

Chapter 5

An ethical framework

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Chapter overview

- A key aim of a policy framework in this complex and sensitive area must be to seek areas of **shared consensus**, including identifying values with which people starting from many different positions may nonetheless agree.
- The role of the state with respect to donation should be understood as one of **stewardship**, actively promoting measures that will improve general health (thereby reducing the demand for some forms of bodily material), facilitating donation, and removing inequalities that affect disadvantaged groups or individuals with respect to donation.
- **Altruism**, long promulgated as the only ethical basis for donation of bodily material, should continue to play a central role in ethical thinking in this field. While some of the claims made about altruism may be overblown, the notion of altruism as underpinning important communal values expresses something very significant about the kind of society in which we wish to live. Understood in this way, altruism has much in common with solidarity: **an altruistic basis for donation helps underpin a communal, and collective, approach to the provision of bodily material for others' needs**, where generosity and compassion are valued.
- However, an altruistic basis for donation does not necessarily exclude other approaches: **systems based on altruism and systems involving some form of payment are not mutually exclusive**. We distinguish between altruist-focused interventions (that act to remove disincentives from, or provide a spur to, those already inclined to donate); and non-altruist-focused interventions (where the reward offered to the potential donor is intended alone to be sufficient to prompt action). Non-altruist-focused interventions are not necessarily unethical but may need to be subject to closer scrutiny because of the threat they may pose to wider communal values.
- **Donation for research purposes may differ in important ways from donation for treatment purposes**. While both forms of donation seek to benefit others, the contribution that any one research donor or healthy volunteer makes to the health of any other identifiable person is exceptionally hard to pin down. A move away from a primarily altruistic model for research purposes may therefore pose a lesser challenge to solidarity and common values than such a move in connection with donation for treatment.
- We take seriously concerns that some approaches to increasing the supply of bodily material may risk using people, and people's bodies, as 'means' to another's ends. While we do not take the view that payment to a person in connection with donation necessarily implies this, we do **reject the concept of the purchase of bodily material**, where money exchanges hands in direct return for body parts. We distinguish such purchase clearly from the use of money or other means to reward or recompense donors.
- The **welfare of the donor**, and the **potential for harm and exploitation** within donation practices, should be a key determining factor when considering the ethical acceptability of any system for encouraging people to come forward as donors. While proper consent procedures, underpinned by sufficient information, are clearly essential in order to protect those coming forward as living donors, consent alone may not be sufficient to justify particular donation practices if such practices might put other potential donors, or wider communal values, at risk.
- **Decisions about deceased donation should be based on the known wishes of the donor**, so far as this is ascertainable. In ethical terms, the permissibility of such donation should be understood to be on the basis of the **authorisation, or willingness to donate**, of the deceased, rather than on their consent. We distinguish 'authorisation'/willingness to donate' from 'consent' in these circumstances, on the grounds of the potentially different informational requirements involved. In contrast to those consenting to donate during life, those authorising donation after death do not expose their health to any risks, and the minimum informational requirements for donors are correspondingly lower.
- Professional and relational values such as **trust and respect** play an essential part in creating and maintaining systems in which people will be willing to consider donation. This is true both of trust in individual professionals, for example that they will exercise a duty of care towards donors and respect their confidentiality; and of trust in systems, that they are the subject of good and responsible governance.

Arguing for a framework

- 5.1 We begin Part II of this report with the most fundamental question: what *reasons* do we have to try to match the supply of bodily material to demand? The question needs to be asked before we examine the legitimacy of any particular effort to increase supply of bodily materials, or to reduce demand for them. We take the reasons on a case by case basis.
- 5.2 For **blood** and **organ** donation we believe that the case can be made quite uncontroversially: blood and organs are essential contributors to basic human health and functioning, and the fact that they can be replaced is part of the contemporary medical environment. In some

circumstances blood transfusion or organ transplantation may save or extend lives; in others they may significantly enhance quality of life. We recognise that demand may never be satisfied, and that it is, in any case, created and encouraged by medical developments; however, ever-increasing demand is also found in connection with many other kinds of treatment, and in our opinion the fact that a demand may be ever-rising cannot constitute a reason for not taking reasonable measures to meet it. In the case of organs for transplant, we accept that on a patient-by-patient basis there is at present a chronic shortfall in terms of patient needs and expectations. Blood supplies are more stable but shortages do still intermittently arise, particularly for the less common blood groups (see paragraph 3.5). This creates a strong case for aiming to institute a range of public health measures that will reduce the chance that people will need blood or organs from others. At the same time, even if effective public health measures reduce the need for donation for some, medical services are still likely to be presented with many individuals who require donated organs and donated blood to maintain their ongoing basic health.

- 5.3 Thus we start from the standpoint that policies that aim to increase supply of, or reduce demand for, blood and organs are fundamentally justified through an appeal to the importance of ensuring, as far as is practical and ethical, the ongoing good health of members of society. Policy-makers must, of course, set these policies within a broader context of health policy more generally, and they will be aware of trade-offs and resource constraints within health budgets as a whole. To use a stark example, it may be that regulations requiring motorcycle riders to wear crash-helmets result in reductions in the availability of organs for donation. However, this clearly would not constitute any sort of justification for reversing the law on wearing crash-helmets: lives lost on the roads are just as significant, from an ethical perspective, as lives lost to shortage of organs.
- 5.4 As we have seen in Chapter 1 of this report, the gamut of donated human **tissue** – from bone to corneas – is put to a very wide range of purposes (see paragraph 1.10). While tissue use is much less well-known, it too may serve to save life (for example through skin grafts) or significantly to enhance quality of life (for example through corneal transplants restoring sight). Such potential uses suggest that the same moral justification for seeking to ensure an adequate supply of many forms of tissue exists as for blood and organs: a key difference, however, being that, in ordinary circumstances, supply within the UK for therapeutic use *is* currently adequate. Moreover, to a greater extent than blood or organs, tissue may be used for non-urgent as well as for urgent procedures, and in such cases any 'urgency' of matching supply to demand is correspondingly diminished. By contrast, access to tissue for research purposes (which again may in the long-term help save, extend or enhance quality of life – but where such possible results are both remote and often unrealised) is often problematic, though at times for reasons of access rather than because of actual shortages of the material itself. These considerations suggest that we should not expect responses to supply and demand issues to be uniform across all areas and purposes of donation, either in terms of the urgency with which they should be tackled, or the means used to do so.
- 5.5 **Gamete and embryo** donation raises rather different issues. Where the donation of gametes and embryos results in the birth of a child, this is both life-creating and (for the parents) life-enhancing. As we highlight in Box 1.9, the donation of gametes is often seen as very different from the donation of other forms of bodily material, primarily because of their life-creating capacity. As a result, some argue that shortages of donated gametes are of lesser public concern than shortages in other forms of bodily material, because they are seen as 'non-essential' in orthodox health terms. Others find gamete donation hard to rank in such a scale, precisely because gametes are perceived as belonging in a quite different category.⁵⁰⁵ The

⁵⁰⁵ Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader), p26; Hudson N, Culley L,

argument is also sometimes put that the numbers of vulnerable children in need of fostering or adoption should serve as a reason for not prioritising fertility treatment (with or without donated gametes) at all.⁵⁰⁶

- 5.6 There is no doubt that infertility is a significant cause of emotional pain and distress. Under certain conditions, it is classified by the WHO as a disease,⁵⁰⁷ and in many circumstances the use of donated gametes to enable a would-be parent to bear a child could be compared to the use of tissue in treatment to improve a person's quality of life. We are unconvinced that the pressing social need to provide secure families for children who are already in existence should be set against the desires of women or couples to bear a child of their own: we see no direct conflict between the two areas of social policy, and see no reason why support of the latter should be regarded as detrimental to the former. In short, we take the view that there is an ethical justification for taking steps to promote gamete donation. However, we note here that the very nature of gametes, that they may give rise to another person whose well-being is a matter of both private and public concern, means that this additional consideration has to be taken into account whenever donation in this context is contemplated. Such a consideration does not, of course, apply to the use of gametes for research purposes (whether research related to fertility or other health-related research), where no future child will ever result. The latter uses could again be compared to the use of tissue for research: the future benefit is uncertain but potentially highly valuable to health.
- 5.7 Society has responded to these various scarcities in different ways, as highlighted in Chapter 3 of this report. In relation to **first-in-human trials**, it could be claimed that scarcity has been averted by allowing payments (sometimes substantial ones) to research participants, albeit such payments are formally couched in terms of compensation for time and inconvenience, rather than as inducements to participate. In recent years payment-in-kind schemes have been developed for gametes, and the courts have taken a relatively relaxed approach to the reimbursement of expenses to surrogate mothers (see paragraph 2.35). In the face of persisting shortages, some ethics commentators have suggested the establishment of a regulated market in organs,⁵⁰⁸ and others have urged the Government to rethink the basis for authorising removal of organs from a dead body.⁵⁰⁹ However, public policy within the UK has remained wedded to altruism and to the importance of explicit consent, choosing instead to seek to boost organ donation, for example, by improving the infrastructure that supports deceased donation and widening the scope for living donation. In what follows, we pay considerable attention to the justification for this stance. Given that, in the UK, altruism and consent are frequently pitched against the prospect of payment, the role of money and the market must also be examined.
- 5.8 There is a significant global dimension to questions about the supply and demand of bodily material and we acknowledge the interconnectedness of nations with respect to the provision of such material. This means that in failing to take measures to stimulate supply in their own country, regulators may in effect divert demand for material to other countries, for example through so-called 'cross-border reproductive care' and 'transplant tourism'. This does not, of

Rapport F, Johnson M, and Bharadwaj A (2009) "Public" perceptions of gamete donation: a research review *Public Understanding of Science* 18: 61-77.

⁵⁰⁶ See, for example, Sunday Mercury (31 August 2003) *Free IVF couples urged to adopt: 700 unwanted Midland children in need of home*, available at: <http://www.thefreelibrary.com/%3a+FREE+IVF+COUPLES+URGED+TO+ADOPT%3b+700+unwanted+Midland+children+in+...-a0107118958>.

⁵⁰⁷ See: Zegers-Hochschild F, Adamson GD, de Mouzon J *et al.* (2009) The International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary on ART terminology, 2009 *Human Reproduction* 24: 2683-7, which defines infertility as "a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse."

⁵⁰⁸ See, for example: Harris J, and Erin C (2002) An ethically defensible market in organs *BMJ* 325: 114-5; Satel S, and Steelman A (2009) *When altruism isn't enough: the case for compensating kidney donors* (Washington DC: American Enterprise Institute for Public Policy Research); Hippen B, and Matas A (2009) Incentives for organ donation in the United States: feasible alternative or forthcoming apocalypse? *Current Opinion in Organ Transplantation* 14: 140-6
10.1097/MOT.0b013e3283295e0d; Wilkinson S (2003) *Bodies for sale: ethics and exploitation in the human body trade* (London: Routledge); Savulescu J (2003) Is the sale of body parts wrong? *Journal of Medical Ethics* 29: 138-9.

