

Human bodies:
donation for medicine
and research
a guide to the report

NUFFIELD
COUNCIL ON
BIOETHICS

Contents

Introduction 01

What bodily material can be donated? 02

How donation is regulated 04

Supply and demand 06

Our ethical framework 08

Recommendations affecting individuals 10

Recommendations for organisations 12

Introduction

The Nuffield Council on Bioethics has published a report, *Human bodies: donation for medicine and research*, which considers the ethical and social issues that arise when people are asked to donate bodily material (such as organs, blood, eggs and sperm) to benefit others.

In this report we try to answer two questions:

- 1 How far should society go in trying to encourage people to donate their bodily material?** For example, is it acceptable to offer people money?
- 2 What is the role of the government and others in responding to the demand for bodily material?** For example, how can barriers to donation be removed, and how can the need for donated bodily material be reduced?

The report was produced by an expert Working Party and focuses mainly on the situation in the UK. In coming to its conclusions, the Working Party consulted a wide range of people, including members of the public, patient and user organisations, faith groups, academics and researchers, people involved in regulating donation and research, and professionals involved in transplantation and fertility services. This guide sets out some of the conclusions and recommendations that are discussed in more detail in the report.



What bodily material can be donated?

Many different forms of human bodily material may be donated for the treatment of others, or for research that aims to improve medical treatment in future. Bodily material may be donated after death, during life, or both depending on the type of donation.

The diagram opposite shows the different types of bodily material that can be donated.

After death, the whole body may be donated for medical education and training. The whole body may also be 'loaned' for medical purposes during life – for example in testing a new medicine as a healthy volunteer.

The recipient of the material may be an individual patient, such as someone in need of a kidney transplant, or a couple who cannot conceive with their own eggs or sperm. Alternatively it may be a researcher or a research organisation, using donated tissue to research new ways of treating diseases such as cancer.

Many different health professionals and a whole range of processes are involved in making donation possible. These include doctors, nurses, technical staff, researchers, and specialist facilities for screening, testing, storing and transporting donated material.

Living donors

Blood

Used for transfusions and to treat diseases such as anaemia and haemophilia. Blood samples may be given for research

Liver lobes

Used for transplantation

Kidneys

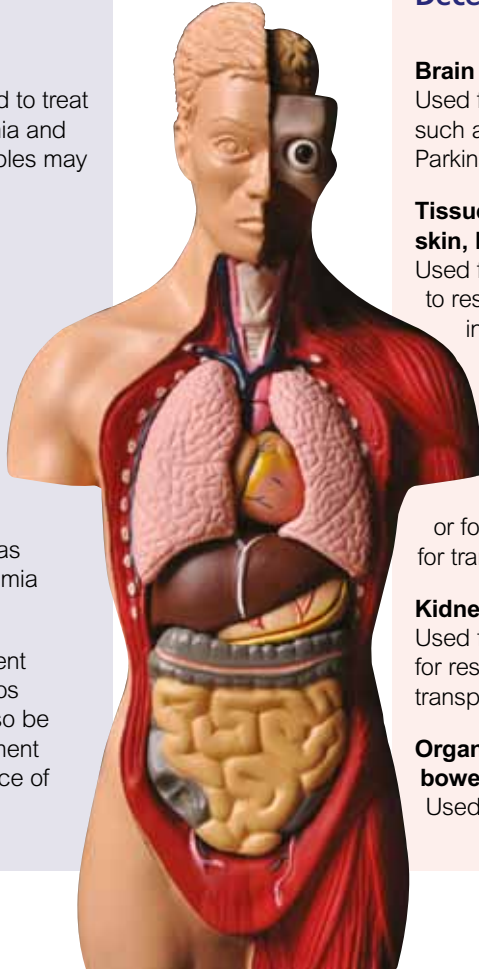
Used for transplantation

Stem cells

from bone marrow or circulating blood (also from cord blood). Used for treatment of blood disorders such as leukaemia and thalassaemia

Eggs and sperm

Used for infertility treatment and for research. Embryos created after IVF may also be donated for fertility treatment or research, or as a source of embryonic stem cells



