Chapter 1

Human bodily material in medicine and research: overview
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- A wide range of forms of human bodily material may be provided by one person for the treatment of others, or for medical research that aims to improve medical treatment in future.
- Bodily material can only be derived from the body of a person – hence the ethical challenges with which this report is concerned – and yet what can be done with that material, once separated from the body, appears to be ever-expanding. Such developments bring their own ethical challenges: in particular, they highlight the crucial role played by transactions and intermediaries in the sphere of donation. While many donors may see themselves as donating in a very immediate way to another person in need, in practice many complicated networks are required to connect the sources and recipients of donated bodily material. Diverse intermediaries (specialist nurses, transport services, technical and ancillary staff to name just a few) are involved in processing the material to facilitate its use by the end-recipient. Thus, while we note that potential donors are often encouraged to come forward by agencies focusing on the needs of a single symbolic recipient, any consideration of policy surrounding donation must take into account the complex transactions and multiple intermediaries involved in the process.
- The range of materials described in this report makes explicit the very different circumstances under which people can donate. The person providing the material may be living or deceased; the material may be used almost immediately or stored for long periods of time; the material may be used „raw” or heavily processed; the material may be used in the direct treatment of others or for research purposes; the „recipient” may be an individual patient, or research organisation; the material itself may be healthy or it may be diseased. Different forms of material have very different meanings for different people. Throughout this report, by making comparisons, and by identifying similarities, distinctions, and apparent incompatibilities of approach between these different forms of material and the purposes for which they are donated, we aim to pinpoint what is specific to the ethical issues that arise in particular cases and what may lie in common with others.

1.1 This report looks at the 'donation' of bodily material for medical treatment or medically related research, that is, circumstances where people donate so that in the short term or the long term others may benefit. The original 'source' of the material is colloquially known as the 'donor' of that material, and we shall see throughout this report why this terminology is important. Behind the 'need' for bodily materials are the needs of a population seeking health, or better health than presently enjoyed. It is important not to lose sight of this, which is why in this opening paragraph we have put 'use', 'donor', 'source' and 'need' initially within inverted commas: we do not wish the terms to convey something entirely mechanistic or abstract about the process of donation. On the contrary, it is important to keep in mind the people involved, whether the donors, or the professionals who facilitate the process, or a distant and unspecifiable part of a future population who may benefit from pharmaceutical development.

1.2 The population in the UK, with which this report is primarily concerned, is not alone in seeing a constantly changing profile of diseases and conditions that affect the emphasis of medical attention. Examples include the ageing of the population and hence the increasing number who will suffer from the diseases of old age; factors such as obesity and diabetes, which are, in part, attributable to changing patterns of diet and exercise; new possibilities for therapy afforded for example by genetic screening, and so forth. For as long as bodily health is generally recognised as a marker of personal well-being, there will be a need for society to do what it can to promote the practice of medicine and pursue research into the functioning of the human body. These public health factors are discussed at greater length in Chapter 3 (see paragraphs 3.48 to 3.49).

1.3 The crucial role played by volunteers who donate their blood for life-saving transfusions, or the possibility of a person’s life being transformed by the donation of a kidney after the chance death of a stranger, are both widely understood. Less well known is the broad range of forms of

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24 As we note in the Preface, however, UK policy has to be considered in the context of the international trade in human bodily material, and many other jurisdictions are wrestling with very similar issues.
"bodily material"\textsuperscript{25} that have potential value for other types of medical treatment or research; the many purposes for which these can be used; the complex network of relationships that often exist in between the person providing the material and the end recipient; or the key role of organisations in creating the circumstances in which donation is made possible. This chapter provides an overview of these issues, and suggests that a comparative approach, identifying both similarities and distinctions in the nature and use of these materials, may help to illuminate and explain many of the ethical concerns that arise in connection with these practices.

Scope of human bodily material and its uses

Box 1.1: Forms of bodily material and „loaning” of the body

A wide range of forms of human bodily material may be provided by one person for the treatment of others, or for medical research that aims to improve medical treatment in the future. Any attempt to divide these various forms of bodily material into discrete categories is inevitably imperfect, given the complex and overlapping relationships between them. However, for the sake of clarity in this report, we propose the following very broad categories, following in certain cases divisions created by existing regulatory frameworks:

- Blood and blood products, including 'adult' (multipotent) stem cells derived from cord blood or bone marrow (see paragraphs 1.4 to 1.8);
- Solid organs, including part organs (see paragraph 1.9);
- Tissue, including bone, skin, arteries and corneas (see paragraphs 1.10 to 1.15);\textsuperscript{*}
- Material associated with reproduction, including gametes (egg and sperm), embryos, fetal material and embryonic stem cells (see paragraphs 1.17 to 1.23);
- The 'loan' of the whole living body for medical or quasi-medical purposes, for example through participation in first-in-human 'healthy volunteer' clinical trials, or for surrogacy (see paragraphs 1.24 to 1.25);
- The whole body after death for education, training or research (see paragraph 1.26).

\* We note here that the term 'tissue' is widely used in clinical practice to cover all forms of bodily material, excluding gametes and embryos. However, in this report we follow common non-clinical usage in separating out solid organs and blood from other forms of tissue.

1.4 Blood is essential for transfusion and many other medical purposes such as treatment of anaemia, leukaemia and haemophilia.\textsuperscript{26} Donated blood may be used for research if not needed for treatment, and samples of blood will often be taken during medical investigations, as part of a clinical trial or other research project, or in the context of population or longitudinal studies (see paragraphs 1.12 to 1.16 for more on research uses). A national system for blood donation has been in place in the UK since 1946.\textsuperscript{27} Blood is classified into four main groups, and giving someone blood from the wrong group may be life-threatening.\textsuperscript{28}

1.5 Whole blood is used relatively rarely, for cases of severe blood loss, and hence donated blood is usually separated into its individual components: red cells, white cells, platelets and plasma. For example, red cells may be used to treat anaemia; white cells can boost the immune system of patients suffering from life-threatening infections; platelets can be used to treat leukaemia; and 'fresh-frozen' plasma may be used to replace post-natal blood loss. Plasma may also be processed into a range of medical products, including immunoglobulins (antibodies) to provide protection from disease for patients with low levels of antibodies, coagulation factors (to improve blood clotting) and albumin (used for restoring blood volume). Currently, because of concerns about the possibility of vCJD infection, plasma derived from UK-donated blood is only used in the form of fresh-frozen plasma for patients over 16 years. Fresh-frozen plasma for under-16s is obtained from Austria,\textsuperscript{29} and plasma for processing into plasma proteins is currently sourced

\textsuperscript{25} The term "bodily material" is used throughout this report to mean all forms of human biological material that are donated for use in medical treatment and medical research, from individual cells to solid organs. While such material can be deployed in many ways, and may undergo modification, it can only be obtained from a person.