⁵⁰⁹ See, for example, English V (2007) Is presumed consent the answer to organ shortages? Yes *BMJ* 334: 1088.

course, automatically mean that policy must always aim to ensure that domestic supply meets domestic demand. First, if people seeking treatment travel to regimes that are themselves well-regulated, such 'cross-border' treatment may be ethically unproblematic. Second, since some ways of meeting demand for bodily material may give rise to ethical concerns, a given jurisdiction is not obliged to meet all demands, even if other less scrupulous jurisdictions may be willing to do so. Third, there is room for reasonable pluralism among jurisdictions regarding the acceptability of particular interventions to increase supply or reduce demand. This by itself may have the result that countries with more plentiful supplies of material may meet the demand of countries with lower levels of supply. In spite of all this, regulators must be aware of the ways in which a failure to introduce practicable and ethically justifiable measures for reducing demand and increasing supply can contribute to exploitative, fraudulent and harmful treatment of vulnerable individuals in countries where illegal or poorly regulated systems for obtaining bodily material become established.

- 5.9 The global dimension, especially in relation to organ donation involving developing countries, has a further lesson for ethical debate. The adoption of (national and international) protocols intended to protect the welfare of donors may be only a first step in ensuring that proper ethical appraisal takes place in any particular case. This is not just because implementation may be an issue; it is also because formal safeguards can only ever be part of the picture. Difficulties in ensuring appropriate ethical appraisal on the ground may particularly arise where health and after-care provision in general is uncertain. In effect, the dominant focus on national and international protocols may serve more to provide reassurance to future recipients of material (or to researchers recruiting healthy volunteers for first-in-human trials) that the material has been 'ethically' obtained, than deal with key ethical issues arising at the point of origin.⁵¹⁰

Demand-side ethics

- 5.10 Public policy often approaches scarcity issues most explicitly via the supply side of the equation – if something we value is in short supply we must find ways to make or secure more of it. However, it is just as important (though sometimes politically more delicate) to acknowledge the possibility of addressing scarcity through managing demand.
- 5.11 Outside a formal market we are denied the possibility of manipulating price to drive down demand. Indeed, one of the arguments against a marketplace in this context is that the 'goods' in question (here bodily material required for treatment purposes) should be fairly distributed, and using price to manage demand would be unjust, for it would lead to the poor being disadvantaged by not having effective access to widely acknowledged benefits.
- 5.12 However, markets do exist in the provision of health care in the UK – the provision of infertility services being the obvious example – and in recent years the shortage of donor gametes has been addressed at an individual level by couples travelling abroad to purchase services which include the provision of gametes (see paragraph 3.83). It is striking that public attitudes to markets in health care appear to differ significantly, depending on the care under consideration. Fertility treatment appears to be regarded by many in a light that allows it to leave the nationally-funded health service without too much public complaint. For example, although the National Institute for Health and Clinical Excellence (NICE) has recommended that women between the

⁵¹⁰ That is, meeting formal requirements on paper may be seen as having dealt with the ethics of procurement, which then can be put to one side. Indeed, it may be argued that the international enthusiasm for conceptualising donation as a gift can serve to conceal other ethical problems in the real-life conditions under which 'donations' take place (Scheper-Hughes N (2008) *Illegal organ trade: global justice and the traffic in human organs*, in *Living donor organ transplantation*, Gruessner RWG, and Benedetti E (Editors) (London: McGraw Hill), Lundin SM (2010) *Organ economy: organ trafficking in Moldova and Israel* *Public Understanding of Science*). Petryna similarly talks about regulatory concerns in relation to clinical trials that seem to work primarily at the level of 'data production': the construction of "airtight documentary environment[s] ensuring the portability of clinical data": Petryna A (2009) *When experiments travel: clinical trials and the global search for human subjects* (Princeton: Princeton University Press).

age of 23 and 39 years should be offered "up to three" cycles of IVF where there is a known fertility problem or unexplained infertility for at least three years,⁵¹¹ in practice, many people still experience difficulties in accessing NHS fertility services.⁵¹² Indeed it is interesting that to some extent the growth of cross-border reproductive care has proved less controversial than attempts by specialists in the field of fertility treatment to drive down demand by educating women regarding their fertility, and encouraging attempts to become pregnant earlier.⁵¹³ Individual liberty seems to be the value at stake here.

- 5.13 The problem of demand is in part a problem in the ethics of public health. There are 'softer' elements of policy, by means of which one might encourage behaviours that lower the overall need for donated material, for example by taking action to tackle obesity and levels of alcohol intake or by making it easier for women to have babies earlier in their careers. And there are 'harder' elements of policy, which might conceivably deny material to those who are thought to be particularly reckless with their health. A 'liberal' approach to public health would aim to provide information and promote environments that make it comparatively easy for people to choose healthy lifestyles, while stopping short of compelling healthy habits in the population. In its earlier report on public health the Nuffield Council went beyond this liberal approach, by adopting what it called the 'stewardship' model (see Box 5.1).⁵¹⁴ Here the Council pointed out that public health schemes, if they are to be effective, cannot be based on individual consent, because by definition they affect large sections of society. Moreover, in its report, the Council took seriously the view that it is the role of states to limit health inequalities. A stewardship model, then, will aim to provide environments conducive to health, in ways that reflect collectively-endorsed commitments to reasonably healthy lifestyles. It will also seek to reduce the bases of socially inequitable need for bodily material, by reducing the socio-economic contributors to health inequality.

Box 5.1: The stewardship model in public health

The Nuffield Council's report on public health sets out a clear obligation on the part of states to "enable people to lead healthy lives". In order to ensure that all groups and individuals have a fair opportunity to lead a healthy life, the report further requires that governments work to remove inequalities that affect disadvantaged groups or individuals. The 'stewardship model' proposed in light of these principles is very relevant to this report, in that several of the goals of that model relate to improving the ability of groups and individuals to protect and improve their health, thus potentially reducing the need for medical interventions involving donated human tissues or organs.

The public health report clearly states that public health programmes should not be coercive in their approach, and that measures should largely be implemented after consultation. It also advises that the goal of improving the public's health should be balanced against a commitment to secure and protect important aspects of private or personal life such as privacy. However, it would be consistent with the principles set out in the public health report to give states a responsibility to advise and assist citizens in avoiding practices injurious to their health and encourage and facilitate practices which will benefit them – particularly where the means of addressing resultant health problems are in short supply.

In the current context it would be particularly relevant to consider the approach the report takes to the issue of obesity which is pertinent to both the causes of disease resulting in organ failure, and the success of subsequent transplants. Similarly alcohol consumption is clearly linked to liver disease.

- 5.14 In proposing 'demand-side' solutions, it is important to acknowledge and analyse the difficulties experienced in previous attempts to drive down the need for medical interventions, and the variable effects they may have on different subpopulations. For example, it has been suggested that approaches taken at present in diabetes prevention may not be appropriate for some ethnic

⁵¹¹ National Institute for Clinical Excellence (2004) *Fertility assessment and treatment for people with fertility problems*, available at: <http://www.nice.org.uk/nicemedia/live/10936/29269/29269.pdf>, paragraph 11.8.

⁵¹² All Party Parliamentary Group on Infertility (2011) *Holding back the British IVF revolution? A report into NHS IVF provision in the UK today*, available at: <http://www.infertilitynetworkuk.com/uploadedFiles/InfertilityAwareness/appg%20IVF%20report.pdf>; The Independent (5 June 2011) *NHS fertility clinics told to lift restrictions on IVF treatment*, available at: <http://www.independent.co.uk/life-style/health-and-families/health-news/nhs-fertility-clinics-told-to-lift-restrictions-on-ivf-treatment-2293212.html>.

⁵¹³ See, for example, the responses to Bewley S, Davies M, and Braude P (2005) Which career first? *BMJ* 331: 588-9 at <http://www.bmj.com/content/331/7517/588/reply>.

⁵¹⁴ Nuffield Council on Bioethics (2007) *Public health: ethical issues*, available at: <http://nuffieldbioethics.org/sites/default/files/Public%20health%20-%20ethical%20issues.pdf>.

minority communities in the UK.⁵¹⁵ There is also the possibility of genetic components to disease, where some populations may simply be more susceptible to particular conditions than others, thereby limiting the effectiveness of demand-focused interventions. Therefore, to ensure that no population is disadvantaged by a solution to scarcity that seeks to manage demand, as opposed to increase supply, any solutions adopted must be evidence-based and culturally sensitive.

Supply-side ethics

- 5.15 Many respondents to our consultation put great weight on the notion of ownership or property in respect of their body parts, in their ethical assessment of the rights and wrongs of organ donation. Some felt that since they obviously 'owned' their bodies, they should be able to sell body parts in just the same way that they can, for example, sell their cars.⁵¹⁶ Others felt that recognising any rights of ownership in the body involved an unjustifiable form of objectification or even commodification of the body, arguing that it is persons who exist as embodied beings, and persons should not be treated as commodities.
- 5.16 As noted in Chapter 2, English law has historically given the verdict that individuals do not have 'property rights' in their own bodies or body parts, although this position has recently been challenged by the Court of Appeal decision in *Yearworth* (see paragraphs 2.31 and 2.32). There is also the long-standing legal principle that others may acquire property rights in body parts once separate from the body, if, as a result of the application of skill they have changed the attributes of the material.
- 5.17 The report returns at a later point (see paragraph 7.21) to the question of what legal rights it may be appropriate to vest in professionals who use, and transform, bodily material provided by donors. Our concern here is to highlight the pitfalls that arise when attempting to characterise the relationship between persons and their own bodily material by means of a blanket conception of „property“.
- 5.18 Whereas the legal concept of property (aptly described as a "negotiated and evolving legal concept"⁵¹⁷) leads very quickly to thinking about market relations, the concept of ownership can be used with a broader moral resonance.⁵¹⁸ We suggest that often when people talk about 'owning' their bodies or body parts, even if they use the language of property, their primary concern is with *control* over those materials: with the right not only to give or withhold consent to material being removed in the first place, but also to have some say over its future use.⁵¹⁹ Such

⁵¹⁵ See, for example, Randhawa G (2010) Renal health disparities in the United Kingdom: a focus on ethnicity *Seminars in nephrology* 30: 8-11; House of Lords European Union Committee (2008) *Increasing the supply of donor organs within the European Union: volume I report*, available at: <http://www.publications.parliament.uk/pa/ld200708/ldselect/ldcom/123/123i.pdf>, paragraph 330.

⁵¹⁶ Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics).

⁵¹⁷ Harmon SHE, and Laurie GT (2010) *Yearworth v. North Bristol NHS Trust: property, principles, precedents and paradigms* *The Cambridge Law Journal* 69: 476-93.

⁵¹⁸ Without getting into arguments about the relationship between body ownership and self-ownership, it may be noted that writers have at various times tried to invest the concept of ownership with the moral force of personal control – and caretaking – with respect to oneself and one's body that may be asserted in direct contrast to the presumptions of commodification. A classic text is Petchesky RP (1995) *The body as property: a feminist re-vision*, in *Conceiving the new world order: the global politics of reproduction*, Ginsburg FD, and Rapp R (Editors) (Berkeley: University of California Press). See also the essays in Davies M, and Naffine N (2001) *Are persons property? Legal debates about property and personality* (Aldershot: Ashgate).

