



Human bodies: donation for medicine and research

NUFFIELD
COUNCIL ON
BIOETHICS

Human bodies: donation for medicine and research

Nuffield Council on Bioethics

Professor Albert Weale FBA (Chair)

Professor Hugh Perry FMedSci (Deputy Chair)

Professor Steve Brown FMedSci

Dr Amanda Burls

Professor Robin Gill

Professor Sian Harding FAHA FEDC

Professor Ray Hill FMedSci

Professor Søren Holm

Dr Rhona Knight FRCGP

Professor Graeme Laurie FRSE

Dr Tim Lewens

Professor Ottoline Leyser CBE FRS

Professor Anneke Lucassen

Professor Michael Moran FBA*

Professor Alison Murdoch FRCOG

Dr Bronwyn Parry

Professor Nikolas Rose

Professor Dame Marilyn Strathern FBA**

Dr Geoff Watts FMedSci

Professor Jonathan Wolff

* co-opted member of the Council while chairing the Working Party on *Emerging biotechnologies*

** co-opted member of the Council while chairing the Working Party on *Human bodies: donation for medicine and research*

Secretariat

Hugh Whittall (Director)

Kate Harvey

Katharine Wright

Tom Finnegan

Dr Alena Buyx

Varsha Jagadesham

Dr Peter Mills

Carol Perkins

Catherine Joynson

Sarah Bougourd

The terms of reference of the Council are:

1. to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concerns;
2. to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body; and
3. in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

**The Nuffield Council on Bioethics is funded jointly by
the Medical Research Council, the Nuffield Foundation, and the Wellcome Trust**

Acknowledgments

In writing this report, we have sought input from a wide range of sources and in a variety of ways (see Appendices 1 and 2). We launched a public consultation to which both those professionally engaged in these issues, and interested individuals responded. We commissioned 'snapshot' reviews of the published evidence concerning three aspects of our enquiry: regulatory approaches in a number of other jurisdictions; factors identified as disposing people to donate, or not to donate; and the empirical results of offering material incentives in order to encourage people to donate. We held a series of fact-finding meetings with experts, in order to inform the Working Party about technical and regulatory aspects of donation, and benefited from the generosity of many individuals willing to respond to specific queries. Towards the end of the Working Party's deliberations, we sought external comment on an earlier draft of the report from 13 peer reviewers working in a wide range of fields.

We were very aware that even a well-publicised open consultation process will elicit responses primarily from those who are already interested in the issues at stake, whether for professional or personal reasons. Yet anyone may potentially be affected by the issues discussed in this report: both the possibility of donating one's bodily material, and the possibility of benefiting medically from others' donations may arise for anyone out of the blue. We were therefore keen to hear the voice of members of the public who do not at present have a particular stake in these issues but who at any point may acquire one as a potential donor or recipient. At a one-day 'deliberative event' organised on behalf of the Council, 40 members of the public were encouraged to consider and debate these issues.

The responses we have received from these various consultative and evidence-gathering processes have played a central role in steering the Working Party's deliberations and in shaping the final report. We would like to express our gratitude to all those who were so generous with their time, expertise and experience. In addition to those named in Appendices 1 and 2, we would like to thank Kamal Ahuja, Sue Barnes, Mark Brown, Scott Brubaker, Michael Chapman, Hannah Darby, Catherine Elliott, Kara Flynn, Kirstin Goldring, Shaun Griffin, Martin Guttridge, Jane Hair, Rachel Johnson, Mark Jones, Sonia Kawa, John Kearney, Caroline Lewis, Helen Lovell, Monir Moniruzzaman, Pamela Niven, Rosa Parker, Antonio Pellicer, Mandeep Rai, John Richardson, Will Scott, Ken Taylor and Emma Winstanley.

Foreword and key points

Answers depend much on the way questions are asked. The Nuffield Council on Bioethics has posed a huge question: how far can society go in its demands on people to act in what many regard as a good cause – that of providing bodily material to benefit others? It has done so in relation to areas of medicine that may seemingly touch only a few, although they could in fact touch anyone, as well as contributing to research where outcomes will be long term and incalculable. In the way it has posed the question, it has invited us to think laterally, and working through the ramifications of this invitation shows something we already know, yet need to go on 'knowing': that society is not 'out there' – it is all of us. The question about how far society can go is also a question about how far national regulations or the NHS or clinicians or procurement agencies can go; and the question can equally be asked of prospective donors or recipients of bodily material, of their relatives and friends, or of anyone who holds opinions and views about these matters. There are countless decisions to be made, and no single answer to what might be appropriately limited or enabled. However, in making the question into an ethical one, the Council in effect asks another „how far“ question: how far it is possible to identify an assemblage of values and practices that might guide some of the decision-making? The report makes it clear that, in this kind of exercise at least, one can go quite far.

The Working Party asked by the Council to assist its deliberations has in places pulled back from making recommendations; however, where it has paused this has been for good reason, notably for lack of evidence, either because it was not in a position to collect the information or because such information is not to be found. There is work here for the future.

The report as such comes from the Council. As chair of the Working Party, I record here my personal thanks to a magnificent team that came into being for an engrossing 18 months. At once part of the team and with an input that far exceeded any expectations one might have had of the famous Nuffield secretariat, Katharine Wright, Kate Harvey and Catherine Joynson are owed a very special acknowledgment.

Context of this report

This report has been written in the context of a fast-changing landscape. As the Working Party has been engaged with the task assigned to it by the Council, both the regulatory structures governing the donation of bodily material within the UK, and (in England) the NHS services in which most such donations takes place, have been in a state of considerable organisational flux. This changing environment has been highly significant in our considerations. The shifting nature of institutions clearly affects how our recommendations are couched, and to whom they might usefully be addressed. Indeed, the current upheaval affecting health service organisations within the UK has challenged us to identify very clearly the values that we think should underpin the donation of bodily material by one person for the benefit of others. It also encouraged us to look to the future, and to the next generation, for whom these issues are likely to loom large as the need for, and possible uses of, bodily material continue to expand.

This report focuses primarily on the UK policy position. However, the UK does not exist in isolation, and both people and bodily material readily cross national borders. Examples from other jurisdictions provide snapshots of alternative regulatory approaches for the purpose of comparison. In any event, policy within the UK is influenced both by internationally agreed standards and norms, and by the fact that borders are permeable: activities regulated or banned in one country may emerge in another country with a different regulatory approach. The issues we consider are not confined to richer 'developed' countries – indeed many developing countries are grappling with the same issues, both in connection with their own populations and in response to the growing trend of medical tourism where patients travel abroad (often to poorer countries) for treatment. We hope that our report, despite our primary UK policy focus, may also be helpful where these or similar matters have to be faced elsewhere.

Reader's guide

No one is thanked for making things needlessly complicated, and the broad remit that the Council gave to the Working Party may seem to have added further complexity to the already difficult topics of organ transplantation, gamete donation or participation in 'first-in-human' trials as a healthy volunteer, among others. In fact, the very breadth of this enquiry has enabled us to *compare* how particular ethical ideas and concepts are used in different circumstances, and has thus helped us understand the importance of the *context* in which decisions and actions take place. Taking complexity into account has been part of the job.

Time and again, the report comments on how concepts in this area of donation and volunteering are understood in different ways, at different times, in different circumstances, and by different people. Taking account of how meanings may shift and change has been an important part of our analysis. Yet multiple meanings can become a hindrance when it comes to drawing clear conclusions and making recommendations for action. That is why it has been necessary at various points to be explicit about the particular emphasis that we have decided to place on certain terms. What works in one context need not work in others. Take the very idea of „donation“. It has been suggested that we could have used a much more neutral term such as „procurement“. However, we have retained it not only because of its widespread usage in the UK and beyond, but because it signals a specific value. Calling the source a „donor“ draws attention to the human subject, the person, whose body is of medical interest to others. This is one reason why we have referred to participation in clinical trials in terms of donation as well, although the kind of donation in question is in the form of a „loan“.

The report lays out a great deal of material, and although it cannot expect to cover „everything“, we hope that it covers enough to enable anyone interested to relate our approach to those areas with which they are particularly concerned. People will be looking for different things, and to help this we have divided the report into two parts, each of which has a different coloured edge to the pages. Each chapter begins with a summary box drawing together the key points made in the chapter.

In **Part I**, which has blue edges to its pages, we take an empirical approach, setting the scene, by describing the ways in which one person's bodily material is currently used in the treatment of others and in research (**Chapter 1**); the different ways in which the donation of different forms of material, and the volunteering of the body, are regulated (**Chapter 2**); the mismatch, for many forms of bodily material, between current 'supply' and the ever-increasing needs and demands of professionals and patients (**Chapter 3**); and the nature of the ethical concerns routinely arising in the context of the donation of bodily material (**Chapter 4**).

In **Part II** (indicated by green-edged pages) we set out our own thinking on some of these issues. **Chapter 5** explains the ethical approach taken here: in particular the report argues for a continuing role for altruism in donation, as underpinning important communal values that express something very significant about the kind of society in which we would wish medicine and research to flourish. An altruistic basis for donation helps underpin a communal, and collective, approach to the provision of bodily material for others' needs. However, we also argue that systems based on altruism and systems involving some form of payment are not necessarily incompatible. This chapter also discusses the role of consent, concluding that the person's own willingness to be a donor is central in ensuring that material is 'properly given' rather than 'improperly taken'. Importantly, it highlights the key role played by professional and interpersonal values such as trust, compassion and generosity in creating and maintaining systems in which people will feel able to donate.

In Chapters 6 and 7, we consider the implications of this ethical approach for the donation of different forms of bodily material and for participation in first-in-human trials as a healthy volunteer. Crucially, we distinguish 'encouraging' individuals to donate or volunteer, from 'facilitating' donation by addressing organisational barriers. We then highlight a number of areas where we felt we could usefully offer specific recommendations.

Chapter 6 looks specifically at the question of using incentives to encourage donation or volunteering, and we put forward an 'Intervention Ladder' as a tool for considering the ethical acceptability of different forms of encouragement. The 'rungs' on the Intervention Ladder vary from rung 1 (simple

information about the possibilities of donating or volunteering) to rung 6 (financial incentives that leave the donor/volunteer in a better financial position as a result of their participation). The report argues that the forms of encouragement that correspond to the rungs of the ladder should not be regarded as moving from 'ethical' to 'less ethical' or 'unethical': rather that the higher one goes on the Intervention Ladder, the more there will be a requirement for close examination of the ethical implications in this particular context. In our consideration of the ethical acceptability of incentives for various different forms of donation, we conclude, for example, that the payment of funeral expenses for those who consent in advance to the donation of their organs after death, the removal of the current cap on the reimbursement of gamete donors' expenses (including lost earnings), and the offer of financial reward to those willing to donate gametes for research purposes, could all be ethically justified. We do not, however, consider that any form of financial reward for living organ donors should be introduced.

In **Chapter 7**, we draw on the Council's earlier public health report, emphasising the 'stewardship' role of the state, both in promoting public health measures that could help reduce the demand for bodily material in the first place, and in emphasising the public aspects of what are sometimes seen as purely private transactions between donors and recipients. In particular, we emphasise the responsibility of the state, and of public institutions such as NHS organisations and regulatory bodies, to remove barriers to donation and to address inequalities that disadvantage particular groups or communities in terms of their access to the benefits arising out of donation. Our recommendations include the creation of a much more coherent infrastructure for gamete donation, drawing on the lessons learnt with respect to blood and organ donation; and a more explicit recognition on the part of researchers of their responsibilities in return for public willingness to donate bodily material for the public good of research. Tangible ways in which this recognition could be expressed include willingness on the part of the commercial sector to contribute to public tissue banks; readiness on the part of individual researchers and research institutions to provide access to donated material to others on the basis of scientific merit; and a recognition of donors and volunteers as partners in a joint enterprise of research.

We recognise that in this complex arena, everyone will have their own qualifications or additions to make to the report. But if the conceptual arguments we have put forward in making these comparisons prompt the reader to think of other situations, further examples, different combinations of issues, or distinctions ignored or over-emphasised, one at least of the purposes of the report will have been accomplished.

A handwritten signature in black ink that reads "Marilyn Strathern". Below the signature is a short horizontal line.

Professor Marilyn Strathern
Chair of the Working Party

Members of the Working Party

Professor Marilyn Strathern

Former Mistress of Girton College Cambridge and William Wyse Professor of Social Anthropology, University of Cambridge

Professor Janet Darbyshire

Emeritus Professor of Epidemiology, University College London; formerly Director of the MRC Clinical Trials Unit and Joint Director of the NIHR Clinical Research Network

Professor Bobbie Farsides

Professor of Clinical and Biomedical Ethics, Brighton and Sussex Medical School

Professor Sian Harding

Professor of Cardiac Pharmacology at the National Heart and Lung Institute, Imperial College London

Dr Tim Lewens

Reader in Philosophy of the Sciences, Department of History and Philosophy of Science, University of Cambridge

Dr Gillian Lockwood

Medical Director, Midland Fertility Services, West Midlands

Professor Theresa Marteau

Professor of Health Psychology, King's College London, and Director of the Behaviour and Health Research Unit, Institute of Public Health, University of Cambridge

Professor Naomi Pfeffer

Honorary Research Associate, Department of Science and Technology Studies, University College London

Professor David Price

Professor of Medical Law, De Montfort University

Mr Keith Rigg

Consultant Transplant Surgeon, Nottingham University Hospitals NHS Trust

Professor Bob Simpson

Professor of Anthropology, Durham University

Professor Chris Womack

Principal Clinical Histopathologist, AstraZeneca, and Honorary Professor in the School of Cancer and Enabling Sciences, University of Manchester

Terms of reference

1. To identify and consider the ethical, legal and social implications of transactions involving human bodies and bodily material in medical treatment and research.
2. To consider, with reference to different forms and purposes of donation or volunteering, what limits there should be, if any, on the promotion of donation or volunteering, including consideration of:
 - a the role of payment and any other form of remuneration or exchange;
 - b the role of consent;
 - c the question of subsequent use, ownership and control of donated materials;
 - d the role of those acting as intermediaries between donors and recipients; and
 - e the cultural and international perspectives, including regulatory differences.
3. To draft a Report and make recommendations on these issues.

Table of Contents

Nuffield Council on Bioethics	iii
Acknowledgments	v
Foreword and key points	vii
Members of the Working Party	x
Terms of reference	xi
Summary and recommendations	1
Introduction	25
Part I	31
Chapter 1 - Human bodily material in medicine and research: overview	34
Scope of human bodily material and its uses	35
Transactions involving human bodily material	42
A comparative approach	45
Chapter 2 - Regulatory landscape: overview	52
Introduction	52
Consent	56
Control and 'ownership' of bodily material	63
Permissibility of commercial dealings in bodily material	66
Safety	74
Licensing	76
The growth of regulatory frameworks	77
Issues arising in current regulation	79
Chapter 3 - Supply and demand	84
Introduction	84
Supply and demand in the UK: the current picture	85
Examples of factors influencing demand	93
Examples of factors influencing supply	101
Chapter 4 - Debates over ethics	118
Ethical values	118
The public and the private	122
The question of obligation	124
The gift relationship	124
The role of money	126
Making moral judgments	127
Part II	129

Chapter 5 – An ethical framework.....	132
Arguing for a framework	132
Implications for ethical choice	152
Ethical conclusions and policy considerations	155
Chapter 6 - Actions affecting individuals	160
Introduction.....	160
Motivations and barriers to donation and volunteering	161
Incentives and decision-making	165
An „Intervention Ladder“ for promoting donation	167
Consent	170
Implications for different forms of bodily material.....	171
Chapter 7 - Actions addressing organisations	188
Introduction.....	188
Preventive action	189
Alternatives to donation.....	190
Public and private concerns	191
Implications for intermediaries by form of material.....	197
Chapter 8 - Afterword from the Working Party Chair	214
Appendices	219
Appendix 1: Method of working	220
Appendix 2: Wider consultation for the report	225
Appendix 3: The Working Party.....	229
Glossary	231
List of abbreviations	238
Index.....	241

Summary and recommendations

Human bodily material in medicine and research: overview (Chapter 1)

1. A wide range of forms of human bodily material may be provided by one person for the treatment of others, or for research that aims to improve medical treatment in future. These include:
 - **Blood and blood products**, including stem cells derived from cord blood or bone marrow;
 - **Solid organs**, including part organs;
 - **Tissue**, including bone, skin, arteries and corneas;
 - **Material associated with reproduction**, including gametes (egg and sperm), embryos, fetal material and embryonic stem cells;
 - The 'loan' of the **whole living body** for medical purposes, for example through participation in first-in-human 'healthy volunteer' clinical trials, or for surrogacy; and
 - **The whole body after death** for education, training or research.
2. 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: for example, 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 focussing 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.
3. 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. Throughout this report, we aim to pinpoint what is specific to the ethical issues that arise in particular cases and what may lie in common with others.

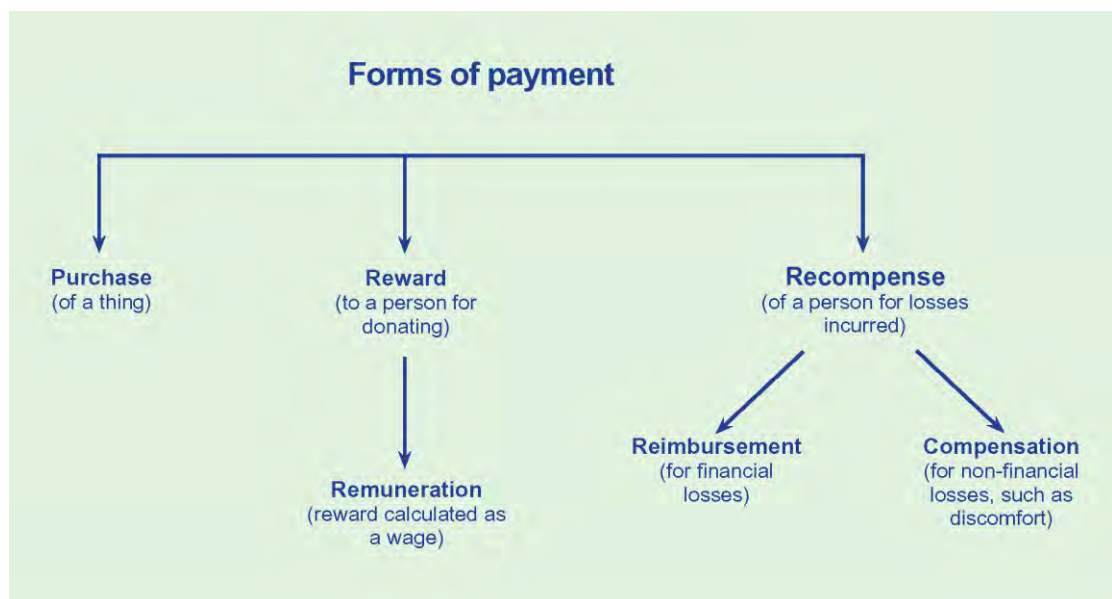
Regulatory landscape: overview (Chapter 2)

4. Since the publication of the Council's report *Human Tissue: ethical and legal issues* in 1995, the regulatory frameworks governing the donation, storage and use of human bodily material have changed and multiplied, leading to a very different regulatory environment from fifteen years ago. Regulations within the UK generally include requirements for consent and safety, provision as to future control of material once separate from the body, and restrictions on commercial dealings in bodily material. Nevertheless, the detailed aspects of regulation vary significantly both in terms of the form of bodily material, and the purposes for which it has been donated.
5. 'Regulation' may prohibit, require, or permit particular actions. Where regulation is permissive, its actual impact is likely to depend on the extent to which the permitted activity is supported, encouraged or, on the contrary, discouraged – and hence will be strongly influenced by the approach taken by relevant organisations. In the UK these at present include the Human Tissue Authority (HTA), the Human Fertilisation and Embryology Authority (HFEA), NHS Blood and

Transplant (NHSBT), and individual NHS bodies. Both the HTA and HFEA are due to be abolished by 2015, with their functions absorbed into other statutory bodies, and the English NHS is currently undergoing a process of organisational change. This current state of fluidity in organisational and regulatory infrastructure has been important in the Council's consideration of the practical implications of possible policy recommendations.

6. Although the primary focus of this report concerns donation practice within the UK, regulation of the donation and use of human bodily material cannot be confined within national borders. European Union (EU) legislation must be made effective within the UK, and international principles and declarations that seek to set minimum standards world-wide influence regulatory and public attitudes within individual countries. Both people and bodily materials cross national boundaries, and hence regulatory frameworks within other jurisdictions may have a direct impact on UK residents who choose to travel to other jurisdictions for treatment they are unable to access at home. Bodily materials used within the UK may be imported from other jurisdictions where they were donated under different regulatory frameworks; and in some circumstances material donated in the UK may similarly be used abroad.
7. Bodily material thus circulates within a global market-place: while almost all countries prohibit donors from deriving financial gain from the donation of their bodily material (gametes being a common exception), money does change hands in connection with the many medical and technical services required to handle and process that material, whether for treatment or research purposes. **In order to achieve some clarity in this area, we propose the following terminology in respect of payments made in connection with bodily material:**

- **Payment:** a generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as recompense, reward or purchases;
- **Recompense:** payment to a person in recognition of losses they have incurred, material or otherwise. This may take the form of the **reimbursement** of direct financial expenses incurred in donating bodily material (such as train fares and lost earnings); or **compensation** for non-financial losses (such as inconvenience, discomfort and time).
- **Reward:** material advantage gained by a person as a result of donating bodily material, that goes beyond 'recompensing' the person for the losses they incurred in donating. If reward is calculated as a wage or equivalent it becomes **remuneration**.
- **Purchase:** payment in direct exchange for a 'thing' (e.g. a certain amount for a kidney, or per egg). [paragraph 2.44]



Supply and demand (Chapter 3)

8. The increasing possibility of using many forms of bodily material to benefit others in medical treatment and research has brought about a constant pressure within the UK to meet demand. There is a continual need to recruit new blood donors in order to maintain an adequate supply of blood; three people die every day while waiting for an organ transplant; many fertility clinics are not able to meet requests for treatment involving donor eggs or sperm; and research organisations cite difficulties in accessing bodily material as a key factor limiting research progress. 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. Talking starkly in this way, in terms of 'supply' and 'demand', may resonate with the experiences of many professionals and patients (potential recipients) who are only too aware of the impact of any shortage in supply; at the same time, however, it may imply a lack of consideration of the human nature of their source. While using these impersonal terms throughout this report, we emphasise that, on both sides of the equation, we are talking about people and people's lives.
9. The relationship between supply and demand for human bodily material is, moreover, a complex one. 'Demand' for material is inherently elastic: as scientific developments make more treatments possible, the demand for that treatment is likely to increase, and the development of alternatives may lead to more people overall being treated, rather than necessarily reducing demand. Wider public health factors in the population as a whole, such as high levels of obesity, diabetes, and alcohol consumption, play a key part in determining the demand for organs in particular, while the trend towards later motherhood increases the number of women who are likely to need medical help, including the use of donor gametes, to conceive. Public expectations of what medical science can achieve may serve to put further upward pressure on demand.
10. Discussions around how best to increase supply of bodily material often focus on questions of donor motivation: how individuals may best be encouraged to donate different forms of bodily material. Considerable effort is put into coordinated advertising campaigns to recruit blood and organ donors, and proposals to incentivise potential donors through benefits in money or in kind regularly emerge in academic circles. However, individual motivation and choice is only one part of the picture: the central role of organisations, organisational procedure and intermediary professionals in facilitating donation is becoming better understood, as is the importance of trust in these systems.
11. Examples of such organisational factors include the significant changes to the management of organ donation services made in recent years, with the aim of ensuring that whenever a person dies in circumstances where organ donation is a possibility, this possibility may be raised with their family. The issue of consent – of whether, for example, organs might routinely be taken after death unless the deceased had explicitly objected in advance, or whether people might be required to log their consent or objection to organ donation during their lifetime – continues to be a subject of fierce debate. Blood donation services are arranged in such a way as to make it as easy as possible for those inclined to donate to do so, and a central NHS organisation acts to co-ordinate the donation of tissue after death for treatment purposes. Examples are beginning to emerge of the NHS, universities and commercial companies working closely together to ensure that patients' willingness to donate bodily material for research purposes may be properly utilised through effective arrangements for tissue banking and the accurate recording of consent.

Ethical values in debate (Chapter 4)

12. Two unifying factors governing the bodily materials considered in this report are that they all come from persons, and that their intended use is to benefit others rather than the person who is the source of the material. These two aspects of the donation or volunteering of bodily material have generated a number of (sometimes competing) ethical concerns. The concerns

focus on such issues as: control and ownership of the human body; the adequacy of consent procedures to protect the donor; and the wider (common) goods arising from donation. Ethical values often invoked in response to such concerns include: altruism; autonomy; dignity; justice; maximising health and welfare; reciprocity; and solidarity. Other pertinent values highlighted in response to our consultation included those that might be classed as 'professional' values (such as the exercise of duties of care and confidentiality, respect and honesty) and positive values inherent in interpersonal relations (including love, generosity, compassion and trust).

13. Responses to the Council's consultation document demonstrated how many of these ethical values may be interpreted in diverse and sometimes contradictory ways. This potential for conflicts in usage does not mean that these values are made redundant; but rather that the way they are being used in particular circumstances needs to be made explicit and, where necessary, justified. For example, the traditional emphasis on the importance of the „gift“ has been criticised both because it may fail to prompt sufficient donors to meet demand, and because it may at times be used as a cover for coercive or exploitative relationships. However, it is clear that for many the notion of the gift elicits the sense of a supremely „social“ act in its orientation towards others. It also plays an important role in drawing attention to the person (the gift-giver) whose body is at issue. No-one would deny that it epitomises the opposite of theft and seizure by force, and in so doing it points to the desirability of material properly given rather than improperly taken. We suggest that only by 'unpacking' ethical claims made around donation practices in this way can we hope to understand the context in which these values may be understood.
14. Two other sets of concepts that generate strong, and sometimes conflicting, reactions are the notion of what is 'public' (the public sector, the state, action that takes place in public) versus what is 'private' (of interest only to the individual/family, the private sector); and the meanings associated with money. We suggest that donation is a multi-layered process with each layer having its own public and private meanings. It may therefore be more helpful to think of public and private as being complementary and overlapping rather than in opposition (see Box 4.3). Money, in turn, may be conceptualised in many ways, including as 'cash' (negatively as 'naked cash' or positively as transferable currency that may be used for any purpose); as influence; as a pricing mechanism; and as a reward (see Box 4.4). Throughout this report, the Council has sought to be clear as to how these very different meanings and associations are being applied in different circumstances.
15. Finally, we touch on the psychological aspects of how individuals arrive at moral judgments: these may often be based on rapid intuitions, which may then be followed by slower moral reasoning, in which intuited values may be made explicit. Certain kinds of transactions, for example the notion of attaching monetary value to things considered priceless, may be considered by many as 'taboo'. Although they might not do so readily, however, some people may be willing to attach monetary values to such 'priceless' things as organs if they believe that doing so will achieve an end that they value, such as saving lives. For others, such a consideration will not alter their rejection of the use of money in this context, as they perceive that it would violate deeply-held intuitions, or have an unacceptable long-term impact on societal values. Such views cannot necessarily be simply shifted by new evidence: moral judgments may be rapid, strongly held and intractable. Yet policy still has to be made in the context of such competing public views.

An ethical framework (Chapter 5)

16. We take the view that policy in this complex and sensitive area must start with a recognition of the pluralism that characterises people's values, attitudes, beliefs and behaviours in relation to the human body, including their own bodies. A key aim of a policy framework must therefore be to seek areas of shared consensus, including identifying values with which people starting from many different positions may nonetheless agree. [paragraph 5.82]
17. First, the role of the state with respect to donation should be understood as one of **stewardship**, actively promoting measures that will improve general health (thereby reducing

the demand for some forms of bodily material) and facilitating donation. Such a stewardship role should extend to taking action to remove inequalities that affect disadvantaged groups or individuals with respect to donation.

18. **Altruism**, long promulgated as the only ethical basis for donation of bodily material, should continue to play a central role in ethical thinking in this field. While some of the claims made for altruism may be overblown, the notion of altruism as underpinning important communal values expresses something very significant about the kind of society in which we wish to live. Understood in this way, altruism has much in common with solidarity: an altruistic basis for donation helps underpin a communal, and collective, approach to the provision of bodily material for others' needs, where generosity and compassion are valued.
19. 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. This holds in two circumstances: first, in the absence of reward, where payment may be used to recompense the donor for costs actually incurred in donating (that is, in order to avoid financial losses as a result of donation); and second, in the presence of reward, where some forms of reward (monetary or otherwise) may in fact co-exist with altruistic intent. We distinguish between **altruist-focused interventions** (that act to 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 action). 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.
20. Donation for research purposes may differ in important ways from donation for treatment purposes. While both forms of donation seek to benefit others, the contribution that any one research donor or healthy volunteer makes to the health of any other identifiable person is exceptionally hard to pin down. A move away from a primarily altruistic model in donation for research purposes may therefore pose a lesser challenge to solidarity and common values than such a move in connection with donation for treatment.
21. We take seriously concerns that some approaches to increasing the supply of bodily material may risk using people, and people's bodies, as 'means' to another's ends. While we do not take the view that payment to a person in connection with donation necessarily implies this, we do reject the concept of the purchase of bodily material, where money exchanges hands in direct return for body parts. We distinguish such purchase clearly from the use of money or other means to reward or recompense donors.
22. The **welfare of the donor**, and the **potential for harm and exploitation** within donation practices, should be a key determining factor when considering the ethical acceptability of any system for encouraging people to come forward as donors. While proper consent procedures, underpinned by sufficient information, are clearly essential in order to protect those coming forward as living donors, consent alone may not be sufficient to justify particular donation practices if such practices might put other potential donors, or wider communal values, at risk.
23. Decisions about deceased donation should be based on the **known wishes of the donor**, so far as this is ascertainable. In ethical terms, the permissibility of such donation should be understood to be on the basis of the authorisation, or willingness to donate, of the deceased, rather than on their consent. We distinguish 'authorisation'/'willingness to donate' from 'consent' in these circumstances, on the grounds of the potentially different informational requirements involved. In contrast to those consenting to donate during life, those authorising donation after death do not expose their health to any risks, and the minimum informational requirements for donors are correspondingly lower.
24. Professional and relational values such as **trust and respect** play an essential part in creating and maintaining systems in which people will be willing to consider donation. This is true both of

trust in individual professionals, for example that they will exercise a duty of care towards donors and respect their confidentiality; and of trust in systems, that they are the subject of good and responsible governance.

Applying our ethical framework

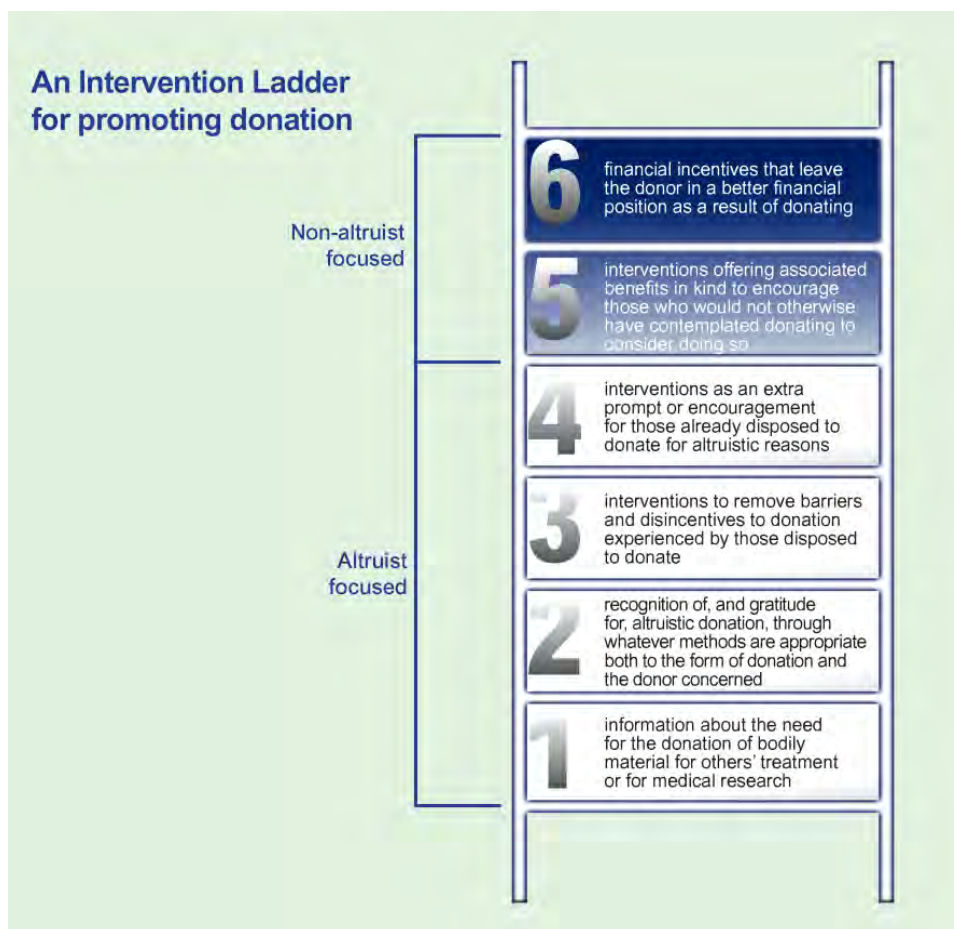
25. In the remainder of this report, we consider the demand for various forms of bodily material from two perspectives. The first (Chapter 6) concerns the degree to which it is ethically acceptable to 'encourage' individuals to donate their bodily material. The second (Chapter 7) takes up what can be done by institutions and organisations to „facilitate“ donation, whether through improving procedures or reducing demand. Both reflect on the kind of society we would wish to see and on the manner in which persons flourish.

Actions affecting individuals (Chapter 6)

26. In the Nuffield Council's earlier report *Public health: ethical issues*, the Council set out the idea of an 'Intervention Ladder' as a way of thinking about the acceptability of, and justification for, a range of public health policies. We suggest that an Intervention Ladder would similarly provide a useful tool to help those considering what, if any, forms of additional encouragement should be offered to potential donors to increase the supply of bodily materials or healthy volunteers, whether for treatment or research. We emphasise here that the rungs of the Intervention Ladder take the form of *inputs*: how individuals respond to such inputs will clearly vary from person to person, and indeed inevitably there will be some degree of overlap in how people respond to neighbouring 'rungs'. *We also note that the ladder should not be seen as moving from 'ethical' actions to 'unethical' actions, but rather from actions that are ethically straightforward to those that are ethically more complex.* Thus, action in accordance with the higher rungs may only be ethical in particular circumstances or contexts. Finally, we emphasise that such a tool clearly cannot capture every consideration of ethical relevance, but rather serves to highlight some of the most common ethical concerns that are likely to arise. With these provisos in mind, we draw on the categorisation of forms of encouragement set out in Chapter 3, and present an Intervention Ladder with the following 'rungs':

- **Rung 1: information** about the need for the donation of bodily material for others' treatment or for medical research;
- **Rung 2: recognition** of, and gratitude for, altruistic donation, through whatever methods are appropriate both to the form of donation and the donor concerned;
- **Rung 3: interventions to remove barriers and disincentives to donation** experienced by those disposed to donate;
- **Rung 4: interventions as an extra prompt or encouragement** for those already disposed to donate for altruistic reasons;
- **Rung 5: interventions offering associated benefits in kind** to encourage those who would not otherwise have contemplated donating to consider doing so; and
- **Rung 6: financial incentives** that leave the donor in a better financial position as a result of donating. [paragraph 6.23]

As an Intervention Ladder, with rung 1 starting at the bottom, the six rungs will thus look like this:



27. While we distinguish the first four 'rungs' of the Intervention Ladder as involving different degrees of organisational involvement and (potentially) cost, we do not distinguish them on *ethical* grounds: all are 'altruist-focused interventions'. We do not consider that refunding expenses involved in donation or providing minor tokens as a „spur“ to donation involve ethical compromises in a way that information campaigns or letters of thanks do not. Thus the rationale for deciding between these four rungs will effectively be empirical: is it necessary to advance a 'rung' to ensure that people who are potentially willing to donate are facilitated in doing so? Indeed, if there is evidence that people who would like to be able to donate are prevented from doing so by cost (for example if a person who wishes to donate a kidney to a family member cannot afford the time off work involved), then it would seem only just to ensure that they are as well able to donate as someone who is sufficiently wealthy not to be affected by such considerations.
28. Moving from these altruist-focused interventions to the two final 'rungs' on the Ladder, which we class as non-altruist-focused interventions, are, on the other hand, ethically significant steps: scrutiny will be required to determine whether, in the circumstances, they may be ethically justified. Some will regard any intervention that encourages donation of bodily material primarily for non-altruistic purposes as simply 'mis-valuing' body parts, and would not consider such interventions to be acceptable in any circumstances. Others strongly disagree. Public policy has to find a way forward in the light of such competing views: key areas of common ground lie in consideration of the potential harms that might arise from such interventions, to the person donating, to others closely concerned, and to wider social values and relationships.
29. **We therefore recommend that, where a health need is not being met by altruist-focused interventions, the following factors should be closely scrutinised in order to ascertain**

whether offering a form of non-altruist-focused intervention might or might not be harmful:

- the welfare of the donor: this should be understood very broadly, including physical and psychological risks at the time of donation, physical and psychological risks in the future, and the extent to which the donor feels they have other options open to them;
- the welfare of other closely concerned individuals;
- the potential threat to the common good: for example the possible impact on existing donation systems, and the risk of increasing social inequalities;
- the professional responsibilities of the health professionals involved; and
- the strength of the evidence on all the factors listed above. [paragraph 6.26]

30. We also suggest that interventions providing associated benefits in kind may be less likely than those offering a straightforward financial reward to be perceived as a 'purchase' of a body part: indeed, for egg-sharing we have noted the argument that the benefit being received is not financial at all in nature but rather the *opportunity* to bear a child. Given that one of the key concerns around any form of non-altruistic-focused intervention is the risk of material being mis-valued, we distinguish between these two approaches through rungs 5 and 6 on the Intervention Ladder. We also emphasise that the 'benefits in kind' envisaged in rung 5 are benefits that are closely associated with the donated material, as in, for example, the covering of cremation costs where bodies have been donated for medical education. In such cases the benefit in kind is clearly situated within the domain of what has been donated. Non-associated benefits in kind (for example high-value vouchers) fall within rung 6, in that their primary purpose is to offer a straightforward financial benefit. In relation to rung 6, then, the key question is what may constitute ethical payment, and in what circumstances. We suggest that, where the intervention involves a direct payment of money or equivalent, it is an essential pre-requisite that the payment is understood, by all parties, in terms of reward to the *person* for their act of providing bodily material, rather than a purchase of material itself.

Blood

31. While blood stocks fluctuate, and there may be intermittent pressures on stocks of particular blood groups, blood shortages in the UK are rare. Blood is also the 'paradigm' case of donation: attitudes to blood donation have long strongly informed assumptions about other forms of donation. **We conclude that it is neither necessary nor appropriate to suggest any significant change at present to the current systems operating within the UK for encouraging people to donate blood.** [paragraph 6.35]

Organs: living organ donation

32. Living organ donation in the UK is at present on the increase, and current policy towards potential donors includes action on the first three rungs of our Intervention Ladder: provision of information; the recognition of living donation as a worthy act; and full reimbursement of all costs incurred by donors. Any form of payment that exceeds the direct reimbursement of costs actually incurred by the donor is forbidden in UK legal jurisdictions, by European Directive, and by numerous international agreements and statements. Nonetheless, there are regular calls for some form of regulated 'market' (which could be understood either as regulated 'purchase' of the organs themselves, or as a system of fixed financial rewards for those willing to donate) to be introduced. Such calls are based on the belief that the creation of an incentivised system would increase the overall number of living kidney donors in the UK, reduce the numbers waiting (and dying) on the organ transplant waiting list, and remove or reduce the temptation to travel abroad for an illegal transplant operation, using an organ sold by someone who is likely to be in desperate circumstances and who is unlikely to receive high quality follow-up health care.
33. The offer of financial reward in return for living organ donation would clearly constitute the final 'rung' of our Intervention Ladder, and require consideration of the factors listed in paragraph 29. While the physical risks to which a rewarded donor would be exposed would not differ from

those incurred by donors under the current system, we consider that the creation of a rewarded system might threaten the common good of altruistic donation within the UK without necessarily significantly increasing the total number of donors coming forward. We also consider that any encouragement of people to come forward for essentially financial reasons would be perceived internationally as a direct challenge to internationally-endorsed principles of solidarity and unpaid donation, and could undermine other countries' attempts to put a stop to unregulated and illegal organ sales. We therefore conclude that such a challenge would constitute a potential threat not only to the common good of altruistic donation within the UK, but also to the welfare of potential donors in other countries.

34. We acknowledge that there are serious gaps in the current evidence base, and we recognise too, that those in the UK who call for the introduction of financial incentives do so out of a genuine concern for the welfare of those waiting for an organ transplant. However, we suggest that, in a situation where there is a strong international consensus as to the importance of the current solidarity-based system in protecting both individual donors and the common good, an approach of 'precautionary thinking' is demanded: the burden of proof of the benefits of an alternative system must fall on the side of those demanding change. **We endorse the current position, that no payment, over and above the direct reimbursement of costs incurred in being a donor, should be made to living organ donors. We also conclude that systems assigning priority to those who have earlier expressed a willingness to donate are inappropriate, given the wide range of circumstances in which people are held to be ineligible to donate different forms of bodily material.** [paragraph 6.40]
35. **We do, however, endorse the current guidance by the Department of Health that the costs incurred by living organ donors (including actual lost earnings) should be fully reimbursed by their local Primary Care Trusts. Given the current organisational changes within the NHS in England, under which both Primary Care Trusts and the Human Tissue Authority will be abolished in their current form, we urge the Department of Health to ensure that this guidance is given proper weight within the new organisational structures. Possible ways of achieving this would include through legally binding Directions or through the Code of Practice issued under the Human Tissue Act.** [paragraph 6.41]

Organs: deceased donation

36. The possibility of financial incentives has also been raised as a potential way of increasing levels of deceased organ donation: for example by the NHS offering to meet funeral expenses for those who sign up in advance to the Organ Donor Register (ODR) and subsequently become organ donors. Such an incentive might seem sufficiently strong to encourage people to register as donors simply to spare their relatives the financial burden of a funeral and hence constitute rung 6 of our Intervention Ladder: however, such a decision would still include an altruistic component, in the aim to benefit others (the donor's relatives). As these arguments demonstrate, when decisions are made in the context of families, the Intervention Ladder will only be one factor to take into account.
37. We consider that payment of funeral expenses in these circumstances could be ethically justified. Under such a scheme, donors could not be physically harmed; those close to the donor might benefit directly; and relatives would also clearly have the option of declining the offer of expenses if they preferred not to accept them. While there is no direct evidence as to how effective or popular such an incentive would be, the similar system in place for those who donate their bodies to medical schools for educational purposes appears to be regarded by both professionals and families as an appropriate acknowledgment of the person's gift. This suggests that the extension of such a scheme to organ donors would not be detrimental either to professional values or the common good. **We recommend that NHS Blood and Transplant should consider establishing a pilot scheme to test the public response to the idea of**

offering to meet funeral expenses for those who sign the ODR and subsequently die in circumstances where they could become organ donors. [paragraph 6.46]

38. The proposal is regularly mooted that the current 'opt-in' system of consent for deceased organ donation should be replaced by an 'opt-out' system. Two models of opt-out systems are often distinguished: a 'hard' system, in which organs would automatically be taken unless the person had objected during their lifetime, and a 'soft' system, in which relatives would be able to veto organ donation even if no formal objection had been made in the past by the deceased person. **In our opinion, the importance to be attached to the person's own wishes rules out absolutely any consideration of introducing a 'hard' opt-out approach to deceased organ donation, given the impossibility of ensuring that everyone would be sufficiently well-informed to have the opportunity of opting out during their lifetime.** Our position on a 'soft' approach is more finely-balanced, and much would depend on how, in practice, the relatives were approached under such a system. [paragraph 6.48]
39. **We would not oppose on ethical grounds a soft opt-out system, in which families had the opportunity (without pressure) of contributing their knowledge of the person's own views and, where appropriate, of determining that the person would not have wished to become a donor, or indeed that donation would cause the family significant distress. We do, however, note some practical difficulties.** [paragraph 6.50] First we suggest that initial assumptions as to the numbers of additional organs that might be obtained in such a way should be modest, if families do indeed continue to feel genuinely free to express any objections they have. Second, we note the strong opposition in some quarters to the notion of any form of opt-out scheme, and the associated concerns that the state (acting through health professionals and the health care system) would be intervening to 'take' organs rather than facilitating their being 'given'. In these circumstances, there is at least a risk that some degree of trust in the system may be lost.
40. We note that the Welsh Assembly has expressed a clear intention to adopt the 'opt-out' approach in Wales. **If an opt-out system is introduced in Wales we recommend that this is accompanied by robust research, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change (as opposed to any confounding factors such as system changes) has had on the numbers of organs donated.** Such research would provide a clear evidence base for any proposals for change elsewhere in the UK, or indeed further afield. [paragraph 6.51]
41. Other possible changes with respect to consent defaults include the introduction of mandated choice or prompted choice systems of consent, where individuals are either required or prompted at points during their lifetime to register their views with respect to deceased organ donation. A pilot version of a prompted choice system linked with driver registration is due to begin during 2011. **We conclude that, in principle, both mandated choice and prompted choice systems present ethical options for seeking authorisation in advance to deceased organ donation.** [paragraph 6.54] We have emphasised repeatedly the importance we place on clear information about individuals' wishes, and hence systems that encourage people both to think about their own willingness to donate and to document their decision are strongly to be encouraged.
42. We also endorse the use of a pilot scheme to track the effectiveness of the proposed 'prompted choice' system via the Driver and Vehicle Licensing Agency (DVLA), and urge that the scheme is accompanied by robust research as to its impact. However, we are concerned about the decision not to include the option of registering *objection* to organ donation in the DVLA scheme: any system that is based on explicit authorisation must also allow for explicit refusal. **We recommend that any system set up to document people's wishes that mandates a response to a question about organ donation should also include the option of expressing objection; to do otherwise significantly undermines commitment to following the wishes of the deceased and even, arguably, fails to comply with the spirit of current legislation with its central focus on consent. We further recommend that any system set up to document people's wishes regarding donation (including the current Organ Donor**

Register) should also be able to register objections. Indeed, such a system might in practice act to *increase* donations, in that families who are unsure about their deceased relative's views could be reassured that they had not actively chosen to opt-out. [paragraph 6.55]

43. Difficult issues arise in connection with the amount of information needed for a legally valid consent; and the possibility of signing up to the Organ Donor Register on the basis of very little information about the process of donation has been raised as a matter of concern. **We note again the ethical distinction we have drawn between *consent* for interventions on the body for the purposes of donation during life and *authorisation* of interventions on the body for the purposes of donation after death, which we consider could well provide a helpful framework for distinguishing between the informational requirements in two very different sets of circumstances.** [paragraph 6.56]
44. Some people would prefer not to know any details of how organs will be removed, but simply wish to have the option of specifying some organs rather than others, and to be reassured that, once organs have been removed, their deceased body will not appear disfigured to their relatives. For them, this is sufficient to cover 'what is involved'. Others, by contrast, may wish to have detailed information about the process of organ retrieval, treatment and transplantation. **We conclude that information must be *available* to those considering donation and it must always be clear that more information is available if people desire it. If people make it clear that they wish to agree to donation, whether in advance via the Organ Donation Register, or on behalf of a deceased relative, even if they do not want to know any details about the process, this should be accepted as sufficient expression of their wishes.** [paragraph 6.57]

Gametes: donation for reproduction

45. Current attitudes and policies towards the donation of gametes are strikingly different from those applied to blood and organs. In contrast to the well-funded nationally organised networks promoting and facilitating blood and organ donation, only very limited support is available to raise general awareness of the need for donor gametes. Advertising for gamete donors therefore mainly takes place in the form of *ad hoc* campaigns by individual clinics, and there is little cooperation between clinics. There are no 'official' ways in which gamete donation is celebrated, although individual clinics or recipients may have their own systems for recognising and thanking donors. While travel and other out-of-pocket expenses incurred by gamete donors are reimbursed in full, lost earnings are capped at £250 per cycle of donation. Egg donors, in particular, may therefore potentially be out-of-pocket as a result of their donation. Although the Tissues and Cells Directive calls for gametes to be procured on a "voluntary and unpaid basis", interpretation within EU member states varies considerably as to what forms of compensation are permitted in conjunction with this definition. Outside Europe, there is no international consensus around payment for gametes, and indeed the straightforward 'purchase' of gametes, with differential pricing depending on the number of eggs and the qualities of the egg or sperm donor, is accepted in several jurisdictions.
46. It is clear to us that the starting point in any consideration of the ethical promotion of gamete donation must be the need for 'altruist-focused' action within the first four rungs of the Intervention Ladder. Until such interventions have been tried and evaluated, we consider it highly premature to conclude that a system based primarily on altruism has been shown to 'fail'. In particular, we highlight here the absence of organisational systems necessary for its success, such as the creation of a national infrastructure for egg and sperm donation, on the lines of the structures currently in place for organ donation. Such an infrastructure would be well-placed not only to manage the kind of coordinated information campaigns envisaged in the first rung of our Intervention Ladder, but also to share best practice in recruiting, retaining and 'recognising' donors (rung 2). We return to this point in Chapter 7.

47. Moving to rung 3 of the Intervention Ladder, we see no reason why gamete donors should suffer financial disadvantage as a result of their donation. Where time has to be taken off work in order to donate gametes, particularly in the more invasive procedures involved in egg donation, **we recommend that the current cap of £250 on lost earnings that may be reimbursed should be removed, and that lost earnings, where applicable, should be reimbursed in full in the same way as other expenses such as travel costs.** [paragraph 6.63] The clear aim should be to ensure that the donor is in the same financial position as a result of their donation, as they would have been if they had not donated.
48. Moving to consideration of rungs 5 and 6 of the Intervention Ladder, we consider that it is quite inappropriate to consider introducing new forms of non-altruistic-focused intervention in the UK before action on the lower rungs of the Intervention Ladder has properly been explored. However, given the existence of such interventions elsewhere in the world, and the recent debate on this issue within the UK, we make a number of observations.
49. **The Council rejects outright the concept of paying a 'purchase' price for gametes, where any payment made is understood as payment for the gamete itself, rather than as recompense or reward to the donor herself or himself.** [paragraph 6.66] Insofar as the 'price' of gametes depends on quantity, or on inferred qualities (for example those associated with the appearance or intelligence of the donor), such a transaction may only be understood as a 'purchase'.
50. **We consider that the welfare of the potential donor, especially with respect to egg donors, is central in determining what constitutes acceptable practice in this area.** [paragraph 6.67] Clearly, the physical risks of egg donation are not, in themselves, affected by whether a woman agrees to donate eggs primarily out of concern for other women unable to conceive with their own eggs, or primarily for reward. However, where egg donation is considered for essentially financial reasons, women may be more likely to consider repeat donations, and may be more likely to continue donating despite potential risks to their health. The lack of good-quality data on the long-term risks of repeat egg donation is a matter of concern here.
51. **We endorse the good practice guidance issued by the European Society of Human Reproduction and Embryology (ESHRE) on the treatment of egg donors in the context of cross-border reproductive care, and note its potential relevance also for domestic care. In particular, we endorse ESHRE's call for national registers of gamete donors to be established, and for centres to participate in the collection of national or international data. In addition we recommend, as a matter of urgency, that action is taken by licensed clinics to start collecting data on a systematic basis (if possible retrospectively, as well as through the new registers) to track the long-term health effects of repeat egg donations.** Good-quality evidence on these effects is essential in order for proper concern to be given to the welfare of egg donors in any future policy. We further note that individual clinics currently, as a matter of good practice, take a number of steps to minimise risk to egg donors, for example by encouraging women to donate only after they have completed their own families, and by limiting the number of times a woman may donate. **We recommend that the Royal College of Obstetricians and Gynaecologists and the British Fertility Society should work with the HFEA to review what is currently regarded as best practice in the UK with respect to measures taken to safeguard egg donors, with a view to issuing guidance that will send out a clear public signal about how the welfare of egg donors should underpin any consideration of donation.** [paragraph 6.69]
52. Finally, in the context of incentives designed to reward, rather than simply recompense, donors (egg and sperm alike), we highlight the question of the welfare of any future child. This is a hotly contested area: on the one hand, concerns are expressed as to the effect on any future child of the knowledge (if shared with him or her) that their biological mother or father provided their biological material for financial gain; on the other, it is argued that there is no evidence to show detriment, that children are conceived in all sorts of circumstances that have little or no effect on how they are subsequently loved and treated, and that indeed it can be the case that the

very lengths to which the child's legal parents are prepared to go to conceive a child demonstrate how wanted and loved they are. **We conclude that, in order properly to inform this debate, good quality empirical research evidence is urgently needed as to what, if any, effects financially incentivised gamete donation has on children conceived as a result of such donation and, indeed, on the wider context of how responsibilities towards children are understood.** [paragraph 6.70]

53. The discussion above has been concerned with 'new' non-altruist-focused interventions. However, one non-altruist-focused intervention – egg-sharing – is currently permitted in the UK, providing some women, who are not able to access NHS fertility services, the possibility of receiving free or reduced-price treatment in return for „sharing“ their eggs. We note that women who become egg donors through egg-sharing arrangements do not undergo any additional physical risks in the procedure itself; and that current data suggest that their chance of becoming pregnant after the transfer of fresh embryos is on a par with non-egg-sharers, although their „cumulative“ pregnancy rate will be lower because they will have fewer frozen embryos for subsequent transfers after their initial treatment. We also note that, in circumstances where would-be egg-sharers do not in fact produce enough eggs for their own treatment and that of another woman, they should be entitled to use all the eggs for their own treatment, while still receiving the promised rebate on their treatment fees. **We note, and welcome, recent statements by Ministers urging Primary Care Trusts and their successor organisations to ensure that access to IVF is more routinely made available in accordance with the guidance issued by the National Institute for Health and Clinical Excellence (NICE). However, given the likelihood that some women will continue to experience difficulties in accessing NHS IVF treatment, we do not think it appropriate to recommend any changes to the current policy within the UK of permitting egg-sharing in these circumstances.** [paragraph 6.72]
54. However, we strongly caution that it is *not* appropriate to use the notional value of egg-sharing arrangements (that is, the financial rebate offered on the cost of private IVF treatment) as an argument for creating a straightforward financial incentive for egg donation for reproductive purposes.

Gametes: donation for research

55. Women who decide to donate eggs for research as 'volunteer egg donors' (that is, not as part of an egg-sharing agreement), are likely to have rather different motivations from those donating to help a woman conceive. We consider that the most relevant comparison here, across all the different forms of donation and volunteering noted in this report, is with first-in-human trial volunteers. In contrast with circumstances where eggs are donated for treatment purposes, there is no direct recipient of the donated material and no possibility of a child being born as a result of the donation. Like healthy volunteers in first-in-human trials, women who donate eggs for research undergo medical procedures that involve discomfort, inconvenience and potential health risk, with the aim of enhancing scientific knowledge and hence potentially producing long-term health benefit. The potential gains by others are thus uncertain, remote, and impossible to link with any identifiable individual.
56. We have taken the view that these differences between donation for research purposes and donation for treatment purposes have ethical implications. In particular, we consider that where there are no clear recipients (known or unknown) of the donated material, a move away from a primarily altruistic model of donation may not present a risk of undermining solidarity, as expressed for example in a communal commitment to the provision of materials needed by others for the preservation or improvement of their health. While research egg donors' willingness to contribute to scientific knowledge may certainly be understood in terms of solidarity (a willingness to contribute to the collective good of research), altruism does not appear in this context to be a key value underpinning that contribution to solidarity. Rather, we suggest that another value, justice, becomes applicable here, and that, if donors are prepared

to undertake these procedures to benefit scientific endeavour and the wider community, it is only just that their contribution should be explicitly recognised, as it is in first-in-human trials. In circumstances where altruism does not play a central role, there appears to be much less justification for avoiding the use of financial reward as a form of recognition.

57. **We conclude that it would be appropriate to set up a pilot scheme to explore the possibility of offering some form of payment to those prepared to come forward as egg donors for research. Payment could be made on the basis of compensation for the time, inconvenience and discomfort involved in donating (in direct parallel to the language used in first-in-human trials), or as a form of remuneration. We draw further on parallels with healthy volunteers in first-in-human trials by recommending that donors coming forward in this way should be regarded as research participants, with all associated protections.** [paragraph 6.81]

Healthy volunteers participating in first-in-human trials

58. Payments for healthy volunteers participating in first-in-human trials are routinely described as payments in return for time or inconvenience. While such payments could potentially be described as recompense for the losses (financial and non-financial) incurred in volunteering, rather than as reward, in practice it seems fairly clear that, for most volunteers, payment constitutes a primary reason for participation, and that the current system is in fact a clear example of a non-altruist-focused intervention, on rung 6 of our Intervention Ladder.
59. We have already emphasised that non-altruist-focused interventions are not necessarily unethical: their ethical acceptability will depend on the context in which they are deployed. Moreover, as we have just argued in the context of donating gametes for research, where those who may benefit from the actions of the healthy volunteer are more remote (and may indeed never materialise), the key value here underpinning solidarity may not be altruism on the part of volunteers, but rather justice on the part of others in relation to the way they treat the volunteer. We conclude that payment for participation by healthy volunteers in first-in-human clinical trials within the UK constitutes an example of an ethically justified rung 6. In relation to the factors we have been considering, therefore, there is no reason to challenge the payment for participation by such volunteers in first-in-human clinical trials. **The major risk from the payment system to the welfare of the volunteer lies not in participation in the trial itself, but in the medical risks involved when volunteers take part in repeated, or even concurrent, trials.** [paragraph 6.86] Further aspects of concern become relevant in countries without universal health care systems: these include the possibility that participants may not receive appropriate monitoring and follow-up care, and may not be eligible to participate on an equal basis in their country's own health care system. We return to these wider concerns below.

Actions addressing organisations (Chapter 7)

60. This report has emphasised the complex and transactional nature of the donation of bodily material; highlighted how organisations and institutions, such as licensed clinics and biobanks, act as intermediaries between donors and recipients; and drawn attention to the various ways in which donation may be facilitated – or alternatively to the ways in which the need for donation may be reduced – by action at professional, organisational, and state level. Such action can be construed as an ethical responsibility, and we next consider specific action in connection with particular forms of bodily material. Before doing so, we comment on a number of over-arching questions that we believe policy-makers need to address in tandem with the question of how best to make use of the material that people donate.

Preventive action

61. Public health factors play a significant role in increasing demand for bodily material, in particular organs for transplant and gametes for fertility treatment. Changing patterns of behaviour in the population including diet, physical activity and consumption of alcohol, contribute to increasing

levels of cardiovascular disease, liver failure, and, to a lesser extent, kidney failure. Fertility declines with age and hence the later motherhood is attempted, the more difficult pregnancy is to achieve with a woman's own eggs. In other words, 'demand' for these materials is not a simple unmodifiable 'fact'. However, these potentially modifiable public health factors appear to be almost entirely absent in the general debate about the difficulty in meeting demand for bodily material.

62. In considering lifestyle factors, we are not concerned here with the question of whether these factors should be used in determining who should have priority in receiving an organ or donated gametes. Indeed, in its 2007 report *Public health: ethical issues*, the Council highlighted that there are significant ethical difficulties inherent in taking such an approach, and **we endorse here the current approach to the allocation of bodily material based on clinical factors, such as the urgency of the person's condition and the compatibility of the available material.** [paragraph 7.4] Rather, we are considering the issue from a policy perspective and asking the question: *What action should policy-makers take in response to these public health challenges?* In the context of organs, the challenge is often put to policy-makers that the current shortage constitutes a national emergency, in response to which radical measures would be justified. We highlight here the central role of public health initiatives in limiting the scale of that emergency in the first place.
63. In the case of organ transplants, we recognise, of course, that there are many existing public health initiatives supported by UK health departments that aim to reduce levels of (among others) the diseases that contribute to the growing demand for donor organs. **We argue that it is crucial that the policy-makers and health professionals concerned with organ transplantation should also explicitly highlight these contributory causes in relation to the 'gap' between demand for, and supply of, donor organs. In so doing, they could both add weight to the arguments surrounding the role of government in promoting good public health, and also act to raise public awareness of the avoidable causes of some organ failure.** [paragraph 7.6]
64. As we have noted in several other contexts in this report, the position regarding gametes is rather different from that of organs. While it is broadly accepted that it is appropriate for the public health agenda to include consideration of diseases that may impact on later fertility, there is no such consensus that any state-sponsored organisation should seek to influence childbearing patterns, such as the age at which women have children. We note, however, that the state *has* taken a role in discouraging teenage pregnancy, and that the NICE guidelines on fertility services specifically refer to age in that the recommendations on access to IVF services apply to women aged between 23 and 39 years. There is thus a precedent in public interest in the age of childbearing. The factors that influence the age at which women have their first child are complex – and many relate to social and economic issues well outside the range of this report. Nevertheless, we suggest that there is a potential role here for public health education and advice to improve awareness among women about the consequences of delaying childbearing.

Public and private concerns

65. Any consideration of the role of intermediaries, whether in the form of individuals or of organisations, inevitably raises the question of what is a matter of public interest (with the connotation that the state or state-sponsored organisations, in particular, might have duties to act); and what is essentially private (in this context emphasising non-interference by the state or others). First we consider explicitly the **role of the state** in responding to the mismatch between demand and supply for bodily material in medicine and research. We return here to the idea of the state as the 'steward' of good health, and reiterate the stance that **the underpinning concept of the state as steward of public health is equally applicable to the responsibilities of states with respect to the donation of bodily materials.** [paragraph 7.12] In our view, this stewardship role is as applicable to the donation of reproductive material as it is

to other forms of bodily material, notwithstanding the view (very firmly expressed by some) that fertility is essentially a private concern.

66. We have emphasised that the role of the stewardship state also includes taking action to minimise inequalities and to promote the welfare of those who would, without positive action, be excluded from benefits or services. In the context of donation, black and minority ethnic populations are significantly less likely to become donors (across a range of different forms of bodily material). Where immunological differences mean that low levels of donation from particular ethnic communities translate directly into particular difficulties of access for potential recipients from these communities, then this leads to clear difficulties for the NHS in responding equitably towards all its patients. **We therefore suggest that a stewardship state has a direct responsibility to explore the reasons why some populations are hesitant to donate, and if appropriate to take action to promote donation.** [paragraph 7.15]
67. Second, we consider the issue of **research**. It is only too easy for any consideration of the donation of bodily materials to concentrate on their use in direct treatment, and overlook, or take as of secondary importance, their possible research uses. **We state here our view that research, and the future health benefits that research seeks to bring, are of vital public interest.** [paragraph 7.16] The stewardship role of the state includes supporting and facilitating environments in which health-related research may flourish. Much health-related research using tissue or healthy volunteers is, of course, carried out within the private (ie commercial) sector. **We consider, however, that while such research may lead to significant financial gain, such private interests do not in themselves extinguish the public good of what they produce:** that is, the treatments and medicines on which all health systems (public and private) and individual patients (private individuals, members of the public) rely. [paragraph 7.17]
68. We note the concerns that financial gain arising out of material that has been donated freely may be seen by some as 'unjust enrichment'. We do not, however, support the argument that the individual whose donated bodily material has been used in research that ultimately leads to high financial returns should, in retrospect, exercise a claim to share in these profits on a personal level. Any commercial return would be many years after the initial donation, and the particular contribution of any individual would in most circumstances, be impossible to measure. We suggest therefore, that although it is clearly just that commercial companies in such circumstances should seek in some way to share the financial benefits of their research more widely, such benefit-sharing should take place in a wider context, rather than in response to the financial potential of bodily material from particular individuals.
69. Two potential ways in which such benefit-sharing or partnership might emerge include: first, active financial support from the commercial sector for tissue banks as a „public good“ for researchers from all sectors; and second, the development of ongoing relationships between tissue donors and the research teams (whether in the public, voluntary or commercial sector) whose work depends on access to their samples. Such a relationship between donors and recipients (in the form of research organisations) provides one way in which the 'gift relationship' between donor and recipient may be both maintained and mutual. Such a 'relationship' should not, of course, be imagined as a personal relationship: rather, the donor should be treated (if they wish) as part of a recognised community of research participants.
70. Third, questions of what is public and what is private also apply to the question of the potential for **property rights in bodies and body parts**. We suggest that often when people talk about 'owning' their own bodies or body parts, even if they use the language of property, their primary concern is with *control* over those materials: with the right not only to give or withhold consent to material being removed in the first place, but also to have some say over its future use. While property may be understood as a 'thing', an item owned, it can also be understood in terms of rights, and such rights need not be seen as full rights of ownership. For example, property may be viewed as a 'bundle of rights', such that the bundle may be dismantled into 'sticks' including rights to buy, sell, use, transfer to another, lend to another, exclude others from, and so forth. We suggest that greater clarity will be achieved by giving attention to the specific *elements* of

the 'bundle' of rights that we may wish to accord to people with respect to their body parts, and how these may be appropriately protected and promoted.

71. While the legislative frameworks of the Human Tissue Act and the Human Fertilisation and Embryology Act provide mechanisms for safeguarding some aspects of donors' rights, particularly with respect to consent, they are far from complete. Unless a wider range of remedies for the source of material (for example compensation if donated materials are used outside the scope of the granted consent) is developed through legislation, it seems likely that further attempts will be made in the courts to develop property rights to protect donors' interests. **We recommend that, by whatever means the law develops in this area, a clear distinction should be retained between the property rights of the source of the material with respect to control and compensation (that is, compensation for misuse rather than recompense in the form of economic gain), and property rights with respect to income.** [paragraph 7.20]
72. Finally, we raise the question of public interest in the issue of cross-border health care and questions of **national self-sufficiency**. **We endorse the current international consensus, expressed through the Declaration of Istanbul, the World Health Organization Guiding Principles and other statements, that 'organ trafficking' and 'transplant tourism' should be banned. We further emphasise the importance of concerted action being taken to enforce this stance, so that such practices cannot continue with impunity.** [paragraph 7.22]
73. The situation, however, is potentially rather different where the activities in question – for example the selling of gametes – are perfectly legal in the country of origin. The question then arises whether there can be any public interest in seeking to exert control over individuals travelling abroad to access such treatment, or over NHS institutions obtaining materials that have been provided in such circumstances. Concerns about individual liberty make it hard to imagine circumstances in which individuals seeking treatment that is lawful in the destination country should be prevented from travelling. However, UK regulators need to consider the action they should or could take if clinics and doctors regulated within the UK refer patients abroad for treatment that is forbidden in the UK.
74. EHSRE takes the view that “if a home practitioner refers the patient to a specific clinic, the practitioner shares a responsibility for the general standards used in that center (such as the complication rate). The specific treatment of the individual abroad remains the responsibility of the local professional team.” We agree. **We conclude that, where clinics and professionals within the UK make arrangements to refer patients to clinics and professionals abroad, they should share professional responsibility for the general standards prevailing at the receiving centre. Such 'general standards' include factors such as the protocols used to recruit donors (with particular reference to the hazards of using intermediate agencies for such recruitment) and the routine measures taken by the clinic to safeguard the welfare of donors. Regulatory bodies such as the General Medical Council should maintain general oversight in this area, in the same way as they oversee other aspects of professional standards.** [paragraph 7.24]
75. We further note that, while the ESHRE guidance highlights the importance of protecting against the abuse of donors coming from abroad, and guarding against trafficking, in the European context, these concerns clearly arise worldwide. We also note that various international statements on the donation and use of bodily material, such as the WHO Guiding Principles, exclude reproductive material from their remit. **We recommend that the World Health Organization should develop appropriate guiding principles to protect egg donors from abuse or exploitation.** [paragraph 7.25]
76. Once bodily material has been separated from its source, it, too, readily crosses borders: for example much of the plasma used in the UK comes from abroad sourced from paid blood

donors. We emphasise here the central importance of transparency, and suggest that one way of achieving such transparency might be through a 'fair-trade' labelling system, building on the existing safety and quality requirements of the EU Tissues and Cells Directive, together with relevant professional standards. Where payment is currently made to the overseas donors of material imported into the UK, the same set of concerns set out in paragraph 29 should be considered in relation to whether such payment is ethically acceptable.

77. Finally, we consider to what extent there is a public interest in seeking to ensure that individuals do not feel tempted to 'get round' UK regulation in this way: in other words, what, if any, duty is there on the state (or other interested organisations) to ensure that there is a sufficient supply of bodily material donated within the UK so that demand is not simply diverted to other, potentially less-scrupulous, sources? We conclude here that while the existence of such 'cross-border health care' certainly constitutes evidence of the *extent* of the pressure for certain forms of bodily material within the UK, such a consideration cannot be a deciding factor in policy-making. **We have already argued that the state has a stewardship role in maximising the donation of bodily materials, where these have the potential to contribute to improved health, and within ethical limits. To that extent, and no further, the aim of national self-sufficiency is clearly laudable. However, where this national self-sufficiency cannot be achieved without taking action that would otherwise be regarded as unethical, the fact that people may still choose to travel abroad should not force a change of policy.** [paragraph 7.27]

Blood and cord blood

78. The various systems currently in place within the UK for facilitating blood donation clearly already seek to minimise physical barriers for those inclined to donate. Barriers to blood donation are not, of course, only physical, and as in organ donation there may be other factors hindering particular communities from feeling able to donate. Differences in donation levels become very important if factors such as immunological requirements mean that lower donations from particular communities render the NHS unable to respond to patient need in an egalitarian way. In such circumstances, we consider that the intermediary organisations concerned, such as the National Blood Service, have a duty to engage with communities, both through dialogue to seek to understand concerns, and through direct promotion of the benefits of donation to the community. We commend here the work of the National Blood Service and the African Caribbean Leukaemia Trust, for example, in initiatives such as Daniel De-Gale week, to encourage both blood and bone marrow donation from black and mixed race communities.
79. By contrast with blood donation by adults, the idea of obtaining **cord blood** from the umbilical cord, in order to obtain stem cells from a baby at birth, has been much more controversial, particularly where the cord blood is subsequently stored only for private use. We note the growing evidence as to the potential value of *publicly-accessible* sources of stem cells, and the procedures recommended by the Royal College of Obstetricians and Gynaecologists to protect the welfare of mothers and babies where donation of cord blood is considered. We conclude that the collection of cord blood in these circumstances for public use is an example of a justified public intervention, and endorse the work of the NHS Cord Blood Bank, Anthony Nolan Trust and others in facilitating the collection of cord blood for this use. We note the recent report from the UK Stem Cell Strategic Forum calling for a significant increase in the UK's 'inventory' of cord blood and recommending that a UK Stem Cell Advisory Forum should be established in order to manage a UK cord blood inventory, along with a UK stem cell registry and a database of patient outcomes following transplantation. **We endorse these recommendations.** [paragraph 7.32]

Organs

80. Our approach to the donation of bodily material, focusing on intermediary professionals and organisations, is, of course, far from novel. Such an approach was at the heart of the recommendations made by the Organ Donation Taskforce. **The Working Party endorses the Organ Donation Taskforce's focus on tackling the structural problems that have, in the**

past, hindered the optimal use of the organs that are potentially available. [paragraph 7.33]

81. Both centralised and local aspects of the English NHS are currently experiencing significant levels of organisational restructuring; moreover, while the NHS has been protected to a degree within the current spending round, there is continuing and ongoing pressure on health budgets. **There is clearly a risk that, in the face of such organisational changes and pressure on budgets, valuable systemic improvements that have led in recent years to significant increases in the number of organs made available for transplantation might be lost. We recommend that the Department of Health should monitor closely the impact of these changes on organ donation services, and be prepared if necessary to act to protect systems that have been shown to work well.** [paragraph 7.34]
82. We have indicated that some population groups within the UK, in particular South Asian and African Caribbean communities, are less likely than others either to sign the Organ Donation Register, or to agree to the donation of the organs of a deceased family member. As a result, the NHS experiences difficulties in responding equally to need for donated material within these communities. The Council is aware of the work undertaken by the Organ Donation Taskforce in seeking a better understanding of how religious belief may affect the possibility of organ donation; and of significant research currently being funded by the National Institute for Health Research (NIHR) into ethnicity, donation and transplantation. An overview of the current evidence with respect to inequalities in donation and transplantation, published by the Race Equality Foundation in 2011, argued that while the UK is recognised as being “at the forefront worldwide” in many of its initiatives with regard to culturally competent organ donation educational materials, the success of these initiatives has been limited by a lack of a clear strategy and implementation plan bringing together the various strands of a multi-faceted problem.
83. We note that this is a highly complex area, and that we have not been in a position to collect evidence on this issue that might enable us to make specific recommendations as to appropriate actions. We therefore limit ourselves here to highlighting what we believe is an important ethical position: the relevance of our notion of the stewardship role of the state. **That stewardship role includes a duty to take positive action to remove inequalities that affect disadvantaged groups or individuals. In this context, the stewardship role of the state (exercised here by intermediary bodies such as NHS Blood and Transplant and individual hospital trusts and professionals) includes taking action actively to promote donation, in order to ensure that the NHS is able to offer fair access to donation services to all UK residents.** [paragraph 7.38] Such an awareness of the stewardship role of the state in this respect highlights the importance of ongoing dialogue not only at central level between NHSBT and community and faith leaders, but also at the level of individual NHS trusts and their local communities. **We endorse the call of the Race Equality Foundation for a clear strategy and action plan to take forward the lessons emerging from the research in this field.** [paragraph 7.38]
84. While considerable effort has gone into improving cooperative working in the area of organ transplantation, such cooperation does not necessarily extend across different fields of donation. The ODR, for example, does not make any reference to donating either organs or tissue for research. While we recognise that logistical challenges may limit the extent to which the current system established to facilitate deceased organ donation for transplantation may become the single route for all forms of deceased donation, we reiterate that research should not be seen as a peripheral or 'second-class' use of bodily material. An understanding of research as a mainstream use of donations has implications both for the ways individuals are encouraged to authorise the donation of material in advance of their own death, and for the ways in which families are approached after their relative's death. **We suggest that routine information about the Organ Donor Register should include explicit reference to the**

potential research uses of organs and tissue, and that potential donors should have the option of authorising such uses in advance. [paragraph 7.40]

85. The possibility of donating material for research use should similarly be routinely raised with the person's family when authorisation for the removal and use of organs or tissue is sought after death. We recognise that there are some concerns among transplant professionals that such requests risk distressing families, leading to their refusing to agree to a transplant that they might otherwise have granted. Others argue that, if properly approached, families appreciate the potential value of contributing to research. We therefore recommend that such an approach should first be piloted, with the impact both on donation rates and on families' experiences of being approached for donation being carefully monitored. **Should such a pilot scheme prove successful, we recommend that the possibility of donating for research purposes (distinguishing between research as part of the transplantation process, and research undertaken with material that would otherwise not be used for transplantation) should be included within the standard consent/authorisation documentation for deceased donation.** [paragraph 7.41]
86. Finally on the issue of organ donation, we note the importance of robust information systems both in ensuring proper use of donated material and in maintaining trust among the general public. A recent independent review into errors made in recording organ donation preferences on the ODR highlighted how the Register was being used for operational functions for which it was never designed, and recommended that "NHS Blood and Transplant should design and commission a new register which will be better equipped to deal with the operational demands now placed on it." **The Working Party endorses this recommendation. It should not be the case that the public's willingness to donate is undermined by information technology systems that are unable to account accurately for potential donors' preferences.** [paragraph 7.43]

Tissue

87. In contrast to most other forms of bodily material, tissue for therapeutic use within the UK is usually sufficient to meet demand. One reason for this may be that the potential donor 'pool' – the number of those who die in circumstances in which they can become a tissue donor – is much larger than in deceased organ donation. However, NHSBT Tissue Services also appear to offer an example of how good infrastructure may contribute to meeting need by making it as easy as possible for people who are willing to donate to do so.
88. Considerable access issues, however, are reported in connection with tissue for research use, despite apparent willingness on the part of both patients and members of the public to donate if asked to do so. Factors cited as problematic include concerns around the use of generic consent; a lack of willingness at times to share samples and their associated data; funding difficulties; and licensing and governance arrangements that were perceived to be disproportionate and overlapping.
89. A 'vision document' on human tissue resources published in 2011 by UK research funders is very clear that **generic consent** for the use of tissue should always be sought unless there is good reason in a particular case not to do so. This recommendation applies equally where researchers are seeking consent for a specific research project: additional generic consent should also be sought, so that any material not used up in the initial project may be made available for other research use via a tissue bank. The funders, moreover, aim to ensure widespread adherence to this principle, by making the seeking of generic consent in this way a funding requirement.
90. **We endorse the research funders' position that it is appropriate routinely to seek generic consent (where necessary in addition to specific consent) for the research use of blood and tissue.** [paragraph 7.48] We make the additional observations listed below:

- Generic consent need not mean 'blanket' consent. We have already emphasised the potential value of an ongoing relationship between donors and researchers as a meaningful way of recognising donors' continuing interests in their donated bodily material and of emphasising the importance of the 'relationship' in the notion of the gift relationship. Such a relationship need not be burdensome to the individual researcher: examples of good practice already exist in the form of dedicated webpages or electronic newsletters providing general information for donors on the progress of research. However, we recognise that this form of 'broad' consent is likely to be more applicable to circumstances where the possibility of donation to a particular tissue bank is known at the time of donation. It may be less applicable where generic consent is sought in the context of a specific research project, with the aim simply of protecting the possibility of future use and avoiding waste.
 - We also highlight the possibility of 'tiered' consent, where it is possible to categorise particular uses that are known to be controversial, and hence enable donors to consent to some, but not all, unknown future uses. Clearly, in order to offer this option to potential donors, researchers will need to be confident that information systems are in place that will accurately record the donor's preferences.
91. **We further endorse the funders' commitment “actively [to] develop and promote detailed guidance on seeking generic consent, incorporating views of patient and public groups”. We recommend that the process of developing the guidance should involve consideration of the 'broad' and 'tiered' approaches to consent outlined above. [paragraph 7.49] In addition, we recommend that the Medical Research Council and other research funders should work to increase public awareness of the key role of donated tissue in scientific and clinical research. [paragraph 7.50]**
 92. On the question of **willingness to share samples** and associated data, we note that the use of tissue samples for research purposes in any setting, public or private, has the common goal of improving understanding of disease in order to improve patient care. In pursuit of that goal, there is a general acceptance that an appropriate approach is of fair and equitable access to samples that have been legally and ethically collected, based on scientific merit. **We conclude that where material is freely donated by patients or by members of the public, it is not acceptable for individual researchers or research groups to hinder, inhibit or refuse access to other researchers for scientifically valid research, unless there are sound reasons for doing so. Indeed, we take the view that where material has been donated for research use, there is an ethical imperative to make the most efficient use possible of it. [paragraph 7.52]**
 93. We note that the UK research funders' vision includes strong measures to promote better sharing of samples, with future funding to be dependent on applicants meeting a number of criteria including registering collections in a publicly accessible directory, and making appropriate arrangements for fair access. We endorse this approach. **We also welcome the funders' further commitment to ensuring that there is clear guidance on how the interests of investigators who invest time and effort in sample collections are recognised. We note that the UK funders make reference to the importance of ensuring that “funding mechanisms for long-term storage and curation are considered”, and recommend that particular attention should be given to this issue in initial funding decisions. [paragraphs 7.52 and 7.53]**
 94. A more fundamental question of principle arises in connection with the **funding** of major tissue resources. While access to samples is sought by those working in the public, charitable and private sectors, the samples themselves are donated almost entirely from within the public sector (the NHS), and tissue resources may be conceptualised as a 'public good', with donors providing their material as an act of public benefit. The question therefore arises as to whether it is appropriate for the commercial sector to contribute in some additional way to the costs of

maintaining tissue banks, to reflect the fact that their one of their ultimate aims, unlike that of public and charitable sector researchers, is to make profit for shareholders.

95. The Council's 1995 report *Human tissue: ethical issues* specifically recommended that tissue banks should operate on a not-for-profit basis, a recommendation which we support. We also repeat our earlier observation, that bodily material donated freely by NHS patients and the general public should be understood as a public good. **We conclude that it is appropriate for commercial companies to make an explicit, and additional, contribution, in some way, to the costs of maintaining these public goods to reflect the value of the public's donation. We therefore recommend that any prospective sample collection for research (whether national or local) should be underpinned by a business plan that includes funding contributions from the full range of public, charitable and private sources, depending on where research users for the particular collection are likely to be located. Any such business plan should ensure that the financial value of the materials that patients and members of the public have freely donated should be recognised as being on the 'public' side of the balance sheet.** [paragraph 7.58]
96. Finally, we address the issue of **governance** arrangements. **We reiterate here our view that good governance systems, accompanied by transparency of process, are an essential requirement if potential donors are to have the trust necessary for them to contemplate donation in the first place.** [paragraph 7.61] Patients and the public are only likely to give generic consent for research, for example, if they are able to trust in the integrity, not only of the individual professionals involved, but in the organisational systems that will be required to ensure that their consent is properly recorded, their donated material is properly stored and handled, and the research they wish to support is appropriately facilitated.
97. In response to widespread concerns about the fragmented nature of research regulation, the Academy of Medical Sciences recommended in early 2011 that a new overarching „Health Research Agency“ (HRA) should be established to oversee the regulation and governance of health research. **We endorse the overarching aim of simplifying and clarifying research regulation, with particular reference both to the points of difficulty highlighted above and to the ethical requirement of good and responsible governance. We do not take a stance on what particular form such governance ought to take; we do, however, commend the ethical approach taken in this report to those responsible for regulation of this area in the future.** [paragraph 7.62]
98. We conclude our consideration of tissue donation by highlighting the central importance of ensuring the necessary **infrastructure** is in place before people are actively encouraged to donate. The point was made repeatedly to the Working Party that it can be very distressing to offer to donate material but for the system to be unable to meet the expectations it has raised. This issue arises specifically in the context of seeking material from deceased donors for research. **We recommend that the National Institute for Health Research and the Medical Research Council should take a lead in discussing with research organisations in both the academic and commercial sectors, and with NHSBT Tissue Services, whether there is sufficient demand for a more structured approach to access to tissue from deceased donors for research purposes around the country.** One possible output of such discussions could be the creation of model guidance on acceptable procedures to follow should individual NHS trusts, companies or universities wish to set up local arrangements to support local research. [paragraph 7.64]

Gametes

99. We commented earlier on the striking contrast between the national infrastructure established to maximise blood and organ donation, with the absence of any similar coherent structure in respect of gametes. We recognise that there are significant differences between these forms of donation that may have led to these differences of approach: first, that blood and organ donation have much greater public acceptance than gamete donation; and second, that both blood and organ donation take place firmly within the NHS, while infertility treatment and

gamete donation take place predominantly (although not solely) in the private sector. However, we do not accept that these differences are sufficient to justify such a wholesale difference of approach.

100. **We conclude that there should be a coherent and managed infrastructure for egg and sperm donation, on the lines of the structures currently in place for organ donation.** [paragraph 7.66] We note that, over ten years ago, the HFEA proposed that “serious consideration” should be given to the idea of such a national or regional 'donor service'. **We recommend that the Department of Health, in consultation with the HFEA and its successor body/bodies, should initiate consultation with clinics as to how such an infrastructure could best be created,** drawing as appropriate on the lessons of recent initiatives such as the 'hub and spoke' model in Manchester [paragraph 7.67]. We emphasise that by 'infrastructure' we do not necessarily mean a new organisational entity. The precise shape or legal status of the infrastructure will be of much less importance than its overall aim of creating an organisational framework able to develop the best possible practice in handling all aspects of the recruitment of donors on behalf of clinics.
101. In recommending the establishment of a pilot scheme to evaluate the effects of offering financial reward to those willing to come forward as egg donors for *research* (see paragraph 57), we noted that the risks of repeated egg donation are unknown, and potentially of concern, and that institutional protections within the system would be important. **We recommend that an essential part of the pilot scheme should be the development of protections both to limit the number of times a woman may donate eggs for research purposes, and to guard against the inappropriate targeting of potential donors in other countries.** [paragraph 7.68]

Healthy volunteers in first-in-human trials

102. The role of healthy volunteers in first-in-human trials has been considered in this inquiry primarily as a source of comparison with the donation of bodily material. We therefore limit ourselves to making the following observations with respect to two themes that have arisen earlier in this report: partnership and governance.
103. We have suggested above that the recognition of a partnership between donors of bodily material and future users of that material may be valuable, especially in the context of long-term research studies. We suggest here that the concept of partnership may also be of some value in conceptualising the relationship between healthy volunteers in first-in-human trials and the researchers and institutions running the trial. While recognising that in some cases the 'partnership' may be short, we consider that the approach still has value, because it emphasises the mutual nature of the relationship: the contribution of the volunteer is recognised not only in payment but also through an acknowledgment that she or he has an interest in the outcome of the project.
104. Finally, we consider the role of governance. If the research in question has been subject to ethical and scientific review and found to be satisfactory, then the key question for intermediaries is not whether it is appropriate to recruit participants at all, but rather whether there are particular ethical concerns about particular participants, or categories of participant. One class of participant about whom there could legitimately be professional concern would be those who 'over-volunteer' for paid research, either by volunteering for more than one trial at once, or by participating in serial trials (or both). We suggest that a key element of governance will be for trial organisers to take responsibility for actively ensuring that potential participants are not 'over-volunteering'. One way in which this might be achieved would be through compulsory use of the 'TOPS' database designed to prevent over-volunteering: trial organisers could be required both to register details of all participants on the database, and to check it closely when recruiting to a new trial. **We welcome the voluntary accreditation scheme for units conducting phase 1 trials, established in 2008 by the Medicines and Healthcare products Regulatory Authority (MHRA), which requires that accredited units must have a**

procedure in place to address over-volunteering. We recommend that the MHRA should monitor closely any units that do not apply for accreditation, with a view to making requirements to guard against over-volunteering compulsory if necessary. We further recommend that the National Research Ethics Service should consult on the possibility of limiting the total number of first-in-human trials in which any one individual should take part. [paragraphs 7.73 and 7.74]

Afterword from the Working Party chair (Chapter 8)

105. There are all kinds of ways in which people become involved in the health of others. But there has to be something quite special about that involvement when it draws on other people's own bodily material. In producing this report, the Working Party has tried to keep that sense of „something special“. Whatever the source, whether from someone known or unknown, from a living body or a deceased one, and whatever the body part in question, from a whole organ to a drop of blood contributing to a research project, we have been mindful that such material has come from the body of a person. [paragraph 8.1]

Introduction

In 1995, the Nuffield Council on Bioethics published its report *Human tissue: ethical and legal issues*. The report received widespread recognition for its analysis of the ethical concerns arising in the use of human bodily material for a range of purposes, and for the framework it provided for those working with such material.¹ Why, therefore, has the Council decided to return to this topic?

Much has changed since 1995. The regulatory landscape has altered beyond recognition, both in response to new scientific and clinical developments and in response to public opinion. Notably, two major pieces of legislation in the UK, the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, have attempted to respond to the public concerns first voiced in 1999 regarding widespread 'tissue retention' in UK hospitals.

The outcry in 1999 in reaction to this discovery of tissue retention, with particular distress where the material in question was from the bodies of dead children, demonstrated very clearly how in many cases 'clinical' views of bodily material differed markedly from those of the general public.² While some of the retained material, especially that at the Alder Hey Children's Hospital, was kept non-consensually in circumstances that no professional would defend,³ in other cases, material had been taken and stored with what was believed to be proper consent, with the very proper purpose of carrying out clinical research. In other cases, material had been taken with the best of intentions for research purposes without explicit consent in the belief that in such cases consent was not legally or ethically required, given that the prevailing law was couched in terms of 'absence of objection'.⁴ One significant problem, however, was that for most people, the word 'tissue' conjured up the idea of something very small, a few cells – not a whole organ, for example, and certainly not a whole heart. Thus, even where consent was sought, there was a significant disjunction between what professionals understood parents to have consented to, and what those parents themselves understood.

The particular distress caused by the retention of hearts of children who had died following surgery at the Bristol Royal Infirmary⁵ demonstrated a further distinction between a clinical approach to tissue and that of patients and their families. From a clinical or scientific perspective a heart can be seen as a piece of machinery that has a key role in a living body, and no role in a dead one. From the non-clinical⁶ perspective, however, hearts have many other meanings and associations. So do other parts of the body: it is striking that those who are willing to donate their kidneys for transplantation after death may nonetheless withhold consent for other body parts, in particular hearts and eyes (corneas).⁷ While it is unlikely that these distinctions between 'clinical' and 'non-clinical' attitudes were not also present in 1995, it was only in 1999 that the nature of these widespread misunderstandings clearly emerged. Moreover, while the events at Alder Hey and elsewhere were mainly concerned with

¹ Indeed, some of its recommendations, for example those regarding the importance of the 'respectful disposal' of bodily material (see paragraph 4.4 of the 1995 Report), were prescient of the public concerns expressed four years later when the extent of 'tissue retention' became widely known.

² Campbell AV, and Willis M (2005) They stole my baby's soul: narratives of embodiment and loss *Medical Humanities* 31: 101-4.

³ See, for example, the account of the "remorseless increase in the number of organs stored in containers", the "large majority" of which remained untouched at Alder Hey: see House of Commons (2001) *The Royal Liverpool Children's Inquiry report* (London: House of Commons), p4, paragraph 1.4.

⁴ Human Tissue Act 1961, section 1(2).

⁵ The Bristol Royal Infirmary Inquiry (2001) *The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995*, available at: http://www.bristol-inquiry.org.uk/final_report/the_report.pdf.

⁶ The 'clinical/non-clinical' distinction is obviously not a simple one of profession: people with no link to the health professions may have 'clinical' attitudes to their bodies, and individual health professionals may assign 'non-clinical' meanings and associations to parts of their own bodies.

⁷ Eighty nine per cent of those registered on the Organ Donor Register (ODR) as at 31 March 2011 were prepared to donate all of their organs. Of those not prepared to donate all of their organs ('restricted donors'), 86 per cent were not prepared to donate their corneas, and 25 per cent were not prepared to donate their heart. In terms of the total percentage of all ODR registrants, this comprises 9.7 per cent and 2.9 per cent respectively: NHS Blood and Transplant (NHSBT), personal communication, 5 August 2011.

material retained after death – as opposed, for example, to diseased material retained after an operation – the legislative frameworks put in place in the subsequent years covered material from both living and deceased individuals. All this in turn has had an effect on public opinion. Fifteen years later, the endorsement in the Council's 1995 report of the practice of 'surplus' tissue after an operation being used for research with need for neither consent nor review by a Research Ethics Committee⁸ seems difficult to justify at the level of a general principle. Yet the demand for bodily material, whether for medical treatment or for research, remains as pressing as ever.

The present report notes some of the reasons underlying this demand for bodily material that apply both in the UK and elsewhere, including: changing patterns of diseases; the development of stem cell and regenerative medicine; the completion of the sequencing of the human genome in 2003, leading to new genomic technologies such as genome-wide association studies (GWAS) and high-throughput sequencing,⁹ and an increased need for human material for research to reduce, refine and replace animal research.¹⁰ Attitudes towards medicine and medical care have been changing as well, in the context of a general shift in society towards a greater focus on care of the self, and the role of the patient in determining how health services should be delivered,¹¹ and the increasing expectation that medicine will be able to intervene to overcome problems formerly regarded as insoluble. Consumerism is one manifestation of this, as discussed in the Council's recent report *Medical profiling and online medicine*,¹² there is also greater expectation of partnership between patients and their doctors,¹³ and a greater mixing of public and private medical care, including an increasing emphasis on partnership between the NHS and the pharmaceutical industry.¹⁴

It is, therefore, striking that, in this context of a more „consumerist“ approach to care, the traditional emphasis on the importance of unpaid and voluntary donation as the only means of obtaining bodily material for medical purposes continues to be widely upheld. While the general shift in attitudes to health care may have led to a new kind of awareness of the body and its potential value to others, there is little evidence to suggest that this has discouraged people from donating freely: we note, for example, that organ donation is on the increase. This is a delicate context, then, in which to suggest that as a society we need to do *more*; in which to say once again that, despite the generosity with which many already give, the demand for what people can give remains high.

We are dealing with an issue that does not seem to go away – the demand for bodily material for medical treatment and research. However, bodily material is not like any other, and the question of how it is obtained and used raises all kinds of further questions. This is where, for instance, the unpaid and voluntary nature of donation comes in: why is this aspect valued, and what are the ethical concerns to which this emphasis has been the response? The Working Party was asked to identify and consider the ethical, legal and social implications of transactions involving human bodies and bodily material in medical treatment and research. It was also asked to consider what limits there should be, if any, on the promotion of donation or volunteering.

It follows that this report is not seeking simply to re-visit the approach and conclusions of the Council's 1995 report in the light of the past 15 years' experience. Rather, it is attempting something broader. Its

⁸ See paragraph 4.2 of the 1995 Report.

⁹ Lander ES (2011) Initial impact of the sequencing of the human genome *Nature* **470**: 187-97.