\textsuperscript{26} See: National Blood Service (2010) How blood is used, available at: http://www.blood.co.uk/about-blood/how-blood-is-used/ for the "top 10 users of blood".


\textsuperscript{28} The four groups are O, A, B and AB; blood in each of these groups will also be 'rhesus positive' or 'rhesus negative', depending on the presence or absence of the D antigen.

\textsuperscript{29} NHSBT, personal communication, 7 February 2011.
from the US, primarily from a plasma supplier wholly owned by the English Department of Health.\textsuperscript{30}

1.6 Stem cells are used primarily in research, but increasingly also in treatment, to renew or repair damaged cells. Embryonic stem cells derived from an early embryo are unspecialised or uncommitted: that is, they can become any type of cell, which is why they are called 'totipotent' or 'pluripotent' (see paragraph 1.21 for further discussion of embryonic stem cells and stem cell lines). 'Adult' stem cells, most commonly derived from bone marrow and cord blood, on the other hand, are 'multipotent': that is, they are committed precursors of one of the cells that constitute the various bodily tissue and fluids. Small quantities of adult stem cells are found in organs, tissues and fluids such as heart, brain and fat, as well as in cord blood.

1.7 At present, the only routine use of adult stem cells in clinical practice is the transplantation of blood stem cells (the precursors of blood cells: 'haematopoietic stem cells' or 'HSCs') to treat blood disorders such as leukaemia and thalassaemia, and failures in the immune system. Healthy HSCs may be isolated either in cord blood or in bone marrow, and then transplanted into another person ('allogeneic' transplantation). In allogeneic transplants, the source and the recipient of the HSCs must be sufficiently immunologically compatible. Adult cells of various kinds, for example skin cells, can also be transformed into pluripotent stem cells by the introduction of the factors found to be active in embryonic stem cells (see paragraph 1.21). These 'induced pluripotent cells' (iPSCs) can then become any cell type in the body, having some similar properties to embryonic stem cells (ESCs).\textsuperscript{31}

1.8 In England, cord blood is collected from a small number of NHS maternity units (currently only in London, Luton, and Leicester) and stored in a 'public' cord blood bank to be allocated for treatment on the basis of need.\textsuperscript{32} It is also possible in some circumstances for families to arrange for cord blood to be taken and stored in a 'private' cord blood bank, to be allocated for possible later personal use.\textsuperscript{33} Such private banking is, however, controversial, both because of the potential for the collection to interfere with the birth process if not appropriately managed, and because of the low likelihood of the banked blood being medically useful for the individual concerned in the future.\textsuperscript{34} The NHS, however, will facilitate the collection of cord blood from a newborn child for the 'private' use of the child's sibling, where that sibling suffers from a condition such as leukaemia. Adults who volunteer to donate stem cells through the bone marrow registries may either donate stem cells from circulating blood (which involves being injected with a drug to increase significantly the number of stem cells in the circulating blood), or bone marrow itself, which involves the removal of stem cells from hip bones under general anaesthesia.\textsuperscript{35}

1.9 Whole organs, such as the kidneys, heart, liver, lungs, pancreas and the small bowel may be donated after death either for transplantation or for research. Other organs, such as the brain, large bowel, bladder and prostate, are not currently transplanted but may still be donated for research purposes. Organs donated after death for transplantation are allocated on the basis of patient need and immunological compatibility, although in exceptional cases priority may be

\textsuperscript{30} DCI Biologicals Inc.
\textsuperscript{33} See, for example, Cells Ltd. (2010) \textit{Why choose cells}?, available at: \url{http://www.cells4life.co.uk}.
Human bodies: donation for medicine and research

given to a family member or close friend of the deceased person (see paragraph 2.29). It is also possible to donate some organs during life: at present the organs provided by living donors are primarily kidneys, but liver lobes may also be donated, and partial donations of the lung have taken place in the past. Living kidney donation involves a major surgical operation: the risk of death is cited as one in 3,000, and the risk of significant post-operative morbidity (involving, for example, a longer hospital stay than planned) is two to four per cent.36 Such ‘living donations’ will usually be ‘directed’: that is, for the benefit of a named individual, such as a child or sibling, although ‘stranger donations’ are now permitted and facilitated under the Human Tissue Act 2004.

1.10 A very wide range of tissue37 such as corneas, skin, bone, heart valves, tendons and cartilage, may be donated for transplantation or research. While many of these forms of tissue may only be donated after death, some such as bone may be provided by living donors: for example heads of femur removed during an operation to replace a hip joint are sometimes processed and ‘recycled’38 (see also paragraph 1.12 for research uses of tissue donated during life). Tissue donated for transplantation after death is governed by the same rules as organs: it enters a common pool to be used according to need and its use cannot be directed to a particular individual. Tissue donated by a living person may theoretically be donated to benefit another specific person but in practice this will not generally be necessary, and hence the donated tissue will be for general use.39

1.11 Tissue from one deceased donor may be transplanted into as many as 100 people,40 and in 2009/2010 8,500 tissue products were supplied by NHSBT Tissue Services for surgery.41 Tissue transplants range from life-saving treatment (for example in the treatment of catastrophic burns) to cosmetic enhancement (for example penis or breast enlargement).42 Some tissue is used ‘neat’: that is, it is used more or less unaltered from the condition in which it is found. Cadaver corneas, for example, are used to restore sight, cadaver heart valves replace damaged ones and extend life, and cadaver tendons and ligaments may be used in repairing sporting injuries. Other tissue, however, is processed into products that are almost unrecognisable as bodily material, and that are handled as consumables, like bandages and creams. Skin, for example, may be cut into conveniently sized dressings, incorporated into gels, or fashioned into slings for use in surgery. Bone is incorporated into hundreds of different products and sold in a global medical market: as dust which forms a firm foundation for dental implants, putty used in spinal fusion, and pellets which are implanted as replacements of excised diseased bone. If a deceased individual (or their relatives after their death) has consented to the use of any part of their body for the treatment of others, much can be put to use: ligaments, cartilage, connective and adipose tissue, glands and nerves can all be used for therapeutic purposes. ‘Composite’ tissue transplants, such as face and hand transplants have also received much publicity, although these remain very rare and are still essentially experimental.