⁵¹⁹ A 2005 study across four European countries (Cyprus, Germany, the Netherlands, Sweden) came to this conclusion: "Although the participants frequently refer to the notion of ownership when talking about the human body, this does not necessarily imply that they consider the body as some piece of private property available for commerce. On the contrary, the concept of ownership often rather seems to serve as a metaphor for autonomy and bodily self-determination, principles which can as well imply a rejection of commercialization." Schweda M, and Schicktanz S (2009) *The "spare parts person"? Conceptions of the human body and their implications for public attitudes towards organ donation and organ sale* *Philosophy, Ethics, and Humanities in Medicine* 4: 4.

rights may certainly be secured through property rights – but this is not the only way of achieving that aim. For example, the Human Tissue Act and the Human Fertilisation and Embryology Act provide a statutory basis for some degree of control over donated bodily material (as in the right to withdraw consent for the use of donated gametes up to the point when they have been used by being transferred into a woman's body) without needing to turn to the legal concept of property.

- 5.19 However there is also flexibility in the notion of property itself. While property may be understood as a 'thing', an item owned, it can also be conceptualised in terms of rights (between persons with respect to the thing or item), and such rights need not be seen only as absolute and full rights of ownership. For example, property is viewed by some as a 'bundle of rights', such that the bundle may be dismantled into „sticks“ including rights to buy, sell, use, transfer to another, lend to another, exclude others from, and so forth.⁵²⁰ Distinct ethical justifications may underpin each of these different alleged entitlements.
- 5.20 It would not therefore be impossible to develop a legal doctrine of property in relation to body parts that was limited to the notion of control (encompassing, for example, a right to exclude, a right to transfer, and also a right to a remedy where these rights are infringed), without creating any rights in connection with buying or selling. Indeed, when the Court of Appeal in *Yearworth* recognised property rights in the men's stored sperm, it was primarily concerned with ensuring a remedy for the men who had suffered from what was accepted to be negligent action. However, a disadvantage of using the concept of property in these circumstances is that the notion of property is commonly associated with 'things' as opposed to „persons“. Bodily material may, at one and the same time, be characterised both as a 'thing' and as part of the 'person', a dual characteristic that may explain the unease many people feel at the idea of property in the body.⁵²¹ We therefore suggest that greater clarity will be achieved by giving attention to the specific *elements* of the 'bundle' of rights that we may wish to accord to people with respect to their body parts, and how these may be appropriately protected and promoted. In what follows, we ask a series of lower-level questions about the form of **control** individuals should be allowed over uses of their body parts, and the extent to which they should be entitled to **reward or recompense**, and then, separately, what legal form any such entitlements should take.
- 5.21 Our preferred way forward in formulating an ethic of supply is to begin by attempting to make sense of the current approach to encouraging the provision of bodily materials, and of the ethical assumptions that appear to underlie it. We then move on to examine these assumptions critically, and to construct our own ethical framework. We must stress that we do not assume that a 'one-size-fits-all' approach is necessary or desirable: our view is that different purposes, different contexts and different forms of material may warrant different interventions with respect to supply of bodily materials.
- 5.22 It may seem that the status quo is incoherent, with diverse forms of incentivisation and compensation being offered across a variety of domains. Indeed, we highlight in Chapter 2 the range of apparently different approaches used for different forms of donation, both in the UK and beyond. However, we conclude here that, in the UK, at least, the regulations currently in force suggest a more unified view underlying all of these disparate domains than appears at first to be the case. Direct payment in money or money's worth in exchange for materials donated for therapeutic purposes, whether they be blood, organs, tissue or gametes, is generally not allowed. The rationale offered (often by regulators) is that donation must be founded on altruistic decisions. However, in most cases this does not rule out some degree of recompense for lost earnings; nor does it prevent organisations charging for their services, as long as they do not

⁵²⁰ Honore A (1961) Ownership, in *Oxford essays in jurisprudence*, Guest AG (Editor) (Oxford: Oxford University Press); Munzer S (1990) *A theory of property* (Cambridge: Cambridge University Press).

⁵²¹ There are, of course, many other ways of expressing this ambiguity, for example in the notion of the 'extended self': See, for example, Sperling D (2007) Me or mine? On property from personhood, symbolic existence and motivation to donate organs *Transplantation* **193**: 200.

charge specifically for the material itself (see paragraph 2.35). A few words are needed to make sense of this situation, beginning with altruism.

The issue of altruism

- 5.23 Altruism can be defined in various ways.⁵²² A useful distinction for our purposes is between behavioural and motivational definitions of the term. Motivational conceptions of altruism define altruistic action in terms of the internal psychological states that produce behaviours. An altruistic action, on this view, is something done because the person concerned wishes to contribute to the welfare of another. Behavioural definitions of altruism, by contrast, focus solely on the costs and benefits of action to the person concerned, without reference to the internal motivational state that may have produced the action in question. A hypothetical example may help to illustrate the difference between the two definitions. Suppose someone gives all their money to charity in the false hope that it will bring fame and increased social status. This action is not motivationally altruistic, but the fact that it may benefit others at great cost to the individual concerned means that it will be regarded as behaviourally altruistic.
- 5.24 Motivational conceptions of altruism – henceforth referred to in this report simply as 'altruism' – usually underlie debates about the ethics of donation, because these debates often concern the sorts of motivating reasons that are appealed to when encouraging donation. Many advocates of altruistic donation see altruism as an important *virtue*, hence as resting on an underlying set of moral and psychological dispositions. We return later in this chapter to a discussion of the potential social value of the promotion of altruism as a virtue (see paragraph 5.42). It is important to stress that if altruistic donation appears insufficient to meet demand in some areas, we face a *choice* of whether or not to move to an incentivised system: it is not a necessary step, and we have not assumed in our deliberations that the choice made must be the same across all domains of donation.
- 5.25 For the purposes of this report, we define an altruistic action as one that is motivated by concern for the welfare of the recipient of some beneficent behaviour, rather than by concern for the welfare of the person carrying out the action. We do not think it important from an ethical perspective that altruism is thoroughly 'pure'. First, someone may donate biological materials because it also makes them feel good to help others. In a sense the donor's own pleasure may lie at the root of their decision. But cases such as these remain altruistic for our purposes, on the grounds that concern for the welfare of others is a genuine motivator, and on the grounds that a disposition to help others can be reckoned as virtuous whether or not founded on the pleasure such action brings to the donor. Second, someone may wish to help others, but they may also be concerned about how much of their own time they can afford to sacrifice. In these sorts of situations, reimbursement for loss of time, or loss of earnings, can facilitate altruism rather than eliminate it. Third, many real-life cases will feature mixed motivations: someone who is paid well for charitable work may undertake this work for a combination of reasons, including a genuine desire to assist others and a desire to improve their own quality of life. Their altruism remains genuine here, for it might explain why they choose charity work as a career rather than some other (potentially better paid) job.
- 5.26 Crucially, the removal of barriers to donate need not render a decision to donate non-altruistic. So, we can imagine a person whose desire to donate a kidney is genuinely motivated by concern for the welfare of a stranger. And yet, the potential donor feels that they cannot donate, because they cannot afford to take the time off work required to undergo surgery and recover

⁵²² Broad C (1971) Egoism as a theory of human motives, in *Broad's critical essays in moral philosophy*, Cheney D (Editor) (London: Allen and Unwin); Williams B (1973) Egoism and altruism, in *Problems of the self*, Williams B (Editor) (Cambridge: Cambridge University Press); Wilson DS (1992) On the relationship between evolutionary and psychological definitions of altruism and selfishness *Biology and Philosophy* 7: 61-8; Sober E, and Wilson D (1998) *Unto others: the evolution and psychology of unselfish behavior* (Cambridge MA: Harvard University Press).

from it. Under these circumstances, a system of reimbursement of lost earnings, or payments for inconvenience, makes donation more likely, without thereby undermining the initial motivational concern to promote the welfare of the recipient. The same is the case for a range of initiatives that reduce barriers to donate for those already inclined to help others, such as workplace blood donation schemes.

- 5.27 This observation has important consequences. First, initiatives that reduce barriers to donate can change the decision someone is likely to make, because they change the balance of costs and benefits associated with donation. But the mere fact that these initiatives alter people's decisions does not mean that they are manipulative. We suggest that initiatives of this sort are unobjectionable, in that they simply remove barriers to an action the individual is already inclined to take. Second, it is useful to distinguish two types of intervention, both of which aim at increasing donation by changing its costs and benefits. The first we call '**altruist-focused interventions**': they typically involve the removal of various disincentives to act, and in so doing they remove countervailing concerns that may hinder altruists from acting on their altruistic motivations. Altruist-focused interventions may also offer some form of token reward or „thank you“, that might prompt the person into action but would not on its own provide a reason for acting if altruistic motivation were lacking. The second we call '**non-altruist-focused interventions**': these interventions are targeted at potential donors who have no strong motivation to help others through the donation of their bodily material, and who therefore, if they are to donate, need to be provided with different reasons for action, perhaps in the form of payment going well beyond the reimbursement of expenses. Inevitably, in some cases, the line between these two forms of intervention will be blurred, and in such cases particular care is required.
- 5.28 We regard egg-sharing regimes to encourage women to donate their eggs as non-altruist-focused interventions. This is true whether the reward involved in egg sharing is viewed either in terms of reduced-price fertility treatment, or as an opportunity to access fertility treatment that would otherwise not be available. (A non-altruist-focused intervention need not involve money.) In other words, it gives women who might not otherwise have contemplated donating eggs on altruistic grounds a reason to do so all the same. Indeed, we have already noted some evidence that women may not be inclined to share eggs with other couples if they have access to IVF treatment funded by their health care system (see paragraph 3.77): this suggests that the fact of their own reduced-price treatment, rather than aid to other couples, can be a major motivator when participating in egg sharing schemes.
- 5.29 It must, of course, be repeated that individuals who are paid, or otherwise rewarded, for their services can also be altruists. Many egg sharers undoubtedly care for the welfare of couples to whom they have donated, and may regard pregnancies enabled by their donation very positively.⁵²³ We accept that non-altruist-focused interventions will sometimes make altruists even keener to act on their altruistic motivation. But such interventions also give individuals who are not concerned with the welfare of others a motivation to donate. We emphasise here, that in our view, donation unaccompanied by altruistic intent is not necessarily unethical in itself: this will depend on all the circumstances surrounding the donation (a point we discuss in greater detail later: see paragraph 6.23). However, we believe that the distinction between those donating with altruistic intent and those donating primarily for other reasons is a valuable one, both in analysing the current regulatory approaches, and in developing our own ethical framework.
- 5.30 It seems to us, then, that a deep commitment to preserving a culture of altruistic donation is what lies at the root of the current approach to the donation of various forms of bodily material. This commitment is expressed in a number of international codes and resolutions on donation, by the regulators with whom we met, and by many of the respondents to our consultation. It is a

⁵²³ See, for example, Blyth E (2004) Patient experiences of an "egg sharing" programme *Human Fertility* 7: 157-62; and Ahuja KK, Simons EG, Mostyn BJ, and Bowen-Simpkins P (1998) An assessment of the motives and morals of egg share donors: policy of 'payments' to egg donors requires a fair review *Human Reproduction* 13: 2671-8.

separate question, however, whether this commitment is, or is not, compatible with a wide-ranging series of financial interventions and facilitating regimes that make it easier for people to act on these altruistic motivations. And as indicated above, it is another question again, whether altruistic intent is always a necessary component of any 'ethical' action in this field.

