

Chapter 6

Actions affecting
individuals

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Chapter overview

Applying the values set out in Chapter 5, we suggest an 'Intervention Ladder' as a useful tool in analysing the ethical acceptability of different forms of encouragement for donating bodily material in various circumstances. Such an Intervention Ladder would include the following 'rungs':

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

While we distinguish the first four 'rungs' of the Intervention Ladder as involving different degrees of organisational involvement and (potentially) cost, we do not distinguish them on ethical grounds: all are 'altruist-focused interventions', intended to stimulate people's altruistic motivation. The two final 'rungs' on the Ladder, which we class as non-altruist-focused interventions, do, on the other hand, involve ethically significant steps: scrutiny will be required to determine whether, in the circumstances, they may be ethically justified. We therefore recommend that, where a health need is not being met by altruist-focused interventions, the following factors should be closely scrutinised, in order to ascertain whether offering a form of non-altruist-focused intervention might or might not be harmful:

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

While the Intervention Ladder will be helpful in analysing the ethical acceptability of interventions that aim to encourage people in general to donate, there will also be circumstances in which other considerations will be relevant, such as where parents donate to their children; or where the lack of immediate benefit to others, as in many forms of research, may reduce the significance of altruism.

Our conclusions and recommendations with respect to 'how far one should go' in encouraging people to donate bodily material include:

- Living organ donors should not receive payment other than the direct reimbursement of costs incurred in being a donor;
- We suggest the introduction of a pilot scheme in which the NHS would meet funeral expenses for those who sign the ODR and subsequently die in circumstances where they could become organ donors;
- Robust research is needed on the effects of an opt-out system for organ donation if this is introduced in Wales, as currently planned, in order to obtain a clear evidence base for any proposals for change elsewhere in the UK;
- We recommend the use of the term 'authorisation' rather than 'consent' with respect to choices about deceased donation, to reflect potentially different informational requirements between deceased and living donation;
- Mandated choice and prompted choice systems (which should include the option of saying no) are ethical options for seeking authorisation in advance to deceased organ donation;
- Lost earnings should be fully reimbursed for those donating gametes for others' treatment;
- We suggest the introduction of a pilot scheme offering payment to those who are prepared to donate eggs for research purposes;
- Payment for participation by healthy volunteers in first-in-human clinical trials within the UK should be retained as ethically justified.

Introduction

- 6.1 In this first of two chapters that set out the Council's conclusions as to 'how far one should go' in trying to meet demand for bodily material, we focus on the appropriateness of encouraging donors as individual persons. People may be influenced by many considerations, and there is much debate as to their likely responsiveness both to particular forms of encouragement and to particular ways in which their consent may be sought.

- 6.2 Chapter 4 highlighted how the values generally associated with the donation of bodily material – altruism and the idea of 'the gift', dignity, autonomy and justice, to name only a few – could be interpreted in diverse and sometimes contradictory ways. This certainly does not mean, however, that we consider that they become redundant. Rather, we emphasise that the way in which they are being used in particular circumstances should be made explicit and, where necessary, justified. In Chapter 5 we explored some of the many ways in which the idea of 'altruism' is used, and suggested that the aspect of altruism that perhaps most encapsulates the strong appeal of 'altruistic donation' very evident in UK society, is that of altruism as an expression of communal virtues (see paragraph 5.42). Such an idea of altruism is closely linked with solidarity: both may be seen as aspirational, setting a standard for the kind of society that one would wish to live in, particularly in the context of the way that society provides health care as a basic good. Similarly, the succinctness and comprehensiveness of the notion of 'the gift' (see paragraphs 4.9 to 4.14) continues to make it a good image with which to think. It makes a valuable contribution to the vocabulary with which the common good is conceptualised in this context, and is particularly powerful in the way that it joins up with individual motivation.
- 6.3 Such an aspiration, and such a concept of the 'common good', do not, however, by themselves, exclude other approaches to the donation of any particular form of bodily material. For example, if there were clear evidence that other approaches to donation would be very much more successful in terms of satisfaction of demand, then any loss of 'communal virtues' might have to be accepted as the price to be paid. In this chapter we apply our ethical framework with this in mind, considering also the issue of evidence.

Motivations and barriers to donation and volunteering

- 6.4 We start with a consideration of existing research on why people decide (or not) to donate bodily material or to participate in a first-in-human trial as a healthy volunteer. In order to inform its deliberations, the Council commissioned a snapshot review of the literature concerned with the motivating and deterring factors associated with decisions to donate blood, organs, tissue and gametes, or to participate in a first-in-human trial as a healthy volunteer.⁵⁶³ Because of the very large amount of literature in this field, the part of the review concerned with the donation of bodily material was limited to empirical studies based in the UK or Ireland, published in journals between 2000 and 2010. Twenty papers in total were identified: five on blood donation, nine on organ donation, two on tissue donation and four on egg donation (including egg-sharing). The review of the factors disposing people to participate in first-in-human trials was not limited to the UK, as long as they were reported in English-language journals; in total 15 studies were identified, carried out in Italy, Germany, the Netherlands, Portugal, Spain, the UK and the US.
- 6.5 For blood donors, key factors identified by donors in influencing their decision to donate included their awareness of the need for donated blood, advertising campaigns boosting that awareness, and trust in the blood transfusion service.⁵⁶⁴ One prospective study also found that belief in the personal benefits to be gained from donating (that is, that donation would make donors feel good about themselves) was the best predictor of future donation behaviour.⁵⁶⁵ Reasons given by non-donors were more wide-ranging: in one study 42 per cent of non-donors cited medical contraindications, with other factors being fear of needles, a simple lack of interest

⁵⁶³ See Appendix 1 for details of the evidence review and the criteria for inclusion. Because of the very large number of papers originally identified, the part of the review concerned with the donation of bodily material focused specifically on potentially modifiable factors relating to motivators and deterrents to donation rather than the personality characteristics of donors and non-donors.

⁵⁶⁴ Harrington M, Sweeney MR, Bailie K *et al.* (2007) What would encourage blood donation in Ireland? *Vox Sanguinis* **92**: 361-7; Sojka BN, and Sojka P (2008) The blood donation experience: self-reported motives and obstacles for donating blood *Vox Sanguinis* **94**: 56-63.

⁵⁶⁵ Ferguson E, Farrell K, and Lawrence C (2008) Blood donation is an act of benevolence rather than altruism *Health Psychology* **27**: 327-36.

in giving blood, and time constraints.⁵⁶⁶ The role of fear and anxiety was raised in a number of studies: such fears include anxiety about the process of blood donation itself (for example fear of needles or of fainting), fear of the unknown, and concerns about the risk of negative outcomes, such as contracting a blood-borne disease.⁵⁶⁷ In another, both donors and non-donors identified the same top three factors (a major disaster, more frequent mobile units and being specifically invited) as being most likely to encourage them to donate.⁵⁶⁸ The issue of easy access to donation facilities arose in a number of studies.⁵⁶⁹

- 6.6 Similar themes arose from the studies on those willing, or not, to contemplate being a deceased organ donor. Knowledge of organ donation and an absence of 'squeamishness' emerged as factors associated with those willing to 'sign up' as an organ donor, as did a sense of responsibility or obligation.⁵⁷⁰ Squeamishness about the idea of deceased donation (described by one author as the 'ick' factor) was strongly associated with a lack of willingness to sign up, as were beliefs that it is bad luck to contemplate one's own death (described as 'jinx').⁵⁷¹ Two other factors highlighted in these studies included medical mistrust (more prevalent in Black Caribbean, Black African and Indo-Asian respondents, but also significant for White respondents), and concern about disfigurement and the importance of remaining intact after death (specifically raised by many participants in a study of Muslim Indo-Asians living in the UK).⁵⁷² Medical mistrust was expressed both through the anxiety that a potential organ donor would not receive appropriate medical care (for example by less effort being put into resuscitation) and through concern that organs might be taken for other purposes than transplantation, or additional organs taken without consent.⁵⁷³
- 6.7 The two UK studies on tissue donation found a very positive response to requests for tissue for research, both in practice (where the study related to a retrospective review of the notes of patients invited to consent before surgery to subsequent use of their excised tissue)⁵⁷⁴ and in theory (a study questioning prostate cancer patients about their possible attitudes to donating surplus prostate tissue taken during biopsy for research).⁵⁷⁵ The first study is particularly striking in that, of over 3,000 patients asked to consent to the use of their tissue removed during surgery for commercial research, just 1.2 per cent refused. Reasons for refusing included mistrust of how the material would be used, and concern that their own care might be compromised (for example by not enough material being retained for their own diagnosis).

⁵⁶⁶ Harrington M, Sweeney MR, Bailie K *et al.* (2007) What would encourage blood donation in Ireland? *Vox Sanguinis* **92**: 361-7.

⁵⁶⁷ Giles M, McClenahan C, Cairns E, and Mallet J (2004) An application of the theory of planned behaviour to blood donation: the importance of self-efficacy *Health Education Research* **19**: 380; McVittie C, Harris L, and Tiliopoulos N (2006) I intend to donate but: non-donors' views of blood donation in the UK *Psychology, Health and Medicine* **11**: 1-6.

⁵⁶⁸ Harrington M, Sweeney MR, Bailie K *et al.* (2007) What would encourage blood donation in Ireland? *Vox Sanguinis* **92**: 361-7.

⁵⁶⁹ For example, Giles M, McClenahan C, Cairns E, and Mallet J (2004) An application of the theory of planned behaviour to blood donation: the importance of self-efficacy *Health Education Research* **19**: 380.

⁵⁷⁰ Bennett R, and Savani S (2004) Factors influencing the willingness to donate body parts for transplantation *Journal of Health & Social Policy* **18**: 61 - 85; Farsides T (2010) Perceived responsibility to act: an investigation with respect to registering willingness to become a posthumous organ donor *British Journal of Psychology* **101**: 503-17.

⁵⁷¹ O'Carroll RE, Foster C, McGeechan G, Sandford K, and Ferguson E (2011) The "ick" factor, anticipated regret, and willingness to become an organ donor *Health Psychology* **30**: 236.

⁵⁷² Morgan M, Hooper R, Mayblin M, and Jones R (2006) Attitudes to kidney donation and registering as a donor among ethnic groups in the UK *Journal of Public Health* **28**: 226-34; AlKhawari FS, Stimson GV, and Warrens AN (2005) Attitudes toward transplantation in UK Muslim Indo-Asians in West London *American Journal of Transplantation* **5**: 1326-31.

⁵⁷³ Morgan M, Hooper R, Mayblin M, and Jones R (2006) Attitudes to kidney donation and registering as a donor among ethnic groups in the UK *Journal of Public Health* **28**: 226-34; AlKhawari FS, Stimson GV, and Warrens AN (2005) Attitudes toward transplantation in UK Muslim Indo-Asians in West London *American Journal of Transplantation* **5**: 1326-31. See also: NHS Blood and Transplant (24 February 2009) *Will they respect my body after I am dead?*, available at: http://www.organdonation.nhs.uk/ukt/newsroom/news_releases/article.jsp?releaseId=226, which details an online survey which found that, of respondents who stated that they were undecided or against joining the ODR, more than half said that they were worried about how their body would be treated after death.

⁵⁷⁴ Jack AL, and Womack C (2003) Why surgical patients do not donate tissue for commercial research: review of records *BMJ* **327**: 262.

⁵⁷⁵ Fitzpatrick PE, McKenzie KD, Beasley A, and Sheehan JD (2009) Patients attending tertiary referral urology clinics: willingness to participate in tissue banking *BJU international* **104**: 209-13.

