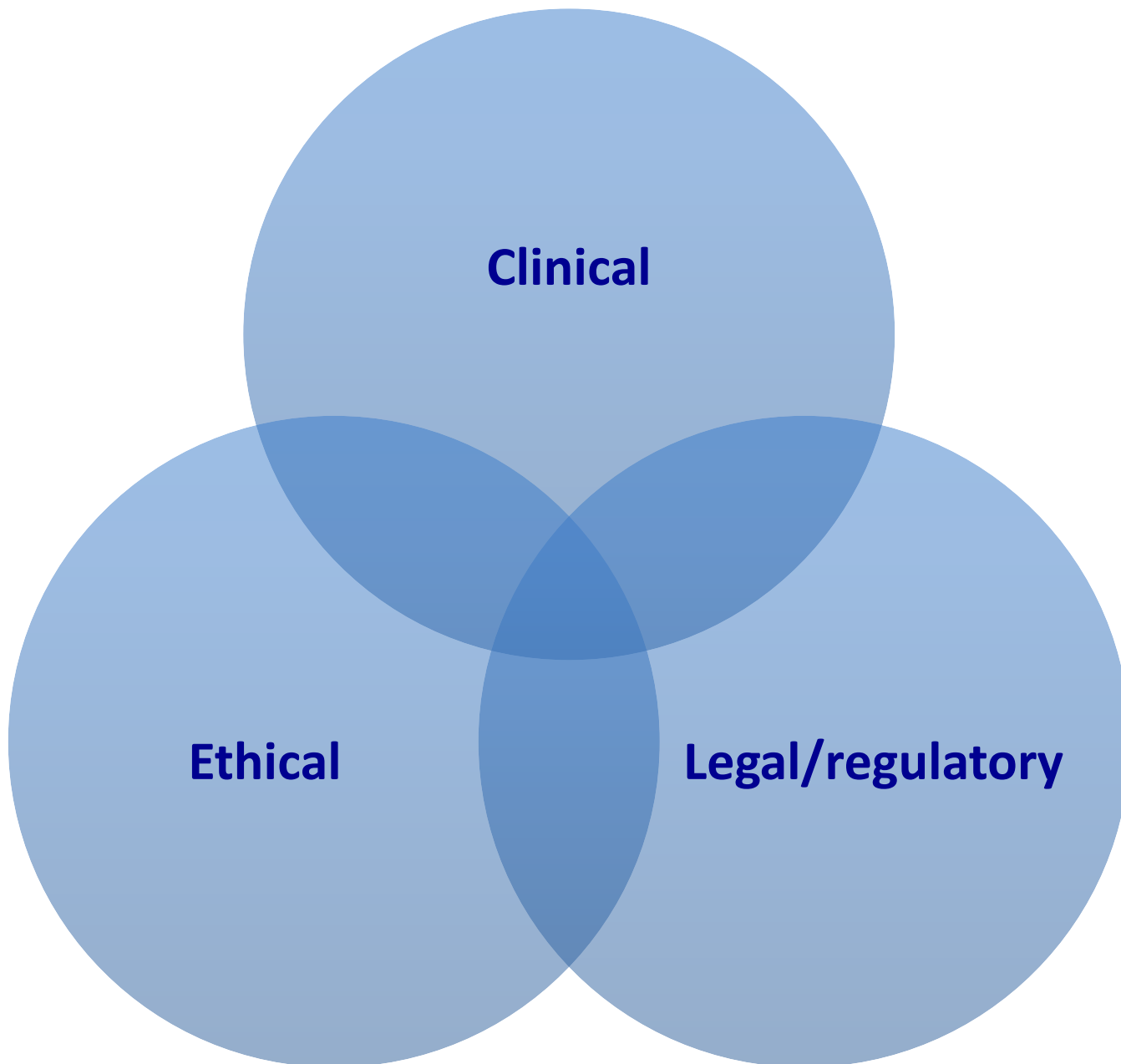


Organ transplantation in practice: clinical considerations

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Clinical

Ethical

Legal/regulatory

What drives the ethical issues?

- Transplantation is option of choice
- Organ shortage
- Desire for innovation

What are the ethical issues?

Deceased donors

- Diagnosis of death
- Consent process for donor
- Consent process for recipient
- Allocation
- Use of extended criteria donors

Living donors

- The live donor procedure
- Unconventional donor/recipient pairings
- Higher risk recipient
- Payment (regulated or unregulated)

Future technologies

**Ethics should be proactive rather than
reactive**



‘Let me give you a definition of ethics: It is good to maintain and further life it is bad to damage and destroy life.’

