated; and

(d) determine fitness or otherwise for transplantation of a human organ into any other body.

6. Transplantation to be carried out by the team of transplant surgeons and physicians, etc.— (1) The transplantation of human organ or tissue or removal of any part of human organ for the purpose of transplantation shall only be carried out by the recognized professionals who shall, before the removal of any human organ from the body of the deceased, ensure that written certification has been obtained from the Evaluation Committee that death has occurred.

(2) For the purpose of sub-section (1) a person shall be deemed to be medically and legally dead at the time when in the opinion of the Evaluation Committee, based upon acceptable standard of medical practice, there is—

(a) an absence of natural respiratory and cardiac functions and attempt at resuscitation are not successful in restoring those functions; or

(b) an irreversible and permanent cessation of all brainstem functions and future attempt of resuscitation or continued supportive maintenance would not be successful in restoring such natural functions.

(3) On the commencement of this Act the [5] [Government] shall on the recommendation of the Monitoring Authority, by notification in the official Gazette, publish the list of medical institutions and hospitals as recognized medical institutions and hospitals for practice of operative surgery in transplantation of human organs and tissues. The [6] [Government] may revise the list from time to time.

(4) No hospital or medical institution shall carry out transplantation of human organs and tissues unless it is recognized as provided in sub-section (3).

7. Effects etc., to the donor and the recipient.— (1) No transplantation of a human organ and tissue from a donor other than defined in sub-section (1) of section 3 shall be carried out without prior permission of the appropriate Evaluation Committee and only at such medical institutions and hospitals which have been notified under sub-section (3) of section 6; provided that such donation by Pakistani citizens shall not be permissible to citizens of other countries.

(2) No human organ or tissue shall be removed from the body of a living person except for the purposes of section 3 and no transplantation team of a recognized medical institution or hospital shall undertake the removal or transplantation of any human organ or tissue from a living donor unless they have explained the effects, complications and hazards connected with the removal of organ or tissue for transplantation to the donor and its outcome in the recipient respectively in such manner as may be prescribed.

8. Monitoring Authority.— [7] (1) The Government shall, by notification in the official Gazette, constitute a Monitoring Authority consisting of the following:-

(i)	Minister for Health or a nominee of the Chief Minister;	Chairperson
(ii)	Secretary to the Government, Health Department;	Member/Secretary
(iii)	Secretary to the Government, Home Department or his representative not below the rank of Additional Secretary;	Member
(iv)	President, Transplantation Society of Pakistan or his nominee;	Member
(v)	Executive Director Pakistan Medical Research Council or his nominee;	Member
(vi)	President, Ophthalmologic Society of Pakistan or his nominee;	Member
(vii)	President, Pakistan Medical Association of Pakistan or his nominee;	Member
(viii)	President, Pakistan Society of Gastroenterology or his nominee;	Member
(ix)	Surgical Transplant Specialist nominated by the Government;	Member

(x) Chairperson of the Punjab Health Care Commission or a nominee of the Health Care Commission; and

Member

(xi) any other outstanding Medical Specialist nominated by the Government.

Member]

(2) The Authority so constituted shall—

(a) monitor transplantation and enforce prescribed standards for recognized medical institutions and hospitals;

(b) investigate and hold inquiry into the allegations of breach of any provision of this Act;

(c) inspect recognized medical institutions and hospitals for examination of quality of transplantation, follow up medical care of donor and recipient and any other matter ancillary thereto and also periodically inspect institutions wishing to be recognized;

(d) cause establishment of a National Registry and national and regional networks for evaluating quality and outcome of transplant centers and cause enhancement and promotion of transplantation; and

(e) due to shortage of available human organs for transplantation to meet lifesaving patient needs; the Monitoring Authority will explore and support the international collaboration of xenotransplantation in future, after considering all ethical and safety risks and also continue to examine and collect global data on the practices, safety, quality, efficacy and epidemiology of stem cell as well as non-human organ transplantation.

(3) The Monitoring Authority shall appoint an Administrator, preferably from the medical profession, in consultation with the [8][Government] and also appoint such other officers as may be required, on terms and conditions, to be determined by it, to carry out the day-to-day business of the Authority, for which the [9][Government] shall provide a reasonable annual grant.