- 6.8 The one study of 'egg sharers' included in the review highlighted that 'personal gain' (defined in the study as the possibility of achieving motherhood) was a primary motivation for entering into an egg-sharing arrangement. The study did, however, suggest that empathy with those needing donor eggs in order to have the chance to conceive was also experienced as a motivating factor.⁵⁷⁶ Other studies of egg sharers not included within the review similarly noted that those entering in egg-sharing arrangements describe their motivations as both self-interested and altruistic.⁵⁷⁷ The three remaining studies explored factors associated with the intention of donating eggs outside the context of egg sharing, both for another person's treatment and for research: identified factors include positive attitudes towards the value of egg donation and the importance of parenthood, a sense of control over the decision-making process, and support from others.⁵⁷⁸ A systematic review of English-language peer-reviewed studies on egg donation, published in 2009, noted 12 studies that included volunteer egg donors: motivations cited in these studies included both general altruistic motives for donation and personal experiences of infertility (for example through family and friends).⁵⁷⁹
- 6.9 Finally, the studies concerned with the motivations of healthy volunteers in first-in-human clinical trials overwhelmingly highlighted the importance of the financial rewards offered: between 45 per cent and 90 per cent of respondents in various different surveys highlighted this as the main motivating factor.⁵⁸⁰ Other motivating factors, in many cases running alongside the interest in the financial reward, included the wish to contribute to scientific progress (40 per cent and 48 per cent in two studies),⁵⁸¹ a sense of social responsibility, and curiosity.⁵⁸² In two of the studies, 8.8 per cent and 14 per cent of participants respectively stated that they would have participated even if no financial reward were offered.⁵⁸³
- 6.10 Inevitably, the research evidence cited above can only touch the surface of the available literature. We also flag here the well-known difficulty of interpreting what is told to the researcher: that one's description of one's own motivation in any particular case may only ever

⁵⁷⁶ Rapport F (2003) Exploring the beliefs and experiences of potential egg share donors *Journal of Advanced Nursing* **43**: 28-42.

⁵⁷⁷ Ahuja K, Mostyn B, and Simons E (1997) Egg sharing and egg donation: attitudes of British egg donors and recipients *Human Reproduction* **12**: 2845-52; Ahuja KK, Simons EG, Mostyn BJ, and Bowen-Simpkins P (1998) An assessment of the motives and morals of egg share donors: policy of 'payments' to egg donors requires a fair review *Human Reproduction* **13**: 2671-8; Blyth E (2004) Patient experiences of an "egg sharing" programme *Human Fertility* **7**: 157-62.

⁵⁷⁸ Purewal S, and van den Akker OBA (2006) British women's attitudes towards oocyte donation: ethnic differences and altruism *Patient Education and Counseling* **64**: 43-9; Purewal S, and van den Akker OBA (2009) Attitudes and intentions towards volunteer oocyte donation *Reproductive BioMedicine Online* **19**: 19-26; Purewal S, and van den Akker O (2010) Attitudes and intention to donate oocytes for research *Fertility and Sterility* **93**: 1080-7.

⁵⁷⁹ Purewal S, and van den Akker O (2009) Systematic review of oocyte donation: investigating attitudes, motivations and experiences *Human Reproduction Update* **15**: 499. The studies included took place in Australia, Finland, New Zealand and the UK.

⁵⁸⁰ Hermann R, Heger-Mahn D, Mahler M *et al.* (1997) Adverse events and discomfort in studies on healthy subjects: the volunteer's perspective: a study conducted by the German Association for Applied Human Pharmacology *European Journal of Clinical Pharmacology* **53**: 207-14; Tishler C, and Bartholomae S (2002) The recruitment of normal healthy volunteers: a review of the literature on the use of financial incentives *Journal of Clinical Pharmacology* **42**: 365-75; Almeida L, Azevedo B, Nunes T, Vaz-da-Silva M, and Soares-da-Silva P (2007) Why healthy subjects volunteer for phase I studies and how they perceive their participation? *European Journal of Clinical Pharmacology* **63**: 1085-94; Ferguson PR (2008) Clinical trials and healthy volunteers *Medical Law Review* **16**: 23-51.

⁵⁸¹ Hermann R, Heger-Mahn D, Mahler M *et al.* (1997) Adverse events and discomfort in studies on healthy subjects: the volunteer's perspective: a study conducted by the German Association for Applied Human Pharmacology *European Journal of Clinical Pharmacology* **53**: 207-14; Almeida L, Azevedo B, Nunes T, Vaz-da-Silva M, and Soares-da-Silva P (2007) Why healthy subjects volunteer for phase I studies and how they perceive their participation? *European Journal of Clinical Pharmacology* **63**: 1085-94.

⁵⁸² Hermann R, Heger-Mahn D, Mahler M *et al.* (1997) Adverse events and discomfort in studies on healthy subjects: the volunteer's perspective: a study conducted by the German Association for Applied Human Pharmacology *European Journal of Clinical Pharmacology* **53**: 207-14; Almeida L, Azevedo B, Nunes T, Vaz-da-Silva M, and Soares-da-Silva P (2007) Why healthy subjects volunteer for phase I studies and how they perceive their participation? *European Journal of Clinical Pharmacology* **63**: 1085-94; Ferguson PR (2008) Clinical trials and healthy volunteers *Medical Law Review* **16**: 23-51.

⁵⁸³ Almeida L, Azevedo B, Nunes T, Vaz-da-Silva M, and Soares-da-Silva P (2007) Why healthy subjects volunteer for phase I studies and how they perceive their participation? *European Journal of Clinical Pharmacology* **63**: 1085-94; Almeida L, Falcao A, Coelho R, and Albino-Teixeira A (2008) The role of socioeconomic conditions and psychological factors in the willingness to volunteer for phase I studies *Pharmaceutical Medicine* **22**: 367-74.

provide part of the picture. There is an important distinction to be made between, on the one hand, asking people whether or not they would be motivated by money to carry out a particular action, and, on the other, actually offering the money and finding out how many act as they had envisaged (see paragraph 6.19). Keeping these qualifications in mind, we would suggest that a number of points can, tentatively, be made from the research reviewed above.

- 6.11 First, certain themes arose repeatedly, and across different domains of donation. Common barriers were squeamishness and feelings of unease about the idea of donation, and medical mistrust (expressed both as fears, however unfounded,⁵⁸⁴ of the consequences for one's own care, and in terms of the future use of the donated material). „Squeamishness“ in connection with the donation of blood also took more concrete form in terms of fear and anxiety about the use of needles, fainting and other negative outcomes. Deceased donation brought its own particular concerns both about the 'jinx' effect of contemplating one's own death, and anxiety about disfigurement and lack of bodily integrity in death. Factors disposing people to donate, on the other hand, included good awareness of the positive benefits for others (or for medical science more generally), a sense of social responsibility, and good practical arrangements that minimise the burden of making a donation. Such factors support the notion of the 'two-pronged' approach set out in paragraph 5.84: of considering both how individuals may personally be encouraged (for example by measures to improve awareness of the impact of donation) and how organisations may remove barriers (for example by making donation as efficient, and as convenient to the individual as possible). Importantly, in identifying the role of „squeamishness“, anxiety and 'jinx' factors, the studies highlight a subgroup of individuals whose behaviour will be relatively difficult to influence; and by implication it could be argued that any efforts to increase donation rates by changing behaviour would best be targeted at those without such concerns.
- 6.12 Second, the figure of 98.8 per cent of patients who agreed to allow their excised tissue to be used for commercial research is striking. It suggests that, if approached appropriately, the vast majority of patients do not have any objection either to permitting research use of tissue excised during surgery, or to such uses being commercial. Again, this suggests that there is little, if any, value in pursuing those who clearly do not feel comfortable with such uses, while emphasising the value of systematic approaches to informing patients of potential research uses of their tissue and seeking their consent at an appropriate time.⁵⁸⁵
- 6.13 Third, while 'medical mistrust' may have wide range of sources (many of which will be beyond the scope of this report), examples of such mistrust cited in the studies included anxiety about how donors' consent might be abused: for example using material for other purposes than that stipulated in the original consent, or taking material (other organs or tissue, for example) not included in the consent. We return to this issue when we consider possible changes to consent defaults later in this chapter (see paragraph 6.47).
- 6.14 Fourth, the relatively high figure of non-blood-donors in one study who stated that there were medical reasons why they did not donate (42%) highlights the point made earlier in this report (see paragraph 3.6) that not everyone is 'eligible' to be a donor, whether of blood or other materials.⁵⁸⁶ Such a consideration highlights the serious difficulties involved in schemes that aim to increase donation by giving priority in allocation to those willing to give, however attractive and reasonable such schemes may seem at first sight (see paragraphs 2.48 and 3.74).
- 6.15 Finally, the studies on healthy volunteers demonstrate very clearly that, for the majority of healthy volunteers in first-in-human trials, the financial reward offered in return for their involvement is perceived as an incentive to participate, and not simply as a reimbursement of

⁵⁸⁴ We note here that, although very clear systems are in place in the UK to ensure that decisions about possible organ donation cannot affect a patient's own health care, nevertheless, a more general lack of trust in the system may mean that this fear, however unfounded, will still affect some individuals' decisions.

⁵⁸⁵ This evidence cannot, of course, be extrapolated to the situation of non-patient donors, for whose views evidence comes from other sources, see paragraph 6.82.

⁵⁸⁶ The figure of 42 per cent certainly seems high, and may reflect either misperceptions of eligibility or a desire to find a socially acceptable reason to explain one's non-donation status; however, the key point remains that not everyone can donate.

their lost time or earnings. At the same time, most participants were still keen to emphasise that other more „social“ motivations, such as a desire to contribute to developments in science, had played a part in their decision, alongside the financial incentive. This leads us on to a consideration of the potential role of such incentives in the donation of bodily material itself.

Incentives and decision-making

- 6.16 Chapter 5 referred briefly to the limited evidence available as to the impact of financial incentives on the supply of bodily materials, and referred forward to this chapter for a more detailed account of that evidence. The Council commissioned a review of English-language peer-reviewed studies presenting data on the impact of offering a financial incentive to potential donors, on either the quality or the quantity of material donated (blood, eggs, kidneys from living donors, and liver from living donors), or on the quality of the decision to donate.⁵⁸⁷ Only studies that explicitly compared two groups (non-incentivised and incentivised) were included. In total, 22 studies were identified that considered the effect of an incentive on the quality of the donated material, and four that considered the effect of an incentive on the quantity (two dealing with both). None was found that contrasted the quality of the decision-making process (for example how carefully risk was considered, or the extent to which the donor later endorsed or regretted their decision to donate) between an incentivised and non-incentivised group in the same study.
- 6.17 Of the 22 studies comparing the effect of incentives on the **quality** of material donated, 14 concerned blood⁵⁸⁸ and eight kidneys.⁵⁸⁹ No studies on gametes were found that met the review criteria. For blood, offering financial incentives to donors is associated with greater levels of infection in blood, unless the incentive itself is contingent upon the provision of good-quality blood (for example, by withholding the incentive until after satisfactory results from testing). Similarly, for kidneys, financial incentives are associated with worse outcomes (measured in

⁵⁸⁷ See Appendix 1 for more detail of the evidence review. Exchanges of little or no financial value, such as badges, certificates or mugs were excluded; however reward in kind, such as egg-sharing schemes, were included.

⁵⁸⁸ The studies took place in China, Germany, India, Lithuania, Nigeria, Switzerland and the US: Singh YN, Malaviya AN, Tripathy SP *et al.* (1990) Human immunodeficiency virus infection in the blood donors of Delhi, India *JAIDS Journal of Acquired Immune Deficiency Syndromes* **3**: 152; Dawson GJ, Lesniewski RR, Stewart JL *et al.* (1991) Detection of antibodies to hepatitis C virus in US blood donors *Journal of Clinical Microbiology* **29**: 551-6; Strauss RG, Ludwig GA, Smith MV *et al.* (1994) Concurrent comparison of the safety of paid cytopheresis and volunteer whole-blood donors *Transfusion* **34**: 116-21; Jha J, Banerjee K, and Arankalle V (1995) A high prevalence of antibodies to hepatitis C virus among commercial plasma donors from Western India *Journal of Viral Hepatitis* **2**: 257-60; Wu R-R, Hata A, Sasaki M *et al.* (1995) Seroprevalence of hepatitis C virus infection and its genotype in Lanzhou, Western China *Journal of Medical Virology* **45**: 174-8; Dille BJ, Surowy TK, Gutierrez RA *et al.* (1997) An ELISA for detection of antibodies to the E2 protein of GB virus C *Journal of Infectious Diseases* **175**: 458-61; Strauss RG (2001) Blood donations, safety, and incentives *Transfusion* **41**: 165-7; Durosinmi M, Mabayoje V, Akinola N, Adegunloye A, and Alabi A (2003) A retrospective study of prevalence of antibody to HIV in blood donors at Ile-Ife, Nigeria *The Nigerian postgraduate medical journal* **10**: 220; Kretschmer V, Weippert-Kretschmer M, Slonka J, Karger R, and Zeiler T (2004) Perspectives of paid whole blood and plasma donation *Transfusion Medicine and Hemotherapy* **31**: 301-7; Erhabor O, Ejele O, and Nwauche C (2006) The risk of transfusion-acquired hepatitis-C virus infection among blood donors in Port Harcourt: the question of blood safety in Nigeria *Nigerian Journal of Clinical Practice* **9**: 18-21; Jeremiah ZA, Koate B, Buseri F, and Emelike F (2008) Prevalence of antibodies to hepatitis C virus in apparently healthy Port Harcourt blood donors and association with blood groups and other risk indicators *Blood Transfusion* **6**: 150; Kalibatas V (2008) Payment for whole blood donations in Lithuania: the risk for infectious disease markers *Vox Sanguinis* **94**: 209-15; Goette L, Stutzer A, and Zentrum UBW (2008) *Blood donations and incentives: evidence from a field experiment* (Basel: Wirtschaftswissenschaftliches Zentrum (WWZ) der Universität Basel); Lacetera N, Macis M, and Slonim R (2009) Will there be blood? incentives and substitution effects in pro-social behavior *IZA Discussion Papers*: No. 4567.

