

Organ donation: an ethical framework

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Organ donation

Facts & figures

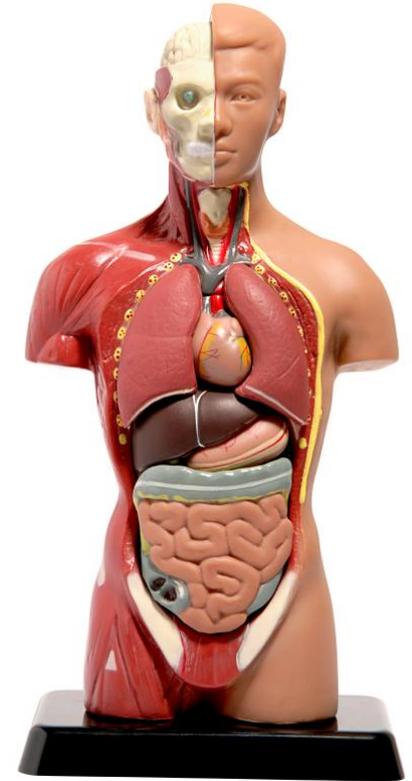
Living: kidneys, liver lobes

Deceased: heart, lungs, kidneys, liver, pancreas, bowel

- 8000 people waiting for an organ – 3 die every day
- 20,000 people on dialysis – £30K pa each
- 18 million people signed Organ Donor Register
- Few will die in circumstances where it is possible to donate organs
- 1010 deceased donors and 1045 living (mainly kidney) donors in 2010/11

What bodily material can be donated?

- Blood and blood products
- Solid organs
- Tissue, including bone, skin, arteries and corneas
- Eggs, sperm, embryos
- Whole bodies after death
- Whole living bodies as 'healthy volunteers' for clinical trials



After death and/or during life
For treatment and/or research

Regulation of donation in the UK

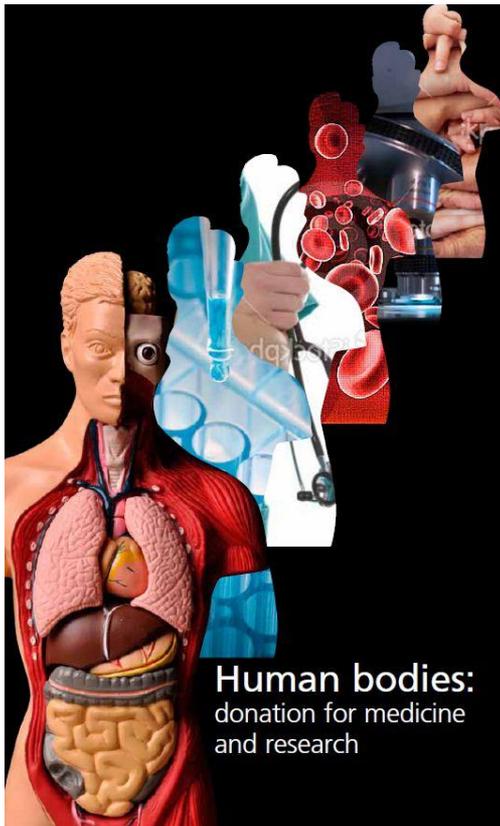
- Oversight by HTA or HFEA
- **Consent** required from donor
- Donation of bodily material for treatment:
 - no **payment** allowed, although ‘egg sharing’ permitted
 - full **expenses** reimbursed for living organ donors, but cap of £250 for egg and sperm donors
- Donation for research: **payment** not illegal
- Whole body for medical education: **funeral expenses**
- Healthy volunteers in clinical trials: **payment allowed**

International comparisons

- International consensus that paying for organs is inappropriate, but organ trafficking persists
- **Spain and Belgium** have 'opt-out' systems for deceased organ donation
- **Iran** permits payment for living organ donors through national system

The report

Human bodies: donation for medicine and research



Human bodies:
donation for medicine
and research

- 12 Working Party members
- Met Jan 2010 to May 2011
- Meetings with regulators, researchers, clinicians
- Public consultation: 180 responses
- Workshop with 43 recruited members of public

The role of the State

- A 'stewardship' role
- Work to improve public health
 - Reduce the need for bodily material (demand)
 - Make donation as easy as possible (supply)
- Remove inequalities
- Protect disadvantaged groups or individuals

Supply and demand

High demand for bodily material due to:

- increasing possibilities for using bodily material
- high levels of obesity, diabetes, alcohol consumption
- public expectations of medical science

Ways of reducing demand:

