The Leeds Teaching Hospitals NHS
NHS Trust

An introduction to ethical considerations in organ transplantation

Thursday 30th September 2021

Dr Matthew Welberry Smith
Consultant Kidney Transplant Physician
BTS Ethics Committee
With thanks to Dr *Refik Gokemen for supplying some of the slides*

Outline

- What is ethics?
- What is not ethics?
- Examples of ethical issues in transplantation
  - Opt out in deceased donation
  - Defining death
  - Peri-mortem interventions
  - Allocating organs
  - Payments for donation

Ethics is everywhere – just another day in transplantation:

- 25 year old man, donating a kidney to his father. Tells the LD team that the family have insinuated that he may be written out of his father's will if he doesn't donate
  - What do we do?
- The deceased donor family who specify that they will only agree to donation if the organs go to a recipients with specific characteristics (ethnicity, religion, etc)
  - What do we do?
- Potential live liver donor tells different members of the team different information about his available social support, casting doubt on his openness in the wider process
  - What do we do?

What is ethics?

- English "*ethics*"
  - from the Ancient Greek
    ēthikós (ἠθικός) "relating to one's character"
  - from root word *êthos* (ἦθος) meaning "character, moral nature"

- Remarkably hard to give a simple definition!

- *But a day to day level, ethics is trying to answer those "What do we do?" questions*

What is ethics?

- Range of areas
  - Meta-ethics
  - Normative ethics
  - Applied ethics

What is goodness?
What is a "right" action?
How do we know?

How should we act
in general terms?

How should we act *in this specific situation?*

What is ethics?

- Systematic analysis of what it means to lead a decent life

- "A set of concepts and principles that guide us in determining what behaviour helps or harms sentient creatures"

  - Paul & Elder 2006
  - *The Miniature Guide to Understanding the Foundations of Ethical Reasoning*

A case

- Deceased donor family specify that they will only agree to donation if the organs go to a recipient with specific characteristics

  - “We are Blue people”
  - “We want Blue people to benefit”
  - “The organs can only be donated if they go to Blue people”

Ethical considerations

- "Concepts and principles that guide us in determining what behaviour helps or harms sentient creatures"

- Equity / fairness?
  - What about the other people waiting on the list?

- Utility
  - Will the organ last longer if allocated on different criteria (ignoring whether someone is Blue) ?
  - Does that matter to the decision?

Ethical considerations

- "Concepts and principles that guide us in determining what behaviour helps or harms sentient creatures"

- Consequences
  - For the transplant waiting list:
    - Is it better that *some* people (Blue, in this case) are removed from the waiting list through these organs being donated? That may free up future opportunities for others….
    - Or does this create a multi-tier unequal system where social choices lead to social advantages? (systems of privilege)
  - For the social structure we live in:
    - Would this endorse social division into groups? (Blue people cf. not Blue people)
    - Do we want our society to be divided in that way?

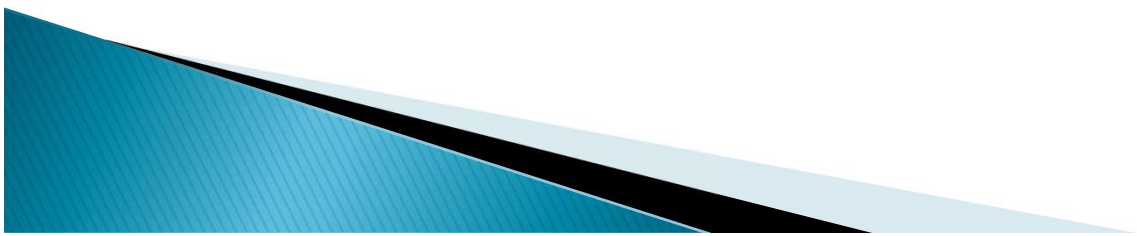
Ethical considerations

- "Concepts and principles that guide us in determining what behaviour helps or harms sentient creatures"

- Consent
  - Is it reasonable for the family to set conditions of consent on this basis?
  - Is it acceptable for no donation to happen if they refuse because their preferred conditions are not met?
  - Is it acceptable for donation to happen without their conditions being met, even if they don't want that?
  - What do we know about the deceased donor's own understanding?
    - On organ donor register?

What is *not* ethics?

- People (often) confuse ethics with behaving in accordance with social conventions, religious beliefs, the law, and do not treat ethics as a stand-alone concept
  - Paul & Elder 2006 *The Miniature Guide to Understanding the Foundations of Ethical Reasoning*
- Not a set of prohibitions particularly concerned with sex
- Not an ideal system which is all very noble in theory but no good in practice
- Not something intelligible only in the context of religion
- Not something that is relative or subjective
  - Peter Singer, *Practical Ethics* 1979



Conflict of interest declaration!

- Noone comes to ethics objectively
- I am best described as a
  - Non-cognitive moral skeptic; and
  - Pyrrhonist

Moral judgements are not capable of being objectively true

Conflict of interest declaration!