Albert Schweitzer

- Ethical principles
- Live donation
- Deceased donation

Ethical principles

What are the key ethical principles?

- Altruism
- Autonomy
- Dignity and concerns about commodification
- Justice
- Maximising health and welfare
- Reciprocity
- Solidarity
- Importance of trust and professional values

... but these principles often compete

Examples of ethical dilemmas

- Is it always right to try and meet demand?
- Does the offer of any significant incentive act as a form of undue influence and compromise the voluntary nature of their donation?
- How can we guard against the risk of coercion in the family context?
- Should those who are prepared to donate bodily material be entitled to specify the recipient?
- What role should families (or health care professionals) play in deciding whether a deceased person's bodily material be used to benefit others?
- Should the state intervene if one person is willing to sell a body part that another wishes to buy?

Live donation

Live donation

- Types of living donors
- What are the issues?
- What are the safeguards?
- Dealing with >1 potential donor
- Dealing with the complex donor/recipient pairing

Types of living donors

Predominantly kidney

- Genetically/emotionally related
- Paired/pooled exchange
- Non-directed altruistic
- Directed altruistic
- Paid donation

What are the issues?

- Organ type
- Higher risk recipient
- Genetically/emotionally related
- Paired/pooled exchange
- Non-directed altruistic
- Directed altruistic
- Paid organ donation

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Organ type

Kidney

- Is now routine, but significant ethical concerns 25-30 years ago ['first do no harm']
- Informed consent – risk of death 1:3000; morbidity 2-4%
- Avoid coercion or reward

Liver

- Is becoming more routine, but greater risks
- Risk of death for adult to adult 1:200; morbidity 10-20%

What level of risk is acceptable?

What are the issues?

- Organ type
- Higher risk recipient
- Genetically/emotionally related
- Paired/pooled exchange
- Non-directed altruistic
- Directed altruistic
- Paid organ donation

High risk recipients

- Medically or immunologically higher risk
- Transplantation considered better option than dialysis
- Higher risk of graft failure or early recipient death
- Need for detailed informed consent
- Recognize impact of early graft failure or patient death on donor, family and wider transplant programme

What are the issues?

- Organ type
- Higher risk recipient
- **Genetically/emotionally related**
- Paired/pooled exchange
- Non-directed altruistic
- Directed altruistic
- Paid organ donation

Genetically related (living related)

- Siblings, parents, children, cousin.....
- How to prove identity?
- Spectrum of altruism

Selfishness

**Self
interest**

Reciprocity

Obligation

Selflessness



- Hidden coercive forces may be in play

Living unrelated

A wide spectrum

- Emotionally related
- Paired/pooled donation
- Non-directed altruistic donation
- Directed altruistic donation
- Paid organ donation



Ethically
more
challenging

Emotionally related (living unrelated)

- Who? Spouse, partner, in-law, friend....
- How to define meaningful relationship?
- How to prove relationship?
- Exploring motivation
- What is risk of coercion or reward?

What are the issues?

- Organ type
- Higher risk recipient
- Genetically/emotionally related
- **Paired/pooled exchange**
- Non-directed altruistic
- Directed altruistic
- Paid organ donation

Paired/pooled exchange

- Option for pairs where conventional live donation is not possible for immunological reasons
- All parties need to be fully informed
- Confidentiality is important to avoid potential conditionality
- Timing of donor operations – what is risk of pulling out?

What are the issues?

- Organ type
- Higher risk recipient
- Genetically/emotionally related
- Paired/pooled exchange
- **Non-directed altruistic**
- Directed altruistic
- Paid organ donation

