Chapter 7

Actions addressing organisations

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Chapter overview

In this concluding chapter, we consider the role of organisations (public, private and voluntary), and the state in facilitating donation. With respect to 'public' interests in donation, we argue that:

- The state has a 'stewardship' role in relation to promoting good health in the population, in facilitating the donation of bodily materials, and in taking action to reduce inequalities with respect to access to donated materials.
- Changing patterns of behaviour in the population contribute to increasing levels of disease and in turn to increasing demand for organ transplants. Policy-makers and health professionals concerned with organ transplantation should explicitly highlight how improved public health measures would help lessen the 'gap' between demand for, and supply of, donor organs.
- Medical research, and the health benefits it seeks to bring, are of vital public interest. That public interest is not extinguished by the private financial gains that may also accrue as a result of research carried out within the commercial sector.
- National self-sufficiency in the supply of bodily materials is a laudable aim. However, where national self-sufficiency cannot be achieved without taking action that would otherwise be regarded as unethical, the fact that people may still choose to travel abroad should not force a change of policy.
- We endorse the current international consensus that 'organ trafficking' and „transplant tourism' should be banned. We further recommend that the WHO should develop appropriate guiding principles to protect gamete donors from abuse or exploitation.

Our conclusions and recommendations with respect to the facilitation of particular forms of bodily material include:

- The Department of Health should monitor closely how current organisational changes within the English NHS may affect organ donation services, and be prepared if necessary to act to protect systems that have been shown to work well.
- The possibility of donating material after death for research purposes, as well as for transplantation, should be made more explicit in the documentation produced about deceased donation.
- People donating material for research purposes, or volunteering in first-in-human trials, should be treated as partners in the research, and their ongoing interest in the progress of the research recognised.
- Good governance systems, accompanied by transparency of process, are an essential requirement if potential donors are to have the trust necessary for them to contemplate donation in the first place.
- Once donated for research purposes, material should be regarded as a public good: researchers should make the most efficient use of it possible, and must be willing to share it on the basis of scientific merit.
- A national or regional 'donor service' should be established, to provide a coherent and managed infrastructure for egg and sperm donation, on the lines of the structures currently in place for organ donation.
- Where fertility clinics and professionals within the UK make arrangements to refer patients to clinics and professionals abroad, they should share professional responsibility for the general standards prevailing at the receiving centre, including the protocols used to recruit egg donors and the routine measures taken by the clinic to safeguard the welfare of donors.
- The registration of healthy volunteers in first-in-human trials on a national database should be a compulsory requirement for ethical approval of such trials, in order to limit the harms of 'over-volunteering'.

Introduction

7.1 We described earlier how the difference between levels of demand and levels of supply for various forms of bodily material have triggered calls for the creation of incentive systems. We have set out in Chapters 5 and 6 our conclusions with respect to a range of ethical considerations that should be borne in mind by policy-makers when responding to such calls. However, we have also highlighted repeatedly throughout this report our conviction that the focus on individual motivation, as exemplified by the call for incentives, is only one aspect of a much bigger picture when considering the ethical challenges raised by the donation of bodily material. In Chapter 1 we emphasised the 'transactional' nature of donation (see paragraph 1.28) and highlighted how organisations and institutions, such as licensed clinics and biobanks,

act as intermediaries between donors and recipients.[643] The role of these intermediaries forms the focus of the present chapter. Where the state and its agencies act to affect individual decision-making, this has been treated under Chapter 6. Here in Chapter 7 we are concerned with the infrastructure and support systems that facilitate donation; with the role of organisations and institutions, including non-state institutions such as professional organisations, the voluntary sector and faith groups; and also with the role of the state itself, as both legislator and service-provider. Given the crucial role played by intermediaries in almost all aspects of donation, we acknowledge that this division is not always clear. But we think it is nevertheless very helpful in drawing attention to the many ways in which donation may be facilitated – or alternatively the ways in which the need for donation may be reduced – by action at professional, organisational, and state level. Such action, we further suggest, can be construed as an ethical responsibility.

7.2 The second part of this chapter (see paragraphs 7.28 and following), considers what 'facilitating' donation might mean for different forms of bodily material: such facilitation might include factors such as the accessibility of services for potential donors; the way potential donors are approached; the structures in place to ensure that consent is sought at the appropriate time and documented in a way that will maximise future use of the material; and funding arrangements for services. The key questions here for each form of bodily material are: *What barriers are there to making the best possible use of the material that people are willing to donate – and how can these barriers be removed?* Before we consider these material-specific issues, however, we highlight a number of over-arching questions that we believe policy-makers need to address:

- What action can be taken at national, or organisational, level to *reduce* the need for bodily material?
- What action can be taken at national, or organisational, level to promote the availability of alternatives to bodily material?
- On what basis do we distinguish between matters of public and private concern?

Each of these issues is considered in more depth below.

Preventive action

7.3 Chapter 3 emphasised some of the factors (social and scientific) both driving and, in some cases, reducing demand for bodily material. We return here to the question of the public health factors that are playing a significant role in increasing demand for bodily material, in particular for organs for transplant and for gametes for fertility treatment (see paragraphs 3.48 to 3.49). Changing patterns of behaviour in the population, including diet, physical activity and consumption of alcohol, contribute to increasing levels of cardiovascular disease, liver failure, and, to a lesser extent, kidney failure. Fertility declines with age and hence the later motherhood is attempted, the more difficult pregnancy is to achieve with a woman's own eggs. In other words, 'demand' for these materials is not a simple unmodifiable 'fact'. However, these potentially modifiable public health factors appear to be almost entirely absent in the general debate about the difficulty in meeting demand for bodily material.

7.4 We emphasise here that this report is *not* concerned with the issue of how materials in short supply should most ethically be allocated for treatment. Thus we are not concerned here with the question of whether lifestyle factors should be used in determining who should have priority in receiving an organ or donated gametes. Indeed, in its 2007 report *Public health: ethical issues* the Council highlighted that there are significant ethical difficulties inherent in taking such an approach, and **we endorse here the current approach to the allocation of bodily material based on clinical factors, such as the urgency of the person's condition and the compatibility of the available material**. Rather, we are considering the issue from a policy

[643] 'Recipients' include both individual patients, and researchers/research organisations using bodily material in their research.

perspective and asking the question: *What action should policy-makers take in response to these public health challenges?* In the context of organs, the challenge is often put to policy-makers that the current shortage constitutes a national emergency, in response to which radical measures would be justified.[644] We highlight here the central role of public health initiatives in limiting the scale of that emergency in the first place.