(4) The [10][Government] in consultation with the Monitoring Authority shall establish a fund consisting of grants by the Federal and Provincial Governments and contributions by NGOs, philanthropists and other individuals for the transplantation or indigent patients including post transplant care and medicines.

(5) The pool of voluntary donors and registry of potential recipients shall be established and regulated as may be prescribed.

9. Prohibition of removal or transplantation of human organs for any purpose other than therapeutic purpose.— No donor and no person empowered to give authority for removal of any human organ shall authorize the removal of any human organ for any purpose other than the therapeutic purposes.

10. Punishment for removal of human organ without authority.—

(1) Whoever renders his services to or at any medical institution or hospital and who for the purposes of transplantation, conducts, associates with or helps in any manner, in the removal of any human organ without authority, shall be punished with imprisonment for a term which may extend to ten years and with fine which may extend to one million rupees.

(2) Where any person convicted under sub-section (1) is a registered medical practitioner, his name shall also be reported to the Pakistan Medical and Dental Council for appropriate action including removal of his name from the register of the Council for a period of three years for the first offence and permanently for subsequent offence.

11. Punishment for commercial dealings in human organ.—

Whoever,—

(a) makes or receives any payment for the supply of, or for an offer to supply, any human organ;

(b) seeks to find a person willing to supply for payment of any human organ;

(c) offers to supply any human organ for payment;

(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply any human organ—

(i) takes part in the management or control of a body of persons, whether a society, firm, or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or

(ii) publishes or distributes or causes to be published or distributed any advertisement,—

(a) inviting persons to supply for payment of any human organ;

(b) offering to supply any human organ for payment; or

(c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d),

shall be punished with imprisonment for a term which may extend to ten years and with fine which may extend to one million rupees.

12. Punishment for contravention of any other provision of this Act.—

Whoever contravenes any provision of this Act or any rule made, or any condition of the registration granted thereunder for which no punishment is separately provided in this Act, shall be punished with imprisonment for a term which may extend to three years or with fine which may extend to three hundred thousand rupees or with both.

13. Offences by companies.— Where any offence, punishable under this Act has been committed by a company, its Chief Executive or Director or any other person who, at the time the offence was committed was incharge of, and was responsible to, the company for the conduct of business of the company, as well as the Company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that a company shall be liable to pay fine only:

Provided further that nothing contained in this section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

Explanation.— For the purposes of this section,—

(a) "company" means any body corporate and includes a firm or other association of individuals; and

(b) "director", in relation to a firm, means a partner in the firm.

14. Cognizance of offences.— (1) No Court inferior to that of the Magistrate of First Class empowered under section 30 of the Code of Criminal Procedure, 1898 (Act V of 1898) shall try an offence punishable under this Act.

(2) No court shall take cognizance of an offence under this Act except on a complaint in writing made by,—

(a) the Monitoring Authority or its Secretary; or

(b) an aggrieved person who has given notice of not less than fifteen days, in such manner as may be prescribed, to the Monitoring Authority, of the alleged offence and of his intention to lodge a complaint.

(3) Notwithstanding anything in section 32 of the Code of Criminal Procedure, 1898 (Act V of 1898) it shall be lawful for a Magistrate referred to in sub-section (1) to pass any sentence authorized by this Act even if such sentence exceeds his powers under the said section.

(4) Notwithstanding anything in the Code of Criminal Procedure, 1898 (Act V of 1898) the offences punishable under this Act shall be non-bailable.

15. Savings.— Neither the grant of any facilities of any authority for removal of any human organ from the body of the donor deceased or alive in accordance with the provisions of this Act nor removal of any human organ or tissue from the body of a deceased person with due care in pursuance of such authority shall be deemed to be an offence punishable under section 297 of the Pakistan Penal Code (Act XLV of 1860).

16. Protection of actions taken in good faith.— (1) No suit, prosecution or other legal proceedings shall lie against any person for anything which is done in good faith or intended to be done in pursuance of the provisions of this Act or rules made thereunder.

17. Power to make rules.— The [\[12\]](#)[Government] may, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

18. Removal of difficulties.— If any difficulty arises in giving effect to any provision of this Act, the [\[13\]](#) [Government] may make such order as [\[14\]](#)[it] considers necessary or expedient for the purpose of removing the difficulty.