Deceased donors

Brain

Used for research into diseases such as Alzheimer's and Parkinson's disease

Tissue, including corneas, skin, bone

Used for treatment (for example to restore sight, treat burns and in surgery) and in research

Organs, including heart, lungs, liver, pancreas and small bowel

Used for transplantation, or for research if not suitable for transplantation

Kidneys

Used for transplantation, or for research if not suitable for transplantation

Organs including the large bowel, bladder and prostate

Used only for research

How donation is regulated

The laws governing the donation of bodily material in the UK emphasise the importance of consent from the donor and set limits on commercial dealings in bodily material. However, the details vary significantly, depending on the type of material and the purpose for which it has been donated.

- **Consent** is almost always required before a person may donate material as a living donor, and they must be given information about what the procedure involves. After death, organs or tissue may be taken from the deceased if they had signed the Organ Donor Register or if their family give permission.
- It is against the law to offer or accept **financial reward** to donate blood, tissue or organs for the treatment of others. However, it is not explicitly illegal to offer or accept payment to donate these bodily materials for other purposes, such as research.
- Financial reward for donating eggs or sperm is against the law. However, women who agree to provide some of their eggs for another woman's infertility treatment or for research ('egg-sharers') may receive free or reduced-cost infertility treatment for themselves from private clinics.
- People who donate their bodies after death to medical schools for medical education and training purposes may have their funeral costs paid by the medical school.
- People who volunteer to take part in clinical trials to test new medicines may receive payment to compensate them for their time, and for any discomfort and inconvenience involved.
- People who donate organs or bone marrow as living donors have all their **expenses**, including any lost earnings, reimbursed by the NHS. People who donate eggs and sperm are reimbursed a maximum of £250 for lost earnings.
- Expenses are also incurred by the professionals and organisations involved in donation and transplantation. Payment for the many medical and technical services needed to handle and process bodily material does not count as 'commercial dealings' and is allowed.

International comparisons

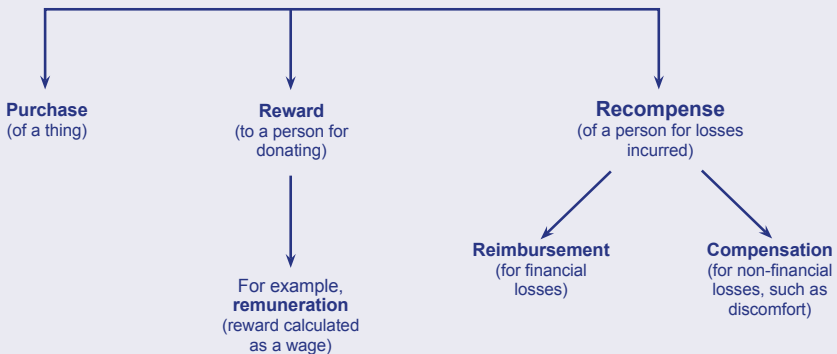
Although this report is mainly concerned with donation in the UK, both people and bodily materials cross national boundaries. People often travel to other countries, with different regulatory systems, for treatment they are unable to access at home. Bodily materials used in the UK may be imported from other countries.

Examples of different regulatory systems in other countries include:

- Spain and Belgium have ‘opt-out’ systems for deceased organ donation, where it is assumed that people consent to donation unless they objected to this before they died, or their family objects.
- Iran permits financial reward for living organ donors through a nationally-organised system. It is the only country in the world to do so, and it does not permit foreigners to participate in the scheme. International bodies such as the World Health Organization, however, oppose any form of monetary reward in return for organs.
- Many states in the USA do not place any restrictions on paying for eggs or sperm for infertility treatment. Different amounts may be paid, depending on factors such as the education, appearance and social status of the person donating.

Forms of payment

We use the following terminology to refer to the various uses of money in the context of donation:



Supply and demand

The increasing possibilities for using bodily material in treatment and research, and the health effects of changing lifestyles, have led to high demand for all kinds of bodily material.

Three people in the UK die every day while waiting for an organ transplant, and many fertility clinics are not able to meet requests for treatment involving donor eggs or sperm. Shortages of supply may affect particular subgroups of the population more than others, because of the need to match material according to immunological criteria or age.