7.5 Governmental, regulatory and professional bodies are currently grappling with the broad question of how the current demand for a wide range of bodily material may better be met in a variety of ways. Examples include the establishment of the ODT by UK health departments (see paragraph 3.52); the ongoing call for a shift to an 'opt-out' system for deceased organ donation by the British Medical Association;[645] and the consultation in early 2011 by the HFEA on how sperm and egg donors should be compensated (see paragraph 2.35). Notably absent from these public discussions is consideration of how demand could be reduced by preventive public health action.[646]

7.6 In the case of organ transplants, we recognise, of course, that there are many existing public health initiatives that aim to reduce levels of (among others) the diseases that contribute to the growing demand for donor organs. **We argue that it is crucial that the policy-makers and health professionals concerned with organ transplantation should also explicitly highlight these contributory causes in relation to the 'gap' between demand for, and supply of, donor organs. In so doing, they could both add weight to the arguments surrounding the role of government in promoting good public health, and also act to raise public awareness of the avoidable causes of some organ failure**.

7.7 As we have noted in several other contexts in this report, the position regarding gametes is rather different from that of organs. While it is broadly accepted that it is appropriate for the public health agenda to include consideration of sexually transmitted diseases such as chlamydia that may impact on later fertility, there is no such consensus that any state-sponsored organisation should seek to influence childbearing patterns, such as the age at which women have children. We note, however, that the state *has* taken a role in discouraging teenage pregnancy,[647] and that NICE guidelines on fertility services specifically refer to age, in that the recommendations on access to IVF services apply to women aged between 23 and 39 years.[648] There is thus a precedent in public interest in the age of childbearing. As we emphasised earlier (see paragraph 3.49), the factors that influence the age at which women have their first child are complex – and many relate to social and economic issues well outside the range of this report. Nevertheless, we suggest that there is a potential role here for public health education and advice to improve awareness among women about the consequences of delaying childbearing.

Alternatives to donation

7.8 Chapter 3 sets out a number of ways in which scientific developments may potentially decrease demand for donated material, either through reducing the levels of need that arise in the first place, or by providing artificial substitutes. Developments in the first category include:

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[644] See, for example, Spital A, and Taylor JS (2007) Routine recovery of cadaveric organs for transplantation: consistent, fair, and life-saving *Clinical Journal of the American Society of Nephrology* **2**: 300-3.

[645] British Medical Association (2 July 2011) *Doctors stick with opt-out organ donation policy*, available at: http://web2.bma.org.uk/nrezine.nsf/wd/RTHS-8J9KX8?OpenDocument&C=2+July+2011.

[646] We note, however, that this issue does arise when considering the particular difficulties faced by some ethnic communities in accessing compatible organs: see Randhawa, G (2011) *Achieving equality in organ donation and transplantation in the UK: challenges and solutions*, available at: http://www.better-health.org.uk/sites/default/files/briefings/downloads/health23-3.pdf.

[647] See, for example, the work of the Teenage Pregnancy Independent Advisory Group, which published its final report in 2010: Teenage Pregnancy Independent Advisory Group (2010) *Teenage pregnancy: past successes - future challenges*, available at: http://education.gov.uk/publications/standard/publicationDetail/Page1/TPIAG-FINAL-REPORT.

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

- techniques that may enable those wishing to conceive to use their own gametes, for example through the use of intracytoplasmic sperm injection (ICSI), pre-implantation genetic diagnosis (PGD), and developments in egg freezing (paragraphs 3.44 to 3.46); and
- techniques that extend the life of transplanted organs, hence reducing demand for subsequent transplants (paragraph 3.35).

Work on artificial substitutes includes:

- the possibility of using technological devices in place of a donated organ, such as the use of left ventricular assist devices (LVADs) to replace, rather than bridge the gap before, heart transplants (paragraph 3.36);
- the development of artificial bodily materials such as blood, corneas, and skin (paragraph 3.42);
- regenerative medicine, where stem cells may be used to repair the original damaged material (paragraph 3.41);
- other uses of stem cells, from the creation of platelets to the use of cells to create tissue on which new medicines could be tested (paragraphs 3.39 to 3.40); and
- xenotransplantation, such as the use of pigs' heart valves (already routine) in heart operations (paragraph 3.43).

7.9 The Council has not considered the merits or promise of any particular development in reducing demand for bodily material in the future. It seems clear, nevertheless, that in some areas of medicine at least, such developments are likely to start playing a role in meeting need that, in the past, might have been met by donated material. The speed at which this may happen, however, should not be over-estimated: what appear to be exciting research results often take many years before developing into routine procedures. It may well also be the case that, in so doing, they act not to *replace* demand for bodily material, but rather to *supplement* it, with the end result being more patients treated, but just as many (or more) still waiting (see paragraph 3.26). It is therefore exceedingly hard to make any meaningful predictions as to whether, and to what extent, demand for any particular form of material might drop in the future. We do, however, make the following observations:

- These developing areas pinpoint the importance of research within the donation field. Research on the optimisation of organs donated after death, with the aim of improving transplant outcomes, for example, may lead to a good outcome in itself (longer graft life) and at the same time reduce the need for other bodily material (by reducing the need for re-transplantation). This demonstrates how closely entwined 'treatment' and 'research' may be, and the very direct personal benefits that may be felt from research. We return to this point below (see paragraph 7.16).
- We therefore welcome the fact that medical research has been protected in the current very difficult funding environment, and welcome the commitment thus shown to the high value of such research.
- We highlight the importance of ensuring material is available for research, a point to which we return below (see paragraphs 7.40 to 7.41 and 7.45 to 7.63).
- We also note that some, at least, of the developments might be regarded not just as alternatives to donation, but indeed as preferable to the use of donated material: the ability to use one's own (frozen) eggs rather than donated eggs being one example. Other developments might be regarded as more neutral replacements: the main criterion, for example, in choosing between a donated cornea and an artificial cornea if available, would be likely to be clinical safety and effectiveness, rather than source.

Public and private concerns

7.10 The themes of 'public' and 'private' activity have emerged repeatedly throughout this report, and Chapter 4 analysed the complex ways in which they often interact (see paragraphs 4.5 to 4.6). Any consideration of the role of intermediaries, whether in the form of individuals or of

organisations, inevitably raises the question of what is a matter of public interest (with the connotation that the state or state-sponsored organisations, in particular, might have duties to act); and what is essentially private (in this context emphasising non-interference by the state). Chapter 5 set out the view that the "the ongoing good health of members of society" provides a strong ethical basis for attempting to meet the health needs highlighted by the demand for bodily material – whether through public health measures or through ethically acceptable ways of increasing supply. We have indicated various 'public' initiatives that could contribute towards this aim, in the form of public health interventions likely to reduce demand, and in the form of active support for medical research that may reduce demand or provide substitutes for supply. Here we consider the wider implications for policy of the various (and interlocking) public and private aspects of donation.