¹⁰ Archibald K, Coleman R, and Foster C (2011) Open letter to UK Prime Minister David Cameron and Health Secretary Andrew Lansley on safety of medicines *The Lancet* **377**: 1915. See also: *Nature Immunology* Editorial (2010) Reduce, refine, replace *Nature Immunology* **11**: 971.

¹¹ See, for example, the implementation of the NHS improvement plan: Department of Health (2005) *Creating a patient-led NHS: delivering the NHS improvement plan*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4106507.pdf.

¹² Nuffield Council on Bioethics (2010) *Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age* (London: Nuffield Council on Bioethics).

¹³ General Medical Council (2008) *Consent: patients and doctors making decisions together*, available at: http://www.gmc-uk.org/static/documents/content/Consent_0510.pdf.

¹⁴ See, for example, Department of Health (2007) *Ministerial Industry Strategy Group: long-term leadership strategy*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_065170.pdf, and Association of the British Pharmaceutical Industry (2010) *Equity and excellence: liberating the NHS - white paper: ABPI submission*, available at: http://www.abpi.org.uk/publications/briefings/WhitePaperConsultation_ABPI%20submission_5Oct10_FINAL.pdf.

primary purpose is to seek to answer the question: *How far should society go in attempting to encourage or facilitate the donation of bodily material?* In approaching that question, our primary focus is on the issues for the donor arising around the act of donation, including questions as to the future use and governance of donated bodily material to the extent that they affect the donor's decision to donate. A consideration of broader governance issues falls outside our scope.

The possibility of donation may arise both during life and after death. The concern and distress caused by the retention of organs after death demonstrated the value very often placed on the physical body by those close to the deceased person, and it hardly need be added that, in life, too, people place value on particular aspects of their own body. Yet there is also ample evidence as to the enormous value human bodily material may have for others, in terms of lives saved, prolonged, enhanced, and even created, through transplantation, through fertility treatment and through medical research. In this report we attempt to assist deliberation on these questions, and to throw light on the tensions that arise when it comes to reconciling public need with individual feelings on the matter. As one respondent to the consultation commented: "Human biological samples can ultimately be provided only by individuals, not by organisations. If individuals do not accept that responsibility in sufficient numbers, the current system will fail."¹⁵

Although this report is primarily concerned with policy and practice in the United Kingdom (UK), we are of course aware of the global context. Patients, professionals, and indeed bodily material itself, may readily cross borders in response to demand and availability, and in accordance with differing regulatory approaches. We therefore highlight both the international dimension (for example where international statements or agreements exist) and examples of the diverse regulatory approaches taken in other jurisdictions. We note, too, the potential for regulatory changes within the UK to have an impact on others outside its national boundaries.

The first half of the report encompasses all forms of human bodily material made up of cells¹⁶ – including blood, tissue, organs and gametes¹⁷ – that may be provided by one person for the treatment of others or for research, without any expectation of personal health gain. We emphasise that our focus here is on treatment or research carried out with the aim of improving, maintaining, or limiting deterioration in health, and not on procedures carried out for cosmetic purposes alone, nor on material provided for non-health-related research or public display. We do not cover circumstances where material is taken from a person's body solely in connection with their own treatment ('autologous' donation), although we note that in day-to-day clinical practice procedures involving autologous donation will take place alongside the procedures involved in donating material for the benefit of others. Nor do we consider the specific issues raised by genetic research, although our general comments on research using bodily material will in many cases also be relevant for genetic research. Part I of the report also covers circumstances in which the living body may be 'loaned' for medical purposes: by participating as a 'healthy volunteer' in a first-in-human clinical trial (where new medicinal products are tested on healthy volunteers with no expectation of their receiving medical benefit¹⁸) or by bearing a child as a 'surrogate mother' on behalf of another person or couple.

It should be emphasised that, in setting itself such as broad remit in Part I, the Council is *not* starting with the assumption that a single approach necessarily could, or should, be used for the ethical regulation of all these forms of donation or volunteering of human bodily material. Rather, it has taken the view that much may be learned from *comparing* different forms of donation, their different regulatory structures, and the ethical assumptions that underpin these structures. Such comparisons

¹⁵ Professor Peter Furness, responding to the Working Party's consultation.

¹⁶ We include here material, made up of cells, that may subsequently be processed to create an acellular product, such as the processing of blood to separate out plasma.

¹⁷ We discuss these broad categories of bodily material further in Chapter 1, where we highlight how such categories are inevitably indistinct and overlapping.

¹⁸ Healthy volunteers in such trials (which are a small sub-section of all clinical trials) do not expect to benefit their own health, but choose to participate for other reasons (or combinations of reasons), such as financial reward or desire to help promote scientific knowledge in a particular medical field.

may help identify inconsistencies in approach that appear hard to justify; they may also help us elucidate important distinctions that lie beneath those differences in approach. Our aim, in taking this comparative approach, is first to provide a broad context in which to situate particular concerns, and then to sharpen our focus, as will be seen in the second half of the report (Part II), on a specific number of policy areas where recommendations, made on a clearly-articulated ethical basis, may usefully be made. We highlight here that there are some forms of donation covered in Part I, in particular the use of surrogacy arrangements and the donation of whole bodies for medical education and training, that are not covered separately in Part II, but which nevertheless played a very helpful comparative role in our deliberations.

If one factor that unites the many different forms of material covered in this report is that they have a single source (the body of a person),¹⁹ another is that the desired outcome of these actions is benefit to others, whether or not these others are in mind at the time.²⁰ In this report, we use the terms 'donor' and 'donation' as broad categories to cover transactions that people might think of as sacrifice, gift or loan, or as simply putting material at the disposal of others, as opposed to some form of 'taking' under coercion or even by seizure. Transactions involving buying and selling ordinarily share the characteristics of a 'voluntary act', but in the UK it is often thought that the voluntary nature of such transactions is compromised by the element of calculation or financial gain, and many people would contrast such transactions with the making of a gift. However, we follow general UK usage in keeping to the term 'donation' for all kinds of non-coerced disposal.²¹

Distinctions give rise to comparisons.²² We have already noted possible distinctions between bodily material from living individuals and bodily material from deceased individuals; and, indeed, the way the law now makes relatively little distinction between these has been the subject of complaint by some clinicians. Other key distinctions relate to the inducements or incentives that are permissible in the context of encouraging people to participate in these forms of bodily donation, and to the degree of control that the donor may have over the future use of what has been donated. To take two examples that appear to be at opposite ends of the spectrum of inducement: the National Blood Service (NBS) in the UK relies on voluntary donations of blood by altruistic donors, while the pharmaceutical industry may pay healthy volunteers significant sums to participate in the testing of new medicinal products. At first sight, there may appear to be very clear distinctions between the two cases that more than explain the regulatory differences. The National Health Service (NHS) is a public health service, from which anyone ordinarily resident in the UK is entitled to benefit free at the point of delivery, and in giving blood, donors may have the impression of giving their blood directly to another individual in need, as an act of public benefit in turn. First-in-human clinical trials, on the other hand, often operate on a commercial basis, with significant profits at stake if the product turns out to be effective; potential beneficiaries, however, seem a long way down the line – and indeed will often never materialise.²³

Yet, when more closely examined, these distinctions seem rather less clear. Blood is now rarely used 'whole' but is separated into components (red cells, white cells, platelets and plasma); plasma may be further processed to extract products such as albumin or clotting agents, although the plasma processed in this way in the UK is currently purchased from abroad because of the theoretical risk of variant Creutzfeldt-Jakob disease (vCJD) infection. Some first-in-human clinical trials are funded by the public sector, and the aim of all such trials (whether conducted on a commercial or public-sector basis) is to find new treatments, which will then be available to benefit individual NHS patients. Such

¹⁹ We use the term 'person' in this report to indicate a social being in relationship with other social beings.

²⁰ We include here basic scientific research, which has both the 'impersonal' value of the advancement of understanding but also the long-term aim of contributing to the health benefit of identifiable, albeit unknown and future, individuals.

²¹ We note here that others have taken a contrary approach: see, for example, Dickenson D (2008) *Body shopping: the economy fuelled by flesh and blood* (Oxford: Oneworld Publications). It is a matter of record that in coercive contexts, such as typify the global trafficking of organs, the term 'donation' is used as a gloss for circumstances that are far from free and voluntary: see, for example, Lundin SM (2010) Organ economy: organ trafficking in Moldova and Israel *Public Understanding of Science* (published online before print, 26 July 2010): 1-16.

²² Indeed, in drawing comparisons, the Working Party is doing what people do all the time in reflecting on their own circumstances.

²³ Approximately 11 per cent of new medicines that are the subject of first-in-human trials are finally registered: Kola I, and Landis J (2004) Can the pharmaceutical industry reduce attrition rates? *Nature Reviews Drug Discovery* 3: 711-6.

closer examination may or may not suggest new comparisons; it may also challenge us to consider more closely the ethical justification for these practices.

Part I

Chapter 1

Human bodily material in
medicine and research:
overview

Chapter 1 - Human bodily material in medicine and research: overview

Chapter overview

- 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,²⁴ 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

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'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);*
- 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.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 1946.²⁷ Blood is classified into four main groups, and giving someone blood from the wrong group may be life-threatening.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,²⁹ and plasma for processing into plasma proteins is currently sourced

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.

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".

²⁷ NHS Blood and Transplant (2011) *About blood*, available at: <http://www.blood.co.uk/about-blood/>.

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.

²⁹ NHSBT, personal communication, 7 February 2011.

from the US, primarily from a plasma supplier wholly owned by the English Department of Health.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).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.³² It is also possible in some circumstances for families to arrange for cord blood to be taken and stored in a 'private' bank, run on a commercial basis, for possible later personal use.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.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.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

³⁰ DCI Biologicals Inc.

³¹ Yoshida Y, and Yamanaka S (2010) Recent stem cell advances: induced pluripotent stem cells for disease modeling and stem cell-based regeneration *Circulation* **122**: 80-7.

³² NHS Blood and Transplant (2011) *The NHS Cord Blood Bank*, available at: <http://www.nhsbt.nhs.uk/cordblood/index.asp>; The Anthony Nolan Trust (2011) *How to donate: donate your umbilical cord*, available at: <http://www.anthonynolan.org/What-you-can-do/donate-your-umbilical-cord/How-to-donate.aspx>.

³³ See, for example, Cells Ltd. (2010) *Why choose cells?*, available at: <http://www.cellslimited.com/> and Cells4Life (2010) *Stem cell collection the Cells4Life way*, available at: <http://www.cells4life.co.uk/>.

³⁴ See, for example, Royal College of Obstetricians and Gynaecologists (2006) *Umbilical cord blood banking (Science Advisory Committee opinion paper 2)*, available at: <http://www.rcog.org.uk/files/rcog-corp/uploaded-files/SAC2UmbilicalCordBanking2006.pdf>, paragraph 6.3.

³⁵ See the NHSBT website for more details: NHS Blood and Transplant (2011) *British Bone Marrow Registry*, available at: <http://www.nhsbt.nhs.uk/bonemarrow/>. See also: Welsh Blood Service (2010) *Bone Marrow Donor Registry*, available at: <http://www.welsh-blood.org.uk/giving-blood/bone-marrow-donor-registry/> for details of the Welsh Bone Marrow Donor Registry, and The Anthony Nolan Trust (2010) *Join the Register*, available at: <http://www.anthonynolan.org/What-you-can-do/save-a-life.aspx> for the work of the Anthony Nolan charity.

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 **tissue**³⁷ 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.

³⁶ British Transplantation Society (2011) *United Kingdom guidelines for living donor kidney transplantation*, available at: <http://www.bts.org.uk/transplantation/standards-and-guidelines/>.

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.

³⁸ NHSBT Tissue services works with 75 hospitals to bank bone: see NHS Blood and Transplant (2010) *Tissue services*, available at: <http://www.nhsbt.nhs.uk/tissueservices/index.asp>. Around 4,000 heads of femur per year are banked: NHSBT, personal communication, 16 February 2011.

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.

⁴⁰ Youngner S, Anderson M, and Schapiro R (2003) *Transplanting human tissue: ethics, policy and practice* (Oxford: Oxford University Press), page xi.

⁴¹ NHS Blood and Transplant (2010) *Saving lives and improving lives: annual review 2009/10*, available at: http://www.nhsbt.nhs.uk/annualreview/pdf/22187_Annual_Review.pdf, p10.

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 procedure⁴³ 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.⁴⁴ 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 urine⁴⁵ – 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.⁴⁶ 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).⁴⁷ As a consequence of this diagnostic

⁴³ As many as 150 million samples of tissue are tested every year in the UK: see: Furness P, and Sullivan R (2004) The Human Tissue Bill *BMJ* **328**: 533-4.

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.⁴⁸ 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.⁴⁹
- 1.17 **Gametes** (eggs and sperm), and also **embryos**, may be donated for use in fertility treatment or research.⁵⁰ 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.⁵¹ 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.⁵² 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

⁴⁸ 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>.

⁴⁹ See: UK Biobank (2010) *Why is it important that I take part?*, available at: <http://www.ukbiobank.ac.uk/assessment/takepart.php>; Time (2009) *10 ideas changing the world right now: biobanks*, available at: http://www.time.com/time/specials/packages/article/0,28804,1884779_1884782_1884766,00.html.

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,⁵³ 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.⁵⁴ 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.⁵⁵ 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.⁵⁶
- 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;⁵⁷ or by parthenogenesis, where an unfertilised egg is stimulated to develop into an embryo.⁵⁸ 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.⁵⁹ When stimulated with specific growth factors, they can become cells of any body part. Researchers may request ESC lines from the UKSCB, but

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).

⁵⁷ Stojkovic M, Stojkovic P, Leary C *et al.* (2005) Derivation of a human blastocyst after heterologous nuclear transfer to donated oocytes *Reproductive BioMedicine Online* **11**: 226-31.

⁵⁸ Revazova ES, Turovets NA, Kochetkova OD *et al.* (2007) Patient-specific stem cell lines derived from human parthenogenetic blastocysts *Cloning and Stem Cells* **9**: 432-49.

⁵⁹ See: UK Stem Cell Bank (2011) *UK Stem Cell Bank homepage*, available at: <http://www.ukstemcellbank.org.uk/>.

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

⁶⁰ Information on the process of applying to the UK Stem Cell Bank is available on the Bank's website: UK Stem Cell Bank (2010) *How to access stem cell lines from the UK Stem Cell Bank*, available at:

<http://www.ukstemcellbank.org.uk/stemcelllines/obtainingstemcelllines/notestoresearchersaccessingstemcells.cfm>.

⁶¹ National Institute for Clinical Excellence (2010) *Donor breast milk banks: quick reference guide*, available at:

<http://www.nice.org.uk/nicemedia/live/12811/47522/47522.pdf>.

⁶² For more information, see: United Kingdom Association for Milk Banking (2010) *United Kingdom Association for Milk Banking: homepage*, available at: <http://www.ukamb.org/>.

⁶³ Human Fertilisation and Embryology Act 2008, section 54.

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

⁶⁵ Medicines and Healthcare products Regulatory Agency (2010) *About clinical trials for medicinal products*, available at: <http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Clinicaltrialsformedicinalproducts/index.htm>.

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.⁶⁶ Now covered by the Human Tissue Act 2004 and regulated by the Human Tissue Authority (HTA),⁶⁷ 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.

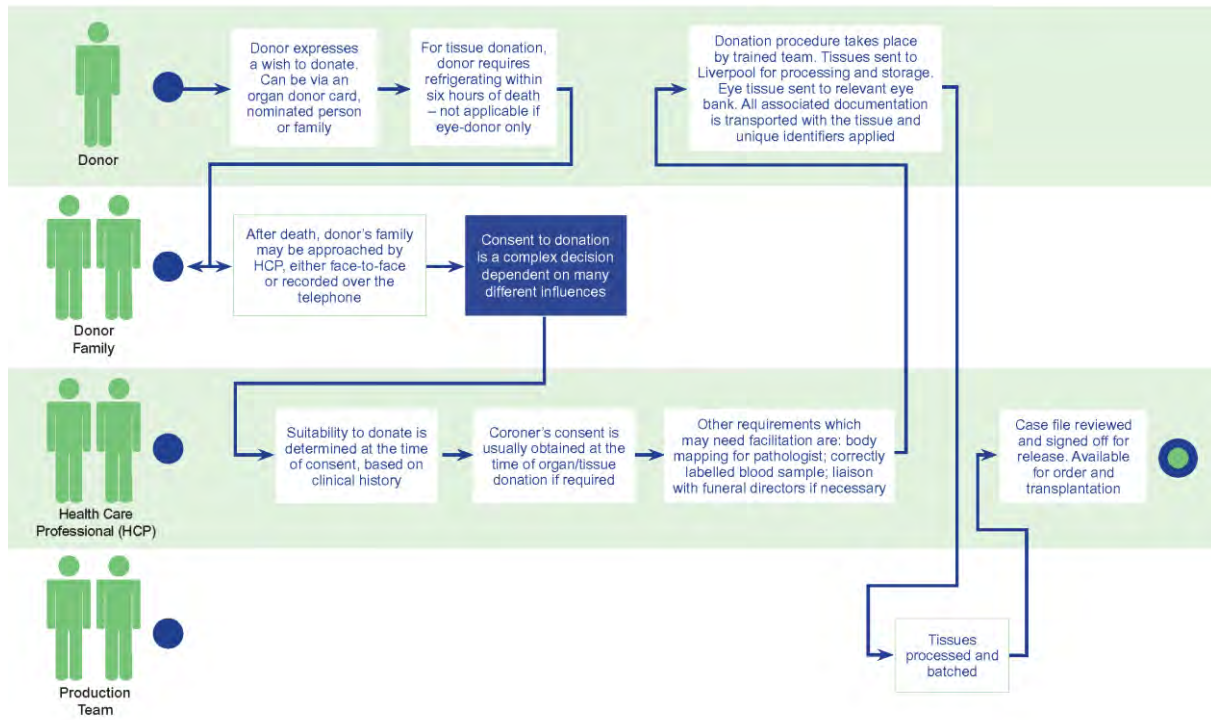
⁶⁶ Dada MA, and Ansari NA (1996) Origins of... the postmortem examination in diagnosis *Journal of Clinical Pathology* **49**: 965-6.

⁶⁷ The Human Tissue Authority (HTA) has no role in regulating anatomy teaching in Scotland. Guidance from the Scottish Government directs people who wish to donate their whole body to Scottish medical schools to contact individual medical schools directly: Scottish Government Health Directorates (2010) *Body donation factsheet*, available at: <http://www.scotland.gov.uk/Topics/Health/health/organdonation/bodydonationfactsheet>.

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.⁶⁸

Figure 1

Complex links between deceased tissue and organ donors and the recipient



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

⁶⁸ Figure 1 is adapted from an original diagram provided by NHSBT Tissue Services, August 2011.

surgeon.⁶⁹ Such an approach was direct both in terms of time (the donated material was used immediately or almost immediately) and in terms of the connection between donor and recipient (family member, close friend or colleague, or as in the last example coincidental link via the doctor). The transaction between donor and recipient was therefore a relatively straightforward one.

The limitations of this direct approach led to developments in cold storage techniques in the early 20th Century, but it was only during the Spanish civil war, with its large-scale casualties, that the 'indirect' method of blood donation became common: donors were recruited, their blood group identified, and their blood stored and dispatched to field hospitals. The direct link between donor and recipient was thus broken, and the role of intermediaries (those recruiting the donors, taking their blood, storing it, transporting it, and using it in the treatment of injured soldiers) became increasingly important. The nature of the transactions involved similarly became increasingly complex. After the Spanish civil war, the indirect method of obtaining bodily material both for the treatment of others and for research developed rapidly: the first 'blood bank' was in operation by 1937 at Cook County Hospital in Chicago; and the first cadaver eye bank was established in Odessa using eyes (packed in storage medium in glass containers) sent by rail from a Moscow trauma centre. The US Navy Tissue Bank, set up in 1949 as a research facility investigating how cadaver tissue could be transformed into stable medical products, promoted the use of 'freeze dried' material, including bone, skin and arteries, that could be easily stored, transported and reconstituted for use when needed.

Although there is no UK single supplier for tissue – with tissue provided from both public organisations and private businesses – NHSBT Tissue Services is the largest multi-tissue establishment in the UK, and coordinates most donations of cadaver tissue.⁷⁰ In addition, nine out of ten corneas transplanted in the UK are handled by the Corneal Transplant Service based in Bristol and Manchester, which is supplied with cadaver corneas by over 200 hospitals.⁷¹ Tissue banks of material for research purposes may be held by a wide range of bodies, including 'public' organisations such as NHS hospitals and universities, charitable or not-for-profit organisations such as medical research organisations, and commercial organisations, such as pharmaceutical companies.

Although the governance requirements of the Human Tissue Act are now encouraging organisational management of sample collections (as opposed to past practice where individual researchers collected samples for their own research), co-operation between tissue banks is still relatively limited. Networks of research tissue banks have emerged covering areas such as rare diseases, disease-specific charities and research groupings, but these, by their nature, tend to be narrow in scope. National and international efforts have focused on 'best practice' for tissue banks rather than delivering a mechanism for the comprehensive nationwide sharing of research samples. In the meantime a human 'biosample supply' industry has evolved internationally, with multiple providers competing in a market driven by, among other things, the biotechnology and pharmaceutical company search for biological markers (biomarkers) in human disease.⁷² Thus the transactions involved between the original 'source' or 'donor' of the material, the amount of processing of the material involved, and the commercial nature of some of those transactions, are becoming ever-more complex.

- 1.30 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)

⁶⁹ Pfeffer N (2009) Histories of tissue banking, in *Tissue and cell donation: an essential guide*, Warwick RM FD, Brubaker SA and Eastlund T (Editor) (Oxford: Wiley-Blackwell).

⁷⁰ Meeting with Dr Ruth Warwick, NHSBT, March 2010.

⁷¹ NHS Blood and Transplant (2009) *Cornea transplantation*, available at:

http://www.uktransplant.org.uk/ukt/newsroom/fact_sheets/cornea_transplantation_fact_sheet.jsp.

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.⁷³ 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.⁷⁴ It has now been reconstituted as a limited company also wholly owned by the Department of Health.⁷⁵

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

⁷³ Parry B (2008) Entangled exchange: reconceptualising the characterisation and practice of bodily commodification *Geoforum* 39: 1133-44.

⁷⁴ NHS Blood and Transplant (2010) *Saving lives and improving lives: annual review 2009/10*, available at: http://www.nhsbt.nhs.uk/annualreview/pdf/22187_Annual_Review.pdf, p7. See also: NHS Blood and Transplant (2011) *Small numbers, big hearts: annual review 2010/11*, available at: http://www.nhsbt.nhs.uk/annualreview/pdf/nhsbt_annual_review_2010-2011.pdf, p5.

⁷⁵ See: Bio Products Laboratory (2011) *Transfer of Bio Products Laboratory to Limited Co.*, available at: <http://www.bpl.co.uk/about-bpl/news/q/date/2011/01/05/transfer-of-bio-products-laboratory-to-limited-co/>. DCI and BPL Ltd are now part of the same holding company.

bodily material, and a wide range of circumstances, including diverse purposes,⁷⁶ 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

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.⁷⁷ 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.

Differences

- 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 (NGDT'S) 'Give a Toss' campaign⁷⁸).
- 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,⁷⁹ or in Sri Lanka during the civil war.⁸⁰ 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

⁷⁸ Third Sector (27 March 2007) *Sperm donation site comes in for criticism*, available at: <http://www.thirdsector.co.uk/channels/Communications/Article/646460/Sperm-donation-site-comes-criticism/>.

⁷⁹ See, for example, Waldby C, and Mitchell R (2006) *Tissue economies: blood, organs and cell lines in late capitalism* (Durham, NC: Duke University Press), pp1-6 (section entitled 'Blood, community, and September 11th').

⁸⁰ Simpson B (2009) 'Please give a drop of blood': blood donation, conflict and the haemato-global assemblage in contemporary Sri Lanka *Body & Society* 15: 101-22; Simpson B (2011) Blood rhetorics: donor campaigns and their publics in contemporary Sri Lanka *Ethnos* 76: 254-75.

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, melanesia and reproductive gift exchanges between British ova donors and recipients* (New York: Berghahn Books).

Chapter 2

Regulatory landscape:
overview

Chapter 2 - Regulatory landscape: overview

Chapter overview

- Regulations within the UK governing the donation, storage and use of bodily material generally include requirements for consent and safety, provision as to future control of material once separate from the body, and restrictions on commercial dealings in bodily material. Nevertheless, the detailed aspects of regulation vary significantly both in terms of the form of bodily material, and the purposes for which it has been donated.
- 'Regulation' may prohibit, require, or permit particular actions. Where regulation is permissive, its actual impact is likely to depend on the extent to which the permitted activity is supported, encouraged or, on the contrary, discouraged – and hence will be strongly influenced by the approach taken by relevant organisations. In the UK these at present include the Human Tissue Authority (HTA), the Human Fertilisation and Embryology Authority (HFEA), NHS Blood and Transplant (NHSBT), and individual NHS bodies. Both the HTA and HFEA are due to be abolished by 2015, with their functions absorbed into other statutory bodies, and the English NHS is currently undergoing a process of organisational change. This current state of fluidity in organisational and regulatory infrastructure has been important in the Council's consideration of the practical implications of possible policy recommendations.
- Although the primary focus of this report concerns donation practice within the UK, regulation of the donation and use of human bodily material cannot be confined within national borders. European Union (EU) legislation must be made effective within the UK, and international principles and declarations that seek to set minimum standards world-wide influence regulatory and public attitudes within individual countries. Both people and bodily materials cross national boundaries, and hence regulatory frameworks within other jurisdictions may have a direct impact on UK residents who choose to travel to other jurisdictions for treatment they are unable to access at home. Bodily materials used within the UK may be imported from other jurisdictions where they were donated under different regulatory frameworks; and in some circumstances material donated in the UK may similarly be used abroad.
- Bodily material thus circulates within a global market-place: while almost all countries prohibit financial gain arising directly out of the donation of bodily material (gametes being a common exception), money exchanges hands in connection with the many medical and technical services required to handle and process that material, whether for treatment or research purposes. In order to achieve some clarity in this area, we propose the following terminology in respect of payments made in connection with bodily material:

Payment: a generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as recompense, reward or purchases;

Recompense: payment to a person in recognition of losses they have incurred, material or otherwise. This may take the form of the **reimbursement** of direct financial expenses incurred in donating bodily material (such as train fares and lost earnings); or **compensation** for non-financial losses (such as inconvenience, discomfort and time);

Reward: material advantage gained by a person as a result of donating bodily material, that goes beyond 'recompensing' the person for the losses they incurred in donating. If reward is calculated as a wage or equivalent it becomes **remuneration**;

Purchase: payment in direct exchange for a 'thing' (e.g. a certain amount for a kidney, or per egg).

Introduction

- 2.1 Since the publication of the Council's report *Human tissue: ethical and legal issues* in 1995, the regulatory frameworks governing the donation, storage and use of human bodily material have changed and multiplied, leading to a very different regulatory environment from 15 years ago. This chapter first provides an overview of key aspects of the regulatory frameworks, highlighting similarities and differences in the way various forms of bodily material are treated in areas such as consent, control, commercial transactions, and safety; and with respect to their future proposed use. It then goes on to consider some of the contexts of scientific development, medical scandal and social change that have influenced the development of the frameworks governing organs and tissue, blood, reproductive materials and first-in-human trials within England/Wales/Northern Ireland, Scotland, and the EU; and to discuss the areas of concern raised with us by the regulators. We note here that 'regulation' may be understood and invoked in a variety of different ways: regulation may *prohibit* particular actions; it may *require* particular actions; or it may *permit* particular actions. Where regulation is permissive, then its actual

impact is likely to depend on the facilitative regimes in place: that is, on the extent to which the permitted activity is supported, encouraged or, on the contrary, discouraged. To the extent that regulation is permissive, therefore, the approach taken by influential organisations will be central in determining its effect.

- 2.2 As demonstrated by the growing phenomenon of individuals travelling abroad for treatment that may not be available or affordable in their own country (colloquially known as 'medical tourism'⁸³), regulation of the donation and use of human bodily material cannot be wholly confined within national borders. Moreover, it is not just patients or would-be patients who cross national boundaries. Health professionals, scientists, and investigators carrying out clinical trials all travel widely too, pharmaceutical companies have global reach, and bodily material itself is becoming ever more transportable as storage techniques have developed.⁸⁴ Such international movement may be the unintended consequence of differing regulatory approaches (see, for example, the increasing trend to 'out-source' clinical trials to countries where regulation is perceived to be lighter or populations are less likely to have received previous medical interventions and costs are less⁸⁵) or may, by contrast, result from an express political aim, as for example under the World Trade Organization's General Agreement on Trade in Services (GATS 1995), which seeks to encourage global trade through the removal of protectionist barriers.⁸⁶ We therefore highlight international principles and declarations that seek to set minimum standards worldwide, and sketch out the regulatory frameworks in a number of other countries to indicate the range of regulatory approaches currently in existence.
- 2.3 Key legal and policy instruments that govern the donation, storage and use of human bodily material in the UK include those listed below.
- The Human Tissue Act 2004 governs the removal, storage and use of organs and tissue, other than reproductive tissue, within England, Wales and Northern Ireland.⁸⁷ Its regulatory functions are currently performed by the HTA (but see paragraph 2.5), and detailed guidance on its requirements are set out in statutory Codes of Practice.
 - The Human Tissue (Scotland) Act 2006 governs three distinct uses of human bodily material in Scotland: donation for transplantation, research, training and audit; removal, retention and use of material after a post-mortem examination; and donation of the whole body to medical science. The Act does not establish a regulatory authority; however by agreement with Scottish Ministers, the HTA oversees arrangements for living organ donation in Scotland as well as in the rest of the UK.⁸⁸
 - The Human Fertilisation and Embryology Act 1990, as amended and supplemented by the Human Fertilisation and Embryology Act 2008, sets out the required standards for the use of human gametes and embryos in fertility treatment and research within the whole of the UK.

⁸³ 'Transplant tourism' and 'cross-border reproductive care' are particular examples of medical tourism: they are the source of specific ethical concerns that may not arise in other forms of medical tourism in that they may involve activities that may be illegal in the patient's home country, or indeed also in the country where the treatment is being provided.

⁸⁴ See, for example, Brown N, Machin L, and McLeod D (2011) Immunitary bioeconomy: the economisation of life in the international cord blood market *Social Science & Medicine*: in press.

⁸⁵ Petryna A (2009) *When experiments travel: clinical trials and the global search for human subjects* (Princeton: Princeton University Press).

⁸⁶ For a discussion of the importance of GATS to health policy, see World Health Organization (2004) *GATS and health related services: managing liberalization of trade in services from a health policy perspective*, available at:

http://www.searo.who.int/LinkFiles/Global_Trade_and_Health_GTH_No6.pdf. Under the GATS, governments may choose (or not) to trade health services to achieve their national health objectives, and some have encouraged health care exports (classified as „mode 2“ or „consumption abroad“) through treating foreign patients entering their territory, on the grounds that they promote economic development, boost reserves of foreign currencies, and create a more favourable balance-of-trade position. The EU is also subject to the GATS and member states are obliged to allow free movement of services and goods within the union.

⁸⁷ The Act's powers with respect to the *removal* of bodily material are limited to material removed after death; however its powers with respect to the storage and use of bodily material cover material removed both during life and after death.

⁸⁸ For a summary of the Human Tissue (Scotland) Act 2006 and arrangements with the Human Tissue Authority, see: Scottish Executive Health Department (2006) *Human Tissue (Scotland) Act 2006: a guide to its implications for NHS Scotland*, available at: http://www.sehd.scot.nhs.uk/mels/hdl2006_46.pdf.

Its provisions are currently supervised by the HFEA (but see paragraph 2.5 below), and again detailed guidance is found in a statutory Code of Practice.

- The Medicines for Human Use (Clinical Trials) Regulations 2004⁸⁹ provide the regulatory framework for all clinical trials of medicinal products within the UK, including healthy volunteer 'first-in-human' trials, and implement the requirements of the EU Clinical Trials Directive.⁹⁰
- The Blood Safety and Quality Regulations 2005⁹¹ set out the regulatory requirements for blood and blood components throughout the UK. These regulations implement European Directives⁹² on blood quality and safety, and make the MHRA responsible for maintaining standards of quality and safety in the collection, testing, processing, storage and distribution of human blood and blood components.
- The NHS Research Governance Framework⁹³ sets out principles of good research governance that apply to all research carried out within the NHS in England. Similar guidance is available in Scotland,⁹⁴ Wales,⁹⁵ and Northern Ireland.⁹⁶
- The European Union Tissues and Cells Directives (EUTCD)⁹⁷ set out a harmonised approach to the regulation of tissue and cells (including reproductive material) across Europe, setting minimum standards to be met when carrying out any activity involving tissue for therapeutic purposes. The Directives have been implemented in the UK primarily through the Human Tissue Act and the Human Fertilisation and Embryology Act, and the HTA and the HFEA are currently designated as the 'competent bodies' responsible for ensuring that the Directives' requirements are met in the UK.⁹⁸
- The European Union Organ Directive 2010/45/EU concerning "standards of quality and safety of human organs intended for transplantation" came into force in July 2010, and is due to be implemented by all member states by August 2012. The HTA has been designated as the 'competent body' responsible for ensuring the requirements of the Directive are met in the UK.

2.4 In addition to domestic and European law,⁹⁹ there are many relevant international conventions and statements that may influence UK policy on the donation and use of human bodily material and on participation as a healthy volunteer in first-in-human clinical trials, without being legally binding.

- The Council of Europe's *Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine*, known as the *Oviedo Convention*, requires signatories to "protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."¹⁰⁰ The

⁸⁹ SI 2004/1031.

⁹⁰ Directive 2001/20/EC.

⁹¹ SI 2005/50.

⁹² Directive 2002/98/EC and Directive 2004/33/EC, with further technical requirements found in Directive 2005/61/EC and Directive 2005/62/EC.

⁹³ Department of Health (2005) *Research governance framework for health and social care: second edition*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4122427.pdf.

⁹⁴ Scottish Executive Health Department (2006) *Research governance framework for health and community care: second edition*, available at: <http://www.cso.scot.nhs.uk/publications/ResGov/Framework/RGFEdTwo.pdf>.

⁹⁵ Welsh Assembly Government (2009) *Research governance framework for health and social care in Wales: second edition*, available at: <http://wales.gov.uk/docs/dhss/publications/governance/090929researchen.pdf>.

⁹⁶ Department of Health, Social Services and Public Safety (2006) *Research governance framework for health and social care*, available at: http://www.dhsspsni.gov.uk/research_governance_framework.pdf.

⁹⁷ The EUTCD is made up of three Directives: the 'parent' Directive (2004/23/EC) which provides the framework legislation and two technical directives (2006/17/EC and 2006/86/EC), providing the detailed requirements of the EUTCD.

⁹⁸ Including in Scotland, by arrangement with Scottish Ministers: Scottish Executive Health Department (2006) *Human Tissue (Scotland) Act 2006: a guide to its implications for NHS Scotland*, available at: http://www.sehd.scot.nhs.uk/mels/hdl2006_46.pdf. Other instruments implementing the EUTCD include the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (SI 2007/1523) and the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (SI 2007/1522).

⁹⁹ Once EU Directives have been adopted, member states must implement them in domestic law within the time-frame stipulated within the Directive.

¹⁰⁰ Council of Europe (1997) *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>.

Convention was extended in 2002 by an additional protocol on "transplantation of organs and tissues of human origin" (excluding reproductive material and blood);¹⁰¹ and in 2005 by an additional protocol "concerning biomedical research".¹⁰² The UK is not at present a signatory to the Convention.¹⁰³

- Further guidance regarding research use of bodily material from the Council of Europe was issued in 2006 in the shape of a *Recommendation of the Committee of Ministers to member states on research on biological materials of human origin*. The Recommendation applies "to the full range of research activities in the health field involving the removal of biological materials of human origin to be stored for research use," excluding embryonic or fetal tissue.¹⁰⁴
- The World Health Organization (WHO) first issued *Guiding Principles* on human organ transplantation in 1991. A revised and expanded version of these Principles, covering both organs and tissue (excluding reproductive material), was endorsed by the 63rd World Health Assembly on 21 May 2010.¹⁰⁵
- The *Declaration of Istanbul on Organ Trafficking and Transplant Tourism* was formulated in 2008 by a summit meeting convened by The Transplantation Society and the International Society of Nephrology, in response to concerns about the sale and trafficking of organs. The Declaration states that "organ trafficking and transplant tourism violate the principles of equity, justice and respect for human dignity and should be prohibited", and called for action to prevent the purchase and sale of human organs, along with ancillary activities such as advertising, medical screening and transport.¹⁰⁶
- The *Declaration of Helsinki* has been developed by the World Medical Association as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.¹⁰⁷
- International *Ethical guidelines for biomedical research involving human subjects* were first published in 1993 by the Council for International Organizations of Medical Sciences (CIOMS), in association with WHO, and revised in 2002.¹⁰⁸

2.5 Regulation at both UK and EU level implies the existence of regulatory bodies to implement the law. The HFEA and the HTA were established by the Human Fertilisation and Embryology Act 1990 and the Human Tissue Act 2004 respectively, to undertake the regulatory roles set out in the legislation. However, this aspect of the UK regulatory landscape is currently in a state of flux, since the Department of Health announcement in July 2010 that both bodies would be

¹⁰¹ Council of Europe (2002) *Additional protocol to the Convention on Human Rights and Biomedicine, on transplantation of organs and tissues of human origin*, available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm>.

¹⁰² Council of Europe (2005) *Additional protocol to the Convention on Human Rights and Biomedicine, concerning biomedical research*, available at: <http://conventions.coe.int/treaty/en/treaties/html/195.htm>.

¹⁰³ House of Commons Hansard (4 December 2002) c907W, available at: <http://www.parliament.the-stationery-office.co.uk/pa/cm200203/cmhansrd/vo021204/text/21204w29.htm>. However, it is possible that aspects of the Oviedo Convention could indirectly affect UK law, through influencing interpretations of the European Convention on Human Rights (which in turn is directly applicable within the UK through the Human Rights Act 1998).

¹⁰⁴ Council of Europe (2006) *Recommendation 2006(4) of the Committee of Ministers to member states on research on biological materials of human origin*, available at: <https://wcd.coe.int/wcd/ViewDoc.jsp?id=977859&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogge d=FFAC75>.

¹⁰⁵ World Health Organization (2010) *WHO guiding principles on human cell, tissue and organ transplantation*, available at: http://www.searo.who.int/LinkFiles/BCT_WHO_guiding_principles_organ_transplantation.pdf; World Health Assembly (2010) *Human organ and tissue transplantation: WHA63.22*, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf.

¹⁰⁶ Steering Committee of the Istanbul Summit (2008) *Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul* *The Lancet* **372**: 5-6; see also: The Declaration of Istanbul Custodian Group (2008) *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*, available at: http://www.declarationofistanbul.org/index.php?option=com_content&view=article&id=73&Itemid=59.

¹⁰⁷ World Medical Association (2008) *WMA Declaration of Helsinki: ethical principles for medical research involving human subjects*, available at: [http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=[page]/[toPage]), last amended in 2008.

¹⁰⁸ Council for International Organizations of Medical Sciences in collaboration with the World Health Organization (2007) *International ethical guidelines for biomedical research involving human subjects*, available at: http://www.cioms.ch/publications/layout_guide2002.pdf.

abolished before the end of the current Parliament (i.e. 2015).¹⁰⁹ The Department of Health has stated that the regulatory framework itself will not change, but rather that the functions of the two 'arm's length' bodies "will be transferred to other organisations to achieve greater synergies where appropriate".¹¹⁰ The Government's aim is in future to have one regulatory body concerned with quality issues, one with economic matters, one with medicines and devices, and one with research.¹¹¹ Precisely how these regulatory bodies will absorb the current functions of the HFEA and HTA is currently unclear. Further proposed changes to the NHS in England include the abolition of primary care trusts (PCTs; currently responsible for commissioning health services for their local populations) and the transfer of their functions to consortia of general practitioners (GPs).¹¹²

Consent

- 2.6 The need for consent is at the heart of all current systems of regulatory control governing the donation and use of human bodily material. However, the nature of the consent required – including who may provide it, how 'informed' it must be, what procedural safeguards surround it – varies, depending on the form of the material, and also on the jurisdiction concerned.

Valid consent for medical procedures and research participation

- 2.7 The 'valid' consent of participants in both medical research and medical procedures is a standard ethical and legal requirement around the world.¹¹³ In the UK, common law governs both consent to treatment and consent to research participation (with additional provisions and safeguards added through legislation as indicated below). The medical procedures involved in donating bodily material as a living donor, from providing a blood sample for a research project to undergoing an operation to donate eggs or a kidney, are governed by the same common law framework as consent to medical treatment for one's own benefit. Under the common law, consent for the procedures involved in donating bodily material will only be valid if the person giving consent:

- has the legal capacity to make this particular decision;
- has been provided with information about the nature and purpose of the procedure; and
- is acting voluntarily, without pressure or undue influence being exerted.¹¹⁴

Under common law, there is no requirement that consent should be in writing. The existence of a signed consent form is simply evidence (which may be rebutted) that consent has been sought and given.

- 2.8 Where an adult (that is, an individual aged 18 years or over) has the capacity to decide for themselves whether or not to provide some form of bodily material while living, only that adult can provide consent. In England, Wales and Northern Ireland, a child of sufficient maturity and understanding, regardless of age, can provide valid consent to the donation of bodily material such as bone marrow, although court approval should be sought for the donation of an organ or

¹⁰⁹ Department of Health (2010) *Liberating the NHS: report of the arm's-length bodies review*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_118053.pdf.

¹¹⁰ *Ibid*, paragraph 3.3.

¹¹¹ *Ibid*, paragraph 3.10.

¹¹² Department of Health (2010) *Equity and excellence: liberating the NHS*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117352.pdf.

¹¹³ We follow here legal norms in the UK in referring to 'valid' rather than 'informed' consent when referring to legal requirements. What is required for legally valid consent may differ in different circumstances, a point to which we return in Chapter 5. However, the term 'informed consent' is routinely used in guidance on research involvement: see, for example, World Medical Association (2008) *WMA Declaration of Helsinki: ethical principles for medical research involving human subjects*, available at: [http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=[page]/[toPage]).

¹¹⁴ See: Department of Health (2009) *Reference guide to consent for examination or treatment*, available at: http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103653.pdf, for a detailed account of the law on consent.

part organ.¹¹⁵ If the child is not legally 'competent' in this way, or prefers someone else to make the decision, a person with parental responsibility may do so, on the basis of the child's best interests.¹¹⁶ Children who are not competent to provide a valid consent on their own (for example to provide a blood sample for a longitudinal study) may still be invited to 'assent', alongside their parent's consent.

- 2.9 An adult who lacks capacity to make a decision to provide bodily material for use in another's medical treatment may only be considered as a donor if it is judged to be in that adult's own best interests, and court approval must be sought for the donation of solid organs, bone marrow or peripheral blood stem cells. Participation in research (which may include providing bodily material such as blood samples) is only lawful if the research has the capacity to benefit that person, or where the risk involved is 'negligible'.¹¹⁷ Adults lacking capacity may only participate in clinical trials if the procedures either produce a benefit to the subject or produce no risk at all.¹¹⁸
- 2.10 In Scotland, young people of 16 years and above are presumed to have capacity to consent for themselves.¹¹⁹ Children under 16 years and adults who lack capacity to decide for themselves are not permitted to donate organs or part organs as living donors, unless the organ or part organ is being removed as part of their own treatment. However, they may donate bone marrow or peripheral blood stem cells subject to a number of protections.¹²⁰ Under the Human Tissue (Scotland) Act 2006, a child aged 12 years or above may also give a written authorisation to donate organs after their death.
- 2.11 Valid consent requirements apply not only to the process of donating bodily material, but also to the retention and use of any associated personal details and health-related information from the donor. In the case of transplantation, the ability to trace the donated material back to the donor is important (see paragraph 2.54), while in the case of research, medical information associated with donated samples will add considerably to the research value of the material (see paragraph 1.13). When being asked for valid consent for the retention of information, the donor should be clear as to the nature of the information being retained: for example, whether an ongoing link is envisaged to the donor's health records; or whether a more limited dataset of information will be extracted from the person's records or provided at the time of donation in questionnaire form, and then linked permanently to the sample. It is also important that the person understands what procedures are in place to protect their privacy: for example whether material is being fully anonymised (so that no link can ever be made back to the donor's personal details such as name and address); or whether a code will be used to enable linkage to be made between the sample, the available data, and the donor's personal details. In the latter case, researchers will not have access to the 'key' to the code, and hence will never see the donor's personal details. Even under such systems, complete anonymity cannot be promised, as in some cases the material may be sufficiently exceptional (for example a very rare tumour) for a particular researcher/clinician to identify its source. However, in all cases, researchers working with

¹¹⁵ Scrutiny by a panel of three HTA independent assessors is also required if a proposed living organ donor is under 18 years: Human Tissue Authority (nd) *Guidance for transplant teams and independent assessors: living donor transplantation*, available at: http://www.hta.gov.uk/db/documents/IA_Guidance_FINAL_201101045322.pdf, paragraph 44.

¹¹⁶ Human Tissue Authority (2009) *Human Tissue Act code of practice 1*, available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm>, paragraph 142.

¹¹⁷ Mental Capacity Act 2005, section 31.

¹¹⁸ The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, Schedule 1, Part 5.

¹¹⁹ Age of Legal Capacity (Scotland) Act 1991, section 1.

¹²⁰ Scottish Executive Health Department (2006) *Human Tissue (Scotland) Act 2006: a guide to its implications for NHS Scotland*, available at: http://www.sehd.scot.nhs.uk/mels/hdl2006_46.pdf.

donated tissue and associated data will be bound both by a professional duty of confidentiality and the requirements of the Data Protection Act.¹²¹

Additional ethical oversight of consent procedures in medical research

2.12 While the requirements for valid consent are the same for research participation as they are for medical treatment, additional protections are in place for research participants through the requirements for review by Research Ethics Committees (RECs).¹²² Such scrutiny is required for any research categorised as a clinical trial by the Clinical Trials Regulations,¹²³ and for any research carried out within the NHS (that is, involving NHS staff, premises, patients or data).¹²⁴ REC scrutiny includes consideration of the adequacy of the information available to potential participants when making their decision whether or not to participate, and scrutiny of any payment offered (see paragraph 2.34). The Clinical Trials Regulations further specify that all participants in clinical trials should have an interview with a member of the investigating team in which they should be "given the opportunity to understand the objectives, risks and inconveniences of the trial".¹²⁵ Consent by research participants will usually be given in writing.

Scope of consent for material donated for research

2.13 When consent is sought for the storage and use of a person's bodily material for research purposes, the *scope* of that consent may vary considerably. The person providing the material may be asked for:

- *'specific' consent*: for a particular research project or projects which can be clearly described at the time the donation is made (future use for other purposes without new consent not usually permitted); and/or
- *'generic' consent*: permitting use in future (approved) research projects. By definition, details of such potential projects cannot be provided at the time the consent is sought.

Generic consent may be understood as 'blanket' consent, where no limits at all are placed on the future use of the material. However, 'fettered' or 'tiered' consent may also be seen as categories of generic consent: these terms refer to consent where the participant is invited to agree to the future use of their tissue in unknown projects, but given the option of specifying particular categories of research that they wish to exclude. Where such options are offered to potential donors, it is clearly important that information systems are in place to ensure that the chosen exclusions are properly recorded and maintained. The concept of 'broad' consent, envisaging a wide (but not limitless) range of future uses, together with an ongoing relationship between the researchers and the donors, is a further category of generic consent that is increasingly being used. Such a relationship might involve regular information for donors about the progress and outcomes of research projects, and provide the opportunity for donors

¹²¹ Medical Research Council (2006) *Data and tissues tool kit: confidentiality arrangements - requirements for researchers accessing identifiable data*, available at: http://www.dt-toolkit.ac.uk/routemaps/station.cfm?current_station_id=418&useCache=false.

¹²² These have long been in place as a matter of policy, but now have a statutory basis in the UK as a result of the Clinical Trials Directive 2004.

¹²³ Defined as: "any investigation in human subjects, other than a non-interventional trial, intended (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products, (b) to identify any adverse reactions to one or more such products, or (c) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products" – Regulation 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, as amended.

¹²⁴ Department of Health (2005) *Research governance framework for health and social care: second edition*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4122427.pdf. The Human Tissue Act and the Mental Capacity Act also make additional stipulations regarding REC involvement.

¹²⁵ Medicines for Human Use (Clinical Trials) Regulations, SI 2004/1031, as amended, Schedule 1, Part 3.

specifically to opt in or out of their donated material being used in particular research projects in the future.¹²⁶

- 2.14 The Code of Practice issued under the Human Tissue Act recommends the use of generic consent, in order to facilitate the use of human tissue in research: by definition, such consent permits the use of donated material for future research projects without the need to trace donors, perhaps many years later, to seek further consent.¹²⁷ A 'vision document' for human tissue resources, published in 2011 by the major UK funders of research using human tissue, similarly advocates generic consent; indeed it goes further by suggesting that funders should *require* researchers routinely to request generic consent (in addition, where appropriate, to specific consent for a particular project) as a condition of their funding.¹²⁸ Some major projects holding population data and samples, such as UK Biobank (see paragraph 1.16), have already adopted the approach of broad consent, with the aim of maintaining a more active relationship with their donors. The initial information leaflet provided to potential UK Biobank participants, for example, makes clear that taking part in UK Biobank may involve being re-contacted (although any request to provide further information or samples would clearly be optional); and updates on ongoing research are regularly provided to its 'supporters' (the term used by UK Biobank for those who have provided samples and medical information).¹²⁹

'Appropriate consent' for the removal of material after death

- 2.15 The Human Tissue Act 2004 requires that "appropriate consent" must be given before any bodily material may be taken from the deceased for "scheduled purposes" such as transplantation or research.¹³⁰ Definitions of appropriate consent in the Act relate primarily to the *identity* of the person who is able to provide the consent: that is, the deceased person if he or she has made a clear decision before their death; a representative nominated for this purpose by the deceased person; or a person in a "qualifying relationship" with the deceased person. The Act sets out a hierarchy of qualifying relationships: this starts with the spouse/partner (including civil partner) and moves through the categories of parent, child, sibling, grandparent, grandchild, niece or nephew, step-parent, half sibling and friend of long standing. Consent is only needed from one person in the relevant category, and should be obtained from a person in the highest ranked category available. If this person refuses, their answer is taken as final: it is not possible to seek consent instead from others.¹³¹ However, while the Act itself does not specify the nature of 'appropriate consent', the Code of Practice on consent issued by the HTA makes clear that consent under the Act must also meet the requirements of 'valid consent' described above (see paragraph 2.7). In Scotland, a similar approach is taken, although the legislation uses different terminology: the removal or use of any part of a person's body after death is only permitted in circumstances where either the person has 'authorised' this before their death, or the person's 'nearest relative' (defined in a similar way to the 'qualifying relative' elsewhere in the UK) provides the authorisation in their place.¹³² Guidance issued by the Scottish Government makes it clear that the two terms should be treated as equivalent, and that

¹²⁶ Hansson MG, Dillner J, Bartram CR, Carlson JA, and Helgesson G (2006) Should donors be allowed to give broad consent to future biobank research? *The Lancet Oncology* 7: 266-9.

¹²⁷ Human Tissue Authority (2009) *Human Tissue Act code of practice* 9, available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm>, paragraph 47.

¹²⁸ UK Clinical Research Collaboration (2011) *UK funders' vision for human tissue resources*, available at: <http://www.ukcrc.org/infrastructure/expmed/>.

¹²⁹ For more detail, see the UK Biobank website: UK Biobank (2010) *UK Biobank: improving the health of future generations*, available at: <http://www.ukbiobank.ac.uk/>.

¹³⁰ 'Scheduled purposes' are set out Schedule 1 of the Human Tissue Act 2004, and also include anatomical examination; determining the cause of death; obtaining scientific or medical information that may be relevant to another person (including a future person); and public display.

¹³¹ Human Tissue Act 2004, sections 3 and 27.

¹³² Human Tissue (Scotland) Act 2006, sections 6, 7 and 50.

this equivalence is "an essential part of the continuation of the arrangements for sharing organs and tissue across the UK in order to obtain the best outcomes for recipients".¹³³

- 2.16 Despite the emphasis on valid consent (including sufficient information) in the HTA Code of Practice, there is in practice little, if any, control over how much information is available to individuals when they decide to sign up to the ODR. The Organ Donation Taskforce raised this issue as a matter of concern in its 2008 report, noting that "when seeking to increase the number of registered donors, agencies must ensure that sufficient and appropriate information is provided to be sure that consent is valid and robust".¹³⁴ More recently, a report considering the robustness of the data held by the ODR suggested that the necessary level of information could appropriately be conveyed by sending out 'Q&A' information from the NHSBT website to new registrants as part of their 'thank you pack', along with guidance on how to change registration wishes, and that it would not be necessary to introduce any kind of additional confirmation stage.¹³⁵

Consent for the storage and use of bodily material

- 2.17 Under the Human Tissue Act 2004, appropriate consent is also required for the storage and use of (non-reproductive) material taken from both living and deceased donors. There are some limited exceptions, however, in connection with material taken from living patients in connection with their own treatment, and where the material is no longer needed for the patient's own care. Such material may be stored and used for a number of further purposes without consent, including for clinical audit; education or training related to human health; public health monitoring; and quality assurance.¹³⁶
- 2.18 This is on the basis that these activities are a necessary part of providing a safe and high-quality health service, and that it would therefore not be appropriate to give patients the option of 'opting-out' of such essential activity.¹³⁷ These exceptions to the general rule that consent is always required for storage and use do not apply to material taken from the deceased.

Exceptions to consent procedures for medical research

- 2.19 Under the Human Tissue Act, it may also be permissible to store and use (non-reproductive) material from living donors for research without consent if both the following criteria are met:
- the researcher is not in a position to identify the person from whom the material came; and
 - a REC has approved the research proposal, in the knowledge that explicit consent to this use of the material has not been obtained. (Consent would, of course, have had to have been obtained for the initial taking of the tissue.)¹³⁸

This exception applies both where individuals have provided the initial material for a specific research project, and where the material is 'residual' blood or tissue left over from diagnostic procedures. These exemptions do *not*, however, apply to material taken after death, where consent must be in place for any future storage or use.

¹³³ Scottish Executive Health Department (2006) *Human Tissue (Scotland) Act 2006: a guide to its implications for NHS Scotland*, available at: http://www.sehd.scot.nhs.uk/mels/hdl2006_46.pdf, paragraph 8.

¹³⁴ Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf, paragraph 4.8.

¹³⁵ Department of Health (2010) *Review of the Organ Donor Register*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_120579.pdf, recommendation 7.

¹³⁶ Human Tissue Authority (2009) *Human Tissue Act code of practice 1*, available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm>, paragraph 114.

¹³⁷ See, for example, Herring J (2006) *Medical law and ethics* (Oxford: Oxford University Press), p350.

¹³⁸ Human Tissue Authority (2009) *Human Tissue Act code of practice 1*, available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm>, paragraph 117.

2.20 Detailed recommendations by the Council of Europe regarding the use of bodily material in research similarly place emphasis on the importance of seeking appropriate consent for the future research use of 'residual' material, but permit research on identifiable bodily material without such consent (subject to ethical review) if all four of the following conditions are met:

- it is not possible with reasonable efforts to contact the person to seek consent; and
- there is no evidence that the person had expressly opposed such research use; and
- the research addresses an important scientific interest; and
- the research cannot be reasonably achieved using material where consent can be obtained.

The Council of Europe Recommendation also permits the use of 'unlinked anonymised' bodily material (that is, material that can no longer be traced back to its original donor source and hence where confidentiality concerns should no longer apply) without consent, provided that the research does not violate any restrictions placed by the person before the removal of anonymity.¹³⁹

'Effective consent' for the storage and use of gametes

2.21 The Human Fertilisation and Embryology Act requires written consent for the storage and future use of donated sperm, eggs or embryos.¹⁴⁰ Clinics licensed to provide such facilities are required to ensure that such consent is 'effective': that is, it has not been withdrawn. The HFEA Code of Practice sets out detailed requirements as to the information that must be provided before consent is sought, in order to ensure that donors have:

- enough information to enable them to understand the nature, purpose and implications of their treatment or donation;
- a suitable opportunity to receive proper counselling about the implications of the steps that they are considering taking; and
- information about the procedure for varying or withdrawing any consent given, and about the implications of doing so.¹⁴¹

Along with 'effective consent' for the use of gametes, clinics must also ensure that they take proper account of the welfare of the future child, before providing treatment.

Approach to consent at the European and international level

2.22 The EU Tissues and Cells Directive and the EU Organ Directive (see paragraph 2.3) also make reference to need for consent before any kind of material is taken from a person, living or deceased. However, as described in more detail below (see paragraph 2.26), approaches to consent for the removal of organs and other tissue after death vary considerably across member states, with some such as Spain, Belgium and Austria providing for the removal of organs from anyone after their death as long as they had not, in their lifetime, registered their objection (the so-called 'opt-out' approach to organ donation). The Organ Directive therefore simply requires compliance with the requirements "relating to consent, authorisation or absence of any objection" in force in the member state in question, while emphasising in its introductory recitals the importance of a living donor being in a position to take "an independent decision on the basis of all the relevant information."¹⁴² The Tissues and Cells Directive also requires that

¹³⁹ Council of Europe (2006) *Recommendation 2006(4) of the Committee of Ministers to member states on research on biological materials of human origin*, available at: <https://wcd.coe.int/wcd/ViewDoc.jsp?id=977859&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75>, Articles 22 and 23.

¹⁴⁰ Human Fertilisation and Embryology Act 1990, Schedule 3.

¹⁴¹ Human Fertilisation and Embryology Authority (2009) *Code of practice*, available at: http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf, section 5, box 5B.

¹⁴² EU Organ Directive, Directive 2010/45/EU, Article 14 and Recital 23

consent procedures be determined by member states, although it specifies necessary informational requirements for living and deceased donors respectively.¹⁴³ The WHO's Guiding Principles (see paragraph 2.4) permit cells, tissues and organs to be removed from the body of a deceased person if any consent required by law is obtained, and if there is no reason to believe that the deceased person objected.

- 2.23 The Oviedo Convention and additional protocol (see paragraph 2.4) similarly recognise that approaches to consent vary significantly across Europe. The protocol's requirements as regard consent for the use of organs or tissue after death echo those of the EU Directives, specifying that the "consent or authorisation required by law" must have been obtained, and that material may not be removed if the deceased person had objected. However, it is more specific with respect to living donors, requiring the "free, informed and specific consent" of the donor, who may freely withdraw consent at any time. The Convention itself also specifies that body parts may only be used for a different purpose from that from which they were removed if this is done "in conformity with appropriate information and consent procedures".¹⁴⁴

Additional protections for living donors

- 2.24 Domestic legislation within the UK, EU Directives and Council of Europe instruments all recognise, in various forms, the need for particular protection of living donors, especially as regards living organ donation. In the UK, the HTA regulates all living organ donations, with the aim of ensuring that the consent provided by the living donor is fully informed and that there is no evidence of coercion, duress or reward (for definition of 'reward' in the Human Tissue Act, see paragraph 2.34).¹⁴⁵ Donors are only accepted after detailed medical and psychosocial assessment, along with assessment of the organs themselves. Where a person is offering to donate an organ to a stranger, rather than to a relative or friend, approval must first be sought from a panel of at least three members of the HTA; the same process applies to 'pooled' and 'paired' donations (see paragraph 3.60). The EU Organ Directive requires that "the highest possible protection of living donors should be ensured".¹⁴⁶
- 2.25 The Oviedo Convention and its additional protocol on transplantation similarly recognise the risk both of duress and of physical harm to the donor: the protocol specifies, for example, that organ removal from a living donor may only take place where the donor has a close personal relationship with the recipient, or under conditions defined by law and with the approval of an independent body.¹⁴⁷ It also explicitly bans organ or tissue removal that would pose a serious risk to the life or health of the donor.¹⁴⁸ The Convention, however, goes further than domestic legislation within the UK, specifying that the removal of organs or tissue from a living person for transplantation purposes should only be carried out where there is no suitable organ or tissue available from a deceased person, and where no other alternative therapeutic method of comparable effectiveness is available.¹⁴⁹ The WHO's Guiding Principles demonstrate similar concerns in urging that donation from deceased persons should be "developed to its maximum therapeutic potential", and in stating that in general living donors should be genetically, legally or emotionally related to their recipients.

¹⁴³ EU Tissues and Cells Directive, Directive 2004/23/EC, Annex A(3).

¹⁴⁴ Council of Europe (1997) *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine*, available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>, Article 22.

¹⁴⁵ See: Human Tissue Authority (2009) *Human Tissue Act code of practice 2*, available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm>, paragraph 36. In Scotland, oversight of living organ donation is not formally specified by law but is carried out by the Human Tissue Authority on behalf of the Scottish Executive: Scottish Executive Health Department (2006) *Human Tissue (Scotland) Act 2006: a guide to its implications for NHS Scotland*, available at: http://www.sehd.scot.nhs.uk/mels/hdl2006_46.pdf, paragraph 23.

¹⁴⁶ EU Organ Directive, Directive 2010/45/EU, Recital 23.

¹⁴⁷ Council of Europe (2002) *Additional protocol to the Convention on Human Rights and Biomedicine, on transplantation of organs and tissues of human origin*, available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm>, Article 10.

¹⁴⁸ *Ibid*, Article 11.

¹⁴⁹ Council of Europe (1997) *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine*, available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>, Article 19(1).

Comparisons with other jurisdictions

- 2.26 The Working Party commissioned a review of the legal provisions affecting donation in a number of other jurisdictions, in order to obtain a snapshot of a range of regulatory approaches (see Appendix 1).¹⁵⁰ On consent, the main variation in approach related to deceased donation: Spain and Belgium operate 'opt-out' systems of consent, whereby the deceased person is presumed to have consented to donate organs unless they have specifically objected (see paragraph 3.53). It was noted, however, that in practice such systems differed less than might be imagined from the 'opt-in' system in the UK. In Spain, there is no requirement to express opposition to organ donation in any particular form, and hence it is standard practice to seek 'consent' from the family, on the basis that they will be well placed to know whether or not the deceased person was opposed to donation.¹⁵¹ In Belgium, the legal provisions governing consent for organ donation did not introduce a new social arrangement of 'opt-out', but rather codified existing arrangements whereby it had been standard practice in university hospitals to remove kidneys in the absence of formal objection. The legislation also introduced an explicit right of objection on the part of immediate family members. In the early years of the legislation, it was assumed that this right only arose if the family took the initiative to object; however, some centres felt that such a legal right should imply an obligation on the part of doctors explicitly to ask for their permission.¹⁵²
- 2.27 Legal provisions relating to consent on the part of living donors, however, do not appear to vary significantly between jurisdictions, perhaps reflecting the general ethical consensus as to the central role played by consent in such cases. Legislation relating to the donation of material for research (such as that set out in the US at federal level for research supported by federal agencies,¹⁵³ or in the Spanish law on biomedical research¹⁵⁴) may list, for example, the kind of information that must be provided to a person before they consent, but little guidance is given on how much detail is required. Practical issues surrounding the amount and specificity of the information required for consent (particularly generic consent) to be legally valid are the subject of academic and professional disagreement across a range of jurisdictions.

Control and 'ownership' of bodily material

- 2.28 We have seen that a key legal and ethical concept governing the provision of bodily material to benefit others is that of consent on the part of the source of the material. The provisions regarding consent relate variously to the 'taking', the 'storage' and the 'use' of bodily material. A further question arises as to how far the person providing the bodily material may continue to influence the 'use' to which it is put: to what extent may controls, or conditions, be placed upon the future use of the donated material?
- 2.29 Within the UK, the scope of personal control varies significantly, depending on the type of bodily material being donated, and whether the person from whose body the material has come is living or dead.
- Blood for therapeutic purposes is donated into a common pool.

¹⁵⁰ The countries included in the review were Belgium, India, Iran, Israel, Spain and the US (at both federal and state level). The review focused on specific issues for each country, rather than attempting a detailed overview of every aspect of the legislation governing the donation of bodily material.

¹⁵¹ Quigley M, Brazier M, Chadwick R, Michel MN, and Paredes D (2008) The organs crisis and the Spanish model: theoretical versus pragmatic considerations *Journal of Medical Ethics* 34: 223-4.

¹⁵² Michielsen P (1996) Presumed consent to organ donation: 10 years' experience in Belgium *Journal of the Royal Society of Medicine* 89: 663-6.

¹⁵³ 45 CFR 46.116(a), available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>. CFR stands for Code of Federation Regulations. [US]

¹⁵⁴ Law 14/2007 on biomedical research, Article 4(1), available at: http://www.isciii.es/htdocs/terapia/pdf_comite/SpanishLawonBiomedicalResearchEnglish.pdf. [Spain]

- Living organ donors may specify the recipient (and indeed this is the usual reason for donating, although 'stranger donation' is now permitted).
- Bone marrow donors may donate either to a named individual or to a common pool.
- Gamete donors may donate either to named individuals, or to an unknown recipient. They may also currently specify the category of recipient, for example by restricting the use of their donated material to married couples or women under a particular age, although this ability to restrict use to recipients with particular characteristics is currently subject to review as to its compatibility with equality legislation. Gamete donors may also change their minds and withdraw their consent up until the point where the donated gametes have been 'used': this has been interpreted (in the context of donation for therapeutic purposes) as the point when an embryo created using the donor gamete(s) has been implanted in a woman.¹⁵⁵
- Deceased organ or tissue donors (or those providing consent on their behalf) may have specified that their donated material should be used for the broad classes of 'transplantation' or 'research'. They cannot restrict their donation to a particular class of recipient, in the way currently permitted for gamete donors. However, requests that a deceased donation be directed towards a particular person may now exceptionally be endorsed, although donors cannot make this a condition of their donation.¹⁵⁶

2.30 The regulatory focus on consent enables the individual to have control over any such decision to donate (at least during life). At the same time it side-steps questions of whether, and to what extent, bodily material may be the subject of property rights. However, the increasingly 'transactional' nature of dealings concerning human bodily material (see paragraph 1.27) is putting the question of ownership and property rights over bodily material into the spotlight.

2.31 There is a long legal tradition in the UK and many other countries that there can generally be no property rights in a human body, living or dead. The rights of individual persons in connection with their own bodies are not legally those of 'property ownership', and individuals cannot be owned as property by others. However, the courts have, in certain circumstances been willing to recognise exceptions to this rule, particularly in relation to parts of bodies.¹⁵⁷ It is now well established that where body parts "have acquired different attributes by virtue of the application of skill", then they may become property: preserved human body parts used for training surgeons, for example, have been held to be property and hence protected by the law of theft.¹⁵⁸ Thus any form of tissue that is 'processed' into new products in the way described in Chapter 1 (see paragraph 1.11) may be considered 'property' and may legitimately be sold (though not by the person who provided the source material).¹⁵⁹ Moreover, courts are often prepared to protect the possession of body parts in the hands of third parties, such as the police or coroners, where this is in the service of some proper function.¹⁶⁰

2.32 The law in England and Wales, however, appears to be in a state of flux. In 2009, in the case of *Yearworth*, the Court of Appeal held that sperm was capable of being the property of the men who had produced it, in circumstances where it had been frozen on behalf of men undergoing chemotherapy (in order to protect their fertility) and then by error destroyed.¹⁶¹ The Court made clear that it did not base its finding on the fact that human skill had been used to freeze the sperm, commenting that "developments in medical science now require a re-analysis of the

¹⁵⁵ *Evans v Amicus Healthcare Ltd & Others* [2004] EWCA 727.

¹⁵⁶ A request for a 'directed donation' may be considered if a named relative or friend of long-standing is in need of the organ, and a number of other criteria are met. An independent oversight group will decide whether or not the request should be granted, and priority will always be given to a patient in urgent clinical need. See: Department of Health (2010) *Requested allocation of a deceased donor organ*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_114803.pdf. This policy is agreed by all UK health administrations.

¹⁵⁷ See, for example, *AB v Leeds Teaching Hospital* where Gage J stated that the "principle that part of a body may acquire the character of property which can be the subject of rights of possession and ownership is now part of our law": [2005] 2 WLR 358, at 394.

¹⁵⁸ *R v Kelly and Lindsay* [1999] QB 621.

¹⁵⁹ Human Tissue Act 2004, section 32: see also paragraph 2.34 below.

¹⁶⁰ See, for example, *R v Welsh* [1974] RTR 478; *R v Bristol Coroner ex parte Kerr* [1974] 1 QB 652; *R v Rothery* [1976] RTR 550.

¹⁶¹ *Yearworth and others v North Bristol NHS Trust* [2009] EWCA Civ 37.

common law's treatment of and approach to the issue of ownership of parts or products of a living human body". The implications of this judgement, that bodily material may in some circumstances now legally be considered to be the property of the person from whom it came (that is, the source of the material), remain to be seen. We return, in Chapters 5 and 7, to the ethical, as well as legal, dimensions of ownership.

Comparative material from other jurisdictions

2.33 The snapshot review commissioned by the Working Party of legal provisions in a number of other jurisdictions (see paragraph 2.26 and Appendix 1) highlighted the wide range of potential approaches to the issue of the future control of donated material:

- Living kidney donation is very widely carried out on the basis of 'directed donation': indeed, as noted above, in the absence of material incentives to donate, the desire to benefit a known individual will appear to be the primary motivating factor in such a decision. Regulation differs however, in the extent to which it attempts to control individuals' freedom to donate to those who are *not* known to them. Such donation is permitted in the UK and the US. India, on the other hand, explicitly limits living kidney donation to near relatives of those with a tie of "affection or attachment": potential donors thus do not have the (legal) option of donating an organ, as a living donor, to a stranger.¹⁶² This prohibition was introduced in 1994 in response to concerns about widespread organ trafficking; however, further regulation was introduced in 2008 in an attempt to clamp down on the many ways in which this requirement was being subverted, for example by impersonation or by the use of false marriage certificates.¹⁶³
- On gamete donation, completely opposite positions exist. In the US, directed donation for reproductive purposes is commonly allowed, with recipients often choosing their own donors (for example via direct advertisements).¹⁶⁴ In Spain, by contrast, recipients are not permitted to choose their own donors: this must be done, by law, by the medical team in order to preserve anonymity.¹⁶⁵
- The question of ownership, specifically of tissue, has been considered most comprehensively in the US courts. The case of *Moore* (also seen as influential in the UK) resulted in the decision that Mr Moore had no proper interests in the material excised from his body during treatment for leukaemia, and hence no entitlement to any profits from the commercialised cell-line subsequently developed from it.¹⁶⁶ Subsequent cases (*Greenberg*¹⁶⁷ and *Catalona*¹⁶⁸) upheld the principle that the sources of the material could neither benefit financially from subsequent commercial exploitation nor control the subsequent destination of the tissue. Both did so on the basis that any proprietary rights the sources of the material might initially have possessed had evaporated when the material was voluntarily handed over. However, it could be argued that, in taking this approach, these courts had recognised that such rights could indeed exist but had in these cases been voluntarily relinquished. Legal commentators have thus suggested that the US courts may indeed, in future, recognise individuals as having property rights in tissue detached from their own bodies, and that such rights could be retained if, for example, this was made explicit at the time of donation.¹⁶⁹ A rather different angle on questions of ownership and use is highlighted by Spanish law: while it is silent on the question of any property rights on the part of the source of the material, it states that biobanks are expected to share samples unless there is good reason to refuse,

¹⁶² The Transplantation of Human Organs Act 1994. [India]

¹⁶³ Muraleedharan VR, Jan S, and Ram Prasad S (2006) The trade in human organs in Tamil Nadu: the anatomy of regulatory failure *Health Economics, Policy and Law* 1: 41-57; Transplantation of Human Organ (Amendment) Rules 2008. [India]

¹⁶⁴ See, for example, Levine AD (2010) Self-regulation, compensation, and the ethical recruitment of oocyte donors *Hastings Center Report* 40: 25-36.

¹⁶⁵ Law 14/2006 on assisted human reproduction techniques, Article 6(4). [Spain]

¹⁶⁶ *Moore v Regents of the University of California*, 793 P 2d 479 (Cal SC 1990).

¹⁶⁷ *Greenberg v Miami Children's Hospital Research Institute* 264 F Supp 2d 1064 (US DC Florida 2003).

¹⁶⁸ *Washington University v Catalona* 437 F Supp 2d 985 (US DC Ed Mo 2006).

¹⁶⁹ Hardcastle RJ (2007) *Law and the human body: property rights, ownership and control* (Oxford: Hart Publishing), pp76-7.

thus implying that such samples should be seen as a common good.¹⁷⁰ We return to this issue in Chapter 7 (see paragraph 7.51).

Permissibility of commercial dealings in bodily material

2.34 The issue of the permissibility of commercial dealings in human bodily material is distinct from questions of legal rights of property ownership. Where property rights are explicitly recognised (for example, where bodily material has been processed into a product through the application of skill), then such rights will typically include the entitlement to trade the product in commercial transactions. However, the absence of any clear property rights in other circumstances does not, in itself, mean that commercial dealings are unlawful. In the UK, various regulatory statutes explicitly forbid 'commercial dealings' in some circumstances, but are silent or permissive in others.

- The Human Tissue Act explicitly prohibits "commercial dealings in human material for transplantation" unless it has acquired the character of property "because of an application of human skill". This prohibition is given effect through the creation of an offence of giving or receiving a "reward" in connection with the donation of organs, tissue or blood, where the donated material is intended for the direct treatment of another. It does not cover reproductive material. "Commercial dealings" are not defined, as such, in the Act, but a reward is defined as "any description of financial or other material advantage".¹⁷¹ It is also explicitly stated that reimbursement in "money or money's worth" of any expenses or loss of earnings directly incurred by the donor as a result of making their donation is not prohibited.¹⁷² It is therefore an offence to offer to buy or sell a kidney; but it is not an offence for the NHS to reimburse any expenses incurred in the process of donating a kidney as a live donor.
- The Human Tissue (Scotland) Act similarly prohibits commercial dealings and the giving or receiving of a reward in connection with the supply of any part of a human body for transplantation.¹⁷³ Again, reward is defined as "any description of financial or other material advantage", other than payment in "money or money's worth" to defray expenses and costs.
- Commercial dealings in organs, non-reproductive tissue and blood for any purposes other than transplantation are not covered by the HTA prohibition, and the Scottish provisions similarly relate only to transplantation. It would not, therefore, be unlawful under the Act to offer, or take, a payment in the UK when providing material for research for example.¹⁷⁴ However, such payments do not appear to be widely offered to donors within the UK. One example of a benefit in kind is offered by medical schools who may cover cremation costs where a person has donated their whole body after death for the purposes of medical education and training.¹⁷⁵
- Under the Human Fertilisation and Embryology Act, "no money or other benefit shall be given or received" in respect of the supply of gametes or embryos unless authorised by directions issued by the HFEA.¹⁷⁶ Current directions do not permit "money" to be given or received in exchange for eggs or sperm, whether these are donated for treatment purposes, or for research. However, the Directions do permit what are known as 'egg-sharing' arrangements, where women may be offered reduced fees for their private IVF treatment if they make some

¹⁷⁰ Law 14/2007 on biomedical research, Article 69, available in English at http://www.isciii.es/htdocs/terapia/pdf_comite/SpanishLawonBiomedicalResearchEnglish.pdf. [Spain]

¹⁷¹ Human Tissue Act 2004, section 32(11).

¹⁷² Human Tissue Act 2004, section 32(7).

¹⁷³ Human Tissue (Scotland) Act 2006, sections 17 and 20.

¹⁷⁴ It is however possible that a court would find any such arrangements as unenforceable, as contrary to public policy.

¹⁷⁵ For example, the University of Bristol states that it will bear the cremation costs for a body which is donated to and used by its Centre for Comparative and Clinical Anatomy: University of Bristol (2010) *Donating your body to the Centre for Comparative and Clinical Anatomy, University of Bristol*, available at: <http://www.bristol.ac.uk/anatomy/documents/uobanat2.pdf>.

¹⁷⁶ Human Fertilisation and Embryology Act 1990, section 12(1)(e), as amended.

of their eggs available for another woman's use.¹⁷⁷ Donation of eggs in such circumstances may thus be regarded as resulting in indirect payment of considerable value. This approach has now been extended, at present on a one-off basis, to the 'sharing' of eggs for research.¹⁷⁸

- Under the Surrogacy Arrangements Act 1985, it is an offence to broker a surrogate arrangement "on a commercial basis".¹⁷⁹ This prohibition does not apply to the commissioning parties or the surrogate mother; however, courts scrutinise what payments have been made when deciding whether to award parental rights to the commissioning parents (see below).

2.35 While the regulatory frameworks established under the Human Tissue Act, the Human Tissue (Scotland) Act and the Human Fertilisation and Embryology Act thus ban financial reward for donors in most circumstances, it is, however, recognised that donors may well incur expenses in the process of making a donation. Again, arrangements within the UK as to the reimbursement of expenses, the definitions of what is covered, and whether any expenses are capped, vary depending on the form of bodily material being donated.

- At present, blood donors' expenses are not routinely reimbursed; and indeed the infrastructure for donation is so extensive (for example through systems of work-place donation, and the ready availability of blood centres) that significant costs would not ordinarily be incurred. Such reimbursement would, however, be legal under the Human Tissue Act, and in fact some platelet donors are currently reimbursed for parking when they are donating at city centre sites.¹⁸⁰
- Provision is made for the reimbursement of all expenses, including any lost earnings or welfare benefits, incurred by bone marrow and living organ donors. Guidance from the Department of Health makes clear that while the NHS is not legally obliged to make such payments, NHS trusts and PCTs should do so if the live transplant is permitted under the Human Tissue Act.¹⁸¹
- For gamete donors, the HFEA Code of Practice specifies that travel and other out-of-pocket expenses should be reimbursed in full but that lost earnings should be capped at £250 per cycle of egg donation or course of sperm donation. These rules on reimbursement are currently under review.¹⁸²
- For surrogacy arrangements, the commissioning couple may pay for "expenses reasonably incurred", but any other payments may jeopardise the making of a 'parental order' giving parental rights to the commissioning parents.¹⁸³ In December 2010, however, the High Court did grant a parental order in a case where payments over and above expenses were paid to an overseas surrogate, noting that the welfare of the child (which in this case was held to lie in being brought up by the commissioning parents) was the paramount concern.¹⁸⁴

¹⁷⁷ Human Fertilisation and Embryology Authority (2010) *Directions given under the Human Fertilisation and Embryology Act 1990 as amended*, available at: http://www.hfea.gov.uk/docs/2009-06-03_GENERAL_DIRECTIONS_0001_Gamete_and_Embryo_donation_-_approved.pdf, paragraph 6.

¹⁷⁸ Human Fertilisation and Embryology Authority (2007) *Minutes of the meeting of the HFEA Ethics and Law Committee, 16 January 2007*, available at: http://www.hfea.gov.uk/docs/ELC_Minutes_Jan07.pdf.

¹⁷⁹ Surrogacy Arrangements Act 1985, section 2(2), as amended.

¹⁸⁰ HC Hansard (9 May 2011) *c1040W*, available at: <http://www.publications.parliament.uk/pa/cm201011/cmhansrd/cm110509/text/110509w0004.htm#11050951000004>.

¹⁸¹ Department of Health (2009) *Reimbursement of living donor expenses by the NHS*, available at: http://www.dh.gov.uk/en/Healthcare/Longtermconditions/Vascular/Renal/RenalInformation/DH_4069293; NHS Blood and Transplant (2011) *Bone marrow donation: after your donation*, available at: <http://www.nhsbt.nhs.uk/bonemarrow/qa/>.

¹⁸² Human Fertilisation and Embryology Authority (2010) *Directions given under the Human Fertilisation and Embryology Act 1990 as amended*, available at: http://www.hfea.gov.uk/docs/2009-06-03_GENERAL_DIRECTIONS_0001_Gamete_and_Embryo_donation_-_approved.pdf, paragraph 4. The HFEA's conclusions on reimbursement for gamete donors will be announced at a meeting of its Authority members on 19 October 2011.

¹⁸³ Human Fertilisation and Embryology Act 2008, section 54.

¹⁸⁴ *Re L (A Minor)* EWHC [2010] 3146 (Fam).

- 2.36 In the same way that the regulatory frameworks make provision for the reimbursement of expenses incurred by individuals when making a donation, it is also accepted that costs will inevitably arise for the intermediaries involved in facilitating donation and transplantation. The Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 both exempt financial transactions necessary for such essential activities as transporting, removing, preparing, preserving or storing bodily material from the general prohibition on commercial dealings in connection with transplantation.¹⁸⁵ Payment for such activities is thus not considered to constitute 'commercial dealings'. Directions issued under the Human Fertilisation and Embryology Act 1990 similarly permit licensed fertility centres supplying donor gametes or embryos to other licensed centres to reclaim "the reasonable expenses incurred in the supply of the gametes or embryos" from the receiving centre.¹⁸⁶
- 2.37 By contrast with the above, there is no statutory restriction at all on payments made to healthy volunteers participating in first-in-human clinical trials: indeed the Association of the British Pharmaceutical Society argues that it is "right" for participants to be paid "more than just any expenses they may incur".¹⁸⁷ The amount of the payment "should be related to the duration of residence on the unit, the number and length of visits, lifestyle restrictions and the type and extent of the inconvenience and discomfort involved. As a guide, payments should be based on the minimum hourly wage and should be increased for procedures requiring extra care on the part of the subject or involving more discomfort. Payment must never be related to risk." In other words, volunteers are financially remunerated. For many, the offer of such remuneration will be a key factor in their decision to participate.¹⁸⁸

European and international standards

2.38 There is clear consensus also at European level that financial reward (ie payment that goes beyond covering the costs incurred in the donation) for donors of any form of human bodily material is inappropriate. The EU Tissues and Cells Directive requires member states to "endeavour to ensure" that all donations from both living and deceased donors should be "voluntary and unpaid",¹⁸⁹ while the Organ Directive states more forcefully that member states "shall ensure" that organ donations from both deceased and living donors are voluntary and unpaid.¹⁹⁰ The Oviedo Convention and Additional Protocol require adherence to the principle that "the human body and its parts shall not, as such, give rise to financial gain"; the same phrase is used in the Council of Europe Recommendation from the Committee of Ministers in connection with biological materials donated for research. Allowance is generally made for the reimbursement of expenses, but there are significant differences in terminology in the different instruments, and with respect to different forms of bodily material, as to how such payments should be construed:

- The Organ Directive permits reimbursement that is "strictly limited to making good the expenses and loss of income related to the donation".
- The Tissues and Cells Directive (which covers both reproductive and non-reproductive tissue, hence cutting across HTA and HFEA boundaries) by contrast permits reimbursement "strictly limited to making good the expenses and inconveniences related to the donation". In contrast

¹⁸⁵ Human Tissue Act 2004, section 32(7); Human Tissue (Scotland) Act 2006, sections 17 and 20.

¹⁸⁶ Human Fertilisation and Embryology Authority (2010) *Directions given under the Human Fertilisation and Embryology Act 1990 as amended*, available at: http://www.hfea.gov.uk/docs/2009-06-03_GENERAL_DIRECTIONS_0001_Gamete_and_Embryo_donation_-_approved.pdf, paragraph 10.

¹⁸⁷ Association of the British Pharmaceutical Industry (2007) *Guidelines for phase 1 clinical trials*, available at: <http://www.abpi.org.uk/our-work/library/guidelines/Documents/phase1-trial-guidelines.pdf>, p19.

¹⁸⁸ See, for example, Hermann R, Heger-Mahn D, Mahler M *et al.* (1997) Adverse events and discomfort in studies on healthy subjects: the volunteer's perspective: a survey conducted by the German Association for Applied Human Pharmacology *European journal of clinical pharmacology* **53**: 207-14 and Ferguson PR (2008) Clinical trials and healthy volunteers *Medical Law Review* **16**: 23-51. The conditions surrounding the remuneration here seem to distinguish it from a simple hire of labour (employment), to which it might otherwise be compared.

¹⁸⁹ 2004/23/EC, Article 12.

¹⁹⁰ 2010/45/EU, Article 13.

to the Organ Directive, the Tissues and Cells Directive thus permits compensation for non-monetary as well as monetary losses.

- The additional protocol to the Oviedo Convention on transplantation (covering organs and non-reproductive tissue, but not blood and reproductive tissue) permits "compensation for loss of earnings or other justifiable expenses on the part of the donor".

2.39 The rather looser definition of what may be reimbursed in the Tissues and Cells Directive, permitting reimbursement for 'inconveniences', has led to significant disparity of interpretation within the member states of the EU (see paragraph 2.51).

2.40 The various European instruments also recognise in different ways that legitimate costs may be incurred by the organisations and individuals involved as 'intermediaries' between those providing bodily material, and those ultimately benefiting from it. The EU Tissues and Cells Directive states that member states should "endeavour" to ensure the procurement of tissues and cells is carried out on a non-profit basis¹⁹¹ while the Organ Directive is more prescriptive, stating that states "shall ensure" that procurement is carried out on a non-profit basis.¹⁹² The additional protocol to the Oviedo Convention on transplantation permits "a justifiable fee for legitimate medical or related technical services",¹⁹³ and the explanatory memorandum to the Recommendation of the Committee of Ministers concerning biological materials notes that payments for "legitimate scientific or technical services rendered in connection with the use of such biological materials" would not be affected by the recommendation.¹⁹⁴

2.41 Both EU and Council of Europe instruments also promote the importance of equitable access to services, on the basis that systems that encourage voluntary and unpaid donation should ensure that those encouraged to donate may also have fair access to transplantation services should the need arise.¹⁹⁵ The additional protocol to the Oviedo Convention, for example, requires that:

- a system exists to provide equitable access to transplantation services for patients; and
- procedures for distribution across participating countries take into account the principle of solidarity within each country.¹⁹⁶

The EU Organ Directive similarly highlights the importance of the "allocation of organs based on transparent, non-discriminatory and scientific criteria".¹⁹⁷

2.42 At international level, the distinctions between different forms of bodily material become rather more overt. The WHO Guiding Principles on human organ transplantation (which also apply to non-reproductive tissue) take a very similar approach to the UK and European instruments: they ban "any monetary payment or other reward of monetary value", while permitting the reimbursement of "reasonable and verifiable expenses incurred by the donor, including loss of income"). They also make reference to "societal recognition of the altruistic nature of cell, tissue and organ donation"; and call for the allocation of organs, cells and tissues to be "guided by

¹⁹¹ 2004/23/EC, Article 12.

¹⁹² 2010/45/EU, Article 13.

¹⁹³ Council of Europe (2002) *Additional protocol to the Convention on Human Rights and Biomedicine, on transplantation of organs and tissues of human origin*, available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm>, Article 21(1).

¹⁹⁴ Council of Europe (2006) *Draft Recommendation Rec (2006) of the Committee of Ministers to member states on research on biological materials of human origin: draft explanatory memorandum*, available at: <https://wcd.coe.int/wcd/ViewDoc.jsp?Ref=CM%282006%2921&Language=lanEnglish&Ver=add&Site=CM&BackColorIntranet=DBGDF2&BackColorIntranet=FDC864&BackColorLogged=FDC864>, paragraph 35.

¹⁹⁵ That is – with the aim of ensuring that there is not an 'underclass' of those donating bodily material, who do not themselves have access to health care when they need it. This approach contrasts with a system such as that being introduced in Israel, where those who promise to donate obtain *enhanced* access to a transplant should they need one in the future (see paragraph 2.48).

¹⁹⁶ Council of Europe (2002) *Additional protocol to the Convention on Human Rights and Biomedicine, on transplantation of organs and tissues of human origin*, available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm>, Article 3.

¹⁹⁷ 2010/45/EU, paragraph 20.

clinical criteria and ethical norms, not financial or other considerations". The Declaration of Istanbul calls for the prohibition of 'transplant commercialism' (defined as where "an organ is treated as a commodity, including by being bought or sold or used for material gain"), while clarifying that "comprehensive reimbursement of the actual, documented costs of donating an organ" does not constitute purchase of the organ.¹⁹⁸

- 2.43 By contrast, there is no similar international consensus statement concerning commercial dealings in eggs, sperm and embryos, and as discussed below, practice varies considerably around the world (see paragraphs 2.50 and 2.51).

Box 2.1: Terminology used with respect to „payment“: a summary

- The Human Tissue Act prohibits **commercial dealings** and **rewards** in connection with the provision of human material for the treatment of another. A "reward" is defined as "any description of financial or other material advantage". However, the reimbursement in "money or money's worth" of any expenses or loss of earnings directly incurred by the donor as a result of making their donation is explicitly *not* prohibited.
- The Human Tissue (Scotland) Act prohibits **commercial dealings** and the giving or receiving of a **reward** in connection with the supply of any part of a human body for transplantation. **Reward** is defined as "any description of financial or other material advantage", other than payment in "money or money's worth" to defray expenses and costs.
- The Human Fertilisation and Embryology Act prohibits **money or other benefit** in respect of the supply of gametes, unless explicitly authorised by Directions.
- The EU Tissues and Cells Directive requires Member States to "endeavour" to ensure that tissues and cells are donated on a **voluntary and unpaid** basis, and procured on a **non-profit** basis.
- The EU Organ Directive requires organ donations to be **voluntary and unpaid** and procurement to be on a **non-profit** basis.
- The Oviedo Convention states that the human body and its parts **shall not, as such, give rise to financial gain**.
- The World Health Organization's Guiding Principles ban **any monetary payment or other reward of monetary value**.
- The Declaration of Istanbul calls for the prohibition of **transplant commercialism**, defined as a policy or practice in which an organ is treated as a commodity including by being **bought or sold or used for material gain**.
- The Association of the British Pharmaceutical Industry (ABPI) Guidelines for phase 1 clinical trials state that it is right to **pay** those who volunteer for phase 1 trials **more than just any expenses they incur**. Such **payments** should be based on the minimum wage, and should be increased for procedures requiring extra care on the part of the participant or involving more discomfort. Payment should never be related to risk.

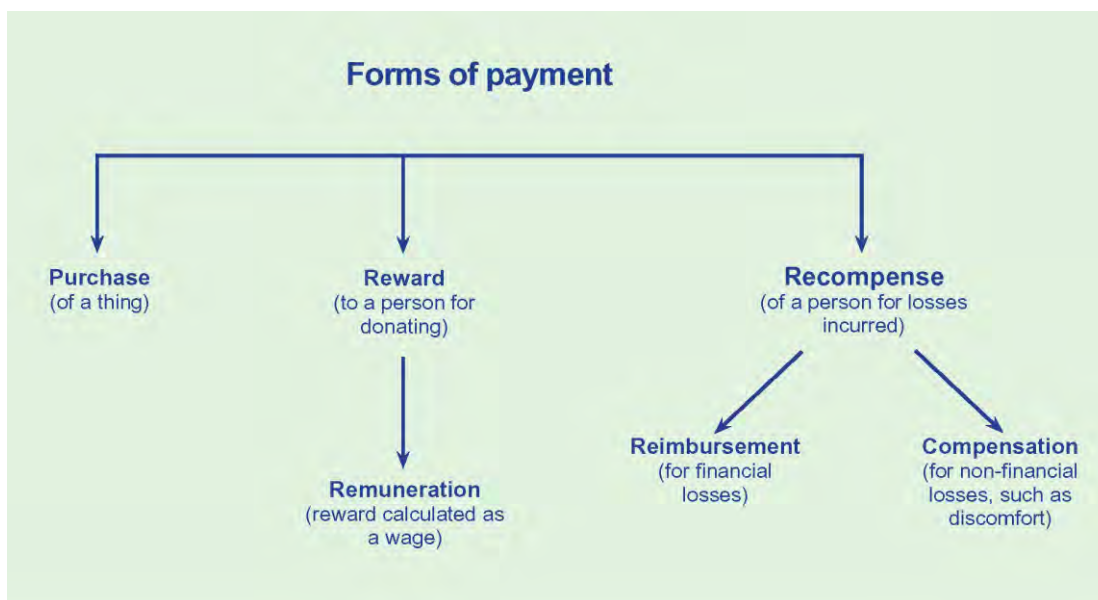
- 2.44 **As the preceding paragraphs demonstrate, a number of different terms are used to capture national and international concerns about the use of money in the context of human bodily material. To do justice to the complexity of these various terms as they are used in everyday life, while at the same time being as clear as possible for the purposes of this report, we propose the following terminology** (see also the Glossary):

- **Payment**: a generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as recompense, reward or purchases.
- **Recompense**: payment to a person in recognition of losses they have incurred, material or otherwise. This may take the form of the **reimbursement** of direct financial expenses incurred in donating bodily material (such as train fares and lost earnings); or **compensation** for non-financial losses (such as inconvenience, discomfort and time).
- **Reward**: material advantage gained by a person as a result of donating bodily material, that goes beyond 'recompensing' the person for the losses they incurred in donating. If reward is calculated as a wage or equivalent it becomes **remuneration**.
- **Purchase**: payment in direct exchange for a 'thing' (e.g. a certain amount for a kidney, or per egg).