[\[1\]](#)This Act of Majlis-e-Shoora (Parliament) received the assent of the President on the 17th March, 2010, and published in the Gazette of Pakistan (Extraordinary), dated 18th March 2010, pp.89-96.

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This Act was originally in the Federal ambit, however, the subject on which this law was enacted, devolved to the provinces by virtue of 18th Amendment in the Constitution, hence it was adopted, with amendments, for the province of the Punjab by the Punjab Transplantation of Human Organs and Tissues (Amendment) Act 2012 (LVII of 2012) w.e.f. 1st November 2012.

[2]Substituted for the word “Pakistan” by the Punjab Transplantation of Human Organs and Tissues (Amendment) Act 2012 (LVII of 2012).

[3]Inserted *ibid*.

[4]Substituted for the words “Federal Government” by the Punjab Transplantation of Human Organs and Tissues (Amendment) Act 2012 (LVII of 2012).

[5] Substituted for the words “Federal Government” by the Punjab Transplantation of Human Organs and Tissues (Amendment) Act 2012 (LVII of 2012).

[6] *Ibid.*

[7] Substituted by the Punjab Transplantation of Human Organs and Tissues (Amendment) Act 2012 (LVII of 2012).

[8] Substituted *ibid.*, for the words “Federal Government”.

[9] Substituted for the words “Federal Government” by the Punjab Transplantation of Human Organs and Tissues (Amendment) Act 2012 (LVII of 2012).

[10] *Ibid.*

[11] Substituted for the words “Federal Government” by the Punjab Transplantation of Human Organs and Tissues (Amendment) Act 2012 (LVII of 2012).

[12] *Ibid.*

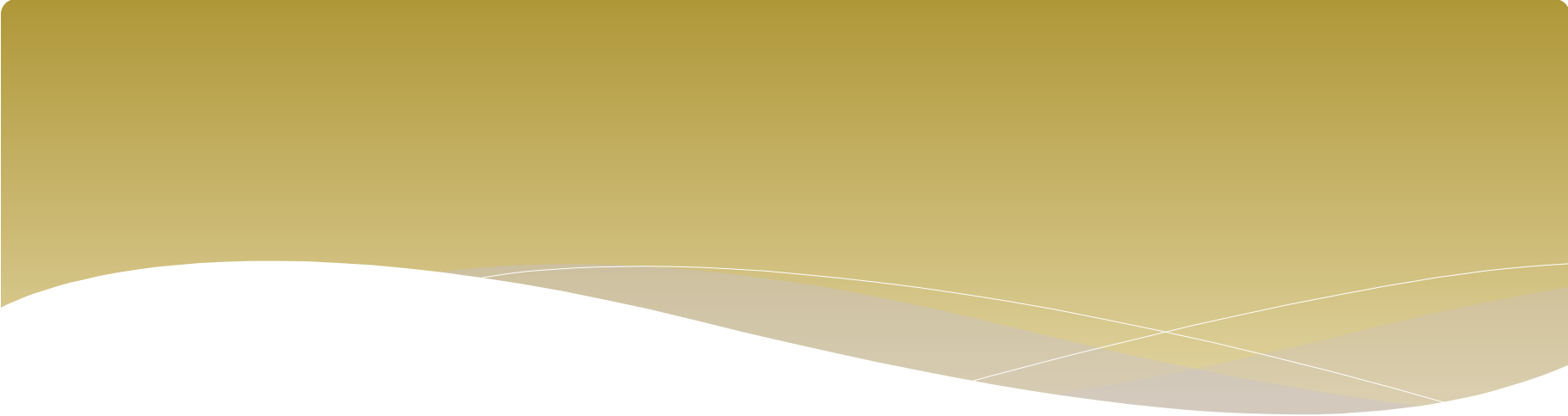
[13] *Ibid* for the word “President”.

[14] *Ibid* for the word “he”.