7.11 First we consider explicitly the **role of the state** in responding to the mismatch between demand and supply for bodily material in medicine and research. We have alluded above (see paragraph 7.4) to the way that 'policy-makers', such as government and governmental organisations, parliaments, and relevant professional organisations, are often called upon to present solutions to this mismatch; and we gave some examples of how they have responded in paragraph 7.5. Such a discourse suggests a strong belief within the regulatory establishment, the media, and (arguably) the wider general public, that some forms of donation are indeed a matter of great 'public' interest: that if needs that are widely seen as being legitimate (the need for blood and for organs for transplantation reflecting perhaps the broadest area of consensus) are not being met, then it is the 'job' of 'those in charge' to take action.[649] We have already suggested that the potential benefits to health to be achieved through the donation of bodily material for treatment and research represent a sufficient ethical justification for taking action, within ethical limits, whether this takes the form of reducing demand or increasing supply. Such conclusions, however, leave open the question of who or what (if anyone) is responsible for ensuring such interventions take place.

7.12 We return here to the idea of the state as the 'steward' of good health presented in our earlier report *Public health: ethical issues*. As we suggest in Chapter 5, such a 'stewardship model' sets out a clear obligation on the part of states to enable people to live healthy lives, both by promoting and facilitating healthy lifestyles and by taking positive action to remove inequalities that affect disadvantaged groups or individuals (see paragraph 5.13). Many of the specific recommendations in that earlier report, particularly those relating to obesity and excessive alcohol use, are clearly highly relevant to the subject of this report. **However, we also conclude that the underpinning concept of the state as steward of public health is equally applicable to the responsibilities of states with respect to the donation of bodily materials**. We endorse the views of those respondents to our consultation who saw responsibility as appropriately resting with the state, while noting at the same time the common-sense constraint that, while organisations may have responsibilities, only individuals have the bodies from which bodily material may come.[650]

7.13 In our view, this stewardship role is as applicable to the donation of reproductive material as it is to other forms of bodily material, notwithstanding the view (very firmly expressed by some) that fertility is purely a private concern.[651] As we have noted earlier, the state does already take a role in regulating fertility treatment via the Human Fertilisation and Embryology Act and the HFEA; there is public policy guidance from NICE recommending that publicly-funded IVF treatment should be made available to all eligible women; and it is widely accepted that the state should have a role in protecting the welfare of children. We conclude that the donation of

[649] Department of Health (20 December 2010) *Andrew Lansley urges people to give blood*, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_122978.

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

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

reproductive materials is a matter of public, as well as private, concern, as reflected in our recommendations.

7.14 We have emphasised that the role of the stewardship state also includes taking action to minimise inequalities and to promote the welfare of those who would, without positive action, be excluded from benefits or services. In the context of donation, we point to the statistics that demonstrate that BME populations are significantly less likely to become donors (across a range of different forms of bodily material) and hence are also significantly less likely to benefit from materials where immunocompatibility is an issue, because acceptable 'matches' are more likely to be found within ethnic populations (see, for example, paragraph 3.28).[652]

7.15 In Chapter 6, we suggested that one conclusion that could be drawn from the limited literature we were able to review on people's attitudes to donation was that individuals differ markedly in their instinctive attitudes towards and anxiety about donation (in the context of both blood and deceased donation). We concluded that it might therefore be more practical to focus organisational efforts on reaching those individuals who are not particularly troubled by these anxieties (see paragraph 6.11). However, such an approach will only be appropriate where it is irrelevant *who* donates as long as sufficient material overall is obtained. Where immunological differences mean that low levels of donation from particular ethnic communities translate directly into particular difficulties of access for potential recipients from these communities, then this leads to clear difficulties for the NHS in responding equitably towards all its patients. **We therefore suggest that a stewardship state has a direct responsibility to explore the reasons why some populations are hesitant to donate, and if appropriate, to take action to promote donation**.

7.16 Second, we consider the issue of **research**. It is only too easy for any consideration of the donation of bodily materials to concentrate on their use in direct treatment, and overlook, or take as of secondary importance, their possible research uses. We have, however, highlighted very clearly in Part I of this report the central role that bodily materials play in research, and how difficulties in access to the necessary tissue are acting in some cases as the key factor limiting progress in research (see paragraph 3.21). Paragraph 7.9 notes the direct links that may exist between research and meeting needs for bodily material. **We state here our view that research, and the future health benefits that research seeks to bring, are of vital public interest**. If we argue (as we do) that the state has an interest in promoting the good health of its citizens, and has a role as a steward in supporting and facilitating environments in which good health may flourish, then such an interest will also include supporting and facilitating environments in which health-related research may flourish. We have highlighted elsewhere in this report that the difficulties experienced in accessing tissue for research are essentially different in kind from the 'shortages' described in other fields: the available evidence suggests that, if asked, plenty of people are more than willing to permit their tissue to be used for research purposes (see paragraph 6.82).[653] The difficulties that arise relate therefore not so much to encouraging people to consider donating, but rather in the need for much better systems to be in place to ensure that consent is sought and documented appropriately; and that materials are appropriate shared.

7.17 Much health-related research using tissue or healthy volunteers is, of course, carried out within the private (i.e. commercial) sector. **We consider, however, that while such research may lead to significant financial gain, such private interests do not in themselves extinguish the public good of what they produce**: that is, the treatments and medicines on which all health systems (public and private) and individual patients (private individuals, members of the

[652] Morgan M, Hooper R, Mayblin M, and Jones R (2006) Attitudes to kidney donation and registering as a donor among ethnic groups in the UK *Journal of Public Health* **28**: 226-34.

[653] We note here that the donation of gametes for research raises very different issues from other forms of material, and we return to this subject separately later in this chapter.

public) rely. It is worth pointing out that, while most members of the public will not, at any point in their lives, directly benefit from donated blood, organs or gametes, almost all will benefit in some way from new medicines developed using donated tissue and tested on healthy volunteers.

7.18 We note the concerns that financial gain arising out of material that has been donated freely may be seen by some as 'unjust enrichment'. We do not, however, support the argument that the individual whose donated bodily material has been used in research that ultimately leads to high financial returns should, in retrospect, exercise a claim to share in these profits on a personal level. Any commercial return would be many years after the initial donation, and the particular contribution of any individual would in most circumstances be impossible to measure. We suggest therefore, that although it is clearly just that commercial companies in such circumstances should seek in some way to share the financial benefits of their research more widely, such benefit sharing should take place in a wider context, rather than in response to the financial potential of bodily material from particular individuals.