Non-directed altruistic

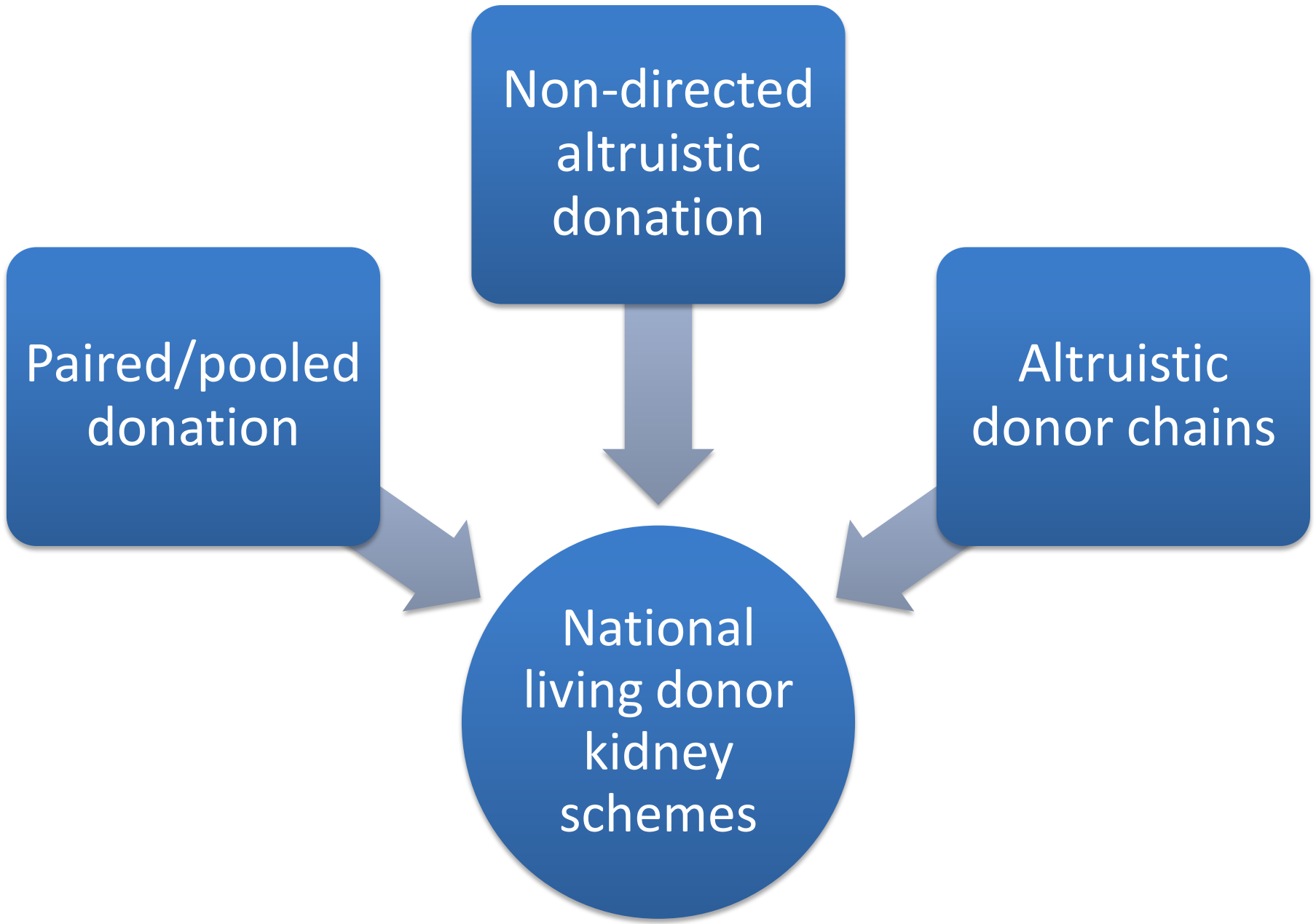
- Why would anyone choose to do this?
- ‘Must be mad, bad or sad’
- Autonomy & informed consent may still lead to ‘poor choice’
- Recognise that some people are generous & altruistic
- Ensure no current mental health issues
- Explore motivation and previous altruistic acts
- Anonymity
- Allocation criteria

Non-directed
altruistic
donation

Paired/pooled
donation

Altruistic
donor chains

National
living donor
kidney
schemes



What are the issues?

- Organ type
- Higher risk recipient
- Genetically/emotionally related
- Paired/pooled exchange
- Non-directed altruistic
- **Directed altruistic**
- Paid organ donation

Directed altruistic donation

- Different scenarios – media appeal, friend of a friend, social media etc
- ‘Relationships’ formed for purpose of organ donation
- Increased risk of reward
- What is motivation?
- Maybe more understandable that non-directed altruistic donation

Altruistic directed LURD is prone to become a fiction if all the following are met:

1. Commerce in organs is a criminal offence
2. There are social stakeholders who have vested interests in commerce of organs
3. Altruistic LURD is lawful
4. The test confirming altruism is weak
5. The test excluding commerce is weak

Is altruistic living unrelated organ donation a legal fiction?

M Epstein & G Danovitch. Nephrol Dial Trans 2009: 24; 357-360

What are the issues?