Not everyone who wants to donate can. For example, only a limited number of people die in circumstances where it is possible to donate organs, and blood donation may not be allowed if it could cause harm to either the donor or the recipient.

Reducing demand

High levels of obesity, diabetes and alcohol consumption have all contributed to increased demand for bodily material, particularly organs. Public health initiatives that attempt to improve the health of the population have an important role to play in reducing this demand.

Increasing supply: encouraging individuals to donate

When people think about how to increase the supply of bodily material, they often concentrate on how potential donors may best be encouraged to come forward. Possible ways of encouraging people to donate include:

- providing **information** about the need for bodily material for others' treatment or for research;
- **recognising** altruistic donation (for example letters of thanks and certificates);
- **removing barriers and disincentives** to donation (for example full reimbursement of financial losses incurred in donating);
- offering **token prompts** to donate that may also be understood as a 'thank you' (for example lottery tickets or low-value vouchers);
- providing **benefits in kind** closely associated with the donation (for example free IVF treatment in exchange for egg donation);
- introducing **financial incentives** that leave the donor in a significantly better financial position.

Increasing supply: approaches to consent

It is sometimes suggested that more organs might be available if the UK changed to the opt-out system that has been adopted in Spain and Belgium. Supporters feel that the health needs of people who require organs justify removing the need for explicit consent. Others disagree, and point to a lack of evidence that an opt-out system would increase the number of donors. The opt-out system continues to be a subject of fierce debate in the UK, but may soon be introduced in Wales.

Other approaches to consent include 'prompted choice' and 'mandated choice' schemes, where people are prompted or required to make a choice during their lifetime. Asking whether people want to join the Organ Donor Register on the UK driving licence registration form has led to over six million people making their wishes known.

Increasing supply: the role of organisations

The important part played by organisations, processes and professionals in making donation easier is becoming better understood, as is the importance of trust in these systems.

The UK has introduced a number of organisational changes in an attempt to increase donation rates. For example, a UK-wide network of special organ retrieval teams has been set up, and more nurses who specialise in liaising with families of potential deceased donors have been employed by the NHS.

Blood donation services make it as easy as possible for those inclined to donate to do so, and a central NHS organisation coordinates the donation of tissue after death for treatment purposes.

Egg, sperm and embryo donation in the UK is managed by both private and NHS-funded fertility clinics and there is little coordination between them.



Our ethical framework

A key aim for policy makers in this complex and sensitive area must be to find areas of consensus. This involves identifying values shared by many different people, even if sometimes for different reasons.

We conclude...

- The state should have a ‘stewardship’ role with respect to donation. This means it should work to improve general public health, and so reduce the demand for bodily material. It should help make donation as easy as possible, and take steps to remove inequalities that affect disadvantaged groups or individuals.
- **Altruism** should continue to play a central role in ethical thinking about donation. The idea of altruistic donation - giving bodily material because another person needs it - underpins a communal and collective approach where generosity and compassion are valued.
- However, an altruistic basis for donation does not necessarily exclude other approaches. **Systems based on altruism and systems involving some form of payment are not mutually exclusive.** We distinguish between two different kinds of action to promote donation:
 - **altruist-focused interventions** that remove disincentives from, or provide a spur to, those already inclined to donate; and
 - **non-altruist-focused interventions**, where the reward offered to the potential donor is intended alone to be sufficient to prompt them to donate.Non-altruist-focused interventions are not necessarily unethical but may need to be subject to closer scrutiny because of the threat they may pose to wider communal values (see page 10).
- **Donation for research purposes may differ in important ways from donation for treatment purposes.** In particular, the contribution that any one research donor or healthy volunteer makes to the health of another person is very hard to pin down, whereas material donated for treatment benefits another individual directly. Research donors may wish to contribute to the common good without necessarily seeing this as an ‘altruistic’ act.