¹⁹⁸ Steering Committee of the Istanbul Summit (2008) Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul *The Lancet* **372**: 5-6; see also: The Declaration of Istanbul Custodian Group (2008) *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*, available at: http://www.declarationofistanbul.org/index.php?option=com_content&view=article&id=73&Itemid=59.

We use this terminology throughout this report, with the exception of where we cite directly from others' usage.

Figure 2



Regulatory approaches in other countries

2.45 Notwithstanding the existence of these international statements and declarations governing 'reward', 'monetary payment', and 'benefit' in connection with some forms of material (specifically organs and tissue), attitudes to the role of payment in the donation of bodily material differ significantly around the world, as highlighted by examples below from our snapshot review.¹⁹⁹

2.46 **Iran** is the one country in the world that explicitly renders reward for organs legal. Although Iran is widely described as promoting a 'legal market' in organs, the permitted payment is in fact described as a 'social gift', administered by a non-governmental agency.²⁰⁰ What we might want to see as a boundary between reward (for a person) and purchase (of a thing) is thus blurred. Donors or recipients may be put in touch with each other by the agency, or may approach it as a ready-formed pair. There are, however, strict controls on circumstances in which foreigners may be recipients: while foreign nationals may receive or donate an organ in an Iranian hospital, they must be 'paired' with someone of the same nationality, and the donor may not receive the payment.²⁰¹ The amount paid, ten million Iranian Rials (approximately US\$1,000), has not increased since the system was introduced in 1988;²⁰² other benefits include free life-long health insurance and an annual donor-appreciation event.²⁰³ However, additional (illegal) payments are also frequently made between the parties involved and it is reported that the

¹⁹⁹ See Appendix 1.

²⁰⁰ The scheme (i.e. the current system in Iran offering payment (as *sacrifice gift*) to living donors) was not set up by legislation: rather it is a service offered by a number of NGOs. The terms 'social gift' and 'sacrifice gift' are both used. (Professor Alireza Bagheri, personal communication, 19 February 2011).

²⁰¹ Ghods AJ (2009) Ethical issues and living unrelated donor kidney transplantation *Iranian Journal of Kidney Diseases* **3**: 183-91; Bagheri A (2006) Compensated kidney donation: an ethical review of the Iranian model *Kennedy Institute of Ethics Journal* **16**: 269-82.

²⁰² Ghods AJ (2009) Ethical issues and living unrelated donor kidney transplantation *Iranian Journal of Kidney Diseases* **3**: 183-91.

²⁰³ Haghghi AN, and Ghahramani N (2006) Living unrelated kidney donor transplantation in Iran *Nature Clinical Practice Nephrology* **2**: E1-E.

major part of the sum received by the donor now comes from the recipient. While such payments are against the law, their use appears to be openly tolerated with, for example, advertisements widely posted outside hospital entrances and not removed by hospital authorities.²⁰⁴

- 2.47 **India** explicitly prohibits all 'commercial dealings' in the context of living organ donation.²⁰⁵ The law is silent on whether reimbursement of actually incurred expenses would constitute commercial dealings, and at present no such reimbursement is provided.²⁰⁶ Although the prohibition on commercial dealings was introduced in 1994, in an attempt to tackle widespread organ trafficking, it proved very difficult to enforce: the 'authorising committees' responsible for reviewing donations were expected to cover as many as 700 cases a year; 'middlemen' brokering illicit transactions often held jobs with the hospital where the surgery was due to take place and could coach donors and recipients on how to 'beat the system'; and hospitals and transplant surgeons appeared to turn a blind eye to these and other problems.²⁰⁷ In an attempt to deal with these problems, the 1994 Act was amended in 2008 to increase the resources and independence of the authorising committees: they are now expected to review around 25 cases a year; doctors from the transplant team are excluded from membership; and better records are required.²⁰⁸ There is little information, as yet, as to how well these new measures are working. In 2009, a regulatory review committee also recommended that benefits such as coverage of medical expenses, medical insurance and travel concessions should be introduced for living donors, and these are currently being considered.²⁰⁹
- 2.48 **Israel** prohibits all 'rewards' for organs, except for specified categories.²¹⁰ These permitted categories include payment for burial and transportation costs after death, a certificate of recognition (providing free entrance to national parks and nature reserves) and "allowable reimbursements".²¹¹ Others might regard these 'reimbursements' as a form of reward; they include up to 40 days' sick leave, up to one week's stay in a hotel after the operation and capped contributions to life, health and employment insurance for up to five years.²¹² Israel has also very recently introduced a "priority points" system, under which those who consent in advance to donate after their deaths, or those who donate an organ during their lifetime, earn points to increase their own priority (or that of a parent, sibling, child or spouse) for an organ should they need one in the future.²¹³ The degree of priority depends on the circumstances of donation: a living donor of an organ will obtain "maximum" priority for themselves or their close family members in need of an organ, while holding a donor card will lead to "priority" for the card-holder and "second priority" for their family members.²¹⁴ However, it should be noted that allocation criteria are categorised as 'status 1' (medical criteria such as degree of medical need and compatibility) and 'status 2'; and these priority criteria will only be relevant as 'status 2' considerations. Policy officials therefore do not expect the new system to have a major effect on the allocation of organs, but are optimistic that it will encourage more people to sign donor cards.²¹⁵

²⁰⁴ Ghods AJ (2009) Ethical issues and living unrelated donor kidney transplantation *Iranian Journal of Kidney Diseases* 3: 183-91.

²⁰⁵ Transplantation of Human Organs Act 1994, section 19, http://medlineindia.com/acts/THOA/chapter_VI.html. [India]

²⁰⁶ Sickand M, Cuerden M, Klarenbach S *et al.* (2009) Reimbursing live organ donors for incurred non medical expenses: a global perspective on policies and programs *American Journal of Transplantation* 9: 2825-36.

²⁰⁷ Muraleedharan VR, Jan S, and Ram Prasad S (2006) The trade in human organs in Tamil Nadu: the anatomy of regulatory failure *Health Economics, Policy and Law* 1: 41-57.

²⁰⁸ Transplantation of Human Organ (Amendment) Rules 2008. [India]

²⁰⁹ Sickand M, Cuerden M, Klarenbach S *et al.* (2009) Reimbursing live organ donors for incurred non medical expenses: a global perspective on policies and programs *American Journal of Transplantation* 9: 2825-36.

²¹⁰ Organ Transplant Act 2008, section 2(3). [Israel]

²¹¹ Organ Transplant Act 2008, Articles 30, 23 and 22 respectively. [Israel]

²¹² Personal communication via Dr Kathy Liddell, 28 November 2010.

²¹³ Provision for such a scheme is made under Article 9(b)(4) of the 2008 Act.

²¹⁴ Lavee J, Ashkenazi T, Gurman G, and Steinberg D (2010) A new law for allocation of donor organs in Israel *The Lancet* 375: 1131-3.

²¹⁵ Personal communication via Dr Kathy Liddell, 28 November 2010.

- 2.49 In its National Organ Transplantation Act 1984 (NOTA), the **US** prohibits at federal level any "valuable consideration" for organs, defined to include "kidney, liver, lung, pancreas, bone marrow, cornea, eye, bone and skin, and any other human organ or part thereof".²¹⁶ Reimbursement of donors' expenses is, however, permitted.²¹⁷ In the light of the length of waiting lists for donated organs, a number of attempts have been made at both state and federal level to introduce changes to NOTA, one example being the Specter Bill that sought to redefine valuable consideration to permit reward in kind offered by federal, state and local governments.²¹⁸ To date, all such attempts have been unsuccessful. There is, however, a current legal challenge to the inclusion of bone marrow in the definition of 'organ' by the organisation *Moremarrowdonors.org*, which would like to introduce a system of payments in kind, such as college scholarships, housing allowances or donations to charity, to encourage more bone marrow donors to come forward. The case argues that the prohibition on the payment of valuable consideration for bone marrow is unconstitutional, and is arbitrarily and unjustifiably blocking US citizens' liberty to pay bone marrow donors for their trouble and discomfort.²¹⁹ At the time of writing the decision on this case is still awaited. While bone marrow is included within the NOTA provisions, blood plasma is treated as a separate matter and payments (reported as being between \$20 and \$30 per donation, although this will vary from clinic to clinic) are permitted.²²⁰
- 2.50 The US position on payment for gametes contrasts sharply with that taken on organs: many state laws are silent (hence permissive) on this issue²²¹ and payments of \$5,000 to \$10,000 for eggs for fertility treatment are commonly made.²²² To all intents and purposes, the transaction is a purchase. While guidelines from the American Society for Reproductive Medicine (ASRM) state that payments over \$5,000 require justification and those over \$10,000 are not appropriate,²²³ nevertheless amounts offered for eggs are reported to go as high as \$50,000 where donors have specific physical, cultural or intellectual traits (examples cited include good-looking Ivy-League students, or East Asian or Jewish women).²²⁴ Sperm donors on the other hand may obtain in the order of \$75, although the recipient may have to pay \$250 to \$400 to the clinic.²²⁵ The amounts paid to those willing to provide eggs for treatment contrast sharply with those providing eggs for research where payment is much rarer. Guidelines published by the National Academy of Sciences permit only the reimbursement of expenses incurred in donating,

²¹⁶ The Act applies to transfers of human organs obtained from both living or deceased donors for transplantation. It does not cover material donated for research.

²¹⁷ "Reasonable payments" associated with removal, transportation, implantation, processing, preservation, quality control, storage, travel, housing, and lost wages are excluded from the definition of "valuable consideration": 42 USC 274e(c)(2).

²¹⁸ Satel S, and Steelman A (2009) *When altruism isn't enough: the case for compensating kidney donors* (Washington DC: American Enterprise Institute for Public Policy Research), p129.

²¹⁹ The case remains undecided at the time of writing. See: United States Courts for the Ninth Circuit (2011) Doreen Flynn v Eric H. Holder Jr., no 10-55643, available at: http://www.ca9.uscourts.gov/media/view_subpage.php?pk_id=0000007018.

²²⁰ Plasma Protein Therapeutics Association, personal communication, 1 August 2011.

²²¹ Bercovici M (2007) Biotechnology beyond the embryo: science, ethics, and responsible regulation of egg donation to protect women's rights *Women's Rights Law Reporter* 29: 193. Two exceptions include Louisiana which expressly prohibits payments and Virginia which expressly permits them: Ertman M (2010) The upside of baby markets, in *Baby markets: money and the new politics of creating families*, Goodwin MB (Editor) (Cambridge: Cambridge University Press), pp23-40, at p27.

²²² Spar D (2007) The egg trade: making sense of the market for human oocytes *New England Journal of Medicine* 356: 1289-91; Elster NR (2010) Egg donation for research and reproduction: the compensation conundrum, in *Baby markets: money and the new politics of creating families*, Goodwin MB (Editor) (Cambridge: Cambridge University Press), pp226-36.

²²³ Ethics Committee of the American Society for Reproductive Medicine (2004) Financial incentives in recruitment of oocyte donors *Fertility and Sterility* 82: 240-4: this guidance is however reportedly being challenged as a 'restraint of trade': Court House News Service (2011) *Kamakahi v. American Society for Reproductive Medicine et al.*, No. 11 CV 1781, complaint filed (N.D. Cal. Apr. 12, 2011), available at: <http://www.courthousenews.com/2011/04/13/Ova.pdf>.

²²⁴ Krawiec KD (2010) Price and pretense in the baby market, in *Baby markets: money and the new politics of creating families*, Goodwin MB (Editor) (Cambridge: Cambridge University Press), pp41-55; Levine AD (2010) Self-regulation, compensation, and the ethical recruitment of oocyte donors *Hastings Center Report* 40: 25-36.

²²⁵ Spar D (2006) *The baby business: how money, science and politics drive the commerce of conception* (Boston: Harvard Business School Publishing Corporation), p39.

such as costs "associated with travel, housing, child care, medical care, health insurance and actual lost wages".²²⁶

- 2.51 **Spain**, like the UK, is subject to the EU Tissues and Cells Directive which requires donation to be "voluntary and unpaid", but which permits reimbursement that is "strictly limited to making good the expenses and inconveniences related to the donation" (see paragraph 2.38). However, in the context of gamete donation, Spanish law has interpreted these requirements rather differently from the UK. The National Commission of Assisted Reproduction currently sets the rate of compensation at €916, based on an estimate of the amount of work time lost (38 hours at €15 per hour), travel expenses (€270), meals (€40), and discomfort for hormone injections (€36).²²⁷ While the total figure is therefore clearly presented as compensation for monetary and non-monetary losses, it is often depicted in the form of a reward.²²⁸

Safety

- 2.52 Finally, a key factor in all regulatory schemes is that of safety. Safety concerns relate both to potential harm to the *individual* who is either providing bodily material as a live donor or taking part in a first-in-human trial; and to the future *recipients* of donated material.
- 2.53 We have alluded above (see paragraph 2.24) to the protections set out in both EU and domestic legislation with respect to the safety and well-being of living donors. More detailed requirements are set out in domestic guidance, for example through the HTA Code of Practice which requires that potential organ donors undergo a full assessment of their medical suitability to donate before referral for scrutiny by the HTA itself.²²⁹ Similarly, bone marrow donors must receive a full medical 'work-up' to determine whether they are suitable for the procedure,²³⁰ and the HFEA requires that clinics should take medical and family histories before permitting prospective donors to provide gametes.²³¹ The National Blood Service lists a number of reasons why people should not become blood donors because of the risks to their own health, including weighing less than 50 kilograms, currently taking antibiotics, or waiting for hospital treatment; and requires potential donors to fill in a 'donor health check' questionnaire and provide a drop of blood to check that they are not anaemic, before going ahead.²³²
- 2.54 Safety factors are clearly also central to the regulation both of first-in-human trials and, more widely, of any research involving human participants. Domestic and EU regulations alike make explicit reference to acceptable levels of risk to research participants. First-in-human clinical trials may only take place if the anticipated therapeutic and public health benefits justify the risks;²³³ and in addition to the requirements for ethical review (see paragraph 2.12), trials must be authorised by the MHRA before they may go ahead. International standards, in the form of "Good Manufacturing Practice" (GMP) for all trial medicines²³⁴ and "Good Clinical Practice" (GCP) standards must be met in all trials of medicines, with provision for these to be inspected by the MHRA.²³⁵ GMP ensures that medicinal products are produced and controlled to the

²²⁶ National Academies' Human Embryonic Stem Cell Research Advisory Committee (2010) *Final report of the National Academies' Human Embryonic Stem Cell Research Advisory Committee and 2010 amendments to the National Academies' guidelines for human embryonic stem cell research*, available at: https://download.nap.edu/catalog.php?record_id=12923.

²²⁷ Professor Antonio Pellicer, personal communication, 26 July 2011.

²²⁸ Lenk C, and Beier K (2011) Is the commercialisation of human tissue and body material forbidden in the countries of the European Union? *Journal of Medical Ethics*: electronically published ahead of print.

²²⁹ Human Tissue Authority (2009) *Human Tissue Act code of practice 2*, available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm>, paragraph 59.

²³⁰ Human Tissue Authority (2009) *Human Tissue Act code of practice 6*, available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code6donationofbonemarrow.cfm>, paragraph 49.

²³¹ Human Fertilisation and Embryology Authority (2009) *Code of practice*, available at: http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf, paragraph 11.8.

²³² NHS Blood and Transplant (2011) *What happens when I give blood*, available at: <http://www.blood.co.uk/giving-blood/what-happens/>.

²³³ The Medicines for Human Use (Clinical Trials) Regulations 2004, Schedule 1, Part 2, paragraph 14.

²³⁴ Commission Directive 2003/94/EC.

²³⁵ Commission Directive 2005/28/EC.

quality standards appropriate to their intended use and as required by the marketing authorisation or product specification. GCP comprises a set of internationally recognised ethical and scientific quality requirements which must be observed in the design, conduct, recording and reporting of clinical trials involving human subjects. The 'TOPS' database ('The Over-Volunteering Prevention System') provides the opportunity for trial centres to record when healthy volunteers take part in trials anywhere in the UK, to help prevent people from participating too often.²³⁶

- 2.55 At Council of Europe level, the Oviedo Convention sets out the principle that any medical research on humans is permissible only if "there is no alternative of comparable effectiveness to research on humans" and if "the risks which may be incurred by that person are not disproportionate to the potential benefits of the research".²³⁷ The Declaration of Helsinki states that "medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects" and that "physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed".²³⁸
- 2.56 In order to promote the safety of the recipients of donated material, the EU Directives on organs, tissues and cells, and blood respectively all call for a unified framework for quality and safety to be established in all member states, and for all material to be traceable from donor to end-recipient.²³⁹ The WHO Guiding Principles on organ and non-reproductive tissue similarly require the implementation of quality systems, including systems for traceability and adverse event reporting. When the Working Party met with a number of regulators (see paragraph 2.70), the crucial role played by these safety and traceability requirements was emphasised by several of those present, despite concerns about the associated bureaucratic demands that might act as a disincentive to researchers, or the potential burden on the provider of material such as the requirement to submit to screening and intrusive questioning.²⁴⁰
- 2.57 A key safety concern is that of minimising the risks of transmitting disease from donor to recipient, in the case of both living and deceased donation. Hence, where bodily material is donated either in life or after death, enquiries are made into a potential donor's social, behavioural and medical history. Where the donor is dead, these enquiries are addressed to their GP and family members. In addition to these safety precautions at the time of donation, it is also important to ensure that bodily material can later be easily traced and linked: donors after death can, for example, donate multiple organs or tissues, and if there is a problem with one transplant, it is important for medical reasons to be able to trace other recipients of material from the same person.²⁴¹ While tissue is 'quarantined' for a period after donation (in contrast to organs which are transplanted as quickly as possible), thus reducing the risk of infection being

²³⁶ TOPS (2010) What is TOPS?, available at: <http://www.tops.org.uk/site/cms/contentChapterView.asp?chapter=1>.

²³⁷ Council of Europe (1997) *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine*, available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>, Article 16.

²³⁸ World Medical Association (2008) *WMA Declaration of Helsinki: ethical principles for medical research involving human subjects*, available at: [http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=[page]/[toPage]), Articles 21 and 20.

²³⁹ It is beyond the scope of this report to summarise how these requirements are implemented in the UK; however, detailed requirements relating to the safety of donated materials are set out in the Code of Practice published by the Human Fertilisation and Embryology Authority and in the Human Tissue Authority licensing requirements under the Quality and Safety Regulations (see: Human Fertilisation and Embryology Authority (2009) *Code of practice*, available at: http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf; Human Tissue Authority (2010) *Licensing under the Quality and Safety Regulations*, available at: <http://www.hta.gov.uk/licensingandinspections/licensingunderthequalityandsafetyregulations.cfm>).

²⁴⁰ Meeting held with regulators on 23 June 2010 – see Appendix 1.

²⁴¹ A well-publicised example of how dispersed such future use may be arose in connection with tissue illegally harvested from cadavers in the US, including that of the broadcaster Alistair Cooke: The Guardian (6 January 2007) *Hospitals refuse to warn of bone contamination*, available at: <http://www.guardian.co.uk/society/2007/jan/06/hospitals.health>.

identified too late, nevertheless errors involving tissue may have more extensive implications given the very large number of potential recipients. Moreover, in the case of tissue recipients, the donated material may in some cases be used for procedures to improve quality of life, such as cartilage transplants, rather than life-saving procedures: in such situations patients may well have a different approach to the degree of risk they are willing to accept.

- 2.58 Where material is donated during life, there are additional reasons for ensuring traceability. Where material is donated for research purposes, clinical findings that may affect the donor's own health may emerge at a later stage, and where material such as blood is donated for therapeutic purposes, routine safety testing may produce results that are significant for the donor's own health care.²⁴² Similar concerns arise where reproductive material is donated. However, as noted below (see paragraph 2.74), additional, very different, reasons for traceability now exist in the case where a child is born as a result of egg or sperm donation: information about the donor must be retained so that any child born as a result of the donation can access it at the age of 18 years. These 'social' reasons for traceability clearly have rather different implications from the medical reasons described here.

Licensing

- 2.59 Many of the regulations discussed above imply authorised bodies that are able to oversee the transaction at issue. Between the individuals concerned (donors, clinicians, researchers and so forth), and the protocols and regulations that govern their behaviour, are intermediaries of another kind: the institutions, clinics, hospitals, and research laboratories that carry out procedures. Another area of regulation is thus concerned with the oversight of such institutions, which is achieved within the UK by a licensing regime: treatment or research using donated materials may only proceed under licence. The role of licensing bodies is thus highly influential in determining the impact of regulation on day-to-day practice.
- 2.60 Under the Human Tissue Act 2004, a number of activities are only lawful in England, Wales and Northern Ireland if licensed by the HTA. These include:
- Carrying out an anatomical examination;
 - Making a post-mortem examination;
 - Removing organs and tissue from a deceased person (other than for the purposes of transplantation where no licence is required);
 - Storing organs and tissue from a living or deceased person for the treatment of patients, or for research (other than for a specific ethically approved research project).

On behalf of the Scottish Government, the HTA also licenses organisations in Scotland that procure, store, test, process, distribute, import or export human tissues or cells that are intended to treat patients.

- 2.61 The Human Fertilisation and Embryology Act 1990²⁴³ similarly sets out a number of activities that are only lawful if licensed by the HFEA. These include storing gametes or embryos, creating embryos *in vitro*, and using sperm,²⁴⁴ eggs or embryos in fertility treatment services. Research activities are licensed separately from treatment services, and centres that both undertake research and offer treatment services require separate licences for each activity.

²⁴² See, for example, NHS Blood and Transplant (2007) *Tests on your blood*, available at: http://www.blood.co.uk/pdf/tests_on.pdf, where it is stated: "If your blood gives a positive test result we will inform you and offer you appropriate advice. If the result is significant to your health you will be asked to discuss the results with one of our doctors and, with your permission, we will arrange a referral to your own doctor or a specialist."

²⁴³ As amended by the Human Fertilisation and Embryology Act 2008.

²⁴⁴ Other than partner-donated sperm that has not been processed or stored.

The growth of regulatory frameworks

2.62 The historical events lying behind the development of these various regulatory frameworks – both within the UK and on an international basis – can be broadly divided into two categories: response to medical accident or scandal; and response to the challenges of new technologies.

Response to medical accident or scandal

2.63 The regulation of medicines has evolved gradually over the last century, as the production of medicines moved from individual pharmacists' premises to mass production, and from an emphasis on following old 'recipes' to the development of new medicines based on pharmaceutical research. This gradual process leading towards the current system of mandatory testing and licensing has, however, been given extra stimulus by highly publicised medical accidents such as: the marketing of 'elixir sulfanilamide' (a liquid form of an existing drug, inadvertently containing a poison in the solution) in the US in 1937;²⁴⁵ and the dangerous effects of thalidomide in the UK in the 1950s and early 1960s. In the UK, the outcry over thalidomide led to the setting up of the Committee on Safety of Drugs in 1963, and a new system of licensing under the Medicines Act 1968.²⁴⁶ The Committee on Safety of Drugs subsequently became the Committee on Safety of Medicines and in 2005 merged with the Medicines Commission to become the Commission on Human Medicines (CHM).

2.64 The CHM's main role is to provide independent scientific advice on the safety, quality, and efficacy of new medicines.²⁴⁷ The Commission was not initially involved in the appraisal of clinical trials, but gained this role in 2007 after the serious adverse reactions suffered by six volunteers taking the experimental compound TGN1412 at Northwick Park hospital in 2006. A series of recommendations made as a result of the subsequent inquiry into the events at Northwick Park aimed to improve the reduction and management of risk, and emphasised the importance of good communication with RECs at an early stage.²⁴⁸ The CHM may now be requested by the MHRA to offer expert advice on first-in-human trials where this is thought necessary.²⁴⁹

2.65 A similar history of 'scandal' lies behind much of current regulatory structure governing organs and tissue in the UK. The Human Organ Transplants Act 1989 was enacted in order to prohibit the sale of organs, in direct response to allegations that kidneys from paid donors had been transplanted at a London hospital.²⁵⁰ The Human Tissue Act 2004, which replaced both the 1989 Act, and other earlier legislation, retained this policy of not commercialising organs. However, as noted earlier in this report, the 2004 Act was not just a consolidation measure: it was also a response to concerns about inappropriate organ and tissue retention at Alder Hey Hospital in Liverpool, Bristol Royal Infirmary, and other NHS hospitals.²⁵¹ The public outcry about the retention, ostensibly for research purposes, of bodily material from dead children, without valid consent from the parents, or on the basis of consent given without proper

²⁴⁵ See the FDA website for a history of the 'sulfanilamide disaster':

<http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/ucm2007257.htm>.

²⁴⁶ Medicines and Healthcare products Regulatory Agency (2008) *Medicines and medical devices regulation: what you need to know*, available at: <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websitesresources/con2031677.pdf>, p3.

²⁴⁷ Medicines and Healthcare products Regulatory Agency (2011) *Commission on Human Medicines*, available at: <http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/CommissiononHumanMedicines/index.htm>.

²⁴⁸ Department of Health (2006) *Expert scientific group on phase one clinical trials: final report*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_073165.pdf.

²⁴⁹ The decision to refer trial applications to CHM will be based on an assessment of risk factors. For further information on the circumstances where the CHM may be consulted for advice, see: Medicines and Healthcare products Regulatory Agency (2009) *Applications first time in man (FTIM) trials with novel compounds*, available at: <http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Commonissues/index.htm>.

²⁵⁰ House of Commons (16 May 1989) Second Reading Committee on the Human Organ Transplants Bill, column 3.

²⁵¹ Department of Health (2001) *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065047.pdf.

understanding of how much material was being taken, led to a new focus on the need for explicit consent before any material could be retained and used. This represented a significant shift from the earlier approach in the Human Tissue Act 1961, which relied on 'lack of objection' as a legal basis for bodily material to be used after death for therapeutic purposes, medical education or medical research, and which furthermore included no penalty for transgression.²⁵²

- 2.66 The first WHO Guiding Principles on human organ transplantation were similarly developed as a result of World Health Assembly concerns about "trade for profit in human organs" in 1987.²⁵³ The Principles were adopted in 1991, and emphasised the importance of no payment for organs and tissues, with the aim of avoiding exploitative or divisive practices; they also encouraged countries to become self-sufficient. The revised Principles, adopted in 2010, while retaining the ban on commercialisation, responded in addition to scientific and social changes (see paragraph 2.69).
- 2.67 Concern about 'trafficking' also led to the production in 2009 of a joint study on the issue by the Council of Europe and the United Nations.²⁵⁴ This report highlighted the important distinction to be made between trafficking in *people* for the purpose of organ removal, and trafficking in organs, tissues and cells themselves. Trafficking in human beings for the purposes of removing organs is covered by existing Council of Europe and United Nations conventions on human trafficking; by contrast, there is no international agreement on what constitutes 'trafficking' in organs, tissues or cells. The joint study called for such a definition to be agreed at an international level, and suggested that the starting point for any such definition should be "the idea that any organ transaction outside the national systems for organ transplantation should be considered organ trafficking".²⁵⁵ The year before, the Declaration of Istanbul had condemned organ trafficking, which it defined as "the recruitment, transport, transfer, harbouring, or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation."²⁵⁶

Response to scientific development

- 2.68 In contrast to the regulation of new pharmaceutical compounds, and dealings in human organs and tissues, regulation governing reproductive materials has evolved in response to technological and medical developments: in particular the birth in 1978 of the first 'test-tube baby' Louise Brown.²⁵⁷ However, it took more than a decade until the Human Fertilisation and Embryology Act was passed in 1990, and hence the practice of infertility treatment using IVF techniques became well established before the regulatory structure came fully into force.²⁵⁸ By the time the 1990 Act was implemented, the use of donor gametes for IVF treatment was also well-established: the use of donor sperm had been possible for many decades, while egg donation was developed in the 1980s.
- 2.69 As we note earlier (see paragraph 2.66), scientific and social developments also played a contribution in the decision to revise the WHO's *Guiding Principles* for organ and tissue

²⁵² Human Tissue Act 1961, section 1.

²⁵³ World Health Assembly (1987) *Fortieth World Health Assembly: WHA40.13 - development of guiding principles for human organ transplants* available at: <http://www.who.int/transplantation/en/WHA40.13.pdf>.

²⁵⁴ Council of Europe and United Nations (2009) *Trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs*, available at: http://www.coe.int/t/dghl/monitoring/trafficking/docs/news/OrganTrafficking_study.pdf.

²⁵⁵ *Ibid*, p8.

²⁵⁶ Steering Committee of the Istanbul Summit (2008) Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul *The Lancet* **372**: 5-6.

²⁵⁷ See, for example, BBC News Online (1978) *On this day: 1978 - first 'test tube baby' born*, available at: http://news.bbc.co.uk/onthisday/hi/dates/stories/july/25/newsid_2499000/2499411.stm.

²⁵⁸ There was, however, an Interim (Voluntary) Licensing Authority which was established in 1985 following the publication of the Warnock report. This operated until the HFEA was established through legislation passed in 1990.

transplantation. In 2004, the World Health Assembly felt it appropriate for the *Principles* to be updated to respond to "current trends in transplantation, particularly organ transplants from living donors and the increasing use of human cells and tissues".²⁵⁹ In addition to setting out requirements that aim to ensure the voluntary nature of donation, prohibit the sale or purchase of cells, tissues and organs, and promote high standards of safety and quality of donated material, the Principles also state that "the maximal development" of deceased donation programmes is to be promoted because of the risks inherent in living donation.

Issues arising in current regulation

Issues raised by individual UK regulators

- 2.70 The Working Party met with representatives from a number of regulatory bodies, from the pharmaceutical industry, and from the National Research Ethics Service (NRES),²⁶⁰ to discuss both the background to regulation in their particular field, and their current focus and concerns.²⁶¹
- 2.71 The HTA told us that their primary concerns are to ensure that consent to donation is voluntary, and that donations are made on the basis of 'altruism' and the 'gift relationship'. (We return to the question of how these terms are understood in Chapters 4 and 5.) The main ethical concerns for the HTA relate to the possibility of coercion and the risks inherent in live donation; and the key ethical principle underpinning their work is that the person making the donation not only has the information necessary to make their decision but also understands it.
- 2.72 For 'first-in-human' trials, those working in the field highlighted the difficulties inherent in ensuring 'consent' is meaningful in circumstances when the risks to humans of the new compound are unknown and possibly unknowable (and indeed where the substances may, by their nature, be becoming increasingly specific for pharmacological targets in humans and therefore not active in other animal species). This issue is of particular concern given that, even in circumstances where the nature of a risk is well established, difficulty is often experienced in communicating that risk to an individual in a way that is meaningful to them.
- 2.73 Both those involved in carrying out pharmaceutical research and the representative of the NRES also highlighted how researchers and RECs alike struggle with ethical concerns around monetary compensation for volunteers.
- 2.74 The HFEA noted two areas where the regulation of reproductive material raises rather different issues from those generated by other kinds of donation. The first relates to the possibility of a future relationship with a person genetically related to the donor: donation of gametes or embryos clearly has the potential to result in a child, a 'third party' in the transaction. Donation is permitted both to known and unknown recipients; moreover, children conceived after 1 April 2005 as a result of donated gametes are entitled to ask for identifying information about their donor once they reach the age of 18 years.²⁶² Thus, depending on the circumstances of donation, the date of the donation, and the individual decisions of the parents bringing up children conceived using donated gametes, children's experiences may vary from a close personal relationship with their donor (for example the child's social 'aunt' who donated eggs to her sister and hence is the genetic mother), to ignorance that they are donor-conceived.

²⁵⁹ World Health Organization (2010) *WHO guiding principles on human cell, tissue and organ transplantation*, available at: http://www.searo.who.int/LinkFiles/BCT_WHO_guiding_principles_organ_transplantation.pdf.

²⁶⁰ NRES is part of the National Patient Safety Agency, and works to protect research participants and facilitate and promote ethical research. It also supports the work of RECs.

²⁶¹ Meeting held with regulators on 23 June 2010 – see Appendix 1.

²⁶² Human Fertilisation and Embryology Authority (2009) *My information: what can my donor-conceived offspring find out about me?*, available at: <http://www.hfea.gov.uk/1974.html>.

Similarly, 'anonymous' donors who have donated since 2005 have to accept that they may be contacted in 18 years' time by their genetic child.

- 2.75 The second point raised by the HFEA was the mainly private sector nature of infertility treatment. Initial development of infertility clinics in the 1970s and 1980s took place largely in the private sector, and although infertility treatment is now available within the NHS, provision has remained patchy.²⁶³ One implication of the private nature of much infertility practice is that there is no national framework either for recruiting egg and sperm donors, or for allocating donated gametes, and hence approaches vary between clinics. Another is that the transactions involved in undergoing fertility treatments are already on a commercial footing, insofar as fees will be payable to the clinic for its services, even though financial reward for the donor of gametes is forbidden. We return to the issue of what is 'public' as opposed to what is 'private' in Chapter 4.

Issues of common concern in regulation

- 2.76 A number of common issues were raised with us both by regulators and by respondents to our public consultation, and these are briefly highlighted in Box 2.2. While we cannot aim to respond to all these issues in this one report, we return to many of the concerns in more detail in later chapters.

Box 2.2: Issues of regulatory concern

Consent

The main regulatory concerns about consent that arise in the context of the donation of human bodily material or volunteering for a first-in-human clinical trial relate to factors that may potentially undermine the *validity* of the consent, and to the question of the *scope* of the consent sought:

- On *validity* of consent, there is controversy as to whether the offer of any significant incentive – whether in the form of direct cash payments or indirect financial benefits such as free or reduced fees for IVF treatment – could act as a form of 'undue influence' on the person considering donating material or participating in a first-in-human trial, thus invalidating their consent. RECs currently struggle with this issue when asked to approve payments to participants in first-in-human trials. Similar concerns about „undue influence“ arise in connection with the possibility of coercion within the family, where one family member is being encouraged to donate bodily material to help another.
- In terms of the *scope* of the consent for research, is it appropriate to encourage the use of generic consent over specific consent, despite the inevitably imperfect information that can be given to the donor at the time consent is sought? And if so, is it more appropriate to develop systems of broad consent, with ongoing commitment to contact between researchers and donors; tiered or fettered consent where particular 'opt-outs' are available; or simple blanket consent, with no limits and no future relationship?

Recompense

The rather different rules applied to recompensing losses incurred in donations of different forms of bodily material (see paragraph 2.35) highlight a number of difficult ethical issues in this area:

- What should recompense be provided for? Should such recompense relate only to receipted expenses, such as travel costs or lost earnings, or should non-financial 'losses', such as inconvenience or discomfort, be recompensed in some way? The EU Tissues and Cells Directive permits such recompense, while the EU Organ Directive does not.
- If lost earnings are to be reimbursed, why not remuneration for a person's time in other circumstances?
- Why is it acceptable to offer benefits in kind, such as 'egg-sharing' to egg donors, but not the equivalent monetary value?
- Given that most, if not all, of those involved as 'intermediaries' between the donor and recipient of material, will be remunerated for their work, is it just that donors cannot be rewarded?

Role of living organ donors

Living kidney donation is positively encouraged in the UK and elsewhere, and has become a significant source of kidneys for transplantation (see paragraph 1.9). However, both the Oviedo Convention and the WHO Guiding Principles emphasise that deceased donation is to be preferred where possible. Given the risks to the donor inherent in living organ donation, how far should regulatory bodies go in actively encouraging living donation?

²⁶³ In a recent survey of the provision of IVF services by PCTs, it was found that, of the PCTs which offer IVF to patients, 39 per cent offer one cycle of treatment; 26 per cent offer two cycles; and 27 per cent offer three. See: All Party Parliamentary Group on Infertility (2011) *Holding back the British IVF revolution? A report into NHS IVF provision in the UK today*, available at: <http://www.infertilitynetworkuk.com/uploadedFiles/InfertilityAwareness/appg%20IVF%20report.pdf>, part 4.

Traceability

While traceability requirements have clearly been adopted in order to enhance the safe use of donated material, they can nevertheless in their turn raise ethical challenges, for example:

- the potential distress caused to the family of a deceased donor if hitherto unknown information about their relative's past lifestyle comes to light;
- implications for the family if information about genetic diseases is revealed;
- whether an organ or tissue that has already been transplanted should be removed if information that affects its suitability as a transplant later emerges.

Chapter 3

Supply and demand

Chapter 3 - Supply and demand

Chapter overview

- The increasing possibility of using many forms of bodily material to benefit others in medical treatment and research has brought about a constant pressure within the UK to meet demand. There is a continual need to recruit new blood donors in order to maintain an adequate supply of blood; three people die every day while waiting for an organ transplant; many fertility clinics are not able to meet requests for treatment involving donor eggs or sperm; and research organisations cite difficulties in accessing bodily material as a key factor limiting research progress. 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.
- The relationship between supply and demand for human bodily material is a complex one. 'Demand' for material is inherently elastic: as scientific developments make more treatments possible, the demand for that treatment is likely to increase, and the development of alternatives may lead to more people overall being treated, rather than necessarily reducing demand. Wider public health factors in the population as a whole, such as high levels of obesity, diabetes, and alcohol consumption, play a key part in determining the demand for organs in particular, while the trend towards later motherhood increases the number of women who are likely to need medical help, including the use of donor gametes, to conceive. Public expectations of what medical science can achieve may serve to put further upward pressure on demand.
- Discussions around how best to increase supply of bodily material often focus on questions of donor motivation: how individuals may best be encouraged to donate different forms of bodily material. Considerable effort is put into coordinated advertising campaigns to recruit blood and organ donors, and proposals to incentivise potential donors through benefits in money or in kind regularly emerge in academic circles. However, individual motivation and choice is only one part of the picture: the central role of organisations, organisational procedure and intermediary professionals in facilitating donation is becoming better understood, as is the importance of trust in these systems.
- Examples of such organisational factors include the significant changes to the management of organ donation services made in recent years, with the aim of ensuring that whenever a person dies in circumstances where organ donation is a possibility, this possibility may be raised with their family. The issue of consent – of whether, for example, organs might routinely be taken after death unless the deceased had explicitly objected in advance, or whether people might be required to log their consent or objection to organ donation during their lifetime – continues to be a subject of fierce debate. Blood donation services are arranged in such a way as to make it as easy as possible for those inclined to donate to do so, and a central NHS organisation acts to co-ordinate the donation of tissue after death for treatment purposes. Examples are beginning to emerge of the NHS, universities and commercial companies working closely together to ensure that patients' willingness to donate bodily material for research purposes may be properly utilised through effective arrangements for tissue banking and the accurate recording of consent.

Introduction

"We should have a system where supply for daily essentials (blood for instance) is greater than demand." - anonymous consultation respondent

"We teach our children from their earliest days that „I want..." is no basis on which to proceed. A demand-driven service will always be running hard to try and catch up with its own shadow." - anonymous consultation respondent

"It's not serious until it's you needing it. None of us need anything [now], so we don't have an issue." - participant at deliberative event²⁶⁴

- 3.1 The possibility of using many forms of bodily material to benefit others in medical treatment and research has brought about a constant pressure within the UK to meet demand. From one perspective, pressure for bodily material may be perceived as being primarily driven by potential recipients: without a recipient's desires, needs and expectations, the concept of 'demand' for material would not exist. However, the momentum of demand is also created by the research

²⁶⁴ See Acknowledgments and Appendix 1 for details of this event involving 43 members of the public.

community: novel treatments are not requested unless they are first developed by researchers, and then made available to patient populations. Talking starkly in terms of 'supply' and 'demand' may resonate with the experiences of many professionals and patients (potential recipients) who are only too aware of the impact of any shortage in supply. We do, however, realise that speaking in these terms may also carry connotations of impersonal procurement, without consideration of the human nature of their source. We emphasise here that, while we use the apparently impersonal terms 'supply' and 'demand' throughout this report, we remain conscious that, on both sides of the equation, we are talking about people and people's lives.

- 3.2 The relationship between levels of demand and supply varies considerably according to the form of bodily material in question, and also whether it is to be used for the purpose of treatment or research. Demand, moreover, is not simply a matter of the *quantity* of a particular type of material being available, but also its *qualities*: in organ, blood and bone marrow donation, for example, donated material has to be 'matched' immunologically to its potential recipient. Corneas, on the other hand, do not always need to be matched on an immunological basis, but do need to be transplanted into a person of similar age to the donor.²⁶⁵
- 3.3 An increasing demand for bodily material may also arise as a result of people living longer.²⁶⁶ As the body ages, it is more likely to need medical treatment and, subsequently, the use of bodily material as part of that treatment.²⁶⁷
- 3.4 While the focus of this chapter is on issues of supply and demand within the UK, we have already noted that both people and bodily material cross borders (see paragraph 2.2). The WHO's third global consultation on organ and tissue donation and transplantation in 2010 raised questions about some of the implications of such movements, defining "organ trafficking" and "transplant tourism" as areas of concern.²⁶⁸ The revised WHO Guiding Principles published after the consultation include a recommendation that countries or sub-regions should aim for self-sufficiency.²⁶⁹

Supply and demand in the UK: the current picture

Blood

"In the case of blood donation, it is likely that it is right to meet the demand." - Professor Jayapaul Azariah, consultation respondent

- 3.5 Around 1.4 million registered blood donors donate almost two million units of whole blood each year, through 24 blood donation centres in England and North Wales, and 100 mobile blood

²⁶⁵ NHS Blood and Transplant (2009) *Cornea transplantation*, available at: http://www.uktransplant.org.uk/ukt/newsroom/fact_sheets/cornea_transplantation_fact_sheet.jsp. The eye banks match recipients with corneas from similar aged donors and recent increases in the age of donors has resulted in a shortage of quality corneas for younger recipients.

²⁶⁶ Over ten million people in the UK are over 65 years old. The latest projections are for 5.5 million more older people in 20 years' time. See: House of Commons Library Research (2010) *Key issues for the new Parliament 2010: the ageing population*, available at: http://www.parliament.uk/documents/commons/lib/research/key_issues/Key%20Issues%20The%20ageing%20population2007.pdf.

²⁶⁷ For example, the incidence of chronic kidney disease is higher in people aged 65 years and over: see Stevens PE, O'Donoghue DJ, de Lusignan S *et al.* (2007) Chronic kidney disease management in the United Kingdom: NEOERICA project results *Kidney International* **72**: 92-9. It should also be noted, however, that older people may contribute to the *supply* of bodily material. For example, bone removed during the course of a hip replacement operation may be donated and used in the treatment of others.

²⁶⁸ World Health Organization (2010) *Sixty-third World Health Assembly: provisional agenda item 11.21 - human organ and tissue transplantation*, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_24-en.pdf.

²⁶⁹ *Ibid.*, paragraph 13.

collection teams which are managed by the National Blood Service (NBS).²⁷⁰ Blood donations made in other countries of the UK are managed by the Northern Ireland Blood Transfusion Service, the Scottish National Blood Transfusion Service, and the Welsh Blood Service (in South Wales). While overall rates of blood donation in the four countries of the UK remain fairly steady,²⁷¹ there is a constant need to recruit new donors: only four per cent of the UK population are blood donors and NHSBT aims to recruit 250,000 new donors each year to replace those who can no longer give blood.²⁷² The Chief Medical Officer's National Blood Transfusion Committee notes that blood shortages in the UK are rare, but that shortage could potentially be caused by situations such as bad weather – where potential donors are unable to travel to blood donation centres – or an outbreak of flu. There may also be a particular need for donors with a certain blood type to donate.²⁷³ The Committee has produced a plan for NHSBT and NHS hospitals to follow in the event of a specific shortage of red cells.²⁷⁴

- 3.6 While national blood donor campaigns (see paragraph 3.69 and Box 3.3) encourage potential donors to come forward, there may be reasons why people are not permitted to donate, such as where the well-being of the donor may be compromised or where evidence suggests that a donation could potentially harm the recipient.²⁷⁵ For example, until recently the NBS asked men who have sex with men not to give blood. However, the Advisory Committee on the Safety of Blood, Tissue and Organs (SaBTO) has now recommended that men who have sex with men should no longer be barred from donating blood, providing that they have not had sex with a man for a year.²⁷⁶ Recent guidance issued by the UK Blood Services Standing Advisory Committee on the Care and Selection of Donors also excludes those with myalgic encephalitis (ME) permanently from giving blood in the UK.²⁷⁷ Visitors to malarial areas should not donate blood until six months after their return from the area, and pregnant women should wait until at least nine months after the baby's birth before donating.²⁷⁸ Such exclusions are subject to review, based on current scientific evidence: for example, in 2008, SaBTO changed its policy on people with type 2 diabetes who were formerly excluded from donating: people with type 2 diabetes who manage their condition by taking tablets and have no complications or other underlying medical conditions are now able to be blood donors.²⁷⁹ Such 'technical' changes to donor criteria may have significant implications for supply when considered cumulatively.

Organs for transplantation

"Whilst we continue to run both a successful heart and lung transplantation programme, the rate-limiting step for both clinical services is the supply of viable organs, with the demand for organs

²⁷⁰ NHS Blood and Transplant (2011) *Small numbers, big hearts: annual review 2010/11*, available at: http://www.nhsbt.nhs.uk/annualreview/pdf/nhsbt_annual_review_2010-2011.pdf, p9.

²⁷¹ In the past five years, whole blood donor rates in the UK varied between 2.23 million donors in 2006-2007 to 2.33 million in 2008-9: NHSBT, personal communication, 12 January 2011; Scottish National Blood Transfusion Service (2010) *From giving to receiving: Scottish National Blood Transfusion Service - 2008-9*, available at: http://www.scotblood.co.uk/pubdocs/SNBTS_Annual_Report_2008-09%5B1%5D.pdf; Northern Ireland Blood Transfusion Service (2010) *Annual report 2009-10*, available at: <http://www.nibts.org/0910%20NIBTS%20Annual%20Report.pdf>; Welsh Blood Service, personal communication, 21 February 2011.

²⁷² NHS Blood and Transplant (1 January 2011) *Successful year for blood and organ donation*, available at: http://www.nhsbt.nhs.uk/news/2011/newsrelease010111_2.html.

²⁷³ For example, in 2010, the Department of Health issued a press release which urged people with Group O negative blood (so-called 'universal donors') to donate blood. See: Department of Health (20 December 2010) *Andrew Lansley urges people to give blood*, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_122978.

²⁷⁴ Chief Medical Officer's National Blood Transfusion Committee (2009) *A plan for NHS Blood and Transplant and hospitals to address red cell shortages*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/@sta/@perf/documents/digitalasset/dh_109118.pdf.

²⁷⁵ See: NHS Blood and Transplant (2010) *Who can't give blood?*, available at: https://secure.blood.co.uk/c11_cant.asp.

²⁷⁶ Advisory Committee on the Safety of Blood, Tissues and Organs (2011) *Donor selection criteria review*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_129909.pdf.

²⁷⁷ NHS Blood and Transplant (8 November 2010) *ME/CFS sufferers permanently deferred from giving blood*, available at: https://safe.blood.co.uk/PressRelease/MS033_081110_RG_ME_CFS_donor_deferral.pdf.

²⁷⁸ NHS Blood and Transplant (2010) *Who can't give blood?*, available at: https://secure.blood.co.uk/c11_cant.asp.

²⁷⁹ Diabetes UK (2008) *New guidelines for blood donors*, available at: http://www.diabetes.org.uk/About_us/News_Landing_Page/2008/New-guidelines-for-blood-donors/.

exceeding, as it has done for many years, the number available. Supply is further compromised in that a high proportion of donor organs are currently not suitable for transplant..." - Royal Brompton & Harefield NHS Foundation Trust, consultation respondent

"It is an exaggeration that the perceived shortage of organs is „critical“; since there is no „right“ to organs ... Judgment should not be clouded by the impression that the demand for organs is critical and that people will die if organs are not donated." - E. J. Toogood, consultation respondent

- 3.7 Probably the best known example of the gap between the supply of, and demand for, bodily material is that of organs for transplant. There are 8,000 people in the UK awaiting a transplant, and a further 2,000 people on the 'suspended' list because they are either too ill or unable to receive a transplant at the present time.²⁸⁰ A figure often highlighted by NHSBT is that three people die each day while waiting for an organ transplant.²⁸¹ It is likely, however, that these numbers under-represent the number of individuals who could potentially benefit from a transplant: patients are listed for transplantation when the benefits clearly outweigh the risks and there is a good prospect of long-term graft and patient survival. As a consequence, not every patient who could potentially benefit from transplantation will be listed: for example, only around 30 per cent of dialysis patients in the UK will be considered suitable for transplantation. The alternatives to transplantation vary for the different types of organ failure: for kidneys it is generally dialysis, for the pancreas it is insulin treatment, for the heart there is the possibility of a left ventricular assist device, while for the liver and lungs there is no alternative and patients will die. Transplantation has become standard practice over the last 50 years, and in that time the short and long-term survival of transplanted organs has consistently improved, but re-transplantation will still be required for a significant number of recipients. Ten-year graft survival is of the order of 67 per cent for kidneys from deceased donors, 80 per cent for kidneys from live donors, 52 per cent for livers, 60 per cent for pancreas, 68 per cent for hearts and 36 per cent for lungs.²⁸²
- 3.8 At the time of writing, nearly 18 million people – or 29 per cent of the UK population – have registered their willingness to donate some or all of their organs after their death, via the ODR.²⁸³ Registering with the ODR makes the person's wishes clear if they die in circumstances where organ donation is an option; however, joining the ODR is not actually a prerequisite for organ donation, as a person in a 'qualifying relationship' with the deceased person may be asked to consent to donation in their place (see paragraph 2.15). In the 2010-2011 financial year, there were 1,010 deceased organ donors, 33 per cent of whom were registered on the ODR.²⁸⁴ NHSBT has been aiming to increase the number of people on the register to 21.6 million by 2013-2014, and to facilitate an increase in deceased organ donation to just under 1,300 by the same date.²⁸⁵ These figures demonstrate the significant difference between the number of people on the ODR compared with the number of people who actually become deceased organ donors: only a limited number of people in fact die in circumstances where it is possible to donate organs.
- 3.9 NHSBT's current targets build on the work of the Organ Donation Taskforce (ODT) which was established in 2006 with a brief to identify the obstacles to deceased organ donation and to

²⁸⁰ NHS Blood and Transplant (2010) *Saving lives and improving lives: annual review 2009/10*, available at: http://www.nhsbt.nhs.uk/annualreview/pdf/22187_Annual_Review.pdf, p17.

²⁸¹ *Ibid.*

²⁸² Mr Keith Rigg, personal communication, 8 September 2011.

²⁸³ NHS Blood and Transplant (2011) *Strategic plan 2011-14*, available at: http://www.nhsbt.nhs.uk/strategicplan/pdf/nhsbt_strategic_plan_2011_14.pdf, p12.

²⁸⁴ NHS Blood and Transplant, personal communication, 20 July 2011.

²⁸⁵ NHS Blood and Transplant (2011) *Strategic plan 2011-14*, available at: http://www.nhsbt.nhs.uk/strategicplan/pdf/nhsbt_strategic_plan_2011_14.pdf, pp11-3.

suggest solutions that would make more organs available (see paragraph 3.52). In its first report, the ODT concluded that a 50 per cent increase in organ donation after death was possible and achievable in the UK within the five years from 2008.²⁸⁶ If this target were achieved, an additional 1,200 transplants could be carried out each year, 700 of which would be kidney transplants. By way of comparison, the ODT report notes the difference in donor rates between Spain – which has the highest organ donation rate in Europe – and the UK. In the former, there were 34 deceased donors per million of population in 2008, whereas in the UK, there were only 14 donors per million of population.²⁸⁷ However, the ODT report notes that there may be many factors behind the difference in donor rates between countries, some of which may be influenced, whereas others cannot. These may include road traffic mortality rates, the incidence of deaths after brain injury, and the availability of intensive care facilities.²⁸⁸

- 3.10 The donation of organs – primarily kidneys – by living donors is becoming increasingly significant in responding to the need for organ donation. The rate of living organ donation has steadily risen in recent years: in 2010-2011, there were 1,045 living organ donors, compared with 1,062 in 2009-2010, 961 in 2008-2009, and 858 in 2007-2008.²⁸⁹ Since 2007-2008, the number of living donors has exceeded the number of deceased donors.²⁹⁰

Gametes and embryos for treatment

"There have always been those who seek to disparage or deprioritise gamete (sperm, egg and embryo) donation on the grounds that the absence of pregnancy is not a disease. However, this reasoning is fallacious. Infertility is classified by the World Health Organization not as a misfortune, but as 'a disease of the reproductive system.'" - Progress Educational Trust, consultation respondent

"Whilst it might be right to try to meet „demand“ for renewable materials such as blood, the 'demand' for female egg donation is potentially limitless." - HEAL (Health Ethics and Law), University of Southampton, consultation respondent

- 3.11 An estimated one in seven couples who wish to have children experience difficulties in doing so.²⁹¹ In both men and women, there may also be concerns about passing on a genetic disease to offspring. In some of these cases, treatment using donor gametes or embryos may be appropriate. Donated sperm, for example, may be effective in managing fertility problems associated with conditions such as severe deficits in semen quality and azoospermia, where

²⁸⁶ Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf, p3.

²⁸⁷ Global Observatory on Donation and Transplantation (2010) *Organ donation and transplantation: activities, laws and organization*, available at: <http://www.transplant-observatory.org/Data%20Reports/2010%20Report%20final.pdf>, p14.

²⁸⁸ Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf, paragraph 3.6. In addition, evidence given to a House of Lords report which addressed increasing the supply of organs within the EU suggested that, *pro rata*, Spain has three times as many intensive care beds as the UK, and also three times as many donors: House of Lords European Union Committee (2008) *Increasing the supply of donor organs within the European Union: volume I report*, available at: <http://www.publications.parliament.uk/pa/ld200708/ldselect/lddeucom/123/123i.pdf>, paragraph 192.

²⁸⁹ NHS Blood and Transplant (2011) *Transplant activity in the UK 2010-11*, available at: http://www.uktransplant.org.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/activity_report_2010_11.pdf. See also: NHS Blood and Transplant (2011) *Statistics: transplants save lives*, available at: <http://www.uktransplant.org.uk/ukt/statistics/statistics.jsp>.

²⁹⁰ NHS Blood and Transplant (2009) *Transplant activity in the UK 2008-9*, available at: http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/2008_09/transplant_activity_uk_2008-09.pdf, p7.

²⁹¹ Human Fertilisation and Embryology Authority (2010) *Fertility facts and figures 2008*, available at: http://www.hfea.gov.uk/docs/2010-12-08_Fertility_Facts_and_Figures_2008_Publication_PDF.PDF, p3. In the UK, this equates to approximately 3.5 million people. The figure of one in seven couples related to couples who are unable to conceive after two years.

there are no measurable levels of sperm in semen.²⁹² In women, egg donation may be suggested because of premature menopause; the removal of ovaries, for example where they are cancerous; and ovarian failure following chemotherapy or radiotherapy.²⁹³ Infectious disease may affect both male and female fertility.²⁹⁴ In addition, donor eggs may be used for women for non-medical reasons to enable them to bear children later in life, and donor sperm to enable single women or lesbian couples to have children.²⁹⁵

- 3.12 In 2008, 1,600 children were born as a result of UK-based treatment involving donated gametes: 977 from sperm donation, 541 from donated eggs, and 82 from donated embryos.²⁹⁶ However, the demand for donor gametes is greater: potential recipients of gametes or embryos for treatment are likely to wait over a year for suitable gametes to be available, and some may abandon the idea of treatment.²⁹⁷ In a review of fertility clinics – 49 of which responded to a specific question about meeting demand for treatment with donor sperm – half reported that they were not able to meet the demand for treatment with donor sperm, with nine of these experiencing particular difficulties matching donors and recipients from minority ethnic groups.²⁹⁸ Of the 39 clinics that responded to a question about the demand for egg donation, 90 per cent said that they were unable to meet demand.²⁹⁹ Half of the clinics responding to the question about donated embryos reported that they were not able to meet the demand for treatment using donated embryos (17 clinics), with the most common reason cited for this being a lack of donated embryos.³⁰⁰
- 3.13 During a meeting with the Working Party, the HFEA noted that there are many limits that apply to gamete donation and may affect supply, some of which are set through regulation, for example that a donor may found a maximum of ten families, and others by donors themselves, such as specifying that their donation may only be used by a particular category of people – for example, married couples.³⁰¹ Other requirements also act to limit who may donate their gametes. Thus egg donors must be aged between 18 and 35 years in order to donate, and sperm donors must be between 18 and 45 years. In addition, each potential donor may be selected only after rigorous screening procedures have taken place. This process includes identifying and screening out persons whose donations could present a health risk to others – such as the possibility of transmitting infections – or health risks to the donors themselves, for example where there may be psychological consequences of donating. In addition, the centre that recruits gamete donors should also consider the personal or family history of heritable disorders.³⁰²

²⁹² National Collaborating Centre for Women's and Children's Health (2004) *Fertility assessment and treatment for people with fertility problems*, available at: <http://www.nice.org.uk/nicemedia/pdf/CG011fullguideline.pdf>, chapter 14.

²⁹³ *Ibid.*, p127.

²⁹⁴ For example, the potential impact on fertility through contracting chlamydia: NHS Choices (2009) *Chlamydia: complications*, available at: <http://www.nhs.uk/Conditions/Chlamydia/Pages/Complications.aspx>.

²⁹⁵ Same sex couples and single women are increasingly seeking treatment with donor sperm. The HFEA reports, for example, that up to 30 per cent of clients at the London Women's Clinic are lesbian couples, representing an increase of about ten per cent from ten years ago: Human Fertilisation and Embryology Authority (2011) *A review of the HFEA's sperm and egg donation policies - 2011*, available at: http://www.hfea.gov.uk/docs/2011-01-13_Donation_review_background.pdf, p3.

²⁹⁶ Human Fertilisation and Embryology Authority (2010) *Donor conception - births*, available at: <http://www.hfea.gov.uk/donor-conception-births.html>.

²⁹⁷ HFEA (2004) *Sperm, egg and embryo donation (SEED) policy review: findings of the clinic survey*, available at: http://www.hfea.gov.uk/docs/Clinics_survey_Seed_review.pdf, p7.

²⁹⁸ *Ibid.*, paragraph 2.3. Ninety nine clinics were surveyed in total.

²⁹⁹ *Ibid.*, paragraph 3.3.

³⁰⁰ *Ibid.*, paragraph 4.1.

³⁰¹ Gamete donors are able to limit their donations by using a consent form for egg or sperm donation supplied by the HFEA where they are asked "do you have any restrictions that you would like to apply to your answers...eg, use for a named recipient?" See: Human Fertilisation and Embryology Authority (2009) *Your consent to the use and storage of your donated eggs*, available at: http://www.hfea.gov.uk/docs/HFEA_WD_form_new_green_ver2_Sept_09_new_file.pdf.

³⁰² Human Fertilisation and Embryology Authority (2009) *Code of practice*, available at: http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf, guidance note 11.

- 3.14 Debate on the levels of supply for gametes has also focused on the removal of the donor's right to anonymity. As noted earlier (see paragraph 2.74), donor-conceived individuals now have the right at the age 18 years to approach the HFEA to obtain information to enable them to trace their donor and contact them directly.³⁰³ The trigger for this change in the law was a High Court judgment in 2002 where it was held that Article 8 of the European Convention on Human Rights (which guarantees respect for private and family life) was engaged in a situation where a donor-conceived person sought to obtain non-identifying information (such as their hair colour or ethnicity) about the donor.³⁰⁴ The government response extended beyond the scope of the judgment (which related only to *non*-identifying information) to specify that identifying information, too, should in future be provided.
- 3.15 There has been considerable dispute over the evidence as to the effect of the removal of donor anonymity on the supply of gametes for treatment. One approach to the evidence is through the examination of the number of *donors* who registered at an HFEA-licensed clinic for the first time before and after the removal of anonymity in 2005. The HFEA reports that in 2004, 224 sperm donors, and 1,032 egg donors registered; in 2006, the number of first-time sperm donor registrants rose to 287, but the number of egg donors dropped to 781; and in 2008, both sperm and egg donation registrants rose, with sperm donors totalling 396, and egg donors 1,150.³⁰⁵ However, it has been suggested that the number of sperm donors had, in fact, already begun to decline before the legislative changes, because of concerns that any future changes regarding donor anonymity might be made to be retroactive (as had been the case with adoption legislation).³⁰⁶ The number of treatments which use donated eggs has, moreover, fallen in recent years: figures published by the HFEA indicate that in 2005, 1,888 treatments used donated eggs, falling to 1,660 in 2006, 1,530 in 2007, and 1,444 in 2008.³⁰⁷ There has been a similar decline in the number of embryos donated for other women's treatment: from 2001, when 326 embryos were donated, to 2006, when 200 embryos were donated.³⁰⁸
- 3.16 The HFEA has also published data on whether sperm donors limit their donation to one family (for example, where the family is known to them) or give permission for their donation to be used to found up to ten families. The number of sperm donors who stated that their donation should be limited to one family only has risen in recent years, with 20 donors stipulating a one family limit in 2007, 48 donors in 2008, and 67 donors in 2009.³⁰⁹ Conversely, the number of UK donors who do not limit their donation to one family has fallen slightly during the same time period (293 donors in 2007, 290 donors in 2008, and 276 donors in 2009). However, when sperm imported into the UK from abroad is included in these figures, the total number of sperm donors who place no limit on their donation has risen slightly overall: in 2007, 340 sperm donors did not limit their donation to one family, rising to 346 donors in 2008, and 355 in 2009.

Gametes and embryos for research

"There is no evidence of a demand from women to be „allowed“ to donate eggs for research. We suggest that this absence of demand has to be taken seriously." - Celia Roberts and Karen Throsby, consultation respondents

³⁰³ The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004, Regulation 2.

³⁰⁴ *R v Secretary of State for Health* (2002) EWHC 1593.

³⁰⁵ Human Fertilisation and Embryology Authority (2010) *New donor registrations*, available at:

<http://www.hfea.gov.uk/3411.html>. Figures for egg donors include both volunteer egg donors and egg sharers.

³⁰⁶ Paul S, Harbottle S, and Stewart JA (2006) Recruitment of sperm donors: the Newcastle-upon-Tyne experience 1994-2003 *Human Reproduction* 21: 150-8.

³⁰⁷ Human Fertilisation and Embryology Authority (2010) *Donor conception - treatments*, available at:

<http://www.hfea.gov.uk/donor-conception-treatments.html>.

³⁰⁸ Human Fertilisation and Embryology Authority (2008) *A long term analysis of the HFEA register data 1991-2006*, available at: http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_91-06.pdf, pp91-3.

³⁰⁹ Human Fertilisation and Embryology Authority (2010) *F-2010-00282: sperm imports to the UK*, available at: <http://www.hfea.gov.uk/docs/sperm-donors.pdf>.

"Human egg and embryo donation for research is another growing area of interest ... Particular regard ought to be given to informing donors of the actual and potential uses of their tissue when researchers seek consent." - National Research Ethics Advisors' Panel (NREAP), consultation respondent

- 3.17 Gametes and embryos may be used for a number of research purposes. Sperm is used primarily in research related to fertility, while eggs and embryos are used more widely: research uses include contributing to basic science research; increasing knowledge about fertility; contributing to knowledge about both heritable and non-heritable diseases; and research using embryonic stem cells. However, the number of eggs donated for research purposes has fallen significantly in recent years. Figures published by the HFEA indicate that in 2001, 2,016 eggs were donated for research, compared with 845 in 2006.³¹⁰
- 3.18 Most embryos donated for research are donated by patients who have undergone IVF, and who do not want to cryopreserve (freeze) their 'spare' embryos.³¹¹ The rate of embryo donation for research appears to have remained more stable than egg donation: HFEA statistics indicate that 4,193 embryos were donated for research in 2001, 3,639 in 2004 and 3,338 in 2006.³¹²

Tissue for medical treatment

"...if human tissue is to be used, it must be used with due respect..." - Miriam Pryke, consultation respondent

"...there is a need to separate materials related to treatment and research, for otherwise research may drive treatment needs." - Lorna Weir, Professor of Sociology and Health, York University, Toronto, Canada

- 3.19 As we discuss in Chapter 1 (see paragraph 1.10), a very wide range of tissue may be used for treatment, including corneas, heart valves, skin, bone, and tendons. In contrast with the pressure on other forms of bodily material, NHSBT Tissue Services state that they are currently able to meet all demands placed on them for all tissue grafts, excluding corneas.³¹³ This may be at least partly explained by the fact that tissue may be retrieved after death in a much wider range of circumstances than organs, hence the 'pool' of potential donors is far greater.³¹⁴ Moreover, different 'matching' issues may arise, compared with organs: corneas, for example, (as we note in paragraph 3.2) do not always need to be matched immunologically, but they do need to be matched by age. Although over 2,000 people a year donate corneas after their death, there is currently a shortfall of approximately 500 corneas per year.³¹⁵

³¹⁰ Human Fertilisation and Embryology Authority (2008) *A long term analysis of the HFEA register data 1991-2006*, available at: http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_91-06.pdf.pdf, pp91-3.

³¹¹ Mounce G, Mardon H, Franklin S, and Turner K (2010) Who donates their embryos to research? *Human Reproduction* 25: I278-I.

³¹² Human Fertilisation and Embryology Authority (2008) *A long term analysis of the HFEA register data 1991-2006*, available at: http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_91-06.pdf.pdf, pp91-3.

³¹³ Meeting with NHS Blood and Transplant Tissue Services, 2 March 2010.

³¹⁴ NHSBT Tissue Services currently obtains tissues (excluding corneas) from around 400 deceased donors, but receive between 5,000 and 6,000 donor referrals a year, the majority of which are deferred as donors as they are medically unsuitable, and do not meet stringent selection criteria which are designed not to introduce risk factors into the graft. In addition, some families decide not to donate and, following discussions with health care professionals, decline to proceed. See: NHS Blood and Transplant (2010) *Tissue services*, available at: <http://www.nhsbt.nhs.uk/tissueservices/index.asp>; NHS Blood and Transplant, personal communication, 28 July 2011. The numbers of dead bodies used as a source of tissue in this way has reduced considerably in the last 20 years: in the early years of tissue retrieval, often only one body part (for example an eye, or some skin or bone) would have been taken, while now, where consent for "any of my organs and tissue" has been granted, almost everything that can be used will be removed from the body.

³¹⁵ NHS Blood and Transplant (2009) *Cornea transplantation*, available at: http://www.uktransplant.org.uk/ukt/newsroom/fact_sheets/cornea_transplantation_fact_sheet.jsp.

- 3.20 Short-term shortages of particular forms of tissue for treatment can arise in emergencies, such as in the aftermath of the 2005 London bombings, where there was an urgent need for donated skin to cover burns and soft tissue injuries.³¹⁶ In these circumstances, clinicians can draw on tissue banks in other European countries.

Blood and tissue for research

"Clearly, uses of tissues for diagnosis and treatment and organs for transplant must take precedence over the needs of researchers." - *Human Tissues Group, consultation respondent*

"Consent rates for surplus surgical tissues remain very high for all such research purposes, so long as the perceived goal involves the development of new diagnostics, prognostics or treatments for disease." - *Anonymous consultation respondent*

- 3.21 Blood and tissue for research³¹⁷ are sought by a number of different parties. These include hospitals, universities, commercial organisations, publicly or charitably-funded tissue banks, national cancer banks, and historic collections. While some researchers experience difficulties in obtaining the bodily materials they need for their research, in many cases these difficulties may arise less as a result of shortages in stocks of the material itself, than from difficulties in *accessing* available material, for example because of inadequate systems in place for obtaining appropriate consent at the time the material is taken. Breakthrough Breast Cancer recently commented that "the main barrier to progress [is] a shortage of good quality tissue - the raw material for research."³¹⁸
- 3.22 In order to access tissue samples, researchers need ethical approval for their research project from a REC and consent from the person providing the material (unless the material comes from a living donor and is anonymised - see paragraph 2.17). The premises where tissue is being removed from deceased donors, or after a post mortem, must be licensed under the Human Tissue Act (see paragraph 2.60). During a meeting with the Working Party about regulation, the HTA suggested that many of the cases where there *are* problems accessing tissue for research may arise from bureaucratic issues within an organisation, rather than as a result of the regulatory requirements of the Human Tissue Act itself.³¹⁹ Researchers have reported a lack of confidence in applying the provisions of the Act,³²⁰ and a recent report by the Academy of Medical Sciences (AMS) cited the processes involved in obtaining permission for research to go ahead from individual NHS trust research and development (R&D) departments as a "major bottleneck" in health research.³²¹
- 3.23 In the same meeting between regulators and the Working Party, problems arising out of reluctance to share research samples were also highlighted. These problems may be due in

³¹⁶ A deceased donor can donate 2,000-4,000cm² of skin, which takes 100 days to convert into a graft-ready tissue. The average adult patient with severe burns uses 2,000-9,000cm² per grafting, but may need 2-3 grafts with a 1-3 day gap between each operation. The London bombings resulted in requests for 31,090cm² to one hospital alone. See: NHS Blood and Transplant (2006) *Blood matters - issue 20*, available at: http://www.blood.co.uk/pdf/publications/blood_matters_20.pdf, p14.

³¹⁷ This includes both diseased tissue which is 'left over' from medical procedures, and healthy tissue provided by volunteers.

³¹⁸ Breast Cancer Campaign (2010) *About the tissue bank*, available at: <http://www.breastcancercampaigntissuebank.org/about-tissue-bank.php>. See also: Thompson A, Brennan K, Cox A *et al.* (2008) Evaluation of the current knowledge limitations in breast cancer research: a gap analysis *Breast Cancer Research* 10: R26.

³¹⁹ Meeting with regulators, 23 June 2010: see Appendix 1. The Authority also highlighted a recent stakeholder report showing that 86 per cent of professionals have confidence in the HTA as a regulator, which, as part of its remit, must maintain and raise standards: Human Tissue Authority (2010) *Professional evaluation 2010*, available at: <http://www.hta.gov.uk/publications/evaluations/professionalevaluation2010.cfm>.

³²⁰ OnCore UK and National Research Ethics Service (2010) *Workshop on ethical principles relating to consent for use of samples and related data in research, 22 September* (Manchester: OnCore UK and National Research Ethics Service).

³²¹ Academy of Medical Sciences (2011) *A new pathway for the regulation and governance of health research*, available at: <http://www.acmedsci.ac.uk/index.php?pid=47&prid=88>, p34 and pp71-2.

part to concerns about maintaining intellectual property rights, and being appropriately credited in subsequent publications.³²²

- 3.24 Despite these difficulties, there are, however, good examples of tissue banks building up substantial resources, with the aim of making them available to researchers on the basis of scientific merit. UK Biobank, for example, has now reached its goal of recruiting 500,000 people to provide samples of blood, saliva and urine.³²³

Participants in first-in-human trials

"Every new treatment has to be used for the first time ... Without first-in-human [trials, there would be] a catastrophic fall in progress in therapeutics."

- Dr J. Reeve, consultation respondent

"I would expect no personal benefit from volunteering the loan of my body for such drugs trials, and fair risks and costs to body and mind, and maybe 'soul' too." - Pat Spallone, consultation respondent

- 3.25 The number of phase I trials using healthy volunteers conducted in the UK appears to be relatively stable: 244 such applications were approved in 2008; 229 in 2009; and 222 in 2010.³²⁴ During a meeting with the Working Party, a representative from NRES noted that the issue of shortage of volunteers was not raised during regular discussions the service holds with phase I trial units, suggesting that this was not a general problem.³²⁵ It was however noted that, at times, there may be 'bottlenecks' in the supply of volunteers, although – perhaps surprisingly – after the events at Northwick Park, where several young men suffered severe adverse reactions to a drug being tested for the first time in man, levels of volunteering for trials reportedly rose. This may be due, in part, to the accompanying publicity which revealed the amount of money the young men were being paid to participate.³²⁶

Examples of factors influencing demand

- 3.26 The relationship between supply and demand for human bodily material is a complex one. 'Demand' for material is inherently elastic: as scientific developments make more treatments possible, the demand for that treatment is likely to increase, and the development of alternatives may lead to more people overall being treated, rather than necessarily reducing demand. Those currently considered 'too ill' to be placed on a transplantation list at present, for example, may still have the potential to benefit if an organ becomes available; and further developments in medical science may lead to an increasing number of transplants becoming clinically appropriate. Wider public health factors in the population as a whole, such as high levels of obesity, diabetes, and alcohol consumption, play a key part in determining the demand for organs in particular, while the need for donated skin for skin grafts is affected by such disparate factors as regulations on fire-resistant clothing (radically reducing the number of severe burns) and large-scale emergencies.³²⁷ Lifestyle factors, including an increasing number of sports injuries and the popularity of cosmetic dentistry, have increased demand for cadaver bone and cartilage.³²⁸ The trend towards later motherhood increases the number of women who need

³²² Meeting with regulators, 23 June 2010.

³²³ UK Biobank (2010) *UK Biobank: improving the health of future generations*, available at: <http://www.ukbiobank.ac.uk/>.

³²⁴ MHRA, personal communication, 7 September 2011.

³²⁵ Meeting with regulators, 23 June 2010: see Appendix 1. In the US, however, it has been observed that employees of pharmaceutical companies may be asked to participate in clinical trials in order to 'keep trials on schedule': Medmarc Protect (2010) *Employee-participants in clinical trials*, available at:

<http://www.medmarc.com/Resources/Documents/Employee%20Participants%20in%20Clinical%20Trials.pdf>.

³²⁶ The Guardian (18 March 2006) *Interest surges in trials despite patients' plight*, available at:

<http://www.guardian.co.uk/science/2006/mar/18/frontpagenews.medicinemandhealth?INTCMP=ILCNETTXT3487>.

³²⁷ Pfeffer N (forthcoming) *Insider trading* (London: Yale University Press).

³²⁸ Professor Naomi Pfeffer, personal communication, 27 July 2011.

medical help, including the use of donor gametes, to conceive.³²⁹ There may therefore be a high level of public expectation, and a consequent drive towards further demand for and use of bodily material. We also note that there may be developments that potentially lead to decreases in demand for one form of bodily material, while increasing demand for another: the increasing use of biomarkers in scientific research is a factor in the growth in the use of various forms of tissue and blood for research purposes, but may in the long term contribute to reducing demand for organs to transplant (see paragraphs 3.30 and 3.37).

- 3.27 As we noted at the beginning of this chapter, demand is partly a response to scientific innovation: there was no 'demand' as such for transplants before they became technically possible, or for donor eggs before the development of IVF procedures or stem cell research. This is clearly not to suggest that needs that could not be met before the expansion of innovation are thereby insignificant: indeed, such an argument would deny value to much medical progress. It should also be noted that consumer-driven demand cannot simply be ignored, as it is likely to emerge elsewhere (see paragraph 3.83).³³⁰ However, recognition of the main influences steering demand is a necessary step in seeking to formulate an appropriate response. Below, we summarise some of the scientific and social³³¹ factors that have been both driving and reducing demand for human bodily material for treatment or for research. Where relevant, we note where these factors seem likely to be amenable to change, for example demand reduction through public health measures, and we return to the question of an appropriate ethical response to imbalances between supply and demand in terms of bodily material in Chapter 5.
- 3.28 Demand may not be spread evenly over the population. There are ethnic communities where organ donation is not a regular practice yet where need is higher than the national average. In addition to factors such as age and underlying patterns of health, the ethnic origin of potential recipients of donated material is of relevance because people are more likely to find an immunologically compatible donor among others of similar origin. Thus, South Asian and African Caribbean people wait on average twice as long as white people for a kidney transplant, both because of lower donation rates in these communities, and because of higher levels of need. Differences in genetic predisposition, increased prevalence of other underlying medical conditions, and poorer access to, and uptake of, services lead to greater risks of developing organ failure.³³² It is important to note, however, that lower rates of donation in such communities are not easily accounted for by simple cultural or religious factors. On the contrary, some researchers have argued that there can be a very active sense of charity and sacrifice where the suffering of others is recognised. Research suggests that reluctance may be attributed to factors such as uncertainties about what is, and is not, sanctioned by religious doctrine, a general lack of trust and confidence in health services, and specific anxieties about the management of death and disposal of the corpse where donation after death is concerned.³³³ Similar observations have been made in relation to assisted conception in British South Asian communities. A study of gamete donation found that doubts about third-party

³²⁹ National Statistics (28 February 2008) *Conception rate for women aged 40 and over reaches record high*, available at: <http://www.statistics.gov.uk/pdfdir/con0208.pdf>.

³³⁰ See also: Nuffield Council on Bioethics (2010) *Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age* (London: Nuffield Council on Bioethics) where we note: "people seeking treatments overseas that are not available or are much more costly in their home countries represents a notable shift in the balance between patient, citizen and consumer roles in health care", p43.

³³¹ We follow common usage in using the term 'society' as a shorthand to refer to any set of factors in human affairs not encompassed by whatever is being taken as the privileged category, here 'scientific' ones.

³³² Randhawa, G (2011) *Achieving equality in organ donation and transplantation in the UK: challenges and solutions*, available at: <http://www.better-health.org.uk/sites/default/files/briefings/downloads/health23-3.pdf>. People of South Asian origin represent 15 per cent of those waiting for a kidney transplant, but only four per cent of the general UK population. For African Caribbean patients, the figures are over seven per cent and two per cent respectively. Only 2.1 per cent of people who donate kidneys after their death are South Asian, and 1.2 per cent African Caribbean.

³³³ See, for example, Randhawa G (1998) An exploratory study examining the influence of religion on attitudes towards organ donation among the Asian population in Luton, UK *Nephrology Dialysis Transplantation* 13: 1949-54; Morgan M, Mayblin M, and Jones R (2008) Ethnicity and registration as a kidney donor: the significance of identity and belonging *Social Science & Medicine* 66: 147-58; Randhawa, G (2011) *Achieving equality in organ donation and transplantation in the UK: challenges and solutions*, available at: <http://www.better-health.org.uk/sites/default/files/briefings/downloads/health23-3.pdf>.

assisted conception reduced both the numbers seeking treatment and the likelihood of donation.³³⁴

Scientific factors increasing demand

- 3.29 **Developments in transplantation and surgery:** since transplantation began in the 1960s, there have been significant developments and improvements in the diagnosis, management and treatment of patients suffering end-stage organ failure, with the result that transplantation has become the preferred treatment option for an increasing proportion of these patients. Over this time there have also been technical advances in areas of transplantation such as tissue typing, immunosuppression and surgical techniques that have made transplantation more successful and feasible for a greater number of people. The development of laparoscopic donor nephrectomy (keyhole surgery), which reduces the hospital length of stay, facilitates earlier return to normal activities, and has fewer long-term complications, has made the procedure less onerous and risky for the living donor and has played an important role in the significant increase in live donations.
- 3.30 **Increased use of tissue for research:** one of the main reasons for the increased demand for human samples in research is the rapid development of technology. For example, it is now possible to identify specific DNA mutations – which may predict how a particular patient will respond to specific drug treatment – on thin slivers of diagnostic biopsy tissue containing as few as 100 tumour cells.³³⁵ Using new 'DNA chip' technology or tissue microarrays (where 0.6mm slices of tissue from hundreds of patients are aggregated) it is also possible to screen for thousands of nucleic acid or protein biomarkers in different disease types and from different patient populations.³³⁶ This can lead to a better understanding of the molecular basis of disease.
- 3.31 Furthermore, new and evolving scientific technologies have delivered new insights into disease. The sequencing of the entire human DNA code identified around 20,000 genes that appear to control the activities of all human cells, enabling further understanding of the role of genes in relation to disease.³³⁷ The ultimate test of the relevance of these DNA and protein molecular processes is when they can be identified in human tissue samples, shown to be associated with specific diseases, and modified by treatment. Analysis of human DNA may also be used to predict the toxicity of a particular drug – an area which is known as 'pharmacogenomics'.
- 3.32 The use of human tissue for research should also be seen in light of a legal and policy agenda that seeks to 'reduce, refine and replace' animal experimentation.³³⁸ The European Union has recently introduced a Directive on the protection of animals used for scientific purposes, which holds that member states must develop "alternative approaches which could provide the same or higher levels of information as those obtained in procedures using animals."³³⁹
- 3.33 **Increased use of tissue for treatment:** using human tissue for treatment is an area of medicine that has developed over recent years. For example, many applications have been and are being found for cadaver musculoskeletal tissue, including treating sports injuries with what are sometimes called 'sports medicine tissues', including tendons, ligaments and cartilage. In addition, innovative uses of whole cadaver bone may allow patients with cancer to avoid

³³⁴ Culley L and Hudson N (2006) *Public perceptions of gamete donation in British South Asian communities*, available at: http://www.dmu.ac.uk/Images/GAMDON%20final%20report_tcm6-11021.pdf.

³³⁵ Mardis ER (2011) A decade's perspective on DNA sequencing technology *Nature* **470**: 198-203.

³³⁶ Sauter G, Simon R, and Hillan K (2003) Tissue microarrays in drug discovery *Nature Reviews Drug Discovery* **2**: 962-72.

³³⁷ Human Genome Project (2008) *About the Human Genome Project*, available at: http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml.

³³⁸ Nature Immunology Editorial (2010) Reduce, refine, replace *Nature Immunology* **11**: 971.

³³⁹ Directive 2010/63/EU, Article 47.

amputation, since replacement of total joints – hips, knees and shoulders – often requires bone grafts in order to strengthen weakened bone that cannot support a prosthesis.³⁴⁰

Scientific factors reducing demand

- 3.34 Scientific developments may also have the capacity to reduce demand through the creation of alternative techniques that bypass or supplant the need to use bodily material. Sometimes ethical controversy over the use of a particular technique or material has encouraged further scientific research, perhaps the best-known example being the push to find alternatives to embryonic stem cells, which was a strong driver in the clinical use of adult bone marrow-derived cells for solid organ regeneration,³⁴¹ and in the development of induced pluripotent cells (see paragraph 3.38).³⁴²
- 3.35 **Extending the life of transplanted organs** ('graft survival') will clearly be key in reducing demand for organs for re-transplantation. Since the beginning of transplantation as a treatment option, there has been an ongoing improvement in both short and long-term graft and patient survival rates. With the advent of new immunosuppressive agents in the 1980s and 1990s, significant improvements were seen in outcomes during the first year after transplantation, as fewer grafts were lost to acute rejection.³⁴³ Over the last decade or so, more attention has been paid to improving the longer-term success of the graft, and the health of the patient, by a more intelligent use of the range of immunosuppressive medicines and by interventions designed to reduce the incidence of cardiovascular disease, bone disease, and infection. However, although improving graft survival rates will reduce the requirement for re-transplantation in individual cases, it is perhaps inevitable that more general improvements in clinical care may make it more likely that re-transplantation will be necessary in more cases, as more transplant patients live longer.
- 3.36 **Technological devices** may, in some circumstances, be able to supplement or supplant the human body's natural mechanisms. Current mechanical methods of managing organ failure already exist, for example, through the use of pacemakers and dialysis. However, new mechanisms are becoming available to supplement pre-existing technologies, and also potentially to reduce the demand for transplants. Left ventricular assist devices (LVADs), for example, are mechanical pumps that can be implanted in a patient in order to help a damaged heart to maintain output. They may be used as a bridge to transplantation and will keep a person alive while they are waiting for a transplant; or in some situations, used as an alternative to heart transplantation. The lack of donor hearts has accelerated the pace of development of LVADs so that they have become smaller and more portable, with longer battery life, and so are effectively a viable medium-term solution to allow patients to live a reasonable life outside hospital. There have even been reports of patients in which a period of support by the LVAD, coupled with drug therapy, has allowed the heart to recover sufficiently, so that the LVAD can be removed or turned off.³⁴⁴
- 3.37 **Biomarkers** are biological indicators that can be used to screen for diseases, and also to monitor disease progression. Many biomarkers can be measured using a person's blood

³⁴⁰ See, for example, Abbas G, Bali S, Abbas N, and Dalton D (2007) Demand and supply of bone allograft and the role of orthopaedic surgeons *Acta Orthopædica Belgica* **73**: 507; Brydone AS, Meek D, and MacLaine S (2010) Bone grafting, orthopaedic biomaterials, and the clinical need for bone engineering *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine* **224**: 1329-43.

³⁴¹ Martin-Rendon E, Brunskill SJ, Hyde CJ *et al.* (2008) Autologous bone marrow stem cells to treat acute myocardial infarction: a systematic review *European Heart Journal* **29**: 1807-18.

³⁴² Klimanskaya I, Chung Y, Becker S, Lu S-J, and Lanza R (2006) Human embryonic stem cell lines derived from single blastomeres *Nature* **444**: 481-5; Meissner A, and Jaenisch R (2006) Generation of nuclear transfer-derived pluripotent ES cells from cloned Cdx2-deficient blastocysts *Nature* **439**: 212-5.

³⁴³ See, for example, NHS Blood and Transplant (2007) *Comparison of survival rates among kidney transplant centres*, available at: http://www.uktransplant.org.uk/ukt/statistics/centre-specific-reports/pdf/comparison_of_survival_rates_among_centres.pdf.

³⁴⁴ Birks EJ, George RS, Hedger M *et al.* (2011) Reversal of severe heart failure with a continuous-flow left ventricular assist device and pharmacological therapy: a prospective study *Circulation* **123**: 381-90.

sample, which is both less risky and less uncomfortable for patients than a biopsy, although biopsies will continue to be required in some circumstances.³⁴⁵ They potentially have a significant role to play in predicting both the future onset of disease (and hence the likely demand for transplanted material) and the success of transplants (see paragraph 3.48). More generally, they may be able to predict adverse events to which the patient may be susceptible. There is a developing experimental field looking at biomarkers in the early diagnosis of patients whose bodies have rejected a transplanted organ, and in identifying those patients who will need lower levels of immunosuppressive medication. For example, a recent study sought to develop a way of detecting tolerance in renal transplant recipients through screening biomarkers in the blood of eleven transplant recipients whose immune systems had established a tolerance to their transplant.³⁴⁶ The possibility of developing biomarkers to detect the future onset of chronic kidney disease has also been highlighted as an area that needs further investigation.³⁴⁷

- 3.38 **Developments in stem cell science** include the production of 'induced pluripotent cells' (iPSCs) directly from skin or other adult cells using viruses to introduce 'stemness' factors (deduced from study of ESCs).³⁴⁸ The source of iPSCs makes them a less controversial option than ESCs, while their ability to produce cells to match the genetic makeup of a patient means that they may be less likely to suffer rejection (though this has been challenged).³⁴⁹ The technology to create iPSCs is rapidly being improved and expanded. However, this is not to say that iPSCs are free of ethical concerns and policy challenges, for example with regard to whether tissue donors should be specifically informed about the possibility of their donated material being subsequently used for the creation of iPSCs.³⁵⁰
- 3.39 Research is also progressing into the use of ESCs, with the establishment of clinical trials to test their application to a number of treatments: it is however still at an early stage, with the world's first clinical trial using ESCs announced in October 2010.³⁵¹ It has recently been reported that blood platelets – which are used to repair damaged tissue and blood vessels – have been produced from human ESCs. This advance, if applied to general patient populations, could supplement supply from blood donors.³⁵²
- 3.40 Another potential application of stem cells is in drug development, where tissue created out of human stem cells might reduce the use of experimental animals, and provide a more specific model for testing efficacy and safety. As well as efforts by individual pharmaceutical companies and academic centres, a PPP (public-private partnership) has been set up by the UK Government and pharmaceutical companies – Stem Cells for Safer Medicines (SC4SM) – to take this forward.³⁵³ Stem cell research may also be valuable in producing cell models for

³⁴⁵ Biomarkers can also be measured from a range of other bodily materials, including skin, saliva, and hair.

³⁴⁶ Sagoo P, Perucha E, Sawitzki B *et al.* (2010) Development of a cross-platform biomarker signature to detect renal transplant tolerance in humans *The Journal of Clinical Investigation* **120**: 1848-61.

³⁴⁷ Fassett RG, Venuthurupalli SK, Gobe GC *et al.* (2011) Biomarkers in chronic kidney disease: a review *Kidney International*: advance online publication.

³⁴⁸ Takahashi K, and Yamanaka S (2006) Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors *Cell* **126**: 663-76.

³⁴⁹ Zhao T, Zhang Z-N, Rong Z, and Xu Y (2011) Immunogenicity of induced pluripotent stem cells *Nature* **474**: 212-5.

³⁵⁰ See, for example, Journal of Medical Ethics Editorial (2008) Time to reconsider stem cell ethics: the importance of induced pluripotent cells *Journal of Medical Ethics* **34**: 63-4. In addition, it has also been suggested that iPSCs may raise safety issues, depending on how they are generated as the risk of integrating retroviruses will be greater for iPSCs than ESCs. See: Gene Therapy Advisory Committee (2010) *Points to consider for UK clinical trials involving cell therapy*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_119086.pdf.

³⁵¹ Geron (11 October 2010) *Geron initiates clinical trial of human embryonic stem-cell based therapy*, available at: <http://www.geron.com/media/pressview.aspx?id=1235>. Approval for a trial using ESCs to treat macular degeneration followed shortly after: Advanced Cell Technology (22 November 2010) *Advanced Cell Technology receives FDA clearance for the first clinical trial using embryonic stem cells to treat macular degeneration*, available at: <http://www.advancedcell.com/news-and-media/press-releases/advanced-cell-technology-receives-fda-clearance-for-the-first-clinical-trial-using-embryonic-stem-cel/>.

³⁵² Lu S-J, Li F, Yin H *et al.* (2011) Platelets generated from human embryonic stem cells are functional *in vitro* and in the microcirculation of living mice *Cell Research* **21**: 530-45.

³⁵³ Stem Cells for Safer Medicines (2011) *Stem Cells for Safer Medicines*, available at: <http://www.sc4sm.org/>.

human diseases ('disease-in-a-dish') in order to study their development, pathology, and drug responsiveness.³⁵⁴

- 3.41 **Regenerative medicine** aims to restore the function of diseased, degenerating or damaged organs or tissues.³⁵⁵ There are several approaches this field of medicine may take in 'regenerating' organs or tissue, some of which have already been carried out for a number of years, such as the use of bone marrow transplants to treat leukaemia. It is, for example, possible to transplant a person's stem cells back into the same person, which avoids the risk of their immune system rejecting the transplant, and reduces the need for an allogeneic transplant. This technique has been used on an experimental basis to try to repair the donor's heart and other organs and involves taking bone marrow cells from the hip of the patient; these are concentrated or partially purified, and then injected into the damaged organ. Bone marrow transplant for organ repair is still at the stage of small clinical trials, with around 1,000 people in total treated in the course of the trial so far for heart disease.³⁵⁶ Small safety trials for adult heart cells also began in 2010, with cells taken from heart biopsies and grown in the laboratory to provide larger numbers, then re-injected.³⁵⁷
- 3.42 Scientific advances have also offered the possibility of developing **artificial bodily material**. This may include artificial muscle where protein-based materials have been found to be able to adopt similar conformations to biomolecules in muscle,³⁵⁸ and artificial corneas.³⁵⁹ The first transplant of an organ formed in a laboratory was carried out in 2011, when surgeons successfully transplanted a trachea that had been grown from the patient's own stem cells and seeded onto an artificial scaffold.³⁶⁰ So-called 'artificial gametes' are brought about from the successful derivation of egg³⁶¹ and sperm³⁶² precursor cells from ESCs, primordial germ cells, or other human cells. This technique has had success using mouse models, but the HFEA's Scientific and Clinical Advances Advisory Committee estimates that while research teams might be able to produce sperm from stem cells in the next few years, the production of eggs from stem cells could take longer. The Committee thought that it would be at least 5-10 years before eggs or sperm could be produced that could potentially be used in treatment.³⁶³ Such developments, like other aspects of research in reproductive medicine, are likely to be controversial.
- 3.43 **Xenotransplantation** refers to organ transplants between animals and humans and was the subject of a Nuffield Council on Bioethics report in 1996.³⁶⁴ This advance offers non-human alternatives to donated bodily material and there have been several widely-publicised studies involving animal-to-human transplants, mainly involving organs from pigs.³⁶⁵ However, the promise of this technology has not yet been realised, with few advances in recent years. This

³⁵⁴ Hussein SMI, Nagy K, and Nagy A (2011) Human induced pluripotent stem cells: the past, present, and future *Clinical Pharmacology & Therapeutics* **89**: 741-5.

³⁵⁵ Parliamentary Office of Science and Technology (2009) *Postnote: regenerative medicine*, available at: <http://www.parliament.uk/documents/post/postpn333.pdf>.

³⁵⁶ Martin-Rendon E, Brunskill SJ, Hyde CJ *et al.* (2008) Autologous bone marrow stem cells to treat acute myocardial infarction: a systematic review *European Heart Journal* **29**: 1807-18.

³⁵⁷ Marban, E (2009) *Cardiosphere-derived autologous stem cells to reverse ventricular dysfunction (CADUCEUS)*, available at: <http://clinicaltrials.gov/ct2/show/study/NCT00893360>.

³⁵⁸ Lv S, Dudek DM, Cao Y *et al.* (2010) Designed biomaterials to mimic the mechanical properties of muscles *Nature* **465**: 69-73.

³⁵⁹ Griffith M, Jackson WB, Lagali N *et al.* (2009) Artificial corneas: a regenerative medicine approach *Eye* **23**: 1985-9.

