

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.

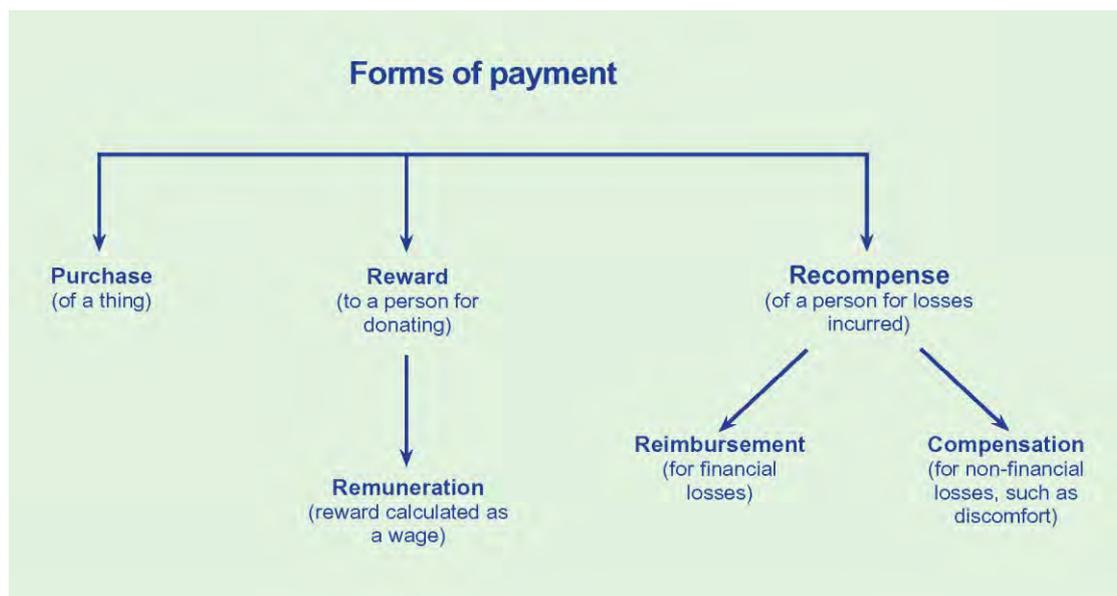
Regulatory landscape: overview (Chapter 2)

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

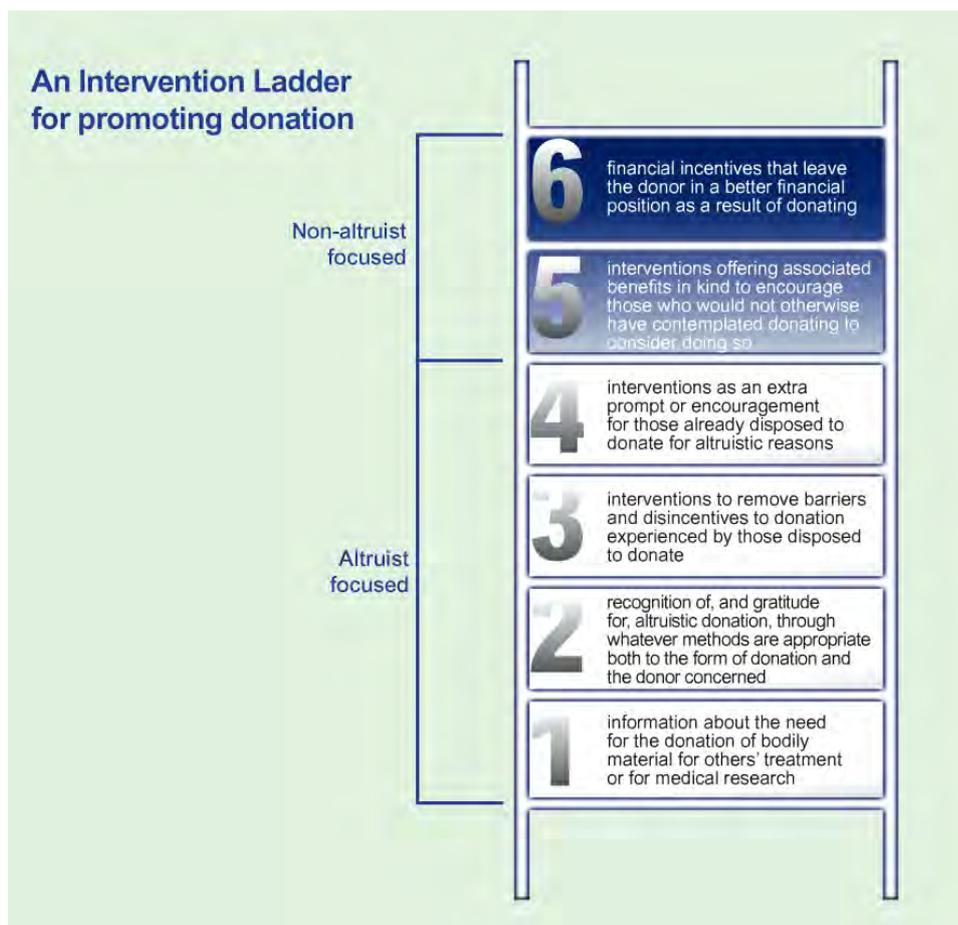
25. In the remainder of this report, we consider the demand for various forms of bodily material from two perspectives. The first (Chapter 6) concerns the degree to which it is ethically acceptable to 'encourage' individuals to donate their bodily material. The second (Chapter 7) takes up what can be 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]