- 5.31 Some of our consultation respondents felt that all 'incentives' were ethically dubious because they altered individuals' perceptions of the relative risks and benefits of donation. The term 'incentive' may be understood very broadly ("a thing that motivates or encourages someone to do something"⁵²⁴), or more narrowly as what we have called a 'non-altruist-focused intervention' where the incentive provides the *primary* motivation for acting. We have suggested our own definition earlier, that an 'incentive' will include some measure of *reward*, as well as recompense for the burdens of donation (see paragraph 3.73). Understood in this light, an incentive could be classed either as an altruist-focused intervention (if the reward is sufficiently small that it would not act on its own to change a person's behaviour) or as a non-altruist-focused intervention (where the reward is calibrated with the aim of providing a reason for action on its own). Again, we recognise that such distinctions may be subjective: what some would regard as a token reward may give ample reason to others for acting.
- 5.32 Whether 'incentive' is understood in a very broad sense, or under our narrower definition, the mere fact that incentives may alter perceptions of risks and benefits is not alone sufficient to show they are objectionable. Effective incentive schemes are *intended* to change the decisions people make, either by providing token prompts for action (such as low-value vouchers) or by increasing the benefits of donation (through significant reward). This alteration of costs and benefits does not, in itself, make incentive schemes inherently coercive, nor, in our view, does it undermine the quality of consent to donate. If there is something objectionable about specific incentive schemes, it must lie in the details of the rewards offered, the population they target, or their broader knock-on effects. We examine these issues below.
- 5.33 The fact that the current system is built on a commitment to an altruistic model does not, of course, by itself justify that commitment. One might take the view that since the appetite for moving away from an altruistic model appears so slight,⁵²⁵ it is not even worth the Council examining the justification for sticking with altruism. Our view, however, is that remaining silent on this issue would evade one of the responsibilities of a wide-ranging investigation such as this one, and would equally fail to provide any sort of rationale to those who wish to defend altruistic donation. Moreover, while the altruistic model is often the first that comes to people's minds when they talk in the abstract about the ethics of donation, it does not serve in all circumstances. We have already seen that the egg-sharing regimes that currently exist in the UK are non-altruist-focused interventions. And altruism is only one among several values that motivate relatives to do things for one another: between kinsfolk – and in other close relationships – self-interest and other-interest are closely entwined. If we turn to another of our examples by way of comparison – namely the use of incentives for healthy volunteers in first-in-human clinical trials – we also find that the altruistic model may not be applicable.
- 5.34 Current industry guidance (though not legally binding) states that pharmaceutical companies should only offer compensation in respect of time, discomfort and inconvenience to those enrolling in such trials (see paragraph 2.37). On the face of things, then, this is another regime in which the altruistic model appears, broadly-speaking, to be respected. However, the true facts of the matter suggest that most healthy volunteers are primarily motivated to take part by

⁵²⁴ Oxford Dictionaries (2011) *Concise Oxford English dictionary*, 11th Edition (Oxford: Oxford University Press).

⁵²⁵ See, for example, the broad European (and, for some forms of material, international) consensus regarding the importance of unpaid donation, summarised in Chapter 2; Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader), p56; and the survey carried out by nef in summer 2010 (see Appendix 1).

the offer of financial reward.⁵²⁶ Indeed, the 'compensation' paid to participants under the Association of the British Pharmaceutical Industry (ABPI) guidance goes far beyond that available to, for example, gamete donors. Why does departure from the altruistic model appear to be widely tolerated in this domain, where individuals are consequently encouraged to take unnecessary risks with their own health in order to improve their financial situation, and when the well-being of immediate 'others' is absent because it is unknown or too far into the future? It is precisely the desire to ensure that this cannot happen that explains adherence to the altruistic model elsewhere.

- 5.35 The example of healthy volunteers in first-in-human clinical trials thus shows that our earlier contention – that adherence to the altruistic model is a thoroughgoing feature of the status quo – is not universally applicable. This in turn suggests that movement to alternative systems may not be far-fetched or intolerable. We have also noted non-altruistic systems of donation in other jurisdictions (see paragraphs 2.45 to 2.51), particularly with respect to the provision of gametes. Hence there are good reasons to evaluate the ethical foundations of altruistic donation.
- 5.36 The following four arguments are frequently used to justify adherence to the altruistic model: many stem from the thought that if donation can be motivated by non-altruistic reasons, then those most in need of money – the poor and vulnerable – will tend to donate in much higher proportions than before. We now turn to a critical appraisal of some of the claims made on behalf of 'altruism', particularly by contrast with the alternative of motivating potential donors through the use of monetary reward.
- 5.37 **'Altruistic donation ensures quality of supply'**: here the thought – put bluntly – is that in moving to a non-altruistic system we might increase the percentage of materials donated by those who are impoverished, socially excluded or otherwise vulnerable, and that such materials are more likely to be infected, unhealthy or low-functioning.⁵²⁷ A review commissioned by the Working Party found that there is limited evidence to suggest that this may be the case for some, though not all, bodily materials, and we return to this issue in Chapter 6. However, we note here that this does not appear to be an especially compelling consideration: even to the extent that it is correct, the remedy surely lies in an effective system of monitoring and quality-control, to be required whatever the regime of donation, in order to ensure that only materials of an appropriate quality are made available to recipients.
- 5.38 **'Altruistic donation prevents exploitation of the poor'**: it seems likely that more poor and vulnerable people would provide bodily material in exchange for money than become donors under the current altruistic regime.⁵²⁸ This is often said to constitute objectionable exploitation, on the grounds that those in need of various forms of bodily material would tend to rely increasingly on the poorest in society for their provision.⁵²⁹ Advocates of regulated markets in tissues often respond with the argument that if the altruistic model is defensible on the basis that comparatively poor people should not be allowed to risk their health in order to make money, then that same principle should also rule out allowing such people to enter dangerous, albeit well remunerated, professions, such as mining or service in the armed forces: since society tolerates the latter, it should tolerate the former. Moreover, they argue, while exploitation of people on low incomes is clearly regrettable, what is more regrettable are the socioeconomic circumstances that lead to impoverishment in the first place. Finally, they add that, given the

⁵²⁶ See, for example, Hermann R, Heger-Mahn D, Mahler M *et al.* (1997) Adverse events and discomfort in studies on healthy subjects: the volunteer's perspective: a survey conducted by the German Association for Applied Human Pharmacology *European journal of clinical pharmacology* **53**: 207-14; Ferguson PR (2008) Clinical trials and healthy volunteers *Medical Law Review* **16**: 23-51.

⁵²⁷ This was one of the main arguments put forward by Titmuss in defending unpaid blood donation schemes: Titmuss R (1970) *The gift relationship: from human blood to social policy* (London: Allen & Unwin).

⁵²⁸ We note here that this may not be the case for all forms of bodily material, in particular for eggs, where donors of high social status and achievement may particularly be sought. See: Levine AD (2010) Self-regulation, compensation, and the ethical recruitment of oocyte donors *Hastings Center Report* **40**: 25-36. In such cases, rather different concerns may arise: for example that potential donors are vulnerable because of their relative youth.

⁵²⁹ See, for example, the discussion in Wilkinson S (2003) *Bodies for sale: ethics and exploitation in the human body trade* (London: Routledge).

widespread existence of impoverishment, the question to ask is whether there is evidence that in fact payment for bodily materials might be a well-informed choice for the individual in question.⁵³⁰

- 5.39 Evidence from countries where payment is made (both legally and illegally) for organs gives a number of reasons for thinking that payment may be detrimental to the donors. Studies in Pakistan, Bangladesh and India, for example, where payment in exchange for organs is illegal, suggest that those selling organs tend to suffer worse health as a result of the procedure, do not succeed in emerging from debt (and do not necessarily received the money initially promised), and would not recommend others to provide organs in these circumstances. In many cases, the experience of selling an organ was also experienced as shameful, and was hidden from the family.⁵³¹ Such feelings of shame and regret may not necessarily be eliminated when payment is legal and more formally regulated. For example, Zargooshi's 2001 study of Iranian kidney providers also reported that the decision to sell was often experienced as shameful and that "if they had another chance 85 per cent would definitely not vend again, and 76 per cent strongly discouraged potential vendors from 'repeating their error'".⁵³² Other studies from Iran, however, have been much more positive, with as many as 90 per cent of respondents stating that they were satisfied with their experience.⁵³³
- 5.40 In many of these respects the decision to exchange an organ for money is quite unlike the decision to join the armed forces, or to work as a miner. Regretful employees in risky enterprises can attempt to find an alternative job; regretful vendors cannot go back on their decision to donate a kidney. There is little stigma or shame attached to risky professions; indeed, regular employment can often contribute directly to self-respect and to the respect accorded by others. By contrast, in the above cases at least, there appeared to be considerable stigma and shame attached to the sale of organs. Finally, secure employment has many further benefits in terms of increasing access to valuable social networks, legal protections (including health and safety requirements and protection against exploitative working practices) and so forth.⁵³⁴ By contrast, the one-off sale of an organ often comes with no such attendant benefits, and with several attendant risks to health and wellbeing. If these were general asymmetries, it would be reasonable on public policy grounds to deny impoverished individuals the opportunity to decide to sell an organ, while allowing them the opportunity to join risky professions.
- 5.41 Those who advocate the outright purchase of organs usually recommend that this takes place in a highly regulated context, where a single purchaser (such as the NHS) would offer a set price to donors, who themselves would be in receipt of extensive counselling and support. In most current organ markets, which lie beyond effective regulation, the people with the most to gain financially by the sale of an organ are also the least likely to be able to access the follow-up care on offer, and their disenfranchisement may leave them ill-treated by the system as a whole.⁵³⁵ Tight market regulation in the context of a high-quality health system might answer

⁵³⁰ See, for example, Radcliffe-Richards J, Daar AS, Guttman RD *et al.* (1998) The case for allowing kidney sales. *International Forum for Transplant Ethics The Lancet* **351**: 1950-2; Erin CA, and Harris J (2003) An ethical market in human organs *Journal of Medical Ethics* **29**: 137-8; Savulescu J (2003) Is the sale of body parts wrong? *Journal of Medical Ethics* **29**: 138-9.

⁵³¹ See, for example, Goyal M, Mehta RL, Schneiderman LJ, and Sehgal AR (2002) Economic and health consequences of selling a kidney in India *The Journal of the American Medical Association* **288**: 1589-93; Naqvi SAA, Ali B, Mazhar F, Zafar MN, and Rizvi SAH (2007) A socioeconomic survey of kidney vendors in Pakistan *Transplant International* **20**: 934-9; Moniruzzaman M (2011) 'Living cadavers' in Bangladesh: bioviolence in the human organ bazaar *Medical Anthropology Quarterly*: accepted and forthcoming.

⁵³² Zargooshi J (2001) Quality of life of Iranian kidney 'donors' *The Journal of Urology* **166**: 1790-9.

⁵³³ See, for example, Heidary Rouchi A, Mahdavi-Mazdeh M, and Zamyadi M (2009) Compensated living kidney donation in Iran: donor's attitude and short-term follow-up *Iranian Journal of Kidney Diseases* **3**: 34-9; Malakoutian T, Hakemi MS, Nassiri AA *et al.* (2007) Socioeconomic status of Iranian living unrelated kidney donors: a multicenter study *Transplantation Proceedings* **39**: 824-5.