³⁶⁰ Baiguera S, Gonfiotti A, Jaus M *et al.* (2011) Development of bioengineered human larynx *Biomaterials* **32**: 4433-42; The Independent (8 July 2011) *First ever transplant or organ grown in laboratory*, available at: <http://www.independent.co.uk/life-style/health-and-families/health-news/first-ever-transplant-of-organ-grown-in-laboratory-2309050.html>.

³⁶¹ Hübner K, Fuhrmann G, Christenson LK *et al.* (2003) Derivation of oocytes from mouse embryonic stem cells *Science* **300**: 1251-6

³⁶² Nayernia K, Nolte J, Michelmann HW *et al.* (2006) In vitro-differentiated embryonic stem cells give rise to male gametes that can generate offspring mice *Developmental cell* **11**: 125-32.

³⁶³ Human Fertilisation and Embryology Authority (2009) *Committee paper: update on in vitro derived gametes*, available at: http://www.hfea.gov.uk/docs/In_vitro_derived_gametes.pdf.

³⁶⁴ Nuffield Council on Bioethics (1996) *Animal-to-human transplants: the ethics of xenotransplantation*, available at: <http://nuffieldbioethics.org/xenotransplantation/xenotransplantation-chapter-downloads>.

³⁶⁵ See, for example, The Times (7 November 2008) *Pig organs 'available to patients in a decade'*, available at: <http://www.timesonline.co.uk/tol/news/science/article5102153.ece>.

may be due, in part, to concerns about disease transmission and the task of ensuring that immunological concerns over xenotransplantation are overcome by extensive work on genes.³⁶⁶ Indeed, the Council's 1996 report concluded that, until the risks associated with xenotransplantation had been adequately dealt with, it was unethical to begin clinical trials of xenotransplantation involving humans.³⁶⁷ However, the emergence of novel methods of gene targeting and better, more efficient, transgenic technology may mean that xenotransplantation should not be discounted as a future advance that may be applied to general patient populations.

- 3.44 In the field of **reproductive technology**, developments in IVF treatment have enabled demand for sperm to be reduced in some circumstances. For example, advances in the use of intracytoplasmic sperm injection (ICSI) have increased the fertility potential of men who have very low numbers of sperm available, or whose sperm have very poor motility or 'swimming ability'. ICSI is a process whereby a single sperm is injected directly into a woman's egg *in vitro*, enabling some men with a low sperm count or who have had a vasectomy to father a child when, in the past, they would have had to consider donor sperm if they wished to have children.³⁶⁸
- 3.45 Technical improvements in egg freezing may also offer women an alternative in some cases to the use of donor eggs. The technique of egg freezing was developed primarily to preserve the fertility of young women with cancer who faced possible sterility as a result of chemotherapy or surgery. Eggs (oocytes) for future use may be harvested and frozen as primordial follicles taken from the ovarian cortex by biopsy, as immature oocytes to undergo *in vitro* maturation, or as mature oocytes following stimulation, as in conventional IVF. Where ovarian cortical strips are taken – for example, where a woman has cancer and there is no time to stimulate her ovaries, collect her eggs, and freeze the resulting embryos³⁶⁹ – they may be re-transplanted back on to the ovarian pedicle in the hope that spontaneous conception will occur. Alternatively, they may be transplanted on to another site altogether (such as under the skin in the forearm).³⁷⁰ IVF procedures would then be required to achieve a pregnancy. Egg freezing is also used by couples who have ethical objections to the freezing of embryos. There is also a growing (but still small) demand for 'social' or 'elective' egg freezing, where a woman has her eggs frozen for her own future use, if required.³⁷¹
- 3.46 Other procedures that have influenced the demand for donor gamete treatment include pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS). These techniques may enable some couples, who previously would have had great anxieties about conceiving children with a high risk of genetic abnormality, to be reassured that only embryos that are free of the specific disorder or abnormality will be transferred to the woman's womb. They may therefore be reassured about the possibility of conceiving using their own gametes, rather than seeking donor gametes.

³⁶⁶ For example, to overcome issues such as the pig virus, which was found to infect human cells in laboratory conditions. See: Wise J (1997) Pig virus transfer threatens xenotransplantation *BMJ* **314**: 623. It should also be noted that, outside of the experimental arena, xenotransplantation is not applicable to reproductive tissues, as there are concerns that animal viruses could be transmitted.

³⁶⁷ Nuffield Council on Bioethics (1996) *Animal-to-human transplants: the ethics of xenotransplantation*, available at: <http://nuffieldbioethics.org/xenotransplantation/xenotransplantation-chapter-downloads>.

³⁶⁸ Human Fertilisation and Embryology Authority (2009) *What is intra-cytoplasmic sperm injection and how does it work?*, available at: <http://www.hfea.gov.uk/ICSI.html>.

³⁶⁹ The Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology (2006) Ovarian tissue and oocyte cryopreservation *Fertility and Sterility* **86**: S142-S7.

³⁷⁰ Oktay K, Aydin BA, Economos K, and Rucinski J (2000) Restoration of ovarian function after autologous transplantation of human ovarian tissue in the forearm *Fertility and Sterility* **74**: S90-S1.

³⁷¹ Stoop D, Nekkebroeck J, and Devroey P (2011) A survey on the intentions and attitudes towards oocyte cryopreservation for non-medical reasons among women of reproductive age *Human Reproduction* **26**: 655-61.

- 3.47 In the UK, parents have the option in some circumstances of attempting to create a sibling for an existing child in need of a stem cell transplant.³⁷² This process occurs when children are born after 'pre-implantation tissue typing', where embryos created through IVF are tested for tissue compatibility with an existing sibling suffering from a serious inherited disorder.³⁷³ In most cases, PGD will also be carried out in order to ensure that only embryos that will not suffer from the same disorder are selected for transfer into the womb.³⁷⁴ Cord blood taken from the sibling at birth, or bone marrow taken at a later stage, can then be used to treat the older child, removing the need to use another third party donor. However, at present the use of these techniques to treat an older child occurs very rarely, with only one reported instance of successful treatment in the UK to date.³⁷⁵

Social factors increasing demand

Public health factors

- 3.48 Increasing demand for some organs, in particular livers, hearts and kidneys, arises from the increase in chronic diseases, with four such diseases accounting for 60 per cent of deaths worldwide: cardiovascular disease, cancer, diabetes, and chronic respiratory disorders. The largely preventable behavioural risk factors associated with these diseases include use of tobacco, harmful alcohol consumption, unhealthy diet, and physical inactivity.³⁷⁶ The importance of reducing these risk factors has been recognised by the World Health Organization which has emphasised that the "highest priority" should be given to prevention and health promotion "in order to reduce the diseases that lead to the need for transplants in the first place."³⁷⁷ Effective interventions to reduce the number of people living with these conditions include regulation of marketing and fiscal measures to increase the prices of alcohol and energy-dense foods, alongside individually targeted behavioural programmes and mass media campaigns.³⁷⁸ The failure to implement such programmes has recently been described as a failure of political will.³⁷⁹ It is hoped that an international framework for the prevention of chronic, non-communicable diseases will be drawn up at a high level meeting of the General Assembly of the United Nations (UN) planned for September 2011.³⁸⁰
- 3.49 Infertility may be caused by a number of avoidable risk factors, such as tubal damage from sexually transmitted disease. Smoking and obesity are also contributory factors to impaired reproduction.³⁸¹ The average age of a first pregnancy in the UK has risen in recent years, and

³⁷² Siblings created through pre-implantation tissue typing are sometimes referred to as 'saviour siblings'.

³⁷³ A list of conditions that are licensed to be tested by the HFEA using PGD is available at: <http://www.hfea.gov.uk/cps/hfea/gen/pgd-screening.htm>.

³⁷⁴ However, if there is no genetic history of the condition in the family, PGD may not be necessary.

³⁷⁵ BBC News Online (21 December 2010) *First successful saviour sibling treatment for UK*, available at: <http://www.bbc.co.uk/news/health-12055034>.

³⁷⁶ Beaglehole R, and Horton R (2010) Chronic diseases: global action must match global evidence *The Lancet* **376**: 1619-21.

³⁷⁷ World Health Organization (2010) *Sixty-third World Health Assembly: provisional agenda item 11.21 - human organ and tissue transplantation*, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_24-en.pdf, paragraph 17.

³⁷⁸ National Institute for Clinical Excellence (2006) *Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children*, available at:

<http://www.nice.org.uk/nicemedia/live/11000/30365/30365.pdf>; Nuffield Council on Bioethics (2007) *Public health: ethical issues*, available at: <http://nuffieldbioethics.org/sites/default/files/Public%20health%20-%20ethical%20issues.pdf>; Capewell S, and Lloyd-Jones DM (2010) Optimal cardiovascular prevention strategies for the 21st century *The Journal of the American Medical Association* **304**: 2057-8; Cecchini M, Sassi F, Lauer JA *et al.* (2010) Tackling of unhealthy diets, physical inactivity, and obesity: health effects and cost-effectiveness *The Lancet* **376**: 1775-84; National Institute for Clinical Excellence (2010) *Alcohol-use disorders: preventing the development of hazardous and harmful drinking*, available at: <http://www.nice.org.uk/nicemedia/live/13001/48984/48984.pdf>; National Institute for Clinical Excellence (2010) *Prevention of cardiovascular disease at population level*, available at: <http://www.nice.org.uk/nicemedia/live/13024/49273/49273.pdf>.

³⁷⁹ Beaglehole R, and Horton R (2010) Chronic diseases: global action must match global evidence *The Lancet* **376**: 1619-21.

³⁸⁰ United Nations General Assembly (2010) *Draft resolution submitted by the President of the General Assembly: scope, modalities, format and organization of the high-level meeting of the General Assembly on the prevention and control of non-communicable diseases*, available at: http://www.un.org/ga/search/view_doc.asp?symbol=A/65/L.50&Lang=E.

³⁸¹ See, for example, European Science Foundation (2010) *Male reproductive health*, available at: <http://www.esf.org/publications/science-policy-briefings.html>; Balen AH, and Anderson RA (2007) Impact of obesity on female reproductive health: British Fertility Society, policy and practice guidelines *Human Fertility* **10**: 195-206; British

as a woman's fertility declines with age, this has an impact on the level of demand for donor eggs.³⁸² There is a widespread assumption, evident from responses to our consultation exercise and from elsewhere, that late childbearing is a matter of choice on the part of individual women. However, while individual choice may play a part, motherhood at an older age is also influenced by a complex range of sociological and demographic factors relating to education, career patterns, financial independence and later marriage. In addition, there may be a lack of awareness among younger women that the number of eggs they have will decrease, and finally disappear, with age, and also that – during a woman's late 30s and early 40s – the eggs that remain are of poorer quality.³⁸³

The role of consumerism

- 3.50 The emergence of a so-called 'buyer's market' in recent years has arguably had an impact on the level of expectation people have of medical treatment: with it may come the attitude that, if a treatment is technically feasible, then it is also a right, as patients come to expect more of their health services.³⁸⁴ Such an attitude may be reinforced in the UK by recent health policy developments, such as the increasing emphasis on the role of the public and patients in influencing not only their own care³⁸⁵ but also the future direction of the health service.³⁸⁶

Examples of factors influencing supply

- 3.51 The imbalance described above between the availability of many forms of human bodily material and the potential for its use in medical treatment and research has led to increasing scrutiny of the methods currently used for encouraging and rewarding people for providing material. We summarise later in this chapter approaches used to encourage individuals to come forward as donors (see Box 3.3), and we have already discussed the current rules governing the various forms of compensation and recognition available to donors within the UK (see paragraph 2.35). However, individual motivation and choice is only one part of the picture: the central role of organisations, organisational procedure and intermediaries generally in facilitating donation is becoming better understood, as is the importance of trust in these systems.³⁸⁷ Families have a particularly important role to play in making decisions about donation both during life and after death: in around 40 per cent of cases where a person dies in circumstances where they could become an organ donor, their family refuses consent.³⁸⁸ Moreover, it should

Medical Association (2007) *Smoking and reproductive life: the impact of smoking on sexual, reproductive and child health*, available at: http://www.bma.org.uk/images/smoking_tcm41-21289.pdf.

³⁸² Office for National Statistics (2010) *Fertility: UK fertility remains high*, available at: <http://www.statistics.gov.uk/cci/nugget.asp?id=951>. The number of women over 40 years of age who have IVF treatment using their own eggs has also risen. In 1991, the number of women in this group numbered 6,457 which increased to 20,718 in 2001. See: Human Fertilisation and Embryology Authority (2007) *A long term analysis of the HFEA register data 1991-2006*, available at: http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_91-06.pdf.

³⁸³ Lister LM, Kouznetsova A, Hyslop LA *et al.* (2010) Age-related meiotic segregation errors in mammalian oocytes are preceded by depletion of cohesin and sgo2 *Current Biology* 20: 1511-21. The Royal College of Obstetricians and Gynaecologists has also recommended that there should be an increase in public awareness of the effects of deferred childbirth on fertility and pregnancy outcome. See: Royal College of Obstetricians and Gynaecologists (2009) *Reproductive ageing*, available at: <http://www.rcog.org.uk/files/rcog-corp/uploaded-files/ReproductiveAgeingConsensus0609.pdf>.

³⁸⁴ Nuffield Council on Bioethics (2010) *Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age* (London: Nuffield Council on Bioethics), paragraphs 2.20-8.

³⁸⁵ General Medical Council (2011) *Good medical practice: doctor patient partnership*, available at: http://www.gmc-uk.org/guidance/good_medical_practice/relationships_with_patients_partnership.asp.

³⁸⁶ See, for example, Department of Health (2010) *Secretary of State for Health's speech: 'my ambition for patient-centred care'*, available at: http://www.dh.gov.uk/en/MediaCentre/Speeches/DH_116643; Department of Health (2005) *Creating a patient-led NHS: delivering the NHS improvement plan*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4106507.pdf.

³⁸⁷ See, for example, Healy K (2006) *Last best gifts: altruism and the market for human blood and organs* (Chicago: University of Chicago Press).

³⁸⁸ An audit of deaths which took place in intensive care units found that 41 per cent of families who were approached to donate their relative's organs denied consent, and that the refusal rate for families of potential donors from ethnic minorities was twice that for white potential donors. See: Barber K, Falvey S, Hamilton C, Collett D, and Rudge C (2006) Potential for organ donation in the United Kingdom: audit of intensive care records *BMJ* 332: 1124-7.

not be overlooked that some of the reasons why there is insufficient bodily material at present to meet the potential demand for it are in themselves very positive in health terms: for example the reduction in the number of avoidable deaths that resulted from the introduction of seatbelt legislation.³⁸⁹

Action currently taken at organisational level to facilitate donation or volunteering

Improvements in donation infrastructure (deceased organ donation)

3.52 The Organ Donation Taskforce (ODT) was set up in 2006 with "a brief to identify the obstacles to organ donation and suggest solutions which would deliver the increase in transplants that was required" (see paragraph 3.9).³⁹⁰ This was in the context of the UK having one of the lowest records for organ donation in Western Europe. It was recognised that a structured and systematic approach to organ donation was required in the areas of donor identification and referral; donor co-ordination; and organ retrieval. Five specific aspects were considered to be in need of attention: legal and ethical issues; the role of the NHS; organisation of coordination and retrieval; training; and public recognition and public promotion. The Taskforce's report, published in 2008, set out 14 recommendations. Most of these recommendations have been acted upon, but the ongoing aim arising out of the ODT's work is to make organ donation a usual rather than unusual event within the NHS. Examples of action taken as a result of the Taskforce's work include:

- expanding and strengthening the network of specialist nurses for organ donation (SN-ODs, formerly known as transplant co-ordinators), and ensuring that they are centrally employed by a UK organ donation organisation (i.e. NHSBT);
- establishing a UK-wide network of dedicated organ-retrieval teams;
- ensuring hospitals where a potential organ donor dies are fully reimbursed for the costs of managing the process of organ donation (£2,055 for each deceased donor is now reimbursed to hospitals);
- creating trust donation committees and appointing 'clinical leads' for donation; and
- establishing the UK Donation Ethics Committee (UKDEC) to advise on ethical aspects of organ donation and transplantation.

Changing the consent defaults (deceased organ donation)

3.53 The current legal position in the UK requires consent ('authorisation' in Scotland) to be given, either by the donor before their death or by their family after death, before organs may be taken from a deceased person (see paragraph 2.15). The proposal that this system should be replaced by an '**opt-out**' system, in which removal of organs after death would be routine unless the person had logged a specific objection in advance, has long been debated within the UK, and views have become very polarised.³⁹¹ During a meeting with members of the Working Party, a Department of Health official noted that when people write to the Department on the issue of the shortage of donor organs, they do not raise questions about payments or other forms of incentive, but rather about whether an opt-out approach should be introduced.³⁹² The

³⁸⁹ Directgov (31 January 2008) *25th anniversary of seatbelts - 60,000 lives saved*, available at: http://www.direct.gov.uk/en/N11/Newsroom/DG_072333.

³⁹⁰ Taken from introduction to ODT report 'Organs for Transplantation': Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf.

³⁹¹ See, for example, Fabre J, Murphy P, and Matesanz R (2010) Presumed consent: a distraction in the quest for increasing rates of organ donation *BMJ* **341**: 922-4; and English V, and Sommerville A (2003) Presumed consent for transplantation: a dead issue after Alder Hey? *Journal of Medical Ethics* **29**: 147-52.

³⁹² Working Party meeting with regulators, 23 June 2010.

divergence of opinion on opt-out was clearly exhibited by participants at the Working Party's deliberative event.³⁹³

- 3.54 In 2008, the ODT was specifically asked to consider whether it would recommend an opt-out system in the UK, and rejected the proposal at the present time.³⁹⁴ It concluded that such a system would potentially undermine the concept of donation as a gift; erode trust in NHS professionals and the Government; and negatively impact on organ donation numbers. The Taskforce noted that it would review the position again if the situation had not significantly improved by 2013. However, the Welsh Assembly Government is currently seeking to introduce a 'soft opt-out' system where those dying in a Welsh hospital would be considered to have consented to organ donation unless they had specified otherwise, or unless their relatives refuse their consent.³⁹⁵
- 3.55 Another approach to the issue of consent would be the introduction of a system of '**mandated choice**', which would actively require everyone to register in advance their views on providing material for treatment or research after their death. In 2009, Professor John Saunders, chairman of the Committee for Ethical Issues in Medicine of the Royal College of Physicians (here writing in a personal capacity) advocated such a system, but emphasised that the choice should not be simply 'yes' or 'no' to the option of donation, but should also include the option that the person would prefer to leave the decision to their family.³⁹⁶ Mandated choice for organ donation has been tried and abandoned in Texas and Virginia in the US in the past 20 years, but in both states it was restricted to a 'yes' or 'no' answer.³⁹⁷ Moreover, in Texas, anyone who did not respond stating their preference was automatically defaulted to the 'no' cohort, which may have significantly influenced the outcome of the policy change. In Illinois, however, a significant increase in registration was observed after the introduction of such a policy in 2008.³⁹⁸ The policy of mandated choice will be further tested in 2013 when New Jersey introduces the New Jersey Hero Act into its State law, which will require individuals who apply for or renew their driver's licence or personal identification card to consider whether they wish to become an organ donor.³⁹⁹

³⁹³ Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader).

³⁹⁴ Department of Health (2008) *The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090303.pdf.

³⁹⁵ Welsh Assembly Government (2010) *Written statement by the Welsh Assembly Government: organ and tissue donation legislative competence order*, available at: <http://www.wales.nhs.uk/sites3/Documents/753/Organ%20and%20tissue%20donation%20LCO%20-%2017%20November%202010.pdf>; National Assembly for Wales (12 July 2011) *The record of proceedings: the Welsh Government's legislative programme 2011-16*, available at: <http://www.assemblywales.org/bus-home/bus-chamber-fourth-assembly-rop.htm?act=dis&id=219617&ds=7/2011#dat2>.

³⁹⁶ Saunders J (2010) Bodies, organs and saving lives: the alternatives *Clinical Medicine, Journal of the Royal College of Physicians* **10**: 26-9.

³⁹⁷ In Virginia, a quarter of the population refused to state a preference, and the Virginia Department of Motor Vehicles now has a policy of asking people registering for a driving licence if he or she wishes to become an organ donor. They are then offered options of 'yes', 'no', or 'I do not wish to answer the question': Virginia Department of Motor Vehicles (2011) *Citizen services: organ donation*, available at: <http://www.dmv.state.va.us/webdoc/citizen/drivers/organs.asp>. In Texas, where stating a preference was made a condition of obtaining a drivers' licence, 80 per cent chose not to donate their organs: Siminoff LA, and Mercer MB (2001) Public policy, public opinion, and consent for organ donation *Cambridge Quarterly of Healthcare Ethics* **10**: 377-86.

³⁹⁸ Illinois has stated that, since 2008, its organ donor register has grown from 38 per cent to 60 per cent of state residents. However, the quoted growth arises in part from the movement of donors from its old register to its new register. See: NHS Blood and Transplant (2011) *Prompted choice*, available at: http://www.nhsbt.nhs.uk/downloads/board_papers/jan11/r11_04b_ODR_Prompted_Choice_Board_Paper_Jan11_v5.pdf.

³⁹⁹ New Jersey State Legislature (2008) *New Jersey Hero Act*, available at: http://www.njleg.state.nj.us/2008/Bills/PL08/48_PDF. Two options will be offered: either a) to sign up as an organ donor; b) review information about the life-saving potential of organ donation, and the consequences of an individual choosing not to agree to become a donor.

- 3.56 Since 1994, people applying for a driver's licence have been invited to consider signing up to the ODR, and almost half of all registrations are made via this route.⁴⁰⁰ A policy change made in August 2011 means that people from England, Scotland, or Wales who either wish to renew their existing driver's licence, or apply for a licence for the first time, are *required* to respond to a question about organ donation when they register online with the DVLA.⁴⁰¹ Under this shift in policy, applicants will be required either to register to donate, to state that they are already registered on the ODR, or note they "do not want to answer this question now" before their application for a licence can be processed. While the scheme has been described as 'prompted choice' rather than 'mandated choice', it shares certain characteristics: in particular that the individual is actively required to consider the question of organ donation.

Box 3.1: Consent terminology

Opt-out (sometimes described as „presumed consent“)

- System in which people are presumed to consent to a course of action, but may opt out of that presumption should they so wish

Mandated choice

- Involves requiring people to make a choice about a certain course of action. If people decide not to „choose“, they may incur a penalty.

Prompted choice

- Refers to a situation where a person is asked to make a choice, but is not penalised if they wish to abstain from making a decision at that time.

Expanding the circumstances in which material may be donated (organs and gametes)

- 3.57 One approach to meeting the shortfall in donated kidneys has been for surgeons to permit donations from 'higher risk' deceased donors, making it possible to use kidneys removed after death that are of relatively poor quality but still within an acceptable range.⁴⁰² This involves using donations that carry a higher risk than would be ideal because of the donor's age or because of lifestyle factors such as drinking, smoking, and drug use. However, it is, of course, true that *all* donations carry some degree of risk. It should also be noted that the demographics of deceased donors as a whole are also changing; deceased donors now tend to be older, more obese, and more likely to die from non-traumatic brain injury, all of which result in poorer outcomes for the recipient of their donation.⁴⁰³
- 3.58 The use of donation after circulatory death (DCD) donors, formerly known as non heart beating donors, has been controversial because of the relatively short time period in which death is declared after the heart has stopped beating.⁴⁰⁴ However, with the fall in conventional „brain dead“ donors (DBD), attention turned to DCD donors and an increasing number of centres have gained experience in transplants from donations made in these circumstances. As a result, there has been a ten-fold increase in the number of DCD donors in the last decade and they have provided an increasing number of organs. Initially, only kidneys were taken from DCD donors, but increasingly liver, pancreas, and lungs may also be donated. Kidneys, lungs, and

⁴⁰⁰ Forty eight per cent of all registrations on the ODR were made via the DVLA, as at 23 June 2011: House of Commons Hansard (29 June 2011) c876W, available at:

<http://www.publications.parliament.uk/pa/cm201011/cmhansrd/cm110629/text/110629w0004.htm#11062982000109>.

⁴⁰¹ Department of Health (1 August 2011) *Licences to drive up organ donation*, available at:

http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_128847.

⁴⁰² In 2009, it was reported that the use of higher risk organ donors had doubled from 13 per cent in 1998 to 26 per cent in 2008:

BBC News Online (24 November 2009) *Organ transplants using 'risky donors' rising*, available at:

<http://news.bbc.co.uk/1/hi/8374269.stm>.

⁴⁰³ NHS Blood and Transplant (2010) *Transplant activity in the UK 2009-10*, available at:

http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/activity_report_2009_10.pdf, paragraph 3.3.

⁴⁰⁴ See, for example, Academy of Medical Royal Colleges (2008) *A code of practice for the diagnosis and confirmation of death* (London: Academy of Medical Royal Colleges), p12; Department of Health (2009) *Legal issues relevant to non-heartbeating organ donation*, available at:

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_109864.pdf.

probably pancreas donated in these circumstances have equivalent long-term results compared with organs donated after brain-stem death; results, however, are poorer for liver transplantation.⁴⁰⁵ Most of the DCD donations have taken place in 'controlled' circumstances where the donor dies in a hospital setting. There has been some experience of 'uncontrolled' DCD donation where patients have died from a cardiac arrest out of hospital, but donation in these circumstances is resource-intensive and requires an appropriately trained surgical team to be available in the donor hospital that can respond immediately. It has been suggested that, for kidneys, such 'uncontrolled' donation could in the future provide a "significant proportion of the functional organs provided for transplant".⁴⁰⁶ At present, however, efforts within the UK are directed towards maximising the potential of controlled DCD donation.

- 3.59 Expanding the circumstances under which gamete donors are able to donate has also been suggested. For example, some recommend that the age limit for sperm donation should be widened.⁴⁰⁷

Facilitation of 'paired' or 'pooled' donations (living kidney donation)

- 3.60 A 'paired' or 'pooled' donation occurs when a living kidney donor is fit and able to donate, but is found to be biologically incompatible with the proposed recipient, who may be, for example, the donor's friend, relative, or partner.⁴⁰⁸ In order to facilitate donation in such cases, the option of 'pairing' the organs with another donor and recipient, or 'pooling' them into a group containing more than one other donor/recipient pair, has been developed. If the donor and recipient decide to go ahead with the paired or pooled donation, they will then be 'matched' with one or more compatible donor/recipient pairs who remain anonymous. The proposed paired or pooled donation must be approved by a panel of three or more members of the HTA before the transplants can take place.⁴⁰⁹ Where approval is given, the kidney transplants for each of the recipients take place simultaneously.⁴¹⁰
- 3.61 Eighteen paired living kidney transplants took place between 1 April 2010 and 31 March 2011.⁴¹¹ The first instance of a three-way 'pool' in the UK took place at the end of 2009,⁴¹² and, in 2010-2011, there were 38 pooled organ donations.⁴¹³ The number of people who may actually benefit from paired or pooled living organ donation, however, is only likely to be 20-30 per cent of those who go into the pairing and pooling system, as the circumstances where the exchange may be appropriate are limited, mainly because of the distribution of recipient blood groups.

⁴⁰⁵ Salvalaggio P, Davies D, Fernandez L, and Kaufman D (2006) Outcomes of pancreas transplantation in the United States using cardiac death donors *American Journal of Transplantation* 6: 1059-65; De Vera M, Lopez Solis R, Dvorchik I *et al.* (2009) Liver transplantation using donation after cardiac death donors: long term follow up from a single center *American Journal of Transplantation* 9: 773-81; De Oliveira NC, Osaki S, Maloney JD *et al.* (2010) Lung transplantation with donation after cardiac death donors: long-term follow-up in a single center *The Journal of Thoracic and Cardiovascular Surgery* 139: 1306-15; Summers D, Johnson R, Allen J *et al.* (2010) Analysis of factors that affect outcome after transplantation of kidneys donated after cardiac death in the UK: a cohort study *The Lancet* 376: 1303-11. Donation of the heart after circulatory death is not yet possible.

⁴⁰⁶ See, for example, Richards L (2009) Transplantation: kidneys from non-heart-beating donors *Nature Reviews Nephrology* 5: 666.

⁴⁰⁷ Human Fertilisation and Embryology Authority (2010) *Scientific and Clinical Advances Advisory Committee paper: maximum age limit for sperm donation*, available at: http://www.hfea.gov.uk/docs/2010-05-13_SCAAC_paper_-_maximum_age_for_sperm_donation.pdf.

⁴⁰⁸ Human Tissue Authority (2009) *Human Tissue Act code of practice 2*, available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm>, paragraph 26.

⁴⁰⁹ The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, Regulation 12.

⁴¹⁰ Human Tissue Authority (2010) *Paired and pooled donations*, available at: http://www.hta.gov.uk/db/documents/Paired_and_pooled_donation_flow_chart.pdf.

⁴¹¹ Human Tissue Authority (2011) *Annual review 2010-11: exercising efficiency*, available at: http://www.hta.gov.uk/db/documents/Annual_Review_2011_FINAL.pdf, p15.

⁴¹² Human Tissue Authority (8 March 2010) *First pooled transplants performed in the UK*, available at: <http://www.hta.gov.uk/media/mediareleases.cfm/837-First-pooled-transplants-performed-in-the-UK.html>.

⁴¹³ Human Tissue Authority (2011) *Annual review 2010-11: exercising efficiency*, available at: http://www.hta.gov.uk/db/documents/Annual_Review_2011_FINAL.pdf, p15.

Facilitating easier access to material (in particular tissue for research)

- 3.62 In some circumstances, shortages of healthy and/or diseased material may arise not because of a lack of material, but because of procedural difficulties.⁴¹⁴ These may include difficulties in navigating regulatory requirements (particularly where multiple regulatory regimes are applicable), a lack of supporting infrastructure, poor coordination between different researchers and organisations, or misunderstandings about the precise nature of legal requirements. The HTA, for example, told us that it was dismayed to hear of some of the barriers to 'generic consent' put in place by some risk-averse NHS organisations.⁴¹⁵ The Codes of Practice issued under the Human Tissue Act make clear the HTA's support for the approach of seeking generic consent for the use of tissue in research (see paragraph 2.13), while also emphasising the importance of explaining to potential tissue donors the types of research that may be involved where tissue is stored for an as yet unknown research purpose, or as part of a tissue bank.⁴¹⁶ On licensing requirements, researchers have expressed concerns about the practical impact of the HTA licensing regime, whereby it is sometimes impossible to remove small amounts of blood or tissue in order to carry out research into the effectiveness of organ transplantation techniques because the hospital premises where the donor organs are being removed are not licensed for research.⁴¹⁷ In the context of university-based research, attention has been drawn to the fact that both the institution (the university) and the premises where the research takes place (e.g. university department) need to have licenses under the Human Tissue Act, potentially increasing costs and bureaucracy for researchers.⁴¹⁸
- 3.63 In Box 3.2, we set out some examples of action currently being taken by regulators and others in an attempt to facilitate access to material for research:

Box 3.2: Streamlining access procedures: examples

- The HTA and NRES have jointly taken action to reduce bureaucratic hurdles to accessing material stored in tissue banks for research purposes. **HTA-licensed tissue banks may obtain generic ethical approval for research using stored tissue**, within terms and conditions agreed with the REC, obviating the need for individual researchers to apply to their local REC for approval of each project. The REC will approve the documentation used to seek generic consent from donors as part of the ethical review. Approved tissue banks may then release non-identifiable samples to other researchers without further ethical approval provided that satisfactory scientific scrutiny has been obtained. Around 200 tissue banks have received approval on this basis to date since 2006.⁴¹⁹
- **A network of 12 brain banks** established by the MRC, 'UK Brain Banks', is currently developing a system to make it easier for people to donate brain tissue for research.⁴²⁰ One of the banks (the Sudden Death Brain and Tissue Bank in Edinburgh) has conducted a trial of a system in which the bank is notified of a sudden death – which requires a post mortem examination – by the procurator fiscal, who decides whether the bank should be given permission to approach the family of the deceased. If permission is given, the bank telephones the next of kin, explaining their reason for calling, and providing an opportunity for the family to make a donation for research. The phone call is then followed-up with a letter, before authorisation forms are sent out to the next of kin, should they wish for a tissue donation to be made. After authorisation is given, a letter of thanks is sent to relatives, and an audit questionnaire is posted to them six months after their relative's death. During the trial, 215 families were approached, 206 of which agreed to authorise post mortem tissue for research. The final number of tissue requests fulfilled was 110.⁴²¹ The study concluded that the majority of families are willing to support research use of tissues donated after death even in the context of sudden bereavement and despite previous adverse publicity.

⁴¹⁴ Initiatives such as the Royal Free/UCL Biobank are seeking to address procedural difficulties by enabling a more streamlined approach to accessing bodily material for research. See: University College London (2011) *UCL Royal Free BioBank*, available at: <http://www.ucl.ac.uk/biobank/uclpphysicalbiobank>.

⁴¹⁵ Meeting with regulators, 23 June 2010.

⁴¹⁶ Human Tissue Authority (2009) *Human Tissue Act code of practice 9*, available at:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm>, paragraph 47.

⁴¹⁷ Cronin AJ, Rose ML, Dark JH, and Douglas JF (2011) British transplant research endangered by the Human Tissue Act *Journal of Medical Ethics* 37: 512-4.

⁴¹⁸ Academy of Medical Sciences (2011) *A new pathway for the regulation and governance of health research*, available at: <http://www.acmedsci.ac.uk/index.php?pid=47&prid=88>, p71.

⁴¹⁹ NRES, personal communication, 26 July 2011.

⁴²⁰ See: Medical Research Council (2011) *How to donate brain tissue for research*, available at:

<http://www.mrc.ac.uk/Ourresearch/Resourceservices/UKBrainBanksnetwork/Donatebraintissue/index.htm>.

⁴²¹ See: Millar, T (2010) *Post mortem tissue donation for research: experience of approaching bereaved families*, available at: <http://www.gengage.org.uk/downloads/Tracey-Millar-presentation.pdf>.

- The **Royal Free Hospital and University College London** have recently launched a biobank facility which will collect, process, and store healthy and diseased tissue recovered during tests, treatments and research. It serves a network of hospitals in London and the south east, with the aim of reducing the cost and management burden for each one, and improving ease of access for researchers.⁴²²
- The **Greater Glasgow and Clyde Bio-repository** comes under the remit of the Great Glasgow and Clyde NHS Health Board and is hosted by the NHS Greater Glasgow & Clyde pathology service. The aim of the repository is to create a working environment where the collection of tissue for research is considered to be the norm, and where all patients undergoing a surgical procedure are given the opportunity to donate any surplus material for this purpose. This involves ensuring that procedures for obtaining tissue dovetail with the procedures involved in patient care (both diagnostic and treatment services). The close working relationship between the repository and these patient services also helps to increase the profile of medical research and to embed research activities as a core part of the NHS. A patient information sheet (available in ten languages and Braille) is sent out to patients with their hospital appointment letter, so that they are asked in advance of their appointment if they wish to donate their surplus tissue prior to surgery. Patients' wishes are recorded electronically as part of their electronic health record (thus facilitating the process of recording any later withdrawal of consent by the patient), and a website is being developed to provide potential donors with further information on the value of human tissue in research. An early audit of this process showed that 96.4 per cent of the nearly 800 patients asked were happy to donate, 1.8 per cent refused and 1.8 per cent asked if they could have a little more time to decide.⁴²³

Review of EU Clinical Trials Directive (first-in-human trials)

3.64 The Clinical Trials Directive is currently under review because of concerns about undue regulatory burden being placed on research.⁴²⁴ It has been argued that the Directive has been implemented in very different ways around the EU, and that the number of clinical trials has declined in countries that have fully implemented it even though other factors affecting research have been favourable.⁴²⁵ In its 2011 review of research governance, the Academy of Medical Sciences (AMS) noted that it is difficult to establish the impact of the Directive on the number of studies taking place in Europe because the Directive has changed the way in which trials are authorised, and hence it is hard to compare the number of trials before and after it came into effect.⁴²⁶ Nevertheless, AMS concluded that the "inadvertent negative impacts" of the Directive were widely recognised, and strongly supported the need for a thorough revision.⁴²⁷

Importing bodily material from abroad (potentially any form of bodily material)

3.65 The UK frequently imports bodily material from abroad for the purposes of treatment or research, although the total extent of these imports cannot be ascertained. Such imports do not necessarily, however, indicate a supply problem within the UK. NHSBT Tissue Services, for example, told us that they would be able to increase the supply of most tissues if demand increased, and that the importing of tissue from US commercial tissue banks may reflect favourable introductory pricing or response to marketing, rather than demonstrating shortage within the UK.⁴²⁸ Global pharmaceutical companies, who have a significant number of collaborators overseas, may also choose to import tissue from collaborator countries because they find it useful to identify geographical patterns in disease similarities and differences.

⁴²² University College London (2011) *UCL Royal Free BioBank*, available at: <http://www.ucl.ac.uk/biobank/uclpphysicalbiobank>.

⁴²³ Jane Hair, personal communication, 25 March 2011.

⁴²⁴ European Commission (2009) *Assessment of the functioning of the 'Clinical Trials Directive' 2001/20/EC: public consultation paper*, available at: http://ec.europa.eu/health/files/clinicaltrials/docs/2009_10_09_public-consultation-paper.pdf. It is foreseen that the proposal for a revision of the Directive will be adopted in 2012. See: European Commission (2010) *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Commission work programme 2011*, available at: http://ec.europa.eu/atwork/programmes/docs/cwp2011_annex_en.pdf.

⁴²⁵ European Medicines Agency (2007) *European Commission-European Medicines Agency conference on the operation of the Clinical Trials Directive (Directive 2001/20/EC) and perspectives for the future: report on the conference*, available at: http://www.eortc.be/services/doc/EUCTD/EC-EMEA_report_CT_20071003.pdf.

⁴²⁶ Academy of Medical Sciences (2011) *A new pathway for the regulation and governance of health research*, available at: <http://www.acmedsci.ac.uk/index.php?pid=47&prid=88>, p44.

⁴²⁷ *Ibid*, p44 and 46.

⁴²⁸ NHSBT Tissue Services, personal communication, April 2011.

- 3.66 Where material is imported, issues of appropriate provenance may arise – as demonstrated, for example, by scandals such as that which occurred in 2006 when it was found that material shipped from the US to several UK hospitals had been obtained illegally from the funeral industry.⁴²⁹ The EU Tissues and Cells Directive requires that imports and exports of tissues and cells between Member States for human use are conducted by tissue establishments that are accredited, authorised and licensed, and that all the provisions of the Directive are complied with, including tracing and safety requirements. The EU Directives on organs, tissues and cells, and blood lay down similar conditions with respect to quality and safety issues, including traceability (see paragraph 2.56).
- 3.67 Reproductive material may also be imported from overseas. In the UK, semen is imported from Denmark and, in November 2010, the HFEA permitted a fertility clinic to import frozen eggs from Russia.⁴³⁰ These imports have led to criticism as to whether either fertility clinics or the HFEA can really give assurances about the provenance of the material, or be confident that there has been no payment to the donor in the exporting country.⁴³¹ There have also been anecdotal reports of UK clinics that have considered 'importing' donors from abroad in response to a particular patient's request. This would involve donors' travel and accommodation costs being paid in return for their donating their gametes.⁴³²

Actions aimed at changing individuals' behaviour

Forms of encouragement

- 3.68 There are different ways of encouraging people to donate bodily material. We summarise below a number of methods that are either currently used in the UK, or have been proposed, and suggest that these various approaches may helpfully be categorised as follows:
- relaying **information** about the need for bodily material for others' treatment or for research (for example information campaigns);
 - according **recognition** of, and gratitude for, altruistic donation, through whatever methods are appropriate both to the form of donation and the donor concerned (for example letters of thanks and certificates);
 - intervening to **remove barriers and disincentives** to donation (for example ensuring 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 vouchers for a cup of coffee);
 - providing **benefits in kind** closely associated with the donation (for example egg-sharing arrangements);
 - introducing **financial incentives** that leave the donor in a significantly better financial position.

⁴²⁹ The Times (10 September 2006) *Stolen body parts implanted in NHS patients*, available at: <http://www.timesonline.co.uk/tol/news/uk/article634341.ece>.

⁴³⁰ BioNews (29 November 2010) *UK clinic granted permission to buy 'Russian eggs'*, available at: http://www.bionews.org.uk/page_83109.asp.

⁴³¹ The Sunday Times (21 November 2010) *Clinic imports Russian eggs*, available at: http://www.thesundaytimes.co.uk/sto/news/uk_news/Health/article455197.ece.

⁴³² Human Fertilisation and Embryology Authority (2010) *Authority paper: 8th September 2010*, available at: http://www.hfea.gov.uk/docs/2010-09-08_Authority_Papers_-_complete.pdf, paragraph 8.9. Guidance published by the HFEA has also recommended that when gametes have been donated abroad and imported into the UK, centres should ensure that the donor has not received compensation for loss of earning that exceeds the amount recommended to UK donors: Human Fertilisation and Embryology Authority (2009) *Code of practice*, available at: http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf, guidance note 13.5.

We note, of course, that the circumstances of donation may affect how a particular form of encouragement is categorised: 'benefit sharing' (see paragraph 3.74), for example, may fall into the categories either of 'recognition' or 'benefits in kind', depending on the nature of the benefits being shared, while what some would consider 'token' prompts might be regarded by others as financial incentives. We return to these distinctions, and to the importance of context, in Part II of the report, when we consider what ethical considerations should apply to the choice of particular forms of encouragement (see paragraphs 6.22 – 6.28). Particular examples of these methods are elaborated below.

Increasing public awareness (blood, organs, gametes)

- 3.69 Considerable effort and expense is put into advertising campaigns, aimed variously at the general public and at particular subsections of the population, to encourage more people to consider becoming a donor. Some recent major campaigns in relation to blood and organs gametes are summarised in Box 3.3.

Box 3.3: Promotional campaigns

Blood donation

Video media

- In 2010, NHSBT launched an advertising campaign which focused on how 'ordinary people' may need a blood donation.⁴³³ For example, a group of workmen are filmed walking through a tunnel. As they progress, the camera focuses on one man, and the caption "severed artery, Monday 11:40am" appears. At the end of each advertisement, a voiceover asks viewers to "give blood, and you can save someone's life. Today. Please don't leave it to someone else."

'Amazing Stories'

- NHSBT has also created an area of its blood.co.uk website which focuses on the 'amazing stories' of people who have received a blood donation. Visitors to the site may read the story of 15-year-old Luke Craig, who suffered severe internal injuries in a car crash, including a tear in his heart, and that how "18 months later, Luke is playing football again and gradually regaining his fitness... To the blood donors who donated the 24 pints he needed to get through his operation, Luke will be eternally grateful."⁴³⁴

'Give and Let Live'

- An educational website was also established by NHSBT in 2007.⁴³⁵ It provides students aged 14 years and over "with the knowledge and understanding of key issues relating to donating parts of their body, either in life or after death, to help others." Several of the case studies used on the website tell the story of people whose lives have been saved or extended through the use of donated blood. These include Adrian Turner, a former Olympic swimmer who had to have his spleen removed as a teenager and needed a blood transfusion. The website also focuses on those who still need blood, such as James Baffoe, a young man with sickle cell anaemia. In a video interview, he notes that "if I don't receive red cell exchanges, I would have a lot more crises; a lot more stays in hospitals, and I hate hospitals."

Give Blood Scotland

- Scotland runs its own campaigns for blood donation, and has produced a number of promotional videos, including some with a patriotic element. One video, for example, tells viewers "Scotland needs you to give blood". Its headline message is "Give blood for Scotland".⁴³⁶

Campaigns aimed at black and minority ethnic (BME) communities

- NHSBT has also focused on increasing the number of BME blood donors. It has recently launched the VIP Appeal, a campaign "to encourage people from the African/Caribbean and south Asian community to become Very Important People by donating blood." The campaign predominantly uses celebrity endorsement to convey its plea for more donors.⁴³⁷

⁴³³ NHS Blood and Transplant (2010) *Give Blood: video audio and leaflets*, available at: <http://www.blood.co.uk/video-audio-leaflets/>.

⁴³⁴ NHS Blood and Transplant (2010) *Amazing stories - Luke Craig*, available at: <http://www.blood.co.uk/giving-blood/amazing-stories/luke/>.

⁴³⁵ NHS Blood and Transplant (2010) *Give and let live: real stories*, available at: <http://www.giveandletlive.co.uk/en/realstories/>.

⁴³⁶ YouTube.com (2009) *Give blood for Scotland*, available at: <http://www.youtube.com/watch?v=6CEe-4Qp7U0>.

⁴³⁷ NHS Blood and Transplant (2010) *The VIP Appeal?*, available at: <http://www.blood.co.uk/vip/index.asp>.

Organ donation

NHSBT campaign

- In 2009, NHSBT told the public "if you believe in organ donation, prove it." The campaign focused on the statement that "nearly all of us would take an organ but most of us put off registering as a donor."⁴³⁸ In addition, NHSBT has also created a 'Wall of Life' website – now completed – where people are encouraged to join the ODR and upload a photograph and message of support once they have joined.⁴³⁹

Donate Wales

- Donate Wales has recently launched a campaign which focuses on encouraging people to "tell a loved one" about their decision to join the ODR. The campaign uses several Welsh celebrities, including Colin Jackson and James Hook. People who register on the ODR are then encouraged to send an e-card to their loved ones, informing them that they have signed up.⁴⁴⁰

Scottish Government

- The Scottish Government has recently launched a new campaign focusing on the message that 'Everyone has the potential to save a life.'⁴⁴¹ The campaign's press release focuses on the 600 people in Scotland who are waiting for an organ transplant.

3.70 Although the need for blood and organ donation are the subject of well-resourced publicity campaigns,⁴⁴² there are other areas that are the focus of few, if any, promotional campaigns. For example, while disease-specific charities or research organisations may run campaigns for certain types of bodily tissue to be donated for research,⁴⁴³ there are no overarching national campaigns to encourage patients to give unneeded tissue remaining after medical procedures for research purposes. The National Gamete Donation Trust (NGDT) is funded by the Department of Health to raise awareness of the need for more sperm, egg and embryo donors,⁴⁴⁴ but its budget for publicity campaigns is very small compared with those available for blood and organ donation.⁴⁴⁵

Recognising the costs of donation (all forms of material and first-in-human trials) and non-financial tokens of gratitude (blood and organs)

3.71 As we noted in Chapter 2, while any reward to donors in return for bodily material is forbidden both in the UK's domestic legislation and at European level, various forms of reimbursement of expenses are permitted, and free or reduced-cost fertility treatment may be offered in return for the donation of eggs (see paragraphs 2.34 and 2.35). Explicit payment for participation in first-in-human trials is, by contrast, routine (see paragraph 2.37).

3.72 It is already usual practice for transplant recipients to be encouraged to write an anonymous letter of thanks to the donor's family. Examples of non-financial tokens of gratitude include inclusion in public memorials such as the service of thanks for people who have donated their body to medical research, held each year at Southwark Cathedral. Similarly, NHSBT's Wall of Life enables people who sign the ODR to leave a message of support.⁴⁴⁶ Regular blood donors may receive awards, such as colour-coded donor cards, key fobs and certificates in recognition

⁴³⁸ NHS Blood and Transplant (2010) *NHS Blood and Transplant: adverts and video*, available at: http://www.organdonation.nhs.uk/ukt/adverts_and_video/adverts_and_video.jsp.

⁴³⁹ NHS Blood and Transplant (2010) *Wall of life*, available at: <http://www.walloflife.org.uk/>.

⁴⁴⁰ Donate Wales (2010) *Donate Wales: before you save a life tell a loved one*, available at: <http://www.donatewales.org/celebrities/?video=play&vid=enRub40>.

⁴⁴¹ The Scottish Government (27 September 2010) *Organ donation campaign*, available at: <http://www.scotland.gov.uk/News/Releases/2010/09/27100402>.

⁴⁴² In 2009-10, NHSBT were able to spend just over £9 million on media advertising to raise awareness of blood and organ donation: NHS Blood and Transplant (2010) *NHS Blood and Transplant annual report and accounts 2009-10*, available at: <http://www.official-documents.gov.uk/document/hc1011/hc00/0083/0083.pdf>, p48.

⁴⁴³ See, for example, Parkinson's UK (2009) *Parkinson's brain donor appeal supporters*, available at: http://www.parkinsons.org.uk/support_us/parkinsons_awareness_week/brain_donor_appeal_supporters.aspx.

⁴⁴⁴ National Gamete Donation Trust (2008) *Give hope, give life*, available at: http://ngdt.co.uk/index.php?option=com_content&view=article&id=93:give-hope-give-life&catid=6&Itemid=88.

⁴⁴⁵ The NGDT has a total annual budget for all its running costs of £60,000: NGDT, personal communication, 23 July 2011.

⁴⁴⁶ NHS Blood and Transplant (2010) *Wall of life*, available at: <http://www.walloflife.org.uk/>.

of their contribution,⁴⁴⁷ and living kidney donors receive a 'Living Donor Pin'.⁴⁴⁸ The Royal College of Physicians has also recently published a collection of letters of thanks from transplant recipients to donors' families.⁴⁴⁹ Schemes such as these were recognised in the ODT's report, which recommended that "appropriate ways should be identified of personally and publicly recognising individual organ donors, where desired. These approaches may include national memorials, local initiatives and personal follow-up to donor families."⁴⁵⁰

The introduction of financial incentives

3.73 The gap between supply and demand for some types of bodily material has led to considerable discussion, in both public and professional forums, over the possibility of introducing some form of financial incentives for potential donors. Such an 'incentive' implies payment over and above reimbursement of all the costs incurred in making a donation (including lost earnings where applicable), and the removal of disincentives: that is, it includes an element of *reward*, as well as recompense (see paragraph 2.44 and paragraph 5.31). Various suggestions for gamete donors and living organ donors have been aired. Such payments could include more generous standardised reimbursement arrangements for expenses (for example a notional fixed figure for 'travel expenses' that may exceed actual costs incurred) or flat-rate compensation payments for 'inconvenience'. They could also include a system for the sale and purchase of organs or gametes, whether at non-market rates via a governmental organisation or in a fully-fledged free market. Other options that have been put forward include the introduction of 'non-cash' incentives (potentially of significant financial value) for donating organs after death, for example by meeting funeral expenses in the same way as for those who donated their body to medical science. The use of 'non-cash' incentives with some (small) monetary value, such as t-shirts, mugs and vouchers has also been suggested in the context of blood donation: such tokens might be regarded as a mild incentive to encourage wider participation in blood donation, or simply as a way of saying 'thank you' after a donation.⁴⁵¹ We discuss the evidence currently available on the effectiveness of such incentives in Chapter 6 (see paragraphs 6.16 to 6.21).

Benefit sharing

3.74 The introduction of a form of 'benefit sharing' would involve establishing a system under which those providing bodily material, or signing the ODR could enjoy non-financial benefits linked with their donation such as priority for an organ, or other bodily material, if in the future they come to need one. Israel has recently introduced such a scheme in respect of organ donation: citizens who commit to donating their own organs after death are promised priority in the queue for an organ transplant, should they ever need one (see paragraph 2.48).⁴⁵²

3.75 An example of benefit-sharing in research is the approach taken by the Human Genome Organisation (HUGO), which prohibits "undue inducement through compensation" for participants in genetic research but argues that the interests of justice compel researchers to share benefits of other kinds, including education, training, and health care provision, with the subjects of their research.⁴⁵³ It has similarly been argued that benefit-sharing on a communal

⁴⁴⁷ NHS Blood and Transplant (2010) *Whole blood donor award scheme*, available at: <http://www.blood.co.uk/giving-blood/donor-award-scheme/whole-blood-donor/>.

⁴⁴⁸ NHS Blood and Transplant (17 March 2011) *1000th pin badge awarded to celebrate living organ donation*, available at: https://www.organdonation.nhs.uk/ukt/newsroom/news_releases/article.jsp?releaseld=266.

⁴⁴⁹ Royal College of Physicians (2010) *Thank you for life* (London: Royal College of Physicians).

⁴⁵⁰ Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf, p17.

⁴⁵¹ Buyx AM (2009) Blood donation, payment, and non-cash incentives: classical questions drawing renewed interest *Transfusion Medicine and Hemotherapy* **36**: 329-39.

⁴⁵² Lavee J, Ashkenazi T, Gurman G, and Steinberg D (2010) A new law for allocation of donor organs in Israel *The Lancet* **375**: 1131-3; Kolber AJ (2003) A matter of priority: transplanting organs preferentially to registered donors *Rutgers Law Review* **55**: 671-740.

⁴⁵³ HUGO Ethics Committee (2000) *Statement on benefit sharing* (Singapore: HUGO).

level (as distinct from reward for individual research participants) is an appropriate way of dealing with public concerns that material donated freely by patients or members of the public may lead to private profits for researchers or companies.⁴⁵⁴

Permitting 'benefits in kind'

- 3.76 Perhaps the most well-known example of a benefit in kind is 'egg sharing' where women can access free or significantly subsidised IVF treatment (see paragraph 1.17) in exchange for donating some of their eggs to a woman who needs donated eggs and who will pay for the entire treatment cycle.⁴⁵⁵ Women are now also able to receive discounted IVF treatment where they donate eggs for research.⁴⁵⁶ Because of the risks of undergoing stimulation for IVF treatment,⁴⁵⁷ some have claimed that egg sharing is ethically preferable to non-patient egg donation, since the egg sharer does not face additional risks (as she has indicated a wish to undergo the treatment for herself to achieve a pregnancy).⁴⁵⁸
- 3.77 Egg sharers are young (usually under 35 years of age)⁴⁵⁹ and are tested to ensure that they have good 'ovarian reserve' and can safely be stimulated to produce enough eggs for their own use and that of the recipient couple without undue risk of serious consequences such as OHSS. Accordingly, the initial pregnancy rates are very similar between egg sharer and recipient.⁴⁶⁰ However, because a reduced number of eggs is available to the egg sharer, she will have fewer frozen embryos, and therefore her cumulative pregnancy rate may be lower than if she had kept all the eggs for own use. There is some evidence to suggest that egg sharing is not an option many women choose if other routes to pregnancy are available.⁴⁶¹ When Belgium introduced 'unlimited' state funding for IVF treatment (which was also available to couples who already had children), for example, clinics noticed a significant drop in the number of women prepared to be egg-sharers.⁴⁶²
- 3.78 The notion that egg sharing represents an indirect financial payment has been challenged: it may, for example, be argued that the benefit received by the donor from egg sharing is not seen as financial, but rather as the *chance* to have a child, where that chance would otherwise be unavailable because of cost.⁴⁶³ Similarly, women who are able to access NHS IVF services, and hence do not have to pay for private fertility treatment, may not regard this as a financial benefit, but rather as a health service like any other.

Encouragement of living organ donation (primarily kidneys)

- 3.79 'Directed' living donation occurs when a relative or close friend donates their organ – usually a kidney, but liver lobes and part-lungs may also be donated – to a family member or friend. Such

⁴⁵⁴ Haddow G, Laurie G, Cunningham-Burley S, and Hunter KG (2007) Tackling community concerns about commercialisation and genetic research: a modest interdisciplinary proposal *Social Science & Medicine* **64**: 272-82.

⁴⁵⁵ Fertility centres may also offer benefits in kind to men who donate sperm: Human Fertilisation and Embryology Authority (2009) *Code of practice*, available at: http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf, paragraph 11.41.

⁴⁵⁶ North East England Stem Cell Institute (2008) *Egg sharing: women to get help with IVF treatment costs for donating eggs to research*, available at: <http://www.nesci.ac.uk/news/item/egg-sharing-women-to-get-help-with-ivf-treatment-costs-for-donating-eggs-to-research>. Currently, this option is only available in one centre, in Newcastle.

⁴⁵⁷ Human Fertilisation and Embryology Authority (2009) *Risks of fertility treatment*, available at: <http://www.hfea.gov.uk/fertility-treatment-risks.html>.

⁴⁵⁸ Ahuja KK, Andonov M, Wang JJ, Linara E, and Nair S (2011) High birth rates for donors and recipients treated in a long term egg sharing programme *Unpublished*.

⁴⁵⁹ National Gamete Donation Trust (2008) *Egg sharing*, available at: <http://www.ngdt.co.uk/egg-sharing>.

⁴⁶⁰ Ahuja KK, Andonov M, Wang JJ, Linara E, and Nair S (2011) High birth rates for donors and recipients treated in a long term egg sharing programme *Unpublished*.

⁴⁶¹ See, for example, tentative findings from Haimes, E and Taylor, K (2011) *An investigation of patients' views and experiences of an IVF egg sharing scheme for somatic cell nuclear transfer research: abstract presented at 27th annual meeting of the European Society of Human Reproduction & Embryology, July 4-6* (Stockholm: European Society of Human Reproduction & Embryology).

⁴⁶² Pennings G, and Devroey P (2006) Subsidized in-vitro fertilization treatment and the effect on the number of egg sharers *Reproductive BioMedicine Online* **13**: 8-10.

⁴⁶³ For example, by participants at a 2010 debate organised by the Progress Educational Trust (PET) entitled *Paying egg donors: a child at any price?* 20 October 2010.

donation has increased significantly over the last decade, with a rise in the number of living organ donors each year for the past ten years.⁴⁶⁴ While the decision to donate an organ as a living donor is an intensely personal one, usually motivated by the need of someone very close to the potential donor, NHSBT has taken active steps to encourage and support living donors: examples include the establishment in 2005 of a 'Renal Taskforce' to support living donation⁴⁶⁵ and the creation in 2010 of the new role of 'Lead Nurse – Living Donation' within NHSBT itself.⁴⁶⁶

- 3.80 So-called 'stranger' living organ donation or non-directed donation, occurs when a healthy person donates an organ to the general pool, so that it goes to someone they do not know.⁴⁶⁷ Figures published by the HTA highlight an increase between 2009-2010 and 2010-2011 in people donating kidneys to strangers, although the number of people who are given approval to become stranger donors in this way remains relatively small, having increased from 23 to 40.⁴⁶⁸

Action taken directly by individuals

- 3.81 In some cases, an individual may decide to act on their own initiative to increase their chance of receiving bodily material. There are a number of routes that individuals may explore.

Personal advertising for donors

- 3.82 Direct advertising for donors is used for a range of bodily materials, from couples placing advertisements for egg donors in local newspapers⁴⁶⁹ to appeals on charity websites for bone marrow donations for named individuals.⁴⁷⁰ Individuals may seek the help of an intermediary in such searches: for example a recently-established website offers to manage the recruitment of egg donors for potential recipients.⁴⁷¹ Such 'personal action' (especially when undertaken via charities) may potentially have a beneficial effect on general public awareness, especially in relation to bone marrow donation.⁴⁷² However, concerns have also been expressed that direct recruitment of donors in this way may potentially lead to the prohibition on financial reward for donors being subverted in some cases.⁴⁷³

⁴⁶⁴ NHS Blood and Transplant (2009) *Transplant activity in the UK 2008-9*, available at: http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/2008_09/transplant_activity_uk_2008-09.pdf, figure 2.2.

⁴⁶⁵ NHS Blood and Transplant (2010) *Could I be a living kidney donor?*, available at: http://www.uktransplant.org.uk/ukt/how_to_become_a_donor/living_kidney_donation/living_kidney_donation.jsp. However, this scheme has now ended and has been subsumed into NHSBT's other activities: NHSBT, personal communication, 9 August 2011.

⁴⁶⁶ NHS Blood and Transplant (7 December 2010) *NHS Blood and Transplant makes new appointment to promote living donation*, available at: http://www.organdonation.nhs.uk/ukt/newsroom/news_releases/article.jsp?releaseld=257.

⁴⁶⁷ Human Tissue Authority (2010) *Non-directed altruistic donation*, available at: <http://www.hta.gov.uk/bodyorganandtissuedonation/organdonations/non-directedaltruisticdonations.cfm>.

⁴⁶⁸ Human Tissue Authority (5 April 2011) *Altruistic kidney donations double in one year*, available at: <http://www.hta.gov.uk/media/mediareleases.cfm/984-Altruistic-kidney-donations-double-in-one-year.html>.

⁴⁶⁹ Daily Mail (15 July 2010) *Couples with fertility problems forced to advertise for egg donors due to national shortage*, available at: <http://www.dailymail.co.uk/health/article-1295016/Couples-fertility-problems-forced-advertise-egg-donors-national-shortage.html>.

⁴⁷⁰ The Anthony Nolan Trust (2010) *Wirral family in desperate search to find their son's lifesaver*, available at: <http://www.anthonynolan.org/News/Wirral-family-in-desperate-search-to-find-their-son.aspx>.

⁴⁷¹ Altrui (2010) *Altrui: seeking the altruistic donor*, available at: www.altrui.co.uk.

⁴⁷² See, for example, the recent campaign by the Anthony Nolan Trust for donors to become a recipient's „one in a million“: YouTube (2009) *'Fix you': campaign for the Anthony Nolan Trust*, available at: <http://www.youtube.com/watch?v=YA7XmMWtb-c>.

⁴⁷³ See, for example, Human Tissue Authority (6 July 2011) *Debate: modern relationships in living organ donation - opportunity or risk?*, available at: <http://www.hta.gov.uk/newsandevents/htanews.cfm/999-Debate--Modern-relationships-in-living-organ-donation--opportunity-or-risk-.html>.

Cross-border care (fertility treatment and organ transplants)

- 3.83 Constraints on UK 'supply', particularly of kidneys for transplant and eggs for fertility treatment, have led to some patients taking the decision to go abroad for treatment, in areas where regulations are either different, or less rigorously enforced. Patients going to other countries where gametes are more readily available to them is widely reported as 'fertility tourism',⁴⁷⁴ although the term 'cross-border reproductive care' is preferred by those working in the fertility field. An online survey of its members carried out by Infertility Network UK (INUK) in 2008 found that 76 per cent of respondents would consider travelling abroad for fertility treatment; of these, just over half were attracted by the availability of donor eggs or sperm.⁴⁷⁵ The Trans-national Reproduction (Transrep) Study has explored the experiences of people who are involved in the process of cross-border reproductive care, as either a 'user' or 'provider' of services.⁴⁷⁶ Initial conclusions suggest that significant drivers for people deciding to travel abroad for fertility treatment include a shortage of egg donors, the risk of long waiting times for treatment, and issues of cost. It was also noted that many participants in the survey had decided to travel abroad following a long process of infertility treatment in the UK, reporting that this was their 'last chance' to have a child.⁴⁷⁷ The process of cross-border fertility treatment may be prompted by clinics, or taken wholly at the initiative of the individual.⁴⁷⁸
- 3.84 Unlike cross-border reproductive care, which generally involves treatment that is legal in the host country, 'transplant tourism' is based almost entirely on illegal activity and is widely condemned.⁴⁷⁹ The preamble to the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (Steering Committee of the Istanbul Summit), 2008, states, for example: "The legacy of transplantation must not be the impoverished victims of organ trafficking and transplant tourism but rather a celebration of the gift of health by one individual to another".⁴⁸⁰ Iran is the only country that permits payment for organs (see paragraph 2.46), but this is within the context of a regulated market, with strict controls on access by foreigners. The WHO estimated conservatively that, in 2005, five per cent of all recipients who received a transplant did so by undergoing commercial organ transplants overseas,⁴⁸¹ and despite the Declaration of Istanbul and the WHO Guiding Principles, the practice of organ trafficking allegedly persists in certain countries of the world. Recent media reports from Kosovo, India and South Africa appear to confirm this.⁴⁸² Yet the practice does not persist by accident: despite being condemned, it is

⁴⁷⁴ Dyer C (2010) UK women seek infertility treatment abroad because of shortage of donor gametes at home, survey finds *BMJ* **341**: c6874.

⁴⁷⁵ Human Fertilisation and Embryology Authority, (2008) *Authority paper: cross-border fertility treatment*, available at: http://www.hfea.gov.uk/docs/AM_Item3_Dec08.pdf, annex D.

⁴⁷⁶ Transrep (2010) *Transrep: project overview*, available at: <http://www.transrep.co.uk/>.

⁴⁷⁷ Romera N, Llacer J, Aula M *et al.* (2010) Session 51: Cross Border Reproductive Care / O-196 Assessment quality of life in cross-border patients using the new tool "fertiqol" / O-197 Travelling abroad for fertility treatment: an exploratory study of UK residents seeking cross-border care / O-198 Favorable pregnancy rates in an embryo donation program: results of seven years of experience / O-199 Cross-border reproductive care for egg-donation in Dutch women *Human Reproduction* **25**: i77-i79.

⁴⁷⁸ Trade shows have been established that aim to provide individuals with information as to how they can access treatment abroad. See, for example, Destination Health (2011) *Destination health: the health and medical tourism show*, available at: <http://www.bluewaterevents.co.uk/desthealth/about.html>.

⁴⁷⁹ See, for example, Scheper-Hughes N (2000) The global traffic in human organs *Current Anthropology* **41**: 191-224 and Starzl T, Teperman L, Sutherland D *et al.* (2009) Transplant tourism and unregulated black-market trafficking of organs *American Journal of Transplantation* **9**: 1484.

⁴⁸⁰ Steering Committee of the Istanbul Summit (2008) Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul *The Lancet* **372**: 5-6. Transplant tourism is defined in the Declaration as existing where "travel for transplantation" "involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals, and transplant centres) devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services for its own population." See also: The Declaration of Istanbul Custodian Group (2008) *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*, available at: http://www.declarationofistanbul.org/index.php?option=com_content&view=article&id=73&Itemid=59.

⁴⁸¹ Shimazono Y (2007) The state of the international organ trade: a provisional picture based on integration of available information *Bulletin of the World Health Organization* **85**: 955-62. This study produced results based on figures obtained in 2005.

⁴⁸² Council of Europe Parliamentary Assembly (2010) *Inhuman treatment of people and illicit trafficking in human organs in Kosovo*, available at: http://assembly.coe.int/CommitteeDocs/2010/20101218_ajdoc462010provamended.pdf; Wired.com (5 August 2007) *Black-market scandal shakes India's ban on organ sales*, available at: http://www.wired.com/medtech/health/news/2007/05/india_transplants_main; The Telegraph (10 November 2010) *South*

rarely an active subject for prosecution, medical professionals are involved, and the number of legal actions for breach worldwide is reputedly minuscule.⁴⁸³

African hospital pleads guilty to organ trafficking, available at:
<http://www.telegraph.co.uk/news/worldnews/africaandindianocean/southafrica/8124710/South-African-hospital-pleads-guilty-to-organ-trafficking-case.html>.

⁴⁸³ Cohen L (2005) Operability, bioavailability, and exception, in *Global assemblages: technology, politics, and ethics as anthropological problems*, Ong A, and Collier SJ (Editors) (Oxford: Blackwell Publishing), pp79-91.

Chapter 4

Debates over ethics

Chapter 4 - Debates over ethics

Chapter overview

- Two unifying factors governing the bodily materials considered in this report are that they all come from persons, and that their intended use is to benefit others rather than the person who is the source of the material. These two aspects of the donation or volunteering of bodily material have generated a number of (sometimes competing) ethical concerns. Ethical values often invoked in response to such concerns include:
 - Altruism
 - Autonomy
 - Dignity
 - Justice
 - Maximising health and welfare
 - Reciprocity
 - Solidarity.
- Other pertinent values highlighted in response to our consultation included:
 - 'professional' values, such as respect, honesty, and the exercise of the duties of care and confidentiality; and
 - positive values inherent in interpersonal relations, including love, generosity, compassion and trust.
- Many of these ethical values may be interpreted in diverse and sometimes contradictory ways. This does not mean that they become redundant but rather that the way they are being used in particular circumstances needs to be made explicit and, where necessary, justified. For example, the traditional emphasis on the importance of the „gift“ has been criticised both because it may fail to prompt sufficient donors to meet demand, and because it may at times be used as a cover for coercive or exploitative relationships. However, it is clear that for many the notion of the gift elicits the sense of a supremely 'social' act in its orientation towards others. It also plays an important role in drawing attention to the person (the gift-giver) whose body is at issue. It epitomises the opposite of theft and seizure by force, and in so doing it points to the desirability of material properly given rather than improperly taken. We suggest that, only by 'unpacking' ethical claims made around donation practices in this way, can we hope to understand the context in which these values may be understood.
- Other concepts that generate strong, and sometimes conflicting, reactions are the notion of the „public“ and „private“ aspects of the donation of bodily material; and the meanings associated with money. In donation, public and private are understood in many different ways, and it may be more helpful to think of public and private as being complementary and overlapping rather than as in opposition. Money in turn may be conceptualised in many ways, including as 'cash' (negatively as 'naked cash' or positively as transferable currency that may be used for any purpose); as influence; as a pricing mechanism; and as a reward.
- Finally, this chapter touches on the psychological aspects of how individuals arrive at moral judgments. Certain kinds of transactions, for example the notion of attaching monetary value to things considered priceless such as organs, may be considered by many as 'taboo'. While some people will in practice be willing to change their view on taboo subjects (for example to achieve a valued end, such as saving lives), others will not, perceiving that it would violate deeply-held intuitions, or have an unacceptable long-term impact on societal values and functioning. Yet policy still has to be made in the context of such competing public views. We note how an awareness of these factors adds to the importance of seeking to find areas of mutual agreement and concern, where particular policies may be supported by diverse audiences for diverse reasons.

Ethical values

- 4.1 We highlighted in the Foreword that two unifying factors govern the bodily materials considered in this report: they all come from persons,⁴⁸⁴ and their intended use is to benefit others rather than the person who is the source of the material. These two aspects of the donation or volunteering of bodily material have generated a number of (sometimes competing) ethical concerns around consent, control, and ownership (See Box 4.1 opposite). In addition, the issue of 'shortage' has created its own area of concern, prompting the question: *How far should society go in attempting to encourage or facilitate the donation of bodily material?* Addressing the legitimate role of public and private bodies in responding to that shortage, the question becomes: *how far should public and private bodies go in encouraging, or even incentivising, people to provide their bodily material or to volunteer for a trial? and should they take action*

⁴⁸⁴ As we note earlier, we use the term 'person' to indicate a social being in relationships with other social beings.

themselves to facilitate donation? The aim of this chapter is to provide an overview of some of the ethical values widely considered to be at stake, before embarking on our own discussion of these issues in Chapter 5. It will also consider the importance of considering the *context* in which appeal is made to these values (see paragraph 4.6, and following sections).⁴⁸⁵

Box 4.1: Examples of ethical dilemmas arising in the context of donation

- Is it right always to try to meet demand? Are some needs or demands more pressing than others?
- How should bodily material be valued? Are some forms of material more valuable in themselves than others? Are some uses more valuable in themselves than others?
- Does the offer of any significant incentive – whether in the form of direct cash payment or indirect financial benefits such as free or reduced fees for IVF treatment – act as a form of „undue influence“ on the person concerned and compromise the voluntary nature of their consent?
- How can we guard against the risk of coercion in the family context – for example to donate bone marrow or a kidney as a living donor – where the „donor“ may not feel able to say no?
- What role should families play in deciding whether a deceased person’s bodily material should be used to benefit others?
- Should those who are prepared to donate bodily material be entitled to specify the recipient?
- Should the state intervene if one person is willing to sell a body part that another wishes to buy?

- 4.2 The consultation document published by the Working Party in April 2010⁴⁸⁶ pinpointed a number of ethical values that are often invoked when people in the UK consider the donation of human bodily material. We reproduce them in expanded form in Box 4.2 overleaf, illuminated by quotes from consultation respondents. The purpose of doing so is to highlight how controversies and disputes that arise in connection with the donation of bodily material are often not so much about the respective merits of particular values, but rather about the ethical dilemmas with which these values are associated, and the way in which values are invoked to make particular claims.

⁴⁸⁵ As Stephen Wilkinson succinctly puts it in relation to an argument about exploitation and instrumentalisation: "What does all the ethical work here is context": Wilkinson S (2003) *Bodies for sale: ethics and exploitation in the human body trade* (London: Routledge), p42.

⁴⁸⁶ Nuffield Council on Bioethics (2010) *Give and take? Human bodies in medicine and research*, available at: <http://www.nuffieldbioethics.org/sites/default/files/Human%20bodies%20in%20medicine%20and%20research%20consultation%20paper.pdf>.

Box 4.2: Ethical values cited in the Working Party's consultation document

“We think that the ‚gift relationship“ is of the essence when bodies and donations are under consideration.” - *Patricia Stoot, Convenor, Health and Bioethics Committee, National Board of Catholic Women*

“As an unfortunate fact of reality, altruism does not produce enough organs.” - *Jonathan Lee*

Altruism is widely understood as entailing a selfless gift to others without expectation of remuneration. For several decades, this understanding of altruism has been presented as the basis of blood and organ donation in the UK. Altruistic giving may be to strangers, or may take place within the context of family or other relationships. The widespread support for this model for donation is found both in the regulatory emphasis on voluntary and unpaid donation (see Box 2.1) and in common descriptions such as „giving the gift of life“. Such descriptions contrast with the not infrequent portrayal of those paid to participate in first-in-human clinical trials as „human guinea-pigs“.

Some argue, however, that a model of individual altruism no longer sits easily in the more commercial world of modern health care: why should those providing material be required to act on an altruistic basis when everyone else involved in the transaction is remunerated in some way? Others express concern that the traditional altruistic model can often be subject to hidden coercive pressures, as when patients on a transplant list might „expect“ a suitable relative to donate an organ to help them.

“Autonomy and the ability of an individual to give or decline consent should be paramount. Values should therefore be prioritised relating first to the individual and then society.” - *Royal College of General Practitioners*

“Autonomy is normally considered a priority, but should not necessarily always take precedence. An example might be when an emerging new infection threatens to become a serious public health issue, in which case testing samples in an existing tissue bank without donor consent could be justified.” - *The Medical Research Council*

Autonomy is often highlighted as the key value underpinning people's entitlement to control their own bodies, either because of the relationship of identity between a person and their body, or because bodies are regarded as „part of“ or as „belonging“ to the individual person. Respect for autonomy is shown primarily through the importance placed on consent: valid consent must be given before bodily material may be taken, and before a person participates in a first-in-human trial (although what constitutes 'valid' consent may differ depending on different conceptions of autonomy). Concerns about coercion and „undue inducement“ undermining valid consent similarly reflect the importance attached to ensuring that decisions about a person's body are freely and autonomously made by the person concerned.

More controversially, it may also be argued that respect for autonomy should entail permitting people to do what they wish with their own bodies, including selling their bodily material as a commercial transaction. Similarly, it may be thought desirable actively to encourage „autonomy“ by making people responsible for their own circumstances, as in the move away from what comes to seem medical paternalism.

“Dignity and justice should always prevail.” - *Jayne Doran*

“Concepts such as dignity and justice have proven ambiguous in practice and should be minimised.” - *Anonymous consultation respondent*

Dignity and concerns about 'commodification'. The concept of the inherent dignity, or special status, of the human body is often expressed in terms of Kantian concerns about using people purely as 'means' rather than as 'ends in themselves'. Bodies have a double position in health care: the body of a patient receiving medical treatment is a source of concern (an 'end in itself'), but when bodily material is being used to treat others, there is the risk that the material is viewed purely as a 'commodity', available as a 'means' to others' ends. Such concerns may be exacerbated if money enters the equation: in a Kantian view, dignity and price are essentially mutually incompatible. Putting a price on a human being, or on part of their body, may be seen as giving it a relative value, whereas human beings are of „incomparable ethical worth“.

For some, donation of bodily material can only respect human dignity if the donation is made with the primary aim of helping others: in such a way the donated material will not become purely a means to another end, but also an expression of the 'ends' of the person making the donation. Others argue that there is nothing inherently undignified in providing bodily material in return for a fee and that degradation depends on one's own perception of what is degrading.

“Equity must be a central component of every aspect of a scheme within which individuals donate any substance, whilst living or after death.” - *Graham Driver*

“Formal equality can be beneficial ... But always treating people the same may lead to other inequalities through failing to recognize their differences.” - *Dr Rachel Ariss*

Justice is concerned with a „fair“ distribution of benefits and burdens within or between societies. Issues of justice arise in at least two distinct contexts in donation and volunteering. On the one hand, concerns arise that those who are most likely to donate or volunteer may be the least likely to benefit from access to the services of which the donation/volunteering is part. Those volunteering for first-in-human trials, for example, may be those who have poor access to health care and are

unlikely to access the resulting benefits. Similarly, a key anxiety about any form of commercial market for bodily material is that it may induce primarily the poorest and most vulnerable members of society into becoming donors, with the main recipients being the better-off. This could occur both within individual countries (low, middle and high income countries alike) and also lead to inhabitants of lower income countries becoming the main source of organs and gametes – „donor nations” – for the inhabitants of wealthier nations.

On the other hand, the question arises as to what constitutes „fair recompense” to the donor or volunteer who in many cases may be the only person concerned *not* to receive any form of remuneration (contrast the salary paid to health care staff involved in the transaction) or direct benefit (as where a recipient derives health benefit from the donated material). Such questions arise especially where the intermediaries concerned in the transaction – for example some fertility clinics or pharmaceutical companies – operate on a commercial basis.

“Maximising health and welfare should be a major priority.” - Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom

“There is no doubt in my mind that the altruistic concepts of „maximising health and welfare”, reciprocity and solidarity are sadly missing from discussions in this area.” - Marlene Rose

Maximising health and welfare: An ethical approach that prioritises the achievement of the best possible outcome for the greatest number, minimising harm and maximising benefit overall. One argument that is sometimes made in favour of an „opt-out” system (where organs are routinely taken after death unless the person has explicitly objected) is that the good to those able to benefit from treatment and research exceeds the harm of the interference with autonomy. A similar argument could be made for a moral duty to participate in research.

On the other hand, arguments based on the maximisation of health and welfare may be deployed against the use of commercial markets in bodily material and the use of payment in first-in-human trials because of concerns about the creation of an underground „shadow economy” of exploited and vulnerable members of society.

“Reciprocity is an opportunistic „value” that should be banned: what if I have nothing to „give” and need to „take”?” - Haris E. Cazlaris

“... reciprocity is a positive concept if it connotes active cooperation among individuals and includes relationships of gratitude and just recompense.” - The Anscombe Bioethics Centre

Reciprocity: Reciprocal relationships involve a notion of exchange between two or more parties in the context of a mutually beneficial relationship. Such a relationship requires both that the parties to the relationship are jointly bound, and that there is some kind of equitable return between them. The value of reciprocity may be used to justify the practice of benefit-sharing or compensation in return for providing bodily material or participating in a first-in-human trial (see also **Justice**). It also underpins the idea of paired organ donation, with one donor/recipient „pair” entering into a reciprocal arrangement with the other.

Thus, reciprocity may be evoked positively, where two parties perceive a sense of mutuality or common purpose, and acknowledge the value of „fair dealing” between themselves; this may be projected on to unknown others, so that a person may act for public benefit in the conviction or hope of „do as you would be done by”. Reciprocity may also be invoked negatively, as in the argument that those who are not prepared to provide bodily material should not, were they to need it, be eligible to receive such material themselves.

“Solidarity is very important as „we are all in it together” in the sense that disease is not chosen and does not strike in a moral way.” - Anonymous consultation respondent

“Solidarity recognises our interconnectedness, the natural compassion that everyone feels (or should feel) toward others in view of the hardships and misfortunes of those others, and it is in compliance with noble values of dignity, respect and mutual help. It emphasises community and mutual obligations.” - Shawn H. E. Harmon

Solidarity expresses the idea that „we’re all in this together”, with an implication of mutual obligations and mutual support within a definable community (based, for example, on geography or on shared interests). It links with values that are communal and collective in origin, encompassing ideas of a „shared humanity” or a „shared life” in which we can all both contribute and receive, and where those who are vulnerable should be given special protection. In the context of the donation of bodily materials, both donors and recipients could, in different ways and circumstances, potentially be „vulnerable” and in need of such protection. „Altruism” and „solidarity” may, in many cases, be overlapping concepts: one may give blood, for example, out of a desire to help others – and also out of an awareness that anyone may, at any time, need blood themselves.

However, there are also degrees of solidarity depending on the narrowness or breadth of the community in question: indeed, by definition, a „community” excludes those outside it. Solidarity can thus work to exclusionary effect, as when minority groups resist identification with the majority or are excluded by it.

- 4.3 In the responses to the consultation exercise, and in the course of our enquiries generally, it was suggested that further pertinent ethical values were:
- **Professional values:** these included ideas of 'doing no harm' (non-maleficence) and of actively seeking to do good ('beneficence'); of exercising a duty of care; of honesty towards, and respect for, patients, donors and research participants; of taking professional responsibility for one's actions; and ensuring respect for confidentiality and privacy. All these values emphasised the special role of the health professional in safeguarding and protecting those in their care, and in promoting practices that are beneficial to health and protect the rights and interests of individual patients.
 - **Values inherent in interpersonal relations:** positive values included love, generosity, compassion and trust. For some respondents, these more 'emotional' values were felt to be far more critical in determining how individuals came to make decisions about donation, and in safeguarding the process of donation, than the more 'abstract' ethical values set out in the consultation document (see Box 4.2).⁴⁸⁷ While in general these relational values were highlighted as being relevant to the behaviour and motivations of potential donors (particularly in the context of families), clearly they also have relevance to the way in which professionals see their role and exercise their professional responsibilities.
- 4.4 These ethical values have been used and combined in a variety of ways. They have been variously taken for granted, adhered to explicitly, and rendered controversial. They can be stretched ('autonomy' taken as a near-prohibition on intervening in others' personal decisions) or shrunk ('reciprocity' seen as no more than a matter of tit-for-tat). They can be appealed to in support of different sides of an argument ('autonomy' versus 'solidarity' say), prioritised (as in regulatory approaches based on the importance of 'autonomy' in giving consent) or superseded in certain contexts, such as by the familial values of 'love' or 'obligation', which may trump everything else (see paragraph 4.3). In what follows, we briefly consider four examples of the way people may be influenced in espousing and deploying these values: first with respect to notions of what is 'public' and what is 'private'; second in respect to understandings of moral obligation; third in respect to the idea of the gift relationship; and fourth with respect to the meanings accorded to money. In conclusion (paragraph 4.17), we offer a comment on an important implication of this pluralism.

The public and the private

- 4.5 The boundary between what is 'public' and what is 'private' emerged repeatedly during the Working Party's inquiry, and provides a very clear example of how particular concepts can be called upon in both positive and negative ways to give strength to a particular argument. We noted in Chapter 2, for example, that the HFEA drew to our attention one significant difference between the use of bodily material in fertility treatment and the use of bodily material in other forms of health care: fertility treatment takes place primarily within the private sector. This 'private' nature of much fertility treatment is used by some as an indication that such treatment is not a 'core' health service but rather a dispensable luxury. Others, by contrast, argue that this 'private' nature takes fertility treatment outside the legitimate scope of 'public' (e.g. state or other regulatory) concern: why should the state intervene in decisions made in the private sphere by autonomous patients and their doctors? We highlight in Box 4.3 some of the many tensions exemplified by the concepts of 'public' and 'private'.

⁴⁸⁷ Note that we do not distinguish between social and ethical values in the abstract: the distinction lies in the way these concepts are held or applied. So social values may be deployed as ethical principles to justify a set of guidelines or win a moral argument, and values stated in ethical contexts may thereby acquire a further aura of social legitimacy.

Box 4.3: Public and private

The Working Party met with a number of social scientists⁴⁸⁸ to discuss how ideas of what is „public“ and what is „private“ influence attitudes to and assumptions about the donation of bodily material. This box draws heavily on that discussion:

- Ideas of 'public' and 'private' are **heavily intertwined**: notions of marriage and family, for example, can be described as concerning both private relationships and publicly-acknowledged status. The 'public' NHS has many 'private' transactions, and the 'public' act of donating may lead to 'private' kinship-like relations, for example between the family of a deceased donor and the recipient. Charities, by definition, must offer 'public benefit', but are often contrasted with the 'public' (state) sector. What appears to be a 'private' decision to donate bodily material may in fact be heavily influenced by 'public' expectations. Doctors are often a 'public' third party in what would otherwise be a 'private' activity, such as conception.
- Donation is a **multi-layered process**, involving a range of individuals, institutions, stages and procedures, each of which may be characterised differently. For example, eggs may be donated for research (public gain), for a stranger's treatment (public gain), for a friend or relative's treatment (private gain), or in exchange for cheaper IVF (private gain). Levels of IVF funding could be characterised as a 'public' issue of health care provision or as a 'private' matter in connection with personal difficulty in conceiving. 'Private' concerns about the future existence of a genetically-related child may affect choices about donating eggs for the 'private' good of another individual. Similarly, a 'private' decision to donate an organ to a family member may affect that family member's autonomy: they may feel that a 'private' matter of how they treat their transplanted organ has acquired 'public' obligations.
- The terms 'public' and 'private' each has a **range of meanings**. 'Public' may refer to the common good (the NHS, public services); the generalised unknowable good (e.g. possible future research benefit); and also by contrast the market (to which all 'publicly' have access). The 'public' may be sub-divided, for example by region ("Scotland needs you to give blood"⁴⁸⁹) or by community (for example campaigns targeting particular ethnic groups). 'Private' may refer to notions of relationship, of exclusivity, and of money: for example informational privacy, personal relationships and personal control (eg over the destination of donated material); but also 'private' health-care where money exchanges hands. In terms of 'private' decisions, to what extent does anyone make decisions entirely on their own?
- The **purpose** of donation may affect our judgment as to the relative benefits of 'public' or 'private' action in particular circumstances: it is very inefficient to have one's own blood stored before an operation, instead of relying on adequate communal (ie 'public') resources - but it is clinically better to have a kidney transplant from a live donor (which will generally be a directed 'private' donation).
- **Interactions** between 'public' and 'private' forms of provision are key in making policy decisions that result in the promotion or regulation of particular forms of activity. As well as considering whether 'private' provision of material may undermine 'public' provision, we should consider the question in reverse, that is, does pressure to achieve goals that serve the public good undermine legitimate private interests? For example, might encouragement to the relatives of a deceased person to allow use of the organs as an act of „public“ spiritedness undermine their 'private' interest as guardians of the integrity of a body?
- When it comes to people's behaviour, are there situations where it is more helpful to think of 'public' and 'private' as **complementary and overlapping**, rather than in opposition? There is some evidence, for example, that those who provide eggs for 'public' research in order to fund their 'private' treatment would also do so for no personal gain once they have had their family, and that enhancing the 'private' needs of others to have a family may give the donor a general 'public' sense of 'doing good'.

- 4.6 The comments in Box 4.3 on ideas about public-private action demonstrate how the meanings of concepts may, at one time, appear to be in direct opposition to one another; and yet, at another time, occupy different points on a spectrum – or even appear to blur into one another. For example, 'private' sector research could be set up in opposition to a 'public' sector approach: the former seen as an activity concerned essentially with commercial gain and the latter with public good. However, commercial research and development may lead to medicines of widespread public benefit, while research originating in the public sector may itself lead to commercial success. Indeed where public sector tissue banks levy higher service charges for 'private' users than for 'public' ones, they could themselves be said to be acting as private bodies. Justification for the chosen meaning comes from the *purposes* for which these concepts are used.

⁴⁸⁸ In the Working Party's 'Opinion Forum' on 2 November 2010: see Appendix 1 for details.

⁴⁸⁹ YouTube (2007) *Scottish blood donation*, available at: <http://www.youtube.com/watch?v=NPvrQyo3VRY&feature=related>.

The question of obligation

- 4.7 The same is true of many other pairings of concepts. One example can be found in the responses we received to our consultation question about 'moral duty'. Those who thought that donation had (or should have) nothing to do with 'duty' or 'obligation' saw these concepts in stark opposition to the exercise of free will, individual choice, autonomy or altruism. This interpretation saw the notion of moral duty as involving coercion or compulsion from others, including from society or the state, which took away or diminished individual freedom of action.⁴⁹⁰ There were others who saw duty as entailing a much more benign sense of compulsion, especially if the impetus came from the self: that is, as an impetus to act according to cherished values, including altruism, or else in the interests of society at large.
- 4.8 Distinctions were also drawn between the concept of duties or obligations that should fall on the state (or on organisations associated with the state) and those that could legitimately be regarded as falling on individuals. Participants at the Working Party's 'deliberative event'⁴⁹¹ felt very strongly that there was a 'moral imperative' on society to meet potential demands for bodily material, but equally strongly that individuals should only donate if they personally thought it was 'the right thing to do', suggesting that such decisions were a matter of private morality, uninfluenced by social pressures.⁴⁹² Such a view chimes with the anxieties noted above, that any suggestion of a personal 'duty' might imply compulsion or coercion. We return in Chapter 7 to a discussion of what duties or obligations public agencies and organisations may reasonably be considered to have, given that, by definition, bodily material may only be sourced from the bodies of persons (see, for example, paragraphs 7.11 to 7.14).

The gift relationship

- 4.9 When, more than 30 years ago, Titmuss was searching for a title to his book comparing blood donation under paying and non-paying regimes, he chanced upon the phrase 'gift relationship'.⁴⁹³ The gift epitomised the benefits of a non-paying system of blood collection – practical and medical advantages came with voluntary and altruistic donations from people who wanted to contribute to the community pool, as part of their 'relationship' to society. Since then the notion has passed into general parlance, to be joined with any kind of donation, sometimes appearing even more persuasive when recipients can be identified (as in live organ transplants) and a relationship imagined with them.
- 4.10 The gift evokes two contrary sets of ideas about the relationship between donor and recipient. One is that of an absolute hand-over where the donor relinquishes any further interest in what is given.⁴⁹⁴ The second is that of the circulation of gifts in interpersonal relationships, where the acknowledgment of an obligation created by the gift, and the possibility of reciprocal return, plays a large part in maintaining those relationships. Where material is donated anonymously,

⁴⁹⁰ In such an interpretation, the separate notions of the existence of a duty, and the enforcement of that duty, have been conflated.

⁴⁹¹ 43 people, drawn from diverse social backgrounds, with no existing special interest in donation: see Appendix 1 for more details.

⁴⁹² Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader), p5. This strongly expressed consensus that 'something should be done' to ensure supply was met but that no individual should feel compelled, contrasted with discussions later during the event on the possibility of moving to an 'opt-out' system of organ donation, where participants disagreed passionately with each other.

⁴⁹³ Oakley A and Ashton J, introduction to new edition of Titmuss: Titmuss R (1997) *The gift relationship: from human blood to social policy* (London: LSE Books), pp7-8. Titmuss examined the nature of the gift specifically in the context of blood donation as distinct from other forms of the gift in other contexts or other cultures.

⁴⁹⁴ For example as in the donor consent form for a blood sample collected as part of the Cambridge University SEARCH Breast Cancer study in 2010: "In a legal sense [your sample] will be treated as a 'gift' and you will have no claim over the sample should the results of this research lead to commercial development." Or as in: "to give something without expecting anything back", egg donor's idea of a gift, quoted by Konrad M (2005) *Nameless relations: anonymity, melanesia and reproductive gift exchanges between British ova donors and recipients* (New York: Berghahn Books), p67.

and hence direct reciprocity is impossible, recipients may thus wish to become donors themselves in order to "give to somebody else the opportunity that I've been able to have".⁴⁹⁵

- 4.11 We emphasise this point because the images through which people think about their situation or that they bring to an argument matter, and the gift is a powerful image in donation. Consider the ethical values set out at the beginning of this chapter. The gift contains the description of an act ('giving') that implies concern towards others, and may be invoked synonymously with altruism. It typifies voluntary donation (autonomy), gives dignity to the donor who is credited with selflessness, and acknowledges the unequal distribution of good health (justice). Gift-giving is an expressive as well as instrumental act, reflecting on the character of the gift-giver as well as achieving some aim, such as helping another. It may express a general desire to maximise health and welfare, possibly as some kind of return for the donor's own good fortune (reciprocity) or out of fellow feeling (solidarity).
- 4.12 By contrast, some of the dilemmas implicit in the quotations from consultation respondents in Box 4.2 point to more negative contexts of the gift: depending on altruistic gifts simply does not save enough lives; autonomy is compromised if the gift becomes coercive; and relying on gifts may in fact diminish the dignity and justice to be found in a proper system of recompense. It could be argued that the desire to allow people to express communal virtues should not get in the way of a realistic concern for maximising health and welfare; that one should not have to depend on people's feelings of solidarity to bring about equitable outcomes; and that any enforced requirement of reciprocity in gift-giving would be full of hazards and pitfalls, not least of bribery and corruption.
- 4.13 Moreover, it should be added that the notion of the gift is often used rhetorically in order to obtain material that then circulates on a commercial basis. This makes some cynical about its usage. Others foretell the 'end' of the gift as such, suggesting that the notion of the gift becomes redundant if it can be shown that the concern for others implicit in altruism can co-exist with monetary reward.⁴⁹⁶ This in turn supports arguments to the effect that a contrast between altruism and payment is not the stark 'trade-off' of incommensurables it once seemed.⁴⁹⁷ Or it may be pointed out that the very yielding-up of control involved in giving a gift sets up a contradiction with respect to material from the body, when the person is often regarded as having an interest in what happens to it in the future.
- 4.14 We would comment that, however cynically, or with diverse motives in mind, people appeal to 'the gift relationship', and however much it is seen to stand in the way of alternative approaches to maximising health and welfare, it is clear that for many it elicits the sense of a supremely 'social' act in its orientation towards others. It also plays an important role in drawing attention to the person (the gift-giver) whose body is at issue. Some would stress it keeps commodification at bay; no-one would deny it epitomises the opposite of theft and seizure by force. In so doing, it points to the desirability of material properly given rather than improperly taken.