LOOPHOLES IN EXISTING
SYSTEM OF HUMAN ORGAN
TRANSPLANT

Demand Outstrips Supply

- ❑ One of the biggest problems faced by patients & doctors
 - ❑ Shortage of donated organs
- ❑ Patients die waiting on long national waiting list with addition of new names to it every few minutes
 - ❑ With more people ageing, the number of people needing an organ may increase
- ❑ This may lead to consequent shrinkage of donor pool

- 
- ❑ Advancement in safety measures(helmets, seat belts, air-bags) make accidents less fatal(leading source of donated organs)

Unfair System

- ❑ Donation & distribution of organs must be made more fair
- ❑ Some regions have far more people than others
 - ❑ Patients are stuck where they happen to live in
- ❑ Some cities receive greater number of sick people and also most challenging cases because of abundant medical facilities

Preference for Young Donors

- ❑ Good and kind but unfair donation system
- ❑ For healthy organ to save someone's life, somebody young has to die so that donated organ is not on its last legs
- ❑ Even organs with minor imperfections are not transplanted

Need for Awareness

- ❑ Many people are not aware of the need, shortage and benefits of organ transplant

Short-Term Preservation of Organs

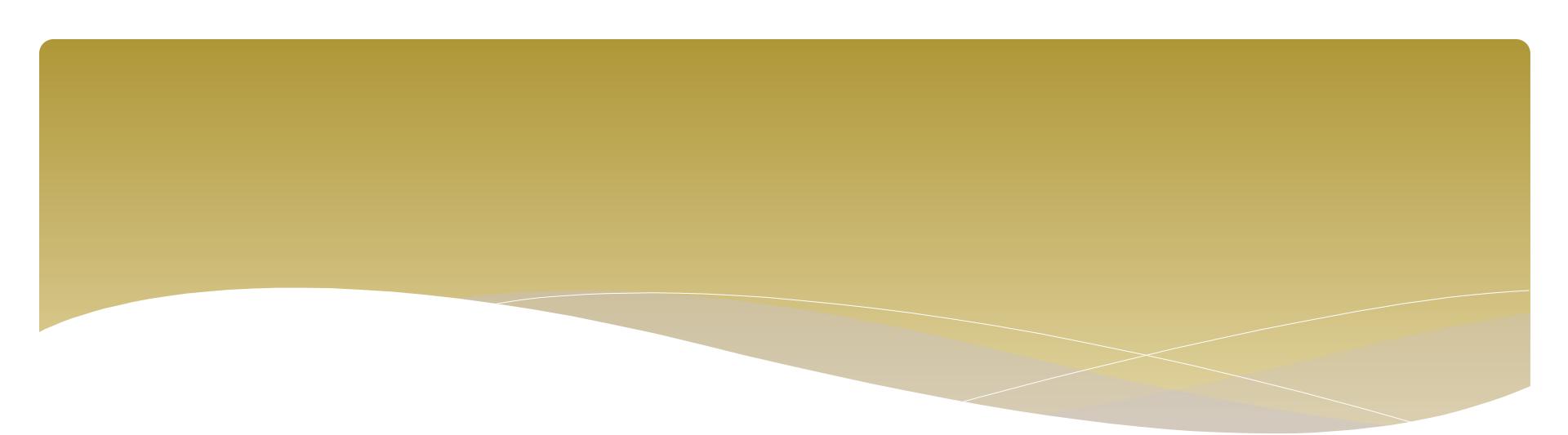
- ❑ Donated organs do not last long outside the body
- ❑ We have a window of about three to four hours from time the donor dies to when an organ must be transplanted into waiting patient for best outcome