7.19 Two potential ways in which such benefit sharing or partnership might emerge include, first, active financial support from the commercial sector for tissue banks as a 'public good' for researchers from all sectors; and second the development of ongoing relationships between tissue donors and the research teams (whether in the public, voluntary or commercial sector) whose work depends on access to their samples. Such a relationship between donors and recipients (in the form of research organisations) provides one way in which the 'gift relationship' between donor and recipient may be both maintained and mutual (see paragraph 5.68), and the donor's 'interest' in their donated material maintained. Such a 'relationship' should not, of course, be imagined as a personal relationship: rather, the donor should be treated (if they wish) as part of a community of research participants that is recognised as such.[654] We note also here that the role of consent at the point of donation, including clear information about possible commercial uses, is clearly central in ensuring ethical treatment of donors in this respect. We return to issues concerning research in more detail below (see paragraphs 7.45 to 7.63).

7.20 Third, questions of what is public and what is private also apply to the question of **property rights in bodies and body parts**. We have already argued that, in the context of the relationship between persons and their bodily material, we need to unpack donors' rights with respect to control over their bodily material, and to ensure that these are appropriately safeguarded (see paragraphs 5.15 to 5.20). While the legislative frameworks of the Human Tissue Act and the Human Fertilisation and Embryology Act provide some mechanisms for such safeguarding, particularly with respect to consent, they are far from complete: we note, for example, that the Court of Appeal in the case of *Yearworth* felt it necessary to recognise men's property rights in their own sperm in order to provide them with a remedy for the harm caused to that sperm when in the custodianship of an NHS hospital (see paragraph 2.32). Unless a wider range of remedies for the source of material (for example compensation if donated materials are used outside the scope of the granted consent) is developed through legislation, it seems likely that further attempts will be made in the courts to develop property rights to protect donors' interests. **We recommend that, by whatever means the law develops in this area, a clear distinction should be retained between the property rights of the source of the material with respect to control and compensation (that is, compensation for misuse rather than recompense in the form of economic gain), and property rights with respect to income**.

7.21 A separate issue arises in connection with the legal status of bodily material once separated from its source. As we noted in Chapter 2 (see paragraph 2.31), where material has been modified by human skill, then it may become the subject of 'full' property rights and be subject to sale, transfer and so forth, like any other commodity. Given that such modified materials are now part of a global marketplace, and taking into account the importance of intellectual property rights in enabling research to continue, it is hard to see how this could be otherwise without

[654] Note, for example, the use of the terminology of „supporters" for those who contributed their health-related information and samples to UK Biobank.

challenging the whole basis on which such transactions currently take place. However, we do raise the question as to what degree of 'modification' or 'skill' should be necessary to achieve this change into a straightforward commodity. Case law has given conflicting answers,[655] with the Court in *Yearworth* most recently suggesting that freezing in liquid nitrogen alone might be sufficient. Such lack of clarity adds to the uncertainty around the legal status of materials that are donated for transplantation: for example, the status of an organ that is being treated prior to transplantation. We suggest that where material is clearly being held (and possibly treated in some way) for the purpose of transplantation, it should be conceptualised as being in the 'custodianship' of third parties. Such a model of custodianship would include rights of possession and use, but only for the purposes envisaged in the original consent. It would also include remedies, for example against misuse or interference by other third parties.

7.22 Finally, we raise the question of public interest in the issue of cross-border health care and questions of **national self-sufficiency**. We have already noted at least one important distinction between travelling abroad for organ transplants and for fertility treatment: in the first case most treatment will be unregulated, depending on organs made available through illegal markets;[656] while in the second case the treatment, using gametes supplied in return for a fee (and also probably anonymously), would be unlawful in the UK, but not necessarily in the country in which it takes place. In Chapter 6 we endorsed the current UK position that no payments should be offered for organs above and beyond the direct reimbursement of costs incurred as a result of the donation (see paragraph 6.40). In accordance both with our conclusions as to the difficulties inherent in systems involving financial rewards for organs, and with the fact that no country in the world provides legal organ transplants from incentivised donors to those travelling from abroad, **we endorse the current international consensus, expressed through the Declaration of Istanbul, the WHO Guiding Principles and other statements, that 'organ trafficking' and „transplant tourism' should be banned. We further emphasise the importance of concerted action being taken to enforce this stance, so that such practices cannot continue with impunity**.

7.23 The situation, however, is potentially rather different where the activities in question – for example the selling of gametes – are perfectly legal in the country of origin. The question then arises whether there can be any public interest in seeking to exert control over individuals travelling abroad to access such treatment, or over NHS institutions obtaining materials that have been provided in such circumstances. The guidance on cross-border reproductive care issued in 2011 by ESHRE cited earlier in the context of reward for donors (see paragraphs 6.67 to 6.69) is also relevant in considering the regulatory aspects of the current position, where women and couples travel from the UK to other countries, either in order to be able to access donor gametes more easily, or to be able to access treatment not permitted in the UK, such as the use of anonymously donated gametes. We have already suggested (see paragraph 5.12) that concerns about individual liberty make it hard to imagine circumstances in which individuals seeking treatment that is lawful in the destination country should be prevented from travelling. However, there is a challenge here for UK regulators: if clinics and doctors regulated within the UK refer patients abroad for treatment that is forbidden in the UK, what, if any, action should (and could) they take? On the one hand, it may be argued that activities taking place legally in a non-UK jurisdiction are simply outside the sphere of interest or influence of UK regulatory bodies. On the other hand, where clinics set up established relationships with clinics in other

[655] Mere preservation was not enough according to *Dobson*, but in *Yearworth* the Court apparently thoughts that freezing in liquid nitrogen would be sufficient: *Dobson v North Tyneside Health Authority* [1997] 1 WLR 596; [1996] 4 All ER 474; *Yearworth and others v North Bristol NHS Trust* [2009] EWCA Civ 37.

[656] We exclude from our consideration here cases where individuals travel to another country in order to receive a voluntarily-donated transplant from a relative, although we note that, as in any such donation in the UK, factors of genuine voluntariness may remain. 'Transplant tourism' is defined in the Declaration of Istanbul as follows: “Travel for transplantation becomes transplant tourism if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals, and transplant centres) devoted to providing transplants from outside a country undermine the country's ability to provide transplant services for its own population”.

countries, and professionals, then directly refer patients within these arrangements, it is hard to argue that the professionals and organisations based in the UK have no professional responsibility for the standards prevailing at the receiving clinic.

7.24 ESHRE takes the view that "if a home practitioner refers the patient to a specific clinic, the practitioner shares a responsibility for the general standards used in that center (such as the complication rate). The specific treatment of the individual abroad remains the responsibility of the local professional team."[657] We agree. **We conclude that, where clinics and professionals within the UK make arrangements to refer patients to clinics and professionals abroad, they should share professional responsibility for the general standards prevailing at the receiving centre. Such „general standards" include factors such as the protocols used to recruit donors (with particular reference to the hazards of using intermediate agencies for such recruitment) and the routine measures taken by the clinic to safeguard the welfare of donors. Regulatory bodies such as the General Medical Council should maintain general oversight in this area, in the same way as they oversee other aspects of professional standards**.