⁵³⁴ See, for example, Sen A (1990) More than 100 million women are missing *New York Review of Books* **37**: 61-6.

⁵³⁵ Scheper-Hughes N (2008) Illegal organ trade: global justice and the traffic in human organs, in *Living donor organ transplantation*, Gruessner RWG, and Benedetti E (Editors) (London: McGraw Hill). Note, however, that where there are

some of the problems of often fraudulent purchase, and associated poor-quality medical care, which certainly characterise illegal organ markets in the global south. Moreover, tight regulation might also help to answer one criticism of those who fear exploitation – namely that the poor would not receive a fair price (or indeed the promised price) for their organ. However, the Iranian experience suggests that regulation alone may not be successful in dealing with all these problems: unregulated payments continue to be made alongside those officially permitted (see paragraph 2.46), and some kidney providers continue to feel stigmatised by their participation. As we further emphasise in Chapter 6, the evidence base for making recommendations for the UK is weak. There are obvious difficulties in using the Iranian context as a model for the UK, and even evidence of the situation in Iran is ambivalent. Even so, the Iranian experience points to a series of significant potential problems with a legalised payment model.

- 5.42 **'Altruistic donation ensures maintenance of communal virtues'**: the virtue in question is a general disposition to be moved to self-sacrifice by the health needs of others. Were donors of bodily material to be motivated primarily by the prospect of financial gain, in this model the act of donation would be converted into a market transaction. Some argue that, if this were to happen, the value of donation would be undermined, because it would no longer stand for selfless motivation or sacrifice on the part of the donor, and nor would it express a sense of shared obligation, of solidarity, to provide that which is essential for life or health. In stark terms, they say, it would undermine a community-wide commitment to provide for others, replacing it with another banal instance of reward for services rendered.⁵³⁶
- 5.43 Worries about the potential for financial incentives to commodify body parts inappropriately, to commercialise body parts, or even to undermine the dignity of the body, often have much in common with this more basic justification for an altruism model. Recent media coverage of people who were paid to act as 'hired friends' may help to explain these worries.⁵³⁷ Friends are basic contributors to well-being. But if people secure friends by hiring them, they mistake what is important about friendship in the first place, even if they thereby obtain some of the features of friendship, such as companionship. Friendship is not a service to be bought and sold, and, as a society, we should resist social changes that might make it so.
- 5.44 Similar concerns underlie the thought that the act of putting a price on a body part may lead to the mis-valuing of health, physical integrity, or indeed children. This justification of the altruism model is of a piece with the more general justification for a stewardship model in public health ethics (see paragraph 5.13). It also helps to make sense of some of the moral complexities of the current regulatory position: when biological materials make the most direct contribution to essential health needs, the positive benefits of a system based on the expression of mutual commitment to meet those needs is most palpable. That, plausibly, is one reason why at present the sale and purchase of hair used in wig-making is tolerated in the UK, but the sale and purchase of organs and blood is not.⁵³⁸ This may also explain why there is less opposition to remuneration for participation in clinical trials: here the contribution that any one participant makes to the health of any other identifiable person is exceptionally hard to pin down. Indeed, it may explain why donation for research purposes may be viewed in some ways as quite different

gross internal disparities in medical care, a system predicated on altruism may have similar effect. Goodwin (Goodwin MB (2006) *Black markets: the supply and demand of body parts* (Cambridge: Cambridge University Press)) shows for the US - where altruistic organ donation is the legal norm - the extent to which members of the black community who provide bodily material like anyone else do not have their own health needs met. In the case of those needing transplants themselves, African Americans are often diagnosed late, wait longer than other members of the population for organs, and more of them die while on the waiting list (African Americans donate at similar rates to others, but suffer proportionately more kidney failure, and thus have a higher need). Disparities may arise for all kinds of reasons – for the UK see, for example, a report on people under-involved in the home regime seeking solutions abroad: Krishnan N, Cockwell P, Devulapally P *et al.* (2010) Organ trafficking for live donor kidney transplantation in Indoasians resident in the West Midlands: high activity and poor outcomes *Transplantation* **89**: 1456-61.

⁵³⁶ Anderson E (1990) The ethical limitations of the market *Economics and Philosophy* **6**: 179-205.

⁵³⁷ The Guardian (21 July 2010) *Would you rent a friend?*, available at: <http://www.guardian.co.uk/lifeandstyle/2010/jul/21/friends-rental-service>.

⁵³⁸ We do not suggest that this is the only reason: the fact that hair sheds naturally, or is cut on a regular basis for other reasons than donation, may also explain differences in current attitudes.

from donation for treatment purposes: while material donated for research will be used with the aim of improving health in the long term, the connection between the donation and that outcome is both extended and uncertain. Gametes, on this view, fall into a contested territory, in part because the question of whether ongoing fertility is a matter of good health or not is itself contested.

- 5.45 We take the view that it is important to distinguish a foundational commitment to a vision of society in which members are motivated to care for the health needs of others, and where values such as generosity and compassion are encouraged and recognised, from the question as to how that vision may be achieved in practice. The Working Party takes the view that basic appeals to solidarity in the domain of health are very persuasive (see Box 4.2). However, we have already noted that in reality many decisions that help others have mixed forms of motivation lying behind them. In some circumstances, solidarity may indeed be undermined by the offer of rewards in return for donation; even so, it is also possible to imagine circumstances in which individuals make decisions to promote the health of others based on a combination of genuine altruism and personal enrichment. It does not follow, then, that the availability of limited non-altruist-focused incentives must necessarily undermine solidarity.
- 5.46 This communal and collective justification for the altruism model explains why departures from altruism seem most appropriate when they are instances of 'payment in kind'. If the emphasis on an altruistic approach reflects the shared notion that we are 'all in this together', and that we all have a similar set of basic needs, then schemes that highlight the fact that the needs of recipients may also be the needs of donors themselves can appear less objectionable than schemes that reward donation with money. An egg-sharing incentive scheme, which reinforces the notion that many other couples are 'in the same boat',⁵³⁹ may therefore undermine social solidarity less than a simple payment model, even though egg-sharing schemes are non-altruist-focused interventions.⁵⁴⁰ Similarly, it may explain why the remuneration of healthy volunteers participating in first-in-human trials is not generally seen as challenging the altruistic basis of the donation of bodily material: while research results may benefit many in the long term, the very uncertain nature of such research means that such beneficiaries seem very remote. Participants may certainly feel a sense of contributing to society or the common good, but are less likely to envisage their actions as an act of altruism towards specific (if unknown) others.
- 5.47 **'Altruistic donation ensures quantity of supply':** The concern is sometimes expressed that offering payment for donated material would 'crowd-out' potential altruistic donors: that is, people would feel less inclined to donate altruistically, perhaps because the argument of solidarity ('we're all in this together') would then exert less moral force, or because the offer of payment might be perceived as a mis-valuation of the bodily materials they were contemplating donating.⁵⁴¹ The review commissioned by the Working Party, however, demonstrated how little empirical evidence there is to support this contention, and that what does exist relates primarily to blood (see paragraphs 6.18 to 6.21). This very limited evidence suggests that, in practice, 'crowding out' is much less of a concern than might be thought from studies that ask people about their *intentions* (as opposed to studying their actual behaviour), at least as far as low-value incentives are concerned; and that token incentives such as lottery tickets and vouchers may in some cases act as a spur to donation, while small amounts of cash do not. We return to these issues in more detail in Chapter 6.
- 5.48 Before setting out our conclusions on altruism, it is necessary to offer one further comment about the way concepts may be used to justify particular practices. When great emphasis is

⁵³⁹ To the extent that both donors and recipients are seeking to get pregnant - although this should not disguise the fact that egg donors are getting quite a different 'deal' from recipients.

⁵⁴⁰ In this case, social solidarity within the UK may also be said to have been undermined by the lack of consistency of NHS IVF provision.

⁵⁴¹ Titmuss R (1970) *The gift relationship: from human blood to social policy* (London: Allen & Unwin).

placed on one particular value such as altruism, the very terminology can become a means of persuasion or even manipulation, as we saw previously in relation to the language of the gift (see paragraph 4.12).⁵⁴² The risk may therefore arise that this ethical impulse (altruism) on the part of potential donors may be misused by those who have strong interests of their own in the donors' bodily materials.⁵⁴³ But while we should be wary of wholesale appeals to altruism, we do not for this reason jettison the concept ourselves.

Conclusions on altruism

- 5.49 We find none of the four considerations outlined above wholly decisive, either one way or the other. It is not possible absolutely to rule out on ethical grounds movement away from a system based solely on altruism. One way to make that vivid is to imagine that we had reliable empirical data showing beyond doubt that significant payment, in the context of a highly regulated system characterised by exemplary follow-up care for donors, would greatly increase supply. Imagine that this regime was accepted to such a degree that there was no conceivable stigma in providing part of one's body in return for money, and indeed that it was an option considered by people across the income range. Under such circumstances, one might regard insistence on the value of shared communal virtues as a principle worth sacrificing in favour of another (maximising health and welfare), given the prospect of a likely gain in health for those in acute need of organs.
- 5.50 This illustrates only that we can *imagine* circumstances in which regulated payments in return for the provision of bodily material might be justifiable. As a matter of fact, the current situation in the UK is characterised by ethical uncertainty in the face of conflicting imperatives, and is exacerbated by very limited empirical evidence regarding the likely effects on supply of a departure from the current altruistic model. It would be necessary to take into account the realities of compliance and the risks, for example, of unregulated systems flowering alongside the regulated scheme with all its careful protections. In situations of uncertainty and partial evidence, a form of precautionary thinking is often considered appropriate. We have intentionally avoided referring to the 'precautionary principle' here, for we are sceptical of the existence of any clear decision rule that tells the decision-maker how to act in cases of uncertainty. Instead, by 'precautionary thinking' we understand a general stance that is humble about the limits of our knowledge, that recommends expanding our knowledge base through the use of small-scale pilot-studies, that is mindful of the potential costs of various likely errors in judgment, and that stresses the wisdom of putting policies in place that can be undone if they prove to be unwise.⁵⁴⁴
- 5.51 We have referred to 'movement' or 'departure' away from the current altruistic model because the dominance of this way of presenting the donation of bodily materials, especially organs, means that no recommendation can start from scratch – any alternative would have to argue the case for radical change from this model. As we have already seen, the model does in any case have limits to its application: for example, it is not the primary basis on which healthy volunteers participate in first-in-human trials, and different values may or may not exist in tandem (such as solidarity or maximising health care). However, its dominance or salience – and this is true internationally – shares a very special feature with the concept of consent. In this field, the altruistic model has become a sign for ethical practice itself. There are other ethical values, as we noted at the start of Chapter 4, and in many situations people do not explicitly act by reference to specific ethical values, even if their actions may retrospectively be justified in such a way. Yet altruism holds a central signifying place in the ethical acceptability of donating materials from the body, in the idea that someone might give part of themselves for the use of another, much as consent does in the negotiations and agreements by which these materials are obtained with the will of the donor. We turn to consent in paragraphs 5.55 to 5.70.

⁵⁴² The same criticism can also be made of any widely accepted procedure, such as obtaining 'consent'.