- Organ type
- Higher risk recipient
- Genetically/emotionally related
- Paired/pooled exchange
- Non-directed altruistic
- Directed altruistic
- **Paid organ donation**

Transplant commercialism

- Worldwide condemnation, but estimated 5% of all transplants worldwide (WHO 2007)
- Exploitation of donors
- Commodification of body parts
- Poorer outcomes for recipients

Organ trafficking is illegal, but...

- Potential donors are desperate
- Potential recipients are desperate
- Ongoing debate about regulated organ sales

Regulated payment

For

- Permits the autonomy of the donor
- Normal standard of care
- Standard payments from independent third party
- Will meet the shortage of kidneys

Against

- Still payment
- Impact on consent
- What will be the impact on 'altruistic' deceased and living donation?
- Against international legislation and guidelines

What are the safeguards?

- Legislation
- Regulation
- International frameworks

Legislation outlawing payment
of organ donors in all countries,
with exception of Iran

EU Organ Directive

Article 13: Principles governing organ donation

- Member states shall ensure that donations of human organs from deceased and living donors are voluntary and unpaid
- The principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of incomes related to the donation. For such cases, Member States shall define the conditions under which compensation may be granted, while avoiding any financial incentives or benefit for a potential donor.

UK Regulatory Framework

- All living donor transplants regulated by Human Tissue Authority under Human Tissue Act (2004)
- Donor & recipient seen by independent assessor using agreed criteria and online report submitted
- Approval by HTA executive or panel of 3 HTA members depending on donor/recipient type
- Legally must be informed consent, no reward and no duress/coercion

Guiding Principle 5

- Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.
- The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

WHO guiding principles on human cell, tissue and organ transplantation 2009



DECLARATION ISTANBUL



Principle 6

- Organ trafficking and transplant tourism violate the principles of equity, justice, and respect for human dignity and should be prohibited. Because transplant commercialism targets impoverished and otherwise vulnerable donors, it leads inexorably to inequity and injustice and should be prohibited. In Resolution 44.25, the World Health Assembly called on countries to prevent the purchase and sale of human organs for transplantation.

Dealing with >1 potential donors

- Consider clinical, social and immunological factors for donor and recipient
- Preference where nature and quality of relationship is clear

Dealing with the complex donor/recipient pairing

- When there is doubt about the stated relationship
- Where there is doubt about the validity of the consent
- When there is doubt about the risk of reward
- When there is doubt about the risk of coercion

Where there is doubt about the stated relationship

- Documentary evidence
- Photographs
- Signed affidavit
- Supporting letters
- Observation of how donor, recipient and wider family interact together

Where there is doubt about the validity of consent

- Three components of consent
 - Voluntary
 - Informed
 - Capacity
- Even if consent is valid, patient can still make poor choice
- Offer second opinion

When there is doubt about the risk of reward

- Nationally agreed regulatory framework for assessment and approval of donors
- Ensure the donor and recipient are aware of the legal position and the penalties involved
- Interviewing donor and recipient separately and together
- Ask the question!
- Approval to proceed given by those independent of transplant teams

When there is doubt about the risk of coercion

- Interviewing donor and recipient separately and together
- Discuss with wider team
- Use of 'cool off' period
- Give donor a 'way out'