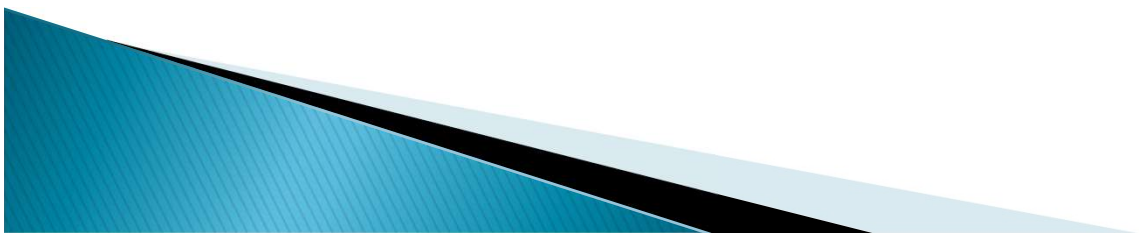
- Noone comes to ethics objectively
- I am best described as a
  - Non-cognitive moral skeptic; and
  - Pyrrhonist

Attempting moral objectivity stops you being happy

- Which means
  - I usually don't believe you can know (moral) things in an absolutely objective form
  - I think trying to do so will ruin your life

So what's the point of ethics?!

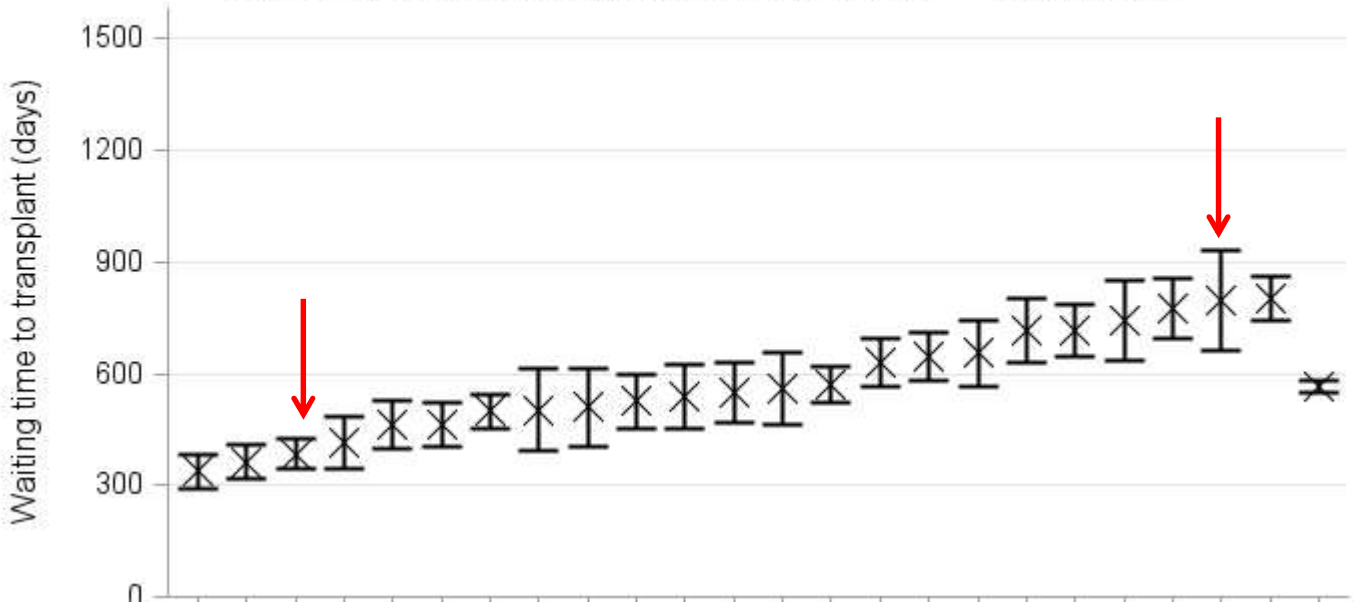
- Aren't we just asking lots of questions?!
- Practical outworkings
  - Different viewpoints, cultures, social situations examining issues together to find integrated solutions to how we can all agree to act
  - Ethics as a forum for doing the work of actually living together in a diverse and complex society



Practical example

- Neighbouring transplant units with different median waiting times to kidney transplantation

Figure 3.12 **Median waiting time to deceased donor transplant for adult patients registered on the kidney transplant list, 1 April 2015 - 31 March 2018**



NHSBT Annual Organ Specific Report on Kidney transplantation 2020/2021

Inequity?

- Massive difference in median waiting time
- Geographical distance ~40 miles
- Is this a true measure of access to transplantation?

- Reasons?
  - Too much risk in one centre?
  - Too little risk in the other centre?
  - Case mix differences?
  - A different “philosophy of transplantation”?

Actions

- Regional collaborative set up
- Relationships built
- Activity shared, best practise shared
- Joint attempts to equalise, positively, for all patients

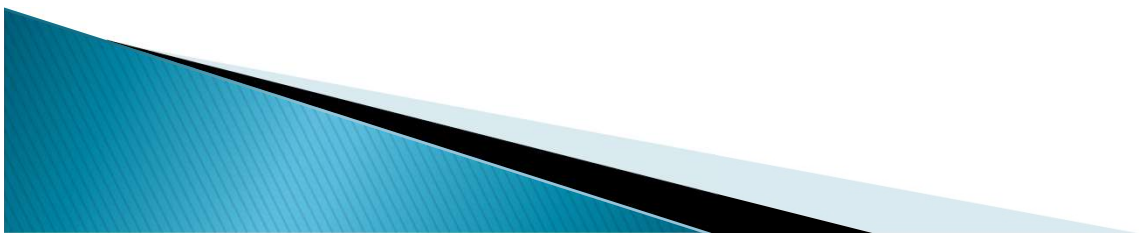
Notice:

- This only happens because of shared ethics
- The joint belief

  "society should not be unequal"

is essential to this – *and is a statement of an ethical position*

- It is not data that drives this change. It is an ethical agreement on equality that *uses* data to drives the change.