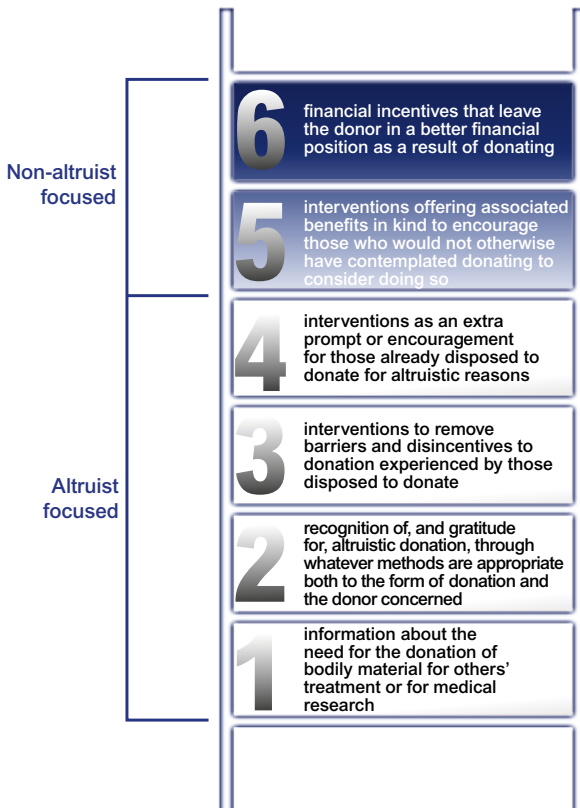
- We take seriously concerns that, in some circumstances, payment for bodily material may lead to people's body parts being seen as 'things' that can simply be bought or sold. We do not take the view that every form of payment for donation implies this. However, we **reject the concept of the sale and purchase of bodily material**, where money exchanges hands in direct return for body parts (rather than to reward or recompense donors for their act of donation).
- **The welfare of the donor, and the potential for harm and exploitation within donation practices**, should be the most important consideration when deciding whether a particular system for encouraging people to donate is ethically acceptable.
- Decisions about deceased donation should be based on the **known wishes of the donor**, so far as these can be discovered. However, instead of using the term 'consent', we suggest using 'authorisation' or 'willingness to donate' to distinguish between the different risks involved in donating during life and after death, and hence the different requirements for information about the procedures involved.
- Values such as **trust and respect** play an essential part in creating systems in which people will be willing to donate. For example, potential donors must be able to trust that professionals will respect their confidentiality, and that their donated materials will be used for the purposes for which they were donated.



Recommendations affecting individuals

We suggest an 'Intervention Ladder' as a useful tool for analysing the ethical acceptability of different forms of encouragement for donating bodily material in various circumstances.

An Intervention Ladder for promoting donation



The first four rungs of the Ladder are all 'altruist-focused interventions', intended to stimulate people's altruistic motivation. The two final rungs on the Ladder are non-altruist-focused interventions. It is an ethically significant step to move on to either of these two rungs and scrutiny will be required to decide whether they may be ethically justified. Factors to consider include:

- the welfare of the donor and other affected individuals;
- the potential threat to the common good;
- the professional responsibilities of the health professionals involved; and
- the strength of the evidence on all these factors.

On organ donation, we conclude...

- Living organ donors should not receive payment other than the direct reimbursement of costs incurred by being a donor.
- We suggest the introduction of a pilot scheme in which the NHS would meet funeral expenses for those who sign the Organ Donor Register and subsequently die in circumstances where they could become organ donors.
- Robust research is needed on the effects of an opt-out system for organ donation if this is introduced in Wales, as currently planned, in order to obtain a clear evidence base for any proposals for change elsewhere in the UK.
- Mandated choice and prompted choice systems (which should include the option of saying 'no') are ethical options for seeking advance authorisation for deceased organ donation.

On egg and sperm donation, we conclude...

- Lost earnings should be fully reimbursed for those donating eggs or sperm for others' treatment, so that they are not left out of pocket.
- Women who donate eggs for research, like healthy volunteers in clinical trials, undergo medical procedures that involve discomfort, inconvenience and potential risks to their health, in order to contribute to the common good of research. We suggest the introduction of a pilot scheme offering payment to those who are prepared to donate eggs for research purposes.

On volunteering for clinical trials, we conclude...

- Payment for participation by healthy volunteers in first-in-human clinical trials within the UK should be retained as ethically justified.