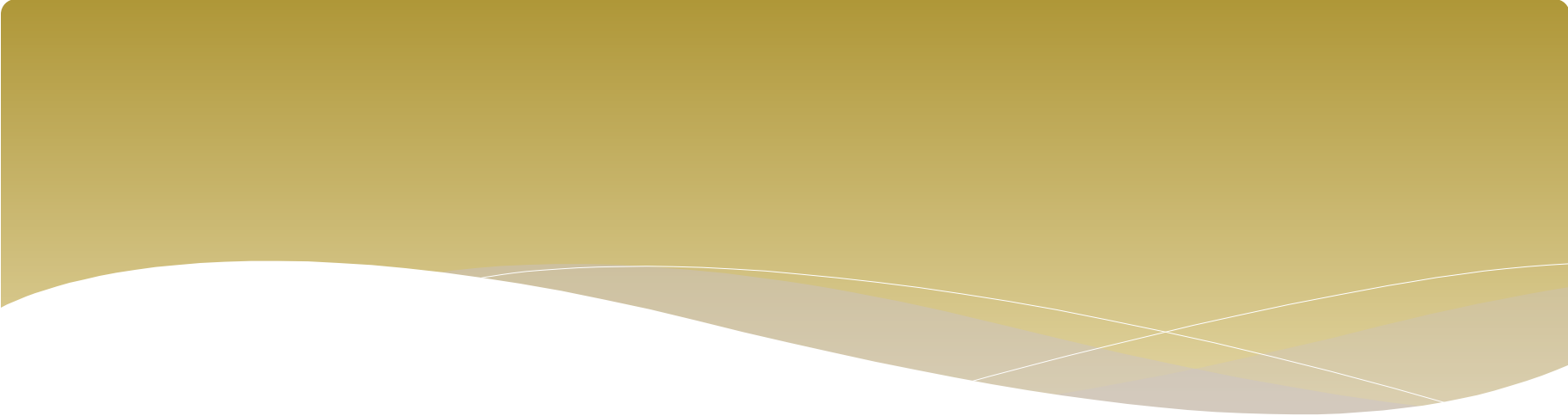
Rejection of Transplanted Organs

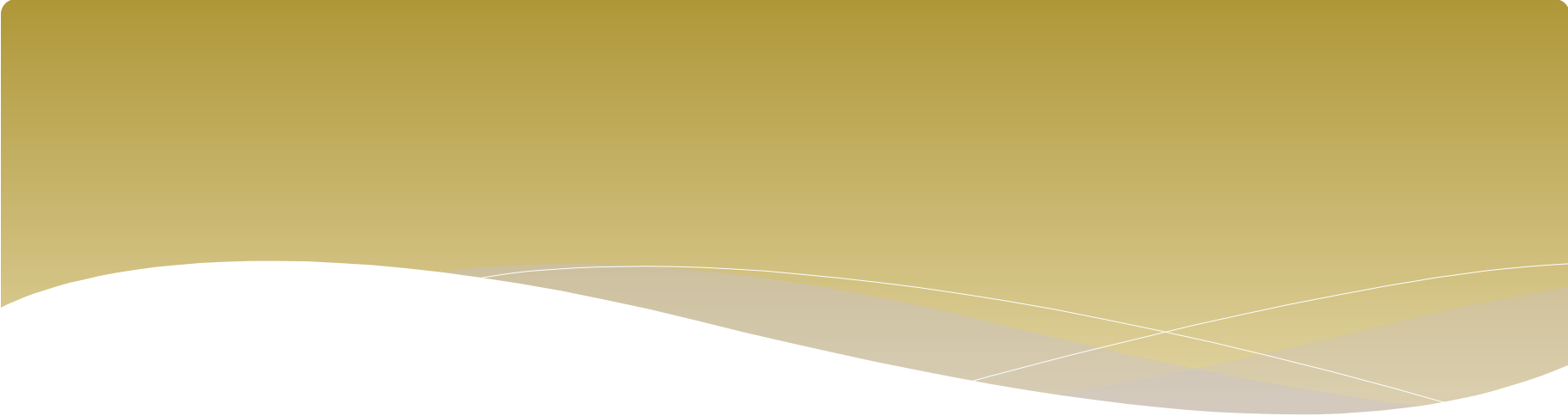
- ❑ The immune system tries to reject and expel the transplanted organ

How to Overcome these Loopholes

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- Fair allocation of organs and distribution to every state depending upon demand and population
 - Consider transplanting organs that meet most but not all transplantation criteria; extended criteria should be brought into practice
 - Organs with some imperfections should be transplanted to increase donor pool; increases life expectancy of recipient before dying of organ failure
 - Underlying diseases should be treated

- 
- ❑ Create awareness about organ donation and convince to donate
 - ❑ Preserve donated organs longer
 - ❑ Don't use organ transplant in the first place
 - ❑ Become your own donor; use of induced pluripotent stem cells(iPSCs) to mimic embryonic stem cells that can be grown into specific tissues

- 
- ❑ Simply replace part of the organ
 - ❑ Control obesity to control diabetes and hypertension; two most common causes of kidney failure; obesity is a risk for heart disease, stroke and fatty liver disease; if controlled it will reduce incidence of organ failure
 - ❑ Overcoming rejection



The End.