But don't we all already basically agree on this stuff?

- No…..

Social differences

Cultural differences

Political differences

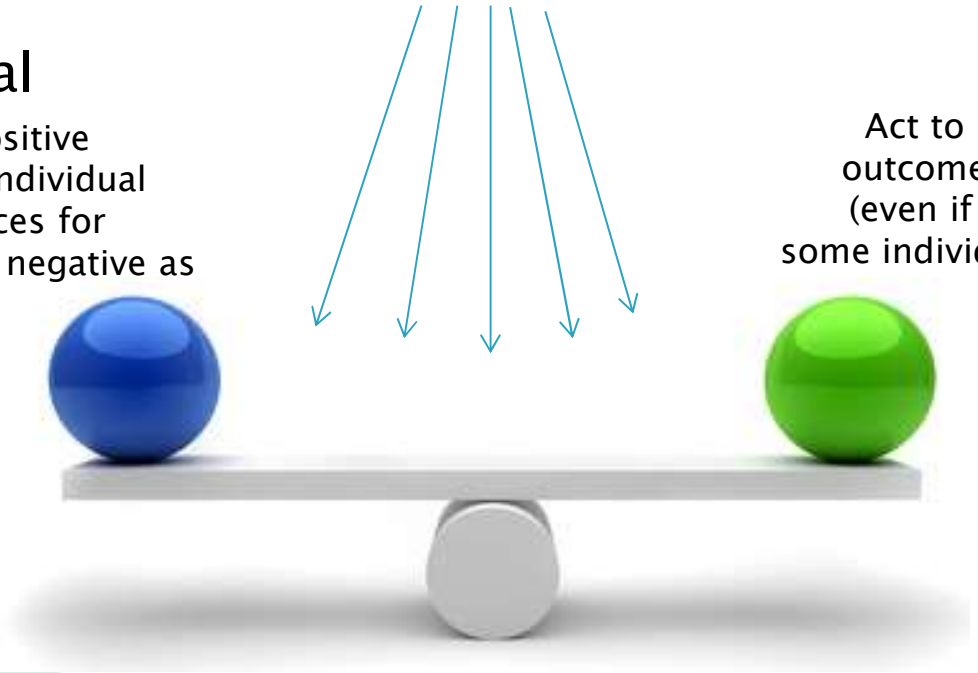
…and many more!

Deontological

Act to maximise positive outcomes for this individual (even if consequences for society at large are negative as a result)

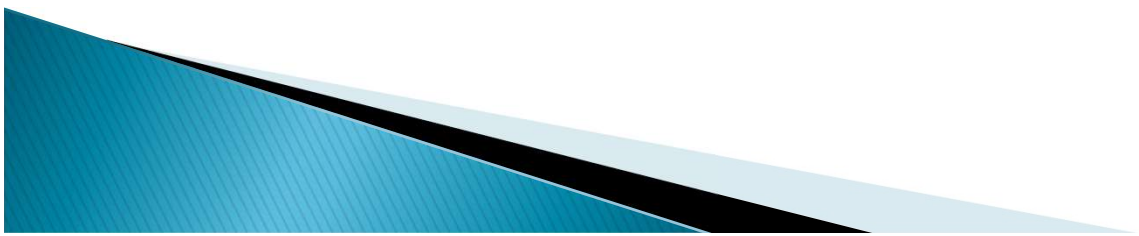
Utilitarian

Act to maximise positive outcomes for the majority (even if consequences for some individuals are negative as a result)



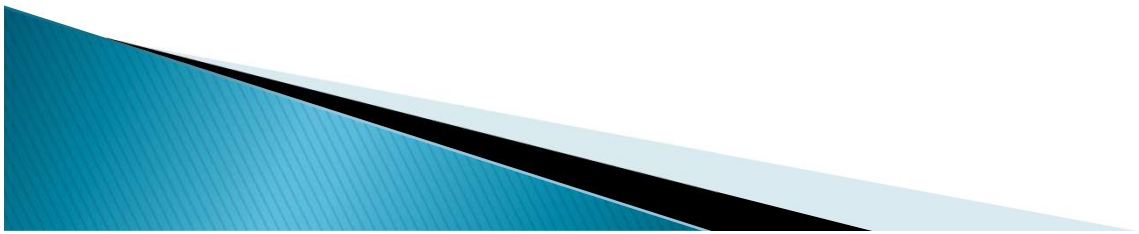
Examples

- Opt-out for deceased organ donation
- Defining death
- Peri-mortem interventions
- Allocating organs
- Payments for donation