37 In the Human Tissue Act 2004 the term ‘tissue’ is used to refer to any, and all, constituent part(s) of the human body formed by cells. In this report, we use ‘tissue’ in its more common usage, to refer to bodily material (consisting of cells) other than solid organs, blood and gametes.
39 An exception where directed tissue donation from a living person might arise is the donation of ovarian tissue, for example where the recipient has had chemotherapy.
42 We note here for completeness the range of potential uses of tissue: we emphasise, however, that the scope of our report is limited to health-related uses and hence our conclusions and recommendations do not necessarily apply to tissues used for these cosmetic and enhancement purposes.
1.12 Both human tissue and blood also have a key role to play in medical research. In clinical trials of new medicines, for example, vital information about the effects of the medicine on an individual is obtained from samples of blood and other materials provided by research participants. However, blood and tissue are also used much more widely in medical research, from early drug ‘discovery’ – such as using human tumour samples to discover possible targets for treatment – to later clinical development where samples may be used to identify which subgroups of the patient populations respond best to the new medicine. Tissue may be used very directly for testing new agents, as in, for example, the use of tumour samples to test new anti-cancer drugs. Frequently, diseased tissue is compared with healthy tissue (which can be harder to obtain), in order to understand mechanisms underlying disease development. Sometimes the tissue is used to understand basic biological processes, such as how oocytes (immature eggs) mature, or the nature of intrinsic organ repair. These forms of ‘basic’ research using human tissue still have an ultimate therapeutic goal in mind, although that goal may be more remote than in the case of research directed to drug discovery.

1.13 The source of tissue used in research may be material 'left over' after a diagnostic procedure or operation; material donated as part of a research project accompanying medical treatment; or material provided specifically for a research project quite unconnected with medical treatment. Tissue provided by a living donor is usually preferable for research purposes, compared with tissue from a deceased donor; however, some forms of tissue, such as brain tissue, may be very hard or impossible to obtain during life. Where tissue is donated for research purposes after death, ideally it should be obtained within six hours of death, and this may create serious logistical challenges for researchers.

1.14 Medical information associated with donated tissue adds significantly to the value of the tissue as a research resource: such information may be obtained either by maintaining a link with the donor’s full health record, or by retaining a particular dataset of information about the person’s medical history. In both cases, in the research setting, the information available will normally be linked with the sample through a code so that the researcher does not directly access identifying information such as names and addresses. Sometimes samples can be collected with some basic non-identifying data, which is then completely separated from the source data and straightforward linkage completely broken (although, in fact, with modern technology it may now be possible to match fragmented DNA in a sample to a specific donor). While we are not concerned in this report with the precise boundaries between bodily material and the associated information, we note the importance of clarity as to the possible use of associated personal information when we discuss issues of consent (see paragraph 2.11).

1.15 Bodily material collected in the course of health care interventions – from whole organs to blood and urine – is stored at least until the results of any required tests are available. Some samples of tissues and fluids are ‘used up’ in the analysis but in the majority of cases, some tissue remains. Other samples taken during medical care may not in fact require analysis. Such ‘leftover’ or ‘unneeded’ material tends to be discarded, for example through incineration. Depending on its nature, however, such tissue may be suitable for research purposes and, usually with the consent of the patient concerned, may be used in specific research projects or stored in research tissue banks (see paragraph 1.29). As a consequence of this diagnostic

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44 This is known as ‘pseudonymisation’: the link with the identity of the donor is retained, but no personal details are available to the researchers using the material.
45 For example, where a kidney is removed because of cancer, or a normal spleen removed as part of major surgery for pancreatic cancer, blood, urine and fluid produced in body cavities in disease may also be removed at the same time.
46 An example of some of the changes referred to in the Introduction, and throughout this report. In the past, surgeons and the general public alike would not have had any compunction about referring to such tissue as ‘waste’ (the 1995 Report, for example, referred to ‘body wastes’ or ‘clinical waste’ in paragraphs 3.7 and 3.8). These days almost anything might be regarded as having a potential use, and almost nothing should be treated without respect for the source from which it was derived – though most people would still follow the 1995 Report in regarding urine and faeces as ordinarily abandoned by the person who takes no further interest in it.
47 There are limited exceptions to the requirement for consent: see paragraph 2.19.
activity, hospital pathology laboratories invariably store many thousands of tissue samples in a format (usually paraffin blocks) that keeps them usable for decades but the majority of these samples are unlikely to be accessed again. The potential research value of these tissue collections will depend on how the samples have been collected and stored and also, as noted above, on the associated information derived from the sample and the donor. Access to this category of samples in pathology archives is also very valuable for education, training, laboratory quality control and development of new tests.

1.16 Samples (both tissue and blood) may be collected during a health care intervention, specifically for research purposes: that is, in addition to the samples required for diagnostic or therapeutic purposes. In these circumstances, the collection of the additional material will be classified within the NHS as 'research', and in addition to seeking the consent of the patient for their involvement in the particular research study, ethical approval by a Research Ethics Committee will be required. Research samples may also be taken outside the context of treatment, from large numbers of patients with a particular condition, or from members of the general public ('patient' or 'population' cohorts), and stored in population biobanks.\(^4\) Samples stored in such population biobanks typically comprise blood and/or material extracted from blood such as DNA, and those contributing samples may also be asked for permission for their samples to be linked back to their health records, or be asked to fill in health and lifestyle questionnaires to provide a specified dataset of information to be linked to the sample. UK Biobank, for example, aims to use its holdings of samples from 500,000 UK residents aged 40-69 years, together with links back to participants' health records, to shed light on many common life-threatening or debilitating conditions such as cancer, heart disease, diabetes and Alzheimer's disease.\(^4\)

1.17 Gametes (eggs and sperm), and also embryos, may be donated for use in fertility treatment or research.\(^5\) Eggs may be donated by women already undergoing in-vitro fertilisation (IVF) procedures as part of an 'egg-sharing' arrangement whereby fees are reduced on the basis that some of the eggs retrieved during the procedure will be made available either for another woman's treatment, or for research. 'Volunteer egg donors', on the other hand, are not themselves trying to conceive, but undergo the procedures involved in egg stimulation and retrieval solely in order to donate these eggs to others. Egg donation involves hormonal medication, first to suppress the normal menstrual cycle and then to stimulate the growth and maturation of multiple eggs; ultrasound scanning to monitor the process; and a surgical procedure to collect the eggs. The principal risk involved in this process is ovarian hyperstimulation syndrome (OHSS): while most women undergoing superovulation are affected by the mild form, the severe form may be life-threatening.\(^5\) Sperm donation is less invasive, but involves a series of appointments for health screening and blood and semen tests before the potential donor is accepted.\(^5\) Embryos may be donated where a woman or couple undergoing IVF have completed their family and have 'spare' frozen embryos that would otherwise perish. Those undergoing IVF may also be invited to consider donating 'spare' embryos during their treatment if they choose not to freeze the embryos, or if freezing them for possible future use.