⁵⁸⁹ The studies took place in Canada, India, Iran, Saudi Arabia and the UK and included patients who had travelled to other countries for (illegal) transplants. See: Qunibi W (1997) Commercially motivated renal transplantation: results in 540 patients transplanted in India *Clinical Transplantation* **11**: 536-44; Morad Z, and Lim T (2000) Outcome of overseas kidney transplantation in Malaysia *Transplantation Proceedings* **32**: 1485-6; Ghods AJ (2002) Renal transplantation in Iran *Nephrology Dialysis Transplantation* **17**: 222-8; Higgins R, West N, Fletcher S *et al.* (2003) Kidney transplantation in patients travelling from the UK to India or Pakistan *Nephrology Dialysis Transplantation* **18**: 851-2; Prasad GVR, and McFarlane PA (2006) Occult nephrolithiasis in prospective kidney donors: a source for hematuria *Transplantation* **82**: 849-50; Gill J, Madhira B, Gjertson D *et al.* (2008) Transplant tourism in the United States: a single-center experience *Clinical Journal of the American Society of Nephrology* **3**: 1820; Krishnan N, Cockwell P, Devulapally P *et al.* (2010) Organ trafficking for live donor kidney transplantation in Indoasians resident in the West Midlands: high activity and poor outcomes *Transplantation* **89**: 1456-61; Alghamdi SA, Nabi ZG, Alkhafaji DM *et al.* (2010) Transplant tourism outcome: a single center experience *Transplantation* **90**: 184-8.

terms, for example, of post-surgical infections, graft survival rates and patient survival rates), although this must be placed in the context of a mainly illegal 'market' in incentivised organs.⁵⁹⁰ Thus, the evidence that does exist tends towards supporting the argument that the quality of some bodily materials may suffer where financial incentives are offered to encourage donors to come forward. However, as we have already suggested in paragraph 5.37, this argument does not seem particularly compelling for the UK, certainly in the context of blood, given the availability of testing. In the context of living kidney donations, the illegal nature of most of those operations on which data are available makes any kind of meaningful comparison exceedingly difficult.

- 6.18 The four studies considering the impact of offering financial incentives on the **quantity** of material provided all concerned blood. One carried out in Sweden among 262 students found that the offer of a small financial incentive (\$7) had neither a positive nor a negative effect overall on determining whether potential blood donors actually donated.⁵⁹¹ Nor did the alternative option of donating the money to charity increase donation rates. A Swiss study (involving over 11,000 participants) similarly found that the offer of a free cholesterol test had no effect on donation rates.⁵⁹² A second Swiss study of 10,000 previous blood donors showed a five per cent higher donation rate in those offered a free lottery ticket (estimated face value \$4.30; speculative value incalculable), over those receiving a simple request to donate, and those being additionally offered a cholesterol test (estimated value \$13).⁵⁹³ It was noted that the increase in donations among those offered a lottery ticket derived from those with a low rate of past donations, with no effect (positive or negative) on those with a past high rate. Finally, an analysis of those attending American Red Cross 'blood drives' in northern Ohio between May 2006 and October 2008 (over 14,000 blood drives) found that overall response rates increased by 16 per cent when incentives such as t-shirts, vouchers and mugs were offered. No impact was noted on the proportion of donors rejected on quality grounds.⁵⁹⁴ These results were replicated in a small-scale field experiment of four pairs of blood drives, where one drive from each pair offered potential donors a gift card (\$5 in two drives and \$20 in the other two), while no incentive was offered to the paired controls. Both turnout and the amount of blood collected at the drives offering the incentives were increased, with larger effects noted in connection with the greater incentive.⁵⁹⁵
- 6.19 Clearly, this is a small number of studies from which to draw firm conclusions (although the substantial size of the cohorts should be noted). However, two points should be highlighted. First, the limited evidence that does exist from these observational and experimental studies does not support the thesis that altruistic donors are 'crowded out' by the availability of a (small) financial incentive. This contrasts with the findings of studies that only ask people about their *intentions* (as opposed to measuring their actual behaviour), which appear to support concerns about the possibility of crowding out.⁵⁹⁶ The same distinction between intention and actual behaviour is demonstrated by the failure in the Swiss studies to recruit additional donors by offering a free cholesterol test, since surveys of intention regularly suggest such an offer would be effective.⁵⁹⁷ On the other hand, studies from Iran (which do not, of course, derive from the kind of controlled experiment or observational study included within our review) note how the

⁵⁹⁰ Iran is the only country that permits financial reward to be offered to living kidney donors.

⁵⁹¹ Mellström C, and Johannesson M (2008) Crowding out in blood donation: was Titmuss right? *Journal of the European Economic Association* 6: 845-63.

⁵⁹² Goette L, Stutzer A, Yavuzcan G, and Frey BM (2009) Free cholesterol testing as a motivation device in blood donations: evidence from field experiments *Transfusion* 49: 524-31.

⁵⁹³ Goette L, Stutzer A, and Zentrum UBW (2008) *Blood donations and incentives: evidence from a field experiment* (Basel: Wirtschaftswissenschaftliches Zentrum (WWZ) der Universität Basel).

⁵⁹⁴ Lacetera N, Macis M, and Slonim R (2009) Will there be blood? incentives and substitution effects in pro-social behavior *IZA Discussion Papers*: No. 4567.

⁵⁹⁵ Ibid.

⁵⁹⁶ See, for example, Goette L, Stutzer A, and Frey BM (2010) Prosocial motivation and blood donations: a survey of the empirical literature *Transfusion Medicine and Hemotherapy* 37: 149-54. See also: Webb TL, and Sheeran P (2006) Does changing behavioral intentions engender behavior change? A meta-analysis of the experimental evidence *Psychological Bulletin* 132: 249-68.

⁵⁹⁷ Glynn SA, Williams AE, Nass CC *et al.* (2003) Attitudes toward blood donation incentives in the United States: implications for donor recruitment *Transfusion* 43: 7-16.

creation of an officially incentivised system has led to a decrease in the number of unpaid related donations: one author suggests that this decrease not only derives from the ready availability of paid unrelated volunteers, but is also due to the elimination of "coercive living-related donor transplants" where families feel emotional coercion to donate.⁵⁹⁸

- 6.20 The second point to highlight is that there is, albeit very limited, evidence to suggest that what might be described as 'token' incentives for donating blood (low-value vouchers or a lottery ticket) can increase donors and donations: by five per cent and 16 per cent in two of the studies cited above (see paragraph 6.18). Such evidence, particularly when set beside 'uncontrolled' data (such as the large number of kidney sellers in Iran, or the ready availability of eggs for others' infertility treatment in the US⁵⁹⁹), serves to suggest that the offer of financial incentives will indeed have an incentivising effect on some people. Given, however, that the 'controlled' studies that do exist relate only to blood (which contrasts with many other forms of donation in that repeat donations are strongly encouraged and hence a strong 'donor base' willing to donate regularly is particularly important), and that it is always very difficult to know how results from one culture and set of circumstances may translate to another, such conclusions should be regarded at this stage as tentative.
- 6.21 Finally, we consider further the point made in paragraph 6.19 in connection with 'crowding-out', that what people say they will do in certain circumstances does not necessarily match what they actually do. In tandem with the public consultation carried out by the Working Party itself, the organisation 'new economics foundation' (nef) set up a 'street talk' project in August 2010, in which nearly 500 people in shopping streets and centres were invited to give their opinions on the efficacy and ethics of various forms of incentives for donation.⁶⁰⁰ A significant majority of respondents thought that direct payments of any size were unethical and would not influence their own decision to donate, while a donation to charity in return for bodily donation was viewed much more positively. As we note above, the lack of response to the offer of a donation to charity in the Swedish study on blood suggests that such offers do not seem necessarily to influence actual behaviour. However, the fact that many people expressed a theoretical liking for and approval of such a suggestion (coupled with dislike of the notion of direct financial payment in return for bodily donation) might be seen as a further endorsement of the *ideal* of a system based on altruism and concern for others, regardless of what decision that individual would personally make in practice. This brings us back, yet again, to the concept of altruism as an expression of 'communal virtues'.

An 'Intervention Ladder' for promoting donation

- 6.22 In the Nuffield Council's earlier report *Public health: ethical issues*, the Council set out the idea of an 'Intervention Ladder' as a way of thinking about the acceptability of, and justification for, a range of public health policies.⁶⁰¹ The bottom 'rung' of the Intervention Ladder will usually be to do nothing or monitor the situation, with successively higher 'rungs' involving action to enable or guide individuals' choices, restricting choices, and finally (at the very top) legislating to remove individual choice altogether. The more intrusive and restrictive the policy on individual choice and liberty, the greater the justification required for the public health policy, in terms both of the possible benefits, and of the strength of the evidence that such benefits will indeed eventuate.

⁵⁹⁸ Ghods AJ, and Savaj S (2006) Iranian model of paid and regulated living-unrelated kidney donation *Clinical Journal of the American Society of Nephrology* 1: 1136-45. See also: Bagheri A (2006) Compensated kidney donation: an ethical review of the Iranian model *Kennedy Institute of Ethics Journal* 16: 269-82.

⁵⁹⁹ Levine A (2011) The oversight and practice of oocyte donation in the United States, United Kingdom and Canada *HEC Forum* 23: 15-30.

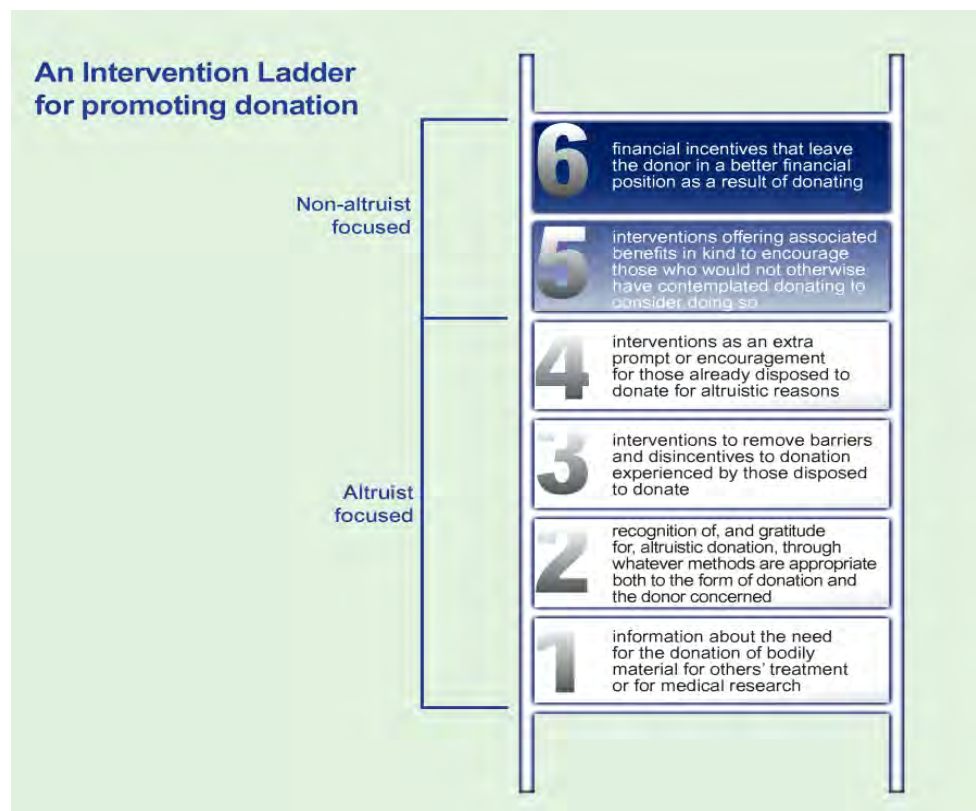
⁶⁰⁰ See Appendix 1 for more details of this project, which was carried out independently of the Working Party by nef, but drew on material in the Working Party's consultation document.