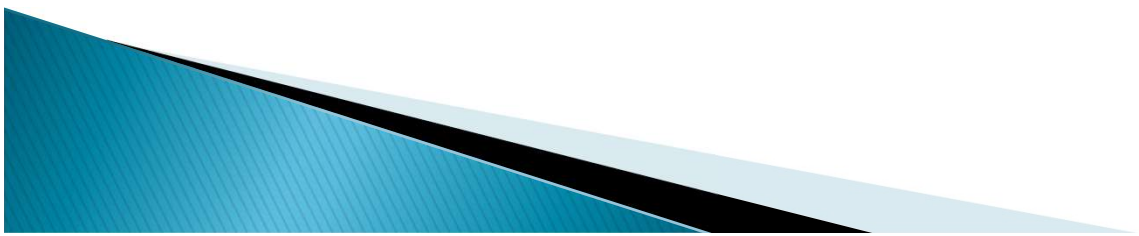
The problem

- ~6000 people on UK transplant waiting lists
- ~300+ die waiting / year



Solutions?

- Compulsory removal of organs from the dead
- ‘Hard opt-out’: no family veto
- ‘Conscripting’ organs from healthy live donors
- Procuring organs from executed prisoners overseas
- Paying incentives for deceased donor families
- Paying live donors: allowing a market in organs
- Voucher system to promote ‘altruism’



The case for confiscating cadaveric organs

- Consider these 3 scenarios

1. Ann suffers from MS. If she does not get medical treatment, she will lead a less than minimally flourishing life
2. Bob has been taken ill to hospital. If he does not get a blood transfusion, he will lead a less than minimally flourishing life
3. Charles has been taken ill to hospital with liver failure. If he does not get a liver transplant, he will die.

- Distributive justice: we are committed to the concept of taxation to alleviate poverty
- Inheritance tax
- Do the sick have a right to the organs of the dead?

Cécile Fabre. *Whose Body is it Anyway?* 2006

Deceased donation

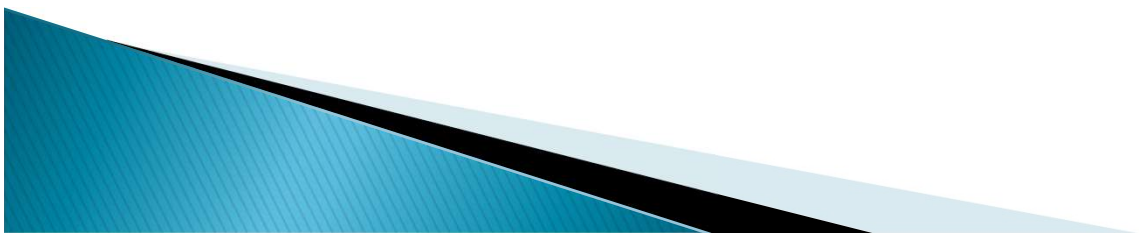
- *Why not take all organs from the dead?*
- Because it assumes a unified worldview across society!
  (and doing so would be presuming to judge those that disagree)

- Traditions of death
  - Ritual disposal of the dead as something that defines humans?

- Possibility of posthumous harm?

  The vanity and presumption of governing beyond the grave, is the most ridiculous and insolent of all tyrannies. Thomas Paine, *Rights of Man*

- Should we respect the wishes of the dead?
  - Individual autonomy?
  - We respect wills of dead with respect to their property, so why not their wishes about their body?



On the other hand….

- We are used to the concept that everyone contributes for the good of all
- Taxation is a practical example
  - and continues after death (inheritance tax!)
- If you do not believe in posthumous harm, and carefully collaborate with death related traditions, couldn't everyone contribute, albeit after death?

Why do families refuse consent to deceased donation?

- The illusion of lingering life
  - A feeling that the integrity of the dead body should be maintained, as if the deceased continues to be regarded as a living person
- The need to respect the dead
  - As a way of showing respect for the individual who once was
- Distrust of the medical establishment
  - And biomedical developments, criteria of brain death; a feeling of anxiety concerning one's powerlessness
- The feeling that transplantation is contrary to nature
  - Discomfort at the thought of one's organs surviving in another person's body, or fear of offending God or Nature

Sanner 1994

Opt out legislation

- Organ Donation (Deemed Consent) Act 2019: England
- Human Transplantation (Wales) Act 2013
- Is presumed consent
  - Necessary?
  - Effective?
  - Ethical?

Other (?preferable) ways to increase organ availability?

Unintended consequences causing reduced donation? Bad press? Negative societal impact on underserved groups? Is a numeric increase worth the potential negatives?

Is this the imposition of a worldview that is not universally shared?

Ethics is not the same as law

- A common confusion
- Law: the system of rules which a particular country / community recognizes as regulating the actions of its members and which it may enforce by the imposition of penalties
- Ethics: concepts and principles that guide us in determining what behaviour helps or harms sentient creatures
- The two may or may not overlap at any particular point!