⁴⁹⁵ Quotation from an egg recipient with regard to further donated eggs in storage: *Ibid*, p199.

⁴⁹⁶ Or the 'end' of any useful distinction between gift and commodity when donation is necessarily supported by a procurement industry, or when new forms of property are created, as in private blood banking, that fall into neither category (see Waldby C, and Mitchell R (2006) *Tissue economies: blood, organs and cell lines in late capitalism* (Durham, NC: Duke University Press); Healy K (2006) *Last best gifts: altruism and the market for human blood and organs* (Chicago: University of Chicago Press)).

⁴⁹⁷ The growing tolerance of commercial or semi-commercial arrangements over a spectrum of institutions, including the NHS, may be a factor here, but the specific point about the co-existence of altruism (the notion of altruism often being a shorthand for 'non-commercial') and monetary reward comes from people reflecting on the motivations of gamete donors or surrogate mothers in particular.

The role of money

- 4.15 We have chosen three sets of circumstances (public and private, the nature of obligation, and the gift relationship) in order to draw attention to the way in which values interact with one another. They are also examples of where the 'social' and the 'ethical' overlap. It is helpful to extend some of these reflections on shifting and overlapping meanings to an aspect of donation that often has a hugely over-determining effect: money. Money does not just evoke complex responses but, more often than not, very firmly-held ones. Indeed, when money appears, it can seem to drive everything else out of the picture.
- 4.16 Responses to our consultation document were illuminating here: they demonstrated a range of terms and attitudes associated with the word 'money', and these are summarised in Box 4.4.⁴⁹⁸ It should be noted that the focus is not on commerce, markets or payments, but on the image of 'money' itself, as a means of exchange. Such concerns may therefore also be just as applicable to 'reimbursement' and 'compensation' as to 'reward' and 'remuneration' (see paragraph 2.44 for definitions of these terms as used in this report).

Box 4.4: Some meanings of money (from consultation responses)

A. Money is cash (cash is cash)

Money shows its character as cash, which gives it image and substance. The few respondents who referred to 'cash' took it as a bottom line in several senses, with 'cash in hand' carrying the negative connotations of money grubbing. Cash may be regarded as a problem in itself ('naked cash'), leading people to make unwise decisions or to participate in harmful pursuits. At the other end of the spectrum it is suggested that *only* money is a suitable reward, for example because it gives people freedom to do what they liked with it or because it is the only transparent way of rewarding the donor.

Another bottom-line attitude is found in those who say that, when it gets down to it, there is no distinction between direct and indirect forms of compensation because it all has a financial value, it is all money in the end. In one case, reimbursement for expenses was included here too as an example of an inappropriate payment.

B. Money has influence

Money may be regarded as affecting things around it, usually negatively: having a contaminating effect. It may be seen not only as breaking down barriers between actions that should be held apart, but also as affecting people's thinking. So while incentives can take many forms, and appear as good or bad influences, monetary incentives can be portrayed as problematic in themselves. This is the sense in which people only have to use the word „payment“ to conjure up inappropriate inducements.

As a medium of exchange, money can render a whole range of things transferable, and convertible into other things. For some, this characteristic suggests that, left to itself, it cannot be contained: "Once money is exchanged for donated bodily material it will be very difficult to stop". The question therefore arises whether such 'containment' may be achieved by categorising money provided for different purposes in different ways. There was broad agreement between respondents that somehow the line can be held by a clear division between, on the one hand, monetary recompense for expenses (although opinions differed as to what should count as an expense), and, on the other, reward that leaves the donor significantly better off as a result of their donation.

Dividing money into 'large' and 'small' amounts does some of same work in judging whether money may provide an inappropriate incentive. Many responses commented on the importance of limiting the amount of money, keeping it to a minimum and so forth.

C. Money puts a price on everything

The fact that money is a standard of value (a pricing mechanism) may be a principal reason why the 'line' should be held against what are seen as inappropriate uses. Quantification leads to a single standard of measurement, rendering everything into its own coin (for example putting a value on „life“). Thus money may be seen to have a reductive effect, especially in this field where certain actions may be regarded as priceless. This common measurement also allows for the calculation of monetary gain. To make or seek monetary profit from the use of the body is seen by some as undignified, as showing lack of respect. Profit itself can be seen as a problem here. Another perceived problem with money is that its use may encourage financial comparisons between different forms of donation: for example between the respective value of donating an egg and donating a kidney.

The expressed fear of commodification relates both to 'money as influence' (the 'contaminating' effect of money), and 'money as price' (the fear that people themselves are being valued in monetary terms).

⁴⁹⁸ For more information, see summary of consultation responses: Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics).

D. Money rewards

Because of the questions being considered, money did not show much of its positive character. One response, however, saw recompense as the appropriate demonstration of care by a responsible society. Financial award was also advocated as part of a multiple reward system. For some, money is seen as a justifiable reward because it stores value, and can be used as a token of value: it may offer a recognition of worth without necessarily implying exchange or pricing.

Divisions similar to those summarised above under 'money as influence' also appeared when people thought about how to 'reward' donors. Here the main issue at stake was seen as the need to defend altruism. Altruism was brought in either to say that any reward would erode the altruistic act, or, by contrast, that altruism was a public virtue that required 'recognition'. Non-monetary recognition was seen as the safest form, but tokens of small financial value were regarded by some as a suitable „containment“ of money. A different tack was to point to advantages of systems that allow reward and non-reward to coexist. It was also argued that non-monetary forms of recognition may themselves be harmful, if they put social or psychological pressure on individuals to donate.

Making moral judgments

- 4.17 We noted earlier (see paragraph 1.41) the importance of accepting as a starting point the plurality of opinion within the UK regarding the meanings and significance of bodily material. To take the last of our examples, Box 4.4 above demonstrates a similar plurality of attitude with regard to the meanings to be attached to money. An important characteristic of social life is the way in which individuals reproduce this pluralism in their own decision-making. The fact that values can be opposed, combined, or seen to overlap with one another enables individuals to act in complex scenarios: they can take into account at one point these particular circumstances and at another point that set of interests; they can identify how particular actions arise out of varying degrees of concern for the self and for others; or they can deal with the contrasts between different forms of bodily material as noted in Chapter 1. However, when it comes to making judgments, other factors also move into view. We note here the importance of taking into account, not only the ethical arguments highlighted in this chapter surrounding the circumstances in which donation may take place, but also psychological research on *how* people make morally significant decisions.
- 4.18 The moral judgments people make can be based on rapid intuitions which are sometimes followed by slower moral reasoning, in which they make their values explicit.⁴⁹⁹ Such judgments are often brought to mind before any conscious processing has taken place. Moral reasoning can thus involve a retrospective search for evidence to support an intuition. That is the point at which ethical values may be articulated. This is not to suggest that some positions are not the result of moral reasoning but, rather, that on many positions moral judgments do not follow from conscious reasoning in advance. Indeed, they may be contained in 'scripts', that is responses made up of family, community or religious values, a kind of ready reference point to how someone in 'my situation' or 'from my milieu' (culture, class, ethnicity) ought to respond. The slower expression of explicit moral 'reasons' may or may not correspond with the script.
- 4.19 This perspective on moral judgment reflects observations that certain transactions are often simply considered taboo, as in attaching monetary value to things people prefer to think of as priceless: for example friendships, children or indeed the procurement of body material.⁵⁰⁰ Although they might not do so readily, some, however, *are* willing to attach monetary values to 'priceless' things such as organs if they believe that doing so will achieve an end that they value, such as saving lives. Such a willingness may, for example, emerge if the individual comes to realise that the taboo conflicts directly with other values that are equally, or more, important to them. For others, such a consideration does not alter their rejection of the use of money in this context, perceiving that it would violate deeply held intuitions about the integrity or sanctity of

⁴⁹⁹ Haidt J (2001) The emotional dog and its rational tail: a social intuitionist approach to moral judgment *Psychological review* **108**: 814.

⁵⁰⁰ Fiske AP, and Tetlock PE (1997) Taboo trade-offs: reactions to transactions that transgress the spheres of justice *Political Psychology* **18**: 255-97; Baron J, and Ritov I (2009) Protected values and omission bias as deontological judgments, in *Psychology of learning and motivation*, Bartels D, Bauman C, Skitka L, and Medin D (Editors) (Oxford: Elsevier).

certain forms of relationships, or have an unacceptable long-term impact on societal values and functioning.

4.20 Such views may not necessarily be shifted by new evidence: moral judgments may be rapid, strongly held and intractable. This can be problematic when it comes to several persons having to reach some kind of joint agreement, or indeed to making policy in the context of strongly competing public views. Solutions offered in this area may take as their starting point the importance of acknowledging the legitimacy of different views, along with a desire to make sure that the outcome is based on consideration of a wide range of evidence with the aim of achieving ultimate judgments that are reasoned rather than intuitive. Suggested approaches include:

- Encouraging groups made up of individuals who hold different views but who are committed to a common solution for a shared problem (such as seeking to increase the availability of bodily material) to devise, elaborate and defend different arguments, with the aim of finding solutions that reflect several perspectives.⁵⁰¹ Anthropologist Alan Fiske and psychologist Philip Tetlock, for instance, use the example of responding to the shortage of donor organs as an example of decision-making by a group searching for "some kind of shared and reflective equilibrium".⁵⁰² They conclude that there need be no single determinate solution; they also conclude that symbolism matters – that the same material transaction can take on very different meanings for different groups. Thus they describe hypothetical scenarios where organ selling might be permitted but with safeguards and concessions (with the aim of meeting some of the specific concerns of those intuitively opposed to a payment model), or where such markets were banned, but financial incentives permitted in the form of honorary awards for community spirit or as compensation for sacrifice.⁵⁰³
- Seeking ways of presenting evidence for and against competing positions in ways that would be likely to appeal to people with different sets of values (for example to those who tend to talk in individualistic terms and those who tend to talk in more egalitarian terms).⁵⁰⁴ Alternatively, evidence could be presented by a diverse range of experts. The aim, in approaching evidence in these ways, is not to persuade people to accept one position or another, but rather to consider all sides of an argument to avoid cultural polarisation.

4.21 While a closer analysis of psychological approaches to moral decision-making goes beyond the scope of this report, we note here the importance of this area of research, both for informing the ways in which organisations and intermediaries seek to approach potential donors, and in the broader realm of over-arching policy-making. In particular we note that one goal on the way to reaching a decision may be to find areas of overlapping consensus, even though particular policies may be supported by diverse audiences for diverse reasons.

⁵⁰¹ We here take up the argument expressed in Fiske AP, and Tetlock PE (1997) Taboo trade-offs: reactions to transactions that transgress the spheres of justice *Political Psychology* 18: 255-97. Oriented to a complex situation in which a diversity of facts, procedures, values and opinions is evident, the paper combines Fiske's (1991) relational theory and Tetlock's (1986) value pluralism model. Four elementary models "give motivational and normative force to social relationships" (1997: 258). These work as four procedures or ways of weighing up arguments, positions, or circumstances. *Communal sharing* (CS) divides world into distinct classes, permitting differentiation but no numerical comparison, e.g. benefit-sharing where there is no metric for internal comparison. *Authority ranking* (AR) constructs an ordinal rank permitting priorities, e.g. privileged access for some. *Equality matching* (EM) defines socially meaningful scales that can be adjusted to make valid choices, e.g. equivalence in compensation. *Market pricing* (MP) makes ratios meaningful so one can combine quantities and values of diverse entities, as in a cost-benefit analysis, e.g. budget deficit as a percentage of GDP.

⁵⁰² Ibid, 294. We cite their example as a model of decision-making, not as a guide to our own arguments (it is not chosen to reflect the Working Party's view). The reference to shared reflective equilibrium is derived from Rawls J (1971) *A theory of justice* (Cambridge MA: Harvard University Press).

⁵⁰³ Ibid. 294.

⁵⁰⁴ Kahan D (2010) Fixing the communications failure *Nature* 463: 296-7.

Part II

Chapter 5

An ethical framework

Chapter 5 – An ethical framework

Chapter overview

- A key aim of a policy framework in this complex and sensitive area must be to seek areas of **shared consensus**, including identifying values with which people starting from many different positions may nonetheless agree.
- The role of the state with respect to donation should be understood as one of **stewardship**, actively promoting measures that will improve general health (thereby reducing the demand for some forms of bodily material), facilitating donation, and removing inequalities that affect disadvantaged groups or individuals with respect to donation.
- **Altruism**, long promulgated as the only ethical basis for donation of bodily material, should continue to play a central role in ethical thinking in this field. While some of the claims made about altruism may be overblown, the notion of altruism as underpinning important communal values expresses something very significant about the kind of society in which we wish to live. Understood in this way, altruism has much in common with solidarity: **an altruistic basis for donation helps underpin a communal, and collective, approach to the provision of bodily material for others' needs**, 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 altruist-focused interventions (that act to 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 action). 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.
- **Donation for research purposes may differ in important ways from donation for treatment purposes**. While both forms of donation seek to benefit others, the contribution that any one research donor or healthy volunteer makes to the health of any other identifiable person is exceptionally hard to pin down. A move away from a primarily altruistic model for research purposes may therefore pose a lesser challenge to solidarity and common values than such a move in connection with donation for treatment.
- We take seriously concerns that some approaches to increasing the supply of bodily material may risk using people, and people's bodies, as 'means' to another's ends. While we do not take the view that payment to a person in connection with donation necessarily implies this, we do **reject the concept of the purchase of bodily material**, where money exchanges hands in direct return for body parts. We distinguish such purchase clearly from the use of money or other means to reward or recompense donors.
- The **welfare of the donor**, and the **potential for harm and exploitation** within donation practices, should be a key determining factor when considering the ethical acceptability of any system for encouraging people to come forward as donors. While proper consent procedures, underpinned by sufficient information, are clearly essential in order to protect those coming forward as living donors, consent alone may not be sufficient to justify particular donation practices if such practices might put other potential donors, or wider communal values, at risk.
- **Decisions about deceased donation should be based on the known wishes of the donor**, so far as this is ascertainable. In ethical terms, the permissibility of such donation should be understood to be on the basis of the **authorisation, or willingness to donate**, of the deceased, rather than on their consent. We distinguish 'authorisation'/willingness to donate' from 'consent' in these circumstances, on the grounds of the potentially different informational requirements involved. In contrast to those consenting to donate during life, those authorising donation after death do not expose their health to any risks, and the minimum informational requirements for donors are correspondingly lower.
- Professional and relational values such as **trust and respect** play an essential part in creating and maintaining systems in which people will be willing to consider donation. This is true both of trust in individual professionals, for example that they will exercise a duty of care towards donors and respect their confidentiality; and of trust in systems, that they are the subject of good and responsible governance.

Arguing for a framework

- 5.1 We begin Part II of this report with the most fundamental question: what *reasons* do we have to try to match the supply of bodily material to demand? The question needs to be asked before we examine the legitimacy of any particular effort to increase supply of bodily materials, or to reduce demand for them. We take the reasons on a case by case basis.
- 5.2 For **blood** and **organ** donation we believe that the case can be made quite uncontroversially: blood and organs are essential contributors to basic human health and functioning, and the fact that they can be replaced is part of the contemporary medical environment. In some

circumstances blood transfusion or organ transplantation may save or extend lives; in others they may significantly enhance quality of life. We recognise that demand may never be satisfied, and that it is, in any case, created and encouraged by medical developments; however, ever-increasing demand is also found in connection with many other kinds of treatment, and in our opinion the fact that a demand may be ever-rising cannot constitute a reason for not taking reasonable measures to meet it. In the case of organs for transplant, we accept that on a patient-by-patient basis there is at present a chronic shortfall in terms of patient needs and expectations. Blood supplies are more stable but shortages do still intermittently arise, particularly for the less common blood groups (see paragraph 3.5). This creates a strong case for aiming to institute a range of public health measures that will reduce the chance that people will need blood or organs from others. At the same time, even if effective public health measures reduce the need for donation for some, medical services are still likely to be presented with many individuals who require donated organs and donated blood to maintain their ongoing basic health.

- 5.3 Thus we start from the standpoint that policies that aim to increase supply of, or reduce demand for, blood and organs are fundamentally justified through an appeal to the importance of ensuring, as far as is practical and ethical, the ongoing good health of members of society. Policy-makers must, of course, set these policies within a broader context of health policy more generally, and they will be aware of trade-offs and resource constraints within health budgets as a whole. To use a stark example, it may be that regulations requiring motorcycle riders to wear crash-helmets result in reductions in the availability of organs for donation. However, this clearly would not constitute any sort of justification for reversing the law on wearing crash-helmets: lives lost on the roads are just as significant, from an ethical perspective, as lives lost to shortage of organs.
- 5.4 As we have seen in Chapter 1 of this report, the gamut of donated human **tissue** – from bone to corneas – is put to a very wide range of purposes (see paragraph 1.10). While tissue use is much less well-known, it too may serve to save life (for example through skin grafts) or significantly to enhance quality of life (for example through corneal transplants restoring sight). Such potential uses suggest that the same moral justification for seeking to ensure an adequate supply of many forms of tissue exists as for blood and organs: a key difference, however, being that, in ordinary circumstances, supply within the UK for therapeutic use *is* currently adequate. Moreover, to a greater extent than blood or organs, tissue may be used for non-urgent as well as for urgent procedures, and in such cases any 'urgency' of matching supply to demand is correspondingly diminished. By contrast, access to tissue for research purposes (which again may in the long-term help save, extend or enhance quality of life – but where such possible results are both remote and often unrealised) is often problematic, though at times for reasons of access rather than because of actual shortages of the material itself. These considerations suggest that we should not expect responses to supply and demand issues to be uniform across all areas and purposes of donation, either in terms of the urgency with which they should be tackled, or the means used to do so.
- 5.5 **Gamete and embryo** donation raises rather different issues. Where the donation of gametes and embryos results in the birth of a child, this is both life-creating and (for the parents) life-enhancing. As we highlight in Box 1.9, the donation of gametes is often seen as very different from the donation of other forms of bodily material, primarily because of their life-creating capacity. As a result, some argue that shortages of donated gametes are of lesser public concern than shortages in other forms of bodily material, because they are seen as 'non-essential' in orthodox health terms. Others find gamete donation hard to rank in such a scale, precisely because gametes are perceived as belonging in a quite different category.⁵⁰⁵ The

⁵⁰⁵ Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader), p26; Hudson N, Culley L,

argument is also sometimes put that the numbers of vulnerable children in need of fostering or adoption should serve as a reason for not prioritising fertility treatment (with or without donated gametes) at all.⁵⁰⁶

- 5.6 There is no doubt that infertility is a significant cause of emotional pain and distress. Under certain conditions, it is classified by the WHO as a disease,⁵⁰⁷ and in many circumstances the use of donated gametes to enable a would-be parent to bear a child could be compared to the use of tissue in treatment to improve a person's quality of life. We are unconvinced that the pressing social need to provide secure families for children who are already in existence should be set against the desires of women or couples to bear a child of their own: we see no direct conflict between the two areas of social policy, and see no reason why support of the latter should be regarded as detrimental to the former. In short, we take the view that there is an ethical justification for taking steps to promote gamete donation. However, we note here that the very nature of gametes, that they may give rise to another person whose well-being is a matter of both private and public concern, means that this additional consideration has to be taken into account whenever donation in this context is contemplated. Such a consideration does not, of course, apply to the use of gametes for research purposes (whether research related to fertility or other health-related research), where no future child will ever result. The latter uses could again be compared to the use of tissue for research: the future benefit is uncertain but potentially highly valuable to health.
- 5.7 Society has responded to these various scarcities in different ways, as highlighted in Chapter 3 of this report. In relation to **first-in-human trials**, it could be claimed that scarcity has been averted by allowing payments (sometimes substantial ones) to research participants, albeit such payments are formally couched in terms of compensation for time and inconvenience, rather than as inducements to participate. In recent years payment-in-kind schemes have been developed for gametes, and the courts have taken a relatively relaxed approach to the reimbursement of expenses to surrogate mothers (see paragraph 2.35). In the face of persisting shortages, some ethics commentators have suggested the establishment of a regulated market in organs,⁵⁰⁸ and others have urged the Government to rethink the basis for authorising removal of organs from a dead body.⁵⁰⁹ However, public policy within the UK has remained wedded to altruism and to the importance of explicit consent, choosing instead to seek to boost organ donation, for example, by improving the infrastructure that supports deceased donation and widening the scope for living donation. In what follows, we pay considerable attention to the justification for this stance. Given that, in the UK, altruism and consent are frequently pitched against the prospect of payment, the role of money and the market must also be examined.
- 5.8 There is a significant global dimension to questions about the supply and demand of bodily material and we acknowledge the interconnectedness of nations with respect to the provision of such material. This means that in failing to take measures to stimulate supply in their own country, regulators may in effect divert demand for material to other countries, for example through so-called 'cross-border reproductive care' and 'transplant tourism'. This does not, of

Rapport F, Johnson M, and Bharadwaj A (2009) "Public" perceptions of gamete donation: a research review *Public Understanding of Science* 18: 61-77.

⁵⁰⁶ See, for example, Sunday Mercury (31 August 2003) *Free IVF couples urged to adopt: 700 unwanted Midland children in need of home*, available at: <http://www.thefreelibrary.com/%3a+FREE+IVF+COUPLES+URGED+TO+ADOPT%3b+700+unwanted+Midland+children+in+...-a0107118958>.

⁵⁰⁷ See: Zegers-Hochschild F, Adamson GD, de Mouzon J *et al.* (2009) The International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary on ART terminology, 2009 *Human Reproduction* 24: 2683-7, which defines infertility as "a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse."

⁵⁰⁸ See, for example: Harris J, and Erin C (2002) An ethically defensible market in organs *BMJ* 325: 114-5; Satel S, and Steelman A (2009) *When altruism isn't enough: the case for compensating kidney donors* (Washington DC: American Enterprise Institute for Public Policy Research); Hippen B, and Matas A (2009) Incentives for organ donation in the United States: feasible alternative or forthcoming apocalypse? *Current Opinion in Organ Transplantation* 14: 140-6
10.1097/MOT.0b013e3283295e0d; Wilkinson S (2003) *Bodies for sale: ethics and exploitation in the human body trade* (London: Routledge); Savulescu J (2003) Is the sale of body parts wrong? *Journal of Medical Ethics* 29: 138-9.

⁵⁰⁹ See, for example, English V (2007) Is presumed consent the answer to organ shortages? Yes *BMJ* 334: 1088.

course, automatically mean that policy must always aim to ensure that domestic supply meets domestic demand. First, if people seeking treatment travel to regimes that are themselves well-regulated, such 'cross-border' treatment may be ethically unproblematic. Second, since some ways of meeting demand for bodily material may give rise to ethical concerns, a given jurisdiction is not obliged to meet all demands, even if other less scrupulous jurisdictions may be willing to do so. Third, there is room for reasonable pluralism among jurisdictions regarding the acceptability of particular interventions to increase supply or reduce demand. This by itself may have the result that countries with more plentiful supplies of material may meet the demand of countries with lower levels of supply. In spite of all this, regulators must be aware of the ways in which a failure to introduce practicable and ethically justifiable measures for reducing demand and increasing supply can contribute to exploitative, fraudulent and harmful treatment of vulnerable individuals in countries where illegal or poorly regulated systems for obtaining bodily material become established.

- 5.9 The global dimension, especially in relation to organ donation involving developing countries, has a further lesson for ethical debate. The adoption of (national and international) protocols intended to protect the welfare of donors may be only a first step in ensuring that proper ethical appraisal takes place in any particular case. This is not just because implementation may be an issue; it is also because formal safeguards can only ever be part of the picture. Difficulties in ensuring appropriate ethical appraisal on the ground may particularly arise where health and after-care provision in general is uncertain. In effect, the dominant focus on national and international protocols may serve more to provide reassurance to future recipients of material (or to researchers recruiting healthy volunteers for first-in-human trials) that the material has been 'ethically' obtained, than deal with key ethical issues arising at the point of origin.⁵¹⁰

Demand-side ethics

- 5.10 Public policy often approaches scarcity issues most explicitly via the supply side of the equation – if something we value is in short supply we must find ways to make or secure more of it. However, it is just as important (though sometimes politically more delicate) to acknowledge the possibility of addressing scarcity through managing demand.
- 5.11 Outside a formal market we are denied the possibility of manipulating price to drive down demand. Indeed, one of the arguments against a marketplace in this context is that the 'goods' in question (here bodily material required for treatment purposes) should be fairly distributed, and using price to manage demand would be unjust, for it would lead to the poor being disadvantaged by not having effective access to widely acknowledged benefits.
- 5.12 However, markets do exist in the provision of health care in the UK – the provision of infertility services being the obvious example – and in recent years the shortage of donor gametes has been addressed at an individual level by couples travelling abroad to purchase services which include the provision of gametes (see paragraph 3.83). It is striking that public attitudes to markets in health care appear to differ significantly, depending on the care under consideration. Fertility treatment appears to be regarded by many in a light that allows it to leave the nationally-funded health service without too much public complaint. For example, although the National Institute for Health and Clinical Excellence (NICE) has recommended that women between the

⁵¹⁰ That is, meeting formal requirements on paper may be seen as having dealt with the ethics of procurement, which then can be put to one side. Indeed, it may be argued that the international enthusiasm for conceptualising donation as a gift can serve to conceal other ethical problems in the real-life conditions under which 'donations' take place (Scheper-Hughes N (2008) *Illegal organ trade: global justice and the traffic in human organs*, in *Living donor organ transplantation*, Gruessner RWG, and Benedetti E (Editors) (London: McGraw Hill), Lundin SM (2010) *Organ economy: organ trafficking in Moldova and Israel* *Public Understanding of Science*). Petryna similarly talks about regulatory concerns in relation to clinical trials that seem to work primarily at the level of 'data production': the construction of "airtight documentary environment[s] ensuring the portability of clinical data": Petryna A (2009) *When experiments travel: clinical trials and the global search for human subjects* (Princeton: Princeton University Press).

age of 23 and 39 years should be offered "up to three" cycles of IVF where there is a known fertility problem or unexplained infertility for at least three years,⁵¹¹ in practice, many people still experience difficulties in accessing NHS fertility services.⁵¹² Indeed it is interesting that to some extent the growth of cross-border reproductive care has proved less controversial than attempts by specialists in the field of fertility treatment to drive down demand by educating women regarding their fertility, and encouraging attempts to become pregnant earlier.⁵¹³ Individual liberty seems to be the value at stake here.

- 5.13 The problem of demand is in part a problem in the ethics of public health. There are 'softer' elements of policy, by means of which one might encourage behaviours that lower the overall need for donated material, for example by taking action to tackle obesity and levels of alcohol intake or by making it easier for women to have babies earlier in their careers. And there are 'harder' elements of policy, which might conceivably deny material to those who are thought to be particularly reckless with their health. A 'liberal' approach to public health would aim to provide information and promote environments that make it comparatively easy for people to choose healthy lifestyles, while stopping short of compelling healthy habits in the population. In its earlier report on public health the Nuffield Council went beyond this liberal approach, by adopting what it called the 'stewardship' model (see Box 5.1).⁵¹⁴ Here the Council pointed out that public health schemes, if they are to be effective, cannot be based on individual consent, because by definition they affect large sections of society. Moreover, in its report, the Council took seriously the view that it is the role of states to limit health inequalities. A stewardship model, then, will aim to provide environments conducive to health, in ways that reflect collectively-endorsed commitments to reasonably healthy lifestyles. It will also seek to reduce the bases of socially inequitable need for bodily material, by reducing the socio-economic contributors to health inequality.

Box 5.1: The stewardship model in public health

The Nuffield Council's report on public health sets out a clear obligation on the part of states to "enable people to lead healthy lives". In order to ensure that all groups and individuals have a fair opportunity to lead a healthy life, the report further requires that governments work to remove inequalities that affect disadvantaged groups or individuals. The 'stewardship model' proposed in light of these principles is very relevant to this report, in that several of the goals of that model relate to improving the ability of groups and individuals to protect and improve their health, thus potentially reducing the need for medical interventions involving donated human tissues or organs.

The public health report clearly states that public health programmes should not be coercive in their approach, and that measures should largely be implemented after consultation. It also advises that the goal of improving the public's health should be balanced against a commitment to secure and protect important aspects of private or personal life such as privacy. However, it would be consistent with the principles set out in the public health report to give states a responsibility to advise and assist citizens in avoiding practices injurious to their health and encourage and facilitate practices which will benefit them – particularly where the means of addressing resultant health problems are in short supply.

In the current context it would be particularly relevant to consider the approach the report takes to the issue of obesity which is pertinent to both the causes of disease resulting in organ failure, and the success of subsequent transplants. Similarly alcohol consumption is clearly linked to liver disease.

- 5.14 In proposing 'demand-side' solutions, it is important to acknowledge and analyse the difficulties experienced in previous attempts to drive down the need for medical interventions, and the variable effects they may have on different subpopulations. For example, it has been suggested that approaches taken at present in diabetes prevention may not be appropriate for some ethnic

⁵¹¹ National Institute for Clinical Excellence (2004) *Fertility assessment and treatment for people with fertility problems*, available at: <http://www.nice.org.uk/nicemedia/live/10936/29269/29269.pdf>, paragraph 11.8.

⁵¹² All Party Parliamentary Group on Infertility (2011) *Holding back the British IVF revolution? A report into NHS IVF provision in the UK today*, available at: <http://www.infertilitynetworkuk.com/uploadedFiles/InfertilityAwareness/appg%20IVF%20report.pdf>; The Independent (5 June 2011) *NHS fertility clinics told to lift restrictions on IVF treatment*, available at: <http://www.independent.co.uk/life-style/health-and-families/health-news/nhs-fertility-clinics-told-to-lift-restrictions-on-ivf-treatment-2293212.html>.

⁵¹³ See, for example, the responses to Bewley S, Davies M, and Braude P (2005) Which career first? *BMJ* **331**: 588-9 at <http://www.bmj.com/content/331/7517/588/reply>.

⁵¹⁴ Nuffield Council on Bioethics (2007) *Public health: ethical issues*, available at: <http://nuffieldbioethics.org/sites/default/files/Public%20health%20-%20ethical%20issues.pdf>.

minority communities in the UK.⁵¹⁵ There is also the possibility of genetic components to disease, where some populations may simply be more susceptible to particular conditions than others, thereby limiting the effectiveness of demand-focused interventions. Therefore, to ensure that no population is disadvantaged by a solution to scarcity that seeks to manage demand, as opposed to increase supply, any solutions adopted must be evidence-based and culturally sensitive.

Supply-side ethics

- 5.15 Many respondents to our consultation put great weight on the notion of ownership or property in respect of their body parts, in their ethical assessment of the rights and wrongs of organ donation. Some felt that since they obviously 'owned' their bodies, they should be able to sell body parts in just the same way that they can, for example, sell their cars.⁵¹⁶ Others felt that recognising any rights of ownership in the body involved an unjustifiable form of objectification or even commodification of the body, arguing that it is persons who exist as embodied beings, and persons should not be treated as commodities.
- 5.16 As noted in Chapter 2, English law has historically given the verdict that individuals do not have 'property rights' in their own bodies or body parts, although this position has recently been challenged by the Court of Appeal decision in *Yearworth* (see paragraphs 2.31 and 2.32). There is also the long-standing legal principle that others may acquire property rights in body parts once separate from the body, if, as a result of the application of skill they have changed the attributes of the material.
- 5.17 The report returns at a later point (see paragraph 7.21) to the question of what legal rights it may be appropriate to vest in professionals who use, and transform, bodily material provided by donors. Our concern here is to highlight the pitfalls that arise when attempting to characterise the relationship between persons and their own bodily material by means of a blanket conception of „property“.
- 5.18 Whereas the legal concept of property (aptly described as a "negotiated and evolving legal concept"⁵¹⁷) leads very quickly to thinking about market relations, the concept of ownership can be used with a broader moral resonance.⁵¹⁸ We suggest that often when people talk about 'owning' their bodies or body parts, even if they use the language of property, their primary concern is with *control* over those materials: with the right not only to give or withhold consent to material being removed in the first place, but also to have some say over its future use.⁵¹⁹ Such

⁵¹⁵ See, for example, Randhawa G (2010) Renal health disparities in the United Kingdom: a focus on ethnicity *Seminars in nephrology* 30: 8-11; House of Lords European Union Committee (2008) *Increasing the supply of donor organs within the European Union: volume I report*, available at: <http://www.publications.parliament.uk/pa/ld200708/ldselect/ldcom/123/123i.pdf>, paragraph 330.

⁵¹⁶ Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics).

⁵¹⁷ Harmon SHE, and Laurie GT (2010) *Yearworth v. North Bristol NHS Trust: property, principles, precedents and paradigms* *The Cambridge Law Journal* 69: 476-93.

⁵¹⁸ Without getting into arguments about the relationship between body ownership and self-ownership, it may be noted that writers have at various times tried to invest the concept of ownership with the moral force of personal control – and caretaking – with respect to oneself and one's body that may be asserted in direct contrast to the presumptions of commodification. A classic text is Petchesky RP (1995) *The body as property: a feminist re-vision*, in *Conceiving the new world order: the global politics of reproduction*, Ginsburg FD, and Rapp R (Editors) (Berkeley: University of California Press). See also the essays in Davies M, and Naffine N (2001) *Are persons property? Legal debates about property and personality* (Aldershot: Ashgate).

⁵¹⁹ A 2005 study across four European countries (Cyprus, Germany, the Netherlands, Sweden) came to this conclusion: "Although the participants frequently refer to the notion of ownership when talking about the human body, this does not necessarily imply that they consider the body as some piece of private property available for commerce. On the contrary, the concept of ownership often rather seems to serve as a metaphor for autonomy and bodily self-determination, principles which can as well imply a rejection of commercialization." Schweda M, and Schicktanz S (2009) *The "spare parts person"? Conceptions of the human body and their implications for public attitudes towards organ donation and organ sale* *Philosophy, Ethics, and Humanities in Medicine* 4: 4.

rights may certainly be secured through property rights – but this is not the only way of achieving that aim. For example, the Human Tissue Act and the Human Fertilisation and Embryology Act provide a statutory basis for some degree of control over donated bodily material (as in the right to withdraw consent for the use of donated gametes up to the point when they have been used by being transferred into a woman's body) without needing to turn to the legal concept of property.

- 5.19 However there is also flexibility in the notion of property itself. While property may be understood as a 'thing', an item owned, it can also be conceptualised in terms of rights (between persons with respect to the thing or item), and such rights need not be seen only as absolute and full rights of ownership. For example, property is viewed by some as a 'bundle of rights', such that the bundle may be dismantled into „sticks“ including rights to buy, sell, use, transfer to another, lend to another, exclude others from, and so forth.⁵²⁰ Distinct ethical justifications may underpin each of these different alleged entitlements.
- 5.20 It would not therefore be impossible to develop a legal doctrine of property in relation to body parts that was limited to the notion of control (encompassing, for example, a right to exclude, a right to transfer, and also a right to a remedy where these rights are infringed), without creating any rights in connection with buying or selling. Indeed, when the Court of Appeal in *Yearworth* recognised property rights in the men's stored sperm, it was primarily concerned with ensuring a remedy for the men who had suffered from what was accepted to be negligent action. However, a disadvantage of using the concept of property in these circumstances is that the notion of property is commonly associated with 'things' as opposed to „persons“. Bodily material may, at one and the same time, be characterised both as a 'thing' and as part of the 'person', a dual characteristic that may explain the unease many people feel at the idea of property in the body.⁵²¹ We therefore suggest that greater clarity will be achieved by giving attention to the specific *elements* of the 'bundle' of rights that we may wish to accord to people with respect to their body parts, and how these may be appropriately protected and promoted. In what follows, we ask a series of lower-level questions about the form of **control** individuals should be allowed over uses of their body parts, and the extent to which they should be entitled to **reward or recompense**, and then, separately, what legal form any such entitlements should take.
- 5.21 Our preferred way forward in formulating an ethic of supply is to begin by attempting to make sense of the current approach to encouraging the provision of bodily materials, and of the ethical assumptions that appear to underlie it. We then move on to examine these assumptions critically, and to construct our own ethical framework. We must stress that we do not assume that a 'one-size-fits-all' approach is necessary or desirable: our view is that different purposes, different contexts and different forms of material may warrant different interventions with respect to supply of bodily materials.
- 5.22 It may seem that the status quo is incoherent, with diverse forms of incentivisation and compensation being offered across a variety of domains. Indeed, we highlight in Chapter 2 the range of apparently different approaches used for different forms of donation, both in the UK and beyond. However, we conclude here that, in the UK, at least, the regulations currently in force suggest a more unified view underlying all of these disparate domains than appears at first to be the case. Direct payment in money or money's worth in exchange for materials donated for therapeutic purposes, whether they be blood, organs, tissue or gametes, is generally not allowed. The rationale offered (often by regulators) is that donation must be founded on altruistic decisions. However, in most cases this does not rule out some degree of recompense for lost earnings; nor does it prevent organisations charging for their services, as long as they do not

⁵²⁰ Honore A (1961) Ownership, in *Oxford essays in jurisprudence*, Guest AG (Editor) (Oxford: Oxford University Press); Munzer S (1990) *A theory of property* (Cambridge: Cambridge University Press).

⁵²¹ There are, of course, many other ways of expressing this ambiguity, for example in the notion of the 'extended self': See, for example, Sperling D (2007) Me or mine? On property from personhood, symbolic existence and motivation to donate organs *Transplantation* **193**: 200.

charge specifically for the material itself (see paragraph 2.35). A few words are needed to make sense of this situation, beginning with altruism.

The issue of altruism

- 5.23 Altruism can be defined in various ways.⁵²² A useful distinction for our purposes is between behavioural and motivational definitions of the term. Motivational conceptions of altruism define altruistic action in terms of the internal psychological states that produce behaviours. An altruistic action, on this view, is something done because the person concerned wishes to contribute to the welfare of another. Behavioural definitions of altruism, by contrast, focus solely on the costs and benefits of action to the person concerned, without reference to the internal motivational state that may have produced the action in question. A hypothetical example may help to illustrate the difference between the two definitions. Suppose someone gives all their money to charity in the false hope that it will bring fame and increased social status. This action is not motivationally altruistic, but the fact that it may benefit others at great cost to the individual concerned means that it will be regarded as behaviourally altruistic.
- 5.24 Motivational conceptions of altruism – henceforth referred to in this report simply as 'altruism' – usually underlie debates about the ethics of donation, because these debates often concern the sorts of motivating reasons that are appealed to when encouraging donation. Many advocates of altruistic donation see altruism as an important *virtue*, hence as resting on an underlying set of moral and psychological dispositions. We return later in this chapter to a discussion of the potential social value of the promotion of altruism as a virtue (see paragraph 5.42). It is important to stress that if altruistic donation appears insufficient to meet demand in some areas, we face a *choice* of whether or not to move to an incentivised system: it is not a necessary step, and we have not assumed in our deliberations that the choice made must be the same across all domains of donation.
- 5.25 For the purposes of this report, we define an altruistic action as one that is motivated by concern for the welfare of the recipient of some beneficent behaviour, rather than by concern for the welfare of the person carrying out the action. We do not think it important from an ethical perspective that altruism is thoroughly 'pure'. First, someone may donate biological materials because it also makes them feel good to help others. In a sense the donor's own pleasure may lie at the root of their decision. But cases such as these remain altruistic for our purposes, on the grounds that concern for the welfare of others is a genuine motivator, and on the grounds that a disposition to help others can be reckoned as virtuous whether or not founded on the pleasure such action brings to the donor. Second, someone may wish to help others, but they may also be concerned about how much of their own time they can afford to sacrifice. In these sorts of situations, reimbursement for loss of time, or loss of earnings, can facilitate altruism rather than eliminate it. Third, many real-life cases will feature mixed motivations: someone who is paid well for charitable work may undertake this work for a combination of reasons, including a genuine desire to assist others and a desire to improve their own quality of life. Their altruism remains genuine here, for it might explain why they choose charity work as a career rather than some other (potentially better paid) job.
- 5.26 Crucially, the removal of barriers to donate need not render a decision to donate non-altruistic. So, we can imagine a person whose desire to donate a kidney is genuinely motivated by concern for the welfare of a stranger. And yet, the potential donor feels that they cannot donate, because they cannot afford to take the time off work required to undergo surgery and recover

⁵²² Broad C (1971) Egoism as a theory of human motives, in *Broad's critical essays in moral philosophy*, Cheney D (Editor) (London: Allen and Unwin); Williams B (1973) Egoism and altruism, in *Problems of the self*, Williams B (Editor) (Cambridge: Cambridge University Press); Wilson DS (1992) On the relationship between evolutionary and psychological definitions of altruism and selfishness *Biology and Philosophy* 7: 61-8; Sober E, and Wilson D (1998) *Unto others: the evolution and psychology of unselfish behavior* (Cambridge MA: Harvard University Press).

from it. Under these circumstances, a system of reimbursement of lost earnings, or payments for inconvenience, makes donation more likely, without thereby undermining the initial motivational concern to promote the welfare of the recipient. The same is the case for a range of initiatives that reduce barriers to donate for those already inclined to help others, such as workplace blood donation schemes.

- 5.27 This observation has important consequences. First, initiatives that reduce barriers to donate can change the decision someone is likely to make, because they change the balance of costs and benefits associated with donation. But the mere fact that these initiatives alter people's decisions does not mean that they are manipulative. We suggest that initiatives of this sort are unobjectionable, in that they simply remove barriers to an action the individual is already inclined to take. Second, it is useful to distinguish two types of intervention, both of which aim at increasing donation by changing its costs and benefits. The first we call '**altruist-focused interventions**': they typically involve the removal of various disincentives to act, and in so doing they remove countervailing concerns that may hinder altruists from acting on their altruistic motivations. Altruist-focused interventions may also offer some form of token reward or „thank you“, that might prompt the person into action but would not on its own provide a reason for acting if altruistic motivation were lacking. The second we call '**non-altruist-focused interventions**': these interventions are targeted at potential donors who have no strong motivation to help others through the donation of their bodily material, and who therefore, if they are to donate, need to be provided with different reasons for action, perhaps in the form of payment going well beyond the reimbursement of expenses. Inevitably, in some cases, the line between these two forms of intervention will be blurred, and in such cases particular care is required.
- 5.28 We regard egg-sharing regimes to encourage women to donate their eggs as non-altruist-focused interventions. This is true whether the reward involved in egg sharing is viewed either in terms of reduced-price fertility treatment, or as an opportunity to access fertility treatment that would otherwise not be available. (A non-altruist-focused intervention need not involve money.) In other words, it gives women who might not otherwise have contemplated donating eggs on altruistic grounds a reason to do so all the same. Indeed, we have already noted some evidence that women may not be inclined to share eggs with other couples if they have access to IVF treatment funded by their health care system (see paragraph 3.77): this suggests that the fact of their own reduced-price treatment, rather than aid to other couples, can be a major motivator when participating in egg sharing schemes.
- 5.29 It must, of course, be repeated that individuals who are paid, or otherwise rewarded, for their services can also be altruists. Many egg sharers undoubtedly care for the welfare of couples to whom they have donated, and may regard pregnancies enabled by their donation very positively.⁵²³ We accept that non-altruist-focused interventions will sometimes make altruists even keener to act on their altruistic motivation. But such interventions also give individuals who are not concerned with the welfare of others a motivation to donate. We emphasise here, that in our view, donation unaccompanied by altruistic intent is not necessarily unethical in itself: this will depend on all the circumstances surrounding the donation (a point we discuss in greater detail later: see paragraph 6.23). However, we believe that the distinction between those donating with altruistic intent and those donating primarily for other reasons is a valuable one, both in analysing the current regulatory approaches, and in developing our own ethical framework.
- 5.30 It seems to us, then, that a deep commitment to preserving a culture of altruistic donation is what lies at the root of the current approach to the donation of various forms of bodily material. This commitment is expressed in a number of international codes and resolutions on donation, by the regulators with whom we met, and by many of the respondents to our consultation. It is a

⁵²³ See, for example, Blyth E (2004) Patient experiences of an "egg sharing" programme *Human Fertility* 7: 157-62; and Ahuja KK, Simons EG, Mostyn BJ, and Bowen-Simpkins P (1998) An assessment of the motives and morals of egg share donors: policy of 'payments' to egg donors requires a fair review *Human Reproduction* 13: 2671-8.

separate question, however, whether this commitment is, or is not, compatible with a wide-ranging series of financial interventions and facilitating regimes that make it easier for people to act on these altruistic motivations. And as indicated above, it is another question again, whether altruistic intent is always a necessary component of any 'ethical' action in this field.

- 5.31 Some of our consultation respondents felt that all 'incentives' were ethically dubious because they altered individuals' perceptions of the relative risks and benefits of donation. The term 'incentive' may be understood very broadly ("a thing that motivates or encourages someone to do something"⁵²⁴), or more narrowly as what we have called a 'non-altruist-focused intervention' where the incentive provides the *primary* motivation for acting. We have suggested our own definition earlier, that an 'incentive' will include some measure of *reward*, as well as recompense for the burdens of donation (see paragraph 3.73). Understood in this light, an incentive could be classed either as an altruist-focused intervention (if the reward is sufficiently small that it would not act on its own to change a person's behaviour) or as a non-altruist-focused intervention (where the reward is calibrated with the aim of providing a reason for action on its own). Again, we recognise that such distinctions may be subjective: what some would regard as a token reward may give ample reason to others for acting.
- 5.32 Whether 'incentive' is understood in a very broad sense, or under our narrower definition, the mere fact that incentives may alter perceptions of risks and benefits is not alone sufficient to show they are objectionable. Effective incentive schemes are *intended* to change the decisions people make, either by providing token prompts for action (such as low-value vouchers) or by increasing the benefits of donation (through significant reward). This alteration of costs and benefits does not, in itself, make incentive schemes inherently coercive, nor, in our view, does it undermine the quality of consent to donate. If there is something objectionable about specific incentive schemes, it must lie in the details of the rewards offered, the population they target, or their broader knock-on effects. We examine these issues below.
- 5.33 The fact that the current system is built on a commitment to an altruistic model does not, of course, by itself justify that commitment. One might take the view that since the appetite for moving away from an altruistic model appears so slight,⁵²⁵ it is not even worth the Council examining the justification for sticking with altruism. Our view, however, is that remaining silent on this issue would evade one of the responsibilities of a wide-ranging investigation such as this one, and would equally fail to provide any sort of rationale to those who wish to defend altruistic donation. Moreover, while the altruistic model is often the first that comes to people's minds when they talk in the abstract about the ethics of donation, it does not serve in all circumstances. We have already seen that the egg-sharing regimes that currently exist in the UK are non-altruist-focused interventions. And altruism is only one among several values that motivate relatives to do things for one another: between kinsfolk – and in other close relationships – self-interest and other-interest are closely entwined. If we turn to another of our examples by way of comparison – namely the use of incentives for healthy volunteers in first-in-human clinical trials – we also find that the altruistic model may not be applicable.
- 5.34 Current industry guidance (though not legally binding) states that pharmaceutical companies should only offer compensation in respect of time, discomfort and inconvenience to those enrolling in such trials (see paragraph 2.37). On the face of things, then, this is another regime in which the altruistic model appears, broadly-speaking, to be respected. However, the true facts of the matter suggest that most healthy volunteers are primarily motivated to take part by

⁵²⁴ Oxford Dictionaries (2011) *Concise Oxford English dictionary*, 11th Edition (Oxford: Oxford University Press).

⁵²⁵ See, for example, the broad European (and, for some forms of material, international) consensus regarding the importance of unpaid donation, summarised in Chapter 2; Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader), p56; and the survey carried out by nef in summer 2010 (see Appendix 1).

the offer of financial reward.⁵²⁶ Indeed, the 'compensation' paid to participants under the Association of the British Pharmaceutical Industry (ABPI) guidance goes far beyond that available to, for example, gamete donors. Why does departure from the altruistic model appear to be widely tolerated in this domain, where individuals are consequently encouraged to take unnecessary risks with their own health in order to improve their financial situation, and when the well-being of immediate 'others' is absent because it is unknown or too far into the future? It is precisely the desire to ensure that this cannot happen that explains adherence to the altruistic model elsewhere.

- 5.35 The example of healthy volunteers in first-in-human clinical trials thus shows that our earlier contention – that adherence to the altruistic model is a thoroughgoing feature of the status quo – is not universally applicable. This in turn suggests that movement to alternative systems may not be far-fetched or intolerable. We have also noted non-altruistic systems of donation in other jurisdictions (see paragraphs 2.45 to 2.51), particularly with respect to the provision of gametes. Hence there are good reasons to evaluate the ethical foundations of altruistic donation.
- 5.36 The following four arguments are frequently used to justify adherence to the altruistic model: many stem from the thought that if donation can be motivated by non-altruistic reasons, then those most in need of money – the poor and vulnerable – will tend to donate in much higher proportions than before. We now turn to a critical appraisal of some of the claims made on behalf of 'altruism', particularly by contrast with the alternative of motivating potential donors through the use of monetary reward.
- 5.37 **'Altruistic donation ensures quality of supply'**: here the thought – put bluntly – is that in moving to a non-altruistic system we might increase the percentage of materials donated by those who are impoverished, socially excluded or otherwise vulnerable, and that such materials are more likely to be infected, unhealthy or low-functioning.⁵²⁷ A review commissioned by the Working Party found that there is limited evidence to suggest that this may be the case for some, though not all, bodily materials, and we return to this issue in Chapter 6. However, we note here that this does not appear to be an especially compelling consideration: even to the extent that it is correct, the remedy surely lies in an effective system of monitoring and quality-control, to be required whatever the regime of donation, in order to ensure that only materials of an appropriate quality are made available to recipients.
- 5.38 **'Altruistic donation prevents exploitation of the poor'**: it seems likely that more poor and vulnerable people would provide bodily material in exchange for money than become donors under the current altruistic regime.⁵²⁸ This is often said to constitute objectionable exploitation, on the grounds that those in need of various forms of bodily material would tend to rely increasingly on the poorest in society for their provision.⁵²⁹ Advocates of regulated markets in tissues often respond with the argument that if the altruistic model is defensible on the basis that comparatively poor people should not be allowed to risk their health in order to make money, then that same principle should also rule out allowing such people to enter dangerous, albeit well remunerated, professions, such as mining or service in the armed forces: since society tolerates the latter, it should tolerate the former. Moreover, they argue, while exploitation of people on low incomes is clearly regrettable, what is more regrettable are the socioeconomic circumstances that lead to impoverishment in the first place. Finally, they add that, given the

⁵²⁶ See, for example, Hermann R, Heger-Mahn D, Mahler M *et al.* (1997) Adverse events and discomfort in studies on healthy subjects: the volunteer's perspective: a survey conducted by the German Association for Applied Human Pharmacology *European journal of clinical pharmacology* **53**: 207-14; Ferguson PR (2008) Clinical trials and healthy volunteers *Medical Law Review* **16**: 23-51.

⁵²⁷ This was one of the main arguments put forward by Titmuss in defending unpaid blood donation schemes: Titmuss R (1970) *The gift relationship: from human blood to social policy* (London: Allen & Unwin).

⁵²⁸ We note here that this may not be the case for all forms of bodily material, in particular for eggs, where donors of high social status and achievement may particularly be sought. See: Levine AD (2010) Self-regulation, compensation, and the ethical recruitment of oocyte donors *Hastings Center Report* **40**: 25-36. In such cases, rather different concerns may arise: for example that potential donors are vulnerable because of their relative youth.

⁵²⁹ See, for example, the discussion in Wilkinson S (2003) *Bodies for sale: ethics and exploitation in the human body trade* (London: Routledge).

widespread existence of impoverishment, the question to ask is whether there is evidence that in fact payment for bodily materials might be a well-informed choice for the individual in question.⁵³⁰

- 5.39 Evidence from countries where payment is made (both legally and illegally) for organs gives a number of reasons for thinking that payment may be detrimental to the donors. Studies in Pakistan, Bangladesh and India, for example, where payment in exchange for organs is illegal, suggest that those selling organs tend to suffer worse health as a result of the procedure, do not succeed in emerging from debt (and do not necessarily received the money initially promised), and would not recommend others to provide organs in these circumstances. In many cases, the experience of selling an organ was also experienced as shameful, and was hidden from the family.⁵³¹ Such feelings of shame and regret may not necessarily be eliminated when payment is legal and more formally regulated. For example, Zargooshi's 2001 study of Iranian kidney providers also reported that the decision to sell was often experienced as shameful and that "if they had another chance 85 per cent would definitely not vend again, and 76 per cent strongly discouraged potential vendors from 'repeating their error'".⁵³² Other studies from Iran, however, have been much more positive, with as many as 90 per cent of respondents stating that they were satisfied with their experience.⁵³³
- 5.40 In many of these respects the decision to exchange an organ for money is quite unlike the decision to join the armed forces, or to work as a miner. Regretful employees in risky enterprises can attempt to find an alternative job; regretful vendors cannot go back on their decision to donate a kidney. There is little stigma or shame attached to risky professions; indeed, regular employment can often contribute directly to self-respect and to the respect accorded by others. By contrast, in the above cases at least, there appeared to be considerable stigma and shame attached to the sale of organs. Finally, secure employment has many further benefits in terms of increasing access to valuable social networks, legal protections (including health and safety requirements and protection against exploitative working practices) and so forth.⁵³⁴ By contrast, the one-off sale of an organ often comes with no such attendant benefits, and with several attendant risks to health and wellbeing. If these were general asymmetries, it would be reasonable on public policy grounds to deny impoverished individuals the opportunity to decide to sell an organ, while allowing them the opportunity to join risky professions.
- 5.41 Those who advocate the outright purchase of organs usually recommend that this takes place in a highly regulated context, where a single purchaser (such as the NHS) would offer a set price to donors, who themselves would be in receipt of extensive counselling and support. In most current organ markets, which lie beyond effective regulation, the people with the most to gain financially by the sale of an organ are also the least likely to be able to access the follow-up care on offer, and their disenfranchisement may leave them ill-treated by the system as a whole.⁵³⁵ Tight market regulation in the context of a high-quality health system might answer

⁵³⁰ See, for example, Radcliffe-Richards J, Daar AS, Guttman RD *et al.* (1998) The case for allowing kidney sales. *International Forum for Transplant Ethics The Lancet* **351**: 1950-2; Erin CA, and Harris J (2003) An ethical market in human organs *Journal of Medical Ethics* **29**: 137-8; Savulescu J (2003) Is the sale of body parts wrong? *Journal of Medical Ethics* **29**: 138-9.

⁵³¹ See, for example, Goyal M, Mehta RL, Schneiderman LJ, and Sehgal AR (2002) Economic and health consequences of selling a kidney in India *The Journal of the American Medical Association* **288**: 1589-93; Naqvi SAA, Ali B, Mazhar F, Zafar MN, and Rizvi SAH (2007) A socioeconomic survey of kidney vendors in Pakistan *Transplant International* **20**: 934-9; Moniruzzaman M (2011) 'Living cadavers' in Bangladesh: bioviolence in the human organ bazaar *Medical Anthropology Quarterly*: accepted and forthcoming.

⁵³² Zargooshi J (2001) Quality of life of Iranian kidney 'donors' *The Journal of Urology* **166**: 1790-9.

⁵³³ See, for example, Heidary Rouchi A, Mahdavi-Mazdeh M, and Zamyadi M (2009) Compensated living kidney donation in Iran: donor's attitude and short-term follow-up *Iranian Journal of Kidney Diseases* **3**: 34-9; Malakoutian T, Hakemi MS, Nassiri AA *et al.* (2007) Socioeconomic status of Iranian living unrelated kidney donors: a multicenter study *Transplantation Proceedings* **39**: 824-5.

⁵³⁴ See, for example, Sen A (1990) More than 100 million women are missing *New York Review of Books* **37**: 61-6.

⁵³⁵ Scheper-Hughes N (2008) Illegal organ trade: global justice and the traffic in human organs, in *Living donor organ transplantation*, Gruessner RWG, and Benedetti E (Editors) (London: McGraw Hill). Note, however, that where there are

some of the problems of often fraudulent purchase, and associated poor-quality medical care, which certainly characterise illegal organ markets in the global south. Moreover, tight regulation might also help to answer one criticism of those who fear exploitation – namely that the poor would not receive a fair price (or indeed the promised price) for their organ. However, the Iranian experience suggests that regulation alone may not be successful in dealing with all these problems: unregulated payments continue to be made alongside those officially permitted (see paragraph 2.46), and some kidney providers continue to feel stigmatised by their participation. As we further emphasise in Chapter 6, the evidence base for making recommendations for the UK is weak. There are obvious difficulties in using the Iranian context as a model for the UK, and even evidence of the situation in Iran is ambivalent. Even so, the Iranian experience points to a series of significant potential problems with a legalised payment model.

- 5.42 **'Altruistic donation ensures maintenance of communal virtues'**: the virtue in question is a general disposition to be moved to self-sacrifice by the health needs of others. Were donors of bodily material to be motivated primarily by the prospect of financial gain, in this model the act of donation would be converted into a market transaction. Some argue that, if this were to happen, the value of donation would be undermined, because it would no longer stand for selfless motivation or sacrifice on the part of the donor, and nor would it express a sense of shared obligation, of solidarity, to provide that which is essential for life or health. In stark terms, they say, it would undermine a community-wide commitment to provide for others, replacing it with another banal instance of reward for services rendered.⁵³⁶
- 5.43 Worries about the potential for financial incentives to commodify body parts inappropriately, to commercialise body parts, or even to undermine the dignity of the body, often have much in common with this more basic justification for an altruism model. Recent media coverage of people who were paid to act as 'hired friends' may help to explain these worries.⁵³⁷ Friends are basic contributors to well-being. But if people secure friends by hiring them, they mistake what is important about friendship in the first place, even if they thereby obtain some of the features of friendship, such as companionship. Friendship is not a service to be bought and sold, and, as a society, we should resist social changes that might make it so.
- 5.44 Similar concerns underlie the thought that the act of putting a price on a body part may lead to the mis-valuing of health, physical integrity, or indeed children. This justification of the altruism model is of a piece with the more general justification for a stewardship model in public health ethics (see paragraph 5.13). It also helps to make sense of some of the moral complexities of the current regulatory position: when biological materials make the most direct contribution to essential health needs, the positive benefits of a system based on the expression of mutual commitment to meet those needs is most palpable. That, plausibly, is one reason why at present the sale and purchase of hair used in wig-making is tolerated in the UK, but the sale and purchase of organs and blood is not.⁵³⁸ This may also explain why there is less opposition to remuneration for participation in clinical trials: here the contribution that any one participant makes to the health of any other identifiable person is exceptionally hard to pin down. Indeed, it may explain why donation for research purposes may be viewed in some ways as quite different

gross internal disparities in medical care, a system predicated on altruism may have similar effect. Goodwin (Goodwin MB (2006) *Black markets: the supply and demand of body parts* (Cambridge: Cambridge University Press)) shows for the US - where altruistic organ donation is the legal norm - the extent to which members of the black community who provide bodily material like anyone else do not have their own health needs met. In the case of those needing transplants themselves, African Americans are often diagnosed late, wait longer than other members of the population for organs, and more of them die while on the waiting list (African Americans donate at similar rates to others, but suffer proportionately more kidney failure, and thus have a higher need). Disparities may arise for all kinds of reasons – for the UK see, for example, a report on people under-involved in the home regime seeking solutions abroad: Krishnan N, Cockwell P, Devulapally P *et al.* (2010) Organ trafficking for live donor kidney transplantation in Indoasians resident in the West Midlands: high activity and poor outcomes *Transplantation* **89**: 1456-61.

⁵³⁶ Anderson E (1990) The ethical limitations of the market *Economics and Philosophy* **6**: 179-205.

⁵³⁷ The Guardian (21 July 2010) *Would you rent a friend?*, available at: <http://www.guardian.co.uk/lifeandstyle/2010/jul/21/friends-rental-service>.

⁵³⁸ We do not suggest that this is the only reason: the fact that hair sheds naturally, or is cut on a regular basis for other reasons than donation, may also explain differences in current attitudes.

from donation for treatment purposes: while material donated for research will be used with the aim of improving health in the long term, the connection between the donation and that outcome is both extended and uncertain. Gametes, on this view, fall into a contested territory, in part because the question of whether ongoing fertility is a matter of good health or not is itself contested.

- 5.45 We take the view that it is important to distinguish a foundational commitment to a vision of society in which members are motivated to care for the health needs of others, and where values such as generosity and compassion are encouraged and recognised, from the question as to how that vision may be achieved in practice. The Working Party takes the view that basic appeals to solidarity in the domain of health are very persuasive (see Box 4.2). However, we have already noted that in reality many decisions that help others have mixed forms of motivation lying behind them. In some circumstances, solidarity may indeed be undermined by the offer of rewards in return for donation; even so, it is also possible to imagine circumstances in which individuals make decisions to promote the health of others based on a combination of genuine altruism and personal enrichment. It does not follow, then, that the availability of limited non-altruist-focused incentives must necessarily undermine solidarity.
- 5.46 This communal and collective justification for the altruism model explains why departures from altruism seem most appropriate when they are instances of 'payment in kind'. If the emphasis on an altruistic approach reflects the shared notion that we are 'all in this together', and that we all have a similar set of basic needs, then schemes that highlight the fact that the needs of recipients may also be the needs of donors themselves can appear less objectionable than schemes that reward donation with money. An egg-sharing incentive scheme, which reinforces the notion that many other couples are 'in the same boat',⁵³⁹ may therefore undermine social solidarity less than a simple payment model, even though egg-sharing schemes are non-altruist-focused interventions.⁵⁴⁰ Similarly, it may explain why the remuneration of healthy volunteers participating in first-in-human trials is not generally seen as challenging the altruistic basis of the donation of bodily material: while research results may benefit many in the long term, the very uncertain nature of such research means that such beneficiaries seem very remote. Participants may certainly feel a sense of contributing to society or the common good, but are less likely to envisage their actions as an act of altruism towards specific (if unknown) others.
- 5.47 **'Altruistic donation ensures quantity of supply'**: The concern is sometimes expressed that offering payment for donated material would 'crowd-out' potential altruistic donors: that is, people would feel less inclined to donate altruistically, perhaps because the argument of solidarity ('we're all in this together') would then exert less moral force, or because the offer of payment might be perceived as a mis-valuation of the bodily materials they were contemplating donating.⁵⁴¹ The review commissioned by the Working Party, however, demonstrated how little empirical evidence there is to support this contention, and that what does exist relates primarily to blood (see paragraphs 6.18 to 6.21). This very limited evidence suggests that, in practice, 'crowding out' is much less of a concern than might be thought from studies that ask people about their *intentions* (as opposed to studying their actual behaviour), at least as far as low-value incentives are concerned; and that token incentives such as lottery tickets and vouchers may in some cases act as a spur to donation, while small amounts of cash do not. We return to these issues in more detail in Chapter 6.
- 5.48 Before setting out our conclusions on altruism, it is necessary to offer one further comment about the way concepts may be used to justify particular practices. When great emphasis is

⁵³⁹ To the extent that both donors and recipients are seeking to get pregnant - although this should not disguise the fact that egg donors are getting quite a different 'deal' from recipients.

⁵⁴⁰ In this case, social solidarity within the UK may also be said to have been undermined by the lack of consistency of NHS IVF provision.

⁵⁴¹ Titmuss R (1970) *The gift relationship: from human blood to social policy* (London: Allen & Unwin).

placed on one particular value such as altruism, the very terminology can become a means of persuasion or even manipulation, as we saw previously in relation to the language of the gift (see paragraph 4.12).⁵⁴² The risk may therefore arise that this ethical impulse (altruism) on the part of potential donors may be misused by those who have strong interests of their own in the donors' bodily materials.⁵⁴³ But while we should be wary of wholesale appeals to altruism, we do not for this reason jettison the concept ourselves.

Conclusions on altruism

- 5.49 We find none of the four considerations outlined above wholly decisive, either one way or the other. It is not possible absolutely to rule out on ethical grounds movement away from a system based solely on altruism. One way to make that vivid is to imagine that we had reliable empirical data showing beyond doubt that significant payment, in the context of a highly regulated system characterised by exemplary follow-up care for donors, would greatly increase supply. Imagine that this regime was accepted to such a degree that there was no conceivable stigma in providing part of one's body in return for money, and indeed that it was an option considered by people across the income range. Under such circumstances, one might regard insistence on the value of shared communal virtues as a principle worth sacrificing in favour of another (maximising health and welfare), given the prospect of a likely gain in health for those in acute need of organs.
- 5.50 This illustrates only that we can *imagine* circumstances in which regulated payments in return for the provision of bodily material might be justifiable. As a matter of fact, the current situation in the UK is characterised by ethical uncertainty in the face of conflicting imperatives, and is exacerbated by very limited empirical evidence regarding the likely effects on supply of a departure from the current altruistic model. It would be necessary to take into account the realities of compliance and the risks, for example, of unregulated systems flowering alongside the regulated scheme with all its careful protections. In situations of uncertainty and partial evidence, a form of precautionary thinking is often considered appropriate. We have intentionally avoided referring to the 'precautionary principle' here, for we are sceptical of the existence of any clear decision rule that tells the decision-maker how to act in cases of uncertainty. Instead, by 'precautionary thinking' we understand a general stance that is humble about the limits of our knowledge, that recommends expanding our knowledge base through the use of small-scale pilot-studies, that is mindful of the potential costs of various likely errors in judgment, and that stresses the wisdom of putting policies in place that can be undone if they prove to be unwise.⁵⁴⁴
- 5.51 We have referred to 'movement' or 'departure' away from the current altruistic model because the dominance of this way of presenting the donation of bodily materials, especially organs, means that no recommendation can start from scratch – any alternative would have to argue the case for radical change from this model. As we have already seen, the model does in any case have limits to its application: for example, it is not the primary basis on which healthy volunteers participate in first-in-human trials, and different values may or may not exist in tandem (such as solidarity or maximising health care). However, its dominance or salience – and this is true internationally – shares a very special feature with the concept of consent. In this field, the altruistic model has become a sign for ethical practice itself. There are other ethical values, as we noted at the start of Chapter 4, and in many situations people do not explicitly act by reference to specific ethical values, even if their actions may retrospectively be justified in such a way. Yet altruism holds a central signifying place in the ethical acceptability of donating materials from the body, in the idea that someone might give part of themselves for the use of another, much as consent does in the negotiations and agreements by which these materials are obtained with the will of the donor. We turn to consent in paragraphs 5.55 to 5.70.

⁵⁴² The same criticism can also be made of any widely accepted procedure, such as obtaining 'consent'.

⁵⁴³ Dickenson D (2007) *Property in the body: feminist perspectives* (Cambridge: Cambridge University Press).

⁵⁴⁴ Lewens T (2008) Taking sensible precautions *The Lancet* **371**: 1992-3.

- 5.52 **The arguments for a complete departure from the altruistic model seem uncertain. Indeed, a rough and ready moral appraisal suggests that, for the moment, a wholesale reconfiguration of the basis for the donation of bodily material (as would be implied by creating a new system of non-altruist-focused interventions) would be reckless, and could run the risk of irreversible damage to important communal virtues. At the same time, our evaluation is not uniform across the domain of donation.** We have already seen that first-in-human trials are an area where departure from an altruistic basis of participation is at present accepted. Similarly, the donation of bodily material for research purposes, where the connection between donation and the well-being of others is much more remote than in donation for treatment, and hence where lesser risk to communal values might arise, could be an area in which various 'pilot studies' might be tolerated. Rigorous evaluation of such studies could then be used to provide a basis for any future consideration of policy in connection with the donation of bodily material more generally.
- 5.53 Gamete donation for treatment purposes presents further ethical complications because it involves the potential generation of a new person. At its most extreme the charge is made that buying and selling gametes allows 'children' to be purchased, and that psychological damage to children born of such arrangements is inevitable, although such claims are strongly contested.⁵⁴⁵ We agree that deliberations over the provision of gametes must take serious account of the well-being of the future child. Some have tried to defend payments for gametes on the grounds that since a given child would not have existed but for the supply of the gamete in question, the transaction cannot be said to have harmed that particular child. However, we are sceptical of using what many would consider a contentious philosophical argument⁵⁴⁶ to establish a potentially wide-reaching policy. It is also, however, important to acknowledge that significant numbers of British couples are travelling abroad to access treatments in countries where more generous compensation arrangements – or indeed a free market – are in place for gametes.
- 5.54 A distinction can be drawn, of course, between paying a donor for the time, discomfort and inconvenience of going through the process of supplying a gamete (which we have characterised as 'reward'), and payment for the gamete itself (which we have characterised as 'purchase'). Distinctions may also be drawn with respect to the size of the payment (for example token or substantial) and whether or not higher payments are made in respect of particular characteristics.⁵⁴⁷ Such distinctions give some room to those who argue that it is possible to incentivise the provision of gametes financially without this amounting in any way to the 'purchase' of children. It should also be noted that most people receiving IVF treatment within the UK do so within the private sector and hence are already paying for the opportunity to conceive a child. We consider that an important issue here concerns the ultimate feelings of the future child: specifically how the child is likely to respond, positively or negatively, to the knowledge both that financial incentivisation was required to secure some of his or her most basic original materials, and of the lengths to which their parents were prepared to go in order to have a child. We return to the issue of research on this question in Chapter 6 (see paragraph 6.70). We note also, however, that the experience of individual children conceived in such

⁵⁴⁵ For an argument concerning the commodification of reproductive material, see: Cohen CB (1999) Selling bits and pieces of humans to make babies: the gift of the Magi revisited *Journal of Medicine and Philosophy* **24**: 288-306. For an alternative perspective, see: Resnick DB (2001) Regulating the market for human eggs *Bioethics* **15**: 1-25.

⁵⁴⁶ Derek Parfit, whose book *Reasons and persons* first outlined the so-called 'non-identity problem', held to what he called the 'no difference view' as a response to the problem. He pointed out that a policy that causes grave long-term damage to the environment may also affect which future people come to exist. One cannot say of any future individual that he or she would have been better off had the damaging policy not been put into place, for without the policy the person would not have existed. Parfit did not conclude that the damaging policy was therefore unobjectionable. Instead, he attempted to find a theory that could account for what he termed 'non-person affecting harm': Parfit D (1986) *Reasons and persons* (Oxford: Oxford University Press).

⁵⁴⁷ See, for example, New York Times (3 March 1999) *\$50,000 offered to tall, smart egg donor*, available at: <http://www.nytimes.com/1999/03/03/us/50000-offered-to-tall-smart-egg-donor.html>; Levine AD (2010) Self-regulation, compensation, and the ethical recruitment of oocyte donors *Hastings Center Report* **40**: 25-36.

circumstances is not the only factor to take into account. Wider social understandings of the context in which children are received and accepted, and the responsibilities that their genetic parents may be thought to have towards them are also important: the extent to which rewards to donors might affect these understandings must be taken into account.

The issue of consent

5.55 Key ethical issues that arise in the context of consent for the donation of bodily material, or participation in first-in-human trials as a healthy volunteer, were indicated in Chapter 2 and include:

- whether the consent is the product of a free and unforced choice (how may such a choice be affected by the offer of an incentive to donate?);
- whether the consent is the product of an informed choice (how is information about risk presented? can opt-out systems meet informational requirements?);
- whether the consent has been unequivocally signalled (again, an important issue in connection with opt-out systems); and
- whether the activity falls within the scope of the consent (how widely may the scope be legitimately defined, especially in terms of material donated for research use? What future connection should there be between the donor and the researcher or research institution?).⁵⁴⁸

Incentives and consent

5.56 We have already made clear our view that the mere fact that incentives act to change people's perceptions of the relative risks and benefits of a particular course of action (in this case, whether or not to donate) does not in itself undermine the quality of consent to donate (see paragraph 5.32). Clearly, important questions arise as to the nature of the information provided about those risks and benefits: any attempt to underplay the risks or exaggerate the benefits would indeed compromise the basis on which consent is given. However, we do not accept the argument that the very *existence* of an incentive puts the free and voluntary nature of a person's consent at risk. This is, of course, not to say that incentives are therefore as a matter of course always ethically unproblematic: as we have already indicated, other values, in particular those of solidarity and of protecting the common good, are relevant here.

Opt-in versus opt-out

5.57 Our consultation responses showed considerable polarisation around the issue of consent, particularly in the context of organ donation after death. On the one hand, some respondents felt that the health needs of those who require scarce organs were so great that this could justify an 'opt-out' system, or perhaps a system of mandated choice (see paragraph 3.53). On the other hand, some respondents felt that in moving to an opt-out system, the state would effectively gain control over, and ownership of, individuals' bodies, and that such a shift would be quite unacceptable.

5.58 All parties agree that 'consent' is important in the context of organ donation, but disagreement focuses on how that consent should be signalled. In considering this issue, we have found it useful to reflect on the success of 'opt-out' schemes in other non-health contexts. A well-documented case looks at the increase in take-up of occupational pensions schemes, prompted simply by changing employees' default status from that of non-enrolment to enrolment.⁵⁴⁹ Equally, one might think that far greater quantities of valuable bodily material could be secured

⁵⁴⁸ *Capacity* to consent is, of course, another key issue in consent to either medical treatment and research; in the context of this report, however, and its focus on the encouragement of donation or volunteering to benefit others, the question of participation where capacity to consent is uncertain does not play a large role. One exception, however, is that of bone marrow donation to a sibling, where the donor will often not have the capacity to give a legally valid consent.

⁵⁴⁹ Thaler RH, and Sunstein CR (2003) Libertarian paternalism *American Economic Review* **93**: 175-9.

by ensuring that the default status is membership of the ODR, with the option to opt out. We find several significant differences between the cases.

- 5.59 First, it is very unlikely that an individual would be unaware of their enrolment in an occupational pension scheme – at least after receipt of their first pay-slip. Evidence of their membership would be represented to them on a weekly or monthly basis and failure to opt-out in these circumstances could legitimately be described as tacit consent rather than opt-out: while the person might not formally be invited to signify consent, there can be little doubt that they are aware of the system and have chosen not to opt out of it. But it is quite possible for someone not to have received, or not to have read or understood, a communication informing them that they will be placed on the ODR. It is also quite possible that people would remain unaware or unengaged with the issue despite national publicity campaigns.
- 5.60 None of this would matter if membership of the register were a trivial matter. But here is the second difference: as our consultation showed, for many people the future uses of their body is something of fundamental personal concern.⁵⁵⁰ Moreover, unlike the allocation of one's pay-packet, a mistake regarding the allocation of bodily materials after death is not easily rectified or repaired. Finally, although we can argue that employees contribute to a pension pool from which others (their dependents) will benefit, they will also benefit directly themselves, and will do so, even if they have contributed unknowingly. A person who chooses actively to donate their organs after death could be said to benefit from the knowledge of that forthcoming act of altruism, but they will not benefit in any way if they never realise that donation lies ahead. The taking of bodily material from a person in these circumstances could be interpreted by some as using a (deceased) person as merely a means to others' ends, rather than as an end in themselves; and hence as a failure to respect their dignity as a person (see Box 4.2).
- 5.61 **Comparison with a successful case of a non-health 'opt-out' scheme, as described above, leads us to the view that the taking of bodily materials after death should be based on the clearest possible information as to the person's wishes. Only in these circumstances can it be described as 'donation'. Such information should, ideally, derive from the person's own expression of these wishes before death, and we discuss later a number of ways in which individuals might be prompted at particular times to express their wishes (see paragraph 6.52 to 6.54).** Where the individual has not recorded their wishes (whether in favour or against donation) in advance of their death, information about their likely wishes should be obtained from those closest to them.
- 5.62 In coming to this conclusion for this kind of donation, we have deliberately avoided the term 'consent'. As we highlighted earlier, what is currently required for 'valid consent' in differing circumstances varies enormously, with very variable amounts of information provided and differing protections offered (see paragraphs 2.7 to 2.21). With respect to deceased organ donation, some health professionals are concerned that signing the ODR is not 'consent' as usually understood in a clinical setting, given the lack of certainty around information provision, competence and understanding.⁵⁵¹ By contrast, suggestions have been made that the information provided to relatives about possible uses of bodily material after death may

⁵⁵⁰ Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics). See also: Department of Health (2008) *The potential impact of an opt out system for organ donation in the UK: supporting information - annex L*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090298.pdf and Sque M, Long T, Payne S, and Allardyce D (2008) Why relatives do not donate organs for transplants: „sacrifice“ or „gift of life“? *Journal of Advanced Nursing* 61: 134-44 for a discussion of families' wish to 'protect' the dead body.

⁵⁵¹ A more specific concern about consent is raised by some who disagree with the current definition used for the diagnosis and confirmation of death used in UK, as set out by the Academy of Medical Royal Colleges (2008) *A code of practice for the diagnosis and confirmation of death* (London: Academy of Medical Royal Colleges). However, given that this definition is used in all clinical practice in the UK (i.e. not just in transplantation), the Working Party was of the view that further consideration of this issue would be beyond its scope.

sometimes be unnecessarily and distressingly detailed.⁵⁵² In the context of embryo donation for research, the issue of 'unfettered' consent has recently caused concern,⁵⁵³ and as we highlighted earlier, there is an ongoing debate over the acceptability of 'generic' consent for future research uses of many different forms of tissue. While 'consent' constitutes a central plank of the Human Tissue Act, the Act is silent on what is in fact required for consent to be legally valid, although guidance is offered in the Codes of Practice. The Human Tissue (Scotland) Act uses the term 'authorisation' rather than 'consent' in connection with deceased donation, and in practice the terms are used synonymously, ensuring that organs and tissue may be allocated across the UK, regardless of the legal regime under which they were donated (see paragraph 2.15).

- 5.63 While we see no need (given the absence of definition of 'valid consent' in the Human Tissue Act itself) to seek to amend legal terminology, **we argue that it is right to make an ethical distinction between legal consent to interventions on the body during life (from blood samples to operations to donate a kidney) and those taking place after death.** The former involves physical intrusion on a living individual and the associated health risks, which will of course vary significantly depending on the procedure. The information made available to the potential donor, and the procedures designed to ensure that the donation reflects their autonomous choice, need to reflect that intrusion and that risk. In the case of interventions after death, we suggest that it is perfectly possible for a person to express meaningful willingness to donate (either on behalf of themselves in the future or on behalf of a deceased relative) with much more limited information – while noting, of course, that some people *will* wish for detailed information, in which case it must clearly be provided. In ethical terms, it may be helpful to distinguish between 'consent' to interventions during life and 'willingness to donate' or 'authorisation' of donation after death.⁵⁵⁴ We return to these issues again in connection with various forms of bodily material in Chapters 6 and 7.

Scope of consent

- 5.64 Questions around the scope of a person's consent link closely with concerns about future *control* of donated material by the source of the material. Key issues that arise include, first, whether it is ethically acceptable to ask a person to consent to unknown future uses (as in requesting generic consent for research using donated tissue, blood and embryos) and second, what control a person may reasonably expect to have over the future use of their tissue (for example in specifying a recipient or category of recipient, or in seeking redress if the material is improperly used).
- 5.65 On the first question, we take the view that it *is* meaningful, and therefore in this sense ethical, to seek generic consent to unknown possible research uses: while, by definition, precise information about the nature of possible projects cannot be given, nevertheless donors may understand in broad terms how their material will be held (for example in a tissue bank), who will be able to use it (for example researchers with approved projects), and what, if any, limitations are placed on future use (for example whether material will only be made available for health-related research projects). They should also be in a position to understand whether the option does, or does not, exist for them to exclude particular types of research from their consent (tiered consent), and the extent to which some form of relationship may continue between donors and the research institution after the initial donation (broad consent).

⁵⁵² Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics); UK Donation Ethics Committee/NRES workshop (November 2010) *Ethics of transplantation*, report to be made available at: <http://www.aomrc.org.uk/donations-ethics-committee/work-programme/231-ethical-issues-in-organ-donation-and-transplantation-research.html>.

⁵⁵³ 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>.

⁵⁵⁴ 'Authorisation', of course, is the term used in Scots law, although not in the Human Tissue Act that governs England, Wales and Northern Ireland.

- 5.66 However, such generic consent is not sought or given in a vacuum: donors are only likely to consider giving generic consent in circumstances where they have already have trust in the professionals and systems concerned. The central nature of trust in such circumstances highlights the importance of what we characterised as 'professional' and 'interpersonal' values in Chapter 4 (see paragraph 4.3): donors are unlikely to give generic consent unless they trust the professionals concerned to exercise a duty of care in how their donated material is used and ensure that the donors' confidentiality is respected. However, while consent may be sought by one individual professional (possibly already known to the donor), the transactional nature of contemporary research using bodily material means that the actions of many others, unknown to the donor, will also be relevant. Thus, questions of good governance and transparency become central in ensuring that those who are asked to consider giving generic consent may have good cause to trust the systems and institutions that will be responsible for safeguarding their donated material.
- 5.67 On the second question, it is helpful to distinguish between consent in the context of donation for treatment, and consent in the context of donation for research. In donation for treatment purposes, once material has been transplanted into another person, there can clearly be no question of active future control of that material, and consent must include full relinquishment of any such claim. We note, of course, that in the case of the donation of gametes or embryos, while no future rights in respect of any resulting child exist for the donor, he or she must accept the possibility of being contacted once the child has reached the age of 18 years, and there is general acceptance that the genetic tie cannot be regarded as severed, despite the donor's lack of future control over any resulting child. In these circumstances, very clear distinctions must be drawn between the possibility of future *interests* in the donated material and any rights of future *control*.⁵⁵⁵
- 5.68 In donation for research, on the other hand, there is no similar good reason that would hinder recognition of an onward interest in the donated material. We have discussed at several points earlier in this report how the donation of bodily material is typically represented as a 'gift relationship'; and we highlight here the importance of paying attention to the notion of 'relationship' as well as to the idea of the 'gift'. Clearly, in the context of research, that relationship will not generally be understood as a personal one: rather, those donating material for research purposes should be understood (to the extent that they wish to be) as partners in the research enterprise. Such an understanding of the 'gift relationship' stands in stark contrast to fears that those donating material for research may be perceived merely as a means to others' ends, 'used' for the benefit of others. We discuss later in this report what the idea of partnership may mean in practice (see paragraphs 7.19 and 7.70). However, we emphasise here that donors' interests in the future research use of their material should not be confused with straightforward rights of control: while the consent process may be used to *limit* how material is used (as for example in tiered systems of consent where specific forms of use may be excluded), donors cannot expect to *determine* use in any positive way: that is, they can refuse consent to particular usages, but they cannot demand that particular use be made of their donated material. Moreover, while the ability to change one's mind and withdraw consent at any later stage is an important safeguard for those giving generic consent, the practical limitations on this right (for example the impossibility in some cases of extracting particular data from large datasets where samples have already been used) must be clearly explained as part of the initial consent process.

⁵⁵⁵ The question does, also, arise as to whether donors should be permitted to control the future use of their material by specifying a category of recipient: for example stipulating that gametes or embryos may only be donated to a married woman under a particular age. The Working Party notes that the HFEA has sought legal advice on the implications of the Equality Act 2010 for this practice, and welcomes the fact that the HFEA will be issuing further guidance in this area (see paragraph 1.18).

Limitations on consent

- 5.69 This report has indicated a number of the important ways in which a focus on consent serves to protect the autonomy of potential donors and volunteers. For interventions carried out during life, legally valid consent, based on appropriate levels of information and protected by procedures that aim to avoid coercion or duress, is central to protect bodily and personal integrity. In the case of interventions carried out after death, the disposal of bodily material should be determined by the known wishes of the deceased, so far as this is possible; we suggest, in the light of paragraph 5.63, that in ethical terms **this expression of views should be distinguished from 'consent' (being considered, instead, as 'authorisation' or 'willingness to donate') in demanding much lower minimum informational requirements.** When material is donated for research purposes, consent processes empower donors to ensure that their material will not be used for purposes that they would regard as unacceptable.⁵⁵⁶ However, we caution here that consent should not be seen as the only, or indeed the primary, focus of ethical concern in this area, for at least two reasons.
- 5.70 First, we repeat our concern that at times the seeking of consent may become simply a procedural hurdle, especially if regarded as no more than the obtaining of a signature on a consent form. In such circumstances, the process may simply serve to protect the actions of the professionals and intermediaries involved, and have little to do with protecting the agency of the donor or volunteer (see paragraph 5.9). Second, we have argued throughout this chapter that systems of donation within any particular society have the potential to affect communal values within that society: in particular the value of providing, on a collective basis, for the health care needs of all. A focus on consent is clearly crucial, in order to balance collective needs with those of the individual potential donor: consent (properly used) serves to protect individual interests. It is also the case, however, that where an individual wishes to consent to a practice (such as the sale of an organ) that others fear may undermine solidarity and the common good, this risk to the common good must be taken into account in determining policy.

Implications for ethical choice

- 5.71 From the outset the Council felt that it was important to acknowledge the **pluralism** in the UK that characterises people's values, attitudes, beliefs and behaviours in relation to the human body.⁵⁵⁷ This pluralism extends beyond the usual sense of variety as a result of differences in cultural, religious or socio-political perspective. While remaining true to certain principled positions, one person can nonetheless hold an assortment of views regarding different bodily parts, products or practices. For example, while someone might hold on to a particular fixed and secure account of what it means to be a person and the moral consequences of their position, they might at the same time consider that they and others can reasonably accept the development of markets or quasi-markets in relation to some personal materials but not others. Similarly, they might consider some forms of exchange intrinsically exploitative, but others permissible or even laudable.
- 5.72 As we have seen throughout, money (and its absence) plays an influential role in people's thinking, and the very idea of money changing hands creates much controversy (see also paragraph 4.15 and Box 4.4 for a discussion of the many different concerns wrapped up in the idea of 'money'). While the consultation exercise gave voice to those who wish to question the moral acceptability of monetary payment of any kind for any bodily part or product, it also strengthened the Council's conviction that each exchange needs to be viewed and evaluated independently, and in light of a thorough understanding of the current situation with regard to

⁵⁵⁶ Where 'tiered' consent processes are not available, clearly this entitlement can only be exercised by the (potential) donor refusing their generic consent altogether.

⁵⁵⁷ Writing about the USA, Fiske and Tetlock note that as 'social values' their four elementary models are incommensurable. "...our pluralist approach treats moral values and social ends as irreducible to any single standard of comparison". In their view, it follows that "pluralizing the decision process affirms, in a symbolically and procedurally significant way, the importance of seeking policy solutions that respect the qualitative complexity of social life." See: Fiske AP, and Tetlock PE (1997) Taboo trade-offs: reactions to transactions that transgress the spheres of justice *Political Psychology* **18**: 255-97.

supply and demand.

- 5.73 While it is wrong to conclude that scarcity in and of itself legitimises any proposed means of increasing supply, certain types of scarcity might permit more radical solutions than others. It might also be argued that certain types of scarcity are seen not to be 'society's business' in quite the same way as others; they are viewed, as it were, as more 'private' than 'public'. They might therefore move into the commercial arena more readily. It is then incumbent upon us to ask (both ethically and empirically) whether we can allow a greater role for financial reward in some activities while keeping others firmly within the realm of altruism. **We reiterate here our view, foreshadowed in paragraph 5.52, that a wholesale shift in the UK to a purchase model for bodily material would be inappropriate, both because of the lack of evidence at present as to likely beneficial effects, and because of more fundamental concerns about the welfare of donors and the potential harmful effect on communal values. By 'purchase model' we mean a system where the guiding principle becomes that of a transaction between buyer and seller, with the payment offered being understood as being in direct exchange for bodily goods. As we have been arguing, however, the simple presence of money in the transaction (for example in the form of reimbursed expenses) does not in itself imply a 'purchase model'.** We consider the implications of this view for various different forms of bodily material in Chapter 6. At the same time, it remains possible and potentially desirable that financial means should be used imaginatively to promote donation among those already disposed to donate.
- 5.74 Alongside pluralism, the Council also acknowledges the **complexity of the exchanges and transactions** that occur in relation to human body parts, and the fact that these rarely, if ever, remain direct and 'private' transactions. In some cases a named person directly donates a body part or product to another known and named individual: living donation of a kidney, donation of bone marrow or stem cells to a relative, or the donation of eggs to a sister being examples. However, even these direct transactions are still governed in the UK by statute (the Human Tissue Act, the Human Tissue (Scotland) Act, and the Human Fertilisation and Embryology Act) and will ordinarily entail the involvement of third parties either of necessity (transplants) or advisedly to ensure safety (sperm donation). Moreover, as we highlight in Chapter 2, the state acts to limit the financial nature of such transactions, regardless of how apparently 'direct' or 'private' they are. Yet again, as we discussed in Chapter 4, the 'private' and 'public' nature of such transactions become inextricably entwined, with state regulation and the involvement of intermediaries imposing a legal and clinical framework that requires due regard to be paid to issues of consent and governance. While at times such frameworks may be criticised for creating bureaucratic hurdles, we suggest that, if implemented proportionately, they have an important role to play in ensuring that both donors and the material they donate are properly handled. Indeed, the existence of good governance systems, accompanied by transparency of process, are an essential requirement if potential donors are to have the trust necessary for them to contemplate donation in the first place.
- 5.75 Where donors donate to a common pool, the contents of that 'pool' are then donated to anonymous beneficiaries on the basis of need. This, too, requires the involvement of intermediaries whose responsibility it is to ensure that appropriate ethical standards pertain to both retrieval and allocation. In order to ensure that no individual person is treated merely as a means to another's ends, action must clearly be taken to make sure that, at the point of donation, their medical needs and well-being are prioritised over any donation process. We take the view that what happens to donated materials *after* the point of donation is also a matter of ethical concern because of an enduring sense of keeping faith with donors who have given something of themselves.⁵⁵⁸ This consideration highlights the importance of ensuring both that donated materials are not wasted, and that they are used for the purposes described when

⁵⁵⁸ That is, the gift of bodily material should be regarded in a different light from other forms of gift, because of the special nature of bodily material as a person's embodiment.

consent was given. There is therefore a strong interest in guaranteeing that bodily materials are subject to ongoing ethical governance once they have been donated or acquired. Furthermore, where the journey a bodily material might take between donation and use is cross-national and complex, it could be seen as important to subject the 'chain of supply' to ethical scrutiny. One example of how such scrutiny might operate in practice may be found in the use of 'fair trade' principles to prevent exploitation of producers in developing countries.⁵⁵⁹ Professional ethics are clearly highly relevant in this context, and there is a strong argument for endorsing the seriousness with which relevant professional groups, whether they are on the supply or demand side of the equation, take account of their obligations to ensure that acts of donation are appropriately managed.

- 5.76 Such ongoing ethical scrutiny can be a challenge even in the clinical setting where donation and transplantation/implantation happen in close succession, but in some cases there is a significant gap in time between donation and usage, and this means that further intermediaries become involved in storage, archiving and eventual allocation. In the case of tissue donation, for example, bone, corneas, skin and so forth can be removed and stored until needed. The chain of supply inevitably becomes more complex than an immediate transfer of a donated solid organ and, depending on the number of transactions involved, the processed tissue becomes more and more remote from the initial personal act of donation. It is thus necessary to be alert to the manner in which the meaning and significance of the body part might gradually be transformed, as it is classified, prepared and stored in a setting quite different from, and separate to, the clinical environment.
- 5.77 Increasing levels of directed donation in some areas (in particular kidneys but also gametes – see paragraphs 3.10 and 3.16) prompt the question as to whether directed donation should be encouraged as the norm, or whether we should try to meet demand in a more communitarian manner. We have already argued that one reason why the emphasis on altruism as a motivating factor in donation is valuable is because it emphasises **solidarity**: that we are 'all in this together' and should try to find communal solutions to communal problems. The altruism that underpins directed donation, on the other hand, is associated more with concern about a specific other individual, than about the community at large. A primary focus on directed living donation, at the expense of developing efficient communal donation systems, might risk losing or diminishing this sense of communal concern. Diverting attention away from deceased donation would also serve to neglect forms of bodily material (for example hearts) that may only be donated after death.
- 5.78 We note here that we live in a world where people will search far and wide (virtually or geographically) to meet their unmet needs. The Council was struck that there appears to be increasing acceptance that individuals or couples will travel abroad to acquire donor eggs in countries where UK regulation has no influence over the fair treatment of the women who provide them. Such acceptance (as shown, for example, through the arrangements some fertility clinics make with clinics abroad) contrasts sharply with the general disapproval of the idea of UK patients travelling abroad to purchase a kidney, as demonstrated by widespread support for the Declaration of Istanbul, which condemns 'transplant tourism' and 'transplant commercialism' (see paragraph 3.84). Yet in both cases, the potential availability of bodily material (kidneys for transplantation or eggs for fertility treatment) depends on individuals in other countries exchanging those materials for money, often in the face of significant economic hardship. If asked to make a comparison, most people would regard the potentially life-saving (and at the least life-enhancing) nature of a kidney transplant as more important than the life-creating nature of fertility treatment using donated gametes,⁵⁶⁰ and yet be less willing to condone or approve that potentially life-saving treatment if undertaken abroad in circumstances that are illegal in the UK.

⁵⁵⁹ For an example of such principles in connection with bodily material, see: Humbyrd C (2009) Fair trade international surrogacy *Developing World Bioethics* 9: 111-8.