\(^{4}\) See, for example, the Avon Longitudinal Study of Parents and Children (ALSPAC) study, a longitudinal study of children's health, available at: http://www.bristol.ac.uk/alspac.


\(^{50}\) An embryo is defined in the Human Fertilisation and Embryology Act 1990 (as amended) as including "an egg that is in the process of fertilisation or undergoing any other process capable of resulting in an embryo": section 1(1)(b). An embryo cannot be kept or used for more than 14 days after its creation (excluding any time during which it is frozen): sections 3(3)(a) and 3(4).

\(^{51}\) A 2007 study aiming to provide an estimate of women's risk in developing OHSS when donating eggs for research found that 14.5 per cent of women needed hospital treatment for OHSS if more than 20 follicles developed as a result of hormonal stimulation, but less than 0.1 per cent developed OHSS if fewer than 20 follicles developed. Seventeen per cent of women in the study had over 20 follicles: Jayaprakasan K, Herbert M, Moody E, Stewart JA, and Murdoch AP (2007) Estimating the risks of ovarian hyperstimulation syndrome (OHSS): implications for egg donation for research Human Fertility 10: 183-7.

\(^{52}\) For further information, see the National Gamete Donation Trust website, available at: http://www.ngdt.co.uk/.
treatment is not considered a viable option by the clinic, or where the embryos are not suitable for implantation but still have value in research.

1.18 Eggs, sperm and embryos donated for treatment may be donated specifically for the benefit of an individual (‘directed donation’), or allocated to an unknown recipient. It is also currently possible for those donating eggs, sperm or embryos to stipulate the category of recipient: for example by specifying that they only wish to donate to a married couple, or to a woman under the age of 40 years, although this practice is under review. Children who are conceived in the UK since 1 April 2005 as a result of an ‘anonymous’ gamete donation are entitled to find out the identity of their donor once they reach the age of 18 years, if they wish to do so.

1.19 Eggs, sperm and embryos are also very important for research, including research into the treatment of infertility, the causes of genetic and congenital disease, miscarriage, and, more generally, for increasing knowledge about the treatment of serious disease. Reproductive cells may also represent an invaluable training resource for scientists and technicians working in the field of assisted reproduction. Fertility centres routinely ask for permission to use non-viable or unused gametes and embryos for training and research purposes.

1.20 Eggs and sperm may usually only be provided by live donors: although it is technically possible to retrieve eggs after death or from aborted fetuses, the use of such is currently banned in the UK for treatment purposes. Sperm may exceptionally be retrieved after death for use by the man’s partner, where there is clear evidence that the man consented to this beforehand.

1.21 Products of conception and birth such as fetal material, amniotic membrane (used in ophthalmic surgery) and stem cells derived from embryos (embryonic stem cells or ESCs) may be used in treatment and research (see also paragraph 1.8 regarding adult stem cells present in cord blood). ESCs are isolated from embryos after the fertilised egg has started to divide, usually after about five days but never more than 14 days. They are isolated from the inner cell mass of the embryo that consists of cells not yet committed to developing into any specific cell type. ESCs may be obtained from supernumerary embryos created through IVF treatment, or from embryos specifically created for research purposes: from donated eggs and donated sperm; by somatic cell nuclear transfer, sometimes called cloning, where the nucleus of an adult cell is inserted into an egg from which the original nucleus has been removed; or by parthenogenesis, where an unfertilised egg is stimulated to develop into an embryo. They are often obtained from couples who have completed their families after IVF and are asked to consider offering any remaining frozen embryos for research, instead of destroying them.

1.22 ESCs can be grown in a liquid culture medium and continue to expand indefinitely. They are then called ESC ‘lines’ and in the UK they must be deposited in the UK Stem Cell Bank (UKSCB) where they are frozen and stored. When stimulated with specific growth factors, they can become cells of any body part. Researchers may request ESC lines from the UKSCB, but

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53 A recent study, Ethical frameworks for embryo donation, funded by the Wellcome Trust, noted that the classification of embryos as ‘spare’ or ‘surplus to treatment requirements’ is not straightforward, as clinics have different policies and philosophies influencing their treatment decisions: Centre for Biomedicine and Society (2010) Ethical frameworks for embryo donation: views, values and practices of IVF/PGD staff, available at: http://www.kcl.ac.uk/content/1/c6/02/53/02/Shortreportforcircpdf.pdf.

54 The Human Fertilisation and Embryology Authority (HFEA) has recently decided to provide more detailed guidance to clinics on conditional donation, whilst continuing to permit conditional donation if it does not relate to characteristics protected by the Equality Act. See: Human Fertilisation and Embryology Authority (2011) Minutes of the Ethics and Law Advisory Committee meeting, 8 June 2011, available at: http://www.hfea.gov.uk/docs/2011-06-08_-_ELAC_minutes.pdf.

55 Human Fertilisation and Embryology Act 1990, section 3A.

56 L v HFEA & Another [2008] EWHC 2149 (Fam).


have to specify the project in which the cells will be used and demonstrate that this use of the cells is not trivial and is directed towards improving human health.60

1.23 Breast milk is donated for premature and sick babies whose mothers are unable to provide sufficient milk. While such babies could be fed with formula milk, breast milk is recommended as the best nourishment for babies, with both short and long-term health benefits.61 Donors, who by definition are mothers of young babies, are asked to express their milk, usually on a regular basis, although some milk banks will accept one-off donations. The donated milk is then screened for potential infection or contamination. Milk donors will not usually meet the babies they have helped feed, but milk banks try to provide more general information to donors about how their milk is used.62

1.24 Surrogacy could be characterised as the temporary donation of one woman’s womb, in order to carry a child (which may or may not be genetically related to her, depending on whether her own eggs or donor eggs were used), for another woman or couple. In other words, it is donated ‘on loan’. A woman may offer to be a surrogate mother to help someone well known to her, such as a sister, or may act as a surrogate to a complete stranger. In UK law, the surrogate mother is the legal mother of the resulting child, and hence cannot be required to give up the child if she does not wish to do so. However, parental rights may pass to the commissioning parties with the consent of the surrogate, through a parental order made by a court.63 Once such an order is made, the surrogate mother will no longer be the legal mother of the child she has borne, although the now-legal parents may choose to retain some form of contact with her.