⁶⁰¹ Nuffield Council on Bioethics (2007) *Public health: ethical issues*, available at: <http://nuffieldbioethics.org/sites/default/files/Public%20health%20-%20ethical%20issues.pdf>, paragraphs 3.37-8.

6.23 On the basis of our ethical discussions set out in Chapter 5, and of the evidence regarding the effectiveness of incentives summarised above, we suggest that an Intervention Ladder would similarly provide a useful tool to help those considering what, if any, forms of additional encouragement should be offered to potential donors to increase the supply of bodily materials or healthy volunteers, whether for treatment or research. We emphasise here that the rungs of the Intervention Ladder take the form of *inputs*: how individuals respond to such inputs will clearly vary from person to person, and indeed inevitably there will be some degree of overlap in how people respond to neighbouring 'rungs'. *We also note that the Intervention Ladder should not be seen as moving from 'ethical' actions to 'unethical' actions, but rather from actions that are ethically straightforward to those that are ethically more complex.* Thus, action in accordance with the higher rungs may only be ethical in particular circumstances or contexts. Finally, we emphasise that such a tool clearly cannot capture every consideration of ethical relevance, but rather serves to highlight some of the most common ethical concerns that are likely to arise. With these provisos in mind, we draw on the categorisation of forms of encouragement set out in Chapter 3 (see paragraph 3.68), and present a ladder with the following 'rungs':

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

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



- 6.24 While we distinguish the first four 'rungs' of the Intervention Ladder as involving different degrees of organisational involvement and (potentially) cost, we do not distinguish them on *ethical* grounds: we consider them all to be 'altruist-focused interventions' (see paragraph 5.27). We do not consider that refunding expenses involved in donation or providing minor tokens as a 'spur' to donation involve ethical compromises in a way that information campaigns or letters of thanks do not. Thus the rationale for deciding between these four rungs will effectively be empirical: is it necessary to advance a 'rung', or start on a higher rung, to ensure that people are not only willing to donate but feel valued for their donation? Indeed, if there is evidence that people who would like to be able to donate are prevented from doing so by cost (for example if a person who wishes to donate a kidney to a family member cannot afford the time off work involved), then it would seem only just to ensure that they are as well able to donate as someone who is sufficiently wealthy not to be affected by such considerations.
- 6.25 Moves from these altruist-focused interventions to the two final 'rungs' on the Intervention Ladder, which we class as non-altruist-focused interventions, are, on the other hand, ethically significant steps: scrutiny will be required to determine whether, in the circumstances, they may be ethically justified. In Chapter 5, we concluded that, while many of the arguments in favour of altruistic models were powerful, none was absolutely decisive, and that ultimately any decision on whether to offer reward either in kind or in money to potential donors would depend on the evidence as to the *effect* of such incentives both on the person donating, and on what might be termed the 'common good'. We acknowledge here that some will regard any intervention that encourages donation of bodily material primarily for non-altruistic purposes as simply 'mis-valuing' body parts, and would not consider such interventions to be acceptable in any circumstances. Others strongly disagree. As we highlight earlier (see paragraphs 4.17 to 4.21), public policy has to find a way forward in the light of such competing views of the importance of the body, and we have suggested that key areas of common ground lie in consideration of the potential harms that are feared might arise from the creation of such interventions, to the person donating, to others closely concerned, and to wider social values and relationships.
- 6.26 **We therefore recommend that, where a health need is not being met by altruist-focused interventions, the following factors should be closely scrutinised in order to ascertain whether offering a form of non-altruist-focused intervention might or might not be harmful:**
- **The welfare of the donor: this should be understood very broadly, including physical and psychological risks at the time of donation, physical and psychological risks in the future, and the extent to which the donor feels they have other options open to them;**
 - **The welfare of other closely concerned individuals;**
 - **The potential threat to the common good: for example the possible impact on existing donation systems, and the risk of increasing social inequalities;**
 - **The professional responsibilities of the health professionals involved; and**
 - **The strength of the evidence on all the factors listed above.**⁶⁰²
- 6.27 We also suggest that interventions providing associated benefits in kind may be less likely than those offering a straightforward financial reward to be perceived as a 'purchase' of a body part: indeed, for egg sharing we have noted the argument that the benefit being received is not

⁶⁰² We note, of course, that considerations such as the welfare of the donor are clearly essential in determining whether *any* form of donation or volunteering is acceptable. The specific question here is whether offering incentives to donate might raise *additional* concerns in any of these areas. In considering what forms of encouragement could be ethically acceptable for donating any form of bodily material, we have taken the status quo in the UK as a starting point: we have not, for example, sought to re-examine the basis of living kidney donation, or the acceptability of the creation of embryos for research purposes.

financial at all in nature but rather the *opportunity* to bear a child.⁶⁰³ Given that one of the key concerns around any forms of non-altruistic-focused intervention is the risk of material being mis-valued, we distinguish between these two approaches through rungs 5 and 6 on the Intervention Ladder. We also emphasise that the 'benefits in kind' envisaged in rung 5 are benefits that are closely associated with the donated material, as in, for example, the covering of cremation costs where bodies have been donated for medical education (see paragraph 2.34).⁶⁰⁴ In such cases the benefit in kind is clearly situated within the domain of what has been donated. Non-associated benefits in kind (for example high-value vouchers) fall within rung 6, in that their primary purpose is to offer a straightforward financial benefit. In relation to rung 6, then, the key question is what may constitute ethical payment, and in what circumstances. We suggest that, where the intervention involves a direct payment of money or equivalent, it is an essential pre-requisite that the payment is understood, by all parties, in terms of reward to the *person* for their act of providing bodily material, rather than a purchase of material itself.

- 6.28 We return to these factors in more detail below, when we consider the various bodily materials where non-altruistic-focused interventions are already offered in the UK, or have been put forward as future options. We also note here that, while the Intervention Ladder is, we believe, helpful in analysing the ethical acceptability of interventions that aim to encourage people in general to donate, there will be circumstances in which other considerations may be much more dominant: for example where the possibility of donation arises in the context of close relationships, as in where parents donate to their children; or in contexts where the lack of immediate benefit to identifiable individuals, as in many forms of research, may reduce the significance of altruism. It will also be less relevant in considering issues around the ongoing post-donation role or interest of the donor in connection with the use of the material.

Consent

- 6.29 As we discuss in Chapter 5, we believe that it is essential for people's wishes regarding donation to be clear before bodily material may be taken (see paragraph 5.61). For living donors, it goes without saying that explicit consent, based on adequate information about the procedure, its implications and the associated risks, is required. For donation after death, explicit expression of the person's views before death is preferable. In the absence of such a record of wishes (including the absence of any evidence of objection), information as to their likely wishes should be sought from those close to the deceased person, who are usually best placed to know the deceased person's wishes, and who themselves, in their bereavement, have a stake in how their deceased relative's body is treated. We take this overall view on the basis that there is sufficient evidence that, for many people, the disposal of their bodily material is a matter of significant personal concern, and that to take material without some evidence that this is in accordance with the person's wishes risks treating the person's body as a means to others' ends.⁶⁰⁵
- 6.30 Clearly not everyone regards their bodily material – during life or during death – in such a way, but the entrenched and opposing views on proposals for an 'opt-out' approach to deceased organ donation highlight the fundamental lack of consensus on this issue within the UK.⁶⁰⁶ However, as we also set out in Chapter 5, we make a distinction between what is required for valid consent to an intervention during one's lifetime, and what should be required for valid

⁶⁰³ Similarly, access to NHS-funded fertility treatment would not usually be regarded as an incentive 'worth' a particular amount of money, although the direct alternative when NHS care is not available is to pay that amount to a private clinic.

⁶⁰⁴ Human Tissue Authority (2011) *How to donate your body*, available at: [http://www.hta.gov.uk/db/documents/Body & brain donation information pack June 2011.pdf](http://www.hta.gov.uk/db/documents/Body%20&%20brain%20donation%20information%20pack%20June%202011.pdf).

⁶⁰⁵ The original ethical point here relates to using persons as means to others' ends. The deceased body is in an ambiguous position. Injury to the body can no longer literally injure the (deceased) person, and what is at issue is the extent to which family, kin and others who knew the person continue to associate the person with the body, so its treatment is significant as a metaphor or sign of their relationship with the person now departed.

⁶⁰⁶ Department of Health (2008) *The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090303.pdf, pp4-5.

consent in respect of a deceased person's bodily material (see paragraph 5.63). In particular, we suggest that the degree of detail required when providing information about the proposed procedure will differ significantly, and that it should be possible for a person to provide legal authority for donation after death on the basis of quite minimal information, if this is sufficient for them to be clear about their own wishes.

- 6.31 Finally, we emphasise here the importance of consent in creating and maintaining trust in health professionals and the health care system as a whole. We noted above (see paragraph 6.13) that where 'medical mistrust', or mistrust of the system, is cited as a reason for people to hold back from donating bodily material, this may be associated with concerns about consent: both that the terms of the consent may be abused (for example by using the donated material in a different way from that envisaged in the consent) and that additional material may be taken without explicit consent. We highlighted in Chapter 4 (see paragraph 4.3) how values such as honesty and trust were raised by our consultation respondents as central in both the professional and personal relationships affected by the donation of bodily material. While we cannot make any clear findings from the evidence available to us as to the *levels* of such mistrust within the UK at present, we conclude that it is a factor that must be taken into account when considering any changes to approaches to consent.

Implications for different forms of bodily material

- 6.32 We now consider the implications both of our Intervention Ladder and of our stance on consent, for the way individuals within the UK are currently encouraged to donate various forms of bodily material or participate as a healthy volunteer for a first-in-human trial. We reiterate here that this Part II of the report does not seek to be comprehensive, but rather focuses on areas where the evidence we have obtained enables us to make useful recommendations. However, we hope that the examples of how the rungs could be used, as in the discussion of blood, organs and gametes that follows, may indicate how the Intervention Ladder can potentially be used by others in terms of material that is not here considered in any detail, such as bone marrow or cord blood.

Blood

- 6.33 While blood stocks fluctuate, and there may be intermittent pressures on stocks of particular blood groups, blood shortages in the UK are rare (see paragraph 3.5). Where stocks do run low (for example because of bad weather leading to cancelled donor sessions), urgent appeals for donors are generally effective in bringing supplies back up to safe levels.⁶⁰⁷ The evidence suggests that, while new donors are always needed in order to ensure a reliable donor base, the current system is broadly effective in meeting the UK's health needs. That current system relies on good publicity and awareness among the general public as to the constant need for blood (see Box 3.3), motivational procedures to retain a loyal donor base (see paragraph 3.72), and an infrastructure of blood centres and mobile units that seeks to make donation as convenient as possible for potential donors.
- 6.34 Blood is also the 'paradigm' case of donation: indeed as we have discussed elsewhere in this report (see for example Box 1.7), attitudes to blood donation have strongly informed assumptions about other forms of donation in a way that may not always have been appropriate or justifiable. Nevertheless, the current system of blood donation is widely seen as an exemplar of how donation practices should be conducted with reference to notions of solidarity and the

⁶⁰⁷ See, for example, the special appeal by NHSBT: NHS Blood and Transplant (14 December 2010) *More winter weather could threaten blood donation*, available at: https://safe.blood.co.uk/PressRelease/MR0425_141210_RG%20-%20Winter%20Weather%20Appeal%20BD.pdf, and the results, as reported by the BBC medical correspondent in his blog: BBC News Online (18 February 2011) *How to feel special - give blood*, available at: http://www.bbc.co.uk/blogs/thereporters/ferguswalsh/2011/02/how_to_feel_special_-_give_blood.html.

common good: this suggests that any significant changes to that system would send strong signals about a much broader shift away from this set of values. Such a consideration would suggest that any changes in policy regarding blood donation should be subject to particular scrutiny as to their impact on wider communal values.