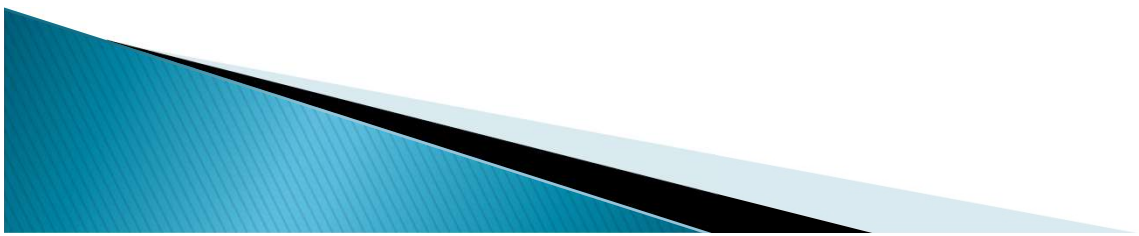
Defining death

UKDEC
UK Donation Ethics Committee

ACADEMY OF
MEDICAL ROYAL
COLLEGES

An ethical framework for donation after confirmation of death using neurological criteria (DBD)

UK donation ethics committee (UKDEC)
April 2016



UKDEC
UK Donation Ethics Committee

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AN ETHICAL FRAMEWORK FOR CONTROLLED DONATION AFTER CIRCULATORY DEATH

EXECUTIVE SUMMARY

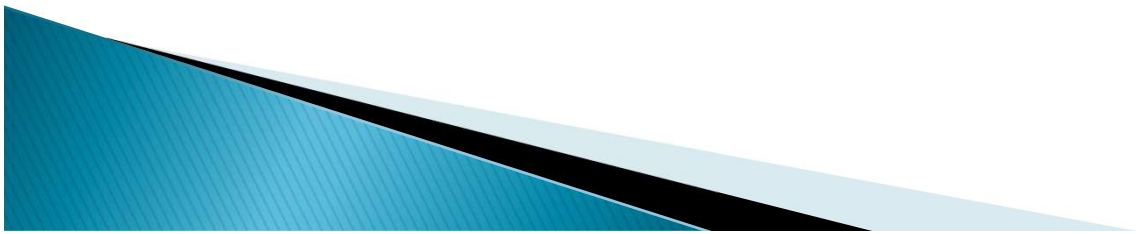
DECEMBER 2011

Ethical questions in DBD donation

- If it becomes apparent that the patient in life, or their family at the bedside, are opposed to donation, should tests to confirm death using neurological criteria take place?

- When a patient or their family has expressed a wish to donate, is it acceptable to conduct other clinical procedures (such as blood tests) aimed at facilitating successful donation before testing to confirm death using neurological criteria?

- When death is strongly clinically suspected, is it acceptable to keep a patient on mechanical ventilation and other intensive care support in order to enable testing to confirm death using neurological criteria to take place?



Peri-mortem interventions in deceased donors

Guiding Principles

There are two guiding principles behind the work of the UK Donation Ethics Committee:

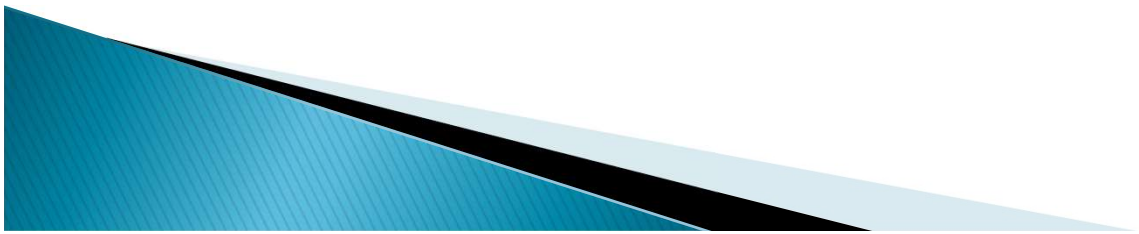
Principle 1: where donation is likely to be a possibility, full consideration should be given to the matter when caring for a dying patient; and

Principle 2: if it has been established that further life-sustaining treatment is not of overall benefit to the patient, and it has been further established that donation would be consistent with the patient's wishes, values and beliefs, consideration of donation should become an integral part of that patient's care plan in their last days and hours.

- Blood tests
- Adjustment in existing treatments
- CT imaging
- Bronchoscopy
- Trans-oesophageal echocardiography
- Institution of ECMO or normothermic regional perfusion
- Organ biopsy
- Non therapeutic elective ventilation

Allocating kidneys

- Scarce resource… we want the maximum benefit from the kidneys that are available.
  - In which recipient will this kidney last the longest?



NZ post-transplant survival probability algorithm

Predicting potential survival benefit of renal transplantation in patients with chronic kidney disease, Walraven et al, CMAJ, 2010 Apr 20;182(7):666-72. doi: 10.1503/cmaj.091661. Epub 2010 Mar 29.

Variable	Points*
Baseline serum albumin level†	
< 25	9
25–27	7
28–32	6
33–37	5
38–39	4
40–41	3
> 41	0
Body mass index†	
< 20.4	1
20.4–25.0	0
25.1–35.7	–1
> 35.7	0
Cause of renal failure†	
Diabetes	3
Hypertension	–1
Glomerulonephritis	–4
Polycystic kidney disease	–6
Other	0
Medical history	
Chronic obstructive pulmonary disease	3
Nonambulatory	3
Congestive heart failure	2
Diabetes requiring insulin	2
Coronary artery disease	2
Peripheral vascular disease	2
Cerebrovascular disease	1
Hypertension	–1
Smoker	3
Currently employed	–2