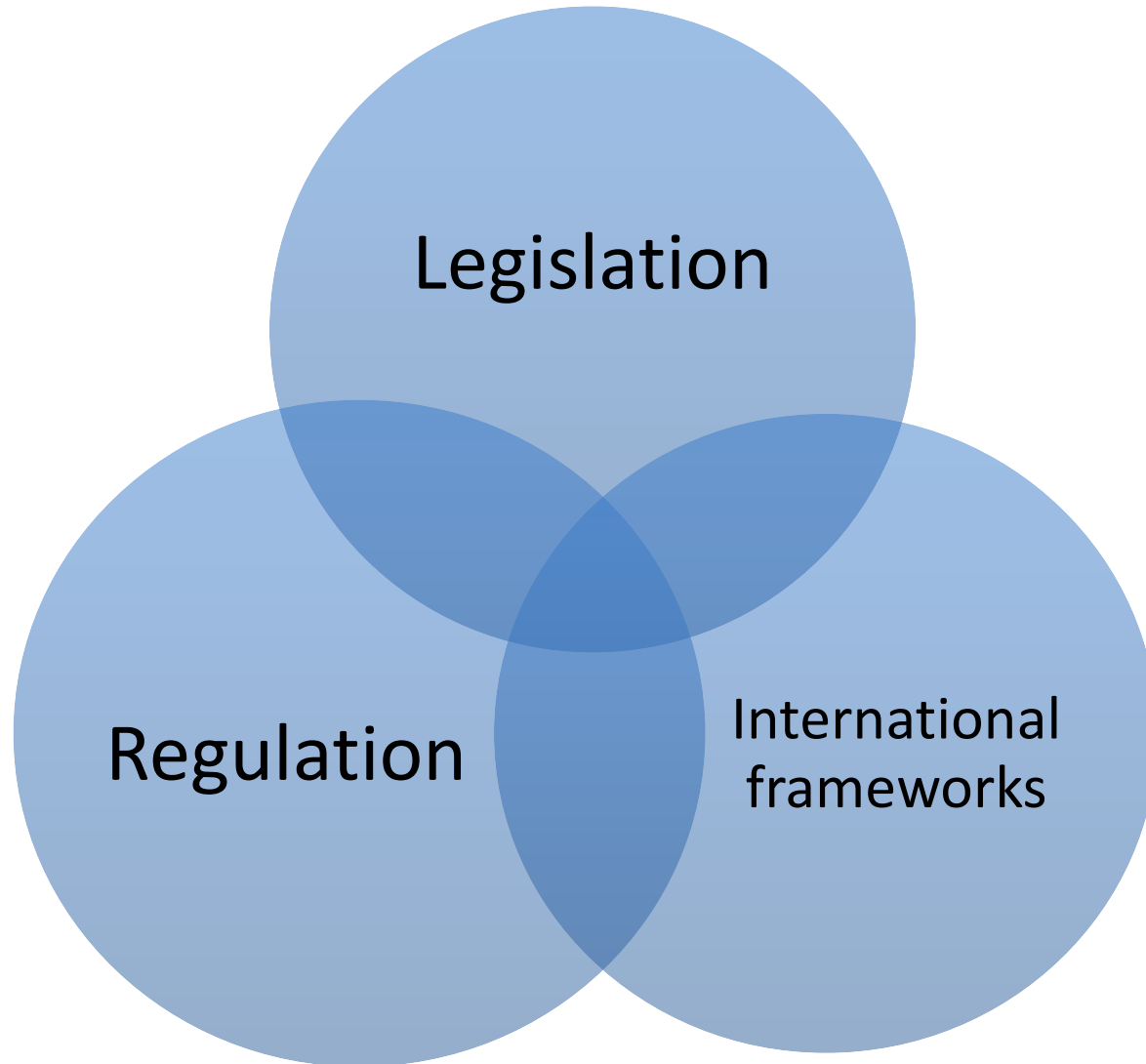
Can we always be certain?

Can we always be certain?

No

But we should be as certain and as satisfied as we can,
and if there is still doubt don't proceed

Robust safeguards



Deceased donation

Deceased donation

- Types of deceased donors
- Allocation
- Use of extended criteria donors

Deceased donors

- Only realistic option for those needing a non-renal organ transplant
- Mature deceased and living donor programmes needed to make a country self-sufficient for organ transplants
- Donation after brain death (DBD) donors
- Donation after circulatory death (DCD) donors

Allocation

What's best for
the patient?



What's best for
the organ?

Allocation

What's best for the patient?

- Clinical urgency
- Prioritization
- Short waiting time



What's best for the organ?

- Good match
- Short cold ischaemic times
- Age matching

Extended criteria donors

- What term to use?
- How to define?
- Do they have to be used?
- How to allocate?
- What to tell the recipient?

Donor factors which might affect outcome following transplantation

- Age
- Race
- Raised terminal creatinine
- Death from a cardiovascular accident
- History of hypertension, cardiac disease or diabetes
- Smoking history
- Other non-trauma cause of death
- Weight / height / BMI
- Length of stay on ITU
- Inotrope use, eg adrenaline

Anatomy

- Multiple vessels
- Retrieval damage

Donation after circulatory death

- Uncontrolled vs controlled donor
- Long agonal/withdrawal phase
- Long asystolic times