- 6.35 **We conclude that it is neither necessary nor appropriate to suggest any significant change at present to the current systems operating within the UK for encouraging people to donate blood.** We note that the approach reflects the bottom two „rungs“ of our Intervention Ladder (awareness and recognition) and also the importance of facilitating access to donation to be discussed further in Chapter 7. We also note that suggestions have been put forward – for example, by a Member of the Scottish Parliament – that employers should permit their staff to have paid time off in order to donate blood.⁶⁰⁸ Such a suggestion would fall into the third rung on our Intervention Ladder – it would constitute an „altruist-focused intervention“ seeking to remove a barrier (possible lost earnings or requirement to make up lost working time, depending on the employer) that might otherwise be hindering people from deciding to donate. We do not consider that there would be ethical concerns about such a change; we would, however, suggest that evidence (for example through carefully monitored pilot schemes) would be helpful in determining its likely efficacy before such a change should be recommended more widely.

Organs

Living organ donation

- 6.36 In the UK at present, living organ donation is on the increase, and indeed in recent years, the number of living donors has exceeded the number of deceased donors (see paragraph 3.10). Most donations are made in response to the need of someone close to the donor; 'stranger' donations (living donations from which complete strangers benefit) are relatively low in number although increasing. Current policy includes action in accordance with the first three rungs of our Intervention Ladder: the HTA provides information to those contemplating donation; NHSBT recognises and promotes living donation as a worthy act; and the Department of Health has issued guidance to PCTs stating that the costs incurred by donors (including lost earnings) should be reimbursed in full (see paragraph 2.35).⁶⁰⁹ Any form of payment that exceeds the direct reimbursement of costs actually incurred by the donor is forbidden in UK legal jurisdictions, by European Directive, and by numerous international agreements and statements (see paragraph 2.34). Nonetheless, there are regular calls for some form of regulated 'market' to be introduced, either through regulated 'purchase' of the organs themselves, or through a system of fixed financial rewards for those willing to donate (see paragraph 5.7). Such calls are based on the belief that the creation of an incentivised system would increase the overall number of living kidney donors in the UK, reduce the numbers waiting (and dying) on the organ transplant waiting list, and remove or reduce the temptation to travel abroad for an illegal transplant operation, using an organ sold by someone who is likely to be in desperate circumstances and who is unlikely to receive high quality follow-up health care.
- 6.37 Such a step would clearly be on to the final 'rung' of our Intervention Ladder and to justify that step, we would have to be satisfied regarding the factors listed in paragraph 6.26 above. We consider that the life-saving nature of the need for organs is such that it is reasonable to consider new approaches to increasing supply (see paragraph 5.2). On the question of the **welfare of donors** we note that since both known and 'stranger' living donations are permitted (indeed encouraged) within the UK, the degree of physical risk involved in being a living donor is currently regarded as acceptable. However, while people who donate kidneys as unpaid living

⁶⁰⁸ The Scottish Parliament (24 September 2009) *Co/20054*, available at:

<http://www.scottish.parliament.uk/business/officialReports/meetingsParliament/or-09/sor0924-02.htm#Co/20054>.

⁶⁰⁹ See also: Scottish Executive Health Department (2004) *Reimbursement of living donor expenses by NHS Scotland*, available at: http://www.sehd.scot.nhs.uk/mels/HDL2004_51.pdf; Welsh Assembly Government (2007) *Live donor expenses commissioning policy*, available at: <http://www.wales.nhs.uk/sites3/Documents/898/CP30%20Live%20Donor%20Expenses.pdf>.

donors appear to express very high levels of retrospective satisfaction with their decision to donate,⁶¹⁰ this contrasts with significant levels of regret reported for organ sellers (see paragraph 5.39).

6.38 We also consider that any encouragement of people to come forward as organ donors for essentially financial reasons would be perceived internationally as a direct challenge to the principles of 'solidarity' and 'unpaid' donation set out in EU Directives and in international agreements such as the Declaration of Istanbul, and could undermine other countries' attempts to put a stop to unregulated and illegal organ sales. We therefore conclude that such a challenge would constitute a potential threat not only to the **common good** of altruistic donation within the UK, but also to the welfare of potential donors in other countries. In terms of the **professional responsibilities** of the health professionals who would be involved in an incentivised system, we note the opposition of the British Transplantation Society (whose membership includes the many different professions involved in transplantation) to the introduction of any financial incentives for donation.⁶¹¹

6.39 Finally, we consider the strength of the **evidence**. On the one hand, the Iranian experience clearly suggests that, if payment is offered, some people will come forward and offer to be living donors, thus potentially increasing the number of kidneys (although not other organs) available. On the other hand, the Iranian context differs from that of the UK in many different ways: in particular in terms of general levels of income and social provision; and in terms of a commitment to a significant programme of deceased donation and associated infrastructure.⁶¹² It is very hard, therefore, to deduce from the Iranian experience how many people in the UK would indeed come forward if a significant financial incentive were offered. We also note that, while concerns about 'crowding out' are not substantiated in the context of minor incentives for blood donors, Iranian authors have commented on how people are less likely to donate to family and friends on a non-paying basis if organs are perceived to be available through other routes (see paragraph 6.19).⁶¹³ We also acknowledge that, precisely because of the international disapproval of payments for organs, there is a lack of direct evidence to back up our concerns as to the potentially detrimental effect such a system would have on the UK's current culture of altruistic donation, or indeed whether professional attitudes and anxieties would shift if regulated incentives were to become the norm.

6.40 We acknowledge these gaps in the current evidence, and we recognise too, that those in the UK who call for the introduction of financial incentives do so out of a genuine concern for the welfare of those waiting for an organ transplant. However, we suggest that, in a situation where there is a strong international consensus as to the importance of the current solidarity-based system in protecting both individual donors and the common good, an approach of 'precautionary thinking' (see paragraph 5.50) is demanded: the burden of proof of the benefits of an alternative system must fall on the side of those demanding change.⁶¹⁴ We come to the conclusion that intervention up to the current 'rung', rung 3 of the Ladder, is appropriate. **Accordingly, we endorse the current position, that no payment, over and above the direct**

⁶¹⁰ See, for example, Franklin PM, and Crombie AK (2003) Live related renal transplantation: psychological, social, and cultural issues *Transplantation* **76**: 1247-52; Jacobs C, Johnson E, Anderson K, Gillingham K, and Matas A (1998) Kidney transplants from living donors: how donation affects family dynamics *Advances in Renal Replacement Therapy* **5**: 89-97.

⁶¹¹ See, for example, the position statement of the British Transplantation Society on Commercial dealings in parts of a human body for transplantation: British Transplantation Society (2011) *Commercial dealings in parts of a human body for transplantation*, available at: <http://www.bts.org.uk/ethics/position-statements/>.

⁶¹² Bagheri A (2006) Compensated kidney donation: an ethical review of the Iranian model *Kennedy Institute of Ethics Journal* **16**: 269-82. See also: House of Commons Library (2009) *The Islamic Republic of Iran: an introduction* (London: House of Commons Library).

⁶¹³ A similar situation is reported in the context of illegal organ selling, where the opportunity to purchase is regarded as saving the sacrifice of a relative (the sacrifice of the donor becomes invisible): Cohen L (2001) The other kidney: biopolitics beyond recognition *Body & Society* **7**: 9.

⁶¹⁴ We note that some authors (for example, Radcliffe-Richards J, Daar AS, Guttman RD *et al.* (1998) The case for allowing kidney sales. International Forum for Transplant Ethics *The Lancet* **351**: 1950-2) argue that the burden of proof should be the other way round, falling on those who resist payment. We have stated in Chapter 5 (see paragraph 5.50) why we disagree.

reimbursement of costs incurred in being a donor, should be made to living organ donors. We also conclude (following paragraph 6.15) that systems assigning priority to those who have earlier expressed a willingness to donate are inappropriate, given the wide range of circumstances in which people are held to be ineligible to donate different forms of bodily material.

- 6.41 We do, however, endorse the current guidance by the Department of Health that the costs incurred by living organ donors (including actual lost earnings) should be fully reimbursed by their local Primary Care Trusts. Given the current organisational changes within the NHS in England, under which both Primary Care Trusts and the Human Tissue Authority will be abolished in their current form, we urge the Department of Health to ensure that this guidance is given proper weight within the new organisational structures. Possible ways of achieving this would include through legally binding Directions or through the Code of Practice issued under the Human Tissue Act.⁶¹⁵

Deceased organ donation: incentives

- 6.42 The possibility of financial incentives has not only been raised in the context of living donors, but has also been suggested as a potential way of increasing levels of deceased organ donation. Such a system might involve either a (presumably small) payment to the person at the time of the decision to join the ODR (at which point their likelihood of becoming a donor is relatively low), or alternatively a (possibly larger) payment to their estate or to a named person if they do in fact become a deceased donor in the future. One way in which such a future payment system might work would be through the NHS meeting the cost of funeral expenses: effectively providing a financial benefit to the deceased's estate or to those who would otherwise bear the costs of the funeral.
- 6.43 A token payment to prompt signing the ODR would constitute the fourth rung of our Intervention Ladder: such an 'altruist-focused intervention' might be the final spur needed for someone disposed to register as a donor to 'get round' to doing so. As such, we do not think such a payment would challenge the current consensus in any ethically significant way. We do, however, note, that it could add significant expense overall to the cost of maintaining the ODR. We also note that there would, of course, be nothing to prevent the person from subsequently changing their mind and removing their name from the ODR (although if they were genuinely already positively inclined towards the idea of organ donation, this seems unlikely). We therefore simply note that if any such system were to be considered, a pilot scheme, carefully monitored, would be essential in order to measure how effective such an intervention really would be, and hence whether it would justify the (potentially significant) extra cost.
- 6.44 The reimbursement of funeral expenses (for example by NHSBT) is ethically more difficult. If offered directly to bereaved relatives who would otherwise refuse permission, it would very clearly constitute a 'non-altruist-focused intervention'. While there would be no risk of the donor suffering physical harm, it might be argued that any decision by their family to consent to donation solely for financial reasons would constitute a very clear example of that person's body being used as a means for others' ends and not as an end in itself (see paragraph 5.60). Given these concerns, coupled with a lack of evidence as to the likely effectiveness of such an intervention, we do not think it should be pursued.
- 6.45 The situation would seem rather different if the payment were triggered by the future donor signing up to the ODR, rather than being offered to the bereaved relatives at the time of death. To the extent that our Intervention Ladder is appropriate in such a family-based scenario,⁶¹⁶ the intervention might constitute 'rung 4': acting as a final spur for a person already inclined to donate, with the added altruistic feature that others, and not the donor themselves, would

⁶¹⁵ Department of Health (2009) *Reimbursement of living donor expenses by the NHS*, available at: http://www.dh.gov.uk/en/Healthcare/Longtermconditions/Vascular/Renal/RenalInformation/DH_4069293.

⁶¹⁶ As we note in paragraph 6.28, donation within families brings other considerations.

benefit. Alternatively, the incentive might seem sufficiently strong for someone to decide to register as a donor simply to spare their relatives the financial burden of a funeral: however, in such a case, the decision would still include an altruistic component, with the aim to benefit others (the donor's relatives). Moreover, while those who are neutral about donation after death might be swayed by such an incentive, it seems unlikely that a person actively opposed to the use of their bodily material after death (for example because of concerns about the integrity of the body) would be tempted to act against those beliefs.

- 6.46 As these arguments demonstrate, when decisions are made in the context of families, the Intervention Ladder will only be one factor to take into account. However, consideration of the factors highlighted in paragraph 6.26, such as the welfare of the donor and the threat to the common good, does suggest that payment of funeral expenses in these circumstances could be ethically justified. Donors cannot be physically harmed – and are highly unlikely to have signified their willingness to donate in these circumstances if they had strong objections. Those close to the donor may benefit directly, and also would clearly have the option of declining the offer of burial costs being met by the NHS. While there is no direct evidence as to how effective or popular such a system would be, the fact that a very similar system exists for covering cremation costs of those who donate their bodies to medical science (which appears to be regarded by both professionals and families as an appropriate acknowledgment of the person's gift),⁶¹⁷ suggests that the extension of such a scheme to organ donors would not be detrimental either to professional values or the common good. **We recommend that NHS Blood and Transplant should consider establishing a pilot scheme to test the public response to the idea of offering to meet funeral expenses for those who sign the Organ Donation Register and subsequently die in circumstances where they could become organ donors.** The precise way in which such a scheme might operate – factors such as what, if any, role family members should have in authorising the use of organs in such circumstances, and whether expenses should be covered if in fact the person's organs prove to be unsuitable for transplant – would be key questions for such a pilot scheme to determine.