7.25 We further note that, while the ESHRE guidance highlights the importance of protecting against the abuse of donors coming from abroad, and guarding against trafficking, in the European context, these concerns clearly arise worldwide. We also note that various international statements on the donation and use of bodily material, such as the WHO Guiding Principles, exclude reproductive material from their remit. **We recommend that the World Health Organization should develop appropriate guiding principles to protect egg donors from abuse or exploitation**.

7.26 As we have pointed out elsewhere, once bodily material has been separated from its source, it too, readily crosses borders: for example, much of the plasma used in the UK comes from abroad sourced from paid blood donors.[658] We make the following observations:

- Transparency, for example with respect to where material has come from, and the circumstances in which it has been obtained, is essential. One way of achieving such transparency might be through a 'fair-trade' labelling system, building on the requirements set out in the EU Tissues and Cells Directive that all material imported from third countries should meet the same quality and safety standards required within EU countries.[659] Legislation is, of course, only one way of ensuring such standards are met, and we note here the influence of professional standards and practices in this area.[660]

- Where payment is currently made to such donors, the same concerns set out in paragraph 6.26 (with respect to the welfare of the donor, the potential threat to the common good and so forth) should be considered, in order to determine whether such payment is acceptable. In the case of plasma, for example, given the importance of the need for plasma, the difficulties in sourcing it at present in the UK because of the theoretical risk posed by vCJD, and the highly regulated nature of the donor recruitment and quality systems,[661] it would seem likely that those tests would be met, and hence that reward for donors in these circumstances would constitute an ethically vindicated rung 6 of our Intervention Ladder.

7.27 The considerations outlined above are mainly concerned with the nature and extent of the public interest in acting to limit private decisions to travel abroad for treatment or to carry out research. However, we also need to consider to what extent there is a public interest in seeking

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[657] Shenfield F, Pennings G, De Mouzon J *et al.* (2011) ESHRE's good practice guide for cross-border reproductive care for centers and practitioners *Human Reproduction* **26**: 1625-7, paragraph 2.5.
[658] BPL, personal communication, 10 June 2011; BPL (2011) *About plasma*, available at: http://www.bpl.co.uk/about-plasma/.
[659] EU Directive 2004/23/EC, Article 9.
[660] See, for example, the role of The British Association for Tissue Banking and the UK Stem Cell Bank: The British Association for Tissue Banking (2011) *The British Association for Tissue Banking homepage*, available at: http://www.batb.org.uk/; UK Stem Cell Bank (2011) *UK Stem Cell Bank homepage*, available at: http://www.ukstemcellbank.org.uk/.
[661] See, for example, BPL (2011) *About plasma*, available at: http://www.bpl.co.uk/about-plasma/.

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

Implications for intermediaries by form of material

Blood

7.28 The various systems currently in place within the UK for facilitating blood donation clearly already seek to minimise physical barriers for those inclined to donate: examples include the wide-ranging use of mobile donation units and the encouragement of 'workplace' donation. Indeed, the work of the NBS in bringing the possibility of blood donation directly into potential donors' day-to-day lives might be regarded as a model of this particular approach.

7.29 Barriers to blood donation are not, of course, only physical, and as in organ donation there may be other factors hindering particular communities from feeling able to donate. As we noted in Chapter 6 (see paragraph 6.11), the fact that some groups may be more troubled by the idea of donation than others, and hence less likely to respond to generalised appeals to donate, may not be important where only the *quantity* of total donations is relevant. However, such differences become very important if factors such as immunological requirements mean that lower donations from particular communities render the NHS unable to respond to patient need in an egalitarian way (see also paragraph 7.36). In such circumstances, we consider that the intermediary organisations concerned, such as the NBS, have a duty to engage with communities, both through dialogue to seek to understand concerns, and through direct promotion of the benefits of donation to the community. We commend here the work of the NBS and the African Caribbean Leukaemia Trust, for example, in initiatives such as Daniel De-Gale week, to encourage both blood and bone marrow donation from black and mixed race communities.[662]

7.30 By contrast with blood donation by adults, the idea of obtaining **cord blood** from the umbilical cord, in order to obtain stem cells from a baby at birth, has been much more controversial. Concerns have been expressed about the possible risk to the baby or mother if the management of the third stage of labour is altered or delayed in order to promote successful cord blood collection;[663] and the issue has been further complicated by the growth of private cord blood banks which offer to store a baby's cord blood for his or her own future use, although the value of this is challenged (see paragraph 1.8).

[662] See: NHS Blood and Transplant (2010) *Daniel De-Gale week*, available at: http://www.blood.co.uk/news/news-and-events/daniel-de-gale-week/.

[663] The Royal College of Obstetricians and Gynaecologists notes that there is considerable debate about the optimal time for cord clamping: Royal College of Obstetricians and Gynaecologists (2006) *Umbilical cord blood banking (Science Advisory Committee opinion paper 2)*, available at: http://www.rcog.org.uk/files/rcog-corp/uploaded-files/SAC2UmbilicalCordBanking2006.pdf, paragraph 5.1.

7.31 'Public' cord blood banking, on the other hand, is widely recognised as providing a vital source of stem cells, supplementing the availability of stem cells available for treatment through bone marrow donation and increasing the chance that a suitable 'match' will be found for waiting patients.[664] The NHS Cord Blood Bank and the Anthony Nolan Trust both collect cord blood from maternity services serving very ethnically mixed populations, with the aim of collecting the greatest variety of tissue types and hence addressing the problem of difficulties in matching minority ethnic populations, and particularly mixed race people, for an adult bone marrow transplant.[665] The Royal College of Obstetricians and Gynaecologists has offered specific recommendations to NHS trusts with respect to cord blood collection, advising that there should be no alteration in the usual management of the third stage of labour, and that cord blood should be collected by a trained third party, not the doctor or midwife in charge of labour. In particular the College has commended the practice of the NHS Cord Blood Bank of collecting blood "aseptically after delivery of the placenta by trained NBS staff within the delivery unit but outside the delivery room."[666]

7.32 We note the growing evidence as to the potential value of publicly-accessible sources of stem cells,[667] and the procedures recommended by the Royal College of Obstetricians and Gynaecologists to protect the welfare of mothers and babies where cord blood donation is considered. We further note the role of the HTA in licensing cord blood collection.[668] We conclude that the collection of cord blood in these circumstances for public use is an example of a justified public intervention, and endorse the work of the NHS Cord Blood Bank, Anthony Nolan Trust and others in facilitating the collection of cord blood for this use. We further note the recent report from the UK Stem Cell Strategic Forum which has called for an increase in the UK's 'inventory' of cord blood from 15,500 units to 50,000 units.[669] In particular, it recommended that a UK Stem Cell Advisory Forum should be established in order to manage a UK cord blood inventory, along with a UK stem cell registry and a database of patient outcomes following transplantation. **We endorse these recommendations**.