Malignancy

- Previous extracranial malignancy
- Current primary intracranial malignancy

Infection risk

- At risk behaviour for HIV
- HBsAg pos
- HCV ab positive

The UNOS definition of an expanded criteria kidney donor

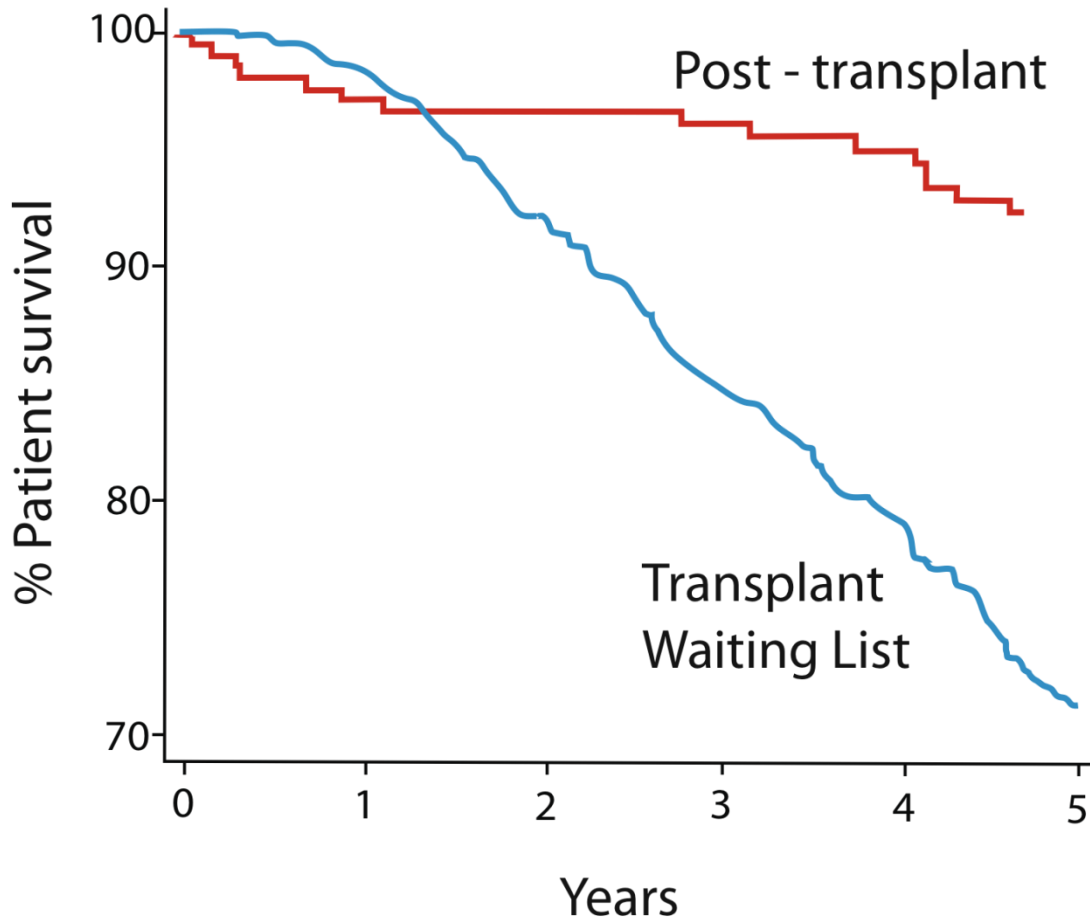


- Over 60 years, or
- Over 50 *plus* two of:
 - Creatinine >132 $\mu\text{mol/L}$ (1.5mg/dL)
 - History of hypertension
 - Death from a cerebrovascular accident

Extended criteria donors

- What term to use?
- How to define?
- **Do they have to be used?**
- How to allocate?
- What to tell the recipient?

Patient survival on RRT: Kidney waiting list versus transplant



ANZ data, NDT 2002; 17: 2212-19

Extended criteria donors

- What term to use?
- How to define?
- Do they have to be used?
- **How to allocate?**
- What to tell the recipient?

Allocation

- Older recipients
- Long waiters
- Patients with high risk of waiting list mortality

In general not for...

- Young recipients
- High risk recipient

Extended criteria donors

- What term to use?
- How to define?
- Do they have to be used?
- How to allocate?
- **What to tell the recipient?**

The patient's choice?

- Should potential recipients be informed specifically about the risks associated with their intended organ?
- Should eligible recipients be allowed to select in order to maximise their own well-being?
or
- Should potential recipients be allocated organs to maximise public health?

Recipient consent

- Paternalism vs partnership
- What to say?
 - Honesty about options, risks and benefits – and the alternatives
- When to say it?
 - At time of listing
 - On annual basis
 - At time of transplant



‘Grub first, then ethics.’

Bertolt Brecht