⁵⁶⁰ See, for example, Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader), p28.

- 5.79 One way of making sense of these attitudes is to suggest that the morally relevant difference for many people lies on the *supply* side of the equation rather than on the demand side: that the welfare of the potential donor and the potential for harm and exploitation, especially given the unregulated nature of existing organ 'markets', is a key determining factor of ethical acceptability. However, in the case of organs, the nature of the good to be achieved – the saving and enhancing of life – provides an impetus to achieve a communitarian solution to the problem of organ scarcity (a system of deceased donation), allowing people the opportunity to contribute to the survival of those who remain strangers to them. **Such a consideration provides a powerful reason to support and encourage an efficient system of deceased donation that will both reduce the temptation to travel abroad for treatment and ensure a more equitable approach to the allocation of available organs.** In terms of solid organ donation, under the present 'altruistic' regime in the UK more people than ever before are donating both in life and after death. We therefore have a reason to preserve the foundations of this improving system, and to do so we might have additional reasons to discourage the attitude of 'whatever means possible' to securing an organ.
- 5.80 Such a communitarian approach is not, at present, evident in the UK with regard to donated eggs or sperm for fertility treatment; and the contrast between the national infrastructure that supports organ donation (from both living and deceased donors) and the lack of any such infrastructure with respect to gamete donation is striking. This lack of a communitarian approach may help explain why there appears to be little public concern regarding women travelling abroad for treatment, especially where the arrangements whereby gametes are obtained are lawful in the destination country, even if not within the UK. However, we would argue that such tolerance is only ethically acceptable to the extent that gamete donors in other countries are being neither exploited nor subjected to unacceptably high levels of risk, and, clearly, very different issues will arise here with respect to egg donors as opposed to sperm donors. We return to these issues further in Chapter 7 (see paragraphs 7.22 to 7.27).
- 5.81 The approach taken in this chapter explicitly acknowledges and works with the idea that there may be 'relevant differences' between the various forms of bodily material, and, as a result, opens the possibility of financial transactions entering at some level in some places. For those who equate any degree of monetary payment with commercialisation, and commercialisation with commodification, this would be unacceptable, but even those without such objections might fear the possibility of a slippery slope – with what looks like 'acceptable commercialisation' in one area quickly leading to unacceptable changes in that same area and maybe others. 'Slippery slope' arguments are rhetorically powerful, whether they are empirical or logical in form, but we remain convinced by the counter argument: that it should be possible to anticipate and protect against unacceptable developments that could potentially follow on from changes made for good reason and with good justification.

Ethical conclusions and policy considerations

- 5.82 We now draw together the main ethical values for which we have been arguing, and that will form the basis for the policy considerations set out in Chapters 6 and 7. Policy in this complex and sensitive area must start with a recognition of the pluralism that characterises people's values, attitudes, beliefs and behaviours in relation to the human body, including their own bodies. A key aim of a policy framework must therefore be to seek areas of shared consensus, including identifying values with which people starting from many different positions may nonetheless agree.
- The role of the state with respect to donation should be understood as one of stewardship, actively promoting measures that will improve general health (thereby reducing the demand for some forms of bodily material) and facilitating donation. Such a stewardship role should extend to taking action to remove inequalities that affect disadvantaged groups or individuals with respect to donation.

- Altruism, long promulgated as the only ethical basis for donation of bodily material, should continue to play a central role in ethical thinking in this field. While some of the claims made about altruism may be overblown, the notion of altruism as underpinning important communal values expresses something very significant about the kind of society in which we wish to live. Understood in this way, altruism has much in common with solidarity: an altruistic basis for donation helps underpin a communal, and collective, approach to the provision of bodily material for others' needs, 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. This is, first, because payment may be used to recompense the donor for costs actually incurred in donating (that is, in order to avoid financial losses as a result of donation); and, second, because some forms of reward (monetary or otherwise) may in fact coexist with altruistic intent. We distinguish between altruist-focused interventions (that act to remove disincentives from, or to 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 action). 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.
- Donation for research purposes may differ in important ways from donation for treatment purposes. While both forms of donation seek to benefit others, the contribution that any one research donor or healthy volunteer makes to the health of any other identifiable person is exceptionally hard to pin down. A move away from a primarily altruistic model in donation for research purposes may therefore pose a lesser challenge to solidarity and common values than such a move in connection with donation for treatment.
- We take seriously concerns that some approaches to increasing the supply of bodily material may risk using people, and people's bodies, as 'means' to another's ends. While we do not take the view that payment to a person in connection with donation necessarily implies this, we do reject the concept of the 'purchase' of bodily material, where money exchanges hands in direct return for body parts. We distinguish such purchase clearly from the use of money or other means to reward or recompense donors.
- The welfare of the donor, and the potential for harm and exploitation within donation practices, should be a key determining factor when considering the ethical acceptability of any system for encouraging people to come forward as donors. While proper consent procedures, underpinned by sufficient information, are clearly essential in order to protect those coming forward as living donors, consent alone may not be sufficient to justify particular donation practices if such practices might put other potential donors, or wider communal values, at risk.
- Decisions about deceased donation should be based on the known wishes of the donor, so far as this is ascertainable. In ethical terms, the basis for such donation should be understood to be on the basis of the authorisation, or willingness to donate, of the deceased, and not on their consent. We distinguish authorisation/willingness to donate from consent in these circumstances, on the grounds of the potentially different informational requirements involved. In contrast to those consenting to donate during life, those authorising donation after death do not expose their health to any risks, and the minimum informational requirements for donors are correspondingly lower.
- 'Professional' values such as trust and respect play an essential part in creating and maintaining systems in which people will be willing to consider donation. This is true both of trust in individual professionals, for example that they will exercise a duty of care towards donors and respect their confidentiality; and of trust in systems, that they are the subject of good and transparent governance.

- 5.83 We conclude our analysis in this chapter by highlighting again the current state of flux in which the health care system within the UK finds itself, both in terms of changes of structure and responsibility for commissioning health care within England, and the proposed changes to regulatory structures that impact more widely across the UK (see paragraph 2.5). **In such a climate of change, it is particularly important that policy makers should remain alert to the importance and value of the donation of bodily material, and should act to ensure that valuable systems currently in place are not inadvertently lost.**

Applying our ethical framework

- 5.84 In the remainder of this report, we consider potential changes in the way the demand for various forms of bodily material might be met, and from two perspectives.⁵⁶¹ The first (Chapter 6) concerns the degree to which it is ethically acceptable to 'encourage' individuals to donate their bodily material. The second (Chapter 7) takes up what can be done by professionals, institutions and organisations to 'facilitate' donation, whether through improving procedures or reducing demand. Both reflect on the kind of society we would wish to see and on the manner in which persons flourish. Indeed, we note the interconnected nature of the two perspectives: for example if an organisation is well respected and trusted (a result of organisational ethos and action), then people may be more likely to make their own individual decisions to donate (individual action).⁵⁶²
- 5.85 There is, of course, already considerable action within the UK in both these areas. With respect to individual decision-making, for example, the HFEA has been carrying out a public consultation on how egg and sperm donors should be compensated (see paragraph 2.35). On organisational aspects, we note that the findings and recommendations of the ODT (see paragraph 3.52) were very much based on the belief that significant increases in the number of organs donated after death could be achieved by improving every aspect of the organ donation infrastructure, from the way potential donors were identified, to the removal of financial disincentives from hospitals expected to carry out the operations to remove the organs, to the training and skills of the specialist nurses working with newly-bereaved families.
- 5.86 Continuing with our comparative approach set out in Chapter 1 of this report (see especially paragraphs 1.34 to 1.42), we consider not only the ethical implications of these approaches, but also the extent to which they are, or are not, applicable to diverse forms of bodily material. We reiterate here, as we have done elsewhere in this report, that we do not assume that an approach that is judged to be ethical and effective in one field will automatically be so in another. We also reiterate, as we set out in our Foreword, that while in Part I of this Report we sought to be as comprehensive as possible, in Part II we restrict ourselves to commenting on, and making recommendations in connection with, a more limited number of areas where we feel we have a contribution to make, based on the evidence that we have gathered during this enquiry. We note here that there are other areas – in particular surrogacy arrangements and the donation of whole bodies to medical schools for education and research – where we have not felt well-placed to make specific recommendations. Nevertheless, we hope that our ethical analysis will also be helpful to those working in these areas.

⁵⁶¹ These are only perspectives: we do not intend to suggest a division between 'individual' and 'society' – individuals are part of society and never act in isolation, while society is found within individuals, in their state of health, financial circumstances, the values to which they adhere, and so forth. However, it is still constructive to distinguish between those policy initiatives that seek primarily to change how individuals behave, and those targeted at the behaviour and functions of organisations.

⁵⁶² See, for example, Harrington M, Sweeney MR, Bailie K *et al.* (2007) What would encourage blood donation in Ireland? *Vox Sanguinis* 92: 361-7.

Chapter 6

Actions affecting
individuals

Chapter 6 - Actions affecting individuals

Chapter overview

Applying the values set out in Chapter 5, we suggest an 'Intervention Ladder' as a useful tool in analysing the ethical acceptability of different forms of encouragement for donating bodily material in various circumstances. Such an Intervention Ladder would include the following 'rungs':

- Rung 1: **information** about the need for the donation of bodily material for others' treatment or for medical research;
- Rung 2: **recognition** of, and gratitude for, altruistic donation, through whatever methods are appropriate both to the form of donation and the donor concerned;
- Rung 3: interventions to **remove barriers and disincentives** to donation experienced by those disposed to donate;
- Rung 4: interventions as an **extra prompt or encouragement** for those already disposed to donate for altruistic reasons;
- Rung 5: interventions offering **associated benefits in kind** to encourage those who would not otherwise have contemplated donating to consider doing so;
- Rung 6: **financial incentives that leave the donor in a better financial position** as a result of donating.

While we distinguish the first four 'rungs' of the Intervention Ladder as involving different degrees of organisational involvement and (potentially) cost, we do not distinguish them on ethical grounds: all are 'altruist-focused interventions', intended to stimulate people's altruistic motivation. The two final 'rungs' on the Ladder, which we class as non-altruist-focused interventions, do, on the other hand, involve ethically significant steps: scrutiny will be required to determine whether, in the circumstances, they may be ethically justified. We therefore recommend that, where a health need is not being met by altruist-focused interventions, the following factors should be closely scrutinised, in order to ascertain whether offering a form of non-altruist-focused intervention might or might not be harmful:

- The **welfare of the donor**;
- The **welfare of other closely concerned 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.

While the Intervention Ladder will be helpful in analysing the ethical acceptability of interventions that aim to encourage people in general to donate, there will also be circumstances in which other considerations will be relevant, such as where parents donate to their children; or where the lack of immediate benefit to others, as in many forms of research, may reduce the significance of altruism.

Our conclusions and recommendations with respect to 'how far one should go' in encouraging people to donate bodily material include:

- Living organ donors should not receive payment other than the direct reimbursement of costs incurred in being a donor;
- We suggest the introduction of a pilot scheme in which the NHS would meet funeral expenses for those who sign the ODR 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;
- We recommend the use of the term 'authorisation' rather than 'consent' with respect to choices about deceased donation, to reflect potentially different informational requirements between deceased and living donation;
- Mandated choice and prompted choice systems (which should include the option of saying no) are ethical options for seeking authorisation in advance to deceased organ donation;
- Lost earnings should be fully reimbursed for those donating gametes for others' treatment;
- We suggest the introduction of a pilot scheme offering payment to those who are prepared to donate eggs for research purposes;
- Payment for participation by healthy volunteers in first-in-human clinical trials within the UK should be retained as ethically justified.

Introduction

- 6.1 In this first of two chapters that set out the Council's conclusions as to 'how far one should go' in trying to meet demand for bodily material, we focus on the appropriateness of encouraging donors as individual persons. People may be influenced by many considerations, and there is much debate as to their likely responsiveness both to particular forms of encouragement and to particular ways in which their consent may be sought.

- 6.2 Chapter 4 highlighted how the values generally associated with the donation of bodily material – altruism and the idea of 'the gift', dignity, autonomy and justice, to name only a few – could be interpreted in diverse and sometimes contradictory ways. This certainly does not mean, however, that we consider that they become redundant. Rather, we emphasise that the way in which they are being used in particular circumstances should be made explicit and, where necessary, justified. In Chapter 5 we explored some of the many ways in which the idea of 'altruism' is used, and suggested that the aspect of altruism that perhaps most encapsulates the strong appeal of 'altruistic donation' very evident in UK society, is that of altruism as an expression of communal virtues (see paragraph 5.42). Such an idea of altruism is closely linked with solidarity: both may be seen as aspirational, setting a standard for the kind of society that one would wish to live in, particularly in the context of the way that society provides health care as a basic good. Similarly, the succinctness and comprehensiveness of the notion of 'the gift' (see paragraphs 4.9 to 4.14) continues to make it a good image with which to think. It makes a valuable contribution to the vocabulary with which the common good is conceptualised in this context, and is particularly powerful in the way that it joins up with individual motivation.
- 6.3 Such an aspiration, and such a concept of the 'common good', do not, however, by themselves, exclude other approaches to the donation of any particular form of bodily material. For example, if there were clear evidence that other approaches to donation would be very much more successful in terms of satisfaction of demand, then any loss of 'communal virtues' might have to be accepted as the price to be paid. In this chapter we apply our ethical framework with this in mind, considering also the issue of evidence.

Motivations and barriers to donation and volunteering

- 6.4 We start with a consideration of existing research on why people decide (or not) to donate bodily material or to participate in a first-in-human trial as a healthy volunteer. In order to inform its deliberations, the Council commissioned a snapshot review of the literature concerned with the motivating and deterring factors associated with decisions to donate blood, organs, tissue and gametes, or to participate in a first-in-human trial as a healthy volunteer.⁵⁶³ Because of the very large amount of literature in this field, the part of the review concerned with the donation of bodily material was limited to empirical studies based in the UK or Ireland, published in journals between 2000 and 2010. Twenty papers in total were identified: five on blood donation, nine on organ donation, two on tissue donation and four on egg donation (including egg-sharing). The review of the factors disposing people to participate in first-in-human trials was not limited to the UK, as long as they were reported in English-language journals; in total 15 studies were identified, carried out in Italy, Germany, the Netherlands, Portugal, Spain, the UK and the US.
- 6.5 For blood donors, key factors identified by donors in influencing their decision to donate included their awareness of the need for donated blood, advertising campaigns boosting that awareness, and trust in the blood transfusion service.⁵⁶⁴ One prospective study also found that belief in the personal benefits to be gained from donating (that is, that donation would make donors feel good about themselves) was the best predictor of future donation behaviour.⁵⁶⁵ Reasons given by non-donors were more wide-ranging: in one study 42 per cent of non-donors cited medical contraindications, with other factors being fear of needles, a simple lack of interest

⁵⁶³ See Appendix 1 for details of the evidence review and the criteria for inclusion. Because of the very large number of papers originally identified, the part of the review concerned with the donation of bodily material focused specifically on potentially modifiable factors relating to motivators and deterrents to donation rather than the personality characteristics of donors and non-donors.

⁵⁶⁴ Harrington M, Sweeney MR, Bailie K *et al.* (2007) What would encourage blood donation in Ireland? *Vox Sanguinis* **92**: 361-7; Sojka BN, and Sojka P (2008) The blood donation experience: self-reported motives and obstacles for donating blood *Vox Sanguinis* **94**: 56-63.

⁵⁶⁵ Ferguson E, Farrell K, and Lawrence C (2008) Blood donation is an act of benevolence rather than altruism *Health Psychology* **27**: 327-36.

in giving blood, and time constraints.⁵⁶⁶ The role of fear and anxiety was raised in a number of studies: such fears include anxiety about the process of blood donation itself (for example fear of needles or of fainting), fear of the unknown, and concerns about the risk of negative outcomes, such as contracting a blood-borne disease.⁵⁶⁷ In another, both donors and non-donors identified the same top three factors (a major disaster, more frequent mobile units and being specifically invited) as being most likely to encourage them to donate.⁵⁶⁸ The issue of easy access to donation facilities arose in a number of studies.⁵⁶⁹

- 6.6 Similar themes arose from the studies on those willing, or not, to contemplate being a deceased organ donor. Knowledge of organ donation and an absence of 'squeamishness' emerged as factors associated with those willing to 'sign up' as an organ donor, as did a sense of responsibility or obligation.⁵⁷⁰ Squeamishness about the idea of deceased donation (described by one author as the 'ick' factor) was strongly associated with a lack of willingness to sign up, as were beliefs that it is bad luck to contemplate one's own death (described as 'jinx').⁵⁷¹ Two other factors highlighted in these studies included medical mistrust (more prevalent in Black Caribbean, Black African and Indo-Asian respondents, but also significant for White respondents), and concern about disfigurement and the importance of remaining intact after death (specifically raised by many participants in a study of Muslim Indo-Asians living in the UK).⁵⁷² Medical mistrust was expressed both through the anxiety that a potential organ donor would not receive appropriate medical care (for example by less effort being put into resuscitation) and through concern that organs might be taken for other purposes than transplantation, or additional organs taken without consent.⁵⁷³
- 6.7 The two UK studies on tissue donation found a very positive response to requests for tissue for research, both in practice (where the study related to a retrospective review of the notes of patients invited to consent before surgery to subsequent use of their excised tissue)⁵⁷⁴ and in theory (a study questioning prostate cancer patients about their possible attitudes to donating surplus prostate tissue taken during biopsy for research).⁵⁷⁵ The first study is particularly striking in that, of over 3,000 patients asked to consent to the use of their tissue removed during surgery for commercial research, just 1.2 per cent refused. Reasons for refusing included mistrust of how the material would be used, and concern that their own care might be compromised (for example by not enough material being retained for their own diagnosis).

⁵⁶⁶ Harrington M, Sweeney MR, Bailie K *et al.* (2007) What would encourage blood donation in Ireland? *Vox Sanguinis* **92**: 361-7.

⁵⁶⁷ Giles M, McClenahan C, Cairns E, and Mallet J (2004) An application of the theory of planned behaviour to blood donation: the importance of self-efficacy *Health Education Research* **19**: 380; McVittie C, Harris L, and Tiliopoulos N (2006) I intend to donate but: non-donors' views of blood donation in the UK *Psychology, Health and Medicine* **11**: 1-6.

⁵⁶⁸ Harrington M, Sweeney MR, Bailie K *et al.* (2007) What would encourage blood donation in Ireland? *Vox Sanguinis* **92**: 361-7.

⁵⁶⁹ For example, Giles M, McClenahan C, Cairns E, and Mallet J (2004) An application of the theory of planned behaviour to blood donation: the importance of self-efficacy *Health Education Research* **19**: 380.

⁵⁷⁰ Bennett R, and Savani S (2004) Factors influencing the willingness to donate body parts for transplantation *Journal of Health & Social Policy* **18**: 61 - 85; Farsides T (2010) Perceived responsibility to act: an investigation with respect to registering willingness to become a posthumous organ donor *British Journal of Psychology* **101**: 503-17.

⁵⁷¹ O'Carroll RE, Foster C, McGeechan G, Sandford K, and Ferguson E (2011) The "ick" factor, anticipated regret, and willingness to become an organ donor *Health Psychology* **30**: 236.

⁵⁷² Morgan M, Hooper R, Mayblin M, and Jones R (2006) Attitudes to kidney donation and registering as a donor among ethnic groups in the UK *Journal of Public Health* **28**: 226-34; AlKhawari FS, Stimson GV, and Warrens AN (2005) Attitudes toward transplantation in UK Muslim Indo-Asians in West London *American Journal of Transplantation* **5**: 1326-31.

⁵⁷³ Morgan M, Hooper R, Mayblin M, and Jones R (2006) Attitudes to kidney donation and registering as a donor among ethnic groups in the UK *Journal of Public Health* **28**: 226-34; AlKhawari FS, Stimson GV, and Warrens AN (2005) Attitudes toward transplantation in UK Muslim Indo-Asians in West London *American Journal of Transplantation* **5**: 1326-31. See also: NHS Blood and Transplant (24 February 2009) *Will they respect my body after I am dead?*, available at: http://www.organdonation.nhs.uk/ukl/newsroom/news_releases/article.jsp?releaseId=226, which details an online survey which found that, of respondents who stated that they were undecided or against joining the ODR, more than half said that they were worried about how their body would be treated after death.

⁵⁷⁴ Jack AL, and Womack C (2003) Why surgical patients do not donate tissue for commercial research: review of records *BMJ* **327**: 262.

⁵⁷⁵ Fitzpatrick PE, McKenzie KD, Beasley A, and Sheehan JD (2009) Patients attending tertiary referral urology clinics: willingness to participate in tissue banking *BJU international* **104**: 209-13.

- 6.8 The one study of 'egg sharers' included in the review highlighted that 'personal gain' (defined in the study as the possibility of achieving motherhood) was a primary motivation for entering into an egg-sharing arrangement. The study did, however, suggest that empathy with those needing donor eggs in order to have the chance to conceive was also experienced as a motivating factor.⁵⁷⁶ Other studies of egg sharers not included within the review similarly noted that those entering in egg-sharing arrangements describe their motivations as both self-interested and altruistic.⁵⁷⁷ The three remaining studies explored factors associated with the intention of donating eggs outside the context of egg sharing, both for another person's treatment and for research: identified factors include positive attitudes towards the value of egg donation and the importance of parenthood, a sense of control over the decision-making process, and support from others.⁵⁷⁸ A systematic review of English-language peer-reviewed studies on egg donation, published in 2009, noted 12 studies that included volunteer egg donors: motivations cited in these studies included both general altruistic motives for donation and personal experiences of infertility (for example through family and friends).⁵⁷⁹
- 6.9 Finally, the studies concerned with the motivations of healthy volunteers in first-in-human clinical trials overwhelmingly highlighted the importance of the financial rewards offered: between 45 per cent and 90 per cent of respondents in various different surveys highlighted this as the main motivating factor.⁵⁸⁰ Other motivating factors, in many cases running alongside the interest in the financial reward, included the wish to contribute to scientific progress (40 per cent and 48 per cent in two studies),⁵⁸¹ a sense of social responsibility, and curiosity.⁵⁸² In two of the studies, 8.8 per cent and 14 per cent of participants respectively stated that they would have participated even if no financial reward were offered.⁵⁸³
- 6.10 Inevitably, the research evidence cited above can only touch the surface of the available literature. We also flag here the well-known difficulty of interpreting what is told to the researcher: that one's description of one's own motivation in any particular case may only ever

⁵⁷⁶ Rapport F (2003) Exploring the beliefs and experiences of potential egg share donors *Journal of Advanced Nursing* **43**: 28-42.

⁵⁷⁷ Ahuja K, Mostyn B, and Simons E (1997) Egg sharing and egg donation: attitudes of British egg donors and recipients *Human Reproduction* **12**: 2845-52; Ahuja KK, Simons EG, Mostyn BJ, and Bowen-Simpkins P (1998) An assessment of the motives and morals of egg share donors: policy of 'payments' to egg donors requires a fair review *Human Reproduction* **13**: 2671-8; Blyth E (2004) Patient experiences of an "egg sharing" programme *Human Fertility* **7**: 157-62.

⁵⁷⁸ Purewal S, and van den Akker OBA (2006) British women's attitudes towards oocyte donation: ethnic differences and altruism *Patient Education and Counseling* **64**: 43-9; Purewal S, and van den Akker OBA (2009) Attitudes and intentions towards volunteer oocyte donation *Reproductive BioMedicine Online* **19**: 19-26; Purewal S, and van den Akker O (2010) Attitudes and intention to donate oocytes for research *Fertility and Sterility* **93**: 1080-7.

⁵⁷⁹ Purewal S, and van den Akker O (2009) Systematic review of oocyte donation: investigating attitudes, motivations and experiences *Human Reproduction Update* **15**: 499. The studies included took place in Australia, Finland, New Zealand and the UK.

⁵⁸⁰ Hermann R, Heger-Mahn D, Mahler M *et al.* (1997) Adverse events and discomfort in studies on healthy subjects: the volunteer's perspective: a study conducted by the German Association for Applied Human Pharmacology *European Journal of Clinical Pharmacology* **53**: 207-14; Tishler C, and Bartholomae S (2002) The recruitment of normal healthy volunteers: a review of the literature on the use of financial incentives *Journal of Clinical Pharmacology* **42**: 365-75; Almeida L, Azevedo B, Nunes T, Vaz-da-Silva M, and Soares-da-Silva P (2007) Why healthy subjects volunteer for phase I studies and how they perceive their participation? *European Journal of Clinical Pharmacology* **63**: 1085-94; Ferguson PR (2008) Clinical trials and healthy volunteers *Medical Law Review* **16**: 23-51.

⁵⁸¹ Hermann R, Heger-Mahn D, Mahler M *et al.* (1997) Adverse events and discomfort in studies on healthy subjects: the volunteer's perspective: a study conducted by the German Association for Applied Human Pharmacology *European Journal of Clinical Pharmacology* **53**: 207-14; Almeida L, Azevedo B, Nunes T, Vaz-da-Silva M, and Soares-da-Silva P (2007) Why healthy subjects volunteer for phase I studies and how they perceive their participation? *European Journal of Clinical Pharmacology* **63**: 1085-94.

⁵⁸² Hermann R, Heger-Mahn D, Mahler M *et al.* (1997) Adverse events and discomfort in studies on healthy subjects: the volunteer's perspective: a study conducted by the German Association for Applied Human Pharmacology *European Journal of Clinical Pharmacology* **53**: 207-14; Almeida L, Azevedo B, Nunes T, Vaz-da-Silva M, and Soares-da-Silva P (2007) Why healthy subjects volunteer for phase I studies and how they perceive their participation? *European Journal of Clinical Pharmacology* **63**: 1085-94; Ferguson PR (2008) Clinical trials and healthy volunteers *Medical Law Review* **16**: 23-51.

⁵⁸³ Almeida L, Azevedo B, Nunes T, Vaz-da-Silva M, and Soares-da-Silva P (2007) Why healthy subjects volunteer for phase I studies and how they perceive their participation? *European Journal of Clinical Pharmacology* **63**: 1085-94; Almeida L, Falcao A, Coelho R, and Albino-Teixeira A (2008) The role of socioeconomic conditions and psychological factors in the willingness to volunteer for phase I studies *Pharmaceutical Medicine* **22**: 367-74.

provide part of the picture. There is an important distinction to be made between, on the one hand, asking people whether or not they would be motivated by money to carry out a particular action, and, on the other, actually offering the money and finding out how many act as they had envisaged (see paragraph 6.19). Keeping these qualifications in mind, we would suggest that a number of points can, tentatively, be made from the research reviewed above.

- 6.11 First, certain themes arose repeatedly, and across different domains of donation. Common barriers were squeamishness and feelings of unease about the idea of donation, and medical mistrust (expressed both as fears, however unfounded,⁵⁸⁴ of the consequences for one's own care, and in terms of the future use of the donated material). „Squeamishness“ in connection with the donation of blood also took more concrete form in terms of fear and anxiety about the use of needles, fainting and other negative outcomes. Deceased donation brought its own particular concerns both about the 'jinx' effect of contemplating one's own death, and anxiety about disfigurement and lack of bodily integrity in death. Factors disposing people to donate, on the other hand, included good awareness of the positive benefits for others (or for medical science more generally), a sense of social responsibility, and good practical arrangements that minimise the burden of making a donation. Such factors support the notion of the 'two-pronged' approach set out in paragraph 5.84: of considering both how individuals may personally be encouraged (for example by measures to improve awareness of the impact of donation) and how organisations may remove barriers (for example by making donation as efficient, and as convenient to the individual as possible). Importantly, in identifying the role of „squeamishness“, anxiety and 'jinx' factors, the studies highlight a subgroup of individuals whose behaviour will be relatively difficult to influence; and by implication it could be argued that any efforts to increase donation rates by changing behaviour would best be targeted at those without such concerns.
- 6.12 Second, the figure of 98.8 per cent of patients who agreed to allow their excised tissue to be used for commercial research is striking. It suggests that, if approached appropriately, the vast majority of patients do not have any objection either to permitting research use of tissue excised during surgery, or to such uses being commercial. Again, this suggests that there is little, if any, value in pursuing those who clearly do not feel comfortable with such uses, while emphasising the value of systematic approaches to informing patients of potential research uses of their tissue and seeking their consent at an appropriate time.⁵⁸⁵
- 6.13 Third, while 'medical mistrust' may have wide range of sources (many of which will be beyond the scope of this report), examples of such mistrust cited in the studies included anxiety about how donors' consent might be abused: for example using material for other purposes than that stipulated in the original consent, or taking material (other organs or tissue, for example) not included in the consent. We return to this issue when we consider possible changes to consent defaults later in this chapter (see paragraph 6.47).
- 6.14 Fourth, the relatively high figure of non-blood-donors in one study who stated that there were medical reasons why they did not donate (42%) highlights the point made earlier in this report (see paragraph 3.6) that not everyone is 'eligible' to be a donor, whether of blood or other materials.⁵⁸⁶ Such a consideration highlights the serious difficulties involved in schemes that aim to increase donation by giving priority in allocation to those willing to give, however attractive and reasonable such schemes may seem at first sight (see paragraphs 2.48 and 3.74).
- 6.15 Finally, the studies on healthy volunteers demonstrate very clearly that, for the majority of healthy volunteers in first-in-human trials, the financial reward offered in return for their involvement is perceived as an incentive to participate, and not simply as a reimbursement of

⁵⁸⁴ We note here that, although very clear systems are in place in the UK to ensure that decisions about possible organ donation cannot affect a patient's own health care, nevertheless, a more general lack of trust in the system may mean that this fear, however unfounded, will still affect some individuals' decisions.

⁵⁸⁵ This evidence cannot, of course, be extrapolated to the situation of non-patient donors, for whose views evidence comes from other sources, see paragraph 6.82.

⁵⁸⁶ The figure of 42 per cent certainly seems high, and may reflect either misperceptions of eligibility or a desire to find a socially acceptable reason to explain one's non-donation status; however, the key point remains that not everyone can donate.

their lost time or earnings. At the same time, most participants were still keen to emphasise that other more „social“ motivations, such as a desire to contribute to developments in science, had played a part in their decision, alongside the financial incentive. This leads us on to a consideration of the potential role of such incentives in the donation of bodily material itself.

Incentives and decision-making

- 6.16 Chapter 5 referred briefly to the limited evidence available as to the impact of financial incentives on the supply of bodily materials, and referred forward to this chapter for a more detailed account of that evidence. The Council commissioned a review of English-language peer-reviewed studies presenting data on the impact of offering a financial incentive to potential donors, on either the quality or the quantity of material donated (blood, eggs, kidneys from living donors, and liver from living donors), or on the quality of the decision to donate.⁵⁸⁷ Only studies that explicitly compared two groups (non-incentivised and incentivised) were included. In total, 22 studies were identified that considered the effect of an incentive on the quality of the donated material, and four that considered the effect of an incentive on the quantity (two dealing with both). None was found that contrasted the quality of the decision-making process (for example how carefully risk was considered, or the extent to which the donor later endorsed or regretted their decision to donate) between an incentivised and non-incentivised group in the same study.
- 6.17 Of the 22 studies comparing the effect of incentives on the **quality** of material donated, 14 concerned blood⁵⁸⁸ and eight kidneys.⁵⁸⁹ No studies on gametes were found that met the review criteria. For blood, offering financial incentives to donors is associated with greater levels of infection in blood, unless the incentive itself is contingent upon the provision of good-quality blood (for example, by withholding the incentive until after satisfactory results from testing). Similarly, for kidneys, financial incentives are associated with worse outcomes (measured in

⁵⁸⁷ See Appendix 1 for more detail of the evidence review. Exchanges of little or no financial value, such as badges, certificates or mugs were excluded; however reward in kind, such as egg-sharing schemes, were included.

⁵⁸⁸ The studies took place in China, Germany, India, Lithuania, Nigeria, Switzerland and the US: Singh YN, Malaviya AN, Tripathy SP *et al.* (1990) Human immunodeficiency virus infection in the blood donors of Delhi, India *JAIDS Journal of Acquired Immune Deficiency Syndromes* **3**: 152; Dawson GJ, Lesniewski RR, Stewart JL *et al.* (1991) Detection of antibodies to hepatitis C virus in US blood donors *Journal of Clinical Microbiology* **29**: 551-6; Strauss RG, Ludwig GA, Smith MV *et al.* (1994) Concurrent comparison of the safety of paid cytopheresis and volunteer whole-blood donors *Transfusion* **34**: 116-21; Jha J, Banerjee K, and Arankalle V (1995) A high prevalence of antibodies to hepatitis C virus among commercial plasma donors from Western India *Journal of Viral Hepatitis* **2**: 257-60; Wu R-R, Hata A, Sasaki M *et al.* (1995) Seroprevalence of hepatitis C virus infection and its genotype in Lanzhou, Western China *Journal of Medical Virology* **45**: 174-8; Dille BJ, Surowy TK, Gutierrez RA *et al.* (1997) An ELISA for detection of antibodies to the E2 protein of GB virus C *Journal of Infectious Diseases* **175**: 458-61; Strauss RG (2001) Blood donations, safety, and incentives *Transfusion* **41**: 165-7; Durosinmi M, Mabayoje V, Akinola N, Adegunloye A, and Alabi A (2003) A retrospective study of prevalence of antibody to HIV in blood donors at Ile-Ife, Nigeria *The Nigerian postgraduate medical journal* **10**: 220; Kretschmer V, Weippert-Kretschmer M, Slonka J, Karger R, and Zeiler T (2004) Perspectives of paid whole blood and plasma donation *Transfusion Medicine and Hemotherapy* **31**: 301-7; Erhabor O, Ejele O, and Nwauche C (2006) The risk of transfusion-acquired hepatitis-C virus infection among blood donors in Port Harcourt: the question of blood safety in Nigeria *Nigerian Journal of Clinical Practice* **9**: 18-21; Jeremiah ZA, Koate B, Buseri F, and Emelike F (2008) Prevalence of antibodies to hepatitis C virus in apparently healthy Port Harcourt blood donors and association with blood groups and other risk indicators *Blood Transfusion* **6**: 150; Kalibatas V (2008) Payment for whole blood donations in Lithuania: the risk for infectious disease markers *Vox Sanguinis* **94**: 209-15; Goette L, Stutzer A, and Zentrum UBW (2008) *Blood donations and incentives: evidence from a field experiment* (Basel: Wirtschaftswissenschaftliches Zentrum (WWZ) der Universität Basel); Lacetera N, Macis M, and Slonim R (2009) Will there be blood? incentives and substitution effects in pro-social behavior *IZA Discussion Papers*: No. 4567.

⁵⁸⁹ The studies took place in Canada, India, Iran, Saudi Arabia and the UK and included patients who had travelled to other countries for (illegal) transplants. See: Qunibi W (1997) Commercially motivated renal transplantation: results in 540 patients transplanted in India *Clinical Transplantation* **11**: 536-44; Morad Z, and Lim T (2000) Outcome of overseas kidney transplantation in Malaysia *Transplantation Proceedings* **32**: 1485-6; Ghods AJ (2002) Renal transplantation in Iran *Nephrology Dialysis Transplantation* **17**: 222-8; Higgins R, West N, Fletcher S *et al.* (2003) Kidney transplantation in patients travelling from the UK to India or Pakistan *Nephrology Dialysis Transplantation* **18**: 851-2; Prasad GVR, and McFarlane PA (2006) Occult nephrolithiasis in prospective kidney donors: a source for hematuria *Transplantation* **82**: 849-50; Gill J, Madhira B, Gjertson D *et al.* (2008) Transplant tourism in the United States: a single-center experience *Clinical Journal of the American Society of Nephrology* **3**: 1820; Krishnan N, Cockwell P, Devulapally P *et al.* (2010) Organ trafficking for live donor kidney transplantation in Indoasians resident in the West Midlands: high activity and poor outcomes *Transplantation* **89**: 1456-61; Alghamdi SA, Nabi ZG, Alkhafaji DM *et al.* (2010) Transplant tourism outcome: a single center experience *Transplantation* **90**: 184-8.

terms, for example, of post-surgical infections, graft survival rates and patient survival rates), although this must be placed in the context of a mainly illegal 'market' in incentivised organs.⁵⁹⁰ Thus, the evidence that does exist tends towards supporting the argument that the quality of some bodily materials may suffer where financial incentives are offered to encourage donors to come forward. However, as we have already suggested in paragraph 5.37, this argument does not seem particularly compelling for the UK, certainly in the context of blood, given the availability of testing. In the context of living kidney donations, the illegal nature of most of those operations on which data are available makes any kind of meaningful comparison exceedingly difficult.

- 6.18 The four studies considering the impact of offering financial incentives on the **quantity** of material provided all concerned blood. One carried out in Sweden among 262 students found that the offer of a small financial incentive (\$7) had neither a positive nor a negative effect overall on determining whether potential blood donors actually donated.⁵⁹¹ Nor did the alternative option of donating the money to charity increase donation rates. A Swiss study (involving over 11,000 participants) similarly found that the offer of a free cholesterol test had no effect on donation rates.⁵⁹² A second Swiss study of 10,000 previous blood donors showed a five per cent higher donation rate in those offered a free lottery ticket (estimated face value \$4.30; speculative value incalculable), over those receiving a simple request to donate, and those being additionally offered a cholesterol test (estimated value \$13).⁵⁹³ It was noted that the increase in donations among those offered a lottery ticket derived from those with a low rate of past donations, with no effect (positive or negative) on those with a past high rate. Finally, an analysis of those attending American Red Cross 'blood drives' in northern Ohio between May 2006 and October 2008 (over 14,000 blood drives) found that overall response rates increased by 16 per cent when incentives such as t-shirts, vouchers and mugs were offered. No impact was noted on the proportion of donors rejected on quality grounds.⁵⁹⁴ These results were replicated in a small-scale field experiment of four pairs of blood drives, where one drive from each pair offered potential donors a gift card (\$5 in two drives and \$20 in the other two), while no incentive was offered to the paired controls. Both turnout and the amount of blood collected at the drives offering the incentives were increased, with larger effects noted in connection with the greater incentive.⁵⁹⁵
- 6.19 Clearly, this is a small number of studies from which to draw firm conclusions (although the substantial size of the cohorts should be noted). However, two points should be highlighted. First, the limited evidence that does exist from these observational and experimental studies does not support the thesis that altruistic donors are 'crowded out' by the availability of a (small) financial incentive. This contrasts with the findings of studies that only ask people about their *intentions* (as opposed to measuring their actual behaviour), which appear to support concerns about the possibility of crowding out.⁵⁹⁶ The same distinction between intention and actual behaviour is demonstrated by the failure in the Swiss studies to recruit additional donors by offering a free cholesterol test, since surveys of intention regularly suggest such an offer would be effective.⁵⁹⁷ On the other hand, studies from Iran (which do not, of course, derive from the kind of controlled experiment or observational study included within our review) note how the

⁵⁹⁰ Iran is the only country that permits financial reward to be offered to living kidney donors.

⁵⁹¹ Mellström C, and Johannesson M (2008) Crowding out in blood donation: was Titmuss right? *Journal of the European Economic Association* 6: 845-63.

⁵⁹² Goette L, Stutzer A, Yavuzcan G, and Frey BM (2009) Free cholesterol testing as a motivation device in blood donations: evidence from field experiments *Transfusion* 49: 524-31.

⁵⁹³ Goette L, Stutzer A, and Zentrum UBW (2008) *Blood donations and incentives: evidence from a field experiment* (Basel: Wirtschaftswissenschaftliches Zentrum (WWZ) der Universität Basel).

⁵⁹⁴ Lacetera N, Macis M, and Slonim R (2009) Will there be blood? incentives and substitution effects in pro-social behavior *IZA Discussion Papers*: No. 4567.

⁵⁹⁵ Ibid.

⁵⁹⁶ See, for example, Goette L, Stutzer A, and Frey BM (2010) Prosocial motivation and blood donations: a survey of the empirical literature *Transfusion Medicine and Hemotherapy* 37: 149-54. See also: Webb TL, and Sheeran P (2006) Does changing behavioral intentions engender behavior change? A meta-analysis of the experimental evidence *Psychological Bulletin* 132: 249-68.

⁵⁹⁷ Glynn SA, Williams AE, Nass CC *et al.* (2003) Attitudes toward blood donation incentives in the United States: implications for donor recruitment *Transfusion* 43: 7-16.

creation of an officially incentivised system has led to a decrease in the number of unpaid related donations: one author suggests that this decrease not only derives from the ready availability of paid unrelated volunteers, but is also due to the elimination of "coercive living-related donor transplants" where families feel emotional coercion to donate.⁵⁹⁸

- 6.20 The second point to highlight is that there is, albeit very limited, evidence to suggest that what might be described as 'token' incentives for donating blood (low-value vouchers or a lottery ticket) can increase donors and donations: by five per cent and 16 per cent in two of the studies cited above (see paragraph 6.18). Such evidence, particularly when set beside 'uncontrolled' data (such as the large number of kidney sellers in Iran, or the ready availability of eggs for others' infertility treatment in the US⁵⁹⁹), serves to suggest that the offer of financial incentives will indeed have an incentivising effect on some people. Given, however, that the 'controlled' studies that do exist relate only to blood (which contrasts with many other forms of donation in that repeat donations are strongly encouraged and hence a strong 'donor base' willing to donate regularly is particularly important), and that it is always very difficult to know how results from one culture and set of circumstances may translate to another, such conclusions should be regarded at this stage as tentative.
- 6.21 Finally, we consider further the point made in paragraph 6.19 in connection with 'crowding-out', that what people say they will do in certain circumstances does not necessarily match what they actually do. In tandem with the public consultation carried out by the Working Party itself, the organisation 'new economics foundation' (nef) set up a 'street talk' project in August 2010, in which nearly 500 people in shopping streets and centres were invited to give their opinions on the efficacy and ethics of various forms of incentives for donation.⁶⁰⁰ A significant majority of respondents thought that direct payments of any size were unethical and would not influence their own decision to donate, while a donation to charity in return for bodily donation was viewed much more positively. As we note above, the lack of response to the offer of a donation to charity in the Swedish study on blood suggests that such offers do not seem necessarily to influence actual behaviour. However, the fact that many people expressed a theoretical liking for and approval of such a suggestion (coupled with dislike of the notion of direct financial payment in return for bodily donation) might be seen as a further endorsement of the *ideal* of a system based on altruism and concern for others, regardless of what decision that individual would personally make in practice. This brings us back, yet again, to the concept of altruism as an expression of 'communal virtues'.

An 'Intervention Ladder' for promoting donation

- 6.22 In the Nuffield Council's earlier report *Public health: ethical issues*, the Council set out the idea of an 'Intervention Ladder' as a way of thinking about the acceptability of, and justification for, a range of public health policies.⁶⁰¹ The bottom 'rung' of the Intervention Ladder will usually be to do nothing or monitor the situation, with successively higher 'rungs' involving action to enable or guide individuals' choices, restricting choices, and finally (at the very top) legislating to remove individual choice altogether. The more intrusive and restrictive the policy on individual choice and liberty, the greater the justification required for the public health policy, in terms both of the possible benefits, and of the strength of the evidence that such benefits will indeed eventuate.

⁵⁹⁸ Ghods AJ, and Savaj S (2006) Iranian model of paid and regulated living-unrelated kidney donation *Clinical Journal of the American Society of Nephrology* 1: 1136-45. See also: Bagheri A (2006) Compensated kidney donation: an ethical review of the Iranian model *Kennedy Institute of Ethics Journal* 16: 269-82.

⁵⁹⁹ Levine A (2011) The oversight and practice of oocyte donation in the United States, United Kingdom and Canada *HEC Forum* 23: 15-30.

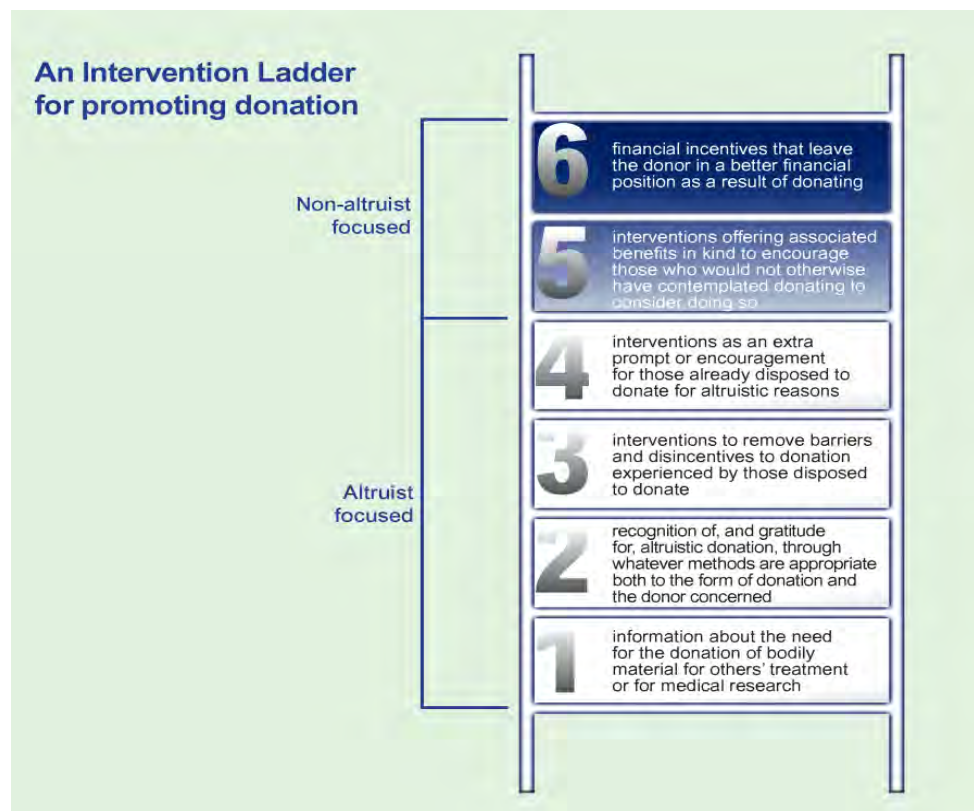
⁶⁰⁰ See Appendix 1 for more details of this project, which was carried out independently of the Working Party by nef, but drew on material in the Working Party's consultation document.

⁶⁰¹ Nuffield Council on Bioethics (2007) *Public health: ethical issues*, available at: <http://nuffieldbioethics.org/sites/default/files/Public%20health%20-%20ethical%20issues.pdf>, paragraphs 3.37-8.

6.23 On the basis of our ethical discussions set out in Chapter 5, and of the evidence regarding the effectiveness of incentives summarised above, we suggest that an Intervention Ladder would similarly provide a useful tool to help those considering what, if any, forms of additional encouragement should be offered to potential donors to increase the supply of bodily materials or healthy volunteers, whether for treatment or research. We emphasise here that the rungs of the Intervention Ladder take the form of *inputs*: how individuals respond to such inputs will clearly vary from person to person, and indeed inevitably there will be some degree of overlap in how people respond to neighbouring 'rungs'. *We also note that the Intervention Ladder should not be seen as moving from 'ethical' actions to 'unethical' actions, but rather from actions that are ethically straightforward to those that are ethically more complex.* Thus, action in accordance with the higher rungs may only be ethical in particular circumstances or contexts. Finally, we emphasise that such a tool clearly cannot capture every consideration of ethical relevance, but rather serves to highlight some of the most common ethical concerns that are likely to arise. With these provisos in mind, we draw on the categorisation of forms of encouragement set out in Chapter 3 (see paragraph 3.68), and present a ladder with the following 'rungs':

- **Rung 1: information** about the need for the donation of bodily material for others' treatment or for medical research;
- **Rung 2: recognition** of, and gratitude for, altruistic donation, through whatever methods are appropriate both to the form of donation and the donor concerned;
- **Rung 3: interventions to remove barriers and disincentives to donation** experienced by those disposed to donate;
- **Rung 4: interventions as an extra prompt or encouragement** for those already disposed to donate for altruistic reasons;
- **Rung 5: interventions offering associated benefits in kind** to encourage those who would not otherwise have contemplated donating to consider doing so;
- **Rung 6: financial incentives** that leave the donor in a better financial position as a result of donating.

As an Intervention Ladder, with rung 1 starting at the bottom, the six rungs will thus look like this:



- 6.24 While we distinguish the first four 'rungs' of the Intervention Ladder as involving different degrees of organisational involvement and (potentially) cost, we do not distinguish them on *ethical* grounds: we consider them all to be 'altruist-focused interventions' (see paragraph 5.27). We do not consider that refunding expenses involved in donation or providing minor tokens as a 'spur' to donation involve ethical compromises in a way that information campaigns or letters of thanks do not. Thus the rationale for deciding between these four rungs will effectively be empirical: is it necessary to advance a 'rung', or start on a higher rung, to ensure that people are not only willing to donate but feel valued for their donation? Indeed, if there is evidence that people who would like to be able to donate are prevented from doing so by cost (for example if a person who wishes to donate a kidney to a family member cannot afford the time off work involved), then it would seem only just to ensure that they are as well able to donate as someone who is sufficiently wealthy not to be affected by such considerations.
- 6.25 Moves from these altruist-focused interventions to the two final 'rungs' on the Intervention Ladder, which we class as non-altruist-focused interventions, are, on the other hand, ethically significant steps: scrutiny will be required to determine whether, in the circumstances, they may be ethically justified. In Chapter 5, we concluded that, while many of the arguments in favour of altruistic models were powerful, none was absolutely decisive, and that ultimately any decision on whether to offer reward either in kind or in money to potential donors would depend on the evidence as to the *effect* of such incentives both on the person donating, and on what might be termed the 'common good'. We acknowledge here that some will regard any intervention that encourages donation of bodily material primarily for non-altruistic purposes as simply 'mis-valuing' body parts, and would not consider such interventions to be acceptable in any circumstances. Others strongly disagree. As we highlight earlier (see paragraphs 4.17 to 4.21), public policy has to find a way forward in the light of such competing views of the importance of the body, and we have suggested that key areas of common ground lie in consideration of the potential harms that are feared might arise from the creation of such interventions, to the person donating, to others closely concerned, and to wider social values and relationships.
- 6.26 **We therefore recommend that, where a health need is not being met by altruist-focused interventions, the following factors should be closely scrutinised in order to ascertain whether offering a form of non-altruist-focused intervention might or might not be harmful:**
- **The welfare of the donor: this should be understood very broadly, including physical and psychological risks at the time of donation, physical and psychological risks in the future, and the extent to which the donor feels they have other options open to them;**
 - **The welfare of other closely concerned individuals;**
 - **The potential threat to the common good: for example the possible impact on existing donation systems, and the risk of increasing social inequalities;**
 - **The professional responsibilities of the health professionals involved; and**
 - **The strength of the evidence on all the factors listed above.**⁶⁰²
- 6.27 We also suggest that interventions providing associated benefits in kind may be less likely than those offering a straightforward financial reward to be perceived as a 'purchase' of a body part: indeed, for egg sharing we have noted the argument that the benefit being received is not

⁶⁰² We note, of course, that considerations such as the welfare of the donor are clearly essential in determining whether *any* form of donation or volunteering is acceptable. The specific question here is whether offering incentives to donate might raise *additional* concerns in any of these areas. In considering what forms of encouragement could be ethically acceptable for donating any form of bodily material, we have taken the status quo in the UK as a starting point: we have not, for example, sought to re-examine the basis of living kidney donation, or the acceptability of the creation of embryos for research purposes.

financial at all in nature but rather the *opportunity* to bear a child.⁶⁰³ Given that one of the key concerns around any forms of non-altruistic-focused intervention is the risk of material being mis-valued, we distinguish between these two approaches through rungs 5 and 6 on the Intervention Ladder. We also emphasise that the 'benefits in kind' envisaged in rung 5 are benefits that are closely associated with the donated material, as in, for example, the covering of cremation costs where bodies have been donated for medical education (see paragraph 2.34).⁶⁰⁴ In such cases the benefit in kind is clearly situated within the domain of what has been donated. Non-associated benefits in kind (for example high-value vouchers) fall within rung 6, in that their primary purpose is to offer a straightforward financial benefit. In relation to rung 6, then, the key question is what may constitute ethical payment, and in what circumstances. We suggest that, where the intervention involves a direct payment of money or equivalent, it is an essential pre-requisite that the payment is understood, by all parties, in terms of reward to the *person* for their act of providing bodily material, rather than a purchase of material itself.

- 6.28 We return to these factors in more detail below, when we consider the various bodily materials where non-altruistic-focused interventions are already offered in the UK, or have been put forward as future options. We also note here that, while the Intervention Ladder is, we believe, helpful in analysing the ethical acceptability of interventions that aim to encourage people in general to donate, there will be circumstances in which other considerations may be much more dominant: for example where the possibility of donation arises in the context of close relationships, as in where parents donate to their children; or in contexts where the lack of immediate benefit to identifiable individuals, as in many forms of research, may reduce the significance of altruism. It will also be less relevant in considering issues around the ongoing post-donation role or interest of the donor in connection with the use of the material.

Consent

- 6.29 As we discuss in Chapter 5, we believe that it is essential for people's wishes regarding donation to be clear before bodily material may be taken (see paragraph 5.61). For living donors, it goes without saying that explicit consent, based on adequate information about the procedure, its implications and the associated risks, is required. For donation after death, explicit expression of the person's views before death is preferable. In the absence of such a record of wishes (including the absence of any evidence of objection), information as to their likely wishes should be sought from those close to the deceased person, who are usually best placed to know the deceased person's wishes, and who themselves, in their bereavement, have a stake in how their deceased relative's body is treated. We take this overall view on the basis that there is sufficient evidence that, for many people, the disposal of their bodily material is a matter of significant personal concern, and that to take material without some evidence that this is in accordance with the person's wishes risks treating the person's body as a means to others' ends.⁶⁰⁵
- 6.30 Clearly not everyone regards their bodily material – during life or during death – in such a way, but the entrenched and opposing views on proposals for an 'opt-out' approach to deceased organ donation highlight the fundamental lack of consensus on this issue within the UK.⁶⁰⁶ However, as we also set out in Chapter 5, we make a distinction between what is required for valid consent to an intervention during one's lifetime, and what should be required for valid

⁶⁰³ Similarly, access to NHS-funded fertility treatment would not usually be regarded as an incentive 'worth' a particular amount of money, although the direct alternative when NHS care is not available is to pay that amount to a private clinic.

⁶⁰⁴ Human Tissue Authority (2011) *How to donate your body*, available at: [http://www.hta.gov.uk/db/documents/Body & brain donation information pack June 2011.pdf](http://www.hta.gov.uk/db/documents/Body%20&%20brain%20donation%20information%20pack%20June%202011.pdf).

⁶⁰⁵ The original ethical point here relates to using persons as means to others' ends. The deceased body is in an ambiguous position. Injury to the body can no longer literally injure the (deceased) person, and what is at issue is the extent to which family, kin and others who knew the person continue to associate the person with the body, so its treatment is significant as a metaphor or sign of their relationship with the person now departed.

⁶⁰⁶ Department of Health (2008) *The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090303.pdf, pp4-5.

consent in respect of a deceased person's bodily material (see paragraph 5.63). In particular, we suggest that the degree of detail required when providing information about the proposed procedure will differ significantly, and that it should be possible for a person to provide legal authority for donation after death on the basis of quite minimal information, if this is sufficient for them to be clear about their own wishes.

- 6.31 Finally, we emphasise here the importance of consent in creating and maintaining trust in health professionals and the health care system as a whole. We noted above (see paragraph 6.13) that where 'medical mistrust', or mistrust of the system, is cited as a reason for people to hold back from donating bodily material, this may be associated with concerns about consent: both that the terms of the consent may be abused (for example by using the donated material in a different way from that envisaged in the consent) and that additional material may be taken without explicit consent. We highlighted in Chapter 4 (see paragraph 4.3) how values such as honesty and trust were raised by our consultation respondents as central in both the professional and personal relationships affected by the donation of bodily material. While we cannot make any clear findings from the evidence available to us as to the *levels* of such mistrust within the UK at present, we conclude that it is a factor that must be taken into account when considering any changes to approaches to consent.

Implications for different forms of bodily material

- 6.32 We now consider the implications both of our Intervention Ladder and of our stance on consent, for the way individuals within the UK are currently encouraged to donate various forms of bodily material or participate as a healthy volunteer for a first-in-human trial. We reiterate here that this Part II of the report does not seek to be comprehensive, but rather focuses on areas where the evidence we have obtained enables us to make useful recommendations. However, we hope that the examples of how the rungs could be used, as in the discussion of blood, organs and gametes that follows, may indicate how the Intervention Ladder can potentially be used by others in terms of material that is not here considered in any detail, such as bone marrow or cord blood.

Blood

- 6.33 While blood stocks fluctuate, and there may be intermittent pressures on stocks of particular blood groups, blood shortages in the UK are rare (see paragraph 3.5). Where stocks do run low (for example because of bad weather leading to cancelled donor sessions), urgent appeals for donors are generally effective in bringing supplies back up to safe levels.⁶⁰⁷ The evidence suggests that, while new donors are always needed in order to ensure a reliable donor base, the current system is broadly effective in meeting the UK's health needs. That current system relies on good publicity and awareness among the general public as to the constant need for blood (see Box 3.3), motivational procedures to retain a loyal donor base (see paragraph 3.72), and an infrastructure of blood centres and mobile units that seeks to make donation as convenient as possible for potential donors.
- 6.34 Blood is also the 'paradigm' case of donation: indeed as we have discussed elsewhere in this report (see for example Box 1.7), attitudes to blood donation have strongly informed assumptions about other forms of donation in a way that may not always have been appropriate or justifiable. Nevertheless, the current system of blood donation is widely seen as an exemplar of how donation practices should be conducted with reference to notions of solidarity and the

⁶⁰⁷ See, for example, the special appeal by NHSBT: NHS Blood and Transplant (14 December 2010) *More winter weather could threaten blood donation*, available at: https://safe.blood.co.uk/PressRelease/MR0425_141210_RG%20-%20Winter%20Weather%20Appeal%20BD.pdf, and the results, as reported by the BBC medical correspondent in his blog: BBC News Online (18 February 2011) *How to feel special - give blood*, available at: http://www.bbc.co.uk/blogs/thereporters/ferguswalsh/2011/02/how_to_feel_special_-_give_blood.html.

common good: this suggests that any significant changes to that system would send strong signals about a much broader shift away from this set of values. Such a consideration would suggest that any changes in policy regarding blood donation should be subject to particular scrutiny as to their impact on wider communal values.

- 6.35 **We conclude that it is neither necessary nor appropriate to suggest any significant change at present to the current systems operating within the UK for encouraging people to donate blood.** We note that the approach reflects the bottom two „rungs“ of our Intervention Ladder (awareness and recognition) and also the importance of facilitating access to donation to be discussed further in Chapter 7. We also note that suggestions have been put forward – for example, by a Member of the Scottish Parliament – that employers should permit their staff to have paid time off in order to donate blood.⁶⁰⁸ Such a suggestion would fall into the third rung on our Intervention Ladder – it would constitute an „altruist-focused intervention“ seeking to remove a barrier (possible lost earnings or requirement to make up lost working time, depending on the employer) that might otherwise be hindering people from deciding to donate. We do not consider that there would be ethical concerns about such a change; we would, however, suggest that evidence (for example through carefully monitored pilot schemes) would be helpful in determining its likely efficacy before such a change should be recommended more widely.

Organs

Living organ donation

- 6.36 In the UK at present, living organ donation is on the increase, and indeed in recent years, the number of living donors has exceeded the number of deceased donors (see paragraph 3.10). Most donations are made in response to the need of someone close to the donor; 'stranger' donations (living donations from which complete strangers benefit) are relatively low in number although increasing. Current policy includes action in accordance with the first three rungs of our Intervention Ladder: the HTA provides information to those contemplating donation; NHSBT recognises and promotes living donation as a worthy act; and the Department of Health has issued guidance to PCTs stating that the costs incurred by donors (including lost earnings) should be reimbursed in full (see paragraph 2.35).⁶⁰⁹ Any form of payment that exceeds the direct reimbursement of costs actually incurred by the donor is forbidden in UK legal jurisdictions, by European Directive, and by numerous international agreements and statements (see paragraph 2.34). Nonetheless, there are regular calls for some form of regulated 'market' to be introduced, either through regulated 'purchase' of the organs themselves, or through a system of fixed financial rewards for those willing to donate (see paragraph 5.7). Such calls are based on the belief that the creation of an incentivised system would increase the overall number of living kidney donors in the UK, reduce the numbers waiting (and dying) on the organ transplant waiting list, and remove or reduce the temptation to travel abroad for an illegal transplant operation, using an organ sold by someone who is likely to be in desperate circumstances and who is unlikely to receive high quality follow-up health care.
- 6.37 Such a step would clearly be on to the final 'rung' of our Intervention Ladder and to justify that step, we would have to be satisfied regarding the factors listed in paragraph 6.26 above. We consider that the life-saving nature of the need for organs is such that it is reasonable to consider new approaches to increasing supply (see paragraph 5.2). On the question of the **welfare of donors** we note that since both known and 'stranger' living donations are permitted (indeed encouraged) within the UK, the degree of physical risk involved in being a living donor is currently regarded as acceptable. However, while people who donate kidneys as unpaid living

⁶⁰⁸ The Scottish Parliament (24 September 2009) *Co/20054*, available at:

<http://www.scottish.parliament.uk/business/officialReports/meetingsParliament/or-09/sor0924-02.htm#Co/20054>.

⁶⁰⁹ See also: Scottish Executive Health Department (2004) *Reimbursement of living donor expenses by NHS Scotland*, available at: http://www.sehd.scot.nhs.uk/mels/HDL2004_51.pdf; Welsh Assembly Government (2007) *Live donor expenses commissioning policy*, available at: <http://www.wales.nhs.uk/sites3/Documents/898/CP30%20Live%20Donor%20Expenses.pdf>.

donors appear to express very high levels of retrospective satisfaction with their decision to donate,⁶¹⁰ this contrasts with significant levels of regret reported for organ sellers (see paragraph 5.39).

6.38 We also consider that any encouragement of people to come forward as organ donors for essentially financial reasons would be perceived internationally as a direct challenge to the principles of 'solidarity' and 'unpaid' donation set out in EU Directives and in international agreements such as the Declaration of Istanbul, and could undermine other countries' attempts to put a stop to unregulated and illegal organ sales. We therefore conclude that such a challenge would constitute a potential threat not only to the **common good** of altruistic donation within the UK, but also to the welfare of potential donors in other countries. In terms of the **professional responsibilities** of the health professionals who would be involved in an incentivised system, we note the opposition of the British Transplantation Society (whose membership includes the many different professions involved in transplantation) to the introduction of any financial incentives for donation.⁶¹¹

6.39 Finally, we consider the strength of the **evidence**. On the one hand, the Iranian experience clearly suggests that, if payment is offered, some people will come forward and offer to be living donors, thus potentially increasing the number of kidneys (although not other organs) available. On the other hand, the Iranian context differs from that of the UK in many different ways: in particular in terms of general levels of income and social provision; and in terms of a commitment to a significant programme of deceased donation and associated infrastructure.⁶¹² It is very hard, therefore, to deduce from the Iranian experience how many people in the UK would indeed come forward if a significant financial incentive were offered. We also note that, while concerns about 'crowding out' are not substantiated in the context of minor incentives for blood donors, Iranian authors have commented on how people are less likely to donate to family and friends on a non-paying basis if organs are perceived to be available through other routes (see paragraph 6.19).⁶¹³ We also acknowledge that, precisely because of the international disapproval of payments for organs, there is a lack of direct evidence to back up our concerns as to the potentially detrimental effect such a system would have on the UK's current culture of altruistic donation, or indeed whether professional attitudes and anxieties would shift if regulated incentives were to become the norm.

6.40 We acknowledge these gaps in the current evidence, and we recognise too, that those in the UK who call for the introduction of financial incentives do so out of a genuine concern for the welfare of those waiting for an organ transplant. However, we suggest that, in a situation where there is a strong international consensus as to the importance of the current solidarity-based system in protecting both individual donors and the common good, an approach of 'precautionary thinking' (see paragraph 5.50) is demanded: the burden of proof of the benefits of an alternative system must fall on the side of those demanding change.⁶¹⁴ We come to the conclusion that intervention up to the current 'rung', rung 3 of the Ladder, is appropriate. **Accordingly, we endorse the current position, that no payment, over and above the direct**

⁶¹⁰ See, for example, Franklin PM, and Crombie AK (2003) Live related renal transplantation: psychological, social, and cultural issues *Transplantation* **76**: 1247-52; Jacobs C, Johnson E, Anderson K, Gillingham K, and Matas A (1998) Kidney transplants from living donors: how donation affects family dynamics *Advances in Renal Replacement Therapy* **5**: 89-97.

⁶¹¹ See, for example, the position statement of the British Transplantation Society on Commercial dealings in parts of a human body for transplantation: British Transplantation Society (2011) *Commercial dealings in parts of a human body for transplantation*, available at: <http://www.bts.org.uk/ethics/position-statements/>.

⁶¹² Bagheri A (2006) Compensated kidney donation: an ethical review of the Iranian model *Kennedy Institute of Ethics Journal* **16**: 269-82. See also: House of Commons Library (2009) *The Islamic Republic of Iran: an introduction* (London: House of Commons Library).

⁶¹³ A similar situation is reported in the context of illegal organ selling, where the opportunity to purchase is regarded as saving the sacrifice of a relative (the sacrifice of the donor becomes invisible): Cohen L (2001) The other kidney: biopolitics beyond recognition *Body & Society* **7**: 9.

⁶¹⁴ We note that some authors (for example, Radcliffe-Richards J, Daar AS, Guttman RD *et al.* (1998) The case for allowing kidney sales. International Forum for Transplant Ethics *The Lancet* **351**: 1950-2) argue that the burden of proof should be the other way round, falling on those who resist payment. We have stated in Chapter 5 (see paragraph 5.50) why we disagree.

reimbursement of costs incurred in being a donor, should be made to living organ donors. We also conclude (following paragraph 6.15) that systems assigning priority to those who have earlier expressed a willingness to donate are inappropriate, given the wide range of circumstances in which people are held to be ineligible to donate different forms of bodily material.

- 6.41 We do, however, endorse the current guidance by the Department of Health that the costs incurred by living organ donors (including actual lost earnings) should be fully reimbursed by their local Primary Care Trusts. Given the current organisational changes within the NHS in England, under which both Primary Care Trusts and the Human Tissue Authority will be abolished in their current form, we urge the Department of Health to ensure that this guidance is given proper weight within the new organisational structures. Possible ways of achieving this would include through legally binding Directions or through the Code of Practice issued under the Human Tissue Act.⁶¹⁵

Deceased organ donation: incentives

- 6.42 The possibility of financial incentives has not only been raised in the context of living donors, but has also been suggested as a potential way of increasing levels of deceased organ donation. Such a system might involve either a (presumably small) payment to the person at the time of the decision to join the ODR (at which point their likelihood of becoming a donor is relatively low), or alternatively a (possibly larger) payment to their estate or to a named person if they do in fact become a deceased donor in the future. One way in which such a future payment system might work would be through the NHS meeting the cost of funeral expenses: effectively providing a financial benefit to the deceased's estate or to those who would otherwise bear the costs of the funeral.
- 6.43 A token payment to prompt signing the ODR would constitute the fourth rung of our Intervention Ladder: such an 'altruist-focused intervention' might be the final spur needed for someone disposed to register as a donor to 'get round' to doing so. As such, we do not think such a payment would challenge the current consensus in any ethically significant way. We do, however, note, that it could add significant expense overall to the cost of maintaining the ODR. We also note that there would, of course, be nothing to prevent the person from subsequently changing their mind and removing their name from the ODR (although if they were genuinely already positively inclined towards the idea of organ donation, this seems unlikely). We therefore simply note that if any such system were to be considered, a pilot scheme, carefully monitored, would be essential in order to measure how effective such an intervention really would be, and hence whether it would justify the (potentially significant) extra cost.
- 6.44 The reimbursement of funeral expenses (for example by NHSBT) is ethically more difficult. If offered directly to bereaved relatives who would otherwise refuse permission, it would very clearly constitute a 'non-altruist-focused intervention'. While there would be no risk of the donor suffering physical harm, it might be argued that any decision by their family to consent to donation solely for financial reasons would constitute a very clear example of that person's body being used as a means for others' ends and not as an end in itself (see paragraph 5.60). Given these concerns, coupled with a lack of evidence as to the likely effectiveness of such an intervention, we do not think it should be pursued.
- 6.45 The situation would seem rather different if the payment were triggered by the future donor signing up to the ODR, rather than being offered to the bereaved relatives at the time of death. To the extent that our Intervention Ladder is appropriate in such a family-based scenario,⁶¹⁶ the intervention might constitute 'rung 4': acting as a final spur for a person already inclined to donate, with the added altruistic feature that others, and not the donor themselves, would

⁶¹⁵ Department of Health (2009) *Reimbursement of living donor expenses by the NHS*, available at: http://www.dh.gov.uk/en/Healthcare/Longtermconditions/Vascular/Renal/RenalInformation/DH_4069293.

⁶¹⁶ As we note in paragraph 6.28, donation within families brings other considerations.

benefit. Alternatively, the incentive might seem sufficiently strong for someone to decide to register as a donor simply to spare their relatives the financial burden of a funeral: however, in such a case, the decision would still include an altruistic component, with the aim to benefit others (the donor's relatives). Moreover, while those who are neutral about donation after death might be swayed by such an incentive, it seems unlikely that a person actively opposed to the use of their bodily material after death (for example because of concerns about the integrity of the body) would be tempted to act against those beliefs.

- 6.46 As these arguments demonstrate, when decisions are made in the context of families, the Intervention Ladder will only be one factor to take into account. However, consideration of the factors highlighted in paragraph 6.26, such as the welfare of the donor and the threat to the common good, does suggest that payment of funeral expenses in these circumstances could be ethically justified. Donors cannot be physically harmed – and are highly unlikely to have signified their willingness to donate in these circumstances if they had strong objections. Those close to the donor may benefit directly, and also would clearly have the option of declining the offer of burial costs being met by the NHS. While there is no direct evidence as to how effective or popular such a system would be, the fact that a very similar system exists for covering cremation costs of those who donate their bodies to medical science (which appears to be regarded by both professionals and families as an appropriate acknowledgment of the person's gift),⁶¹⁷ suggests that the extension of such a scheme to organ donors would not be detrimental either to professional values or the common good. **We recommend that NHS Blood and Transplant should consider establishing a pilot scheme to test the public response to the idea of offering to meet funeral expenses for those who sign the Organ Donation Register and subsequently die in circumstances where they could become organ donors.** The precise way in which such a scheme might operate – factors such as what, if any, role family members should have in authorising the use of organs in such circumstances, and whether expenses should be covered if in fact the person's organs prove to be unsuitable for transplant – would be key questions for such a pilot scheme to determine.

Deceased organ donation: forms of consent

- 6.47 We have already set out above (see paragraphs 5.61 and 6.29) our view as to the central importance of knowledge as to a person's wishes regarding donation after death. At present such knowledge may be obtained by the person choosing to signify their wishes in advance of their own death (for example by signing the ODR); in the absence of such clear indication of the person's own wishes, organs may lawfully be taken on the basis of 'consent' (England, Wales and Northern Ireland) or 'authorisation' (Scotland) on the part of their partner or closest available relative or friend (see paragraph 2.15). The proposal is regularly mooted that this 'opt-in' system should be replaced by an 'opt-out' system (see paragraphs 3.53 to 3.54). Two models of 'opt-out' systems are often distinguished: a 'hard' system, in which organs would automatically be taken unless the person had objected during their lifetime, and a 'soft' system, in which relatives would be able to veto organ donation even if no formal objection had been made in the past by the deceased person.
- 6.48 **In our opinion, the importance to be attached to the person's own wishes rules out absolutely any consideration of introducing a 'hard' opt-out approach to deceased organ donation, given the impossibility of ensuring that everyone would be sufficiently well-informed to have the opportunity of opting out during their lifetime.** Our position on a 'soft' approach is more finely-balanced, and much would depend on how, in practice, families were approached under such a system. If, after a person died in circumstances where they could become an organ donor, their family were approached and advised that their relative had not

⁶¹⁷ Schweda M, and Schicktanz S (2009) Public ideas and values concerning the commercialization of organ donation in four European countries *Social Science & Medicine* 68: 1129-36; Richardson R, and Hurwitz B (1995) Donors' attitudes towards body donation for dissection *The Lancet* 346: 277-9.

registered an objection in their lifetime, and then they were asked whether they had any concerns about donation, either because of the deceased's views, or on their own behalf, then such a system might differ very little from the current system where families are formally approached for 'consent' or 'authorisation'. On the other hand, if families were simply informed that organs would be taken unless they exercised a right of veto, the families' perception of their role in the decision would be significantly different.

6.49 We are aware of the ongoing discussions in the research literature as to whether increases in organ donation in countries such as Spain that have introduced opt-out legislation can be ascribed to the legislative framework, or whether other systemic factors in the way organ procurement is managed are the main contributing factor to the increase. A systematic review of studies comparing 'before and after' donation rates after legislative change in a number of countries, published in 2009, concluded that changing to an opt-out system of consent alone was unlikely to explain the variation in organ donation rates between countries, with many other factors identified as relevant. These included both factors affecting the total number of potential donors available (for example rates of motor accidents, the population's age distribution, and the country's definition of death), and factors affecting how many of those potential donors in fact went on to donate (for example the organisation and infrastructure of the transplant system, wealth and investment in health care, and underlying public attitudes and awareness).⁶¹⁸ Another study, published subsequently, concluded by contrast that opt-out systems *are* associated with relatively higher rates of deceased donation – but also with relatively lower rates of living donation.⁶¹⁹ We are also aware of research modelling the possible effects on organ supply of an opt-out system, based on differing levels of individual and family opt-out.⁶²⁰ We note that, while such models demonstrate a potential increase in the number of available organs (and hence lives saved) on the basis of particular assumptions about numbers opting out, such assumptions clearly remain to be tested.

6.50 **We would not oppose on ethical grounds a soft opt-out system, in which families had the opportunity (without pressure) of contributing their knowledge of the person's own views and, where appropriate, of determining that the person would not have wished to become a donor, or indeed that donation would cause the family significant distress. We do, however, note some practical difficulties.** First we suggest that initial assumptions as to the numbers of additional organs that might be obtained in such a way should be modest, if families do indeed continue to feel genuinely free to express any objections they feel.⁶²¹ It does not automatically follow that families who currently refuse consent to the use of their deceased relative's organs would take a different view under such a system. Indeed, if families in such cases felt coerced in any way, then this would potentially render their role meaningless. On the other hand, if the effect of any policy change were to change attitudes so that donation were seen as 'natural' or 'normal', hence increasing the likelihood that families would conclude that donation would be in line with their deceased relative's wishes, this would be ethically unproblematic. Similarly, if families felt relieved from the requirement actively to make the decision, this too might lead to fewer refusals. Second, given the strong opposition in some quarters to the notion of any form of opt-out scheme, and the associated concerns that the state (acting through health professionals and the health care system) would be intervening to 'take' organs rather than facilitating their being 'given', there is at least a risk that some degree of trust in the system could be lost. In such circumstances, it would be particularly important that systems should be designed in such a way as to minimise such loss of trust, for example by

⁶¹⁸ Rithalia A, McDaid C, Suekarran S, Myers L, and Sowden A (2009) Impact of presumed consent for organ donation on donation rates: a systematic review *BMJ* **338**.

⁶¹⁹ Horvat LD, Cuerden MS, Kim SJ *et al.* (2010) Informing the debate: rates of kidney transplantation in nations with presumed consent *Annals of Internal Medicine* **153**: 641.

⁶²⁰ Bird SM, and Harris J (2010) Time to move to presumed consent for organ donation *BMJ* **340**: c2188.

⁶²¹ Such a system would, of course, enable organs to be obtained when people die in circumstances where they could become an organ donor and there is no-one at all available able to give consent as currently required by the Human Tissue Act.

ensuring that those seeking family views are not themselves subject to targets that might be seen as leading to pressure on families.⁶²²

- 6.51 As we have already shown, there may be a significant difference between how people think or say they will act in particular theoretical situations, and what they actually do if that situation arises (see paragraph 6.19). We are therefore hesitant to rely on research reporting on how people say they would respond to the introduction of a soft opt-out system including all the protections described above. We note, however, that the Welsh Assembly has expressed a clear intention to introduce such a scheme in Wales.⁶²³ **If an opt-out system is introduced in Wales we recommend that this is accompanied by robust research, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change (as opposed to any confounding factors such as system changes) has had on the numbers of organs donated.** Such research would provide a clear evidence base for any proposals for change elsewhere in the UK, or indeed further afield.
- 6.52 As we comment in Chapter 5, the notion of 'opt-out' systems is not the only means of changing the defaults around deceased organ donation (see paragraph 5.61). In particular, we have highlighted ideas of 'mandated choice' (under which people would be required to make a definite decision about organ donation during their lifetime) and 'prompted choice' (under which people would be required at least to consider the question, even if they chose not to answer it). Mandated choice has been criticised for forcing people to choose a straightforward 'Yes' or 'No' to the question of future organ donation at a time when they may not feel they are well placed to make such a decision, and the introduction of a system on these lines may run the risk of being counter-productive in relation to organ supply by encouraging people to say a firm 'No' when their truer views might be 'Don't know at the moment' (see paragraphs 3.54 to 3.56). However, one form of mandated choice put forward recently overlaps to a degree with ideas of 'prompted choice', in that it would include the options of 'Yes', 'No', and 'Ask my family'.⁶²⁴ Such an approach would seek to avoid the risk that people feel coerced into making a decision, but would also enable those who are genuinely unsure at the time of answering the question to indicate that they are happy to delegate their decision to their family, and that they are not actively opposed. Registration with a new GP's practice, or the occasion of a first appointment with a new GP, might provide opportunities for the NHS to log people's wishes in this way on a systematic basis, although care would need to be taken to ensure that individuals did not feel pressured into answering in a particular way.
- 6.53 A pilot version of a system on these lines started in the UK in August 2011, under which all those making an online application to the Driver and Vehicle Licensing Agency (DVLA) for a driver's licence (whether new or renewal) will now be required to answer a question about organ donation before their application can be processed.⁶²⁵ The options are: "Yes, I would like to register"; "I do not wish to answer this question now"; or "I am already registered on the NHS

⁶²² Rodríguez-Arias D, Wright L, and Paredes D (2010) Success factors and ethical challenges of the Spanish Model of organ donation *The Lancet* **376**: 1109-12.

⁶²³ The National Assembly for Wales announced that it will launch a White Paper consultation on an organ donation (Wales) Bill before the end of 2011. The Bill will provide for an opt-out system of organ donation. See: National Assembly for Wales (12 July 2011) *The record of proceedings: the Welsh Government's legislative programme 2011-16*, available at: <http://www.assemblywales.org/bus-home/bus-chamber-fourth-assembly-rop.htm?act=dis&id=219617&ds=7/2011#dat2>. See also: House of Lords Hansard (27 June 2011) *c370W*, available at: <http://www.publications.parliament.uk/pa/ld201011/ldhansrd/text/110627w0001.htm>, where Earl Howe states that "The Welsh Government have now announced that they will press ahead unilaterally with an Assembly Bill to attempt to change the existing system on organ donation and introduce an opt-out system of consent in Wales. The Government will examine thoroughly the detail of the Bill when it is introduced to the National Assembly."

⁶²⁴ Saunders J (2010) Bodies, organs and saving lives: the alternatives *Clinical Medicine, Journal of the Royal College of Physicians* **10**: 26-9.

⁶²⁵ The scheme is described as 'prompted choice', but appears to be closer to 'mandated choice' given that the question has to be answered before the application can be processed.

Organ Donor Register".⁶²⁶ The option for the applicant to object to organ donation is not included.

- 6.54 **We conclude that, in principle, both mandated choice and prompted choice systems present ethical options for seeking authorisation in advance to deceased organ donation.** We have emphasised repeatedly the importance we place on clear information about individuals' wishes, and hence systems that encourage people both to think about their own willingness to donate and to document their decision are strongly to be encouraged. We also endorse the use of a pilot scheme to track the effectiveness of the new 'prompted choice' system via the Driver and Vehicle Licensing Agency (DVLA), and urge that the scheme is accompanied by robust research as to its impact. However, we are concerned about the decision not to include the option of registering *objection* to organ donation in the DVLA scheme: any system that is based on explicit authorisation must also allow for explicit refusal. The possibility of explicit refusal can only strengthen the significance of approval: at the same time it allows for strength of personal feeling to be expressed in both directions (approval and disapproval). The importance of this cannot be overemphasised when the subject matter is bodily material.
- 6.55 **We recommend that any system set up to document people's wishes that mandates a response to a question about organ donation should also include the option of expressing objection; to do otherwise significantly undermines commitment to following the wishes of the deceased and even, arguably, fails to comply with the spirit of current legislation with its central focus on consent. We further recommend that any system set up to document people's wishes regarding donation (including the current Organ Donor Register) should also be able to register objections.** Indeed, such a system might in practice act to *increase* donations, in that families who are unsure about their deceased relative's views could be reassured that they had not actively chosen to opt-out.
- 6.56 As we noted earlier (see paragraph 5.62), difficult issues arise in connection with the amount of information needed for a legally valid consent; and the possibility of signing up to the ODR on the basis of little or no information about the process of donation has been raised as a matter of concern. **We note again the ethical distinction we have drawn in Chapter 5 (see paragraph 5.63), between *consent* for interventions on the body for the purposes of donation during life and *authorisation* of interventions on the body for the purposes of donation after death, which we consider could well provide a helpful framework for distinguishing between the informational requirements in two very different sets of circumstances.**
- 6.57 We do not think that before anyone can sign up to the ODR, or before any family member can agree to the use of the deceased person's organs, they must be given (and required to read) highly detailed information about the procedure. Rather, they must be in a position to understand, in broad terms, what is involved, and they must be in a position to have any further questions they have answered. Some people would prefer not to know any details of how organs will be removed, but simply wish to have the option of specifying some organs rather than others, and perhaps to be reassured that, once organs have been removed, their deceased body will not appear disfigured. For them, this is sufficient to cover 'what is involved'. Others, by contrast, may wish to have detailed information about the process of organ retrieval, treatment and transplantation. **We conclude that information must be *available* to those considering donation and it must always be clear that more information is available if people desire it. If people make it clear that they wish to agree to donation, whether in advance via the Organ Donation Register, or on behalf of a deceased relative, even if they do not want to know any details about the process, this should be accepted as sufficient expression of their wishes.**

⁶²⁶ Department of Health (1 August 2011) *Licences to drive up organ donation*, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_128847.

- 6.58 Preceding paragraphs have alluded repeatedly to the role of those associated intimately with the deceased, as flagged in the term 'family',⁶²⁷ and their involvement in the decision to donate after death. As will have become apparent from our emphasis on the importance of the role of the family in connection with 'soft' opt-out procedures (see paragraph 6.50), we consider it appropriate that the family's own interests with respect to the donation decision should be recognised, even where the deceased has left clear evidence as to their wishes to donate. In practice, it appears that if families are aware of their deceased relative's wishes, then they are very unlikely to refuse consent to organ donation: figures from NHSBT show that fewer than one per cent of families refuse consent to donate a kidney if their deceased relative had made their wish to donate known via the ODR.⁶²⁸ On the rare occasions when this does happen, while the law does permit organs lawfully to be taken on the basis of the deceased's consent, in practice health professionals would not proceed in the light of the refusal of bereaved family members. More significant is the percentage of families (around 40 per cent) who refuse consent for donation when the deceased had not signed the ODR.⁶²⁹ In such cases, we endorse the current position that the option of refusal *should* rest with familial associates of the deceased. Such refusal (where applicable) may be based on families' own knowledge of the deceased's attitudes to donation; however, it may also at times be understood as an expression of their own needs, as bereaved family members. We reiterate again the importance of systems to promote the widespread expression of people's advance wishes regarding donation after death.
- 6.59 Finally, we reiterate here that action that aims to change individuals' behaviour with respect to deceased organ donation is only one part of the picture, and that we will be returning in Chapter 7 to actions at organisational level that may influence levels of organ donation.

Gametes

- 6.60 Current attitudes and policies towards the donation of gametes are strikingly different from those applied to blood and organs. We have described above and in Chapter 3 the considerable use of promotional materials highlighting the need for blood and organs, the systems used to thank donors and recognise the value of their donation, and the availability (in the case of living donors) of clear arrangements to cover the full financial costs incurred by the donor in the process of making their donation. Coupled with these activities (which encapsulate the first three rungs of our Intervention Ladder), there is a strong international consensus that any form of payment for organs (whether in the form of a 'prompt' to donate where a potential donor is already so inclined, or a full-blown financial incentive to consider donation primarily for financial reasons) is wrong.
- 6.61 In contrast to the well-funded nationally organised networks promoting and facilitating blood and organ donation, only very limited support is available to raise general awareness of the need for donor gametes (see paragraph 3.70). Advertising for gamete donors therefore mainly takes place in the form of *ad hoc* campaigns by individual clinics, and there is little cooperation between clinics (a point to which we return in Chapter 7). There are no 'official' ways in which gamete donation is celebrated (although individual clinics or recipients may have their own systems for recognising and thanking donors). While travel and other out-of-pocket expenses

⁶²⁷ We have been using „family“ as a generic term to cover forms of relatedness among people 'intrinsic to one another's existence' (for which an anthropologist might use the word 'kinship'). Depending on context, 'families' include partners/spouses and all others potentially close to the deceased, and may include friends who become family-like. The HTA definition of 'qualifying relative' (see paragraph 2.15) is relevant here, although we offer no opinion on the particular categories used, nor on the order in which they are listed.

⁶²⁸ Just 0.2 per cent of families refuse to donate a kidney, in circumstances where the deceased had previously consented via the ODR. However, around ten per cent of families may then refuse further permission for the heart, pancreas or lung even though the deceased had consented via the ODR. NHSBT, personal communication, 2 November 2010.

⁶²⁹ See, for example, Barber K, Falvey S, Hamilton C, Collett D, and Rudge C (2006) Potential for organ donation in the United Kingdom: audit of intensive care records *BMJ* **332**: 1124-7.

incurred by donors are reimbursed in full, lost earnings are capped at £250 per cycle of donation. Egg donors, in particular, may therefore potentially be out-of-pocket as a result of their donation. Although the Tissues and Cells Directive calls for gametes to be procured on a "voluntary and unpaid basis", interpretation within EU member states varies considerably as to what forms of compensation are permitted in conjunction with this definition. Outside Europe, there is no international consensus around payment for gametes, and indeed the straightforward 'purchase' of gametes, with differential pricing depending on the number of eggs and the qualities of the egg or sperm donor, is accepted in several jurisdictions.⁶³⁰

Gametes for reproduction

- 6.62 It is clear to us that the starting point in any consideration of the ethical promotion of gamete donation must be the need for 'altruist-focused' action within the first four rungs of the Intervention Ladder. Until such interventions have been tried and evaluated, we consider it highly premature to conclude that a system based primarily on altruism has been shown to 'fail'.⁶³¹ In particular, we highlight here the absence of organisational systems necessary for its success, such as the creation of a national infrastructure for egg and sperm donation, on the lines of the structures currently in place for organ donation. Such an infrastructure would be well-placed not only to manage the kind of coordinated information campaigns envisaged in the first rung of our Intervention Ladder, but also to share best practice in recruiting, retaining and 'recognising' donors (rung 2). We return to this point in more detail in Chapter 7.
- 6.63 Moving to rung three of the Intervention Ladder, we see no reason why gamete donors should suffer financial disadvantage as a result of their donation. Where time has to be taken off work in order to donate gametes, particularly in the more invasive procedures involved in egg donation, **we recommend that the current cap of £250 on lost earnings that may be reimbursed should be removed, and that lost earnings, where applicable, should be reimbursed in full in the same way as other expenses such as travel costs.** The clear aim should be to ensure that the donor is in the same financial position as a result of their donation, as they would have been if they had not donated. We do not consider such reimbursements as 'reward', and we do not consider higher levels of reimbursement for higher earners to be unjust by comparison with reimbursement of those on lower earnings (any more than reimbursing the cost of a long-distance train fare is unjust by comparison with reimbursing the cost of a local car or bus journey).⁶³² Where such costs or losses are incurred as a direct result of donation, they should be met in full.
- 6.64 Finally, with respect to rung 4 of the Ladder, we do not think token incentives, such as low-value vouchers, offered with the aim of prompting someone already disposed to donate to take the step of doing so, would be ethically objectionable in themselves. However, there is at present little evidence to support the effectiveness of such a measure, compared with the effectiveness of the better organisational arrangements and full reimbursement of financial losses incurred in the process of donation recommended above.⁶³³ Moreover, as we highlighted in paragraph 6.23, the effect of the 'inputs' set out in the Intervention Ladder may vary in their effect on individuals: what might be perceived as a 'token' incentive to one person might to another constitute a primary reason for donation (and hence rung 6 of the Ladder). Indeed, we note that the 'compensation' offered to Spanish gamete donors, calculated on a standardised basis for

⁶³⁰ See, for example, Ethics Committee of the American Society for Reproductive Medicine (2004) Financial incentives in recruitment of oocyte donors *Fertility and Sterility* 82: 240-4; Gruenbaum BF, Pinchover ZS, Lunenfeld E, and Jotkowitz A (2011) Ovum donation: examining the new Israeli law *European Journal of Obstetrics & Gynecology and Reproductive Biology*: in press.

⁶³¹ See, for example, Bahadur G, Jegede T, Santis M and Ahuja KK (2011) *Recruiting 500 sperm donors: customer relations key to meeting UK demand*, available at: <http://eshre2011.congressplanner.eu/showabstract.php?congress=ESHRE2011&id=643>.

⁶³² We reject the argument that meeting such costs in full constitutes valuing the time of a well-paid gamete donor more than the time of poorly-paid donor. While the time of each may be valued differently by their respective employers, reimbursement seeks only to return them to the financial position they would have occupied, but for their decision to donate.

⁶³³ We note that these latter two steps (full reimbursement and better organisational procedures) have constituted key elements in the attempts to improve organ donation within the UK in recent years.

lost earnings, travel expenses, meals and discomfort (notionally our rung 4), is widely seen as a straightforward 'reward' for donating and hence in fact constitutes rung 6 (see paragraph 2.51). Particular effort would therefore be required to ensure that any incentive offered would be widely understood as just a prompt or a 'thank you' for donating.

- 6.65 Moving to consideration of rungs 5 and 6 of the Intervention Ladder, we consider that it is inappropriate to consider introducing new forms of non-altruistic-focused intervention in the UK with respect to donation for another's treatment, before action on the lower rungs of the Intervention Ladder has properly been explored. However, given the existence of such interventions elsewhere in the world, and the recent debate on this issue within the UK, we make a number of observations.
- 6.66 **The Council rejects outright the concept of paying a 'purchase' price for gametes, where any payment made is understood as payment for the gamete itself, rather than as recompense or reward to the donor herself or himself.** Insofar as the 'price' of gametes depends on quantity, or on inferred qualities (for example those associated with the appearance or intelligence of the donor), such a transaction may only be understood as a 'purchase'.
- 6.67 **We consider that the welfare of the potential donor, especially with respect to egg donors, is central in determining what constitutes acceptable practice in this area.** Clearly the physical risks of egg donation are not, in themselves, affected by whether a woman agrees to donate eggs primarily out of concern for other women unable to conceive with their own eggs, or primarily for reward. However, where egg donation is considered for essentially financial reasons, women may be more likely to consider repeat donations, and may be more likely to continue donating despite potential risks to their health. The lack of good-quality data on the long-term risks of repeat egg donation is a matter of concern here.
- 6.68 We note that many of these concerns have been picked up by good practice guidance for cross-border reproductive care published in 2011 by the European Society of Human Reproduction and Embryology (ESHRE), which states:

"It is essential to propose a stimulation cycle that minimizes the health risk for the oocyte donors. Reliable data regarding risks are scarce, especially in the case of repeated donation. Donors may present themselves several times at the same center or at different centers. In order to obtain information on repeated donations and to be able to verify legal restrictions on donations, it is essential firstly to establish national registers of gametes donors, and secondly for centers to participate in the collection of national or international data.