Organs

7.33 As we noted at the end of Chapter 5 (see paragraph 5.85), an approach to the donation of bodily material that focuses on intermediary professionals and organisations is far from novel. Such an approach was at the heart of the recommendations made by the ODT, which sought to "resolve the problems that result from the unstructured and fragmented arrangements that are currently in place for [deceased] organ donation and, to a lesser extent for organ transplantation."[670] Concrete recommendations included the introduction of a UK-wide network of organ retrieval teams; 'potential donor audits' to identify those who might after their death be able to donate organs; financial reimbursement to hospitals to ensure that hospitals where donors died were not financially disadvantaged; and a requirement for clinical staff involved in

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[664] Ibid, paragraph 4.1; other advantages cited here include lower incidence of viral transmission and lower incidence and severity of graft versus host disease.

[665] See: NHS Blood and Transplant (2011) *Cord blood donation: frequently asked questions*, available at: http://www.nhsbt.nhs.uk/cordblood/faq/.

[666] Royal College of Obstetricians and Gynaecologists (2006) *Umbilical cord blood banking (Science Advisory Committee opinion paper 2)*, available at: http://www.rcog.org.uk/files/rcog-corp/uploaded-files/SAC2UmbilicalCordBanking2006.pdf, paragraphs 7 and 5.1.

[667] The UK Stem Cell Advisory Forum, for example, has identified a need for unrelated stem cell donors, noting that in the UK over 400 patients with fatal diseases could benefit from a stem cell transplant, including through the use of stem cells obtained via cord blood: NHS Blood and Transplant (2010) *The future of unrelated donor stem cell transplantation in the UK,* available at: http://www.nhsbt.nhs.uk/pdf/uk_stem_cell_strategic_forum_report.pdf.

[668] See: Human Tissue Authority (2010) *Guidance document for establishments working with umbilical cord blood*, available at: http://www.hta.gov.uk/_db/_documents/Cord_Blood_Guidance_Document.pdf; Human Tissue Authority (2010) *Regulation of cord blood collection (procurement) by the Human Tissue Authority, letter dated November 2010*, available at: http://www.hta.gov.uk/_db/_documents/Cord_blood_communication_Nov_10.pdf.

[669] The NHS Cord Blood Bank, which collects cord blood from five hospitals in the London area, currently has an inventory of 15,500 cord blood units. The report recommends that the inventory should be increased to 50,000 cord blood units: NHS Blood and Transplant (2010) *The future of unrelated donor stem cell transplantation in the UK*, available at: http://www.nhsbt.nhs.uk/pdf/uk_stem_cell_strategic_forum_report.pdf.

[670] Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf, p21.

the treatment of potential organ donors to receive mandatory training in the principles of donation.[671] **The Working Party endorses the Organ Donation Taskforce's focus on tackling the structural problems that have, in the past, hindered the optimal use of the organs that are potentially available**.

7.34 However, an intrinsic element of such an approach is the secure embedding of systems to facilitate donation within the structures and organisations making up the NHS. Some aspects of these systems are managed on a central basis: these currently include the work of NHSBT itself, the 'specialist nurse – organ donation' (SN-OD) network managed by NHSBT, and the newly-established UK Donation Ethics Committee (UKDEC). Many other aspects are managed at local level, as part of local NHS services. Both centralised and local aspects of the English NHS are currently experiencing significant levels of organisational restructuring (see paragraph 2.5); moreover, while the NHS has been protected to a degree within the current spending round, there is continuing and ongoing pressure on health budgets.[672] **There is clearly a risk that, in the face of such organisational changes and pressure on budgets, valuable systemic improvements that have led in recent years to significant increases in the number of organs made available for transplantation might be lost. We recommend that the Department of Health should monitor closely the impact of these changes on organ donation services, and be prepared if necessary to act to protect systems that have been shown to work well**. We draw attention again here to our earlier recommendation that the Department of Health should act to ensure that living donors' expenses continue to be covered in full, despite the abolition of PCTs (see paragraph 6.41).

7.35 These changes in the NHS in England aim to make services more locally-responsive by putting the main drivers of change in the hands of 'consortia' of GPs.[673] While such changes are in their very early stages, they could be seen as continuing the general move over the past two decades to a more 'primary-care-oriented' NHS, shifting influence away from hospitals and towards general practice and other primary care services. The ODT sought to ensure that organ donation had an influential voice in strategic decision-making, by recommending that each trust should have an identified clinical donation 'champion' (now renamed 'clinical lead'), and a trust donation committee.[674] Given the gradual shift in influence away from hospital trusts, it is likely to become increasingly important that primary care is appropriately represented in these structures.

7.36 We have indicated that some population groups within the UK, in particular South Asian and African Caribbean communities, are less likely than others either to sign the ODR, or to agree to the donation of the organs of a deceased family member. As a result, the NHS experiences difficulties in responding equally to need for donated material within these communities (see paragraph 3.28). The reasons for these lower levels of donation are complex: while studies have consistently demonstrated that African-Caribbean and South Asian individuals in the UK are supportive of organ donation and transplantation, they have not, on the whole, identified what would motivate more people to come forward as potential donors, although there are some indications that 'grassroots' community networking may be more effective than the use of educational materials.[675]

[671] Ibid.
[672] See, for example, The NHS Confederation (2009) *Dealing with the downturn*, available at: http://www.nhsconfed.org/Publications/Documents/Dealing_with_the_downturn.pdf.
[673] Department of Health (2010) *Equity and excellence: liberating the NHS,* available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117352.pdf.
[674] Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf, recommendation 4.
[675] See: Randhawa, G (2011) *Achieving equality in organ donation and transplantation in the UK: challenges and solutions*, available at: http://www.better-health.org.uk/sites/default/files/briefings/downloads/health23-3.pdf for a review of the research in this area.