- Public health initiatives
- Research into alternatives

Possible ways of increasing supply

- Encouraging individuals to donate
 - e.g. information, recognition, removing barriers, offering incentives
- Changing consent rules
 - e.g. opt-out, prompted or mandated choice systems for organ donation
- Improving organisational structures
 - e.g. co-ordinated systems for donation, more transplant professionals

Reducing demand

Diet, lack of exercise, alcohol has led to increasing levels of heart disease, liver and kidney failure

The role of preventable diseases in the increasing demand for organs should be publicised in order to add weight to **public health campaigns**

Research being carried out on e.g. reducing need for organs, extending life of transplanted organs, devices to replace organs

Vital that material is available for **research**

Our ethical framework

- **Altruism** should continue to play a central role
- This does not necessarily exclude other approaches such as reward in some circumstances
- Donor's wishes are central – **consent** important
- The **welfare of the donor** and any potential threat to the **common good** should be the most important considerations
- **Trust and respect** play an essential part in systems in which people will be willing to donate – good **governance**
- We reject the **sale and purchase** of bodily material

Applying the framework...

- There are two kinds of action:
 - altruist-focused interventions
 - non-altruist-focused interventions (these need closer scrutiny)
- Donation for research purposes differs in important ways from donation for treatment purposes
- We suggest use 'authorisation' or 'willingness to donate' instead of consent for deceased donation

'Intervention Ladder' for encouraging individuals to donate

Rung 6: financial incentives

Rung 5: benefits in kind linked with donation

Rung 4: interventions as an extra prompt or encouragement

Rung 3: removing barriers and disincentives

Rung 2: recognition of altruistic donation

Rung 1: information about the need for the donation

Non- altruist focused

Altruist focused

Non-altruist-focused interventions

Factors to consider before moving to final two rungs:

1. The **welfare of the donor** and other affected individuals
2. The potential threat to the **common good**
3. The responsibilities of **health professionals**
4. The strength of the **evidence** on all these factors

Conclusions

Living organ donation

- **Current policy:** information, recognition, full reimbursement of expenses, no payment allowed
- Calls for **regulated market** to increase UK kidney donors (**rung 6 of ladder**). Factors to consider:
 1. Donor welfare? Risk to UK donors is acceptable but could harm donors in other countries
 2. Threat to altruism? Yes
 3. Healthcare professionals? Opposed to payment
 4. Evidence on above? Very little available

Living organ donation: recommendations

- Endorse current position of **no payment**
- Giving priority to organ donors would be **inappropriate**
- Endorse DH guidance on **full reimbursement** of expenses (including lost earnings) – should be given proper weight under new NHS structures

Deceased organ donation: incentives

- **Current policy:** no payment allowed
- Suggestion of paying **funeral expenses** for donors:
 - If offered to people who sign the ODR and go on to donate with the added altruistic feature that family would benefit (**rung 4 or 6**)
 - No harm to donor
 - No direct evidence of effectiveness but similar system for whole body donation to medical science

Deceased organ donation: consent I

- Current policy: **opt-in** system of consent where donor's (or their family's) wishes of central importance
- Suggestions of an **opt-out** system:
 - We reject **'hard'** opt out system given importance of personal choice
 - We do not oppose in principle **'soft'** opt-out system but have some practical concerns e.g. uncertainty of effectiveness and risk of loss of trust in system

Deceased organ donation: consent II

- **Current policy:** required to express wishes on Driver and Vehicle Licensing Agency (DVLA) form ('prompted choice')
- 'Mandated choice' and 'prompted choice' systems are ethical options
- Concerned there is no option of registering **objection** in the DVLA scheme
- Minimum information required – 'authorisation' rather than 'consent'
- Detailed information about donation procedures must be available to people if they want it

Deceased organ donation: recommendations

- Suggest pilot scheme where NHS meets **funeral expenses** of people who sign ODR and become organ donors
- Research needed on effects of **opt-out system** for organ donation if introduced in Wales
- Any system that mandates a response to a question about organ donation should also include the option of **saying no**
- Endorse current international consensus that organ trafficking and transplant tourism should be **banned**
- Imperative to promote **public health** campaigns

Role of organisations

- Organ Donor Taskforce tackled structural problems that may hinder donation
 - Risk that improvements might be lost in face of NHS changes
 - Particular shortage of organs from black and ethnic minority donors
- We endorse the call for action plan to ensure fair access to donation to **all UK residents**
 - Dept of Health should monitor how **NHS changes** affect organ donation and protect systems that work

Summary

- Role of the 'stewardship' State
 - Reduce demand
 - Promote donation
- Ethical Framework
- Intervention ladder
 - Altruistic and non-altruistic donation
- Actions:
 - For individuals
 - For organisations