1.25 The whole body during life may also be donated on 'loan' by healthy volunteers taking part in 'first-in-human' (Phase 1) clinical trials. These trials are defined by regulation as “a clinical trial to study the pharmacology of an investigational medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial”.64 They are used to test the safety of new medicines in humans, after laboratory and animal testing and before testing the efficacy of the medicine in patients.65 Volunteers do not expect to receive any medical benefit from the medicine being tested. In a sense, the volunteer ‘provides' their body for a short period so that researchers can find out how a new medicine acts on the human body. Participants in such trials are usually healthy volunteers; however, for safety reasons (for example where the medicine may be too toxic to be used on a person not suffering from the particular disease), it may sometimes only be appropriate to test the new medicine on a patient with the particular condition being targeted. Where we refer to ‘first-in-human’ or ‘healthy volunteer’ trials in this report, we are concerned only with the circumstances where healthy individuals participate in the phase 1 trial of a new medicine with no expectation of personal medical benefit. It should be emphasised that these trials form a very small percentage of all clinical trials, and that the volunteers concerned constitute an even smaller percentage of those contributing to all forms of research on a voluntary basis (see paragraph 1.16).

1.26 The whole body after death may be donated to medical schools, for the purposes of education, training or research. Detailed dissection and examination of bodies of the deceased

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63 Human Fertilisation and Embryology Act 2008, section 54.

64 The Medicines for Human Use (Clinical Trials) Regulations 2004, regulation 2.

has, for centuries, been an integral part of the expansion of anatomical and medical knowledge and the origin of some of the most important discoveries. Now covered by the Human Tissue Act 2004 and regulated by the Human Tissue Authority (HTA), donated bodies are still used for teaching purposes in medical schools, principally for anatomical and surgical training. The role of the autopsy as a teaching opportunity, previously an integral part of the training of doctors, and to a lesser extent other professional groups, has, however, diminished considerably, especially over the last decade. Sometimes the (deceased) bodies that individuals have donated to medical schools for education or training may be found to be unsuitable, and hence they may occasionally be referred on for research if this is authorised by the terms of the original consent.

Transactions involving human bodily material

1.27 Bodily material may only be derived from the body of a person – hence the ethical challenges with which this report is concerned – and yet what can be done with that material, once separated from the body, appears to be ever-expanding. The past century has seen a considerable increase in the scope of bodily material donated and used in others’ treatment and in research (see Box 1.2 opposite). Such an increase reflects the developments in medical science that have led first to experimentation in areas such as transplantation and embryology, and then to the refinement of techniques and processes that result in innovative and experimental methods becoming routine medical practice. As we go on to discuss in Chapter 3 (see in particular paragraphs 3.29 to 3.44), this area of science continues to be a fast-moving field and such developments bring their own ethical challenges. In particular, they highlight the crucial role played by transactions in the sphere of donation.

1.28 The word ‘transaction’ is often taken in the narrow sense of conducting an exchange involving money or property. Throughout this report, however, the notion of transactions involving human bodily material is used more widely:

- First, transactions may involve things other than money: for example the technical activities and services (removal, transportation, processing, preservation, quality control, and storage) that enable bodily material to be removed from one body and transferred to another body, or to another context of use such as research.
- Second, although the law limits the circumstances in which the human body and its parts may be the subject of trade, some transactions do nevertheless involve an exchange of money, for example through reimbursement of expenses and service charges.
- Third, some transactions involve an exchange in kind, most notably where human eggs are donated in exchange for a reduction in the cost of IVF treatment.
- Fourth, transactions create relationships and changes of status: for example, someone becoming an ‘esteemed donor’ or a ‘grateful recipient’.
- Fifth, transactions may serve to create safeguards from exploitation or misuse: for example through the formal requirements for consent from the potential donor before material may be taken.
- Sixth, transactions are rarely direct and immediate between the source and recipient of the material but rather involve a complex chain of intermediaries: in terms of both people and institutions, as highlighted in Figure 1.

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The Working Party has found the notion of 'transaction' in these wider senses helpful in analysing and understanding the complex sets of exchanges that underlie the many different ways in which human bodily material may be provided by one person for the benefit of others.

Figure 1

1.29 The histories of the many different forms of tissue banking (see Box 1.2) highlight the increasingly complicated and 'transactional' way in which one person's bodily material may be used to help others. The central role played by tissue banks in modern medicine, in providing material for treatment and for research, highlights the complicated networks that may now connect the sources and recipients of donated bodily material, and the many intermediaries involved in processing the material to facilitate its use by the end-recipient. The person providing the material may be living or deceased; the material may be used almost immediately or stored for long periods of time; the material may be used 'raw' or heavily processed; the material may be used in the direct treatment of others (such as the use of skin grafts for serious burns) or for research purposes; the 'recipient' may thus be an individual patient, or a researcher; the material itself may be healthy or it may be diseased (as in tumour banks which store tumours removed during surgery for research purposes).

Box 1.2: Histories of tissue donation and banking

Tissue banks (also known as biobanks, tissue repositories and biorepositories) now play an important role in both treatment and research. For treatment purposes, the very early examples of the donation of human bodily material in the late 19th and early 20th Centuries were direct: skin from mother to child; blood from a donor connected arm-to-arm with the recipient to avoid clotting; a cornea from one patient whose eye had had to be removed to another patient of the same

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68 Figure 1 is adapted from an original diagram provided by NHSBT Tissue Services, August 2011.
The transactions involved in the donation of whole organs, whether after death or during life, are of course rather different from those required for tissue banking: in particular in terms of both the immediacy of use and the potential for a direct link between the donor (or donor’s family) and recipient. Yet it is still appropriate to conceptualise the process in terms of ‘transactions’: organ transplants can only take place if there are specialist nurses to talk with the family of the potential donor and surgeons to carry out the operations; if (in cases of deceased donation) the hospital where the person has died has the necessary infrastructure in place to remove the organs in the required time-frame; if specialist transport services exist in order to move organs about the country; and so forth. The whole field of transplantation also relies on there being an infrastructure of research activity aiming to improve the transplantation process and to minimise rejection of the transplanted organ. Similarly, gamete donors may see themselves as donating directly to a woman or couple in order to facilitate their desire to have a family; but such an outcome is only possible with the involvement of fertility clinics, their staff (medical, nursing, scientific and ancillary) and their facilities. Professional knowledge and expertise is required for the treatment involved in egg donation, for the health screening and testing required in sperm donation, for the embryology involved in creating the embryo in vitro, and for the subsequent transfer of the embryo into the recipient. Specialist facilities are required for treatment, embryology, storage and transport. We have similarly already noted (see paragraphs 1.4 to 1.5).