Variable	Points* by transplantation status: No transplant	Deceased donor	Living donor
Age†			
< 31	0	0	0
31–37.5	3	5	5
37.5–42.5	5	8	8
42.5–46.8	7	11	10
46.8–50.3	8	13	12
50.3–53.7	9	15	14
53.7–57.0	10	17	16
57.0–60.7	11	18	18
60.7–65.3	13	21	20
> 65.3	18	28	27
Ethnicity†			
White	0	0	0
Black	–4	0	–1
Other	–4	–4	–4
Year of first renal replacement therapy†‡			
< 1997	0	0	0
1997	–1	0	–1
1998–1999	–2	0	–2
2000	–3	0	–3
2001	–4	0	–4
2002–2003	–5	1	–5
2004	–6	1	–6
> 2004	–7	1	–7
Time from first renal replacement therapy to listing, mo†			
0	0	0	0
0.1–0.4	3	6	5
0.5–3.6	4	7	6
3.7–5.9	5	8	7
6–8.3	5	9	7
8.4–11.2	6	10	8
11.3–14.9	6	10	8
15–20.6	7	11	8
20.7–31.6	7	12	9
31.7–75.1	9	15	11
Transplantation	–	–26	–26
Time from listing to transplantation, yr			
< 0.51	–	0	0
0.51–1.92	–	0	1
1.93–3.71	–	0	2
> 3.71	–	0	3

UK kidney offering scheme

POL186/11 – Kidney Transplantation: Deceased Donor Organ Allocation

NHS
Blood and Transplant
Copy No:
Effective date: 16/02/2021

- Tiered system prioritising highly sensitised and long waiting patients

- Waiting time for first dialysis or first active listing
- Donor Recipient Risk Index
- HLA match / age combination
- Geographical region
- Matchability
- Donor-recipient age difference
- Total HLA mismatch
- Blood group match

UK kidney offering scheme 2019

Donor-recipient risk index combinations

A donor risk score (DRI) is calculated for each donor on offer using 7 risk factors. A donor is then categorised in to one of 4 groups based on the risk score and by pre-determined cut-off values. D1 (lowest risk), D2, D3 and D4 (highest risk).

DRI = exp { 0.023 x (donor age-50) +
-0.152 x ([donor height-170]/10) +
0.149 x (history of hypertension) +
-0.184 x (female donor) +
0.190 x (CMV +ve donor) +
-0.023 x ([offer eGFR-90]/10) +
0.015 x (days in hospital) }

D1 ≤ 0.79
D2 0.79 – 1.12
D3 1.12 – 1.50
D4 ≥1.50

A recipient risk score (RRI) is calculated, for each eligible patient using 4 risk factors. A recipient is then categorised in to one of 4 groups based on the risk score and by pre-determined cut-off values. R1 (lowest risk), R2, R3 and R4 (highest risk).

RRI = exp { 0 x (recipient age≤25)-75) +
0.016 x ((recipient age>25)-75) +
0.361 x (recipient on dialysis at registration) +
0.033 x ([waiting time from dialysis-950]/365.25) +
0.252 x (Diabetic recipient) }

R1 ≤ 0.74
R2 0.74 - 0.94
R3 0.94 – 1.20
R4 ≥1.20

Points are defined as:

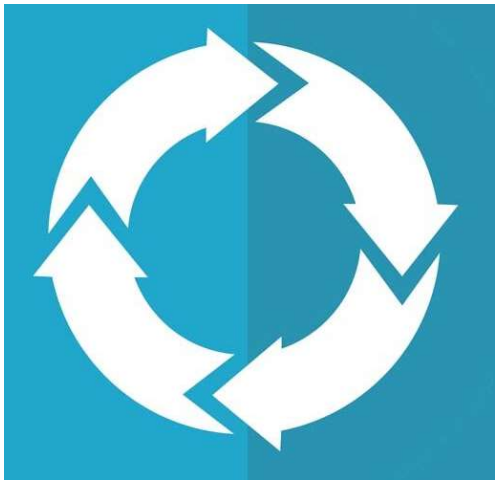
Donor Risk group	Recipient Risk Group			
	R1	R2	R3	R4
D1	1000	700	350	0
D2	700	1000	500	350
D3	350	500	1000	700
D4	0	350	700	1000

Kidneys from older, more hypertensive CMV+ donors, who have poorer renal function at donation, are preferentially offered to recipients who are older (and diabetic)

Ethical aspects

- Age /comorbidity matching may be the best use of the resource
- Age /comorbidity matching may disadvantage older recipients

Iterative process as an ethical consideration



- Allocation scheme is reviewed regularly by protocol
- Groups gaining more/less apparent advantage are identified
- Systems are iteratively adjusted to deal with these factors

Living donation: payment of donors

- Harm to the seller?
- Coercion by poverty?
- Coercion by unrefusable offer?
- Exploitation?
- Impact on altruism?
- Commodification?

Janet Radcliffe-Richards. *The Ethics of Transplants* 2012

Live donation: payment of donors

- *"Some academic commentators believe that an 'ethical market' in human body parts could provide a solution to the problem of organ shortage. The legal and bioethics literature contains well-reasoned arguments in support of a legally sanctioned and well-regulated market in human body parts. The British Transplantation Society opposes this view, however it is prepared to debate this issue as the theoretical and empirical literature evolves"*

- BTS website position statement https://bts.org.uk/chapters-committees/ethics-committee/position-statements/

Incentivising living donation: vouchers?