Deceased organ donation: forms of consent

- 6.47 We have already set out above (see paragraphs 5.61 and 6.29) our view as to the central importance of knowledge as to a person's wishes regarding donation after death. At present such knowledge may be obtained by the person choosing to signify their wishes in advance of their own death (for example by signing the ODR); in the absence of such clear indication of the person's own wishes, organs may lawfully be taken on the basis of 'consent' (England, Wales and Northern Ireland) or 'authorisation' (Scotland) on the part of their partner or closest available relative or friend (see paragraph 2.15). The proposal is regularly mooted that this 'opt-in' system should be replaced by an 'opt-out' system (see paragraphs 3.53 to 3.54). Two models of 'opt-out' systems are often distinguished: a 'hard' system, in which organs would automatically be taken unless the person had objected during their lifetime, and a 'soft' system, in which relatives would be able to veto organ donation even if no formal objection had been made in the past by the deceased person.
- 6.48 **In our opinion, the importance to be attached to the person's own wishes rules out absolutely any consideration of introducing a 'hard' opt-out approach to deceased organ donation, given the impossibility of ensuring that everyone would be sufficiently well-informed to have the opportunity of opting out during their lifetime.** Our position on a 'soft' approach is more finely-balanced, and much would depend on how, in practice, families were approached under such a system. If, after a person died in circumstances where they could become an organ donor, their family were approached and advised that their relative had not

⁶¹⁷ Schweda M, and Schicktanz S (2009) Public ideas and values concerning the commercialization of organ donation in four European countries *Social Science & Medicine* 68: 1129-36; Richardson R, and Hurwitz B (1995) Donors' attitudes towards body donation for dissection *The Lancet* 346: 277-9.

registered an objection in their lifetime, and then they were asked whether they had any concerns about donation, either because of the deceased's views, or on their own behalf, then such a system might differ very little from the current system where families are formally approached for 'consent' or 'authorisation'. On the other hand, if families were simply informed that organs would be taken unless they exercised a right of veto, the families' perception of their role in the decision would be significantly different.

6.49 We are aware of the ongoing discussions in the research literature as to whether increases in organ donation in countries such as Spain that have introduced opt-out legislation can be ascribed to the legislative framework, or whether other systemic factors in the way organ procurement is managed are the main contributing factor to the increase. A systematic review of studies comparing 'before and after' donation rates after legislative change in a number of countries, published in 2009, concluded that changing to an opt-out system of consent alone was unlikely to explain the variation in organ donation rates between countries, with many other factors identified as relevant. These included both factors affecting the total number of potential donors available (for example rates of motor accidents, the population's age distribution, and the country's definition of death), and factors affecting how many of those potential donors in fact went on to donate (for example the organisation and infrastructure of the transplant system, wealth and investment in health care, and underlying public attitudes and awareness).⁶¹⁸ Another study, published subsequently, concluded by contrast that opt-out systems *are* associated with relatively higher rates of deceased donation – but also with relatively lower rates of living donation.⁶¹⁹ We are also aware of research modelling the possible effects on organ supply of an opt-out system, based on differing levels of individual and family opt-out.⁶²⁰ We note that, while such models demonstrate a potential increase in the number of available organs (and hence lives saved) on the basis of particular assumptions about numbers opting out, such assumptions clearly remain to be tested.

6.50 **We would not oppose on ethical grounds a soft opt-out system, in which families had the opportunity (without pressure) of contributing their knowledge of the person's own views and, where appropriate, of determining that the person would not have wished to become a donor, or indeed that donation would cause the family significant distress. We do, however, note some practical difficulties.** First we suggest that initial assumptions as to the numbers of additional organs that might be obtained in such a way should be modest, if families do indeed continue to feel genuinely free to express any objections they feel.⁶²¹ It does not automatically follow that families who currently refuse consent to the use of their deceased relative's organs would take a different view under such a system. Indeed, if families in such cases felt coerced in any way, then this would potentially render their role meaningless. On the other hand, if the effect of any policy change were to change attitudes so that donation were seen as 'natural' or 'normal', hence increasing the likelihood that families would conclude that donation would be in line with their deceased relative's wishes, this would be ethically unproblematic. Similarly, if families felt relieved from the requirement actively to make the decision, this too might lead to fewer refusals. Second, given the strong opposition in some quarters to the notion of any form of opt-out scheme, and the associated concerns that the state (acting through health professionals and the health care system) would be intervening to 'take' organs rather than facilitating their being 'given', there is at least a risk that some degree of trust in the system could be lost. In such circumstances, it would be particularly important that systems should be designed in such a way as to minimise such loss of trust, for example by

⁶¹⁸ Rithalia A, McDaid C, Suekarran S, Myers L, and Sowden A (2009) Impact of presumed consent for organ donation on donation rates: a systematic review *BMJ* **338**.

⁶¹⁹ Horvat LD, Cuerden MS, Kim SJ *et al.* (2010) Informing the debate: rates of kidney transplantation in nations with presumed consent *Annals of Internal Medicine* **153**: 641.

⁶²⁰ Bird SM, and Harris J (2010) Time to move to presumed consent for organ donation *BMJ* **340**: c2188.

⁶²¹ Such a system would, of course, enable organs to be obtained when people die in circumstances where they could become an organ donor and there is no-one at all available able to give consent as currently required by the Human Tissue Act.

ensuring that those seeking family views are not themselves subject to targets that might be seen as leading to pressure on families.⁶²²

- 6.51 As we have already shown, there may be a significant difference between how people think or say they will act in particular theoretical situations, and what they actually do if that situation arises (see paragraph 6.19). We are therefore hesitant to rely on research reporting on how people say they would respond to the introduction of a soft opt-out system including all the protections described above. We note, however, that the Welsh Assembly has expressed a clear intention to introduce such a scheme in Wales.⁶²³ **If an opt-out system is introduced in Wales we recommend that this is accompanied by robust research, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change (as opposed to any confounding factors such as system changes) has had on the numbers of organs donated.** Such research would provide a clear evidence base for any proposals for change elsewhere in the UK, or indeed further afield.
- 6.52 As we comment in Chapter 5, the notion of 'opt-out' systems is not the only means of changing the defaults around deceased organ donation (see paragraph 5.61). In particular, we have highlighted ideas of 'mandated choice' (under which people would be required to make a definite decision about organ donation during their lifetime) and 'prompted choice' (under which people would be required at least to consider the question, even if they chose not to answer it). Mandated choice has been criticised for forcing people to choose a straightforward 'Yes' or 'No' to the question of future organ donation at a time when they may not feel they are well placed to make such a decision, and the introduction of a system on these lines may run the risk of being counter-productive in relation to organ supply by encouraging people to say a firm 'No' when their truer views might be 'Don't know at the moment' (see paragraphs 3.54 to 3.56). However, one form of mandated choice put forward recently overlaps to a degree with ideas of 'prompted choice', in that it would include the options of 'Yes', 'No', and 'Ask my family'.⁶²⁴ Such an approach would seek to avoid the risk that people feel coerced into making a decision, but would also enable those who are genuinely unsure at the time of answering the question to indicate that they are happy to delegate their decision to their family, and that they are not actively opposed. Registration with a new GP's practice, or the occasion of a first appointment with a new GP, might provide opportunities for the NHS to log people's wishes in this way on a systematic basis, although care would need to be taken to ensure that individuals did not feel pressured into answering in a particular way.
- 6.53 A pilot version of a system on these lines started in the UK in August 2011, under which all those making an online application to the Driver and Vehicle Licensing Agency (DVLA) for a driver's licence (whether new or renewal) will now be required to answer a question about organ donation before their application can be processed.⁶²⁵ The options are: "Yes, I would like to register"; "I do not wish to answer this question now"; or "I am already registered on the NHS

⁶²² Rodríguez-Arias D, Wright L, and Paredes D (2010) Success factors and ethical challenges of the Spanish Model of organ donation *The Lancet* **376**: 1109-12.

⁶²³ The National Assembly for Wales announced that it will launch a White Paper consultation on an organ donation (Wales) Bill before the end of 2011. The Bill will provide for an opt-out system of organ donation. See: National Assembly for Wales (12 July 2011) *The record of proceedings: the Welsh Government's legislative programme 2011-16*, available at: <http://www.assemblywales.org/bus-home/bus-chamber-fourth-assembly-rop.htm?act=dis&id=219617&ds=7/2011#dat2>. See also: House of Lords Hansard (27 June 2011) *c370W*, available at: <http://www.publications.parliament.uk/pa/ld201011/ldhansrd/text/110627w0001.htm>, where Earl Howe states that "The Welsh Government have now announced that they will press ahead unilaterally with an Assembly Bill to attempt to change the existing system on organ donation and introduce an opt-out system of consent in Wales. The Government will examine thoroughly the detail of the Bill when it is introduced to the National Assembly."

⁶²⁴ Saunders J (2010) Bodies, organs and saving lives: the alternatives *Clinical Medicine, Journal of the Royal College of Physicians* **10**: 26-9.

⁶²⁵ The scheme is described as 'prompted choice', but appears to be closer to 'mandated choice' given that the question has to be answered before the application can be processed.

Organ Donor Register".⁶²⁶ The option for the applicant to object to organ donation is not included.

- 6.54 **We conclude that, in principle, both mandated choice and prompted choice systems present ethical options for seeking authorisation in advance to deceased organ donation.** We have emphasised repeatedly the importance we place on clear information about individuals' wishes, and hence systems that encourage people both to think about their own willingness to donate and to document their decision are strongly to be encouraged. We also endorse the use of a pilot scheme to track the effectiveness of the new 'prompted choice' system via the Driver and Vehicle Licensing Agency (DVLA), and urge that the scheme is accompanied by robust research as to its impact. However, we are concerned about the decision not to include the option of registering *objection* to organ donation in the DVLA scheme: any system that is based on explicit authorisation must also allow for explicit refusal. The possibility of explicit refusal can only strengthen the significance of approval: at the same time it allows for strength of personal feeling to be expressed in both directions (approval and disapproval). The importance of this cannot be overemphasised when the subject matter is bodily material.
- 6.55 **We recommend that any system set up to document people's wishes that mandates a response to a question about organ donation should also include the option of expressing objection; to do otherwise significantly undermines commitment to following the wishes of the deceased and even, arguably, fails to comply with the spirit of current legislation with its central focus on consent. We further recommend that any system set up to document people's wishes regarding donation (including the current Organ Donor Register) should also be able to register objections.** Indeed, such a system might in practice act to *increase* donations, in that families who are unsure about their deceased relative's views could be reassured that they had not actively chosen to opt-out.
- 6.56 As we noted earlier (see paragraph 5.62), difficult issues arise in connection with the amount of information needed for a legally valid consent; and the possibility of signing up to the ODR on the basis of little or no information about the process of donation has been raised as a matter of concern. **We note again the ethical distinction we have drawn in Chapter 5 (see paragraph 5.63), between *consent* for interventions on the body for the purposes of donation during life and *authorisation* of interventions on the body for the purposes of donation after death, which we consider could well provide a helpful framework for distinguishing between the informational requirements in two very different sets of circumstances.**
- 6.57 We do not think that before anyone can sign up to the ODR, or before any family member can agree to the use of the deceased person's organs, they must be given (and required to read) highly detailed information about the procedure. Rather, they must be in a position to understand, in broad terms, what is involved, and they must be in a position to have any further questions they have answered. Some people would prefer not to know any details of how organs will be removed, but simply wish to have the option of specifying some organs rather than others, and perhaps to be reassured that, once organs have been removed, their deceased body will not appear disfigured. For them, this is sufficient to cover 'what is involved'. Others, by contrast, may wish to have detailed information about the process of organ retrieval, treatment and transplantation. **We conclude that information must be *available* to those considering donation and it must always be clear that more information is available if people desire it. If people make it clear that they wish to agree to donation, whether in advance via the Organ Donation Register, or on behalf of a deceased relative, even if they do not want to know any details about the process, this should be accepted as sufficient expression of their wishes.**

⁶²⁶ Department of Health (1 August 2011) *Licences to drive up organ donation*, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_128847.