70 Meeting with Dr Ruth Warwick, NHSBT, March 2010.
72 The commercial organisation Trans-Hit Biomarkers, for example, states that it can access material for clients from almost 1,000 biobanks worldwide: Trans-Hit Biomarkers (2011) Access to human biospecimen collections, available at: http://www.trans-hit.com/index.php/services/translational-research/access-to-human-collections.
how blood, too, is subject to elaborate processing: separated into components, stored, tested, and used in a wide variety of forms and products.

1.31 Thus, while potential donors are often encouraged to come forward by focusing on the needs of a single symbolic recipient (see also Box 3.3), we emphasise here how any consideration of policy surrounding donation must increasingly take into account the complex transactions and multiple intermediaries involved in the process. Such an awareness highlights the central role inevitably played in the donation and subsequent use of bodily material by organisations and organisational structures: for example in the creation of professional roles such as donation and consent 'coordinators' and the extent to which they are expected to maximise opportunities for donation; in how these professionals approach potential donors and form relationships with them; in how well one part of the system links with another and where responsibility is seen to rest; and in the way professionals in different fields interact and cooperate with one another. It also points to the added complexities in the form of legal agreements, liabilities and obligations that may arise where donated material is transformed, banked or otherwise handled as a commodity by successive intermediaries.

1.32 Finally, we note here the role of commerce. We discuss in more detail in the next chapter the legal restrictions within the UK on 'commercial dealings' in bodily material (see paragraph 2.34), but we highlight here how the transactions involved in the processing of bodily material inevitably incur costs, and hence how organisations (the National Blood Service for example) may legitimately levy charges to their users to cover those costs without being considered to be participating in commercial activities. Such dealings are different in kind from the activities of explicitly commercial organisations, such as pharmaceutical and biotechnology companies or private fertility clinics, where the use of bodily material (whether in research or as part of medical treatment) is an intrinsic part of a profit-making endeavour.

1.33 Commercial use of bodily material is often the subject of ethical scrutiny or concern; but it should not be forgotten that those working in the non-commercial sector (public and charitable alike) may also draw personal benefit, albeit in other ways, from access to freely-donated bodily material: for example through publications, academic prestige and the resulting 'social capital' and career enhancement. Moreover, their employing organisations may also benefit financially from such research. In terms of organisational structure and operating procedures, the distinction between public, charitable and private sector organisations is becoming increasingly blurred: the Bio Products Laboratory (BPL), for example, which supplies a significant share of the UK’s needs for plasma proteins, was part of NHSBT until 2011, but had the strategic objective of “provid[ing] a secure and financially viable source of high quality plasma proteins to NHS patients” and generating its own investment income through international sales. It has now been reconstituted as a limited company also wholly owned by the Department of Health.

A comparative approach

1.34 The range of materials described in the first part of this chapter makes explicit the very different circumstances under which people may donate. It goes without saying that there is a wide spectrum of attachment to, or sense of personal identification with, different parts of the body. In undertaking this enquiry, the Council has quite deliberately considered a wide range of forms of

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bodily material, and a wide range of circumstances, including diverse purposes, surrounding donation. By making comparisons, and by identifying similarities, distinctions, and apparent incompatibilities of approach between these different forms and purposes, we aim to pinpoint what is specific to the ethical issues that arise in particular cases and what may lie in common with others.

1.35 Boxes 1.3 to 1.6 set out some of the multiple tiers of differentiation that may be identified in terms of the nature of the material being donated or ‘loaned’, the purpose for which it will be used, the context in which the decision to donate or loan is made, and the regulatory framework governing both donation and use. Each box gives certain indicative examples, set out in many cases as a series of contrasts (a versus b). The range of regulatory approaches to the donation and use of bodily material will be discussed in greater depth in Chapter 2 but is alluded to in this discussion of comparisons for the sake of completeness.

**Box 1.3: Areas of differentiation: nature of bodily material**
- Material donated on a permanent basis, such as blood samples donated for research, versus material that is ‘loaned’ for a short period, such as the use of the whole body to test new pharmaceuticals or the use of a woman’s womb for a surrogate pregnancy
- Material donated during life versus material that is donated after death
- Material that naturally renews itself, such as blood and sperm, versus non-regenerative or non-replenishable material, such as whole organs
- Reproductive material that has the potential to result in the birth of a child genetically related to the person providing the material versus non-reproductive material
- Healthy material versus diseased material

**Box 1.4: Areas of differentiation: purposes for which material is donated**
- Material donated:
  - for the purposes of treatment versus for the purposes of research
  - for the purposes of treating someone close versus into a common pool to be used on the basis of clinical need
  - for treatment or research that has the capacity to be (a) life-saving or (b) life-prolonging or (c) life-enhancing or (d) life-creating
  - for a specific, known, research project versus for a broad class of research, or indeed any medical research
  - solely for use within the public health system versus for possible use by commercial companies or for private health care

**Box 1.5: Areas of differentiation: the context in which material is donated**
- Where material is already being removed from the body in the course of another procedure (for example excised cancerous material) versus donation of material outside the context of treatment
- Where the action of donating or volunteering could be thought of as ‘work’ (as may be the case in volunteering for first-in-human clinical trials) versus where it is clearly within the context of health care
- Circumstances where the point at which donation is possible is freely chosen (for example when donating blood) versus where it is the result of external (often tragic) events, for example when questions of organ donation arise after a road accident
In addition there are differences in:
- The socioeconomic circumstances of the donor or volunteer, and the question of their vulnerability
- The ability of the donor or volunteer to access health services, or enjoy a healthy lifestyle, or become a recipient themselves, should the need arise
- The age, gender, ethnicity, and nationality of the donor or volunteer