⁵⁴³ Dickenson D (2007) *Property in the body: feminist perspectives* (Cambridge: Cambridge University Press).

⁵⁴⁴ Lewens T (2008) Taking sensible precautions *The Lancet* **371**: 1992-3.

- 5.52 **The arguments for a complete departure from the altruistic model seem uncertain. Indeed, a rough and ready moral appraisal suggests that, for the moment, a wholesale reconfiguration of the basis for the donation of bodily material (as would be implied by creating a new system of non-altruist-focused interventions) would be reckless, and could run the risk of irreversible damage to important communal virtues. At the same time, our evaluation is not uniform across the domain of donation.** We have already seen that first-in-human trials are an area where departure from an altruistic basis of participation is at present accepted. Similarly, the donation of bodily material for research purposes, where the connection between donation and the well-being of others is much more remote than in donation for treatment, and hence where lesser risk to communal values might arise, could be an area in which various 'pilot studies' might be tolerated. Rigorous evaluation of such studies could then be used to provide a basis for any future consideration of policy in connection with the donation of bodily material more generally.
- 5.53 Gamete donation for treatment purposes presents further ethical complications because it involves the potential generation of a new person. At its most extreme the charge is made that buying and selling gametes allows 'children' to be purchased, and that psychological damage to children born of such arrangements is inevitable, although such claims are strongly contested.⁵⁴⁵ We agree that deliberations over the provision of gametes must take serious account of the well-being of the future child. Some have tried to defend payments for gametes on the grounds that since a given child would not have existed but for the supply of the gamete in question, the transaction cannot be said to have harmed that particular child. However, we are sceptical of using what many would consider a contentious philosophical argument⁵⁴⁶ to establish a potentially wide-reaching policy. It is also, however, important to acknowledge that significant numbers of British couples are travelling abroad to access treatments in countries where more generous compensation arrangements – or indeed a free market – are in place for gametes.
- 5.54 A distinction can be drawn, of course, between paying a donor for the time, discomfort and inconvenience of going through the process of supplying a gamete (which we have characterised as 'reward'), and payment for the gamete itself (which we have characterised as 'purchase'). Distinctions may also be drawn with respect to the size of the payment (for example token or substantial) and whether or not higher payments are made in respect of particular characteristics.⁵⁴⁷ Such distinctions give some room to those who argue that it is possible to incentivise the provision of gametes financially without this amounting in any way to the 'purchase' of children. It should also be noted that most people receiving IVF treatment within the UK do so within the private sector and hence are already paying for the opportunity to conceive a child. We consider that an important issue here concerns the ultimate feelings of the future child: specifically how the child is likely to respond, positively or negatively, to the knowledge both that financial incentivisation was required to secure some of his or her most basic original materials, and of the lengths to which their parents were prepared to go in order to have a child. We return to the issue of research on this question in Chapter 6 (see paragraph 6.70). We note also, however, that the experience of individual children conceived in such

⁵⁴⁵ For an argument concerning the commodification of reproductive material, see: Cohen CB (1999) Selling bits and pieces of humans to make babies: the gift of the Magi revisited *Journal of Medicine and Philosophy* **24**: 288-306. For an alternative perspective, see: Resnick DB (2001) Regulating the market for human eggs *Bioethics* **15**: 1-25.

⁵⁴⁶ Derek Parfit, whose book *Reasons and persons* first outlined the so-called 'non-identity problem', held to what he called the 'no difference view' as a response to the problem. He pointed out that a policy that causes grave long-term damage to the environment may also affect which future people come to exist. One cannot say of any future individual that he or she would have been better off had the damaging policy not been put into place, for without the policy the person would not have existed. Parfit did not conclude that the damaging policy was therefore unobjectionable. Instead, he attempted to find a theory that could account for what he termed 'non-person affecting harm': Parfit D (1986) *Reasons and persons* (Oxford: Oxford University Press).

⁵⁴⁷ See, for example, New York Times (3 March 1999) *\$50,000 offered to tall, smart egg donor*, available at: <http://www.nytimes.com/1999/03/03/us/50000-offered-to-tall-smart-egg-donor.html>; Levine AD (2010) Self-regulation, compensation, and the ethical recruitment of oocyte donors *Hastings Center Report* **40**: 25-36.

circumstances is not the only factor to take into account. Wider social understandings of the context in which children are received and accepted, and the responsibilities that their genetic parents may be thought to have towards them are also important: the extent to which rewards to donors might affect these understandings must be taken into account.

The issue of consent

5.55 Key ethical issues that arise in the context of consent for the donation of bodily material, or participation in first-in-human trials as a healthy volunteer, were indicated in Chapter 2 and include:

- whether the consent is the product of a free and unforced choice (how may such a choice be affected by the offer of an incentive to donate?);
- whether the consent is the product of an informed choice (how is information about risk presented? can opt-out systems meet informational requirements?);
- whether the consent has been unequivocally signalled (again, an important issue in connection with opt-out systems); and
- whether the activity falls within the scope of the consent (how widely may the scope be legitimately defined, especially in terms of material donated for research use? What future connection should there be between the donor and the researcher or research institution?).⁵⁴⁸

Incentives and consent

5.56 We have already made clear our view that the mere fact that incentives act to change people's perceptions of the relative risks and benefits of a particular course of action (in this case, whether or not to donate) does not in itself undermine the quality of consent to donate (see paragraph 5.32). Clearly, important questions arise as to the nature of the information provided about those risks and benefits: any attempt to underplay the risks or exaggerate the benefits would indeed compromise the basis on which consent is given. However, we do not accept the argument that the very *existence* of an incentive puts the free and voluntary nature of a person's consent at risk. This is, of course, not to say that incentives are therefore as a matter of course always ethically unproblematic: as we have already indicated, other values, in particular those of solidarity and of protecting the common good, are relevant here.

Opt-in versus opt-out

5.57 Our consultation responses showed considerable polarisation around the issue of consent, particularly in the context of organ donation after death. On the one hand, some respondents felt that the health needs of those who require scarce organs were so great that this could justify an 'opt-out' system, or perhaps a system of mandated choice (see paragraph 3.53). On the other hand, some respondents felt that in moving to an opt-out system, the state would effectively gain control over, and ownership of, individuals' bodies, and that such a shift would be quite unacceptable.

5.58 All parties agree that 'consent' is important in the context of organ donation, but disagreement focuses on how that consent should be signalled. In considering this issue, we have found it useful to reflect on the success of 'opt-out' schemes in other non-health contexts. A well-documented case looks at the increase in take-up of occupational pensions schemes, prompted simply by changing employees' default status from that of non-enrolment to enrolment.⁵⁴⁹ Equally, one might think that far greater quantities of valuable bodily material could be secured

⁵⁴⁸ *Capacity* to consent is, of course, another key issue in consent to either medical treatment and research; in the context of this report, however, and its focus on the encouragement of donation or volunteering to benefit others, the question of participation where capacity to consent is uncertain does not play a large role. One exception, however, is that of bone marrow donation to a sibling, where the donor will often not have the capacity to give a legally valid consent.

⁵⁴⁹ Thaler RH, and Sunstein CR (2003) Libertarian paternalism *American Economic Review* **93**: 175-9.

by ensuring that the default status is membership of the ODR, with the option to opt out. We find several significant differences between the cases.

- 5.59 First, it is very unlikely that an individual would be unaware of their enrolment in an occupational pension scheme – at least after receipt of their first pay-slip. Evidence of their membership would be represented to them on a weekly or monthly basis and failure to opt-out in these circumstances could legitimately be described as tacit consent rather than opt-out: while the person might not formally be invited to signify consent, there can be little doubt that they are aware of the system and have chosen not to opt out of it. But it is quite possible for someone not to have received, or not to have read or understood, a communication informing them that they will be placed on the ODR. It is also quite possible that people would remain unaware or unengaged with the issue despite national publicity campaigns.
- 5.60 None of this would matter if membership of the register were a trivial matter. But here is the second difference: as our consultation showed, for many people the future uses of their body is something of fundamental personal concern.⁵⁵⁰ Moreover, unlike the allocation of one's pay-packet, a mistake regarding the allocation of bodily materials after death is not easily rectified or repaired. Finally, although we can argue that employees contribute to a pension pool from which others (their dependents) will benefit, they will also benefit directly themselves, and will do so, even if they have contributed unknowingly. A person who chooses actively to donate their organs after death could be said to benefit from the knowledge of that forthcoming act of altruism, but they will not benefit in any way if they never realise that donation lies ahead. The taking of bodily material from a person in these circumstances could be interpreted by some as using a (deceased) person as merely a means to others' ends, rather than as an end in themselves; and hence as a failure to respect their dignity as a person (see Box 4.2).
- 5.61 **Comparison with a successful case of a non-health 'opt-out' scheme, as described above, leads us to the view that the taking of bodily materials after death should be based on the clearest possible information as to the person's wishes. Only in these circumstances can it be described as 'donation'. Such information should, ideally, derive from the person's own expression of these wishes before death, and we discuss later a number of ways in which individuals might be prompted at particular times to express their wishes (see paragraph 6.52 to 6.54).** Where the individual has not recorded their wishes (whether in favour or against donation) in advance of their death, information about their likely wishes should be obtained from those closest to them.
- 5.62 In coming to this conclusion for this kind of donation, we have deliberately avoided the term 'consent'. As we highlighted earlier, what is currently required for 'valid consent' in differing circumstances varies enormously, with very variable amounts of information provided and differing protections offered (see paragraphs 2.7 to 2.21). With respect to deceased organ donation, some health professionals are concerned that signing the ODR is not 'consent' as usually understood in a clinical setting, given the lack of certainty around information provision, competence and understanding.⁵⁵¹ By contrast, suggestions have been made that the information provided to relatives about possible uses of bodily material after death may

⁵⁵⁰ Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics). See also: Department of Health (2008) *The potential impact of an opt out system for organ donation in the UK: supporting information - annex L*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090298.pdf and Sque M, Long T, Payne S, and Allardyce D (2008) Why relatives do not donate organs for transplants: „sacrifice“ or „gift of life“? *Journal of Advanced Nursing* 61: 134-44 for a discussion of families' wish to 'protect' the dead body.

⁵⁵¹ A more specific concern about consent is raised by some who disagree with the current definition used for the diagnosis and confirmation of death used in UK, as set out by the Academy of Medical Royal Colleges (2008) *A code of practice for the diagnosis and confirmation of death* (London: Academy of Medical Royal Colleges). However, given that this definition is used in all clinical practice in the UK (i.e. not just in transplantation), the Working Party was of the view that further consideration of this issue would be beyond its scope.

sometimes be unnecessarily and distressingly detailed.⁵⁵² In the context of embryo donation for research, the issue of 'unfettered' consent has recently caused concern,⁵⁵³ and as we highlighted earlier, there is an ongoing debate over the acceptability of 'generic' consent for future research uses of many different forms of tissue. While 'consent' constitutes a central plank of the Human Tissue Act, the Act is silent on what is in fact required for consent to be legally valid, although guidance is offered in the Codes of Practice. The Human Tissue (Scotland) Act uses the term 'authorisation' rather than 'consent' in connection with deceased donation, and in practice the terms are used synonymously, ensuring that organs and tissue may be allocated across the UK, regardless of the legal regime under which they were donated (see paragraph 2.15).