- 6.58 Preceding paragraphs have alluded repeatedly to the role of those associated intimately with the deceased, as flagged in the term 'family',⁶²⁷ and their involvement in the decision to donate after death. As will have become apparent from our emphasis on the importance of the role of the family in connection with 'soft' opt-out procedures (see paragraph 6.50), we consider it appropriate that the family's own interests with respect to the donation decision should be recognised, even where the deceased has left clear evidence as to their wishes to donate. In practice, it appears that if families are aware of their deceased relative's wishes, then they are very unlikely to refuse consent to organ donation: figures from NHSBT show that fewer than one per cent of families refuse consent to donate a kidney if their deceased relative had made their wish to donate known via the ODR.⁶²⁸ On the rare occasions when this does happen, while the law does permit organs lawfully to be taken on the basis of the deceased's consent, in practice health professionals would not proceed in the light of the refusal of bereaved family members. More significant is the percentage of families (around 40 per cent) who refuse consent for donation when the deceased had not signed the ODR.⁶²⁹ In such cases, we endorse the current position that the option of refusal *should* rest with familial associates of the deceased. Such refusal (where applicable) may be based on families' own knowledge of the deceased's attitudes to donation; however, it may also at times be understood as an expression of their own needs, as bereaved family members. We reiterate again the importance of systems to promote the widespread expression of people's advance wishes regarding donation after death.
- 6.59 Finally, we reiterate here that action that aims to change individuals' behaviour with respect to deceased organ donation is only one part of the picture, and that we will be returning in Chapter 7 to actions at organisational level that may influence levels of organ donation.

Gametes

- 6.60 Current attitudes and policies towards the donation of gametes are strikingly different from those applied to blood and organs. We have described above and in Chapter 3 the considerable use of promotional materials highlighting the need for blood and organs, the systems used to thank donors and recognise the value of their donation, and the availability (in the case of living donors) of clear arrangements to cover the full financial costs incurred by the donor in the process of making their donation. Coupled with these activities (which encapsulate the first three rungs of our Intervention Ladder), there is a strong international consensus that any form of payment for organs (whether in the form of a 'prompt' to donate where a potential donor is already so inclined, or a full-blown financial incentive to consider donation primarily for financial reasons) is wrong.
- 6.61 In contrast to the well-funded nationally organised networks promoting and facilitating blood and organ donation, only very limited support is available to raise general awareness of the need for donor gametes (see paragraph 3.70). Advertising for gamete donors therefore mainly takes place in the form of *ad hoc* campaigns by individual clinics, and there is little cooperation between clinics (a point to which we return in Chapter 7). There are no 'official' ways in which gamete donation is celebrated (although individual clinics or recipients may have their own systems for recognising and thanking donors). While travel and other out-of-pocket expenses

⁶²⁷ We have been using „family“ as a generic term to cover forms of relatedness among people 'intrinsic to one another's existence' (for which an anthropologist might use the word 'kinship'). Depending on context, 'families' include partners/spouses and all others potentially close to the deceased, and may include friends who become family-like. The HTA definition of 'qualifying relative' (see paragraph 2.15) is relevant here, although we offer no opinion on the particular categories used, nor on the order in which they are listed.

⁶²⁸ Just 0.2 per cent of families refuse to donate a kidney, in circumstances where the deceased had previously consented via the ODR. However, around ten per cent of families may then refuse further permission for the heart, pancreas or lung even though the deceased had consented via the ODR. NHSBT, personal communication, 2 November 2010.

⁶²⁹ See, for example, Barber K, Falvey S, Hamilton C, Collett D, and Rudge C (2006) Potential for organ donation in the United Kingdom: audit of intensive care records *BMJ* **332**: 1124-7.

incurred by donors are reimbursed in full, lost earnings are capped at £250 per cycle of donation. Egg donors, in particular, may therefore potentially be out-of-pocket as a result of their donation. Although the Tissues and Cells Directive calls for gametes to be procured on a "voluntary and unpaid basis", interpretation within EU member states varies considerably as to what forms of compensation are permitted in conjunction with this definition. Outside Europe, there is no international consensus around payment for gametes, and indeed the straightforward 'purchase' of gametes, with differential pricing depending on the number of eggs and the qualities of the egg or sperm donor, is accepted in several jurisdictions.⁶³⁰

Gametes for reproduction

- 6.62 It is clear to us that the starting point in any consideration of the ethical promotion of gamete donation must be the need for 'altruist-focused' action within the first four rungs of the Intervention Ladder. Until such interventions have been tried and evaluated, we consider it highly premature to conclude that a system based primarily on altruism has been shown to 'fail'.⁶³¹ In particular, we highlight here the absence of organisational systems necessary for its success, such as the creation of a national infrastructure for egg and sperm donation, on the lines of the structures currently in place for organ donation. Such an infrastructure would be well-placed not only to manage the kind of coordinated information campaigns envisaged in the first rung of our Intervention Ladder, but also to share best practice in recruiting, retaining and 'recognising' donors (rung 2). We return to this point in more detail in Chapter 7.
- 6.63 Moving to rung three of the Intervention Ladder, we see no reason why gamete donors should suffer financial disadvantage as a result of their donation. Where time has to be taken off work in order to donate gametes, particularly in the more invasive procedures involved in egg donation, **we recommend that the current cap of £250 on lost earnings that may be reimbursed should be removed, and that lost earnings, where applicable, should be reimbursed in full in the same way as other expenses such as travel costs.** The clear aim should be to ensure that the donor is in the same financial position as a result of their donation, as they would have been if they had not donated. We do not consider such reimbursements as 'reward', and we do not consider higher levels of reimbursement for higher earners to be unjust by comparison with reimbursement of those on lower earnings (any more than reimbursing the cost of a long-distance train fare is unjust by comparison with reimbursing the cost of a local car or bus journey).⁶³² Where such costs or losses are incurred as a direct result of donation, they should be met in full.
- 6.64 Finally, with respect to rung 4 of the Ladder, we do not think token incentives, such as low-value vouchers, offered with the aim of prompting someone already disposed to donate to take the step of doing so, would be ethically objectionable in themselves. However, there is at present little evidence to support the effectiveness of such a measure, compared with the effectiveness of the better organisational arrangements and full reimbursement of financial losses incurred in the process of donation recommended above.⁶³³ Moreover, as we highlighted in paragraph 6.23, the effect of the 'inputs' set out in the Intervention Ladder may vary in their effect on individuals: what might be perceived as a 'token' incentive to one person might to another constitute a primary reason for donation (and hence rung 6 of the Ladder). Indeed, we note that the 'compensation' offered to Spanish gamete donors, calculated on a standardised basis for

⁶³⁰ See, for example, Ethics Committee of the American Society for Reproductive Medicine (2004) Financial incentives in recruitment of oocyte donors *Fertility and Sterility* 82: 240-4; Gruenbaum BF, Pinchover ZS, Lunenfeld E, and Jotkowitz A (2011) Ovum donation: examining the new Israeli law *European Journal of Obstetrics & Gynecology and Reproductive Biology*: in press.

⁶³¹ See, for example, Bahadur G, Jegede T, Santis M and Ahuja KK (2011) *Recruiting 500 sperm donors: customer relations key to meeting UK demand*, available at: <http://eshre2011.congressplanner.eu/showabstract.php?congress=ESHRE2011&id=643>.

⁶³² We reject the argument that meeting such costs in full constitutes valuing the time of a well-paid gamete donor more than the time of poorly-paid donor. While the time of each may be valued differently by their respective employers, reimbursement seeks only to return them to the financial position they would have occupied, but for their decision to donate.

⁶³³ We note that these latter two steps (full reimbursement and better organisational procedures) have constituted key elements in the attempts to improve organ donation within the UK in recent years.

lost earnings, travel expenses, meals and discomfort (notionally our rung 4), is widely seen as a straightforward 'reward' for donating and hence in fact constitutes rung 6 (see paragraph 2.51). Particular effort would therefore be required to ensure that any incentive offered would be widely understood as just a prompt or a 'thank you' for donating.

- 6.65 Moving to consideration of rungs 5 and 6 of the Intervention Ladder, we consider that it is inappropriate to consider introducing new forms of non-altruistic-focused intervention in the UK with respect to donation for another's treatment, before action on the lower rungs of the Intervention Ladder has properly been explored. However, given the existence of such interventions elsewhere in the world, and the recent debate on this issue within the UK, we make a number of observations.
- 6.66 **The Council rejects outright the concept of paying a 'purchase' price for gametes, where any payment made is understood as payment for the gamete itself, rather than as recompense or reward to the donor herself or himself.** Insofar as the 'price' of gametes depends on quantity, or on inferred qualities (for example those associated with the appearance or intelligence of the donor), such a transaction may only be understood as a 'purchase'.
- 6.67 **We consider that the welfare of the potential donor, especially with respect to egg donors, is central in determining what constitutes acceptable practice in this area.** Clearly the physical risks of egg donation are not, in themselves, affected by whether a woman agrees to donate eggs primarily out of concern for other women unable to conceive with their own eggs, or primarily for reward. However, where egg donation is considered for essentially financial reasons, women may be more likely to consider repeat donations, and may be more likely to continue donating despite potential risks to their health. The lack of good-quality data on the long-term risks of repeat egg donation is a matter of concern here.
- 6.68 We note that many of these concerns have been picked up by good practice guidance for cross-border reproductive care published in 2011 by the European Society of Human Reproduction and Embryology (ESHRE), which states:

"It is essential to propose a stimulation cycle that minimizes the health risk for the oocyte donors. Reliable data regarding risks are scarce, especially in the case of repeated donation. Donors may present themselves several times at the same center or at different centers. In order to obtain information on repeated donations and to be able to verify legal restrictions on donations, it is essential firstly to establish national registers of gametes donors, and secondly for centers to participate in the collection of national or international data.

In order to prevent the abuse of donors coming from abroad, one should avoid using intermediate agencies, which may lead to violations of the rules of good clinical practice and, in the worst case, to trafficking. Post-donation care should be provided to the best possible standards at home or abroad."⁶³⁴

- 6.69 **We endorse the good practice guidance issued by the European Society of Human Reproduction and Embryology (ESHRE) on the treatment of egg donors in the context of cross-border reproductive care, and note its potential relevance also for domestic care. In particular, we endorse ESHRE's call for national registers of gamete donors to be established, and for centres to participate in the collection of national or international data. In addition we recommend, as a matter of urgency, that action is taken by licensed clinics to start collecting data on a systematic basis (if possible retrospectively, as well as through the new registers) to track the long-term health effects of repeat egg donations.** Good-quality evidence on these effects is essential in order for proper concern to be

⁶³⁴ Shenfield F, Pennings G, De Mouzon J *et al.* (2011) ESHRE's good practice guide for cross-border reproductive care for centers and practitioners *Human Reproduction* 26: 1625-7, paragraph 2.2.

given to the welfare of egg donors in any future policy. We further note that individual clinics currently, as a matter of good practice, take a number of steps to minimise risk to egg donors, for example by encouraging women to donate only after they have completed their own families, and by limiting the number of times a woman may donate.⁶³⁵ **We recommend that the Royal College of Obstetricians and Gynaecologists and the British Fertility Society should work with the HFEA to review what is currently regarded as best practice in the UK with respect to measures taken to safeguard egg donors, with a view to issuing guidance that will send out a clear public signal about how the welfare of egg donors should underpin any consideration of donation.**

6.70 Finally, in the context of incentives designed to reward, rather than simply recompense, donors (egg and sperm alike), we highlight the question of the welfare of any future child (see paragraph 5.54). This is a hotly contested area: on the one hand, concerns are expressed as to the effect on any future child of the knowledge (if shared with him or her) that their biological mother or father provided their biological material for financial gain; on the other, it is argued that there is no evidence to show detriment, that children are conceived in all sorts of circumstances that have little or no effect on how they are subsequently loved and treated, and that indeed it can be the case that the very lengths to which the child's legal parents are prepared to go to conceive a child demonstrate how wanted and loved they are. **We conclude that, in order properly to inform this debate, good quality empirical research evidence is urgently needed as to what, if any, effects financially incentivised gamete donation has on children conceived as a result of such donation and, indeed, on the wider context of how responsibilities towards children are understood.**

6.71 The preceding paragraphs have been concerned with 'new' non-altruist-focused interventions. However, we have already noted that one non-altruist-focused intervention – egg sharing – is currently permitted in the UK. On our Intervention Ladder, egg-sharing arrangements are classified as being on rung 5: benefits in kind (treatment services) that are associated with what is being donated (a proportion of the eggs produced in response to hormonal stimulation). The limited evidence that currently exists on the experiences and attitudes of those donating some of their eggs in order to access treatment they could not otherwise afford suggests that this is not a choice that most women would make if treatment were available to them in other circumstances (see paragraph 3.77). However, once they have taken the decision to share eggs for these reasons, it is clear that there may well be considerable fellow-feeling between donors and recipients, both of whom are undergoing, albeit in different ways, medical procedures with the aim of bearing children; and that it is far from meaningless to talk about „solidarity“ in the context of their relationships (see paragraph 6.8). Moreover, tentative views arising out of current research being conducted into egg-sharing arrangements in Newcastle (in this case the 'shared' eggs being destined for research purposes) suggest that women who have provided eggs under this scheme are clear that their decision to do so is freely made – albeit not in circumstances of the women's own choosing.⁶³⁶ This position highlights one of the reasons why egg sharing was permitted in the first place: not specifically as a method for recruiting additional egg donors, but in order to enable more people to access IVF procedures in the absence of wider NHS provision.