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76 References to ‘purposes’ relate to the immediate destiny of the donation, for example for transplantation into another person’s body, for the creation of an embryo to be implanted into a woman, or for research. Within this report we are able to allude only briefly to the subsequent ‘life’ of bodily materials, whether in terms of family-like relationships sometimes arising from organ transplantation or gamete donation; in terms of the marketing of body products and the arrangements that underpin the flow of materials; or in terms of the prolongation of potential through the creation of new cell lines.
Box 1.6: Areas of differentiation: regulation

- Permissibility of financial reward in the UK: for example clinical trials (reward permitted) versus organs (reward forbidden).
- Extent to which the expenses incurred in donating/volunteering are fully reimbursed in the UK: for example egg donors (capped expenses only) versus living organ donors (all expenses covered).
- Degree of information required for consent in the UK: for example detailed information required for research protocols versus optional information for donation after death.
- Degree of control over future use of material in the UK: for example organs donated after death (no control permitted) versus gametes donated in life (donor may specify either named recipient or a category of recipients).

1.36 It should be noted that while some of the distinctions highlighted in the boxes above contrast two opposing positions, others are more subtle: the context in which material is donated or decisions made to volunteer one’s body for a first-in-human trial may vary in many ways, and the extent to which the material has emotional significance for an individual will lie anywhere along a wide spectrum, and will differ fundamentally between individuals. Moreover, scientific developments may lead to additional layers of complexity in what currently appear to be simple distinctions: material that is currently non-reproductive for example may, in the future, have reproductive capacities as cloning techniques involving induced pluripotent stem-cells develop.

1.37 The following two sets of comparisons (see Boxes 1.7 and 1.8) explore areas of similarity and contrast between existing categories of material and forms of research participation: firstly between blood and sperm; and second between participation as a healthy volunteer in a first-in-human trial and the donation of eggs for research. These comparisons tend not to arise naturally, but may help illuminate the extent to which apparently distinctive characteristics should be taken as inherent to the nature of the material or activity in question, and the extent to which they may in fact rest on other (sometimes widely varying) beliefs and attitudes. Box 1.7 comes from a range of sources, while Box 1.8 is based largely on a set of comparisons worked through by one of our consultation respondents. Box 1.9, by contrast, is derived from multiple responses to our consultation question as to whether any form of bodily material should be seen as “special”, and illustrates the way in which comparisons are intuitively used to draw distinctions between forms of material, in particular with respect to reproductive material.

**Blood and sperm**

1.38 People would not ordinarily think to make an explicit comparison between blood and sperm: such comparisons were not made spontaneously by our consultation respondents, for example. However, the process of doing so highlights a number of issues significant for policy in the areas of donation, including: the issue of how the donation process is managed; how it is presented to the public (potential donors); the images that come to people’s minds; and the extent to which it is seen as a public or private activity. Not only can body parts have very different meanings for different people, such meanings can change over time according to individual circumstances and medical histories.

Box 1.7: Blood and sperm

**Similarities**

- Both are relatively easily donated and donation does not cause significant discomfort – the threshold for potential donors to overcome appears relatively low, and both might be thought of as easily susceptible to promotional material encouraging donors to come forward.
- Both are easily replenished and involve little physiological consequence for the donor.
- Both can be stored.
- Both need to be carefully screened.

77 Sarah Devaney, responding to the Working Party’s consultation.
In blood collection, medicalisation is played down: blood is collected in workplaces in order to ‘normalise’ donation and render it part of ordinary life. Sperm collection, on the other hand, takes place in a medical setting, partly in order to eliminate public concerns related to sexual gratification (as seen, for example, in complaints about the National Gamete Donation Trust’s (NGDTS) ‘Give a Toss’ campaign). The gender and ethnicity of the blood donor is irrelevant (except on certain medical grounds), whereas people may be highly conscious of the specific traits they would like to see in the sperm donor.

Blood is differentiated and dispersed in its usage and no future connection back to the donor by the recipient is possible. Sperm on the other hand must be carefully retained as a unified substance: heterologous (mixed) sperm use is banned and future linkage is crucial because it results in a genetic connection that in the UK is recognised in law, through the abolition of donor anonymity.

Donating blood may be seen as an example of national solidarity: for example after the September 11th attacks in the US, or in Sri Lanka during the civil war. Blood donation is thus seen as appropriate for public performance, an expression of social solidarity. Sperm donation, on the other hand, is a private procedure that may easily be misvalued.

Possible points of interest

- People’s decisions are influenced by how others behave in similar situations and the context of donation.
- Even where donation appears to be a straightforward transaction between donor and recipient (blood donor to accident victim; sperm donor to woman/couple receiving fertility treatment), in fact multiple transactions take place (screening, storing, treating) involving multiple intermediaries. The role of the intermediary is crucial.
- Donating blood is often seen as the paradigm case of donation. However, the significant differences cited above suggest that care should be taken in making assumptions that what works, or is appropriate, in one field of donation will work, or be appropriate, in another.

Volunteering for research purposes

1.39 Here the comparison is between two ways in which it is possible to volunteer the body for research purposes and the consequences for remuneration; we draw on an example where comparisons were used proactively in some consultation responses to argue for regulatory change. These comparisons challenge us to justify differences in approach to payment (whether in terms of recompense of losses incurred in donation or additional financial reward), and to discuss what role, if any, the possible risk to the welfare of the donor/volunteer should play in these considerations, questions to which we shall return throughout this report.

Box 1.8: Volunteering for research purposes: the egg donor and the participant in first-in-human trials (based largely on one consultation response)

The comparisons offered below highlight areas of similarity and difference between two ways in which the body may be volunteered in order to promote medical research: through participation in first-in-human trials and through the donation of eggs for research purposes (excluding any ‘egg-sharing’ arrangements where different considerations apply). Where appropriate, comparisons with other forms of donation or volunteering are drawn in.

Process and impact on the donor/volunteer

- Providing eggs for research involves first the suppression and then stimulation by medication of a woman’s reproductive cycle, followed by surgical removal of the eggs. Thus, like a participant in a first-in-human trial, the egg donor (a) undergoes an intervention, which (b) carries a risk, (c) for the enhancement of scientific knowledge, (d) in hopes that it will benefit others and (e) in the knowledge it is likely to involve discomfort and inconvenience. Although women providing eggs for research are not designated as ‘research subjects’, since they are not as such the subject of research, some argue that they should be compared to research subjects in so far as the intervention they undergo is undertaken purely for research purposes.