- 5.63 While we see no need (given the absence of definition of 'valid consent' in the Human Tissue Act itself) to seek to amend legal terminology, **we argue that it is right to make an ethical distinction between legal consent to interventions on the body during life (from blood samples to operations to donate a kidney) and those taking place after death.** The former involves physical intrusion on a living individual and the associated health risks, which will of course vary significantly depending on the procedure. The information made available to the potential donor, and the procedures designed to ensure that the donation reflects their autonomous choice, need to reflect that intrusion and that risk. In the case of interventions after death, we suggest that it is perfectly possible for a person to express meaningful willingness to donate (either on behalf of themselves in the future or on behalf of a deceased relative) with much more limited information – while noting, of course, that some people *will* wish for detailed information, in which case it must clearly be provided. In ethical terms, it may be helpful to distinguish between 'consent' to interventions during life and 'willingness to donate' or 'authorisation' of donation after death.⁵⁵⁴ We return to these issues again in connection with various forms of bodily material in Chapters 6 and 7.

Scope of consent

- 5.64 Questions around the scope of a person's consent link closely with concerns about future *control* of donated material by the source of the material. Key issues that arise include, first, whether it is ethically acceptable to ask a person to consent to unknown future uses (as in requesting generic consent for research using donated tissue, blood and embryos) and second, what control a person may reasonably expect to have over the future use of their tissue (for example in specifying a recipient or category of recipient, or in seeking redress if the material is improperly used).
- 5.65 On the first question, we take the view that it *is* meaningful, and therefore in this sense ethical, to seek generic consent to unknown possible research uses: while, by definition, precise information about the nature of possible projects cannot be given, nevertheless donors may understand in broad terms how their material will be held (for example in a tissue bank), who will be able to use it (for example researchers with approved projects), and what, if any, limitations are placed on future use (for example whether material will only be made available for health-related research projects). They should also be in a position to understand whether the option does, or does not, exist for them to exclude particular types of research from their consent (tiered consent), and the extent to which some form of relationship may continue between donors and the research institution after the initial donation (broad consent).

⁵⁵² Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics); UK Donation Ethics Committee/NRES workshop (November 2010) *Ethics of transplantation*, report to be made available at: <http://www.aomrc.org.uk/donations-ethics-committee/work-programme/231-ethical-issues-in-organ-donation-and-transplantation-research.html>.

⁵⁵³ Centre for Biomedicine and Society (2010) *Ethical frameworks for embryo donation: views, values and practices of IVF/PGD staff*, available at: <http://www.kcl.ac.uk/content/1/c6/02/53/02/Shortreportforcircpdf.pdf>.

⁵⁵⁴ 'Authorisation', of course, is the term used in Scots law, although not in the Human Tissue Act that governs England, Wales and Northern Ireland.

- 5.66 However, such generic consent is not sought or given in a vacuum: donors are only likely to consider giving generic consent in circumstances where they have already have trust in the professionals and systems concerned. The central nature of trust in such circumstances highlights the importance of what we characterised as 'professional' and 'interpersonal' values in Chapter 4 (see paragraph 4.3): donors are unlikely to give generic consent unless they trust the professionals concerned to exercise a duty of care in how their donated material is used and ensure that the donors' confidentiality is respected. However, while consent may be sought by one individual professional (possibly already known to the donor), the transactional nature of contemporary research using bodily material means that the actions of many others, unknown to the donor, will also be relevant. Thus, questions of good governance and transparency become central in ensuring that those who are asked to consider giving generic consent may have good cause to trust the systems and institutions that will be responsible for safeguarding their donated material.
- 5.67 On the second question, it is helpful to distinguish between consent in the context of donation for treatment, and consent in the context of donation for research. In donation for treatment purposes, once material has been transplanted into another person, there can clearly be no question of active future control of that material, and consent must include full relinquishment of any such claim. We note, of course, that in the case of the donation of gametes or embryos, while no future rights in respect of any resulting child exist for the donor, he or she must accept the possibility of being contacted once the child has reached the age of 18 years, and there is general acceptance that the genetic tie cannot be regarded as severed, despite the donor's lack of future control over any resulting child. In these circumstances, very clear distinctions must be drawn between the possibility of future *interests* in the donated material and any rights of future *control*.⁵⁵⁵
- 5.68 In donation for research, on the other hand, there is no similar good reason that would hinder recognition of an onward interest in the donated material. We have discussed at several points earlier in this report how the donation of bodily material is typically represented as a 'gift relationship'; and we highlight here the importance of paying attention to the notion of 'relationship' as well as to the idea of the 'gift'. Clearly, in the context of research, that relationship will not generally be understood as a personal one: rather, those donating material for research purposes should be understood (to the extent that they wish to be) as partners in the research enterprise. Such an understanding of the 'gift relationship' stands in stark contrast to fears that those donating material for research may be perceived merely as a means to others' ends, 'used' for the benefit of others. We discuss later in this report what the idea of partnership may mean in practice (see paragraphs 7.19 and 7.70). However, we emphasise here that donors' interests in the future research use of their material should not be confused with straightforward rights of control: while the consent process may be used to *limit* how material is used (as for example in tiered systems of consent where specific forms of use may be excluded), donors cannot expect to *determine* use in any positive way: that is, they can refuse consent to particular usages, but they cannot demand that particular use be made of their donated material. Moreover, while the ability to change one's mind and withdraw consent at any later stage is an important safeguard for those giving generic consent, the practical limitations on this right (for example the impossibility in some cases of extracting particular data from large datasets where samples have already been used) must be clearly explained as part of the initial consent process.

⁵⁵⁵ The question does, also, arise as to whether donors should be permitted to control the future use of their material by specifying a category of recipient: for example stipulating that gametes or embryos may only be donated to a married woman under a particular age. The Working Party notes that the HFEA has sought legal advice on the implications of the Equality Act 2010 for this practice, and welcomes the fact that the HFEA will be issuing further guidance in this area (see paragraph 1.18).

Limitations on consent

- 5.69 This report has indicated a number of the important ways in which a focus on consent serves to protect the autonomy of potential donors and volunteers. For interventions carried out during life, legally valid consent, based on appropriate levels of information and protected by procedures that aim to avoid coercion or duress, is central to protect bodily and personal integrity. In the case of interventions carried out after death, the disposal of bodily material should be determined by the known wishes of the deceased, so far as this is possible; we suggest, in the light of paragraph 5.63, that in ethical terms **this expression of views should be distinguished from 'consent' (being considered, instead, as 'authorisation' or 'willingness to donate') in demanding much lower minimum informational requirements.** When material is donated for research purposes, consent processes empower donors to ensure that their material will not be used for purposes that they would regard as unacceptable.⁵⁵⁶ However, we caution here that consent should not be seen as the only, or indeed the primary, focus of ethical concern in this area, for at least two reasons.
- 5.70 First, we repeat our concern that at times the seeking of consent may become simply a procedural hurdle, especially if regarded as no more than the obtaining of a signature on a consent form. In such circumstances, the process may simply serve to protect the actions of the professionals and intermediaries involved, and have little to do with protecting the agency of the donor or volunteer (see paragraph 5.9). Second, we have argued throughout this chapter that systems of donation within any particular society have the potential to affect communal values within that society: in particular the value of providing, on a collective basis, for the health care needs of all. A focus on consent is clearly crucial, in order to balance collective needs with those of the individual potential donor: consent (properly used) serves to protect individual interests. It is also the case, however, that where an individual wishes to consent to a practice (such as the sale of an organ) that others fear may undermine solidarity and the common good, this risk to the common good must be taken into account in determining policy.

Implications for ethical choice

- 5.71 From the outset the Council felt that it was important to acknowledge the **pluralism** in the UK that characterises people's values, attitudes, beliefs and behaviours in relation to the human body.⁵⁵⁷ This pluralism extends beyond the usual sense of variety as a result of differences in cultural, religious or socio-political perspective. While remaining true to certain principled positions, one person can nonetheless hold an assortment of views regarding different bodily parts, products or practices. For example, while someone might hold on to a particular fixed and secure account of what it means to be a person and the moral consequences of their position, they might at the same time consider that they and others can reasonably accept the development of markets or quasi-markets in relation to some personal materials but not others. Similarly, they might consider some forms of exchange intrinsically exploitative, but others permissible or even laudable.
- 5.72 As we have seen throughout, money (and its absence) plays an influential role in people's thinking, and the very idea of money changing hands creates much controversy (see also paragraph 4.15 and Box 4.4 for a discussion of the many different concerns wrapped up in the idea of 'money'). While the consultation exercise gave voice to those who wish to question the moral acceptability of monetary payment of any kind for any bodily part or product, it also strengthened the Council's conviction that each exchange needs to be viewed and evaluated independently, and in light of a thorough understanding of the current situation with regard to

⁵⁵⁶ Where 'tiered' consent processes are not available, clearly this entitlement can only be exercised by the (potential) donor refusing their generic consent altogether.

⁵⁵⁷ Writing about the USA, Fiske and Tetlock note that as 'social values' their four elementary models are incommensurable. "...our pluralist approach treats moral values and social ends as irreducible to any single standard of comparison". In their view, it follows that "pluralizing the decision process affirms, in a symbolically and procedurally significant way, the importance of seeking policy solutions that respect the qualitative complexity of social life." See: Fiske AP, and Tetlock PE (1997) Taboo trade-offs: reactions to transactions that transgress the spheres of justice *Political Psychology* **18**: 255-97.

supply and demand.

- 5.73 While it is wrong to conclude that scarcity in and of itself legitimises any proposed means of increasing supply, certain types of scarcity might permit more radical solutions than others. It might also be argued that certain types of scarcity are seen not to be 'society's business' in quite the same way as others; they are viewed, as it were, as more 'private' than 'public'. They might therefore move into the commercial arena more readily. It is then incumbent upon us to ask (both ethically and empirically) whether we can allow a greater role for financial reward in some activities while keeping others firmly within the realm of altruism. **We reiterate here our view, foreshadowed in paragraph 5.52, that a wholesale shift in the UK to a purchase model for bodily material would be inappropriate, both because of the lack of evidence at present as to likely beneficial effects, and because of more fundamental concerns about the welfare of donors and the potential harmful effect on communal values. By 'purchase model' we mean a system where the guiding principle becomes that of a transaction between buyer and seller, with the payment offered being understood as being in direct exchange for bodily goods. As we have been arguing, however, the simple presence of money in the transaction (for example in the form of reimbursed expenses) does not in itself imply a 'purchase model'.** We consider the implications of this view for various different forms of bodily material in Chapter 6. At the same time, it remains possible and potentially desirable that financial means should be used imaginatively to promote donation among those already disposed to donate.
- 5.74 Alongside pluralism, the Council also acknowledges the **complexity of the exchanges and transactions** that occur in relation to human body parts, and the fact that these rarely, if ever, remain direct and 'private' transactions. In some cases a named person directly donates a body part or product to another known and named individual: living donation of a kidney, donation of bone marrow or stem cells to a relative, or the donation of eggs to a sister being examples. However, even these direct transactions are still governed in the UK by statute (the Human Tissue Act, the Human Tissue (Scotland) Act, and the Human Fertilisation and Embryology Act) and will ordinarily entail the involvement of third parties either of necessity (transplants) or advisedly to ensure safety (sperm donation). Moreover, as we highlight in Chapter 2, the state acts to limit the financial nature of such transactions, regardless of how apparently 'direct' or 'private' they are. Yet again, as we discussed in Chapter 4, the 'private' and 'public' nature of such transactions become inextricably entwined, with state regulation and the involvement of intermediaries imposing a legal and clinical framework that requires due regard to be paid to issues of consent and governance. While at times such frameworks may be criticised for creating bureaucratic hurdles, we suggest that, if implemented proportionately, they have an important role to play in ensuring that both donors and the material they donate are properly handled. Indeed, the existence of good governance systems, accompanied by transparency of process, are an essential requirement if potential donors are to have the trust necessary for them to contemplate donation in the first place.
- 5.75 Where donors donate to a common pool, the contents of that 'pool' are then donated to anonymous beneficiaries on the basis of need. This, too, requires the involvement of intermediaries whose responsibility it is to ensure that appropriate ethical standards pertain to both retrieval and allocation. In order to ensure that no individual person is treated merely as a means to another's ends, action must clearly be taken to make sure that, at the point of donation, their medical needs and well-being are prioritised over any donation process. We take the view that what happens to donated materials *after* the point of donation is also a matter of ethical concern because of an enduring sense of keeping faith with donors who have given something of themselves.⁵⁵⁸ This consideration highlights the importance of ensuring both that donated materials are not wasted, and that they are used for the purposes described when