Original Clinical Science—General

Vouchers for Future Kidney Transplants to Overcome "Chronological Incompatibility" Between Living Donors and Recipients

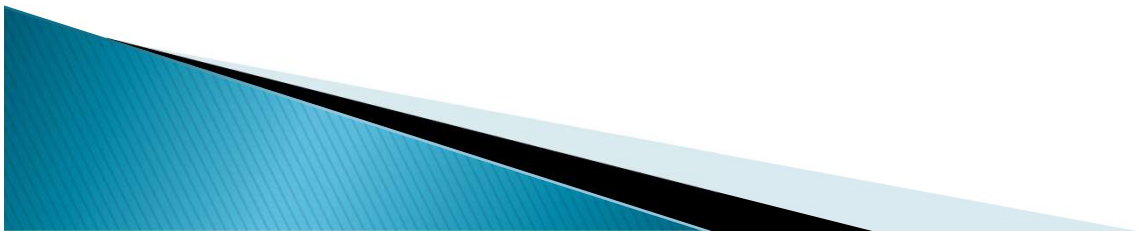
Jeffrey L. Veale, MD,[1] Alexander M. Capron, LLB, MA (Hon),[2,3] Nima Nassiri, MD,[3] Gabriel Danovitch, MD,[1] H. Albin Gritsch, MD,[1] Amy Waterman, PhD,[1] Joseph Del Pizzo, MD,[4] Jim C. Hu, MD, MPH,[4] Marek Pycia, PhD,[5] Suzanne McGuire, RN, BSN,[1] Marian Charlton, RN,[4] and Sandip Kapur, MD[4]

Background. The waiting list for kidney transplantation is long. The creation of "vouchers" for future kidney transplants enables living donation to occur when optimal for the donor and transplantation to occur later, when and if needed by the recipient. **Methods.** The donation of a kidney at a time that is optimal for the donor generates a "voucher" that only a specified recipient may redeem later when needed. The voucher provides the recipient with priority in being matched with a living donor from the end of a future transplantation chain. Besides its use in persons of advancing age with a limited window for donation, vouchers remove a disincentive to kidney donation, namely, a reluctance to donate now lest one's family member should need a transplant in the future. **Results.** We describe the first three voucher cases, in which advancing age might otherwise have deprived the donors the opportunity to provide a kidney to a family member. These 3 voucher donations functioned in a nondirected fashion and triggered 25 transplants through kidney paired donation across the United States. **Conclusions.** The provision of a voucher to potential recipients whose need for a transplant makes them "chronologically incompatible" with their donors may increase the number of living donor transplants.

(*Transplantation* 2017;101: 2115–2119)

Problems with kidney vouchers

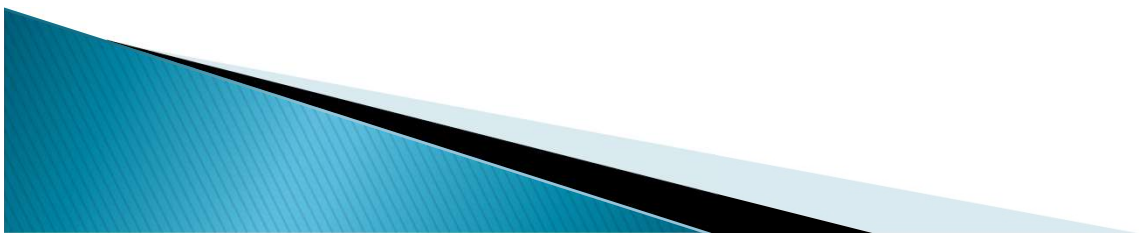
- Uncertainty of payback
- Progressive change in nature of the LD kidney pool: old kidney in, young kidney out…
- Commodification?



Living donation: hidden coercion?

- 25 year old man, donating a kidney to his father. He tells the LD team that the family have insinuated that he may be written out of his father's will if he doesn't donate.

- Bangladeshi family with a child with kidney failure. The divorced aunt, who has no children of her own, has come forward as the only donor. The LD co-ordinator senses that donation may be a way of atoning for shame within the family.

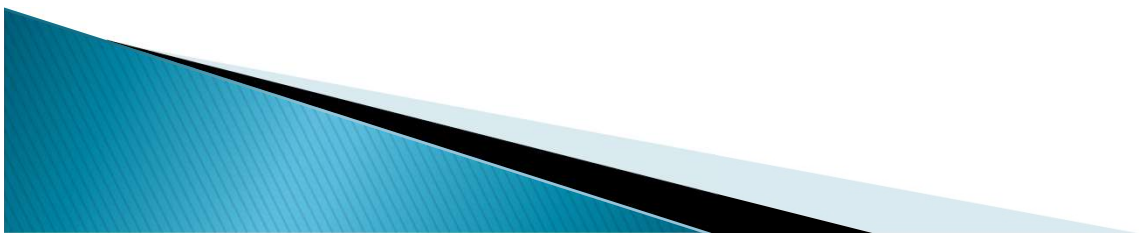


Living donation: mistaken paternity

- Child with kidney failure, on dialysis. Child's father came forward as potential donor, but initial screening demonstrated ABO incompatibility; discussions therefore centred around entry to the sharing scheme rather than direct transplantation
- HLA tissue typing was performed later than usual in the process. This showed a 2-2-2 mismatch between father and child: incompatible with the stated relationship
- What do we do?