In order to prevent the abuse of donors coming from abroad, one should avoid using intermediate agencies, which may lead to violations of the rules of good clinical practice and, in the worst case, to trafficking. Post-donation care should be provided to the best possible standards at home or abroad."⁶³⁴

- 6.69 **We endorse the good practice guidance issued by the European Society of Human Reproduction and Embryology (ESHRE) on the treatment of egg donors in the context of cross-border reproductive care, and note its potential relevance also for domestic care. In particular, we endorse ESHRE's call for national registers of gamete donors to be established, and for centres to participate in the collection of national or international data. In addition we recommend, as a matter of urgency, that action is taken by licensed clinics to start collecting data on a systematic basis (if possible retrospectively, as well as through the new registers) to track the long-term health effects of repeat egg donations.** Good-quality evidence on these effects is essential in order for proper concern to be

⁶³⁴ Shenfield F, Pennings G, De Mouzon J *et al.* (2011) ESHRE's good practice guide for cross-border reproductive care for centers and practitioners *Human Reproduction* 26: 1625-7, paragraph 2.2.

given to the welfare of egg donors in any future policy. We further note that individual clinics currently, as a matter of good practice, take a number of steps to minimise risk to egg donors, for example by encouraging women to donate only after they have completed their own families, and by limiting the number of times a woman may donate.⁶³⁵ **We recommend that the Royal College of Obstetricians and Gynaecologists and the British Fertility Society should work with the HFEA to review what is currently regarded as best practice in the UK with respect to measures taken to safeguard egg donors, with a view to issuing guidance that will send out a clear public signal about how the welfare of egg donors should underpin any consideration of donation.**

6.70 Finally, in the context of incentives designed to reward, rather than simply recompense, donors (egg and sperm alike), we highlight the question of the welfare of any future child (see paragraph 5.54). This is a hotly contested area: on the one hand, concerns are expressed as to the effect on any future child of the knowledge (if shared with him or her) that their biological mother or father provided their biological material for financial gain; on the other, it is argued that there is no evidence to show detriment, that children are conceived in all sorts of circumstances that have little or no effect on how they are subsequently loved and treated, and that indeed it can be the case that the very lengths to which the child's legal parents are prepared to go to conceive a child demonstrate how wanted and loved they are. **We conclude that, in order properly to inform this debate, good quality empirical research evidence is urgently needed as to what, if any, effects financially incentivised gamete donation has on children conceived as a result of such donation and, indeed, on the wider context of how responsibilities towards children are understood.**

6.71 The preceding paragraphs have been concerned with 'new' non-altruist-focused interventions. However, we have already noted that one non-altruist-focused intervention – egg sharing – is currently permitted in the UK. On our Intervention Ladder, egg-sharing arrangements are classified as being on rung 5: benefits in kind (treatment services) that are associated with what is being donated (a proportion of the eggs produced in response to hormonal stimulation). The limited evidence that currently exists on the experiences and attitudes of those donating some of their eggs in order to access treatment they could not otherwise afford suggests that this is not a choice that most women would make if treatment were available to them in other circumstances (see paragraph 3.77). However, once they have taken the decision to share eggs for these reasons, it is clear that there may well be considerable fellow-feeling between donors and recipients, both of whom are undergoing, albeit in different ways, medical procedures with the aim of bearing children; and that it is far from meaningless to talk about „solidarity“ in the context of their relationships (see paragraph 6.8). Moreover, tentative views arising out of current research being conducted into egg-sharing arrangements in Newcastle (in this case the 'shared' eggs being destined for research purposes) suggest that women who have provided eggs under this scheme are clear that their decision to do so is freely made – albeit not in circumstances of the women's own choosing.⁶³⁶ This position highlights one of the reasons why egg sharing was permitted in the first place: not specifically as a method for recruiting additional egg donors, but in order to enable more people to access IVF procedures in the absence of wider NHS provision.

6.72 We note that women who become egg donors through egg-sharing arrangements do not undergo any additional risks in the procedure itself; and that current data suggest that their

⁶³⁵ See, for example, Midland Fertility Services (2010) *Donating eggs*, available at: <http://www.midlandfertility.com/investigations-and-treatments/treatments/donor-treatments/donating-eggs>. In the context of egg donation for research, the Wellcome Trust has suggested that it is appropriate to limit the number of times a woman can undergo the procedure to donate eggs. See: Wellcome Trust (2006) *Re. HFEA consultation on donating eggs for research*, available at: http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTX035514.pdf.

⁶³⁶ They would, however, prefer greater access to NHS funding rather than having to resort to egg sharing to fund their treatment; they would prefer then to be in a position to offer their eggs for research after completion of treatment. Tentative findings by Haimes E and Taylor K, presented at the PEALS annual symposium, 22 and 23 February 2011.

chance of becoming pregnant after the transfer of fresh embryos is on a par with non-egg-sharers, although their 'cumulative' pregnancy rate will be lower because they will have fewer frozen embryos for subsequent transfers after their initial treatment (see paragraph 3.77). We also note that, in circumstances where would-be egg sharers do not in fact produce enough eggs for their own treatment and that of another woman, they will be entitled to use all the eggs for their own treatment, while still receiving the promised rebate on their treatment fees.⁶³⁷ **We note, and welcome, recent statements by Ministers urging Primary Care Trusts and their successor organisations to ensure that access to IVF is more routinely made available in accordance with the guidance issued by the National Institute for Health and Clinical Excellence guidance.**⁶³⁸ **However, given the likelihood that some women will continue to experience difficulties in accessing NHS IVF treatment, we do not think it appropriate at present to recommend any changes to the current policy within the UK of permitting egg-sharing in these circumstances.**

- 6.73 However, we strongly caution that it is *not* appropriate to use the notional value of egg-sharing arrangements (that is, the financial rebate offered on the cost of private IVF treatment) as an argument for creating a straightforward financial incentive for egg donation for reproductive purposes. As we have argued, a clear distinction can be made between the position of donors who in return receive a benefit directly associated with their donation (in the case of egg sharers, the opportunity to receive treatment that would otherwise not be available to them), and those who are invited to donate on the basis of simple financial reward. Any consideration of the possibility of such 'rung 6' incentives to donate gametes should be clearly distinguished from the justifications for permitting egg sharing.

Gametes for research

- 6.74 Women who decide to donate eggs for research as 'volunteer egg donors' (that is not as part of an egg-sharing agreement), are likely to have rather different motivations from those donating to help a woman conceive. We consider that the most relevant comparison here, across all the different forms of donation and volunteering noted in this report, is with first-in-human trial volunteers. In contrast with circumstances where eggs are donated for treatment purposes, there is no direct recipient of the donated material and no possibility of a child being born as a result of the donation. Like healthy volunteers in first-in-human trials, women who donate eggs for research undergo medical procedures that involve discomfort, inconvenience and potential health risk, with the aim of enhancing scientific knowledge and hence potentially producing long-term health benefit (see Box 1.8). The potential gains by others are thus uncertain, remote, and impossible to link with any identifiable individual.
- 6.75 We have taken the view that these differences between donation for research purposes and donation for treatment purposes have ethical implications (see paragraphs 5.46 and 5.82). In particular, we consider that where there are no clear recipients (known or unknown) of the donated material, a move away from a primarily altruistic model of donation may not present a risk of undermining solidarity, as expressed, for example, in a communal commitment to the provision of materials needed by others for the preservation or improvement of their health. While the willingness of donors of eggs for research to contribute to scientific knowledge may certainly be understood in terms of solidarity (a willingness to contribute to the collective good of research), altruism does not appear in this context to be a key value underpinning that contribution to solidarity. Rather, we suggest that another value, justice, becomes applicable here: if women are prepared to undertake these procedures to benefit scientific endeavour and the wider community, is it not just that their contribution should be explicitly recognised? And in

⁶³⁷ Human Fertilisation and Embryology Authority (2009) *Code of practice*, available at: http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf, paragraph 12.20.

⁶³⁸ House of Commons Hansard (12 December 2007) c437, available at: <http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm071212/debtext/71212-0024.htm>.

circumstances where altruism does not play a central role, there appears to be much less justification for avoiding the use of financial reward as a form of recognition.

- 6.76 In these circumstances, we conclude that it would be appropriate to explore the possibility of offering some form of payment to those who are prepared to come forward as egg donors for research. Payment could be made on the basis of compensation for the time, inconvenience and discomfort involved in donating (in direct parallel to the language used in first-in-human trials), or as a form of remuneration. Whether badged as 'compensation' or as 'remuneration', however, we are clear that such a payment would constitute a non-altruist-focused intervention at rung 6 on our Ladder.
- 6.77 We commented earlier that in the context of some forms of research, considerations other than those set out in the Intervention Ladder may be dominant (see paragraph 6.28), and we have highlighted these considerations above. Nevertheless, we suggest that in considering the possibility of non-altruist-focused interventions to promote the donation of any form of bodily material, careful consideration should still be given to the factors listed in paragraph 6.26 concerning the welfare of those concerned, the potential threat to the common good, the professional responsibilities of those involved, and the strength of the evidence on all these aspects.
- 6.78 In connection with the **welfare of the donor**, the considerations are exactly the same as in egg donation for treatment purposes (see paragraph 6.67). The physical risks of donation are currently regarded as acceptable in the context of altruistic donation, and the possibility of reward does not affect this. However, the risks of repeat donation are unknown, and potentially of greater concern. We therefore suggest that if reward were to be offered for egg donation, very clear procedures would need to be in place to ensure a limit on the number of possible donations. The ESHRE guidance quoted above (see paragraph 6.68) also sets out further procedural safeguards that should be followed to avoid the inappropriate targeting of donors from abroad. We return to this point of institutional safeguards in Chapter 7 (see paragraph 7.68).
- 6.79 On the **welfare of other closely concerned individuals**, we repeat that in egg donation in these circumstances, there is no possibility of any resulting child. We have already discussed the **potential threat to the common good**, and have concluded that in the context of research there is no good reason to conclude that a move away from altruism would be harmful or would undermine solidarity. We have, however, little evidence as to how such a change might impact on the **professional responsibilities** of the health professionals involved and on how they might view such a change with regard to professional ethics.
- 6.80 Some of these arguments with respect to egg donation for research potentially apply also by analogy to sperm donors. However, the very different demands placed on egg donors in terms of medical intervention create an important distinction between egg and sperm donors, and suggest that egg donation should be singled out for specific consideration.
- 6.81 **We conclude that it would be appropriate to set up a pilot scheme to explore the possibility of offering some form of payment to those prepared to come forward as egg donors for research. Payment could be made on the basis of compensation for the time, inconvenience and discomfort involved in donating (in direct parallel to the language used in first-in-human trials), or as a form of remuneration. We draw further on parallels with healthy volunteers in first-in-human trials by recommending that donors coming forward in this way should be regarded as research participants, with all the associated protections.**

Tissue

- 6.82 In Chapter 3, we highlighted how there is not a general 'shortage' of tissue, whether donated during life or after death, for therapeutic purposes. The issues arising in the donation of tissue for research purposes are rather different. Two main issues were signalled in Chapter 3: first

that access to tissue provided by living donors may be problematic, primarily for procedural reasons; and second that the systems currently in place to facilitate organ donation after death are not similarly well-calibrated to ensure that those willing to donate tissue are able to do so.⁶³⁹ We also note the UK research examined by our evidence review on motivations and barriers to donation: when patients are asked to consent to the future research use of their 'abandoned' tissue, including for commercial purposes, an overwhelming majority are willing to do so (see paragraph 6.7). While we accept that this evidence derives from just one study (albeit with a large cohort), we also note other examples of practice where, if asked, patients have shown themselves very willing to agree to research use (see Box 3.2). We also mention the experience of UK Biobank, which has succeeded in recruiting half a million volunteers from the general population (i.e. not within the context of being patients) to donate samples and provide detailed health information in order to contribute to long-term research.⁶⁴⁰ We conclude that the difficulties experienced by researchers in obtaining tissue for their research do not derive from individuals' general unwillingness to consent to such use, nor from a lack of interest on the part of patients or the general public in contributing to the communal good of research, but rather to an absence of systems to ensure that this willingness is harnessed. We return to this issue in Chapter 7.

First-in-human trials

- 6.83 Payments for healthy volunteers participating in first-in-human trials are routinely described as payments in return for time or inconvenience (see paragraph 2.37). While such payments could potentially be described as recompense for the losses (financial and non-financial) incurred in volunteering, rather than as reward, in practice it seems fairly clear that, for most volunteers, payment constitutes a primary reason for participation. This suggests that the current system is in fact an example of a non-altruist-focused intervention, on rung 6 of our Ladder. However, while we acknowledge the limited scope of the literature we were able to review, the studies included provided some indications of mixed motivations among participants, with a number of participants emphasising their interest in contributing to scientific progress, alongside their response to financial incentive (see paragraph 6.9).
- 6.84 We have already emphasised that non-altruist-focused interventions are not necessarily unethical: their ethical acceptability will depend on the context in which they are deployed. Moreover, as we have just argued in the context of donating gametes for research, where those who may benefit from the actions of the healthy volunteer are more remote (and may indeed never materialise), the key value here underpinning solidarity may not be altruism on the part of volunteers, but rather justice on the part of others in relation to the way they treat the volunteer.
- 6.85 Using the check-list set out paragraph 6.26, we therefore consider the **welfare** of the participant, any possible threat to the **common good**, the role of **professionals**, and the strength of the **evidence** in respect of all of these factors. We note that:
- Except in exceptional cases, the welfare of the volunteer in the UK is not usually compromised as long as trials are well-run, and it is the role of ethical and scientific scrutiny to keep those risks acceptably low.
 - Payment for participation in trials is currently the norm in the UK, as elsewhere, and appears to co-exist with an interest on the part of at least some healthy volunteers in contributing to the communal benefits of research. There is no evidence to suggest that payments made in this area have in any way served to undermine solidarity with respect to the donation of bodily material more generally.

⁶³⁹ Both issues were raised by delegates at a recent conference organised by the Human Tissue Research Network. See: <http://www.humantissueresearchnetwork.com/Summit2011.aspx>.

⁶⁴⁰ UK Biobank (2010) *UK Biobank: improving the health of future generations*, available at: <http://www.ukbiobank.ac.uk/>.

- There is little evidence to suggest that professional ethics are currently compromised by payments; indeed it has been argued that the tendency to offer *modest* payments to combat anxieties over „undue influence“ creates injustice in that it is more likely to attract primarily those who are less well-off or in more urgent need of money.⁶⁴¹

6.86 We conclude that payment for participation by healthy volunteers in first-in-human clinical trials within the UK constitutes an example of an ethically justified rung 6. In relation to the factors we have been considering, therefore, there is no reason to challenge the payment for participation by such volunteers in first-in-human clinical trials. **The major risk from the payment system to the welfare of the volunteer lies not in participation in the trial itself, but in the medical risks involved when volunteers take part in repeated, or even concurrent, trials.** Further aspects of concern become relevant in countries without universal health care systems: these include the possibility that participants may not receive appropriate monitoring and follow-up care, and may not be eligible to participate on an equal basis in their country's own health care system.⁶⁴² We return to these wider concerns in Chapter 7.

⁶⁴¹ Iltis AS (2009) Payments to normal healthy volunteers in phase 1 trials: avoiding undue influence while distributing fairly the burdens of research participation *Journal of Medicine and Philosophy* **34**: 68-90.

⁶⁴² Elliott C, and Abadie R (2008) Exploiting a research underclass in phase 1 clinical trials *New England Journal of Medicine* **358**: 2316-7.

Chapter 7

Actions addressing
organisations

Chapter 7 - Actions addressing organisations

Chapter overview

In this concluding chapter, we consider the role of organisations (public, private and voluntary), and the state in facilitating donation. With respect to 'public' interests in donation, we argue that:

- The state has a 'stewardship' role in relation to promoting good health in the population, in facilitating the donation of bodily materials, and in taking action to reduce inequalities with respect to access to donated materials.
- Changing patterns of behaviour in the population contribute to increasing levels of disease and in turn to increasing demand for organ transplants. Policy-makers and health professionals concerned with organ transplantation should explicitly highlight how improved public health measures would help lessen the 'gap' between demand for, and supply of, donor organs.
- Medical research, and the health benefits it seeks to bring, are of vital public interest. That public interest is not extinguished by the private financial gains that may also accrue as a result of research carried out within the commercial sector.
- National self-sufficiency in the supply of bodily materials is a laudable aim. However, where national self-sufficiency cannot be achieved without taking action that would otherwise be regarded as unethical, the fact that people may still choose to travel abroad should not force a change of policy.
- We endorse the current international consensus that 'organ trafficking' and 'transplant tourism' should be banned. We further recommend that the WHO should develop appropriate guiding principles to protect gamete donors from abuse or exploitation.

Our conclusions and recommendations with respect to the facilitation of particular forms of bodily material include:

- The Department of Health should monitor closely how current organisational changes within the English NHS may affect organ donation services, and be prepared if necessary to act to 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 more explicit in the documentation produced about deceased donation.
- People donating material for research purposes, or volunteering in first-in-human trials, should be treated as partners in the research, and their ongoing interest in the progress of the research recognised.
- Good governance systems, accompanied by transparency of process, are an essential requirement if potential donors are to have the trust necessary for them to contemplate donation in the first place.
- Once donated for research purposes, 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.
- A national or regional 'donor service' should be established, to provide a coherent and managed infrastructure for egg and sperm donation, on the lines of the structures currently in place for organ donation.
- Where fertility clinics and professionals within the UK make arrangements to refer patients to clinics and professionals abroad, they should share professional responsibility for the general standards prevailing at the receiving centre, including the protocols used to recruit egg donors and the routine measures taken by the clinic to safeguard the welfare of donors.
- 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'.

Introduction

7.1 We described earlier how the difference between levels of demand and levels of supply for various forms of bodily material have triggered calls for the creation of incentive systems. We have set out in Chapters 5 and 6 our conclusions with respect to a range of ethical considerations that should be borne in mind by policy-makers when responding to such calls. However, we have also highlighted repeatedly throughout this report our conviction that the focus on individual motivation, as exemplified by the call for incentives, is only one aspect of a much bigger picture when considering the ethical challenges raised by the donation of bodily material. In Chapter 1 we emphasised the 'transactional' nature of donation (see paragraph 1.28) and highlighted how organisations and institutions, such as licensed clinics and biobanks,

act as intermediaries between donors and recipients.⁶⁴³ The role of these intermediaries forms the focus of the present chapter. Where the state and its agencies act to affect individual decision-making, this has been treated under Chapter 6. Here in Chapter 7 we are concerned with the infrastructure and support systems that facilitate donation; with the role of organisations and institutions, including non-state institutions such as professional organisations, the voluntary sector and faith groups; and also with the role of the state itself, as both legislator and service-provider. Given the crucial role played by intermediaries in almost all aspects of donation, we acknowledge that this division is not always clear. But we think it is nevertheless very helpful in drawing attention to the many ways in which donation may be facilitated – or alternatively the ways in which the need for donation may be reduced – by action at professional, organisational, and state level. Such action, we further suggest, can be construed as an ethical responsibility.

7.2 The second part of this chapter (see paragraphs 7.28 and following), considers what 'facilitating' donation might mean for different forms of bodily material: such facilitation might include factors such as the accessibility of services for potential donors; the way potential donors are approached; the structures in place to ensure that consent is sought at the appropriate time and documented in a way that will maximise future use of the material; and funding arrangements for services. The key questions here for each form of bodily material are: *What barriers are there to making the best possible use of the material that people are willing to donate – and how can these barriers be removed?* Before we consider these material-specific issues, however, we highlight a number of over-arching questions that we believe policy-makers need to address:

- What action can be taken at national, or organisational, level to *reduce* the need for bodily material?
- What action can be taken at national, or organisational, level to promote the availability of alternatives to bodily material?
- On what basis do we distinguish between matters of public and private concern?

Each of these issues is considered in more depth below.

Preventive action

7.3 Chapter 3 emphasised some of the factors (social and scientific) both driving and, in some cases, reducing demand for bodily material. We return here to the question of the public health factors that are playing a significant role in increasing demand for bodily material, in particular for organs for transplant and for gametes for fertility treatment (see paragraphs 3.48 to 3.49). Changing patterns of behaviour in the population, including diet, physical activity and consumption of alcohol, contribute to increasing levels of cardiovascular disease, liver failure, and, to a lesser extent, kidney failure. Fertility declines with age and hence the later motherhood is attempted, the more difficult pregnancy is to achieve with a woman's own eggs. In other words, 'demand' for these materials is not a simple unmodifiable 'fact'. However, these potentially modifiable public health factors appear to be almost entirely absent in the general debate about the difficulty in meeting demand for bodily material.

7.4 We emphasise here that this report is *not* concerned with the issue of how materials in short supply should most ethically be allocated for treatment. Thus we are not concerned here with the question of whether lifestyle factors should be used in determining who should have priority in receiving an organ or donated gametes. Indeed, in its 2007 report *Public health: ethical issues* the Council highlighted that there are significant ethical difficulties inherent in taking such an approach, and **we endorse here the current approach to the allocation of bodily material based on clinical factors, such as the urgency of the person's condition and the compatibility of the available material.** Rather, we are considering the issue from a policy

⁶⁴³ 'Recipients' include both individual patients, and researchers/research organisations using bodily material in their research.

perspective and asking the question: *What action should policy-makers take in response to these public health challenges?* In the context of organs, the challenge is often put to policy-makers that the current shortage constitutes a national emergency, in response to which radical measures would be justified.⁶⁴⁴ We highlight here the central role of public health initiatives in limiting the scale of that emergency in the first place.

- 7.5 Governmental, regulatory and professional bodies are currently grappling with the broad question of how the current demand for a wide range of bodily material may better be met in a variety of ways. Examples include the establishment of the ODT by UK health departments (see paragraph 3.52); the ongoing call for a shift to an 'opt-out' system for deceased organ donation by the British Medical Association;⁶⁴⁵ and the consultation in early 2011 by the HFEA on how sperm and egg donors should be compensated (see paragraph 2.35). Notably absent from these public discussions is consideration of how demand could be reduced by preventive public health action.⁶⁴⁶
- 7.6 In the case of organ transplants, we recognise, of course, that there are many existing public health initiatives that aim to reduce levels of (among others) the diseases that contribute to the growing demand for donor organs. **We argue that it is crucial that the policy-makers and health professionals concerned with organ transplantation should also explicitly highlight these contributory causes in relation to the 'gap' between demand for, and supply of, donor organs. In so doing, they could both add weight to the arguments surrounding the role of government in promoting good public health, and also act to raise public awareness of the avoidable causes of some organ failure.**
- 7.7 As we have noted in several other contexts in this report, the position regarding gametes is rather different from that of organs. While it is broadly accepted that it is appropriate for the public health agenda to include consideration of sexually transmitted diseases such as chlamydia that may impact on later fertility, there is no such consensus that any state-sponsored organisation should seek to influence childbearing patterns, such as the age at which women have children. We note, however, that the state *has* taken a role in discouraging teenage pregnancy,⁶⁴⁷ and that NICE guidelines on fertility services specifically refer to age, in that the recommendations on access to IVF services apply to women aged between 23 and 39 years.⁶⁴⁸ There is thus a precedent in public interest in the age of childbearing. As we emphasised earlier (see paragraph 3.49), the factors that influence the age at which women have their first child are complex – and many relate to social and economic issues well outside the range of this report. Nevertheless, we suggest that there is a potential role here for public health education and advice to improve awareness among women about the consequences of delaying childbearing.

Alternatives to donation

- 7.8 Chapter 3 sets out a number of ways in which scientific developments may potentially decrease demand for donated material, either through reducing the levels of need that arise in the first place, or by providing artificial substitutes. Developments in the first category include:

⁶⁴⁴ See, for example, Spital A, and Taylor JS (2007) Routine recovery of cadaveric organs for transplantation: consistent, fair, and life-saving *Clinical Journal of the American Society of Nephrology* 2: 300-3.

⁶⁴⁵ British Medical Association (2 July 2011) *Doctors stick with opt-out organ donation policy*, available at: <http://web2.bma.org.uk/nrezine.nsf/wd/RTHS-8J9KX8?OpenDocument&C=2+July+2011>.

⁶⁴⁶ We note, however, that this issue does arise when considering the particular difficulties faced by some ethnic communities in accessing compatible organs: see Randhawa, G (2011) *Achieving equality in organ donation and transplantation in the UK: challenges and solutions*, available at: <http://www.better-health.org.uk/sites/default/files/briefings/downloads/health23-3.pdf>.

⁶⁴⁷ See, for example, the work of the Teenage Pregnancy Independent Advisory Group, which published its final report in 2010: Teenage Pregnancy Independent Advisory Group (2010) *Teenage pregnancy: past successes - future challenges*, available at: <http://education.gov.uk/publications/standard/publicationDetail/Page1/TPIAG-FINAL-REPORT>.

⁶⁴⁸ National Institute for Clinical Excellence (2004) *Fertility assessment and treatment for people with fertility problems*, available at: <http://www.nice.org.uk/nicemedia/live/10936/29269/29269.pdf>.

- techniques that may enable those wishing to conceive to use their own gametes, for example through the use of intracytoplasmic sperm injection (ICSI), pre-implantation genetic diagnosis (PGD), and developments in egg freezing (paragraphs 3.44 to 3.46); and
- techniques that extend the life of transplanted organs, hence reducing demand for subsequent transplants (paragraph 3.35).

Work on artificial substitutes includes:

- the possibility of using technological devices in place of a donated organ, such as the use of left ventricular assist devices (LVADs) to replace, rather than bridge the gap before, heart transplants (paragraph 3.36);
- the development of artificial bodily materials such as blood, corneas, and skin (paragraph 3.42);
- regenerative medicine, where stem cells may be used to repair the original damaged material (paragraph 3.41);
- other uses of stem cells, from the creation of platelets to the use of cells to create tissue on which new medicines could be tested (paragraphs 3.39 to 3.40); and
- xenotransplantation, such as the use of pigs' heart valves (already routine) in heart operations (paragraph 3.43).

7.9 The Council has not considered the merits or promise of any particular development in reducing demand for bodily material in the future. It seems clear, nevertheless, that in some areas of medicine at least, such developments are likely to start playing a role in meeting need that, in the past, might have been met by donated material. The speed at which this may happen, however, should not be over-estimated: what appear to be exciting research results often take many years before developing into routine procedures. It may well also be the case that, in so doing, they act not to *replace* demand for bodily material, but rather to *supplement* it, with the end result being more patients treated, but just as many (or more) still waiting (see paragraph 3.26). It is therefore exceedingly hard to make any meaningful predictions as to whether, and to what extent, demand for any particular form of material might drop in the future. We do, however, make the following observations:

- These developing areas pinpoint the importance of research within the donation field. Research on the optimisation of organs donated after death, with the aim of improving transplant outcomes, for example, may lead to a good outcome in itself (longer graft life) and at the same time reduce the need for other bodily material (by reducing the need for re-transplantation). This demonstrates how closely entwined 'treatment' and 'research' may be, and the very direct personal benefits that may be felt from research. We return to this point below (see paragraph 7.16).
- We therefore welcome the fact that medical research has been protected in the current very difficult funding environment, and welcome the commitment thus shown to the high value of such research.
- We highlight the importance of ensuring material is available for research, a point to which we return below (see paragraphs 7.40 to 7.41 and 7.45 to 7.63).
- We also note that some, at least, of the developments might be regarded not just as alternatives to donation, but indeed as preferable to the use of donated material: the ability to use one's own (frozen) eggs rather than donated eggs being one example. Other developments might be regarded as more neutral replacements: the main criterion, for example, in choosing between a donated cornea and an artificial cornea if available, would be likely to be clinical safety and effectiveness, rather than source.

Public and private concerns

7.10 The themes of 'public' and 'private' activity have emerged repeatedly throughout this report, and Chapter 4 analysed the complex ways in which they often interact (see paragraphs 4.5 to 4.6). Any consideration of the role of intermediaries, whether in the form of individuals or of

organisations, inevitably raises the question of what is a matter of public interest (with the connotation that the state or state-sponsored organisations, in particular, might have duties to act); and what is essentially private (in this context emphasising non-interference by the state). Chapter 5 set out the view that the "the ongoing good health of members of society" provides a strong ethical basis for attempting to meet the health needs highlighted by the demand for bodily material – whether through public health measures or through ethically acceptable ways of increasing supply. We have indicated various 'public' initiatives that could contribute towards this aim, in the form of public health interventions likely to reduce demand, and in the form of active support for medical research that may reduce demand or provide substitutes for supply. Here we consider the wider implications for policy of the various (and interlocking) public and private aspects of donation.

- 7.11 First we consider explicitly the **role of the state** in responding to the mismatch between demand and supply for bodily material in medicine and research. We have alluded above (see paragraph 7.4) to the way that 'policy-makers', such as government and governmental organisations, parliaments, and relevant professional organisations, are often called upon to present solutions to this mismatch; and we gave some examples of how they have responded in paragraph 7.5. Such a discourse suggests a strong belief within the regulatory establishment, the media, and (arguably) the wider general public, that some forms of donation are indeed a matter of great 'public' interest: that if needs that are widely seen as being legitimate (the need for blood and for organs for transplantation reflecting perhaps the broadest area of consensus) are not being met, then it is the 'job' of 'those in charge' to take action.⁶⁴⁹ We have already suggested that the potential benefits to health to be achieved through the donation of bodily material for treatment and research represent a sufficient ethical justification for taking action, within ethical limits, whether this takes the form of reducing demand or increasing supply. Such conclusions, however, leave open the question of who or what (if anyone) is responsible for ensuring such interventions take place.
- 7.12 We return here to the idea of the state as the 'steward' of good health presented in our earlier report *Public health: ethical issues*. As we suggest in Chapter 5, such a 'stewardship model' sets out a clear obligation on the part of states to enable people to live healthy lives, both by promoting and facilitating healthy lifestyles and by taking positive action to remove inequalities that affect disadvantaged groups or individuals (see paragraph 5.13). Many of the specific recommendations in that earlier report, particularly those relating to obesity and excessive alcohol use, are clearly highly relevant to the subject of this report. **However, we also conclude that the underpinning concept of the state as steward of public health is equally applicable to the responsibilities of states with respect to the donation of bodily materials.** We endorse the views of those respondents to our consultation who saw responsibility as appropriately resting with the state, while noting at the same time the common-sense constraint that, while organisations may have responsibilities, only individuals have the bodies from which bodily material may come.⁶⁵⁰
- 7.13 In our view, this stewardship role is as applicable to the donation of reproductive material as it is to other forms of bodily material, notwithstanding the view (very firmly expressed by some) that fertility is purely a private concern.⁶⁵¹ As we have noted earlier, the state does already take a role in regulating fertility treatment via the Human Fertilisation and Embryology Act and the HFEA; there is public policy guidance from NICE recommending that publicly-funded IVF treatment should be made available to all eligible women; and it is widely accepted that the state should have a role in protecting the welfare of children. We conclude that the donation of

⁶⁴⁹ Department of Health (20 December 2010) *Andrew Lansley urges people to give blood*, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_122978.

⁶⁵⁰ Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics).

⁶⁵¹ *Ibid*; Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader).

reproductive materials is a matter of public, as well as private, concern, as reflected in our recommendations.

- 7.14 We have emphasised that the role of the stewardship state also includes taking action to minimise inequalities and to promote the welfare of those who would, without positive action, be excluded from benefits or services. In the context of donation, we point to the statistics that demonstrate that BME populations are significantly less likely to become donors (across a range of different forms of bodily material) and hence are also significantly less likely to benefit from materials where immunocompatibility is an issue, because acceptable 'matches' are more likely to be found within ethnic populations (see, for example, paragraph 3.28).⁶⁵²
- 7.15 In Chapter 6, we suggested that one conclusion that could be drawn from the limited literature we were able to review on people's attitudes to donation was that individuals differ markedly in their instinctive attitudes towards and anxiety about donation (in the context of both blood and deceased donation). We concluded that it might therefore be more practical to focus organisational efforts on reaching those individuals who are not particularly troubled by these anxieties (see paragraph 6.11). However, such an approach will only be appropriate where it is irrelevant *who* donates as long as sufficient material overall is obtained. Where immunological differences mean that low levels of donation from particular ethnic communities translate directly into particular difficulties of access for potential recipients from these communities, then this leads to clear difficulties for the NHS in responding equitably towards all its patients. **We therefore suggest that a stewardship state has a direct responsibility to explore the reasons why some populations are hesitant to donate, and if appropriate, to take action to promote donation.**
- 7.16 Second, we consider the issue of **research**. It is only too easy for any consideration of the donation of bodily materials to concentrate on their use in direct treatment, and overlook, or take as of secondary importance, their possible research uses. We have, however, highlighted very clearly in Part I of this report the central role that bodily materials play in research, and how difficulties in access to the necessary tissue are acting in some cases as the key factor limiting progress in research (see paragraph 3.21). Paragraph 7.9 notes the direct links that may exist between research and meeting needs for bodily material. **We state here our view that research, and the future health benefits that research seeks to bring, are of vital public interest.** If we argue (as we do) that the state has an interest in promoting the good health of its citizens, and has a role as a steward in supporting and facilitating environments in which good health may flourish, then such an interest will also include supporting and facilitating environments in which health-related research may flourish. We have highlighted elsewhere in this report that the difficulties experienced in accessing tissue for research are essentially different in kind from the 'shortages' described in other fields: the available evidence suggests that, if asked, plenty of people are more than willing to permit their tissue to be used for research purposes (see paragraph 6.82).⁶⁵³ The difficulties that arise relate therefore not so much to encouraging people to consider donating, but rather in the need for much better systems to be in place to ensure that consent is sought and documented appropriately; and that materials are appropriately shared.
- 7.17 Much health-related research using tissue or healthy volunteers is, of course, carried out within the private (i.e. commercial) sector. **We consider, however, that while such research may lead to significant financial gain, such private interests do not in themselves extinguish the public good of what they produce:** that is, the treatments and medicines on which all health systems (public and private) and individual patients (private individuals, members of the

⁶⁵² Morgan M, Hooper R, Mayblin M, and Jones R (2006) Attitudes to kidney donation and registering as a donor among ethnic groups in the UK *Journal of Public Health* **28**: 226-34.

⁶⁵³ We note here that the donation of gametes for research raises very different issues from other forms of material, and we return to this subject separately later in this chapter.

public) rely. It is worth pointing out that, while most members of the public will not, at any point in their lives, directly benefit from donated blood, organs or gametes, almost all will benefit in some way from new medicines developed using donated tissue and tested on healthy volunteers.

- 7.18 We note the concerns that financial gain arising out of material that has been donated freely may be seen by some as 'unjust enrichment'. We do not, however, support the argument that the individual whose donated bodily material has been used in research that ultimately leads to high financial returns should, in retrospect, exercise a claim to share in these profits on a personal level. Any commercial return would be many years after the initial donation, and the particular contribution of any individual would in most circumstances be impossible to measure. We suggest therefore, that although it is clearly just that commercial companies in such circumstances should seek in some way to share the financial benefits of their research more widely, such benefit sharing should take place in a wider context, rather than in response to the financial potential of bodily material from particular individuals.
- 7.19 Two potential ways in which such benefit sharing or partnership might emerge include, first, active financial support from the commercial sector for tissue banks as a 'public good' for researchers from all sectors; and second the development of ongoing relationships between tissue donors and the research teams (whether in the public, voluntary or commercial sector) whose work depends on access to their samples. Such a relationship between donors and recipients (in the form of research organisations) provides one way in which the 'gift relationship' between donor and recipient may be both maintained and mutual (see paragraph 5.68), and the donor's 'interest' in their donated material maintained. Such a 'relationship' should not, of course, be imagined as a personal relationship: rather, the donor should be treated (if they wish) as part of a community of research participants that is recognised as such.⁶⁵⁴ We note also here that the role of consent at the point of donation, including clear information about possible commercial uses, is clearly central in ensuring ethical treatment of donors in this respect. We return to issues concerning research in more detail below (see paragraphs 7.45 to 7.63).
- 7.20 Third, questions of what is public and what is private also apply to the question of **property rights in bodies and body parts**. We have already argued that, in the context of the relationship between persons and their bodily material, we need to unpack donors' rights with respect to control over their bodily material, and to ensure that these are appropriately safeguarded (see paragraphs 5.15 to 5.20). While the legislative frameworks of the Human Tissue Act and the Human Fertilisation and Embryology Act provide some mechanisms for such safeguarding, particularly with respect to consent, they are far from complete: we note, for example, that the Court of Appeal in the case of *Yearworth* felt it necessary to recognise men's property rights in their own sperm in order to provide them with a remedy for the harm caused to that sperm when in the custodianship of an NHS hospital (see paragraph 2.32). Unless a wider range of remedies for the source of material (for example compensation if donated materials are used outside the scope of the granted consent) is developed through legislation, it seems likely that further attempts will be made in the courts to develop property rights to protect donors' interests. **We recommend that, by whatever means the law develops in this area, a clear distinction should be retained between the property rights of the source of the material with respect to control and compensation (that is, compensation for misuse rather than recompense in the form of economic gain), and property rights with respect to income.**
- 7.21 A separate issue arises in connection with the legal status of bodily material once separated from its source. As we noted in Chapter 2 (see paragraph 2.31), where material has been modified by human skill, then it may become the subject of 'full' property rights and be subject to sale, transfer and so forth, like any other commodity. Given that such modified materials are now part of a global marketplace, and taking into account the importance of intellectual property rights in enabling research to continue, it is hard to see how this could be otherwise without

⁶⁵⁴ Note, for example, the use of the terminology of „supporters“ for those who contributed their health-related information and samples to UK Biobank.

challenging the whole basis on which such transactions currently take place. However, we do raise the question as to what degree of 'modification' or 'skill' should be necessary to achieve this change into a straightforward commodity. Case law has given conflicting answers,⁶⁵⁵ with the Court in *Yearworth* most recently suggesting that freezing in liquid nitrogen alone might be sufficient. Such lack of clarity adds to the uncertainty around the legal status of materials that are donated for transplantation: for example, the status of an organ that is being treated prior to transplantation. We suggest that where material is clearly being held (and possibly treated in some way) for the purpose of transplantation, it should be conceptualised as being in the 'custodianship' of third parties. Such a model of custodianship would include rights of possession and use, but only for the purposes envisaged in the original consent. It would also include remedies, for example against misuse or interference by other third parties.

- 7.22 Finally, we raise the question of public interest in the issue of cross-border health care and questions of **national self-sufficiency**. We have already noted at least one important distinction between travelling abroad for organ transplants and for fertility treatment: in the first case most treatment will be unregulated, depending on organs made available through illegal markets;⁶⁵⁶ while in the second case the treatment, using gametes supplied in return for a fee (and also probably anonymously), would be unlawful in the UK, but not necessarily in the country in which it takes place. In Chapter 6 we endorsed the current UK position that no payments should be offered for organs above and beyond the direct reimbursement of costs incurred as a result of the donation (see paragraph 6.40). In accordance both with our conclusions as to the difficulties inherent in systems involving financial rewards for organs, and with the fact that no country in the world provides legal organ transplants from incentivised donors to those travelling from abroad, **we endorse the current international consensus, expressed through the Declaration of Istanbul, the WHO Guiding Principles and other statements, that 'organ trafficking' and 'transplant tourism' should be banned. We further emphasise the importance of concerted action being taken to enforce this stance, so that such practices cannot continue with impunity.**
- 7.23 The situation, however, is potentially rather different where the activities in question – for example the selling of gametes – are perfectly legal in the country of origin. The question then arises whether there can be any public interest in seeking to exert control over individuals travelling abroad to access such treatment, or over NHS institutions obtaining materials that have been provided in such circumstances. The guidance on cross-border reproductive care issued in 2011 by ESHRE cited earlier in the context of reward for donors (see paragraphs 6.67 to 6.69) is also relevant in considering the regulatory aspects of the current position, where women and couples travel from the UK to other countries, either in order to be able to access donor gametes more easily, or to be able to access treatment not permitted in the UK, such as the use of anonymously donated gametes. We have already suggested (see paragraph 5.12) that concerns about individual liberty make it hard to imagine circumstances in which individuals seeking treatment that is lawful in the destination country should be prevented from travelling. However, there is a challenge here for UK regulators: if clinics and doctors regulated within the UK refer patients abroad for treatment that is forbidden in the UK, what, if any, action should (and could) they take? On the one hand, it may be argued that activities taking place legally in a non-UK jurisdiction are simply outside the sphere of interest or influence of UK regulatory bodies. On the other hand, where clinics set up established relationships with clinics in other

⁶⁵⁵ Mere preservation was not enough according to *Dobson*, but in *Yearworth* the Court apparently thought that freezing in liquid nitrogen would be sufficient: *Dobson v North Tyneside Health Authority* [1997] 1 WLR 596; [1996] 4 All ER 474; *Yearworth and others v North Bristol NHS Trust* [2009] EWCA Civ 37.

⁶⁵⁶ We exclude from our consideration here cases where individuals travel to another country in order to receive a voluntarily-donated transplant from a relative, although we note that, as in any such donation in the UK, factors of genuine voluntariness may remain. 'Transplant tourism' is defined in the Declaration of Istanbul as follows: "Travel for transplantation becomes transplant tourism if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals, and transplant centres) devoted to providing transplants from outside a country undermine the country's ability to provide transplant services for its own population".

countries, and professionals, then directly refer patients within these arrangements, it is hard to argue that the professionals and organisations based in the UK have no professional responsibility for the standards prevailing at the receiving clinic.

- 7.24 ESHRE takes the view that “if a home practitioner refers the patient to a specific clinic, the practitioner shares a responsibility for the general standards used in that center (such as the complication rate). The specific treatment of the individual abroad remains the responsibility of the local professional team.”⁶⁵⁷ We agree. **We conclude that, where clinics and professionals within the UK make arrangements to refer patients to clinics and professionals abroad, they should share professional responsibility for the general standards prevailing at the receiving centre. Such „general standards“ include factors such as the protocols used to recruit donors (with particular reference to the hazards of using intermediate agencies for such recruitment) and the routine measures taken by the clinic to safeguard the welfare of donors. Regulatory bodies such as the General Medical Council should maintain general oversight in this area, in the same way as they oversee other aspects of professional standards.**
- 7.25 We further note that, while the ESHRE guidance highlights the importance of protecting against the abuse of donors coming from abroad, and guarding against trafficking, in the European context, these concerns clearly arise worldwide. We also note that various international statements on the donation and use of bodily material, such as the WHO Guiding Principles, exclude reproductive material from their remit. **We recommend that the World Health Organization should develop appropriate guiding principles to protect egg donors from abuse or exploitation.**
- 7.26 As we have pointed out elsewhere, once bodily material has been separated from its source, it too, readily crosses borders: for example, much of the plasma used in the UK comes from abroad sourced from paid blood donors.⁶⁵⁸ We make the following observations:
- Transparency, for example with respect to where material has come from, and the circumstances in which it has been obtained, is essential. One way of achieving such transparency might be through a 'fair-trade' labelling system, building on the requirements set out in the EU Tissues and Cells Directive that all material imported from third countries should meet the same quality and safety standards required within EU countries.⁶⁵⁹ Legislation is, of course, only one way of ensuring such standards are met, and we note here the influence of professional standards and practices in this area.⁶⁶⁰
 - Where payment is currently made to such donors, the same concerns set out in paragraph 6.26 (with respect to the welfare of the donor, the potential threat to the common good and so forth) should be considered, in order to determine whether such payment is acceptable. In the case of plasma, for example, given the importance of the need for plasma, the difficulties in sourcing it at present in the UK because of the theoretical risk posed by vCJD, and the highly regulated nature of the donor recruitment and quality systems,⁶⁶¹ it would seem likely that those tests would be met, and hence that reward for donors in these circumstances would constitute an ethically vindicated rung 6 of our Intervention Ladder.
- 7.27 The considerations outlined above are mainly concerned with the nature and extent of the public interest in acting to limit private decisions to travel abroad for treatment or to carry out research. However, we also need to consider to what extent there is a public interest in seeking

⁶⁵⁷ Shenfield F, Pennings G, De Mouzon J *et al.* (2011) ESHRE's good practice guide for cross-border reproductive care for centers and practitioners *Human Reproduction* **26**: 1625-7, paragraph 2.5.

⁶⁵⁸ BPL, personal communication, 10 June 2011; BPL (2011) *About plasma*, available at: <http://www.bpl.co.uk/about-plasma/>.

⁶⁵⁹ EU Directive 2004/23/EC, Article 9.

⁶⁶⁰ See, for example, the role of The British Association for Tissue Banking and the UK Stem Cell Bank: The British Association for Tissue Banking (2011) *The British Association for Tissue Banking homepage*, available at: <http://www.batb.org.uk/>; UK Stem Cell Bank (2011) *UK Stem Cell Bank homepage*, available at: <http://www.ukstemcellbank.org.uk/>.

⁶⁶¹ See, for example, BPL (2011) *About plasma*, available at: <http://www.bpl.co.uk/about-plasma/>.

to ensure that individuals do not feel tempted to 'get round' UK regulation in this way: in other words, what, if any, duty is there on the state (or other interested organisations) to ensure that there is a sufficient supply of bodily material donated within the UK so that demand is not simply diverted to other, potentially less-scrupulous, sources? We conclude here that while the existence of such 'cross-border health care' certainly constitutes evidence of the *extent* of the pressure for certain forms of bodily material within the UK, such a consideration cannot be a deciding factor in policy-making. **We have already argued that the state has a stewardship role in maximising the donation of bodily materials, where these have the potential to contribute to improved health, and within ethical limits. To that extent, and no further, the aim of national self-sufficiency is clearly laudable. However, where this national self-sufficiency cannot be achieved without taking action that would otherwise be regarded as unethical, the fact that people may still choose to travel abroad should not force a change of policy.**

Implications for intermediaries by form of material

Blood

- 7.28 The various systems currently in place within the UK for facilitating blood donation clearly already seek to minimise physical barriers for those inclined to donate: examples include the wide-ranging use of mobile donation units and the encouragement of 'workplace' donation. Indeed, the work of the NBS in bringing the possibility of blood donation directly into potential donors' day-to-day lives might be regarded as a model of this particular approach.
- 7.29 Barriers to blood donation are not, of course, only physical, and as in organ donation there may be other factors hindering particular communities from feeling able to donate. As we noted in Chapter 6 (see paragraph 6.11), the fact that some groups may be more troubled by the idea of donation than others, and hence less likely to respond to generalised appeals to donate, may not be important where only the *quantity* of total donations is relevant. However, such differences become very important if factors such as immunological requirements mean that lower donations from particular communities render the NHS unable to respond to patient need in an egalitarian way (see also paragraph 7.36). In such circumstances, we consider that the intermediary organisations concerned, such as the NBS, have a duty to engage with communities, both through dialogue to seek to understand concerns, and through direct promotion of the benefits of donation to the community. We commend here the work of the NBS and the African Caribbean Leukaemia Trust, for example, in initiatives such as Daniel De-Gale week, to encourage both blood and bone marrow donation from black and mixed race communities.⁶⁶²
- 7.30 By contrast with blood donation by adults, the idea of obtaining **cord blood** from the umbilical cord, in order to obtain stem cells from a baby at birth, has been much more controversial. Concerns have been expressed about the possible risk to the baby or mother if the management of the third stage of labour is altered or delayed in order to promote successful cord blood collection,⁶⁶³ and the issue has been further complicated by the growth of private cord blood banks which offer to store a baby's cord blood for his or her own future use, although the value of this is challenged (see paragraph 1.8).

⁶⁶² See: NHS Blood and Transplant (2010) *Daniel De-Gale week*, available at: <http://www.blood.co.uk/news/news-and-events/daniel-de-gale-week/>.

⁶⁶³ The Royal College of Obstetricians and Gynaecologists notes that there is considerable debate about the optimal time for cord clamping: Royal College of Obstetricians and Gynaecologists (2006) *Umbilical cord blood banking (Science Advisory Committee opinion paper 2)*, available at: <http://www.rcog.org.uk/files/rcog-corp/uploaded-files/SAC2UmbilicalCordBanking2006.pdf>, paragraph 5.1.

- 7.31 'Public' cord blood banking, on the other hand, is widely recognised as providing a vital source of stem cells, supplementing the availability of stem cells available for treatment through bone marrow donation and increasing the chance that a suitable 'match' will be found for waiting patients.⁶⁶⁴ The NHS Cord Blood Bank and the Anthony Nolan Trust both collect cord blood from maternity services serving very ethnically mixed populations, with the aim of collecting the greatest variety of tissue types and hence addressing the problem of difficulties in matching minority ethnic populations, and particularly mixed race people, for an adult bone marrow transplant.⁶⁶⁵ The Royal College of Obstetricians and Gynaecologists has offered specific recommendations to NHS trusts with respect to cord blood collection, advising that there should be no alteration in the usual management of the third stage of labour, and that cord blood should be collected by a trained third party, not the doctor or midwife in charge of labour. In particular the College has commended the practice of the NHS Cord Blood Bank of collecting blood "aseptically after delivery of the placenta by trained NBS staff within the delivery unit but outside the delivery room."⁶⁶⁶
- 7.32 We note the growing evidence as to the potential value of publicly-accessible sources of stem cells,⁶⁶⁷ and the procedures recommended by the Royal College of Obstetricians and Gynaecologists to protect the welfare of mothers and babies where cord blood donation is considered. We further note the role of the HTA in licensing cord blood collection.⁶⁶⁸ We conclude that the collection of cord blood in these circumstances for public use is an example of a justified public intervention, and endorse the work of the NHS Cord Blood Bank, Anthony Nolan Trust and others in facilitating the collection of cord blood for this use. We further note the recent report from the UK Stem Cell Strategic Forum which has called for an increase in the UK's 'inventory' of cord blood from 15,500 units to 50,000 units.⁶⁶⁹ In particular, it recommended that a UK Stem Cell Advisory Forum should be established in order to manage a UK cord blood inventory, along with a UK stem cell registry and a database of patient outcomes following transplantation. **We endorse these recommendations.**

Organs

- 7.33 As we noted at the end of Chapter 5 (see paragraph 5.85), an approach to the donation of bodily material that focuses on intermediary professionals and organisations is far from novel. Such an approach was at the heart of the recommendations made by the ODT, which sought to "resolve the problems that result from the unstructured and fragmented arrangements that are currently in place for [deceased] organ donation and, to a lesser extent for organ transplantation."⁶⁷⁰ Concrete recommendations included the introduction of a UK-wide network of organ retrieval teams; 'potential donor audits' to identify those who might after their death be able to donate organs; financial reimbursement to hospitals to ensure that hospitals where donors died were not financially disadvantaged; and a requirement for clinical staff involved in

⁶⁶⁴ Ibid, paragraph 4.1; other advantages cited here include lower incidence of viral transmission and lower incidence and severity of graft versus host disease.

⁶⁶⁵ See: NHS Blood and Transplant (2011) *Cord blood donation: frequently asked questions*, available at: <http://www.nhsbt.nhs.uk/cordblood/faq/>.

⁶⁶⁶ Royal College of Obstetricians and Gynaecologists (2006) *Umbilical cord blood banking (Science Advisory Committee opinion paper 2)*, available at: <http://www.rcog.org.uk/files/rcog-corp/uploaded-files/SAC2UmbilicalCordBanking2006.pdf>, paragraphs 7 and 5.1.

⁶⁶⁷ The UK Stem Cell Advisory Forum, for example, has identified a need for unrelated stem cell donors, noting that in the UK over 400 patients with fatal diseases could benefit from a stem cell transplant, including through the use of stem cells obtained via cord blood: NHS Blood and Transplant (2010) *The future of unrelated donor stem cell transplantation in the UK*, available at: http://www.nhsbt.nhs.uk/pdf/uk_stem_cell_strategic_forum_report.pdf.

⁶⁶⁸ See: Human Tissue Authority (2010) *Guidance document for establishments working with umbilical cord blood*, available at: http://www.hta.gov.uk/db/documents/Cord_Blood_Guidance_Document.pdf; Human Tissue Authority (2010) *Regulation of cord blood collection (procurement) by the Human Tissue Authority, letter dated November 2010*, available at: http://www.hta.gov.uk/db/documents/Cord_blood_communication_Nov_10.pdf.

⁶⁶⁹ The NHS Cord Blood Bank, which collects cord blood from five hospitals in the London area, currently has an inventory of 15,500 cord blood units. The report recommends that the inventory should be increased to 50,000 cord blood units: NHS Blood and Transplant (2010) *The future of unrelated donor stem cell transplantation in the UK*, available at: http://www.nhsbt.nhs.uk/pdf/uk_stem_cell_strategic_forum_report.pdf.

⁶⁷⁰ Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf, p21.

the treatment of potential organ donors to receive mandatory training in the principles of donation.⁶⁷¹ **The Working Party endorses the Organ Donation Taskforce's focus on tackling the structural problems that have, in the past, hindered the optimal use of the organs that are potentially available.**

- 7.34 However, an intrinsic element of such an approach is the secure embedding of systems to facilitate donation within the structures and organisations making up the NHS. Some aspects of these systems are managed on a central basis: these currently include the work of NHSBT itself, the 'specialist nurse – organ donation' (SN-OD) network managed by NHSBT, and the newly-established UK Donation Ethics Committee (UKDEC). Many other aspects are managed at local level, as part of local NHS services. Both centralised and local aspects of the English NHS are currently experiencing significant levels of organisational restructuring (see paragraph 2.5); moreover, while the NHS has been protected to a degree within the current spending round, there is continuing and ongoing pressure on health budgets.⁶⁷² **There is clearly a risk that, in the face of such organisational changes and pressure on budgets, valuable systemic improvements that have led in recent years to significant increases in the number of organs made available for transplantation might be lost. We recommend that the Department of Health should monitor closely the impact of these changes on organ donation services, and be prepared if necessary to act to protect systems that have been shown to work well.** We draw attention again here to our earlier recommendation that the Department of Health should act to ensure that living donors' expenses continue to be covered in full, despite the abolition of PCTs (see paragraph 6.41).
- 7.35 These changes in the NHS in England aim to make services more locally-responsive by putting the main drivers of change in the hands of 'consortia' of GPs.⁶⁷³ While such changes are in their very early stages, they could be seen as continuing the general move over the past two decades to a more 'primary-care-oriented' NHS, shifting influence away from hospitals and towards general practice and other primary care services. The ODT sought to ensure that organ donation had an influential voice in strategic decision-making, by recommending that each trust should have an identified clinical donation 'champion' (now renamed 'clinical lead'), and a trust donation committee.⁶⁷⁴ Given the gradual shift in influence away from hospital trusts, it is likely to become increasingly important that primary care is appropriately represented in these structures.
- 7.36 We have indicated that some population groups within the UK, in particular South Asian and African Caribbean communities, are less likely than others either to sign the ODR, or to agree to the donation of the organs of a deceased family member. As a result, the NHS experiences difficulties in responding equally to need for donated material within these communities (see paragraph 3.28). The reasons for these lower levels of donation are complex: while studies have consistently demonstrated that African-Caribbean and South Asian individuals in the UK are supportive of organ donation and transplantation, they have not, on the whole, identified what would motivate more people to come forward as potential donors, although there are some indications that 'grassroots' community networking may be more effective than the use of educational materials.⁶⁷⁵

⁶⁷¹ Ibid.

⁶⁷² See, for example, The NHS Confederation (2009) *Dealing with the downturn*, available at: http://www.nhsconfed.org/Publications/Documents/Dealing_with_the_downturn.pdf.

⁶⁷³ Department of Health (2010) *Equity and excellence: liberating the NHS*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117352.pdf.

⁶⁷⁴ Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf, recommendation 4.

⁶⁷⁵ See: Randhawa, G (2011) *Achieving equality in organ donation and transplantation in the UK: challenges and solutions*, available at: <http://www.better-health.org.uk/sites/default/files/briefings/downloads/health23-3.pdf> for a review of the research in this area.

- 7.37 The Council is aware of the work undertaken by the ODT in seeking a better understanding of how religious belief may affect the possibility of organ donation: both in clarifying that no major world religion has a clear teaching forbidding organ donation (and indeed the widely shared nature of the position that it may constitute a good act); and in identifying the importance of disentangling 'cultural' from 'religious' concerns about donation.⁶⁷⁶ We are also aware of the 'DonaTE' (Donation, Transplantation and Ethnicity) programme of research currently being funded by the National Institute for Health Research (NIHR) into barriers to organ donation,⁶⁷⁷ and of the various initiatives by NHSBT to support health professionals in approaching families sensitively and appropriately when seeking consent for organ donation.⁶⁷⁸ An overview of the current evidence with respect to inequalities in donation and transplantation, published by the Race Equality Foundation in 2011, argued that while the UK is recognised as being "at the forefront worldwide" in many of its initiatives with regard to culturally competent organ donation educational materials, the success of these initiatives has been limited by a lack of a clear strategy and implementation plan bringing together the various strands of a multi-faceted problem.⁶⁷⁹
- 7.38 We note that this is a highly complex area, and that we have not been in a position to collect evidence on this issue that might enable us to make specific recommendations as to appropriate actions. We therefore limit ourselves here to highlighting what we believe is an important ethical position: the relevance of our notion of the stewardship role of the state (see paragraph 7.12). **That stewardship role includes a duty to take positive action to remove inequalities that affect disadvantaged groups or individuals (see paragraph 5.13). In this context, the stewardship role of the state (exercised here by intermediary bodies such as NHSBT and individual hospital trusts and professionals) includes taking action actively to promote donation, in order to ensure that the NHS is able to offer fair access to donation services to all UK residents.** Such an awareness of the stewardship role of the state in this respect highlights the importance of ongoing dialogue not only at central level between NHSBT and community and faith leaders, but also at the level of individual NHS trusts and their local communities. **We endorse the call of the Race Equality Foundation for a clear strategy and action plan to take forward the lessons emerging from the research in this field.**

Interaction between organ donation for transplantation and other systems

- 7.39 The financial and organisational pressures emphasised above clearly highlight the importance of the many professionals involved in facilitating the donation of bodily material working efficiently and closely together, in order to make best use of available systems and resources. While, as a result of the work of the ODT, considerable effort has gone into improving cooperative working in the area of organ transplantation, a number of respondents to our consultation argued that such cooperation did not necessarily extend across different fields of donation. It was noted, for example, that the ODR does not make any reference to donating either organs or tissue for research; and that those wishing to donate their brains for research could not do so through the 'ordinary' donation channels.⁶⁸⁰ While we recognise that logistical challenges may limit the extent to which the current system established to facilitate deceased organ donation for transplantation may become the single route for all forms of deceased

⁶⁷⁶ Department of Health (2008) *Organs for transplants: the supplement report*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082121.pdf, pp150-7.

⁶⁷⁷ UK Clinical Research Network (2011) *UK Clinical Research Network Portfolio: DonaTE (Donation, Transplantation and Ethnicity) - organ donation and transplantation among ethnic groups*, available at: <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=8837>.

⁶⁷⁸ Randhawa, G (2011) *Achieving equality in organ donation and transplantation in the UK: challenges and solutions*, available at: <http://www.better-health.org.uk/sites/default/files/briefings/downloads/health23-3.pdf>.

⁶⁷⁹ Ibid.

⁶⁸⁰ See also: Ironside, JW (2010) *The UK Brain Banks Network: working together to advance our understanding of brain diseases - presentation given at the Edinburgh International Science Festival* (Edinburgh: MRC UK Brain Bank Network), which included findings from a public engagement exercise carried out by the UK Brain Banks Network which found that 54 per cent of participants thought that the post mortem donation of brain tissue for research should be arranged at the same time as organ donation for transplants.

donation (for example the necessary involvement of a neurosurgeon may render brain donation inevitably a special case), we would make the following observations.

- 7.40 We have already observed in paragraph 7.9, the possibility of close interaction between therapeutic and research uses of bodily material. We reiterate that research should not be seen as a peripheral or 'second-class' use of bodily material, but rather as a mainstream use of donations. Such an approach has implications both for the ways in which individuals are encouraged to authorise the donation of material in advance of their own death, and for the ways in which families are approached after their relative's death. **We suggest that routine information about the Organ Donor Register should include explicit reference to the potential research uses of organs and tissue, and that potential donors should have the option of authorising such uses in advance.** Such information should cover the possibility of therapeutic research taking place alongside donation (in order, for example, to determine the relative effectiveness of established techniques); the possible research use of organs and tissue that are not suitable for transplant in any particular case; and the possible research use of organs and tissue that are not currently used for therapeutic purposes.
- 7.41 The possibility of donating material for research use should similarly be routinely raised with the person's family when authorisation for the removal and use of organs or tissue is sought after death. We recognise that there are some concerns among transplant professionals that such requests risk distressing families, leading to their refusing to agree to a transplant that they might otherwise have granted. Others argue that, if appropriately approached (with enough initial information to be clear about the purpose of the request, and the option of more information later if desired), families appreciate the potential value of contributing to research.⁶⁸¹ We therefore recommend that such an approach should first be piloted, with the impact both on donation rates and on families' experiences of being approached for donation being carefully monitored. **Should such a pilot scheme prove successful, we recommend that the possibility of donating for research purposes (distinguishing between research as part of the transplantation process, and research undertaken with material that would otherwise not be used for transplantation) should be included within the standard consent/authorisation form for deceased donation.**
- 7.42 We also highlight the potential for professionals working with bodily material in one field to take on a more proactive role in connection with other forms of bodily material. We noted above that there may, at times, be good logistical reasons why a brain may not be removed from a deceased body at the same time as other donated organs. However, such logistical reasons should not prevent the NHS providing a single 'point of entry' to donation services by, for example, a specialist nurse in organ donation liaising on behalf of the deceased person and their family with the systems locally in place for brain banking. Similarly, we note the possibility of professionals in one area actively raising awareness of, and facilitating access to, other forms of donation where this appears appropriate: for example, through ensuring that information about signing the ODR, or about local biobanks recruiting donors, is readily available at blood donor sessions.
- 7.43 Finally on the issue of organ donation, we note the importance of robust information systems both in ensuring proper use of donated material and in maintaining trust among the general public. An example of infrastructure failing those who had decided to donate their organs arose in 2010 when it came to light that errors had been made in recording the wishes of would-be organ donors when they expressed their organ donation preferences via the DVLA.⁶⁸² The error

⁶⁸¹ UK Donation Ethics Committee/NRES workshop (November 2010) *Ethics of transplantation*, report to be made available at: <http://www.aomrc.org.uk/donations-ethics-committee/work-programme/231-ethical-issues-in-organ-donation-and-transplantation-research.html>.

⁶⁸² The Guardian (21 January 2011) *NHSBT rapped for incorrect data on 444,000 donors*, available at: <http://www.guardian.co.uk/healthcare-network/2011/aug/30/organ-donor-register-nhsbt-dvla-errors?INTCMP=SRCH>.

affected potential donors who had indicated a wish to donate specific organs, rather than all of their organs. An independent review into how the errors had arisen highlighted how the ODR was being used for operational functions for which it was never designed, and recommended that "NHS Blood and Transplant should design and commission a new register which will be better equipped to deal with the operational demands now placed on it."⁶⁸³ **The Working Party endorses this recommendation. It should not be the case that the public's willingness to donate is undermined by information technology systems that are unable to account accurately for potential donors' preferences.**

Tissue

Therapeutic use

7.44 As we noted earlier, NHSBT Tissue Services are currently able to meet routine NHS demand for tissue for therapeutic use (see paragraph 3.19). One reason for this may be that the potential donor 'pool' – the number of those who die in circumstances in which they can become a tissue donor – is much larger than in deceased organ donation. However, NHSBT Tissue Services also appear to offer an example of how good infrastructure may contribute to meeting need by making it as easy as possible for people who are willing to donate (see Box 7.1).

Box 7.1: NHS Blood and Transplant Tissue Services

NHSBT Tissue Services (part of NHSBT) coordinates, retrieves, processes, banks and supplies human tissue grafts for use in surgery within the NHS.

Tissue Services operates a cost recovery system where charges for the service are made to cover the costs incurred in providing the service. No profit is made. In 2005 it opened a state-of-the-art tissue banking facility at Speke on the outskirts of Liverpool, together with a new blood centre. The tissue facility includes:

- A national donor referral centre where a team of specialist nurses are available 24 hours a day to receive donor referrals, approach potential donor families in order to discuss the options of donation, and complete the consent and donor screening process to allow assessment of the donor in compliance with UK legislation and European Directives. Agreements have been established with four local trusts whereby Tissue Services are routinely notified of deaths and then contact families to discuss donation options. Many other trusts, however, also refer donors.
- An infrastructure to support both tissue and blood banking functions, including operating theatre, cleanrooms, ultra low temperature freezers and a sophisticated environmental monitoring system to ensure that tissues are stored and handled appropriately.
- A consultant specialist in tissue services, supported by a clinical team, who develops clinical policy and is involved in all aspects of tissue services including the development of user and focus groups of surgeons.
- A tissue development laboratory, together with Technology Transfer Centre, in order to exploit developments in cell culture and tissue engineering, and research and development links with universities within the UK.

For more information, see: <http://www.nhsbt.nhs.uk/tissueservices/aboutus/whowhereweare/>.

Research use

7.45 Chapter 3 described some of the many ways in which human tissue is used for research, and its potential value in improving scientific knowledge and developing new medical techniques and treatments. We also highlighted how the main reason for difficulties in accessing tissue for research appears not to be unwillingness on the part of people to donate for research purposes, but rather factors that may arise in connection with the systems and behaviour of intermediaries (both organisational and individual). We summarise these factors below, before looking at action that could be taken in each area:

⁶⁸³ Department of Health (19 October 2010) *NHSBT adopt measures to avoid another error occurring*, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_120653; Department of Health (2010) *Review of the Organ Donor Register*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_120579.pdf.

- bureaucratic difficulties in seeking and documenting consent, and lack of clarity about the scope of the consent to be sought;
- a lack of willingness at times to share samples and their associated data, particularly between the NHS, university and commercial sectors;
- sustainability and source of funding; and
- licensing and governance arrangements that are perceived to be disproportionate and overlapping.

Nonetheless, as set out in Box 3.2, it is clear from a number of examples of good practice that such hurdles can, at least in some circumstances, be overcome. Indeed, the very rationale for the creation of many research tissue banks is to ensure that researchers are able freely to access properly sourced material. We set out below some general conclusions and recommendations as to how such aims might be furthered.

7.46 We begin with **consent**, both in the circumstances where tissue (or blood) is being specifically donated for research purposes, and in the context of consent to the use of tissue excised during surgery or other interventions and no longer required for diagnostic purposes. Chapter 5 sets out our view that any use of tissue should be based on clear information as to the wishes of the person from whom it comes, and we reiterate here that such an approach should also apply to 'excess' material, as well as to material being donated specifically with research in mind. As we discussed at the very beginning of this report, people have very differing views as to the value or personal importance of their bodily material: such views vary widely both between individuals and within one individual as regards different forms of material.⁶⁸⁴ While there is evidence that, if asked, the majority of people are willing to permit their excess material to be used for research purposes, it cannot therefore be concluded that it is not necessary to ask.⁶⁸⁵ However, given that the health professionals responsible for seeking patients' consent to diagnostic interventions and operations will not usually be directly involved in the research, it is clearly important that such procedures are fully integrated into clinical procedures and are not perceived as an undue burden by those responsible for carrying them out. We highlight examples of ways in which this is currently achieved within the UK in Box 7.2.

Box 7.2: Possible approaches to consent used in hospital trusts

- The use of leaflets (distributed both with appointment letters and in out-patient clinics) to seek generic consent for the future research use of any tissue excised during diagnosis or treatment and no longer required for the patient's own care;
- information on the surgical consent form about possible research uses of such tissue, and the opportunity to consent to none, some, or all of the identified uses;
- research nurses, specifically employed to seek patient consent.

7.47 Having established that consent to research use should routinely be sought,⁶⁸⁶ the important question remains as to the *scope* of that consent (see paragraph 2.14). The UK research funders' 'vision document' on human tissue resources published in 2011 is very clear that generic consent for the use of tissue should always be sought unless there is good reason in a particular case not to do so.⁶⁸⁷ This recommendation applies equally where researchers are seeking consent for a specific research project: additional generic consent should also be

⁶⁸⁴ See, for example, Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics).

⁶⁸⁵ See, for example, the 2010 Eurobarometer study of around 1,000 residents in each of 32 European countries, where only six per cent of EU respondents agreed that researchers should be able to use material from biobanks without permission being sought at least once: European Commission (2010) *Europeans and biotechnology in 2010: winds of change?*, available at: http://ec.europa.eu/research/science-society/document_library/pdf_06/europeans-biotechnology-in-2010_en.pdf, p65.

⁶⁸⁶ With the exceptions for 'secondary uses' permitted by the Human Tissue Act (see paragraph 2.19), which were not challenged by the Working Party.

⁶⁸⁷ UK Clinical Research Collaboration (2011) *UK funders' vision for human tissue resources*, available at: <http://www.ukcrc.org/infrastructure/expmed/>.

sought, so that any material not used up in the initial project may be made available for other research use via a tissue bank. The funders, moreover, aim to ensure widespread adherence to this principle, by making the seeking of generic consent in this way a funding requirement.

Box 7.3: Forms of consent

The term 'generic' consent to the future research use of donated material is used in contrast to 'specific' consent to use in one particular study. However, generic consent can come in a number of forms:

- 'blanket' consent, where no limits at all are placed on the future use of the material;
- 'fettered' or 'tiered' consent, where the participant is invited to agree to the future use of their tissue in unknown projects, but given the option of specifying particular categories of research that they wish to exclude; and
- 'broad' consent, envisaging a wide (but not limitless) range of future uses, together with an ongoing relationship between the researchers and the donors.

7.48 **We endorse the research funders' position that it is appropriate routinely to seek generic consent (where necessary in addition to specific consent) for the research use of blood and tissue.** We make the following additional observations:

- Generic consent need not mean 'blanket' consent (see paragraph 2.13 and Box 7.3). We have already pointed to the potential value of an ongoing relationship between donors and researchers as a meaningful way of recognising donors' continuing interests in their donated bodily material and of emphasising the importance of the 'relationship' in the notion of the gift relationship (see paragraph 7.19). Such a relationship need not be burdensome to the individual researcher: examples of good practice already exist in the form of dedicated webpages or electronic newsletters providing general information for donors on the progress of research.⁶⁸⁸ However, we recognise that this form of 'broad' consent is likely to be more applicable to circumstances where the possibility of donation to a particular tissue bank is known at the time of donation. It may be less applicable where generic consent is sought in the context of a specific research project, with the aim simply of protecting the possibility of future use and avoiding waste.
- We also highlight the possibility of 'tiered' consent, where it is possible to categorise particular uses that are known to be controversial, and hence enable donors to consent to some, but not all, unknown future uses. Clearly, in order to offer this option to potential donors, researchers will need to be confident that information systems are in place that will accurately record the donor's preferences. While concerns are sometimes expressed as to the practicality of offering tiered consent options, we are aware of examples where they work well in practice.⁶⁸⁹

7.49 **We further endorse the funders' commitment "actively [to] develop and promote detailed guidance on seeking generic consent, incorporating views of patient and public groups".⁶⁹⁰ We recommend that the process of developing the guidance should involve consideration of the 'broad' and 'tiered' approaches to consent outlined above.**

7.50 We also note here, that while patients who are asked to consent to the future use of their tissue appear very willing to give that consent, levels of knowledge among the general public about the

⁶⁸⁸ See, for example, University of Bristol (2010) *Avon longitudinal study of parents and children: newsletters*, available at: <http://www.bristol.ac.uk/alspac/participants/newsletter/>. We distinguish here between generalised information about research projects and the much more onerous – and at times ethically difficult – question of feeding back information of personal relevance to the tissue donor.

⁶⁸⁹ For example, the Manchester Cancer Research Centre Biobank, in seeking patient consent to the research use of excised cancerous material, specifically offers the opportunity for patients to 'opt-in' to research involving 'xenografts' (where tissue is transplanted into laboratory animals). Professor Chris Womack, personal communication, 14 July 2011.

⁶⁹⁰ UK Clinical Research Collaboration (2011) *UK funders' vision for human tissue resources*, available at: <http://www.ukcrc.org/infrastructure/expmed/>.

research importance of tissue appear relatively low.⁶⁹¹ Improved awareness could only help to make the task of those responsible for seeking consent to the future research use of such tissue less onerous. **We recommend that the Medical Research Council and other research funders should work to increase public awareness of the key role of donated tissue in scientific and clinical research.**

- 7.51 On the question of **willingness to share samples** and associated data, we note that the use of tissue samples for research purposes in any setting, public or private, has the common goal of improving understanding of disease in order to improve patient care. In pursuit of that goal, there is a general acceptance that an appropriate approach is of fair and equitable access to samples that have been legally and ethically collected, based on scientific merit. In Spain, the requirement to share samples is enshrined in the legislation governing tissue banks (see paragraph 2.33). In the UK, a high-profile example of good practice is found in the UK DNA biobanking network, which provides biobank infrastructure to manage samples and data from investigators working throughout the UK, using a common set of agreed principles.⁶⁹² Networks of rare disease collections, such as those relating to childhood cancers, benefit from sharing through aggregated case numbers. However, ensuring what would be seen by the majority to be „fair access“ appears to be difficult to achieve in practice. There are several reasons for this, but the most common is the reluctance of researchers to share samples and data that they have collected using funds and grants that they have acquired for the purpose, usually specifically to further their own (and their institution's) biomedical research activities. Historically, such collections may also be limited by the scope of the consent that has been given by donors, although the funders' recommendations in this area (see paragraph 7.47) should ensure that generic consent is routinely sought in the future.
- 7.52 **We conclude that where material is freely donated by patients or by members of the public, it is not acceptable for individual researchers or research groups to hinder, inhibit or refuse access to other researchers for scientifically valid research, unless there are sound reasons for doing so. Indeed, we take the view that where material has been donated for research use, there is an ethical imperative to make the most efficient use possible of it.** We note that the UK research funders' vision includes strong measures to promote better sharing of samples, with future funding to be dependent on applicants meeting a number of criteria, including: justifying why new tissue collections are necessary; describing how their collection and storage of samples complies with existing good practice; registering collections in a publicly accessible directory; and making appropriate arrangements for fair access. We endorse this approach. **We also welcome the funders' further commitment to ensuring that there is clear guidance on how the interests of investigators who invest time and effort in sample collections are recognised.**
- 7.53 The question of sharing samples is thus closely connected with the issue of **funding**. In the context of individual research projects where new sample collection is necessary, we highlight the practical difficulties that may arise in connection with maintaining a tissue resource when funding for a particular project comes to an end, and hence the difficulty in some cases of ensuring that samples remain available to the research community. **We note that the UK funders make reference to the importance of ensuring that "funding mechanisms for long-term storage and curation are considered", and recommend that particular attention should be given to this issue in initial funding decisions.**

⁶⁹¹ For example, at the Working Party's deliberative event in Bristol, just one person out of 43 attendees mentioned research without being prompted by facilitators. See also: Academy of Medical Sciences (2011) *A new pathway for the regulation and governance of health research*, available at: <http://www.acmedsci.ac.uk/index.php?pid=47&prid=88>, which reported that a patient and public involvement workshop it organised jointly with the Association of Medical Research Charities and INVOLVE highlighted the importance of public communication about the different types of health research.

⁶⁹² Yuille M, Dixon K, Platt A *et al.* (2010) The UK DNA banking network: a "fair access" biobank *Cell and Tissue Banking* 11: 241-51.

- 7.54 A more fundamental question of principle arises in connection with the funding of major tissue resources. Issues of sample collection aside, tissue was considered in the past as financially neutral: as a 'free good'. Now, attention to sample quality, as well as sample storage, processing, distribution and governance requirements in a regulated environment, have all added to research costs. Indeed, securing and maintaining funding for sample collection has been cited by a series of experts as a significant challenge to tissue banks in the next three to five years irrespective of whether they are in the public or private sectors.⁶⁹³
- 7.55 Money for biomedical research in the UK comes from government via a number of routes (including the Department of Health, the Higher Education Funding Councils and the Research Councils), from charities and from the private sector. Access to samples is similarly sought by those working in the public, charitable and private sectors. The samples themselves are donated almost entirely from within the public sector (the NHS), and, as we note above, tissue resources may be conceptualised as a 'public good', with donors providing their material as an act of public benefit (see paragraph 7.19). The question therefore arises as to whether it is appropriate for the commercial sector to contribute in some additional way to the costs of maintaining tissue banks, to reflect the fact that their one of their ultimate aims, unlike that of public and charitable sector researchers, is to make profit for shareholders.
- 7.56 The majority of tissue banks operate on a cost-recovery basis, although commercial tissue suppliers exist to make a profit. Non-profit-making banks may recover their costs either by including an element of infrastructure costs in the fee charged for each item they supply, or by seeking separate contributions to the costs of making samples available, for example through block contracts or start-up grants. Many public sector tissue banks charge a premium to researchers from the private sector, effectively using the private sector to subsidise researchers from the public and charitable sectors. On the one hand, it might be considered that such an arrangement effectively renders the tissue bank itself a commercial institution, charging 'commercial' fees to the private sector; on the other, that such higher fees simply reflect an appropriate return on the part of the private sector for access to 'public goods'.
- 7.57 If the aim is for commercial companies to make – and be seen to make – a specific contribution to the costs of maintaining tissue resources in return for access to the public good of freely donated tissue, then it is certainly the case that one-off contributions, or block contracts, provide a more transparent way to achieve this aim than through differential pricing. However, a number of factors, including the changing nature of the biotechnology sector (with researchers seeking tissue increasingly working in small start-up companies, for example)⁶⁹⁴ and fiscal pressures in the pharmaceutical and biotechnology sectors,⁶⁹⁵ suggest that it may become increasingly difficult for public sector tissue banks to find partners willing to make major one-off contributions. Moreover, enhanced, transparent measures for corporate finance and accounting responsibilities, introduced in response to high profile accounting scandals a decade ago, mean that it is now more difficult for companies simply to donate money to assist setting up of tissue banks, although such accounting requirements do not preclude charitable donations.⁶⁹⁶
- 7.58 The Council's 1995 report *Human tissue: ethical issues* specifically recommended that tissue banks should operate on a not-for-profit basis, a recommendation which we support. We also repeat our earlier observation, that bodily material donated freely by NHS patients and the general public should be understood as a public good. **We conclude that it is appropriate for commercial companies to make an explicit, and additional, contribution, in some way, to the costs of maintaining these public goods to reflect the value of the public's donation. We therefore recommend that any prospective sample collection for research (whether**

⁶⁹³ Betsou F, Rimm DL, Watson PH *et al.* (2010) What are the biggest challenges and opportunities for biorepositories in the next three to five years? *Biopreservation and Biobanking* 8: 81-8.

⁶⁹⁴ CellCentric (2009) *What biotech companies want*, available at: http://www.walescancerbank.com/documents/What_do_Biotech_companies_want-Nessa_Carey.pdf.

⁶⁹⁵ See, for example, Archibald K, Coleman R, and Foster C (2011) Open letter to UK Prime Minister David Cameron and Health Secretary Andrew Lansley on safety of medicines *The Lancet* 377: 1915.

⁶⁹⁶ See, for example, the Bribery Act 2010.

national or local) should be underpinned by a business plan that includes funding contributions from the full range of public, charitable and private sources, depending on where research users for the particular collection are likely to be located. Any such business plan should ensure that the financial value of the materials that patients and members of the public have freely donated should be recognised as being on the 'public' side of the balance sheet. We note that there are a variety of ways in which this may be achieved, particularly given the current climate in which collaborations between industry, the NHS and the academic sector are encouraged.⁶⁹⁷

- 7.59 Finally, we address the issue of **governance** arrangements. Particular criticisms have been raised by researchers whose work is subject to more than one regulatory regime, leading to what are experienced as duplicatory and bureaucratic inspection arrangements.⁶⁹⁸ The HTA and MHRA have recently been exploring the possibility of joint inspections and have announced plans to continue with such joint arrangements in the future.⁶⁹⁹ A memorandum of understanding between the MHRA and HFEA concerning inspections is also under development.⁷⁰⁰ Cooperation of this kind between regulators, that seeks to meet statutory requirements while minimising administrative burdens for the organisation being inspected, is clearly to be welcomed.
- 7.60 Licensing issues under the Human Tissue Act may lead to specific difficulties in accessing tissue for research. The HTA's Code of Practice states that tissue cannot be removed from a deceased person for the purposes of research without a licence being held by the institution where it will take place.⁷⁰¹ Similarly, if bodily material removed for the purpose of transplantation is subsequently used for research, rather than transplantation, the material must be stored on licensed premises, unless it is for a specific research project that has been approved by a research ethics committee.⁷⁰² However, many hospitals where bodily material is removed – either for the purpose of transplantation, or other medical treatment – do not hold an HTA licence, as removing organs for transplantation is explicitly excluded from the licensing requirements. Such hospitals are unable to use any bodily material they remove for research purposes, regardless of the wishes of the deceased person or their relatives. **The Working Party emphasises the need for ongoing dialogue between the Human Tissue Authority and the transplant and communities to find a proportionate way forward.**
- 7.61 **We reiterate here our view that good governance systems, accompanied by transparency of process, are an essential requirement if potential donors are to have the trust necessary for them to contemplate donation in the first place** (see paragraph 5.74). Patients and the public are only likely to give generic consent for research, for example, if they are able to trust in the integrity, not only of the individual professionals involved, but in the organisational systems that will be required to ensure that their consent is properly recorded,

⁶⁹⁷ See, for example, the announcement of a model agreement between pharmaceutical and biomedical industries, universities, and the NHS in order to streamline research contracting processes. The model agreement aims to support clinical collaborations, and is supported by a guidance document setting out how the agreement should be used in developing contracts for specific clinical research collaborations: Department of Health (23 February 2011) *New agreement launched to streamline research collaboration between life sciences industry, universities and the NHS*, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_124576. See also: National Institute for Health Research (2011) *Model industry collaborative research agreement (MICRA)*, available at: <http://www.nihr.ac.uk/infrastructure/Pages/micra.aspx>.

⁶⁹⁸ Human Tissues Group, responding to the Working Party's consultation.

⁶⁹⁹ Human Tissue Authority (2010) *HTA review of the year event 2010*, available at: <http://www.hta.gov.uk/newsandevents/htaevents.cfm/859-Review-of-the-year.html>.

⁷⁰⁰ The House of Commons Science and Technology recommends that the HFEA should be included in a memorandum of understanding with both the MHRA and the HTA: House of Commons Science and Technology Committee (2010) *Bioengineering*, available at: <http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/220/220.pdf>, paragraph 118.

⁷⁰¹ Human Tissue Authority (2009) *Human Tissue Act code of practice 2*, available at:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm>, paragraph 142.

⁷⁰² *Ibid.*, at paragraphs 144-5. However, no licence is required for organ transplantation, see paragraph 135.

their donated material is properly stored and handled, and the research they wish to support is appropriately facilitated.

- 7.62 In response to widespread concerns about the fragmented nature of research regulation, the Academy of Medical Sciences recommended in early 2011 that a new overarching „Health Research Agency“ (HRA) should be established to oversee the regulation and governance of health research.⁷⁰³ **We endorse the overarching aim of simplifying and clarifying research regulation, with particular reference both to the points of difficulty highlighted above and to the ethical requirement of good and responsible governance. We do not take a stance on what particular form such governance ought to take; we do, however, commend the ethical approach taken in this report to those responsible for regulation of this area in the future.**

Research infrastructure

- 7.63 Finally, we highlight the central importance of ensuring the necessary **infrastructure** is in place before people are actively encouraged to donate. The point was made repeatedly to the Working Party that it can be very distressing to offer to donate material, but for the system to be unable to meet the expectations it has raised. This issue arises specifically in the context of seeking material from deceased donors for possible future research use. We recognise that this is a complex issue, but make the following observations with respect to ways forward:
- Tissue from deceased donors is potentially very useful for research, particularly given the difficulties in obtaining some forms of tissue from living donors. All forms of donated tissue (fresh tissue, frozen tissue and fixed tissue⁷⁰⁴) require an efficient infrastructure to be in place in order to ensure that material can be retrieved and processed in the necessary short time-frame.⁷⁰⁵ Additional issues arise in the case of fresh tissue, where potential users must be willing to accept the material as soon as it becomes available, as the window for the research may be as short as a few hours. It is not acceptable to establish systems whereby patients or their relatives are invited to agree to donate tissue, unless there is a realistic chance that the tissue will, in fact, be used.
 - The infrastructure for identifying donors and triggering the process of donating tissue for research potentially exists in the form of the organ donation system. However, discussing the possibility of donating tissue for research may not be uppermost in the minds of health professionals who are primarily concerned with the donation of organs for transplant – a much more obvious and immediate need.
- 7.64 **We recommend that the National Institute for Health Research and the Medical Research Council should take a lead in discussing with research organisations in both the academic and commercial sectors, and with NHSBT Tissue Services, whether there is sufficient demand for a more structured approach to access to tissue from deceased donors for research purposes around the country.** One possible output of such discussions could be the creation of model guidance on acceptable procedures to follow should individual NHS trusts, companies or universities wish to set up local arrangements to support local research.

⁷⁰³ Academy of Medical Sciences (2011) *A new pathway for the regulation and governance of health research*, available at: <http://www.acmedsci.ac.uk/index.php?pid=47&prid=88>, chapter 9.

⁷⁰⁴ Tissue may be used immediately for research purposes („fresh“); or it may be preserved for later use, either through freezing or through being „fixed“ in some form of preservation material (usually formaldehyde solution).

⁷⁰⁵ See, for example, Department of Health (2011) *The Ministerial Advisory Group on Dementia Research: headline report*, available at: http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_127904.pdf, p7, where the importance for dementia research of the prospective recruitment of brain donors and more effective coordination of brain tissue donation is emphasised.

Gametes

Therapeutic use

- 7.65 In Chapter 6, we highlighted the striking contrast between the national infrastructure established to maximise blood and organ donation, with the absence of any similar coherent structure in respect of gametes. We recognise that there are significant differences between these forms of donation that may have led to these differences of approach: first, that blood and organ donation have much greater public acceptance than gamete donation; and second, that both blood and organ donation take place firmly within the NHS, while infertility treatment and gamete donation take place predominantly (although not solely) in the private sector. However, we do not accept that these differences are sufficient to justify such a wholesale difference of approach. We have argued above (see paragraph 7.7) that fertility treatment and gamete donation are accepted as having 'public' features, which are recognised in particular through the creation of regulatory structures to govern them. Treatment using donated gametes is available, albeit on a patchy basis, on the nationally-funded NHS. The donation of gametes through regulated fertility clinics is not purely a private matter. There is a public interest in ensuring that gamete donation services are efficiently managed, that the welfare of donors is seen as a matter of public concern, and that best possible use is made of those willing to donate.
- 7.66 **We conclude that there should be a coherent and managed infrastructure for egg and sperm donation, on the lines of the structures currently in place for organ donation.** Indeed, we note that in 1998 the HFEA proposed that "serious consideration" should be given to the idea of a "national donor service" (or several regional donor services) to provide a coordinated approach to the development of recruitment methods and help maximise the numbers of donors available.⁷⁰⁶
- 7.67 As we suggest in Chapter 6 (see paragraph 6.62), such an infrastructure would be well-placed not only to manage the kind of co-ordinated information campaigns envisaged in the first rung of our Intervention Ladder, but also to develop and share best practice in recruiting, retaining and 'recognising' donors (rung 2). **We recommend that the Department of Health, in consultation with the HFEA and its successor body/bodies, should initiate consultation with clinics as to how such an infrastructure could best be created,** drawing as appropriate on the lessons of recent initiatives such as the 'hub and spoke' model piloted in Manchester.⁷⁰⁷ We emphasise that by 'infrastructure' we do not necessarily mean a new organisational entity. The precise shape or legal status of the infrastructure will be of much less importance than its overall aim of creating an organisational framework able to develop the best possible practice in handling all aspects of the recruitment of donors on behalf of clinics.⁷⁰⁸

Research use

- 7.68 In Chapter 6, we recommended the establishment of a pilot scheme to evaluate the effects of offering financial compensation for time and inconvenience (that might also be understood as remuneration) to those willing to come forward as egg donors for research (see paragraph 6.81). In coming to this conclusion, we noted that the physical risks of egg donation are currently regarded as acceptable in the context of altruistic donation, and that the possibility of

⁷⁰⁶ Human Fertilisation and Embryology Authority (10 December 1998) *Paid egg sharing to be regulated, not banned*, available at: <http://www.hfea.gov.uk/986.html>.

⁷⁰⁷ The central hospital 'hub' provided the majority of donor management, while local 'spoke' centres provided easier access for potential donors: Royal College of Nursing (2010) *Hub and Spoke scheme aims to boost sperm donation*, available at: http://www.rcn.org.uk/development/communities/rcn_forum_communities/midwifery_fertility_nursing/news_stories/hub_and_spoke_scheme_aims_to_boost_sperm_donation.

⁷⁰⁸ See, for example, Bahadur G, Jegede T, Santis M and Ahuja KK (2011) *Recruiting 500 sperm donors: customer relations key to meeting UK demand*, available at: <http://eshre2011.congressplanner.eu/showabstract.php?congress=ESHRE2011&id=643>.

reward does not affect this. However, the risks of repeated egg donation are unknown, and potentially of greater concern. We therefore commented that if reward were to be offered for egg donation, very clear procedures would need to be in place to ensure a clear limit on the number of possible donations. The 2011 ESHRE guidance on cross-border reproductive care also sets out further procedural safeguards that should be followed to avoid the inappropriate targeting of donors from abroad (see paragraph 6.68). **We recommend that an essential part of the pilot scheme should be the development of protections both to limit the number of times a woman may donate eggs for research purposes, and to guard against the inappropriate targeting of potential donors in other countries.**

First-in-human trials

- 7.69 We begin consideration of the role of 'intermediaries' with respect to first-in-human trials by noting that the role of healthy volunteers in such trials has been considered in this inquiry primarily as a source of comparison with the donation of bodily material, and that the extent to which we are in a position to offer specific recommendations in respect of this issue is thus correspondingly limited. However, we make the following observations with respect to two themes that have arisen earlier in this report: partnership and governance.
- 7.70 We have noted earlier (see paragraphs 5.68 and 7.61) the importance in some contexts of the role of partnership between the donor of bodily material and the future user of that material, particularly in the context of research. The notion of partnership may be especially valuable in long-term studies, where participants may, at repeated intervals, provide samples and information, and where there will be regular information to share about the progress of the study. We suggest here that the concept of partnership may also be of some value in conceptualising the relationship between healthy volunteers in first-in-human trials and the researchers and institutions running the trial. The nature and extent of that 'partnership' may, of course, differ considerably from what is possible and meaningful in a longitudinal study: in some first-in-human trials, for example, participants may only receive one dose of the trial compound, and the only information about the progress of the trial may be that a certain number of patients received the drug with some side effects and that it will not proceed any further. In other cases, of course, there will be further progress, to Phase II and III and beyond, and hence more to report. While recognising that in some cases the 'partnership' may be short, we consider that the approach still has value, because it emphasises the mutual nature of the relationship: the contribution of the volunteer is recognised not only in payment but also through an acknowledgment that she or he has an interest in the outcome of the project. We note with interest the MRC's 'Help make history' website, which seeks to create a network of healthy volunteers interested in participating in HIV vaccine trials, as an example of how such a partnership approach may seek to create a different form of relationship from that traditionally envisaged between healthy volunteers and pharmaceutical companies.⁷⁰⁹
- 7.71 Along with the sharing of information, another aspect of such a partnership must be acceptance of responsibility on the part of trial organisers for the clinical follow-up of participants after the trial. Again, what is required in terms of follow-up will vary considerably according to the nature of the trial: volunteers taking doses of a new antibiotic or diuretic are unlikely to need the same kind of stringent follow-up as will be required for new drugs that, for example, target the immune system or have a novel mechanism of action.⁷¹⁰
- 7.72 Finally, we consider the role of governance. Much has been written about the question of payment for healthy volunteers in clinical trials: whether such payment is exploitative in being offered at all, being too low or being too high; whether the potential volunteer is vulnerable and risks making choices they might later regret; and what information they might need to make their

⁷⁰⁹ See: MRC Clinical Trials Unit (2010) *Help make history*, available at: http://www.helpmakehistory.mrc.ac.uk/about_us.aspx.

⁷¹⁰ Department of Health (2006) *Expert scientific group on phase one clinical trials: final report*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_073165.pdf, terms of reference.

decision. Such debates, however, focus very much on the role of how the individual should be approached and what factors steer their decision. We suggest that an alternative approach might be to consider the issue from the position of the responsibilities of the intermediaries concerned. If the review in question has been subject to ethical and scientific review and found to be satisfactory, then the key question for intermediaries is not whether it is appropriate to recruit participants at all, but rather whether there are particular ethical concerns about particular participants, or categories of participant. One class of participant about whom there could, legitimately, be professional concern would be those who 'over-volunteer' for paid research, either by volunteering for more than one trial at once, or by participating in serial trials (or both).

- 7.73 We suggest that a key element of governance will be for trial organisers to take responsibility for actively ensuring that potential participants are not 'over-volunteering'. One way in which this might be achieved would be through compulsory use of the TOPS database (see paragraph 2.54): trial organisers could be required both to register details of all participants on the database, and to check it closely when recruiting to a new trial. **We welcome the voluntary accreditation scheme for units conducting phase 1 trials, established in 2008 by the Medicines and Healthcare products Regulatory Authority (MHRA), which requires that accredited units must have a procedure in place to address over-volunteering.⁷¹¹ We recommend that the MHRA should monitor closely any units that do not apply for accreditation, with a view to making requirements to guard against over-volunteering compulsory if necessary.**
- 7.74 We note that, in its current guidance to the pharmaceutical industry, the ABPI provides advice against over-volunteering, recommending a 'washout period' between studies: in general this is of a minimum of three months but dependent on the compound being studied and its mode of action.⁷¹² However, concerns about 'over-volunteering' relate not just to the potential risks to the individual's health from the particular studies, but more subtly to the notion that 'loaning one's body' through first-in-human trials should not be regarded as a long-term low-paid job.⁷¹³ One way of dealing with this wider concern about the nature of participation would be to restrict the total number of trials a person may ever participate in, regardless of 'washout' periods in between. **We recommend that the National Research Ethics Service (NRES) should consult on the possibility of limiting the total number of first-in-human trials in which any one individual should take part.**

⁷¹¹ Medicines and Healthcare products Regulatory Agency (2007) *Phase 1 accreditation scheme*, available at: <http://www.mhra.gov.uk/home/groups/is-insp/documents/websiteresources/con2033097.pdf>, p7. The majority of commercial phase 1 units in the UK are currently accredited by the scheme: MHRA, personal communication, 28 July 2011.