7.37 The Council is aware of the work undertaken by the ODT in seeking a better understanding of how religious belief may affect the possibility of organ donation: both in clarifying that no major world religion has a clear teaching forbidding organ donation (and indeed the widely shared nature of the position that it may constitute a good act); and in identifying the importance of disentangling 'cultural' from 'religious' concerns about donation.[676] We are also aware of the 'DonaTE' (Donation, Transplantation and Ethnicity) programme of research currently being funded by the National Institute for Health Research (NIHR) into barriers to organ donation;[677] and of the various initiatives by NHSBT to support health professionals in approaching families sensitively and appropriately when seeking consent for organ donation.[678] An overview of the current evidence with respect to inequalities in donation and transplantation, published by the Race Equality Foundation in 2011, argued that while the UK is recognised as being "at the forefront worldwide" in many of its initiatives with regard to culturally competent organ donation educational materials, the success of these initiatives has been limited by a lack of a clear strategy and implementation plan bringing together the various strands of a multi-faceted problem.[679]

7.38 We note that this is a highly complex area, and that we have not been in a position to collect evidence on this issue that might enable us to make specific recommendations as to appropriate actions. We therefore limit ourselves here to highlighting what we believe is an important ethical position: the relevance of our notion of the stewardship role of the state (see paragraph 7.12). **That stewardship role includes a duty to take positive action to remove inequalities that affect disadvantaged groups or individuals (see paragraph 5.13). In this context, the stewardship role of the state (exercised here by intermediary bodies such as NHSBT and individual hospital trusts and professionals) includes taking action actively to promote donation, in order to ensure that the NHS is able to offer fair access to donation services to *all* UK residents**. Such an awareness of the stewardship role of the state in this respect highlights the importance of ongoing dialogue not only at central level between NHSBT and community and faith leaders, but also at the level of individual NHS trusts and their local communities. **We endorse the call of the Race Equality Foundation for a clear strategy and action plan to take forward the lessons emerging from the research in this field**.

Interaction between organ donation for transplantation and other systems

7.39 The financial and organisational pressures emphasised above clearly highlight the importance of the many professionals involved in facilitating the donation of bodily material working efficiently and closely together, in order to make best use of available systems and resources. While, as a result of the work of the ODT, considerable effort has gone into improving cooperative working in the area of organ transplantation, a number of respondents to our consultation argued that such cooperation did not necessarily extend across different fields of donation. It was noted, for example, that the ODR does not make any reference to donating either organs or tissue for research; and that those wishing to donate their brains for research could not do so through the 'ordinary' donation channels.[680] While we recognise that logistical challenges may limit the extent to which the current system established to facilitate deceased organ donation for transplantation may become the single route for all forms of deceased

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[676] Department of Health (2008) *Organs for transplants: the supplement report*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082121.pdf, pp150-7.

[677] UK Clinical Research Network (2011) *UK Clinical Research Network Portfolio: DonaTE (Donation, Transplantion and Ethinicity) - organ donation and transplantation among ethnic groups*, available at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=8837.

[678] Randhawa, G (2011) *Achieving equality in organ donation and transplantation in the UK: challenges and solutions*, available at: http://www.better-health.org.uk/sites/default/files/briefings/downloads/health23-3.pdf.

[679] Ibid.

[680] See also: Ironside, JW (2010) *The UK Brain Banks Network: working together to advance our understanding of brain diseases - presentation given at the Edinburgh International Science Festival* (Edinburgh: MRC UK Brain Bank Network), which included findings from a public engagement exercise carried out by the UK Brain Banks Network which found that 54 per cent of participants thought that the post mortem donation of brain tissue for research should be arranged at the same time as organ donation for transplants.

donation (for example the necessary involvement of a neurosurgeon may render brain donation inevitably a special case), we would make the following observations.

7.40 We have already observed in paragraph 7.9, the possibility of close interaction between therapeutic and research uses of bodily material. We reiterate that research should not be seen as a peripheral or 'second-class' use of bodily material, but rather as a mainstream use of donations. Such an approach has implications both for the ways in which individuals are encouraged to authorise the donation of material in advance of their own death, and for the ways in which families are approached after their relative's death. **We suggest that routine information about the Organ Donor Register should include explicit reference to the potential research uses of organs and tissue, and that potential donors should have the option of authorising such uses in advance**. Such information should cover the possibility of therapeutic research taking place alongside donation (in order, for example, to determine the relative effectiveness of established techniques); the possible research use of organs and tissue that are not suitable for transplant in any particular case; and the possible research use of organs and tissue that are not currently used for therapeutic purposes.

7.41 The possibility of donating material for research use should similarly be routinely raised with the person's family when authorisation for the removal and use of organs or tissue is sought after death. We recognise that there are some concerns among transplant professionals that such requests risk distressing families, leading to their refusing to agree to a transplant that they might otherwise have granted. Others argue that, if appropriately approached (with enough initial information to be clear about the purpose of the request, and the option of more information later if desired), families appreciate the potential value of contributing to research.[681] We therefore recommend that such an approach should first be piloted, with the impact both on donation rates and on families' experiences of being approached for donation being carefully monitored. **Should such a pilot scheme prove successful, we recommend that the possibility of donating for research purposes (distinguishing between research as part of the transplantation process, and research undertaken with material that would otherwise not be used for transplantation) should be included within the standard consent/authorisation form for deceased donation**.

7.42 We also highlight the potential for professionals working with bodily material in one field to take on a more proactive role in connection with other forms of bodily material. We noted above that there may, at times, be good logistical reasons why a brain may not be removed from a deceased body at the same time as other donated organs. However, such logistical reasons should not prevent the NHS providing a single 'point of entry' to donation services by, for example, a specialist nurse in organ donation liaising on behalf of the deceased person and their family with the systems locally in place for brain banking. Similarly, we note the possibility of professionals in one area actively raising awareness of, and facilitating access to, other forms of donation where this appears appropriate: for example, through ensuring that information about signing the ODR, or about local biobanks recruiting donors, is readily available at blood donor sessions.

7.43 Finally on the issue of organ donation, we note the importance of robust information systems both in ensuring proper use of donated material and in maintaining trust among the general public. An example of infrastructure failing those who had decided to donate their organs arose in 2010 when it came to light that errors had been made in recording the wishes of would-be organ donors when they expressed their organ donation preferences via the DVLA.[682] The error

[681] UK Donation Ethics Committee/NRES workshop (November 2010) *Ethics of transplantation*, report to be made available at: http://www.aomrc.org.uk/donations-ethics-committee/work-programme/231-ethical-issues-in-organ-donation-and-transplantation-research.html.

[682] The Guardian (21 January 2011) *NHSBT rapped for incorrect data on 444,000 donors*, available at: http://www.guardian.co.uk/healthcare-network/2011/aug/30/organ-donor-register-nhsbt-dvla-errors?INTCMP=SRCH.

affected potential donors who had indicated a wish to donate specific organs, rather than all of their organs. An independent review into how the errors had arisen highlighted how the ODR was being used for operational functions for which it was never designed, and recommended that "NHS Blood and Transplant should design and commission a new register which will be better equipped to deal with the operational demands now placed on it."[683] **The Working Party endorses this recommendation. It should not be the case that the public's willingness to donate is undermined by information technology systems that are unable to account accurately for potential donors' preferences**.

Tissue

Therapeutic use

7.44 As we noted earlier, NHSBT Tissue Services are currently able to meet routine NHS demand for tissue for therapeutic use (see paragraph 3.19). One reason for this may be that the potential donor 'pool' – the number of those who die in circumstances in which they can become a tissue donor – is much larger than in deceased organ donation. However, NHSBT Tissue Services also appear to offer an example of how good infrastructure may contribute to meeting need by making it as easy as possible for people who are willing to donate (see Box 7.1).