Living donation: mistaken paternity

- Benefits and harms
- Truth-telling: virtue ethics
- Paternalism
- Informed consent



Ethics in transplantation: themes

- Benefits and harms
- Autonomy
- Interests of donors and donor families
- Utility and distributive justice
- Equity
- Societal impact
- Trust

Outline

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- Examples of ethical issues in transplantation
  - Opt out in deceased donation
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  - Peri-mortem interventions
  - Allocating organs
  - Payments for donation

BTS Ethics Commitee

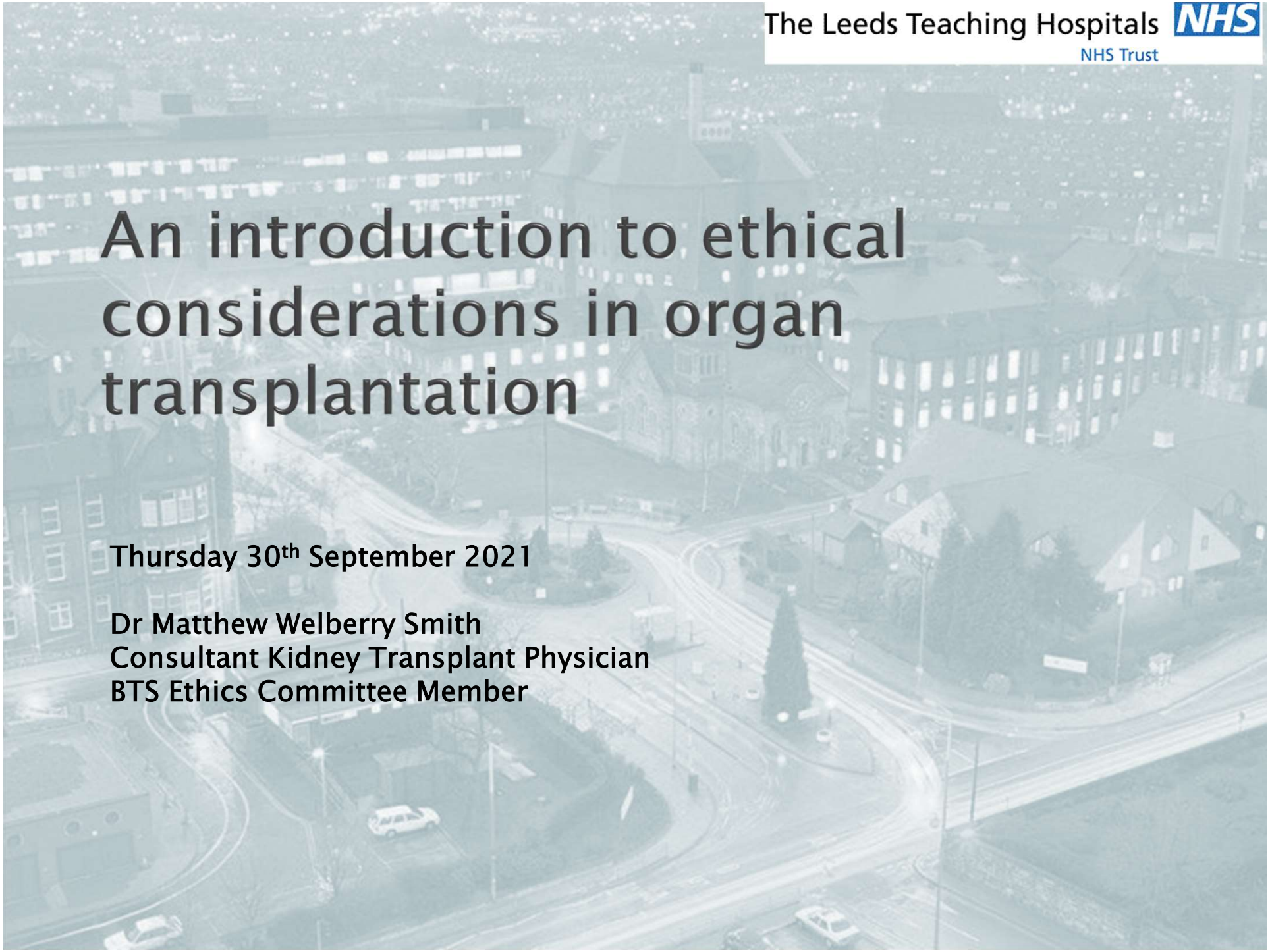
- Chair: Refik Gökemen

- The British Transplantation Society Ethics Committee is responsible for considering current ethical issues in transplantation to assist the Society in having an agreed position in these areas.
- …with an eye to future issue, enabling BTS to develop a defined position as early as possible.
- https://bts.org.uk/chapters-committees/ethics-committee/

Thank you for listening!

Thursday 30th September 2021

Dr Matthew Welberry Smith
Consultant Kidney Transplant Physician
BTS Ethics Committee Member



The Leeds Teaching Hospitals NHS
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Thursday 30th September 2021

Dr Matthew Welberry Smith
Consultant Kidney Transplant Physician
BTS Ethics Committee Member