⁵⁵⁸ That is, the gift of bodily material should be regarded in a different light from other forms of gift, because of the special nature of bodily material as a person's embodiment.

consent was given. There is therefore a strong interest in guaranteeing that bodily materials are subject to ongoing ethical governance once they have been donated or acquired. Furthermore, where the journey a bodily material might take between donation and use is cross-national and complex, it could be seen as important to subject the 'chain of supply' to ethical scrutiny. One example of how such scrutiny might operate in practice may be found in the use of 'fair trade' principles to prevent exploitation of producers in developing countries.⁵⁵⁹ Professional ethics are clearly highly relevant in this context, and there is a strong argument for endorsing the seriousness with which relevant professional groups, whether they are on the supply or demand side of the equation, take account of their obligations to ensure that acts of donation are appropriately managed.

- 5.76 Such ongoing ethical scrutiny can be a challenge even in the clinical setting where donation and transplantation/implantation happen in close succession, but in some cases there is a significant gap in time between donation and usage, and this means that further intermediaries become involved in storage, archiving and eventual allocation. In the case of tissue donation, for example, bone, corneas, skin and so forth can be removed and stored until needed. The chain of supply inevitably becomes more complex than an immediate transfer of a donated solid organ and, depending on the number of transactions involved, the processed tissue becomes more and more remote from the initial personal act of donation. It is thus necessary to be alert to the manner in which the meaning and significance of the body part might gradually be transformed, as it is classified, prepared and stored in a setting quite different from, and separate to, the clinical environment.
- 5.77 Increasing levels of directed donation in some areas (in particular kidneys but also gametes – see paragraphs 3.10 and 3.16) prompt the question as to whether directed donation should be encouraged as the norm, or whether we should try to meet demand in a more communitarian manner. We have already argued that one reason why the emphasis on altruism as a motivating factor in donation is valuable is because it emphasises **solidarity**: that we are 'all in this together' and should try to find communal solutions to communal problems. The altruism that underpins directed donation, on the other hand, is associated more with concern about a specific other individual, than about the community at large. A primary focus on directed living donation, at the expense of developing efficient communal donation systems, might risk losing or diminishing this sense of communal concern. Diverting attention away from deceased donation would also serve to neglect forms of bodily material (for example hearts) that may only be donated after death.
- 5.78 We note here that we live in a world where people will search far and wide (virtually or geographically) to meet their unmet needs. The Council was struck that there appears to be increasing acceptance that individuals or couples will travel abroad to acquire donor eggs in countries where UK regulation has no influence over the fair treatment of the women who provide them. Such acceptance (as shown, for example, through the arrangements some fertility clinics make with clinics abroad) contrasts sharply with the general disapproval of the idea of UK patients travelling abroad to purchase a kidney, as demonstrated by widespread support for the Declaration of Istanbul, which condemns 'transplant tourism' and 'transplant commercialism' (see paragraph 3.84). Yet in both cases, the potential availability of bodily material (kidneys for transplantation or eggs for fertility treatment) depends on individuals in other countries exchanging those materials for money, often in the face of significant economic hardship. If asked to make a comparison, most people would regard the potentially life-saving (and at the least life-enhancing) nature of a kidney transplant as more important than the life-creating nature of fertility treatment using donated gametes,⁵⁶⁰ and yet be less willing to condone or approve that potentially life-saving treatment if undertaken abroad in circumstances that are illegal in the UK.

⁵⁵⁹ For an example of such principles in connection with bodily material, see: Humbyrd C (2009) Fair trade international surrogacy *Developing World Bioethics* 9: 111-8.

⁵⁶⁰ See, for example, Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader), p28.

- 5.79 One way of making sense of these attitudes is to suggest that the morally relevant difference for many people lies on the *supply* side of the equation rather than on the demand side: that the welfare of the potential donor and the potential for harm and exploitation, especially given the unregulated nature of existing organ 'markets', is a key determining factor of ethical acceptability. However, in the case of organs, the nature of the good to be achieved – the saving and enhancing of life – provides an impetus to achieve a communitarian solution to the problem of organ scarcity (a system of deceased donation), allowing people the opportunity to contribute to the survival of those who remain strangers to them. **Such a consideration provides a powerful reason to support and encourage an efficient system of deceased donation that will both reduce the temptation to travel abroad for treatment and ensure a more equitable approach to the allocation of available organs.** In terms of solid organ donation, under the present 'altruistic' regime in the UK more people than ever before are donating both in life and after death. We therefore have a reason to preserve the foundations of this improving system, and to do so we might have additional reasons to discourage the attitude of 'whatever means possible' to securing an organ.
- 5.80 Such a communitarian approach is not, at present, evident in the UK with regard to donated eggs or sperm for fertility treatment; and the contrast between the national infrastructure that supports organ donation (from both living and deceased donors) and the lack of any such infrastructure with respect to gamete donation is striking. This lack of a communitarian approach may help explain why there appears to be little public concern regarding women travelling abroad for treatment, especially where the arrangements whereby gametes are obtained are lawful in the destination country, even if not within the UK. However, we would argue that such tolerance is only ethically acceptable to the extent that gamete donors in other countries are being neither exploited nor subjected to unacceptably high levels of risk, and, clearly, very different issues will arise here with respect to egg donors as opposed to sperm donors. We return to these issues further in Chapter 7 (see paragraphs 7.22 to 7.27).
- 5.81 The approach taken in this chapter explicitly acknowledges and works with the idea that there may be 'relevant differences' between the various forms of bodily material, and, as a result, opens the possibility of financial transactions entering at some level in some places. For those who equate any degree of monetary payment with commercialisation, and commercialisation with commodification, this would be unacceptable, but even those without such objections might fear the possibility of a slippery slope – with what looks like 'acceptable commercialisation' in one area quickly leading to unacceptable changes in that same area and maybe others. 'Slippery slope' arguments are rhetorically powerful, whether they are empirical or logical in form, but we remain convinced by the counter argument: that it should be possible to anticipate and protect against unacceptable developments that could potentially follow on from changes made for good reason and with good justification.

Ethical conclusions and policy considerations

- 5.82 We now draw together the main ethical values for which we have been arguing, and that will form the basis for the policy considerations set out in Chapters 6 and 7. Policy in this complex and sensitive area must start with a recognition of the pluralism that characterises people's values, attitudes, beliefs and behaviours in relation to the human body, including their own bodies. A key aim of a policy framework must therefore be to seek areas of shared consensus, including identifying values with which people starting from many different positions may nonetheless agree.
- The role of the state with respect to donation should be understood as one of stewardship, actively promoting measures that will improve general health (thereby reducing the demand for some forms of bodily material) and facilitating donation. Such a stewardship role should extend to taking action to remove inequalities that affect disadvantaged groups or individuals with respect to donation.

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

- 5.83 We conclude our analysis in this chapter by highlighting again the current state of flux in which the health care system within the UK finds itself, both in terms of changes of structure and responsibility for commissioning health care within England, and the proposed changes to regulatory structures that impact more widely across the UK (see paragraph 2.5). **In such a climate of change, it is particularly important that policy makers should remain alert to the importance and value of the donation of bodily material, and should act to ensure that valuable systems currently in place are not inadvertently lost.**

Applying our ethical framework

- 5.84 In the remainder of this report, we consider potential changes in the way the demand for various forms of bodily material might be met, and from two perspectives.⁵⁶¹ The first (Chapter 6) concerns the degree to which it is ethically acceptable to 'encourage' individuals to donate their bodily material. The second (Chapter 7) takes up what can be done by professionals, institutions and organisations to 'facilitate' donation, whether through improving procedures or reducing demand. Both reflect on the kind of society we would wish to see and on the manner in which persons flourish. Indeed, we note the interconnected nature of the two perspectives: for example if an organisation is well respected and trusted (a result of organisational ethos and action), then people may be more likely to make their own individual decisions to donate (individual action).⁵⁶²
- 5.85 There is, of course, already considerable action within the UK in both these areas. With respect to individual decision-making, for example, the HFEA has been carrying out a public consultation on how egg and sperm donors should be compensated (see paragraph 2.35). On organisational aspects, we note that the findings and recommendations of the ODT (see paragraph 3.52) were very much based on the belief that significant increases in the number of organs donated after death could be achieved by improving every aspect of the organ donation infrastructure, from the way potential donors were identified, to the removal of financial disincentives from hospitals expected to carry out the operations to remove the organs, to the training and skills of the specialist nurses working with newly-bereaved families.
- 5.86 Continuing with our comparative approach set out in Chapter 1 of this report (see especially paragraphs 1.34 to 1.42), we consider not only the ethical implications of these approaches, but also the extent to which they are, or are not, applicable to diverse forms of bodily material. We reiterate here, as we have done elsewhere in this report, that we do not assume that an approach that is judged to be ethical and effective in one field will automatically be so in another. We also reiterate, as we set out in our Foreword, that while in Part I of this Report we sought to be as comprehensive as possible, in Part II we restrict ourselves to commenting on, and making recommendations in connection with, a more limited number of areas where we feel we have a contribution to make, based on the evidence that we have gathered during this enquiry. We note here that there are other areas – in particular surrogacy arrangements and the donation of whole bodies to medical schools for education and research – where we have not felt well-placed to make specific recommendations. Nevertheless, we hope that our ethical analysis will also be helpful to those working in these areas.

⁵⁶¹ These are only perspectives: we do not intend to suggest a division between 'individual' and 'society' – individuals are part of society and never act in isolation, while society is found within individuals, in their state of health, financial circumstances, the values to which they adhere, and so forth. However, it is still constructive to distinguish between those policy initiatives that seek primarily to change how individuals behave, and those targeted at the behaviour and functions of organisations.

⁵⁶² See, for example, Harrington M, Sweeney MR, Bailie K *et al.* (2007) What would encourage blood donation in Ireland? *Vox Sanguinis* 92: 361-7.