- Other possible comparisons: the clinical process of donating eggs for research purposes is identical to egg donation for treatment purposes. Egg extraction may also be compared in terms of procedure and discomfort to bone marrow extraction. Both egg donors (for research) and participants in first-in-human trials might also be compared to living ‘stranger’ kidney donors who donate to an unknown recipient: such a donor similarly undergoes an intervention which carries a risk in the hope it will benefit others and in the knowledge it is likely to involve discomfort and
CHAPTER 1

Human bodies: donation for medicine and research

inconvenience. Those undertaking stranger donation differ from research participants and research egg donors, however, in that they undertake the process with the aim of benefiting a single, identifiable (if unknown) individual.

Risk

■ Serious physical risks associated with egg extraction are low in frequency although potentially extremely severe in effect. Risks in first-in-human trials must be assessed as ‘minimal’ in order for the trial to be approved but are inherently unknowable, and very serious outcomes may on occasion eventuate.

■ Other possible comparisons: the physical risks undertaken by women donating eggs for research are identical to those undertaken by women undergoing IVF solely in order to donate eggs for another woman’s treatment. They may be slightly lower than the risks accepted by women donating eggs as part of the process of their own IVF treatment, as non-patient donors will, by definition, not go on to become pregnant after the ovarian stimulation.

Payment

■ Participants in first-in-human trials receive cash payments in return for their time, their inconvenience and their discomfort (payments must not be calculated with reference to risk). Women providing eggs for research receive (capped) expenses.

■ Other possible comparisons: women providing eggs for another woman’s treatment receive capped expenses (unless they do so in the context of ‘egg-sharing’, where they will be eligible for discounted treatment); the Department of Health recommends that those donating a kidney to a stranger as a living donor should have their expenses (including their lost earnings) reimbursed in full.

Possible points of interest

■ If those who contribute to the advancement of medicine and science through participation in first-in-human trials receive financial reward for so doing, why should not those who similarly undergo medical procedures in order to provide eggs for the same aim? What distinguishing features, if any, explain the difference in treatment?

■ What role does the ‘risk’ to the welfare of the donor/volunteer play in determining the appropriateness, or otherwise, of financial reward?

■ What is the difference between paying for a person’s time, and reimbursing their lost earnings?

The ‘uniqueness’ of reproductive material

1.40 Eggs, sperm and embryos are widely considered to come in a different category from other forms of human bodily tissue. This ‘difference’ is captured in regulatory form by governance under a separate Act, the Human Fertilisation and Embryology Act, and their exclusion from the Human Tissue Act (see Chapter 2). The Nuffield Council’s own 1995 report on human tissue largely excluded gametes and embryos from its terms of consideration, on the basis of this regulatory distinction. Responses to the Working Party’s consultation document provided a valuable range of views as to the extent and nature of that difference.

Box 1.9: ‘Uniqueness’ of reproductive material (based on multiple responses to consultation question 281)

Many responses to the question whether any forms of human bodily material are ‘special’ in any way brought up the question of gametes. The reasons people gave for their views fell into three main categories:

A. No difference between gametes and other forms of bodily material

■ because no form of bodily material is ‘special’ (for example because it’s all ‘just meat’ or because anything ‘special’ depends on what is done with it, not its inherent nature); or

■ because all material is special (for example because it all contains DNA; some suggested that all material has the potential to replicate life).

B. Radical difference between gametes and other forms of bodily material

■ seen as self-evident (‘gametes’ typically selected as special without the need for further explanation); or

■ because of the possible consequences of use (even if these do not eventuate): the possible outcome of the creation

81 Question 2 of the Working Party’s consultation paper asked: “Should any particular type(s) of human bodily material be singled out as ‘special’ in some way?”
of a new person, leading to questions of identity and rights of the child, genetic parenthood and responsibility, and kinship relations. Such consequences do not arise when donating other forms of bodily material; or
■ because of the circumstances in which the choice to donate is made: choosing to create a new life is different in kind from enhancing an existing life; or
■ because the use of gametes is seen as creating specific ethical issues.

C. Similarities between gametes and other (specified) forms of bodily material
■ through the potential of stem cell research to blur the distinctiveness of the life-creating properties of gametes; or
■ through association with the person’s sense of their ‘identity’: gametes were identified as ‘special’ by some respondents along with brain, eyes and heart; or
■ through other ‘linkages’ between donor and future ‘beneficiary’, such as the risk of transmission of infection; or
■ through comparisons of need: the need of the potential parent for medical help with conception is often likened to (and usually ranked lower than) the need of patients for a donated organ or tissue; or
■ through procedural and regulatory similarities: for example over the future control of the donated gamete or organ.

Possible points of interest
■ The reasons given for radical difference between gametes and other forms of bodily material were broadly consistent, while the ways in which respondents identified possible similarities or argued for no difference were more disparate and sometime mutually opposing. Consultation responses on this issue demonstrate vividly the pluralism of opinion with which policymakers in the UK must grapple.
■ The view (widely but not universally) held that eggs and sperm constitute a unique form of human bodily material is primarily constructed through difference from other forms of material in terms of all the consequences associated with the creation of a new life (rights, responsibilities, kinship). For some, however, eggs and sperm are inherently special regardless of the actual outcome (that is, even if no new life is created). Most comments by implication referred to gametes for reproductive, rather than research purposes.
■ The claim to uniqueness on the basis that gametes create specific ethical issues appears to lead to a tautology, the specialness attributed to gametes and to ethics being mutually dependent. However, this claim may be understood as another way of expressing the view that eggs and sperm are inherently special because of their potential for new life, regardless of actual consequences.

1.41 The comparisons offered here point to the cultural significance of different forms of material, which must sit alongside cross-cutting factors that we have already highlighted such as the important role of transactions and intermediaries. We take as our starting point that strong and at times conflicting views cannot (and should not) be wished or argued away: any realistic policy approach has to accept that a range of views exists within society. We return to this issue in Chapters 4 and 5.

1.42 We also note that, while there are many circumstances in which the image of giving allows donors and recipients to think of each other in some kind of relationship,82 there are other circumstances (for example in the context of research) where the need cannot be visualised quite in these terms. Exploring the diversity of need is one of the aims of this report.

82 See, for example, Konrad M (2005) Nameless relations: anonymity, melaniesia and reproductive gift exchanges between British ova donors and recipients (New York: Berghahn Books).