Recommendations for organisations

There are many ways to make donation easier and to reduce the need for donation by action on the part of professionals, organisations and the Government.

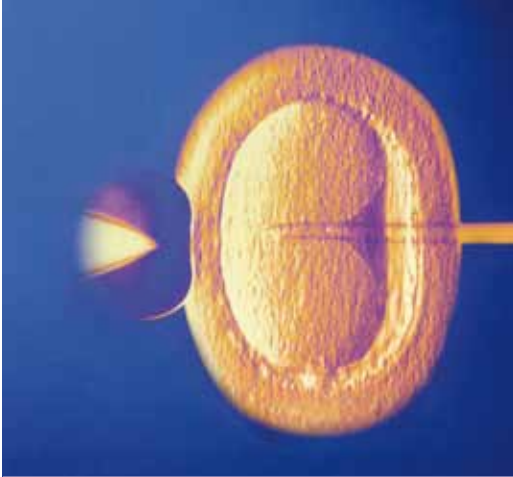
We argue that there is a strong **public interest** in donation, and in the communal provision of donated material in response to health needs. This is true not just of organs and blood, mainly donated and used within the NHS, but also of eggs and sperm, where the majority of treatment takes place in the private sector. There is also a strong public interest in medical research, and the health benefits it aims to achieve, even where research carried out in the commercial sector leads also to private financial gains.

On organ donation, we conclude...

- The role of preventable diseases in the increasing demand for organs should be publicised in order to add weight to public health campaigns.
- The Government should monitor closely how planned changes within the English NHS affect organ donation services, and should protect systems that have been shown to work well.
- The possibility of donating material after death for research purposes, as well as for transplantation, should be made clearer in public information about the Organ Donor Register.
- We endorse the current international consensus that organ trafficking and transplant tourism should be banned.

On tissue for research, we conclude...

- Good governance systems are an essential requirement if potential donors are to have the trust necessary for them to consider donation in the first place.
- People donating material for research purposes should be treated as partners in the research, and their ongoing interest in the progress of the research recognised.
- Once donated for research purposes, bodily material should be regarded as a public good: researchers should make the most efficient use of it possible, and must be willing to share it on the basis of scientific merit.



© Midland Fertility Services

On egg and sperm donation, we conclude...

- A national or regional donor service should be established to provide an infrastructure for egg and sperm donation, along similar lines to the structures currently in place for organ donation.
- Where UK fertility clinics and professionals refer patients to clinics and professionals abroad, they should share responsibility for the general standards prevailing at the receiving centre, including how egg donors are recruited and how the welfare of donors is safeguarded.
- The World Health Organization should develop guiding principles to protect egg donors from abuse or exploitation.

On volunteering for clinical trials, we conclude...

- People volunteering in first-in-human trials should be treated as partners in the research, and their ongoing interest in the progress of the research should be recognised.
- The registration of healthy volunteers in first-in-human trials on a national database should be a compulsory requirement for ethical approval of such trials, in order to limit the harms of over-volunteering.

Summary

The increasing possibilities for using human bodily material (such as organs, blood, eggs, sperm and whole bodies) in treatment and research, and high levels of conditions such as obesity and diabetes, have all contributed to high demand for all kinds of bodily material.

This report tries to answer two questions:

- 1 How far should society go in trying to encourage people to donate their bodily material?
- 2 What is the role of the Government and others in responding to the demand for bodily material?

An ethical framework sets out:

- shared values based around the 'stewardship' role of the state in reducing the demand for bodily material;
- the differences between donating for treatment and donating for research purposes, and;
- the central roles that altruism, the welfare of the donor and trust should play in any donation system.

Specific recommendations for policy makers are made, with the intention of reaching both individuals and organisations involved in donation.

Copies of the report and this guide are available to download from the Council's website:
www.nuffieldbioethics.org

To order a printed copy, please email bioethics@nuffieldbioethics.org

Published by

Nuffield Council on Bioethics
28 Bedford Square
London WC1B 3JS
Telephone: +44 (0)20 7681 9619
Internet: www.nuffieldbioethics.org

© Nuffield Council on Bioethics 2011

Published October 2011