6.72 We note that women who become egg donors through egg-sharing arrangements do not undergo any additional risks in the procedure itself; and that current data suggest that their

⁶³⁵ See, for example, Midland Fertility Services (2010) *Donating eggs*, available at: <http://www.midlandfertility.com/investigations-and-treatments/treatments/donor-treatments/donating-eggs>. In the context of egg donation for research, the Wellcome Trust has suggested that it is appropriate to limit the number of times a woman can undergo the procedure to donate eggs. See: Wellcome Trust (2006) *Re. HFEA consultation on donating eggs for research*, available at: http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTX035514.pdf.

⁶³⁶ They would, however, prefer greater access to NHS funding rather than having to resort to egg sharing to fund their treatment; they would prefer then to be in a position to offer their eggs for research after completion of treatment. Tentative findings by Haimes E and Taylor K, presented at the PEALS annual symposium, 22 and 23 February 2011.

chance of becoming pregnant after the transfer of fresh embryos is on a par with non-egg-sharers, although their 'cumulative' pregnancy rate will be lower because they will have fewer frozen embryos for subsequent transfers after their initial treatment (see paragraph 3.77). We also note that, in circumstances where would-be egg sharers do not in fact produce enough eggs for their own treatment and that of another woman, they will be entitled to use all the eggs for their own treatment, while still receiving the promised rebate on their treatment fees.⁶³⁷ **We note, and welcome, recent statements by Ministers urging Primary Care Trusts and their successor organisations to ensure that access to IVF is more routinely made available in accordance with the guidance issued by the National Institute for Health and Clinical Excellence guidance.**⁶³⁸ **However, given the likelihood that some women will continue to experience difficulties in accessing NHS IVF treatment, we do not think it appropriate at present to recommend any changes to the current policy within the UK of permitting egg-sharing in these circumstances.**

- 6.73 However, we strongly caution that it is *not* appropriate to use the notional value of egg-sharing arrangements (that is, the financial rebate offered on the cost of private IVF treatment) as an argument for creating a straightforward financial incentive for egg donation for reproductive purposes. As we have argued, a clear distinction can be made between the position of donors who in return receive a benefit directly associated with their donation (in the case of egg sharers, the opportunity to receive treatment that would otherwise not be available to them), and those who are invited to donate on the basis of simple financial reward. Any consideration of the possibility of such 'rung 6' incentives to donate gametes should be clearly distinguished from the justifications for permitting egg sharing.

Gametes for research

- 6.74 Women who decide to donate eggs for research as 'volunteer egg donors' (that is not as part of an egg-sharing agreement), are likely to have rather different motivations from those donating to help a woman conceive. We consider that the most relevant comparison here, across all the different forms of donation and volunteering noted in this report, is with first-in-human trial volunteers. In contrast with circumstances where eggs are donated for treatment purposes, there is no direct recipient of the donated material and no possibility of a child being born as a result of the donation. Like healthy volunteers in first-in-human trials, women who donate eggs for research undergo medical procedures that involve discomfort, inconvenience and potential health risk, with the aim of enhancing scientific knowledge and hence potentially producing long-term health benefit (see Box 1.8). The potential gains by others are thus uncertain, remote, and impossible to link with any identifiable individual.
- 6.75 We have taken the view that these differences between donation for research purposes and donation for treatment purposes have ethical implications (see paragraphs 5.46 and 5.82). In particular, we consider that where there are no clear recipients (known or unknown) of the donated material, a move away from a primarily altruistic model of donation may not present a risk of undermining solidarity, as expressed, for example, in a communal commitment to the provision of materials needed by others for the preservation or improvement of their health. While the willingness of donors of eggs for research to contribute to scientific knowledge may certainly be understood in terms of solidarity (a willingness to contribute to the collective good of research), altruism does not appear in this context to be a key value underpinning that contribution to solidarity. Rather, we suggest that another value, justice, becomes applicable here: if women are prepared to undertake these procedures to benefit scientific endeavour and the wider community, is it not just that their contribution should be explicitly recognised? And in

⁶³⁷ Human Fertilisation and Embryology Authority (2009) *Code of practice*, available at: http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf, paragraph 12.20.

⁶³⁸ House of Commons Hansard (12 December 2007) c437, available at: <http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm071212/debtext/71212-0024.htm>.

circumstances where altruism does not play a central role, there appears to be much less justification for avoiding the use of financial reward as a form of recognition.

- 6.76 In these circumstances, we conclude that it would be appropriate to explore the possibility of offering some form of payment to those who are prepared to come forward as egg donors for research. Payment could be made on the basis of compensation for the time, inconvenience and discomfort involved in donating (in direct parallel to the language used in first-in-human trials), or as a form of remuneration. Whether badged as 'compensation' or as 'remuneration', however, we are clear that such a payment would constitute a non-altruist-focused intervention at rung 6 on our Ladder.
- 6.77 We commented earlier that in the context of some forms of research, considerations other than those set out in the Intervention Ladder may be dominant (see paragraph 6.28), and we have highlighted these considerations above. Nevertheless, we suggest that in considering the possibility of non-altruist-focused interventions to promote the donation of any form of bodily material, careful consideration should still be given to the factors listed in paragraph 6.26 concerning the welfare of those concerned, the potential threat to the common good, the professional responsibilities of those involved, and the strength of the evidence on all these aspects.
- 6.78 In connection with the **welfare of the donor**, the considerations are exactly the same as in egg donation for treatment purposes (see paragraph 6.67). The physical risks of donation are currently regarded as acceptable in the context of altruistic donation, and the possibility of reward does not affect this. However, the risks of repeat donation are unknown, and potentially of greater concern. We therefore suggest that if reward were to be offered for egg donation, very clear procedures would need to be in place to ensure a limit on the number of possible donations. The ESHRE guidance quoted above (see paragraph 6.68) also sets out further procedural safeguards that should be followed to avoid the inappropriate targeting of donors from abroad. We return to this point of institutional safeguards in Chapter 7 (see paragraph 7.68).
- 6.79 On the **welfare of other closely concerned individuals**, we repeat that in egg donation in these circumstances, there is no possibility of any resulting child. We have already discussed the **potential threat to the common good**, and have concluded that in the context of research there is no good reason to conclude that a move away from altruism would be harmful or would undermine solidarity. We have, however, little evidence as to how such a change might impact on the **professional responsibilities** of the health professionals involved and on how they might view such a change with regard to professional ethics.
- 6.80 Some of these arguments with respect to egg donation for research potentially apply also by analogy to sperm donors. However, the very different demands placed on egg donors in terms of medical intervention create an important distinction between egg and sperm donors, and suggest that egg donation should be singled out for specific consideration.
- 6.81 **We conclude that it would be appropriate to set up a pilot scheme to explore the possibility of offering some form of payment to those prepared to come forward as egg donors for research. Payment could be made on the basis of compensation for the time, inconvenience and discomfort involved in donating (in direct parallel to the language used in first-in-human trials), or as a form of remuneration. We draw further on parallels with healthy volunteers in first-in-human trials by recommending that donors coming forward in this way should be regarded as research participants, with all the associated protections.**

Tissue

- 6.82 In Chapter 3, we highlighted how there is not a general 'shortage' of tissue, whether donated during life or after death, for therapeutic purposes. The issues arising in the donation of tissue for research purposes are rather different. Two main issues were signalled in Chapter 3: first

that access to tissue provided by living donors may be problematic, primarily for procedural reasons; and second that the systems currently in place to facilitate organ donation after death are not similarly well-calibrated to ensure that those willing to donate tissue are able to do so.⁶³⁹ We also note the UK research examined by our evidence review on motivations and barriers to donation: when patients are asked to consent to the future research use of their 'abandoned' tissue, including for commercial purposes, an overwhelming majority are willing to do so (see paragraph 6.7). While we accept that this evidence derives from just one study (albeit with a large cohort), we also note other examples of practice where, if asked, patients have shown themselves very willing to agree to research use (see Box 3.2). We also mention the experience of UK Biobank, which has succeeded in recruiting half a million volunteers from the general population (i.e. not within the context of being patients) to donate samples and provide detailed health information in order to contribute to long-term research.⁶⁴⁰ We conclude that the difficulties experienced by researchers in obtaining tissue for their research do not derive from individuals' general unwillingness to consent to such use, nor from a lack of interest on the part of patients or the general public in contributing to the communal good of research, but rather to an absence of systems to ensure that this willingness is harnessed. We return to this issue in Chapter 7.

First-in-human trials

- 6.83 Payments for healthy volunteers participating in first-in-human trials are routinely described as payments in return for time or inconvenience (see paragraph 2.37). While such payments could potentially be described as recompense for the losses (financial and non-financial) incurred in volunteering, rather than as reward, in practice it seems fairly clear that, for most volunteers, payment constitutes a primary reason for participation. This suggests that the current system is in fact an example of a non-altruist-focused intervention, on rung 6 of our Ladder. However, while we acknowledge the limited scope of the literature we were able to review, the studies included provided some indications of mixed motivations among participants, with a number of participants emphasising their interest in contributing to scientific progress, alongside their response to financial incentive (see paragraph 6.9).
- 6.84 We have already emphasised that non-altruist-focused interventions are not necessarily unethical: their ethical acceptability will depend on the context in which they are deployed. Moreover, as we have just argued in the context of donating gametes for research, where those who may benefit from the actions of the healthy volunteer are more remote (and may indeed never materialise), the key value here underpinning solidarity may not be altruism on the part of volunteers, but rather justice on the part of others in relation to the way they treat the volunteer.
- 6.85 Using the check-list set out paragraph 6.26, we therefore consider the **welfare** of the participant, any possible threat to the **common good**, the role of **professionals**, and the strength of the **evidence** in respect of all of these factors. We note that:
- Except in exceptional cases, the welfare of the volunteer in the UK is not usually compromised as long as trials are well-run, and it is the role of ethical and scientific scrutiny to keep those risks acceptably low.
 - Payment for participation in trials is currently the norm in the UK, as elsewhere, and appears to co-exist with an interest on the part of at least some healthy volunteers in contributing to the communal benefits of research. There is no evidence to suggest that payments made in this area have in any way served to undermine solidarity with respect to the donation of bodily material more generally.

⁶³⁹ Both issues were raised by delegates at a recent conference organised by the Human Tissue Research Network. See: <http://www.humantissuerechnetwork.com/Summit2011.aspx>.

⁶⁴⁰ UK Biobank (2010) *UK Biobank: improving the health of future generations*, available at: <http://www.ukbiobank.ac.uk/>.

- There is little evidence to suggest that professional ethics are currently compromised by payments; indeed it has been argued that the tendency to offer *modest* payments to combat anxieties over „undue influence“ creates injustice in that it is more likely to attract primarily those who are less well-off or in more urgent need of money.⁶⁴¹

6.86 We conclude that payment for participation by healthy volunteers in first-in-human clinical trials within the UK constitutes an example of an ethically justified rung 6. In relation to the factors we have been considering, therefore, there is no reason to challenge the payment for participation by such volunteers in first-in-human clinical trials. **The major risk from the payment system to the welfare of the volunteer lies not in participation in the trial itself, but in the medical risks involved when volunteers take part in repeated, or even concurrent, trials.** Further aspects of concern become relevant in countries without universal health care systems: these include the possibility that participants may not receive appropriate monitoring and follow-up care, and may not be eligible to participate on an equal basis in their country's own health care system.⁶⁴² We return to these wider concerns in Chapter 7.

⁶⁴¹ Iltis AS (2009) Payments to normal healthy volunteers in phase 1 trials: avoiding undue influence while distributing fairly the burdens of research participation *Journal of Medicine and Philosophy* **34**: 68-90.

⁶⁴² Elliott C, and Abadie R (2008) Exploiting a research underclass in phase 1 clinical trials *New England Journal of Medicine* **358**: 2316-7.