⁷¹² Association of the British Pharmaceutical Industry (2007) *Guidelines for phase 1 clinical trials*, available at: <http://www.abpi.org.uk/our-work/library/guidelines/Documents/phase1-trial-guidelines.pdf>, p17.

⁷¹³ See, for example, Elliott C, and Abadie R (2008) Exploiting a research underclass in phase 1 clinical trials *New England Journal of Medicine* **358**: 2316-7.

Chapter 8

Afterword from the
Working Party Chair

Chapter 8 - Afterword from the Working Party Chair

- 8.1 There are all kinds of ways in which people become involved in the health of others. But there has to be something quite special about that involvement when it draws on other people's own bodily material. In its preparations for this report, the Working Party has tried to keep that sense of 'something special'. Whatever the source, whether from someone known or unknown, from a living body or a deceased one, and whatever the body part in question, from a whole organ to a drop of blood contributing to a research project, we have been mindful that such material has come from the body of a person.
- 8.2 However the body is regarded or treated as an entity, ultimately it cannot be detached from one crucial apprehension of reality, that persons are embodied beings. Indeed this is a premise that, up to a point, informs legal thinking. So what about 'parts' that appear detachable? Without getting into how people think about wholes and parts and whether a part might stand for a whole, one may note that, in the medical arena with which this report is concerned, detachment is not just a matter of physical separation; it is also a matter of re-classifying one person's bodily material as of interest to others. It is absolutely right that the legitimacy of that interest should go on being debated: rendering bodily material usable by others inevitably involves weighing up different interests. With the aim of being true to the world views of many of those with whom we have consulted, and those many more who will be affected by medical developments in the UK, the Working Party has tried to strike its own balance between being neither over-sentimental about the body nor, on the other hand, indifferent to its fate. To think about the persons involved has been crucial here, and our principal focus has been the donor. Keeping in mind the fact that material has come from someone is an ethical premise that informs this report.
- 8.3 We have used the term 'person' as an anthropologist might, to keep in mind another inescapable fact: that people are always found in specific social circumstances. These circumstances include all kinds of factors that affect their lives, as well as the different forms and destinies of donation itself. One example has been the importance of not sidelining gametes: if on a scale that includes the life-saving capacity of blood or organs we find that gametes rank low, we have to ask if that does not simply mean they are out of place on such a scale.
- 8.4 Now in considering gametes we have paid more attention to eggs than to sperm, not just because of their different value for treatment and research but because of the particular demands placed on women; these demands make this form of donation highly gender specific. This in turn impinges on the diverse expectations people have of one another, and thus on their social relations. The Working Party largely addressed the social dimension of donation through the immediate transactions that encourage or facilitate it. However, from time to time it has pointed to larger social issues. Thus it has deliberately kept on the horizon of its vision the practices of both trafficking and profiting, even when they seem to take place elsewhere, for they also form a horizon to what is allowed by regulation in the UK. Within the UK we have taken a general perspective on public interests, but of course the 'public' is not homogeneous. Among other things, the report touches on – although not in detail – some of the particular issues affecting BME communities in Britain, and the special situation of donation among family members. These must stand for all those instances where equitable treatment has to start with recognising the specificity of circumstances.
- 8.5 Among the consultation responses were suggestions that 'social justice', 'empowerment' or straight 'equality' should be among the ethical values we name. But we trust that none of these concepts has been absent from the report. Together they reiterate the point that the circumstances under which donation occurs affect ethical judgment. Indeed, and we hope it is evident throughout the report, the Working Party insisted on considering 'context' and the difference that all manner of 'differences' make. To take one example, people are very aware of the degree of tenacity or conviction or belief with which views are held, so there are

circumstances where they may argue with other people's views or try to influence or educate them; there are also circumstances where conviction – whether or not with a religious base – itself becomes a stance that has to be recognised as such. We hope that we have allowed for this contrast, and that chapters 6 and 7 will have indicated something of our concern with equitable outcomes.

- 8.6 Above all, we have tried to keep in consort with the language that has grown up around 'donation' over the last 40 or 50 years. Language invariably conceals as much as it reveals. The intention of staying with this particular language – donation, altruism and consent, the gift – is not to be uncritical but, rather, to extend conversations that are already going on.



Appendices

Appendix 1: Method of working

Background

The Nuffield Council on Bioethics established the Working Party on *Human bodies: donation for medicine and research* in January 2010. The Working Party met nine times over a period of 17 months. In order to inform its deliberations, it held a public consultation, a deliberative workshop with members of the general public, and a series of 'fact-finding meetings' with external stakeholders and experts. It also commissioned three external evidence reviews from academics working in this area, and sought comments on a draft of the report from thirteen peer reviewers. Further details of each of these aspects of the Working Party's work are given below and in Appendix 2. The Working Party would like to express its gratitude to all those involved, and the invaluable contribution they made to the development of the final report.

Consultation document

The Working Party's consultation document was published in April 2010, and the consultation period extended from April to July 2010. 179 responses were received, of which 116 were submitted by individuals and 63 on behalf of organisations. Those responding to the consultation included members of the public (both those with immediate experience of donation and those with a general interest), patient and user organisations, faith groups, academics and researchers, people involved in regulating donation and research, and professionals involved in transplantation and fertility services. A full list of those responding (excluding those who asked to be anonymous) is set out in Appendix 2, and a summary of the responses is accessible on the Council's website.⁷¹⁴ Copies of individual responses will also be made available on the website, where the Council has permission from respondents to do so.

Fact-finding

As part of its work, the Working Party held a series of 'fact-finding meetings'. These took the form either of lunchtime presentations during Working Party meetings or of half-day events in which invited guests made brief opening statements and then participated in discussion with Working Party members and other guests.

Uses of tissue in treatment and research: 2 March 2010

Dr Ruth Warwick, Consultant Specialist for Tissue Services, NHS Blood and Transplant (since retired) and past President of the British Association of Tissue Banking

Professor Chris Womack, Principal Clinical Histopathologist, AstraZeneca, and Honorary Chair in the School of Cancer and Enabling Sciences, University of Manchester (Working Party member)

Cross-border care: 20 May 2010

Professor Lorraine Culley, Professor of Social Sciences and Health, De Montfort University; currently the principal investigator of Transrep, an exploratory study of UK residents who travel abroad for fertility treatment

Mr Keith Rigg, Consultant Transplant Surgeon, Nottingham University Hospitals NHS Trust (Working Party member)

⁷¹⁴ See: <http://www.nuffieldbioethics.org.uk/humanbodies>.

Regulation of donation of bodily material and participation in first-in-human trials: 23 June 2010

Sir Gordon Duff, Chairman, Commission on Human Medicines

Dr Pablo Fernandez, Medical Director, PharmaNet (nominated by ABPI)

Ms Danielle Hamm, Policy Manager, Human Fertilisation and Embryology Authority

Ms Jane Juniper, R & D Science Policy Leader UK, AstraZeneca (nominated by ABPI)

Mr Adrian McNeil, Chief Executive of the Human Tissue Authority (since retired)

Mr David Neal, Deputy Director (Policy), National Research Ethics Service

Dr Luc Noel, Co-ordinator, Clinical Procedures, Essential Health Technologies, World Health Organization

Ms Triona Norman, Head of Policy, Organ and Tissue Transplantation, Department of Health

Ms Juliet Tizzard, Head of Policy, Human Fertilisation and Embryology Authority

Opinion Forum on public vs private donation: 2 November 2010

Dr Susan Bewley, Consultant Obstetrician/Maternal Fetal Medicine; Honorary Senior Lecturer, King's College London

Professor Janet Carsten, Professor of Social and Cultural Anthropology, University of Edinburgh

Dr Antonia Cronin, MRC Centre for Transplantation, King's College London; Chair of British Transplantation Society's Ethics Committee

Professor Jeanette Edwards, Professor in Social Anthropology, University of Manchester;

Professor Erica Haimes, Founding Executive Director and Professorial Fellow, Policy, Ethics and Life Sciences (PEALS) Research Centre, Newcastle University

Dr Klaus Høyer, Associate Professor, Institute of Public Health, University of Copenhagen

Deliberative event

The Working Party's consultation document was widely publicised, and it was open to anyone who wished to respond to do so. However, the Working Party was aware that members of the public would only be likely to respond if they had a strong existing interests in the issues raised. Yet the donation of bodily materials has the potential to affect anyone without warning, whether as a potential donor, or as a recipient. The Working Party therefore felt it would be very helpful to find a way of obtaining the views of some members of the public who might otherwise not consider responding to its consultation. A Wellcome Trust People Award enabled the research consultancy Opinion Leader, on behalf of the Working Party, to arrange and facilitate a one day deliberative workshop with recruited members of the public to explore their views on the issues raised by donation and volunteering for research. This took place in Bristol on 26 July 2010 and involved 43 members of the public. The workshop consisted of a mix of plenary sessions, presentations, breakout sessions, and individuals and group exercises. Members of the Working Party took part as speakers and observers, and a detailed report was produced by Opinion Leader.⁷¹⁵ The report drew the following conclusions:

- Participants perceived a moral imperative for society to address any mismatch between supply and demand of bodily material. However, they were concerned that individual donation decisions be in the hands of the donors, with no intervention or coercion from outside parties. Relatives should make donation decisions on behalf of deceased people who had not made their wishes clear. Although consensus could not be reached on how to resolve conflicts between a deceased person who wants to donate and a relative who opposes donation, this was seen as indicating a need for families to discuss their wishes with one another beforehand.
- Participants felt that control of donated materials should be in the hands of healthcare professionals under a transparent and fair system of allocation, with the exception of allowing a donor organ to be given directly from one person to another.

⁷¹⁵ For the full report from Opinion Leader, see: <http://www.nuffieldbioethics.org.uk/humanbodies>.

- Cash incentives were seen as potentially coercive and unappealing, and were only suitable for recognising the risks involved in taking part in medical trials, or as a contribution to funeral expenses. Benefits in kind, such as a priority for an organ in future, were seen as having potentially negative impacts on medical decision making and so were generally rejected. It was perceived that donations should be recognised through a thank you letter or a token. However, this was not seen as offering a reason to donate, rather an acknowledgment of that person's decision to donate.

Street Talk stalls organised by nef

The organisation nef (new economics foundation) also received funding in 2010 from the Wellcome Trust in order to test out the effectiveness of using consultation stalls in streets and shopping centres to reach people who would be unlikely to attend public meetings. While this project was carried out independently of the Nuffield Council, nef used the Working Party's consultation materials as a basis for its 'Street Talk' project. Eight stalls were held in Hereford, London and Manchester, reaching 499 people over 15 days. Participants were invited to comment first on the ethical acceptability, and secondly on the likely effectiveness, of different incentives for donating bodily materials or volunteering to test a new anti-cancer drug. The five incentives suggested were: a letter of thanks, a donation to charity, a token payment, a substantial payment, and payment in kind. The forms of donation considered were joining the Organ Donor Register to donate organs after one's death, and donating sperm or eggs to help a childless couple. A report produced for the Working Party by nef concluded that:

- 80 per cent of respondents were comfortable with organ donation, and yet less than half of respondents were actually on the ODR.
- Payments of all sizes, for all donation types, were seen as unethical and ineffective by a majority of respondents.
- Payment in kind was seen as more ethical and more effective than payment in money.
- Donations to charity and letters of thanks were viewed as ethical, but not necessarily effective, incentives.⁷¹⁶

Evidence reviews

In order to inform its deliberations, the Working Party commissioned three evidence reviews from external academics. These covered regulatory approaches in other countries; factors disposing people to donate or not donate; and the effect of incentives on donation practices. The terms of each review are set out below. Because of the vast scale of the literature on donation, it was acknowledged that the reviews could not aim to be comprehensive, and should be regarded rather as snapshots of the available literature in each of these areas.

Review 1: Comparative review of the effects of different regulatory approaches to donated human bodily material and 'healthy volunteer' clinical trials

The brief for Review 1 was as follows:

1. A summary, with reference to the regulatory frameworks in Spain, Belgium, Iran, Israel, India and a North American jurisdiction (e.g. an appropriate US state, with reference where relevant to national regulation/guidance) of:
 - a Requirements for consent before human bodily material may be used in medicine or research (including the role of relatives in decision-making)
 - b The degree of control a donor of human bodily material may exercise over the donated bodily material (e.g. by directing it to a particular person, or not for a particular use or recipient)

⁷¹⁶ For the full report from nef, see: <http://www.nuffieldbioethics.org.uk/humanbodies>.

- c Any restrictions on commercial dealings in human bodily material and any requirements/prohibitions relating to compensation for the donor
 - d Any legal provisions as to property ownership of human bodily tissue
 - e Any legal constraints on payments made to participants in „healthy volunteer“ clinical trials.
2. A summary of the available statistics on donation rates in these countries of the various forms of human bodily material for either medical treatment or research, including trend data before and after any regulatory changes, where available. Similarly, summary data on the numbers participating in healthy volunteer trials.
 3. A literature review of published studies/reports/articles relevant to the following questions:
 - a What is the impact of these regulatory requirements on the availability of human bodily material for medicine and research, or on the numbers participating in healthy volunteer trials?
 - b Are the regulatory requirements followed in practice?
 - c Are there any confounding factors, such as other legal or policy changes potentially affecting donation rates?
 - d What is the quality of the evidence currently available?

The review was carried out by Dr Kathy Liddell, from the Faculty of Law, Cambridge University. In addition to primary legal materials and an extensive English language literature review, Dr Liddell conducted a number of telephone interviews and email exchanges with experts in the relevant countries. Thanks are due to: Anita L Allen (US), Tamar Ashkenazi (Israel), Alireza Bagheri (Iran), Arthur Caplan (US), Maria Casado (Spain), Christine Grady (US), Itziar de Lecuona (Spain), Muireann Quigley (UK), SV Joga Rao (India), and Carlos Romeo Casabona (Spain).

Review 2: review of the evidence as to the factors that dispose individuals to provide human bodily material for treatment or research, or to participate in ‘healthy volunteer’ trials

The brief for Review 2 was as follows:

We would like to be able to answer the following question:

- What evidence is there as to the factors that dispose individuals to provide (or not to provide) human bodily material for medicine or research, or to participate in a 'healthy volunteer' clinical trial with no expectation of personal health benefit?

'Factors' might include (but not be restricted to) the personal attitudes and views of the person concerned, their religious and/or cultural affiliations, and their personal or family situation (e.g. in regard to health or finance).

Guidance for author

Literature review on the evidence relating to the questions above, including:

- Review of published studies and reports and their findings
- Assessment of the quality of evidence
- Further factors that need to be considered

The review was carried out by Dr Lesley M McGregor and Professor Ronan E O'Carroll, Department of Psychology, University of Stirling, and was divided into two parts, Part 1 covering the donation of bodily material and Part 2 covering healthy volunteer trials. Inclusion and exclusion criteria were subsequently set to the initial brief, in order to make the project more manageable. In Part 1, the search was limited to empirical studies published in journals, carried out in the UK since 2000, and

focussing on potentially modifiable factors relating to motivators and deterrents to donation, as opposed to the personality characteristics of donors and non-donors. Part 2 of the review was restricted to articles written in English and published in peer reviewed journals.

Review 3: review of the impact of offering financial or other incentives to encourage people to donate human bodily material

The brief for Review 3 was as follows:

We would like to be able to answer the follow questions:

What is the impact of offering incentives (financial or other) to individuals to encourage them to provide human bodily material, of any form, on

- the quantity of material donated?
- the quality of material donated?
- the quality of the decision to donate (e.g. does the offer of financial incentives alter perceptions of risk involved)?

Draft guidance for author

- Literature review on the evidence relating to the questions above, including:
- Review of published studies and reports and their findings, with a particular focus on experimental studies, where available
- Assessment of the quality of evidence available
- Further factors that need to be considered
- Review of research underway in this area

The review was carried out by Dr Burcu Tung and Professor Theresa M Marteau (Working Party member), of King's College, London. Studies deemed eligible for inclusion were peer-reviewed, experimental or descriptive studies that presented data on the quality and quantity of bodily material provided, and/or the quality of the decision in at least two groups: those providing material when offered a financial incentive, and those providing material with no offer of a financial incentive.

Peer review

An earlier version of the report was reviewed by thirteen individuals with expertise in the areas covered. These were Professor Michael Banner, Professor Peter Braude, Professor Roger Brownsword, Professor Finbarr Cotter, Professor Sarah Franklin, Dr Rosario Isasi, Dr Susan Kerrison, Dr Louise Leong, Professor Eckhardt Nagel, Mr Chris Rudge, Dr Susan Wallace, Professor Heather Widdows and Professor Stephen Wilkinson.

The Working Party deeply appreciates the time and thought that so many individual contributors brought to this investigation.

Appendix 2: Wider consultation for the report

The aim of the public consultation was to obtain views from as wide a range of organisations and individuals interested in donation as possible. The consultation document was published online (available in hard copy on request) and received considerable publicity through the media. Individuals and organisations known to be interested were also directly alerted by email and encouraged to respond. The document was divided into six sections, each containing background information followed by questions. The six sections were:

- the nature of bodily material that may be donated, either during life or after death, to benefit others
- the purposes for which material may be donated
- some of the ethical values at stake
- ways of responding to the demand for bodily material
- the role of consent
- issues of ownership and control over bodily material.

In total, 30 questions were asked, and respondents were encouraged to answer as many, or as few, as they wished. 179 responses were received, 116 from individuals and 63 from organisations. All the responses were circulated to Working Party members, and a summary of responses was considered in detail at a subsequent Working Party meeting.

A summary of the responses received, together with the original consultation paper, is available on the Council's website.⁷¹⁷ Individual responses will also be published in full on the website, where respondents have granted permission for the Council to do so. The responses received played an important role in shaping the Working Party's thinking, and the Working Party is immensely grateful to all those who contributed.

List of respondents to the consultation document

Individuals

Anonymous (15)
 Dr Ray Abrahams
 Dr Rachel Ariss
 Attendees of Ethics Forum at University Hospitals Birmingham, organised by Greg Moorlock
 Professor Dr Jayapaul Azariah
 Susan Bewley, Consultant Obstetrician
 Chris Briscoe
 Graham Brushett
 Andrew Burrow
 Harry Burton
 Haris E. Cazlaris, PhD
 John Champion, Chair SCKPA
 Mrs Cheek
 Dr Brian J. Clark
 Mr T. J. Coldrick
 Alan Craig
 Brian Dale
 Professor Gabriel Danovitch
 Sarah Devaney
 Thomas Dillon

⁷¹⁷ See: <http://www.nuffieldbioethics.org.uk/humanbodies>.

Jayne Doran
Graham Driver
Karen Dyer, Lecturer in Law, University of Buckingham
Dr Howaida Ebead
Dr Miran Epstein
David W. Evans
Dr John Fitton
Michael Fulton
Professor Peter Furness
John Garfield
David Gollancz
C. A. Gowney RN
Zeynep Gurtin-Broadbent
Dr Gill Haddow, ESRC Innogen Centre
Phil Harding
Shawn H. E. Harmon
Dr David J. Hill
Rory Holburn
Dewi Hopkins
David H. Howard, Associate Professor, Department of Health Policy and Management, Emory
University
Marcia C. Inhorn
Dr Ian Jessiman
Dr Kevin D. Johnston
Mr Mark Kennett
Allan King
Jonathan Lee
Jonathan Lepper
Aaron Long
Grant Mackie
Mrs Kay Mason
Professor Arthur Matas, Department of Surgery, University of Minnesota
Rosanna McArdle
Dr Maryon McDonald
Jeff McLwain MD FRCS
Stewart McKane
Councillor John Meikle MBE
John Miller, Glasgow
Stephen Morris
Richard Mountford
Alex Nolan
Dr Petra Nordqvist, University of Manchester
Anne Oberon
Sylwia Maria Olejarz
M. O'Sullivan
A. C. Palmer
Betty Perry
Miriam Pryke
Dr Muireann Quigley
Sue Rabbitt Roff
Dr Paul M. Rea
Dr J. Reeve
Thomsina Rickard
Professor Charis Thompson
Celia Roberts and Karen Throsby
Marlene Rose, Imperial College
Achim Rosemann
Judith Rowley
R. A. Royall
Professor Robert Rubens

Sally Satel
 Miss N. Sethi, AHRC/SCRIPT Centre, School of Law, University of Edinburgh
 Lesley A. Sharp, Professor of Anthropology, Barnard College and Senior Research Scientist, Mailman School of Public Health, Columbia University, NY, USA
 Alex Smith
 Mr G. Smith
 Jonathan Smith of Moseleys, solicitors of Lichfield
 Pat Spallone
 Dr Lindsay Stirton and Jurgen De Wispelaere
 David Thewlis and Stuart Taylor
 Miss E. J. Toogood
 Dr Richard Turner
 Joseph L. Verheijde PhD, Mayo Clinic in Arizona
 Charles Warlow
 Rob Warwick
 Lorna Weir, Professor of Sociology and Health, York University, Toronto, Canada
 James Westerman
 Neil Whitcombe
 R. C. Whiting
 Heather Widdows and Sean Cordell
 Stephen Wilkinson, Professor of Bioethics, Keele University
 Amanda Wilson
 Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre

Organisations

Anonymous (4)
 Mario Abbud-Filho, Medical School FAMERP S.J. Rio Preto
 Academy of Medical Royal Colleges and Faculties in Scotland
 Professor R. Anderson FRCOG, Royal College of Obstetricians and Gynaecologists
 The Anscombe Bioethics Centre, Oxford
 Asterand
 AstraZeneca PLC
 Jamie Borg, Guy's and St. Thomas' Foundation Trust
 British Fertility Society
 British Heart Foundation
 British Medical Association
 The British Psychological Society
 The British Transplantation Society
 CARE
 Centre for Family Research, University of Cambridge
 Christian Medical Fellowship
 Church of England - Mission and Public Affairs Council
 Declaration of Istanbul Custodian Group
 Donor Family Network
 European Society for Organ Transplantation Council
 Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom
 GlaxoSmithKline R&D
 HEAL (Health Ethics and Law), University of Southampton
 The HeLEX Centre, University of Oxford
 Human Tissue Authority (HTA)
 Human Tissues Group
 Infertility Network (Canada)
 International Donor Offspring Alliance
 Kidney Research UK
 The Lewis Prior Foundation
 Liberal Judaism
 The Medical Research Council

MRC Centre for Transplantation, King's College London, NIHR Biomedical Research Centre at Guy's and St. Thomas' NHS Foundation Trust and King's College London - Transplant Theme
National Gamete Donation Trust
National Research Ethics Advisors' Panel (NREAP)
Patient Concern
PHG Foundation
Jean-Paul Pirnay, Laboratory for Molecular and Cellular Technology, Military Hospital, Brussels
PROGAR (British Association of Social Workers Project Group on Assisted Reproduction)
Progress Educational Trust
Royal Brompton & Harefield NHS Foundation Trust
Royal College of General Practitioners
Royal College of Pathologists
Royal College of Pathologists Lay Advisory Committee
Royal College of Physicians
Royal College of Physicians of Edinburgh
Patricia Stoa, Convenor, Health and Bioethics Committee, National Board of Catholic Women
UK Donation Ethics Committee
University Hospitals of Coventry and Warwickshire Clinical Ethics Committee
University of Leicester Medical School - group 1
University of Leicester Medical School - group 3
University of Leicester Medical School - group 8
University of Leicester Medical School - group 11
University of Leicester Medical School - group 13
University of Leicester Medical School - group 14
University of Leicester Medical School - group 15
University of Leicester Medical School - group 21
University of Leicester Medical School - group 22
University of Leicester Medical School - group 24
Wellcome Trust

In addition, the Working Party received several submissions drawing our attention to relevant academic papers, and would like to thank Professor Arthur Caplan, Dr Kathryn Ehrich, Dr Scott Halpern, Professor John Harris, Dr Medard Hilhorst, Dr Daniel Sperling, Dr Celia Roberts, Dr Luis A. Tomatis, and Dr Karen Throsby.

Appendix 3: The Working Party

Marilyn Strathern (Chair), recently retired from the Department of Social Anthropology and from the headship of Girton College, both of Cambridge University, has worked on gender relations and legal anthropology in Papua New Guinea and on kinship and the new reproductive technologies in the UK.

Janet Darbyshire is Emeritus Professor of Epidemiology, University College, London, recently retired from the Directorship of the MRC Clinical Trials Unit and Joint Directorship of the NIHR Clinical Research Network. As a clinical epidemiologist, she has worked on the design, conduct and analysis of clinical trials in the UK and internationally, primarily in HIV infection, tuberculosis and cancer, and on the delivery of clinical research in the NHS.

Bobbie Farsides is Professor of Clinical and Biomedical Ethics at Brighton and Sussex Medical School. She was a member of the Organ Donation Taskforce and has gone on to serve on the UK Donation Ethics Committee. She is currently working on an NIHR funded project looking at donation of organs within the South Asian community in the UK. More broadly her research has focused on the experience of scientists and health care professionals working in ethically contested fields such as embryo and stem cell research and pre-implantation genetic diagnosis, including work on establishing an ethical framework for embryo donation for scientific research.

Sian Harding is a Professor of Cardiac Pharmacology at the National Heart and Lung Institute, Imperial College, London. As a basic scientist with a long-standing interest in heart failure, she uses both human myocardial tissue and embryonic stem cells in her work. She is part of the team leading a first-in-human clinical trial for cardiac gene therapy.

Tim Lewens is Reader in Philosophy of the Sciences at the University of Cambridge, where he is also a Fellow of Clare College. His academic work focuses on the philosophy of biology (with a special interest in Darwinism and evolutionary theory), the philosophy of science, and philosophical bioethics.

Gillian Lockwood is Medical Director of Midland Fertility Services and has worked in the field of assisted conception and reproductive medicine for over 20 years. She has a background in philosophy, ethics and economics, and has published widely on the socio-biology of infertility with special reference to gamete donation.

Theresa Marteau is Professor of Health Psychology at King's College London and Director of the Centre for the Study of Incentives in Health (with the London School of Economics and Queen Mary, University of London). Since January 2011 she is also Director of the Behaviour and Health Research Unit at the Institute of Public Health, University of Cambridge. She studied psychology at the London School of Economics and Political Science, and at the University of Oxford. She is a Fellow of the Academy of Medical Sciences and the Academy of Learned Societies for the Social Sciences.

Naomi Pfeffer is Honorary Research Fellow in the Department of Science & Technology Studies, University College London. She is a medical historian and medical sociologist. Her research interests include infertility and new reproductive technologies, and human tissue collections at the beginning and end of life.

David Price is Professor of Medical Law at De Montfort University School of Law in Leicester where he is Leader of the Healthcare Law Unit. He has been involved in writing and researching aspects of the law and ethics relating to transplantation and the use of human tissue for research for many years, and was a member of the Organ Donation Taskforce investigating the potential impact of an opt out system for organ donation in the UK in 2008.

Keith Rigg is a Consultant Surgeon at Nottingham University Hospitals NHS Trust where he is Director of Transplantation and Vice-chair of the Trust Donation Committee. He has been involved in organ donation and transplantation for over 20 years. He is a non-executive member of the Human

Tissue Authority, Past-President of the British Transplantation Society and has a particular interest in the ethics, public policy and legal issues relating to organ donation and transplantation.

Bob Simpson is a Professor of Anthropology at Durham University. He has written widely on the anthropology of bioethics in relation to new reproductive and genetic technologies, clinical trials and tissue donation. Much of his research has been carried out in South Asia as well as in the UK. He is a former holder of a Wellcome Trust Biomedical Ethics Fellowship.

Chris Womack is a clinical and biobanking histopathologist who worked as a consultant in the NHS for 20 years. He then moved to AstraZeneca Oncology Translational Research in Cheshire where he has responsibility for human sample governance and research programmes to further the understanding of oncology biomarkers in human tissue samples in relation to the development of anti-cancer treatments. He is also pathologist to the Manchester Cancer Research Centre Biobank.

Glossary

Terms in italics are used in this report with a specific definition.

Adipose tissue: Specialised connective tissue that stores energy in the form of fat, also known as fatty tissue.

Adult stem cell: thought to be an undifferentiated cell, found among differentiated cells in a tissue or organ, which can differentiate to yield some or all of the major specialized cell types of that tissue or organ. The primary roles of adult stem cells in a living organism are to maintain and repair the tissue in which they are found. See also **differentiate**.

Allogeneic transplantation: Transplantation of bodily material from one person to another (see also **autologous transplantation**).

Altruism: The concept of 'altruism' is used in many different ways, with one helpful distinction being made between 'motivational' and 'behavioural' definitions of the term. In this report we are concerned with the motivational aspects of altruism, and we define an altruistic action as one that is primarily motivated by concern for the welfare of the recipient of some beneficent behaviour, rather than by concern for the welfare of the person carrying out the action.

Altruistic organ donation: This term is sometimes used to refer to the donation of an organ by a living donor to a person unknown to them, and therefore reflects a very specific use of the term 'altruism'. In this report we use the preferred term 'stranger donation' to describe living organ donation to the common pool (from which organs are allocated on medical criteria), as opposed to donation to a specified individual.

Altruist-focused interventions: Initiatives that seek to change the decision someone is likely to make with respect to donation by removing barriers or disincentives to act. By altering the balance of costs and benefits associated with donation, such initiatives remove countervailing concerns that may prevent altruists from acting on their altruistic motivations. Altruist-focused interventions may also offer some form of token reward or „thank you“ (which may take the form of a small financial incentive), on the basis that such tokens of recognition or thanks may act as the final spur for someone already inclined to donate. In order to remain within the definition of 'altruist-focused interventions', however, such tokens must not be sufficient to constitute a primary reason for donating (across the income range). Also see **non-altruist-focused intervention** and **incentive**.

Amniotic membrane: Thin layer of tissue forming the amniotic sac that surrounds the embryo.

Artificial gametes: Eggs or sperm derived from stem cells (currently experimental).

Autologous transplantation: Transplantation of a person's bodily material in their own treatment, either from one part of the body to another, or after storage (see also **allogeneic transplantation**).

Blanket consent: Consent to any further use of donated bodily material, thus allowing it to be used for any legally and ethically approved purpose (see also **generic consent**).

Biobank: See **tissue bank**.

Biomarker: Biological indicators (derived for example from blood, skin, saliva and hair) that can be used to screen for disease and also to monitor disease progression.

Biomolecule: An organic molecule in a living organism.

Biorepository: See **tissue bank**.

Bodily material (in this report): 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. Note that the definition does not entirely overlap with the definition of 'tissue' in the Human Tissue Act. See also **tissue**.

Bone marrow: The soft tissue filling the cavities of bones. It produces stem cells which produce new blood cells as well as a small population which have the capacity to produce bone, cartilage, fat, and fibrous connective tissue.

Broad consent: A form of generic consent for the future use of donated bodily material, where the donor consents to a wide (but not limitless) range of future uses of their donated material, and an ongoing relationship is maintained between researchers and the donor (see also **generic consent**).

Brain stem death: Death resulting from the irreversible cessation of brain stem function.

Cardiovascular: Relating to the heart and blood vessels.

Cartilage: Hard, thin layer of tissue that covers the end of the bone at a joint.

Cohort: Group of people being studied, usually at different points over time in order to understand how they change.

Commercial dealings (in this report): The giving or receiving of payment that brings profit to the parties involved, typically involving the purchase of an item for which the market sets a price. See also **reward**.

Commodity: An object for which there is demand and which acquires value, typically monetary, when put into circulation with other commodities with which it becomes interchangeable. Such interchange may or may not involve material gain. To turn something into a commodity implies already treating it as an object or 'thing'.

Compensation (in this report): Payment to a person in recognition of non-financial losses they have incurred in donating bodily material, such as time, inconvenience and discomfort. See also **recompense**, **reimbursement** and **reward**.

Congenital: Present from birth and resulting from ante-natal development.

Cord blood: The baby's blood that remains in the placenta and umbilical cord after birth.

Cornea: The clear front part of the eye.

Dataset: Collection of information, organised to be readily retrievable.

DCD (donation after circulatory death): In the UK, donation after circulatory death usually takes place where death is established by the irreversible cessation of the heart, after the withdrawal of life-sustaining cardio-respiratory support on the basis that this support is no longer in the patient's best interests ('controlled' DCD). However, 'uncontrolled' donation after circulatory death, where the donor dies outside hospital of a heart attack, is also possible, despite the inevitable delays before organs may be obtained.

Deceased donation: Donation of bodily material after the death of the donor. Such donation may be authorised in advance by the person concerned, or by others at the time of their death.

Differentiate (of cells): Develop or mature into a more specialised form of cell.

Directed donation: Donation of bodily material to a known recipient.

Donation (in this report): A broad term used to cover voluntary transactions that people might think of as sacrifice, gift or loan, or as simply putting material at the disposal of others, as opposed to some form of 'taking' under coercion or even by seizure. Transactions that involve buying and selling ordinarily share the characteristics of a 'voluntary act', but in the UK it is often thought that the voluntary nature of such transactions is compromised by the element of calculation or financial gain, and many people would contrast such transactions with the making of a gift. However, we follow general UK usage in keeping to the term 'donation' for all kinds of non-coerced disposal.

Egg sharing: Arrangement by which a woman undergoing IVF makes some of her eggs available for another woman's treatment, or for research, in return for free treatment or significantly reduced treatment costs.

Embryo: 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).

Embryonic stem cells (ESCs): Stem cells derived from a fertilised egg after it has started to divide, usually after about five days but never after more than 14 days. ESCs are isolated from the inner cell mass of the embryo that consists of cells not yet committed to developing into any specific cell type (see also **stem cells**).

Fettered consent: See **tiered consent**.

Gametes: Eggs and/or sperm.

Generic consent: Consent for donated bodily material to be used for a range of future (unknown) uses. Generic consent may be **blanket**, **broad**, or **tiered** (see **blanket consent**, **broad consent** and **tiered consent**).

Haematopoietic stem cells (HSCs): Blood stem cells: the precursors of blood cells.

„Hard“ opt-out: Legal system in which organs may automatically be taken from people who die in circumstances where their organs are suitable for donation, unless that person has expressed an objection during their lifetime. The family of the deceased is not entitled to veto donation. See also **„soft“ opt-out**.

Immunosuppression: Suppression of the immune system, for example to prevent rejection of a transplanted organ.

Incentive (in this report): An offer of money, or other good, over and above the reimbursement of all actual costs incurred in making a donation, with the aim of changing a person's decision with respect to donation. In this report, we distinguish between 'token incentives', where the value or nature of the incentive would be insufficient to provide anyone (regardless of income level) with a primary reason for donating, and incentives that seek to provide that primary motive. See also **altruist-focused intervention** and **non-altruist-focused intervention**.

Induced pluripotent stem cells (iPSCs): Adult cells of various kinds, for example skin cells, that have been transformed into pluripotent stem cells by the introduction of the factors found to be active in embryonic stem cells. iPSCs can then become any cell type in the body, having some similar properties to embryonic stem cells. See also **pluripotent** and **embryonic stem cells**.

Intermediary: Individuals, organisations and institutions that mediate the (often long and complex) chain of transactions between donor and eventual recipient (whether the recipient is another person or an organisation). 'Intermediary' is also used as a specific designation for those personnel who facilitate the donation process in face to face contact with donors and recipients. See **transaction**.

Left ventricular assist device (LVAD): Mechanical pump that can be implanted in a patient in order to help a damaged heart to maintain output.

Ligament: Connective tissue joining bone to bone.

Living donation: Donation of bodily material from a living person.

Loan of body: Providing the whole body on a temporary basis for medical or quasi-medical purposes: these include participating in first-in-human trials where the loaned body is used to test the safety of new medicines, and surrogacy arrangements, where a woman carries a child to term on behalf of others.

Musculoskeletal: Relating to both the muscles and bones.

Nephrectomy: Surgical procedure for the removal of a kidney or part of a kidney.

Non-altruist-focused interventions: Initiatives targeted at potential donors who have no initial strong motivation to help others through the donation of their bodily material, and who therefore need to be provided with different reasons for action, for example in the form of benefits in kind, or of payment going significantly beyond the reimbursement of expenses. See also **incentive** and **altruist-focused intervention**.

Nucleus: Structure within the cell, containing most of the cell's DNA and controlling the cell's growth and reproduction.

Oocyte: Egg.

Organ trafficking: Defined in the Declaration of Istanbul as "the recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation".

Ovarian cortex: The outer layer of the ovary, containing the ovarian follicles.

Ovarian follicles: Structures in the ovary that develop, under the influence of hormones, from microscopic to 2cm in diameter, at which point they will contain an oocyte capable of fertilisation (at ovulation or at oocyte retrieval during IVF).

Ovarian hyperstimulation syndrome (OHSS): Condition in which a woman's ovaries over-respond to the hormonal stimulation required during an IVF treatment cycle, producing painful abdominal swelling. The severe form of OHSS is rare but may be life-threatening.

Ovarian pedicle: Contains the ovarian artery and vein that supply blood to the ovary.

Ownership (in this report): In the context of one's own bodily material, ownership may be understood broadly as entitlement to control over its disposition, once separated from the body, or more narrowly as the possession of a significant bundle of (legally enforceable) property rights. See also **property rights**.

Paired donation: Living donors who wish to provide an organ for a named recipient but who cannot do so because of immunological incompatibility may be 'paired' with another donor/recipient, thus ensuring that two patients receive organs at the same time from compatible donors. 'Pooled' donations work on the same basis with three or more sets of donor/recipients.

Parthenogenesis: Process whereby where an unfertilised egg is stimulated to develop into an embryo.

Payment (in this report): A generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as **recompense**, **reward** or **purchase**.

Person (in this report): Used as the primary descriptor of a donor (rather than terms such as individual or self) in order to highlight the fact that people do not act in isolation. The notion of a person implies a social being in relationship(s) with other social beings and as such draws attention to the significance of personal, kinship and economic connections in understanding transactions involving bodily material.

Plasma: The fluid in which all blood cells are carried.

Pluripotent stem cells: Cells that have the potential to develop into many other different kinds of cell.

Pooled donation: See **paired donation**.

Post mortem: Internal examination of the body after death, in order to investigate the cause of death and/or the factors contributing to death.

Pre-implantation genetic diagnosis (PGD): Testing the embryo (created through IVF) for particular genetic conditions, before implantation in the womb. The Human Fertilisation and Embryology Authority must agree that a particular condition is sufficiently serious before clinics are permitted to test for it.

Pre-implantation genetic screening (PGS): Checking the chromosomes of embryos created through IVF for common abnormalities, in order to avoid having abnormal embryos transferred to the womb.

Primordial: In its earliest formation.

Property rights (in this report): Rights that persons have or expect to have with respect to a thing or item, including rights to buy, sell, use, transfer to another, lend to another, exclude others from, and so forth. It is possible to hold some property rights in connection with bodily material (for example those that enable the right-holder to control the use of their bodily material once separated from their body) without necessarily holding others (such as a right to monetary gain from that material).

Prosthesis: An artificial substitute for a body part such as a limb.

Recompense (in this report): A general term for payment made to a person in recognition of losses they have incurred, material or otherwise. In this report, reimbursement of expenses and compensation are both types of recompense (see **reimbursement** and **compensation**).

Reimbursement (in this report): Payment to a person to cover expenses actually incurred in the act of donation, such as travel expenses, meals and lost earnings. Reimbursement returns the person to the same financial position they would have occupied had they not donated, and does not enrich the donor in any way. See also **recompense**, **compensation** and **reward**.

Remuneration (in this report): Material advantage gained by a person as a result of donating bodily material (**reward**), where this is calculated as a wage or equivalent.

Research Ethics Committee (REC): Committee responsible for reviewing research proposals, with the aim of safeguarding the rights, safety, dignity and well-being of people participating in research.

Reward (in this report): Material advantage gained by a person as a result of donating bodily material, that goes beyond 'recompensing' the person for the losses they incurred in donating. 'Reward' is also used in the Human Tissue Act and the Human Tissue (Scotland) Act to mean "any description of financial or other material advantage".

„Soft“ opt-out: Legal system in which organs may automatically be taken from people who die in circumstances where their organs are suitable for donation, unless that person has expressed an objection during their lifetime, or unless the family objects. See also **'hard' opt-out**.

Specific consent: Consent to the use of donated bodily material for a specified project.

Stewardship model: A concept of the role of the state that includes a clear obligation on the part of states to enable people to lead healthy lives.

Stranger donation: The donation of an organ by a living donor to an unknown recipient. Sometimes described as 'altruistic donation': see **altruistic organ donation**.

Supernumerary embryos: Embryos created through IVF that would not be used for a woman's own treatment.

Superovulation: The medical stimulation of the ovary with hormones to induce the production of multiple egg-containing follicles in a single menstrual cycle.

Tiered consent: A form of generic consent for future use of donated bodily material, where the donor is invited to agree to the future use of their tissue in unknown projects, but given the option of specifying particular categories of research that they wish to exclude (see **generic consent**).

Tissue: In the Human Tissue Act, 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. See also **bodily material**.

Tissue bank: Repository for a range of bodily materials for treatment or research purposes (also known as biobanks or biorepositories).

Totipotent stem cells: Stem cells with the potential to develop into any kind of cell.

Transaction (in this report): An umbrella concept used to cover all kinds of dealings, here for therapeutic or research purposes, between persons and/or persons and agencies with respect to human bodily material.

Transplant commercialism: Defined in the Declaration of Istanbul as “a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain”.

Transplant tourism: Colloquial term used to refer to how those waiting for an organ transplant travel abroad to countries where organs are more readily available. It is typically applied to travel for transplantation involving thriving illegal markets where organs are bought and sold. The Declaration of Istanbul distinguishes transplant tourism from other forms of travel for transplantation as follows: “Travel for transplantation becomes transplant tourism if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals, and transplant centres) devoted to providing transplants from outside a country undermine the country's ability to provide transplant services for its own population.”

Valid consent: Consent that meets legal requirements with regard to the capacity of the person making the decision, the adequacy of the information about the nature and purpose of the procedure, and the voluntariness of the decision.

vCJD: Variant Creutzfeldt-Jakob disease, a rare and fatal neurodegenerative disorder, strongly associated with BSE (bovine spongiform encephalopathy) in cattle.

Ventricular assist device (VAD): Mechanical pump that can be implanted in a patient in order to help a damaged heart to maintain output.

Vitrification: An ultra rapid process of freezing gametes or embryos (cryopreservation).

Yearworth (Yearworth and others v North Bristol NHS Trust): a Court of Appeal judgment in which it was held that sperm was capable of being the property of the men who had produced it, in circumstances where it had been frozen on behalf of men undergoing chemotherapy (in order to protect their fertility) and then by error destroyed.

List of abbreviations

ABPI	Association of the British Pharmaceutical Industry
AMS	Academy of Medical Sciences
ASRM	American Society for Reproductive Medicine
ALSPAC	Avon Longitudinal Study of Parents and Children
BME	black and minority ethnic
BPL	Bio Products Laboratory
CHM	Committee on Human Medicines
CIOMS	Council for International Organizations of Medical Sciences
DBD	donation after brain death (donor)
DCD	donation after circulatory death (donor)
DNA	deoxyribonucleic acid
DonaTE	Donation, Transplantation and Ethnicity
DVLA	Driver and Vehicle Licensing Agency
EC	European Commission
ESC	embryonic stem cell
ESHRE	European Society of Human Reproduction and Embryology
EU	European Union
EUTCD	European Union Tissues and Cells Directive
GATS	(World Trade Organization's) General Agreement on Trade in Services
GCP	Good Clinical Practice
GDP	gross domestic product
GMP	Good Manufacturing Practice
GP	general practitioner
GWAS	genome-wide association studies
HFEA	Human Fertilisation and Embryology Authority
HIV	human immunodeficiency virus
HRA	Health Research Agency

HSC	haematopoietic stem cell
HTA	Human Tissue Authority
HUGO	Human Genome Organisation
ICSI	intracytoplasmic sperm injection
INUK	Infertility Network UK
iPSC	induced pluripotent stem cell
IVF	<i>in vitro</i> fertilisation
LVAD	left ventricular assist device
ME	myalgic encephalitis
MHRA	Medicines and Healthcare products Regulation Agency
MRC	Medical Research Council
NBS	National Blood Service
nef	new economics foundation
NGDT	National Gamete Donation Trust
NGO	non-governmental organisation
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NICE	National Institute for Health and Clinical Excellence
NOTA	National Organ Transplantation Act (US)
NRES	National Research Ethics Service
ODR	Organ Donor Register
ODT	Organ Donation Taskforce
OHSS	ovarian hyperstimulation syndrome
PCT	primary care trust
PET	Progress Educational Trust
PGD	pre-implantation genetic diagnosis
PGS	pre-implantation genetic screening
PPP	public–private partnership

R&D	research and development
REC	research ethics committee
SaBTO	Advisory Committee on the Safety of Blood, Tissue and Organs
SC4SM	Stem Cells for Safer Medicine
SN-OD	specialist nurse for organ donation
TOPS	The Overvolunteering Prevention System
Transrep	Trans-national Reproduction Study
UK	United Kingdom
UKDEC	UK Donation Ethics Committee
UKSCB	UK Stem Cell Bank
UN	United Nations
US	United States
VAD	ventricular assist device
vCJD	variant Creutzfeldt–Jakob disease
WHO	World Health Organization
WMA	World Medical Association

Index

Note: page numbers followed by 'n' indicate material appearing in footnotes.

- Academy of Medical Sciences (AMS) 22, 92, 107, 208
- advertising
 - campaigns 86, 109–10
 - for donors, personal 113
 - for gamete donors 110, 179
- African Americans 144n
- African Caribbean Leukaemia Trust 18, 197
- African Caribbean populations 94, 109, 199
- age at childbearing 15, 93–4, 100–1, 190
- ageing, population 34, 85, 85n
- alcohol consumption 136, 192
- Alder Hey Children's Hospital, Liverpool 25–6, 77–8
- allocation of bodily material 15, 189
- allogeneic transplantation 36
- altruism 5, 120, 125, 139–48, 161
 - behavioural definitions 139
 - co-existence with reward 125, 127, 140–1
 - commitment to 140–1
 - defined 139
 - effects of financial incentives 166–7
 - as expression of communal virtues 144–5, 167
 - motivational conceptions 139
 - preventing exploitation of poor 142–4
 - quality of supply effects 142
 - quantity of supply effects 145
 - report conclusions 146–8, 156
 - as a virtue 139
- altruist-focused interventions 5, 140, 156
 - incentives as 141
 - Intervention Ladder 7, 168, 169
- altruistic action, defined 139
- American Society for Reproductive Medicine (ASRM) 73
- amniotic membrane 40
- anatomy teaching 42, 42n
- animal experimentation, reducing 95, 97–8
- anonymity
 - bodily material 57–8, 61
 - gamete donors 90
- Anthony Nolan Trust 18, 198
- anxiety 162, 164
- artificial bodily material 98
- Association of the British Pharmaceutical Industry (ABPI) 68, 70, 142, 211
- Austria 61
- authorisation
 - consent vs 5, 150, 178
 - deceased donation 152, 156
 - Scottish legislation 59–60
- authority ranking 128n
- autologous donation 27
- autonomy 120
- Bangladesh 143
- barriers to donation and volunteering 161–5
- Belgium
 - consent for removal of material after death 61, 63
 - egg sharing 112
- benefit sharing 109, 111–12
- benefits in kind 108, 112
 - altruistic approach and 145
 - egg sharing 66–7, 169–70, 182–3
 - Intervention Ladder 169–70
 - US situation 73
 - whole body donation after death 66
- best interests 57
- biobanks *see* tissue banks
- biomarkers 44, 94, 96–7
- Bio Products Laboratory (BPL) 45
- biorepositories *see* tissue banks
- birth, products of 40–1
- black and minority ethnic (BME) groups
 - barriers to donation 162
 - demand-side ethics 136–7
 - facilitating donation by 18, 19, 197, 199–200
 - promotional campaigns 109, 197
 - stewardship role of state 193
 - supply and demand issues 89, 94–5, 144n
- blanket consent 21, 58, 150, 204
- blood 1, 35–6
 - artificial 191
 - control of donated 63
 - left over/unneeded 38–9, 60–1
 - quality issues 165
 - for research 39, 92–3, 204
 - supply and demand 85–6, 92–3
 - effects of incentives 165, 166
 - reasons for trying to match 132–3
 - report conclusions 172
 - traceability 76, 76n
 - uses 35–6, 38
 - vs sperm 47–8
- blood banks, history 44
- blood components 28, 35–6
- blood.co.uk website 109
- blood donation
 - altruistic and voluntary nature 28–9
 - facilitation by organisations 18, 197–8
 - history 44

- promotional campaigns 109, 110
- blood donors
 - barriers and motivations 161–2, 164
 - encouraging 8, 171–2
 - incentives 67, 110–11, 165
 - recruitment 86
 - safety 74
 - selection 86
 - token incentives 166, 167
- blood groups 35, 35n
- Blood Safety and Quality Regulations 2005 54
- bodily material (human) 34–50
 - artificial 98, 191
 - comparative approach 27–8, 45–50
 - donation *see* donation
 - forms 1, 27, 35–42
 - nature 46
 - sources *see* donors
 - special nature 24, 214
 - transactions involving 42–5
 - use of term 35n
 - uses 35–42
- bone 37, 91, 93, 95–6
- bone marrow 36
 - donors
 - directed donation 64
 - personal advertising for 113
 - reimbursement 67, 73
 - safety legislation 74
 - transplant, for organ repair 98
- brain banks 106, 201
- brain tissue 38, 200–1
- Breakthrough Breast Cancer 92
- breast milk 41
- Bristol Royal Infirmary, heart retention scandal 25, 77–8
- British Fertility Society 12, 182
- British Transplantation Society 173
- broad consent 21, 58–9, 150, 204
- bureaucratic hurdles 92, 106, 203
- cancer
 - increasing trends 100
 - patients 89, 95–6, 99
- capacity, legal 56–7, 148n
- cardiovascular disease 100
- cash, money as 126
- Catalona (Washington University v Catalona, 2006)* 65
- charity, donation of money to 166, 167
- childbearing, age at 15, 93–4, 100–1, 190
- children
 - capacity to give consent 56–7
 - conceived via donated gametes 40
 - numbers 89
 - relationships with donors 79–80
 - right to trace donors 90, 151
 - traceability of donors 76
 - welfare 12–13, 147–8, 182
 - tissue retention scandals (1990s) 25–6, 77–8
- cholesterol test, free 166
- chronic, non-communicable diseases 100
- clinical donation champion (clinical lead) 199
- clinical trials
 - consent to participation 58
 - defined 58n
 - first in human *see* first-in-human clinical trials
 - out-sourcing 53
 - regulation 54, 58, 77
 - use of tissues 38
 - see also* research
- cloning 40
- commerce, role of 45
- commercial dealings (in bodily material) 66–74
 - approaches in other countries 71–4
 - European and international standards 68–71
- commercialisation, acceptable 155
- commercial sector *see* private sector
- Commission on Human Medicines (CHM) 77
- Committee on Safety of Drugs (later Committee on Safety of Medicines) 77
- commodification
 - ethical concerns 120, 126
 - processed bodily material 194–5
- common good 161
 - potential threats 8, 169, 173
- common law framework, consent 56
- communal sharing 128n
- communal virtues, altruism as expression of 144–5, 167
- comparative approach 27–8, 45–50
- compensation 70, 111, 138–9
- complexity of exchanges and transactions 153–4
- conception, products of 40–1
- conditional donation 40, 40n
- confidentiality of information 58
- consent 56–63, 148–52
 - authorisation vs 5, 150, 178
 - blanket (unfettered) 21, 58, 150, 204
 - broad 21, 58–9, 150, 204
 - capacity to 56–7, 148n
 - changing current defaults 102–4
 - ethical oversight 58
 - European and international approaches 61–2
 - generic *see* generic consent
 - incentives and 148
 - for information retention/use 57–8
 - informed 56n
 - limitations on 152
 - opt-out systems *see* opt-out systems
 - other jurisdictions compared 63
 - regulatory concerns 79, 80
 - for removal of organs after death *see under* deceased organ donation

- report conclusions 170–1, 175–9
- scope 58–9, 150–2
- specific 58
- for storage and use of gametes 61
- for storage and use of material 60
- tiered (fettered) 21, 58, 150, 204
- for tissue for research 20–1, 56–7, 58–9, 92, 203–5
- for tissue retention after death 25–6, 77–8
- valid 56–8
- written 56
- consortia of general practitioners 56, 199
- consumerism 26, 101
- control of bodily material 16–17, 194
 - ethical aspects 137–8
 - regulation in other jurisdictions 65–6
 - scope of consent and 150–2
 - UK regulation 63–5
- Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine* see Oviedo Convention
- cord blood 36
 - banking 36, 197, 198
 - collection 18, 36, 198
 - facilitation of donation 18, 197–8
 - saviour siblings 100
- Corneal Transplant Service 44
- corneas 37
 - artificial 98, 191
 - attitudes to donation 25, 25n
 - banks 44
 - supply and demand 85, 91
- Council for International Organizations of Medical Sciences (CIOMS), *Ethical guidelines for biomedical research involving human subjects* 55
- Council of Europe
 - Oviedo Convention see Oviedo Convention
 - Recommendations on research on biological materials* 55, 61, 68
- crash-helmets, motorcycle riders 133
- cremation costs 66, 175
- Creutzfeldt-Jakob disease, variant (vCJD) 28, 35–6, 196
- cross-border health care 53, 114–15, 134–5
 - report conclusions 17–18, 195–7
 - see also transplant tourism
- cross-border reproductive care 53n, 114, 134–5
 - general acceptance 154, 155
 - good practice guidance 181
 - report conclusions 17, 195–6
- crowding out hypothesis 145, 166
- cultural factors 19, 94–5, 199–200
- cultural sensitivity 137
- data linkage 38, 57–8
- Data Protection Act 58
- death, diagnosis and confirmation 149n
- deceased individuals
 - known wishes 5, 152, 156
 - retrieval of gametes 40
 - whole body donation see whole body donation, after death
- deceased organ (and tissue) donation 36–7, 91
 - complexity of transactions 44
 - consent 59–60, 156, 170–1
 - changing defaults 10–11, 102–4, 175–9
 - before death 59, 87
 - international approaches 61–2
 - opt-out systems see opt-out systems
 - qualifying relatives 59–60
 - see also authorisation
 - encouragement at individual level 9–11, 174–9
 - facilitation at organisational level 18–20, 102–5, 111, 198–202
 - financial incentives 9–10, 111, 174–5
 - motivations and barriers 162, 164
 - rates 88
 - for research 38
 - safety of recipients 75–6
 - supply and demand 87–8
- deceased organ donors
 - control over use of material 64
 - donation after circulatory death (DCD) 104–5
 - higher risk 104–5
 - numbers 87
- Declaration of Helsinki 55, 75
- Declaration of Istanbul 55, 70, 78, 114
 - endorsement 17, 195
- demand 26
 - actions to reduce 189–91
 - current picture in UK 85–93
 - in different populations 94–5
 - elasticity 3, 93
 - factors influencing 93–101
 - global dimension 114–15, 134–5
 - reasons for matching to supply 132–5
 - role of state in meeting 15–16, 192–3
 - side ethics 135–7
 - supply and 3, 84–115
- dentistry, cosmetic 93
- Department of Health
 - promotional campaigns 110
 - recommendations to 9, 19, 23, 174, 199, 209
 - reorganisation of regulatory bodies 55–6
- diabetes
 - increasing trends 34, 100
 - prevention 136–7

- type 2, donation of blood 86
- diagnostic procedures, residual blood or tissue 38–9, 60–1
- dialysis 87, 96
- dignity 120
- directed donation 154
 - gametes and embryos 40, 65, 151n
 - organs and tissues 64, 65, 112–13
- disease transmission 75–6
- DNA biobanking network 205
- DNA chip technology 95
- DonaTE 200
- Donate Wales 110
- donation 34
 - alternatives to 190–1
 - barriers to 161–5
 - context of 46
 - coverage of report 27
 - purposes of 46
 - unpaid and voluntary nature 26
 - use of term 28
- donation after circulatory death (DCD) donors 104–5
- donors 28, 34
 - actions to encourage 6–14, 108–13, 160–86
 - motivations 139–48, 161–5
 - potential for harm and exploitation 5, 156
 - supply *see* supply
 - welfare 5, 8, 169, 169n
 - see also specific types of donor*
- Driver and Vehicle Licensing Agency (DVLA) 10–11, 104, 177–8, 201–2
- driver's licence applications 103–4, 177–8
- drug development 38, 97–8
- drug discovery 38
- duties, moral 124
- egg donation
 - complexity of transactions 44
 - national infrastructure 23, 209
 - for research 13–14, 183–4
 - first-in-human trials vs 48–9
 - supply and demand 90–1
- egg donors
 - consent 61
 - financial incentives 14, 49, 180, 182–3, 184, 209–10
 - motivations 163
 - numbers 90
 - personal advertising for 113
 - protection from exploitation 17, 23, 196, 210
 - risks 49
 - selection 89
 - welfare 12, 181–2, 184
 - see also* egg sharing
- eggs
 - artificial 98
 - attention given to 214
 - commercial dealings 66–7, 70, 73–4
 - freezing 99, 191
 - imports from abroad 108
 - influences on demand 100–1
 - numbers donated 89, 91
 - sources and uses 39–40
 - supply and demand 88–91
 - uniqueness 49–50
- egg sharing 13, 39, 112
 - benefits in kind 66–7, 169–70, 182–3
 - legal permissibility 66–7
 - motivation 163
 - as non-altruist-focused intervention 140, 145
- embryo donation
 - complexity of transactions 44
 - directed and conditional 40, 40n
 - rates 90, 91
 - regulation 53–4, 78
 - for research 40, 90–1, 150
- embryonic stem cells (ESCs) 36, 40–1
 - alternatives to 96, 97
 - applications 97, 98
 - lines 40–1
- embryos 39–40
 - commercial dealings 66–7, 70
 - consent for storage and use 61
 - defined 39n
 - pre-implantation tissue typing 100
 - spare 39–40, 40n
 - supply and demand 88–91, 133–4
- emergencies, shortages of tissues 92
- England
 - blood supply and demand 85–6
 - consent by children 56–7
 - regulation 53–4
- equality matching 128n
- equitable access
 - to organs, cells and tissues 69–70, 155
 - to services 19, 69, 200
- equity 120
- ethical dilemmas 119
- ethical framework 4–6, 132–57
 - applying 6, 157
 - arguing for 132–52
 - implications for ethical choice 152–5
 - policy considerations 155–7
- Ethical guidelines for biomedical research involving human subjects* (CIOMS) 55
- ethical values 3–4, 118–22
- ethics
 - demand-side 135–7
 - supply-side 137–55
- ethnic minority communities *see* black and minority ethnic (BME) groups
- European Convention on Human Rights, Article 8 90

- European Society of Human Reproduction and Embryology (ESHRE) 12, 17, 181, 184, 195, 196, 210
- European Union
 animal experimentation 95
 permissibility of commercial dealings 68–71
 regulatory instruments 54
see also Council of Europe
- European Union Clinical Trials Directive, review 107
- European Union Organ Directive 2010/45/EU 54, 61–2, 108
 commercial dealings 68–9, 70
 safety of recipients 75
- European Union Tissues and Cells Directive (EUTCD) 54, 61–2
 commercial dealings 68–9, 70
 imports and exports 108
 safety of recipients 75
- evidence, strength of 8, 169, 173
- expenses, reimbursement of *see* reimbursement
- eye banks 44
- face transplants 37
- family
 consent by bereaved 59–60, 179
 donation of material for research 20, 201
 incentives to bereaved 174–5
 letters of thanks to donor's 110
 opt-out systems of consent 10, 63, 175–7
 refusal of consent 101, 101n, 179, 179n
 use of term 179n
- fear 162, 164
- fertility clinics
 imports from abroad 108
 referrals abroad 17, 195–6
 supply and demand issues 89
- fertility tourism *see* cross-border reproductive care
- fertility treatment
 demand-side ethics 135–6
 development of regulation 78
 ethical aspects 134
 ethnic minority groups 94–5
 NHS provision 13, 135–6, 183, 190
 private nature 80, 122
 recommendations 209
 role of state 192–3
 supply and demand issues 88–90
 travelling abroad for *see* cross-border reproductive care
- fetal material 40
- fettered consent *see* tiered consent
- financial incentives 108, 111–12
- crowding out hypothesis 145, 166
- deceased organ donation 9–10, 111, 174–5
- gamete donors 11–12, 14, 111, 147–8, 179–83, 184, 209–10
- Intervention Ladder 168, 169–70
- living organ donors 8–9, 172–4
- motivational effects 163, 164–5
- quality of supply effects 142, 165–6
- quantity of supply effects 145, 166–7
see also benefits in kind; payment(s)
- first-in-human clinical trials 27, 41, 185–6
- consent issues 79
- defined 41
- encouraging participants 14, 110–11, 185–6
- governance 23–4, 210–11
- motivations of participants 141–2, 161, 163
- Northwick Park Hospital incident (2006) 77, 93
- removing barriers to 107
- risks 49
- roles of organisations 23–4, 210–11
- safety of participants 74–5
- supply of volunteers 93, 134
- vs* egg donation for research 48–9
see also healthy volunteers; research
- Fiske, Alan 128
- fresh-frozen plasma 35–6
- friends, hired 144
- funding, tissue banks 21–2, 194, 205–7
- funeral costs 9–10, 66, 111, 174–5
- gamete donation
 children conceived via *see under* children
- children
 complexity of transactions 44
- directed and conditional 40, 40n, 64, 65, 89
- facilitation at organisational level 22–3, 209–10
- national infrastructure 11, 23, 155, 180, 209
- promotional campaigns 110
- regulation 53–4, 78
see also egg donation; sperm donation
- gamete donors
 actions to encourage 11–13, 179–84
- consent for storage and use 61
- control and ownership 64, 151n
- financial incentives 11–12, 111, 147–8, 179–83, 184, 209–10
- importing, from abroad 108
- lack of anonymity 90
- national registers 12, 181
- numbers 90
- safety 74
- selection 89

- see also egg donors; sperm donors
- gametes
 - artificial 98
 - commercial dealings 66–7, 70, 73–4
 - demand 88–91
 - factors increasing 93–4, 100–1
 - factors reducing 94–5, 99–100
 - reasons for trying to meet 133–4
 - imports from abroad 108, 108n
 - payments for 12, 181
 - reasons for considering 214
 - for research 13–14, 40, 90–1, 183–4, 209–10
 - sources and uses 39–40
 - supply 88–91
 - facilitating 105, 108, 109–10, 111, 112
 - initiatives of individuals 113–14
 - reasons for trying to increase 133–4
 - traceability 76, 90
 - travel abroad to obtain see cross-border reproductive care
 - uniqueness 49–50
 - see also eggs; sperm
- General Agreement on Trade in Services (GATS) 53, 53n
- General Medical Council 17, 196
- generic consent 58–9, 150–1
 - barriers to 106
 - concerns about 80
 - recommendations 20–1, 203–5
- genetic research 27
- gift 4, 124–5, 161
- gift cards 166
- gift relationship 120, 124–5, 151, 194
- Good Clinical Practice (GCP) 74–5
- Good Manufacturing Practice (GMP) 74–5
- governance
 - donated material 154
 - first-in-human trials 23–4, 210–11
 - tissue donated for research 22, 207–8
- government see state
- graft rejection 97
- graft survival 87, 96, 191
- Greater Glasgow and Clyde Bio-repository 107
- Greenberg v Miami Children's Hospital Research Institute* (2003) 65
- haematopoietic stem cells (HSCs) 36
- hair, sale and purchase 144
- hand transplants 37
- health, maximising 121
- health care
 - changing attitudes 26
 - markets 135–6
 - travel abroad for see cross-border health care
- health promotion 100
- Health Research Agency (HRA), proposed 22, 208
- healthy volunteers 27, 27n, 41
 - actions to encourage 14, 185–6
 - clinical follow-up 210
 - motivations 141–2, 161, 163, 164–5
 - payments to 14, 28–9, 68, 110, 141–2, 145, 185–6
 - preventing over-volunteering 23–4, 211
 - roles of organisations 23–4, 210–11
 - safety and welfare 74–5, 185, 186
 - supply and demand 93, 134
- heart(s)
 - attitudes to donation 25, 25n
 - inappropriate retention 25, 77–8
 - increasing demand 100
 - regenerative medicine 98
 - transplantation 86–7, 96
- heart valves 37, 91
- HIV vaccine trials 210
- hospitals (NHS trusts)
 - accessibility of tissue for research 92, 207
 - facilitating organ donation 102
 - reimbursement of expenses 67
 - stewardship role 19, 200
- Human Fertilisation and Embryology Act 1990 49, 53–4, 61
 - commercial dealings 66–7, 68, 70
 - historical background 78
- Human Fertilisation and Embryology Act 2008 53–4
- Human Fertilisation and Embryology Authority (HFEA) 54
 - Code of Practice 61, 67
 - imports from abroad 108, 108n
 - issues raised by 79–80, 122
 - licensing activities 76
 - proposed abolition 55–6
 - recommendations to 12, 23, 182, 209
 - reimbursement of expenses 67
 - safety concerns 74
 - supply and demand 89, 90, 91
- Human Genome Organisation (HUGO) 111–12
- human genome sequencing 95
- Human Organ Transplants Act 1989 77
- Human tissue: ethical and legal issues* (1995; Nuffield Council on Bioethics) 1, 22, 25, 26–7, 52, 206–7
- Human Tissue Act 1961 78
- Human Tissue Act 2004 53
 - access to tissue for research 92, 207
 - Code of Practice on consent 59, 60, 150
 - on commercial dealings 66, 68, 70

- consent for removal of material after death 59–60, 150
 - history of introduction 25, 77–8
- Human Tissue (Scotland) Act 2006 53, 57
 - authorisation of deceased donation 150
 - on commercial dealings 66, 68, 70
 - history of introduction 25
- Human Tissue Authority (HTA) 53, 54
 - access to tissue for research 92, 106
 - anatomy teaching 42
 - Code of Practice 74
 - cord blood collection 198
 - issues raised by 79
 - licensing 76, 106, 207
 - living organ donation 62
 - paired or pooled donations 105
 - proposed abolition 9, 55–6
 - recommendations to 207
- immunosuppressive agents 96
- imports of bodily material 18, 107–8, 196
- incentives 28, 138–9
 - co-existence with altruism 125, 127, 140–1
 - consent and 148
 - decision-making and 165–7
 - defined 141
 - financial *see* financial incentives
 - non-financial 110–11
 - unobjectionable nature 141
- India
 - living organ donation 65
 - organ trafficking 72, 114–15
 - risks to organ sellers 143
- induced pluripotent cells (iPSCs) 36, 97
- infections 75–6, 165
- infertility
 - disease status 88, 134
 - treatment *see* fertility treatment
 - trends 100–1
- Infertility Network UK (INUK) 114
- information
 - associated with donated tissue 38
 - consent to retention/use 57–8
 - to encourage donation 108, 109–10
 - provision, Organ Donor Registry 11, 60, 149–50, 178
- information technology systems, adequacy 20, 201–2
- inspections 207
- intermediaries 1
 - actions to facilitation donation 188–211
 - complex chains 42–3, 44–5
 - financial transactions 68, 69
 - history of role 44
 - licensing 76
 - maintaining ethical standards 153–4
- international context 27
 - consent 61–2
 - regulation of payment 71–4
 - supply and demand 114–15, 134–5
 - see also* cross-border health care
- international conventions and guidelines 54–5, 68–9
- International Society of Nephrology 55
- interpersonal relations, values inherent in 122
- Intervention Ladder 6–8, 167–70, 171–86
 - blood donation 8, 171–2
 - first-in-human trials 14, 185–6
 - gamete donation 11–14, 179–84
 - organ donation 8–11, 172–9
 - tissue donation 184–5
- intracytoplasmic sperm injection (ICSI) 99, 191
- in-vitro* fertilisation (IVF) 39–40, 78
 - access to NHS-provided 13, 183, 190
 - developments 99–100
 - subsidised, as benefit in kind 66–7, 112
 - see also* fertility treatment
- Iran, organ payment system 71–2, 114, 143, 144, 166–7, 173
- Israel 72, 111
- jinx effect 162, 164
- judgments, moral 4, 127–8
- justice 120–1
 - egg donation for research 13–14, 183–4
- kidneys
 - influences on demand 94, 97, 100
 - influences on supply 104–5
 - living donation *see* living kidney donation
 - supply and demand 87
- Kosovo 114–15
- laparoscopic donor nephrectomy 95
- left ventricular assist devices (LVADs) 96, 191
- lesbian couples 89, 89n
- letters of thanks 110, 111
- licensing 76, 100, 106, 207
- lifestyle
 - factors influencing demand 93, 100
 - stewardship model 136
- ligaments 37, 95
- liver transplantation 87, 100, 104–5
- living kidney donation 37, 65
 - concerns in regulation 80
 - directed 112–13
 - effects of incentives on outcomes 165–6
 - encouragement 112–13
 - laparoscopic donor nephrectomy 95
 - paired or pooled 105–6
 - rates 88
- living organ donation 37

- actions to encourage 8–9, 112–13, 172–4
- stranger 62, 65, 113
- living organ donors
 - consent 56–8
 - additional protections 62
 - European and international context 61–2
 - other jurisdictions 63
 - for research, exceptions 60–1
 - for storage and use 60–1
 - directed donation 64, 65, 112–13
 - financial incentives 8–9, 111, 173–4
 - numbers 88
 - priority allocation of organs to 9, 174
 - recognition 111
 - regulatory concerns 79, 80
 - reimbursement of expenses 9, 67, 174
 - rewards in Israel 72
 - safety and well-being 74, 155, 156, 172–3
- living tissue donation 37, 38–9
- loan
 - of whole living body 1, 35, 41
 - of womb 41
- London bombings (2005) 92, 92n
- lost earnings, reimbursement of
 - EU and international standards 68–9, 80
 - gamete donors 11, 12, 180–1
 - living organ donors 9, 174
 - UK regulation 67
- lottery tickets 166, 167
- lung transplantation 86–7, 104–5
- malarial areas, visitors to 86
- Manchester Cancer Research Centre Biobank 204n
- mandated choice 10–11, 103, 104, 177, 178
- market pricing 128n
- markets, health care 135–6
- medical accidents or scandals, regulatory responses 77–8
- medical procedures, valid consent for 56–8
- Medical Research Council (MRC)
 - brain bank 106
 - Help make history website 210
 - recommendations to 21, 22, 205, 208
- medical schools
 - benefits in kind offered 66
 - donation of whole body to 41–2, 42n
- medical tourism *see* cross-border health care
- medical treatment
 - consumerist approach 101
 - control over material donated for 151
 - tissue for 20, 37, 91–2, 95–6, 202
- medicines
 - clinical trials *see* clinical trials
 - development of new 38, 97–8
 - regulation 77
- Medicines Act 1968 77
- Medicines and Healthcare products Regulatory Authority (MHRA)
 - joint inspections 207
 - preventing over-volunteering 23–4, 211
 - responsibilities 54, 74, 77
- Medicines for Human Use (Clinical Trials) Regulations 2004 54, 58
- men who have sex with men 86
- mistrust, medical 162, 164, 171
- money
 - ethical implications 152–3
 - meanings of 4, 126–7
 - see also* financial incentives; payment(s)
- Moore v Regents of the University of California* (1990) 65
- Moremarrowdonors.org 73
- motorcycle riders, crash-helmets 133
- mugs, free 111, 166
- muscle, artificial 98
- myalgic encephalitis (ME) 86
- National Academy of Sciences (US) 73–4
- National Blood Service (NBS) 18, 28, 74, 86, 197
- National Commission of Assisted Reproduction (Spain) 74
- National Gamete Donation Trust (NGDT) 110
- National Health Service (NHS) 28
 - availability of fertility services 13, 135–6, 183, 190
 - facilitating organ donation 199
 - proposed reorganisation 19, 56, 157, 174, 199
 - reimbursement of expenses 67
- National Institute for Health and Clinical Excellence (NICE) 13, 15, 135–6, 183, 190
- National Institute for Health Research (NIHR) 19, 22, 200, 208
- National Organ Transplantation Act 1984 (NOTA) (US) 73
- National Research Ethics Service (NRES) 24, 79, 93, 106, 211
- national self-sufficiency aim 17, 18, 195–7
- nephrectomy, laparoscopic donor 95
- New Jersey Hero Act 103, 103n
- NHS Blood and Transplant (NHSBT) 199
 - encouraging living organ donation 113
 - promotional campaigns 109, 110
 - recommendations to 9–10, 20, 175, 200, 202
 - stewardship role 19, 200
 - supply and demand concerns 87–8, 91
 - Tissue Services 22, 37, 44, 107, 202, 208
 - Wall of Life 110
- NHS Cord Blood Bank 18, 198
- NHS Research Governance Framework 54

- NHS trusts *see* hospitals
- non-altruist-focused interventions 5, 140, 156
 first-in-human trials 14, 185
 gamete donation 181–3, 184
 incentives as 141
 Intervention Ladder 7, 168, 169
 recommendations 169
- non heart beating donors 104–5
- Northern Ireland
 consent by children 56–7
 regulation 53–4
- Northern Ireland Blood Transfusion Service 86
- Northwick Park Hospital, TGN1412 incident (2006) 77, 93
- obesity 34, 100, 136, 192
- obligation 124
- oocytes
 immature, *in vitro* maturation 99
 mature *see* eggs
- opt-out systems 63, 102–3
 defined 104
 ethical argument for 121
 hard 10, 175–6
 non-health example 148–9
 report conclusions 10–11, 175–7
 soft 10, 103, 175, 176–7
 vs opt-in 148–50
- organ(s)
 commercial dealings 66, 67, 68–9, 71–3
 demand 86–8
 actions to reduce 190, 191
 factors increasing 93, 94, 95, 100
 factors reducing 96–7, 98–9
 equitable allocation 69–70, 155
 illegal purchasing *see* organ trafficking
 inappropriate retention (1990s) 25–6, 77–8
 legal purchase systems 71–2, 143–4
 supply 86–8
 factors improving 102–5, 107–11, 112–13
 reasons for trying to increase 132–3
 transplantation *see* transplantation
 uses and sources 36–7
- organ donation
 actions to encourage 8–11, 172–9
 complexity of transactions 44
 facilitation at organisational level 18–20, 198–202
 interactions with other systems 19–20, 200–2
 promotional campaigns 110
 for research 200–1
 see also deceased organ donation;
 living organ donation
- Organ Donation Taskforce (ODT) 18–19, 60, 87–8, 102, 103, 199, 200
- Organ Donor Registry (ODR) 104, 190, 198
 consent issues 149–50
 incentives to join 174–5
 information system design 20, 201–2
 new prompted choice system 10–11, 177–8
 numbers registered 87
 organs or tissue for research 19–20, 200–1
 promotional campaigns 110
 provision of information 11, 60, 149–50, 178
 restricted donors 25n
 wishes of family and 179
- organ failure, management 96
- organisations
 actions facilitating donation 14–24, 102–8, 188–211
 benefits of donated bodily material to 45
 central role 45
 charges levied by non-commercial 45
 licensing 76
- organ-retrieval teams 102
- organ trafficking 85, 114–15
 prohibition in India 72
 regulation 77, 78
 report conclusions 17, 195
 risks to organ sellers 143
 unacceptability 154–5
 see also Declaration of Istanbul
- ovarian failure 89
- ovarian hyperstimulation syndrome (OHSS) 39, 39n
- ovarian transplantation 99
- Oviedo Convention (and additional protocol) 54–5, 62
 commercial dealings 68, 69, 70
 safety of research 75
- ownership of bodily material 16–17, 194–5
 ethical aspects 137–8, 137n
 regulation in other jurisdictions 65–6
 UK regulation 63–5
- pacemakers 96
- paired living organ donations 62, 105–6
- Pakistan 143
- pancreas transplantation 87, 104–5
- parthenogenesis 40
- partnerships, research-oriented 16, 23, 194, 204, 210
- pathology laboratories 39
- payment(s) 111, 138
 definition 2, 70
 egg donation 49
 erosion of communal virtues 144–5
 ethical implications 152–3

- exploitation of poor 142–4
- first-in-human trial participants 14, 28–9, 49, 68, 141–2, 145, 185–6
- for gametes 12, 181
- international approaches 71–4
- in kind *see* benefits in kind
- legal permissibility 66–7, 68–70
- motivational effects 163, 164–5
- quality of supply effects 142, 165–6
- quantity of supply effects 145, 166–7
- report conclusions 146–8, 153, 156, 173–4
- terminology and types 2, 70–1
- unobjectionable nature 140
- see also* incentives; reward; *specific types*
- pharmaceutical industry
 - current concerns 79
 - imports of tissue 107
 - payments to healthy volunteers 28, 141–2
- pharmacogenomics 95
- Phase 1 clinical trials *see* first-in-human clinical trials
- plasma 28, 35–6
 - from abroad 17–18, 196
 - payments for 73
- platelet donors 67
- platelets 97
- pluralism 4, 152
- pooled living organ donations 62, 105–6
- poor people, preventing exploitation 142–4
- precautionary thinking 146, 173
- pregnant women 86
- pre-implantation genetic diagnosis (PGD) 99, 100, 191
- pre-implantation genetic screening (PGS) 99
- pre-implantation tissue typing 100
- prevention, disease 14–15, 100, 189–90
- primary care, increasing role 199
- primary care trusts (PCTs)
 - access to IVF 13, 183
 - proposed abolition 9, 56
 - reimbursement of expenses 9, 67, 174
- privacy, protection of 57–8
- private
 - concerns, policy implications 15–18, 191–7
 - and public, concepts and overlap 4, 122–3
- private sector
 - fertility treatment 80, 209
 - funding of tissue banks 21–2, 194, 206–7
 - public sector overlap 122–3
 - research 193–4
- professional ethics 154
- professional responsibilities 8, 169, 173
 - referrals abroad 17, 196
- professional values 122, 156
- promotional campaigns 86, 109–10
- prompted choice 10–11, 104, 177–8
- property
 - ethical aspects 137–8, 137n
 - permissibility of commercial dealings 66
 - rights 16–17, 19, 64–5, 137–8, 194–5
- pseudonymisation 38n
- public
 - concerns, policy implications 15–18, 191–7
 - and private, concepts and overlap 4, 122–3
- public awareness
 - of donation, increasing 109–10
 - research importance of tissue 204–5
- public good
 - donated tissue as 22, 194, 206
 - private sector contribution 16, 123, 193–4
- public health
 - ethics 136
 - factors increasing demand 14–15, 93, 100–1, 189
 - initiatives, preventive 14–15, 189–90
 - stewardship model 136, 192
- Public health: ethical issues* (2007; Nuffield Council on Bioethics) 6, 15, 167, 192
- public sector
 - benefits of donated bodily material to 45
 - importance of research 193–4
 - private sector overlap 122–3
- purchase, defined 2, 70
- purchase model 153, 156
- qualifying relationships, with deceased individuals 59, 87
- quality of supply 142, 165–6
- quantity of supply 145, 166–7
- Race Equality Foundation 19, 200
- rare disease collections 205
- reasoning, moral 127
- recipients of donated material
 - advertising by potential 113
 - safety concerns 75–6
 - specification by donors *see* directed donation
- reciprocity 121
- recognition (of donors) 108, 110–11
- recompense 111, 127, 138–9
 - concerns in regulation 80
 - defined 2, 70
- regenerative medicine 98, 191
- regulation 1–2, 52–81
 - commercial dealings 66–74
 - control and ownership 63–6
 - history of growth 77–9

- international conventions and guidelines 54–5
- issues of concern 79–81
- licensing 76
- permissive 52–3
- range of approaches 46, 47
- safety 74–6
- UK and EU 53–4
- UK and Europe 25
- see also* consent
- regulatory agencies, UK 53–4
 - cooperation between 207
 - issues raised by 79–81
 - state of flux 55–6
 - see also* Human Fertilisation and Embryology Authority; Human Tissue Authority
- reimbursement (of expenses) 111
 - deceased organ donation 174–5
 - definition 70
 - European and international standards 68–70
 - gamete donors 11–12, 179–81
 - international approaches 72, 73–4
 - legal status in UK 66, 67–8
 - living organ donors 9, 67, 174
 - lost earnings *see* lost earnings, reimbursement of
 - Oviedo Convention 69
 - unobjectionable nature 140
- relational values 122
- relatives
 - nearest 59
 - qualifying 59
 - see also* family
- religious factors 19, 94–5, 200
- remuneration, financial
 - defined 70
 - first-in-human trial participants 68
 - see also* payment(s)
- reproductive materials 1
 - growth of regulation 78
 - imports 108
 - scope 39–41
 - uniqueness 49–50
 - see also* embryos; gametes
- reproductive technology, advances in 99–100
- research
 - acceptability of payment 156
 - consent to participation 56–8
 - current concerns 79
 - ethical oversight 58
 - exceptions 60–1
 - scope 58–9
 - control over material donated for 151
 - current ethical concerns 79
 - within donation field 191
 - embryos for 40, 90–1, 150
 - facilitating donation for 16, 19–20, 200–1
 - gametes for 13–14, 40, 90–1, 183–4, 209–10
 - governance 22, 207–8
 - incentives to participants 111–12
 - infrastructure 208
 - international conventions and guidelines 55
 - public and private concerns 193–4
 - regulation 54, 207–8
 - safety of participants 74–5
 - sample collection for 39
 - tissue for *see under* tissue
 - volunteering for 48–9
 - see also* clinical trials; healthy volunteers
- Research Ethics Committees (RECs)
 - access to tissues 92, 106
 - consent procedures 58, 60
 - monetary compensation issues 79
 - sample collection 39
- research funders, UK 20–1, 59, 203–5
- respect 5–6, 156
- respiratory disorders, chronic 100
- restricted donors 25n
- reward 2, 111, 141
 - co-existence with altruism 125, 127, 140–1
 - definitions 66, 70
 - European and international standards 68–9
 - Israeli system 72, 111
 - legal status in UK 66
 - money 127
 - see also* incentives; payment(s)
- risks
 - egg donation 49
 - first-in-human trials 49
 - recipients of donated material 75–6
- risky professions, tolerance of 142, 143
- Royal College of Obstetricians and Gynaecologists (RCOG)
 - cord blood collection 18, 198
 - recommendation to 12, 182
- Royal College of Physicians 111
- Royal Free Hospital, London 107
- safety
 - regulation 74–6
 - see also* risks
- Safety of Blood, Tissue and Organs (SaBTO), Advisory Committee on 86
- saviour siblings 100, 100n
- scientific innovation
 - increasing demand 94, 95–6
 - reducing demand 96–100, 190–1
 - regulatory responses 78–9
- Scotland

- anatomy teaching 42n
 - consent by children 57
 - licensing 76
 - promotional campaigns 109, 110
 - regulation 53–4
 - removal of material after death 59–60
 - see *also* Human Tissue (Scotland) Act 2006
- Scottish National Blood Transfusion Service 86
- self-sufficiency aims
 - national 17, 18, 195–7
 - WHO guidance 85
- sexually transmitted diseases 100, 190
- shared consensus 155–7
- siblings, saviour 100, 100n
- single women 89, 89n
- skin 37, 91, 92, 92n, 93
- slippery slope arguments 155
- smoking 100
- social factors, increasing demand 100–1
- solidarity 121
 - egg donation for research 183
 - egg sharing 182
 - link to altruism 145, 154, 156, 161
- South Africa 114–15
- South Asian communities, British 94–5, 109, 199
- Southwark Cathedral, annual service of thanks 110
- Spain
 - consent for removal of material after death 61, 63, 176
 - control and ownership of material 65–6
 - permissibility of commercial dealings 74
 - tissue bank legislation 65–6, 205
- Spanish Civil War (1936–1939) 44
- specialist nurses for organ donation (SN-ODs) 102, 199
- specific consent 58
- Specter Bill (US) 73
- sperm
 - attention given to 214
 - commercial dealings 66–7, 70, 73–4
 - imports from abroad 108
 - property rights 64–5, 138, 194
 - reducing demand for donor 98, 99
 - sources and uses 39–40
 - supply and demand 88–90
 - uniqueness 49–50
 - vs blood 47–8
- sperm donation
 - complexity of transactions 44
 - national infrastructure 23, 209
 - for research 91
- sperm donors 184
 - consent 61
 - limits on donation 90, 105
 - numbers 90
 - selection 89
- sports injuries 93, 95
- squeamishness 162, 164
- Standing Advisory Committee on the Care and Selection of Donors 86
- state
 - matching supply and demand 15–16, 192–3, 197
 - public health role 15, 190
 - research-supporting role 16, 193
 - stewardship role see *stewardship role of the state*
- stem cells 191
 - adult 36, 97
 - from cord blood 36, 197–8
 - scientific developments 97–8
 - sources and uses 36
 - transplantation 98, 100
- Stem Cells for Safer Medicines (SC4SM) 97–8
- stewardship model 136, 192
- stewardship role of the state 4–5, 136
 - disadvantaged groups or individuals 16, 19, 193, 200
 - donation of bodily material 15–16, 155, 192–3
 - supporting health research 16, 193
- storage
 - of bodily material 38–9
 - consent for 60
 - ethical scrutiny 154
 - see *also* tissue banks
 - of gametes, consent for 61
- stranger living organ donations 62, 65, 113
- Sudden Death Brain and Tissue Bank, Edinburgh 106
- sulfanilamide elixir 77
- supply
 - chain of 154
 - current picture in UK 85–93
 - and demand 3, 84–115
 - factors influencing 101–15
 - global dimension 114–15, 134–5
 - quality of, effect of payments 142, 165–6
 - quantity of, effect of payments 145, 166–7
 - reasons for matching to demand 132–5
 - role of state in increasing 15–16, 192–3
 - side ethics 137–55
- surgery
 - scientific developments 95
 - tissue collection during 37, 38, 107, 162, 164
- surrogacy 27, 41
 - commercial dealings 67
 - reimbursement of expenses 67
- Surrogacy Arrangements Act 1985 67
- technological devices 96

- teenage pregnancy 15, 190
 tendons 37, 91, 95
 Tetlock, Philip 128
 TGN1412, serious adverse reactions (2006)
 77, 93
 thalidomide 77
 tiered consent 21, 58, 150, 204
 tissue 1, 37–9
 accessibility problems 20, 92–3, 202–3
 associated medical information 38
 consent to use 56–7, 58–9, 92, 150
 defined 37n
 donor–researcher relationships 21,
 194, 204
 equitable allocation 69–70
 facilitating access to 106–7, 202–8
 funding mechanisms 21–2, 205–7
 imports 107–8
 inappropriate retention (1990s) 25–6,
 77–8
 influences on demand 93
 left over/unneded 38–9, 60–1, 203
 processing into new products 37, 64
 for research 38, 39
 access to 20–2, 92, 106–7,
 207
 commercial dealings 66
 consent 20–1, 56–7, 58–9, 92,
 203–5
 ease of collection 162
 facilitating donation 20–2,
 200–1, 202–8
 governance issues 22, 207–8
 increased use 95
 infrastructure needed 22, 208
 sources 38–9
 supply and demand 92–3
 safety issues 75–6
 sharing of samples 21, 92–3, 205
 storage 38–9, 154
 supply and demand 91–3, 184–5
 reasons for trying to match
 133
 for research 92–3
 for treatment 91–2
 for treatment 20, 37, 91–2, 95–6, 202
 uses 37, 38, 92
 tissue banks (biobanks) 39, 202
 access procedures 106–7
 complexity of transactions 43
 cooperation between 44, 205
 funding 21–2, 194, 205–7
 history 43–4
 obtaining supplies 92, 93
 Spanish law 65–6, 205
 tissue donation
 barriers and motivations 162, 164
 deceased *see* deceased organ (and
 tissue) donation
 facilitation at organisational level 20–2,
 202–8
 history 43–4
 living 37, 38–9
 report conclusions 184–5, 200–1
 tissue microarrays 95
 tissue repositories *see* tissue banks
 token incentives/prompts 108, 109, 110–11
 deceased organ donation 174
 gamete donors 180–1
 incentivising effects 166, 167
 TOPS (The Over-Volunteering Prevention
 System) database 23, 75, 211
 traceability
 ethical concerns 81
 requirements 75, 76, 90
 trachea, artificial 98
 trafficking 78
 see also organ trafficking
 transactions 1, 42–5
 complexity 153–4
 direct and private 153
 use of term 42–3
 Trans-Hit Biomarkers 44n
 Trans-national Reproduction (Transrep) Study
 114
 transparency
 of process 22, 207–8
 of sources of imports 18, 196
 transplantation
 animal-to-human 98–9, 191
 equitable access to 69
 graft rejection 97
 graft survival 87, 96, 191
 international conventions and guidance
 55
 organ sources 36–7
 organ supply and demand 86–8
 permissibility of commercial dealings
 66, 68–70, 71–4
 preventive action 15, 190
 scientific developments 95, 96
 UK and European regulation 53, 54
 see also organ(s)
 Transplantation Society 55
 transplant commercialism 70, 154
 transplant co-ordinators 102
 transplant recipients, letters of thanks from
 110, 111
 transplant tourism 53n, 85, 114–15, 134–5
 defined 195n
 general disapproval 154
 report conclusions 17, 195
 see also Declaration of Istanbul
 travel abroad for treatment *see* cross-border
 health care
 treatment *see* medical treatment
 trust 5–6, 151, 156, 171, 176–7, 207–8
 trust donation committee 199

t-shirts, free 111, 166

UK Biobank 39, 59, 93, 185

UK Brain Banks 106

UK Donation Ethics Committee (UKDEC) 102, 199

UK Stem Cell Advisory Forum 18, 198

UK Stem Cell Bank (UKSCB) 40–1

UK Stem Cell Strategic Forum 18, 198

United Kingdom (UK)

regulation 25, 53–4

supply and demand 85–93

United Nations (UN) 100

United States (US)

control and ownership of material 65

imports from 107, 108

mandated choice 103, 103n

permissibility of commercial dealings 73–4

token incentives 166

University College London 107

US Navy Tissue Bank 44

variant Creutzfeldt-Jakob disease (vCJD) 28, 35–6, 196

virtue, altruism as a 139

vouchers 111, 166, 167

vulnerable people, preventing exploitation 142–3

Wales

blood supply and demand 85–6

consent by children 56–7

consent for deceased organ donation 10, 103, 177

regulation 53–4

Washington University v Catalona (2006) 65

waste 38n

websites

promotional 109, 110

recruitment of donors 113

welfare

child conceived via donated gametes 12–13, 182

donors 5, 8, 169, 169n

egg donors 12, 181–2, 184

healthy volunteers 185, 186

living organ donors 172–3

maximising 121

other closely concerned individuals 8, 169, 184

Welsh Assembly 10, 103, 177

Welsh Blood Service 86

whole body donation, after death 1, 41–2, 42n, 66

whole living body, loan of 1, 35, 41

willingness to donate 5, 152, 156

World Health Organization (WHO)

disease prevention 100

Ethical guidelines for biomedical research 55

recommendation to 17, 196

World Health Organization (WHO) *Guiding Principles* 17, 55, 62, 195

on commercial dealings 69–70

history of development 78–9

safety of recipients 75

self-sufficiency aim 85

World Medical Association 55

World Trade Organization 53

xenotransplantation 98–9, 191

Yearworth (*Yearworth and others v North*

Bristol NHS Trust [2009]) 64–5, 137, 138, 194

Previous Nuffield Council Reports

Biofuels: ethical issues

Published April 2011

Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age

Published October 2010

Dementia: ethical issues

Published October 2009

Public health: ethical issues

Published November 2007

The forensic use of bioinformation: ethical issues

Published September 2007

Critical care decisions in fetal and neonatal medicine: ethical issues

Published November 2006

Genetic Screening: a Supplement to the 1993 Report by the Nuffield Council on Bioethics

Published July 2006

The ethics of research involving animals

Published May 2005

The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper

Published March 2005

The use of genetically modified crops in developing countries: a follow-up Discussion Paper

Published December 2003

Pharmacogenetics: ethical issues

Published September 2003

Genetics and human behaviour: the ethical context

Published October 2002

The ethics of patenting DNA: a discussion paper

Published July 2002

The ethics of research related to healthcare in developing countries

Published April 2002

Stem cell therapy: the ethical issues – a discussion paper

Published April 2000

The ethics of clinical research in developing countries: a discussion paper

Published October 1999

Genetically modified crops: the ethical and social issues

Published May 1999

Mental disorders and genetics: the ethical context

Published September 1998

Animal-to-human transplants: the ethics of xenotransplantation

Published March 1996

Human tissue: ethical and legal issues

Published April 1995

Genetic screening: ethical issues

Published December 1993

Published by
Nuffield Council on Bioethics
28 Bedford Square
London WC1B 3JS

Printed in the UK

© Nuffield Council on Bioethics 2011

ISBN 978-1-904384-23-6



NUFFIELD
COUNCIL ON
BIOETHICS