Box 7.1: NHS Blood and Transplant Tissue Services

NHSBT Tissue Services (part of NHSBT) coordinates, retrieves, processes, banks and supplies human tissue grafts for use in surgery within the NHS.

Tissue Services operates a cost recovery system where charges for the service are made to cover the costs incurred in providing the service. No profit is made. In 2005 it opened a state-of-the-art tissue banking facility at Speke on the outskirts of Liverpool, together with a new blood centre. The tissue facility includes:

- A national donor referral centre where a team of specialist nurses are available 24 hours a day to receive donor referrals, approach potential donor families in order to discuss the options of donation, and complete the consent and donor screening process to allow assessment of the donor in compliance with UK legislation and European Directives. Agreements have been established with four local trusts whereby Tissue Services are routinely notified of deaths and then contact families to discuss donation options. Many other trusts, however, also refer donors.
- An infrastructure to support both tissue and blood banking functions, including operating theatre, cleanrooms, ultra low temperature freezers and a sophisticated environmental monitoring system to ensure that tissues are stored and handled appropriately.
- A consultant specialist in tissue services, supported by a clinical team, who develops clinical policy and is involved in all aspects of tissue services including the development of user and focus groups of surgeons.
- A tissue development laboratory, together with Technology Transfer Centre, in order to exploit developments in cell culture and tissue engineering, and research and development links with universities within the UK.

For more information, see: http://www.nhsbt.nhs.uk/tissueservices/aboutus/whowhereweare/.

Research use

7.45 Chapter 3 described some of the many ways in which human tissue is used for research, and its potential value in improving scientific knowledge and developing new medical techniques and treatments. We also highlighted how the main reason for difficulties in accessing tissue for research appears not to be unwillingness on the part of people to donate for research purposes, but rather factors that may arise in connection with the systems and behaviour of intermediaries (both organisational and individual). We summarise these factors below, before looking at action that could be taken in each area:

[683] Department of Health (19 October 2010) *NHSBT adopt measures to avoid another error occurring*, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_120653; Department of Health (2010) *Review of the Organ Donor Register*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_120579.pdf.

- bureaucratic difficulties in seeking and documenting consent, and lack of clarity about the scope of the consent to be sought;
- a lack of willingness at times to share samples and their associated data, particularly between the NHS, university and commercial sectors;
- sustainability and source of funding; and
- licensing and governance arrangements that are perceived to be disproportionate and overlapping.

Nonetheless, as set out in Box 3.2, it is clear from a number of examples of good practice that such hurdles can, at least in some circumstances, be overcome. Indeed, the very rationale for the creation of many research tissue banks is to ensure that researchers are able freely to access properly sourced material. We set out below some general conclusions and recommendations as to how such aims might be furthered.

7.46 We begin with **consent**, both in the circumstances where tissue (or blood) is being specifically donated for research purposes, and in the context of consent to the use of tissue excised during surgery or other interventions and no longer required for diagnostic purposes. Chapter 5 sets out our view that any use of tissue should be based on clear information as to the wishes of the person from whom it comes, and we reiterate here that such an approach should also apply to 'excess' material, as well as to material being donated specifically with research in mind. As we discussed at the very beginning of this report, people have very differing views as to the value or personal importance of their bodily material: such views vary widely both between individuals and within one individual as regards different forms of material.[684] While there is evidence that, if asked, the majority of people are willing to permit their excess material to be used for research purposes, it cannot therefore be concluded that it is not necessary to ask.[685] However, given that the health professionals responsible for seeking patients' consent to diagnostic interventions and operations will not usually be directly involved in the research, it is clearly important that such procedures are fully integrated into clinical procedures and are not perceived as an undue burden by those responsible for carrying them out. We highlight examples of ways in which this is currently achieved within the UK in Box 7.2.

Box 7.2: Possible approaches to consent used in hospital trusts

- The use of leaflets (distributed both with appointment letters and in out-patient clinics) to seek generic consent for the future research use of any tissue excised during diagnosis or treatment and no longer required for the patient's own care;
- information on the surgical consent form about possible research uses of such tissue, and the opportunity to consent to none, some, or all of the identified uses;
- research nurses, specifically employed to seek patient consent.

7.47 Having established that consent to research use should routinely be sought,[686] the important question remains as to the *scope* of that consent (see paragraph 2.14). The UK research funders' 'vision document' on human tissue resources published in 2011 is very clear that generic consent for the use of tissue should always be sought unless there is good reason in a particular case not to do so.[687] This recommendation applies equally where researchers are seeking consent for a specific research project: additional generic consent should also be

[684] See, for example, Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research – summary of public consultation* (London: Nuffield Council on Bioethics).
[685] See, for example, the 2010 Eurobarometer study of around 1,000 residents in each of 32 European countries, where only six per cent of EU respondents agreed that researchers should be able to use material from biobanks without permission being sought at least once: European Commission (2010) *Europeans and biotechnology in 2010: winds of change?*, available at: http://ec.europa.eu/research/science-society/document_library/pdf_06/europeans-biotechnology-in-2010_en.pdf, p65.
[686] With the exceptions for 'secondary uses' permitted by the Human Tissue Act (see paragraph 2.19), which were not challenged by the Working Party.
[687] UK Clinical Research Collaboration (2011) *UK funders' vision for human tissue resources*, available at: http://www.ukcrc.org/infrastructure/expmed/.

sought, so that any material not used up in the initial project may be made available for other research use via a tissue bank. The funders, moreover, aim to ensure widespread adherence to this principle, by making the seeking of generic consent in this way a funding requirement.

Box 7.3: Forms of consent

The term 'generic' consent to the future research use of donated material is used in contrast to „specific" consent to use in one particular study. However, generic consent can come in a number of forms:

- 'blanket' consent, where no limits at all are placed on the future use of the material;
- 'fettered' or 'tiered' consent. where the participant is invited to agree to the future use of their tissue in unknown projects, but given the option of specifying particular categories of research that they wish to exclude; and
- 'broad' consent, envisaging a wide (but not limitless) range of future uses, together with an ongoing relationship between the researchers and the donors.

7.48 **We endorse the research funders' position that it is appropriate routinely to seek generic consent (where necessary in addition to specific consent) for the research use of blood and tissue**. We make the following additional observations:

- Generic consent need not mean 'blanket' consent (see paragraph 2.13 and Box 7.3). We have already pointed to the potential value of an ongoing relationship between donors and researchers as a meaningful way of recognising donors' continuing interests in their donated bodily material and of emphasising the importance of the 'relationship' in the notion of the gift relationship (see paragraph 7.19). Such a relationship need not be burdensome to the individual researcher: examples of good practice already exist in the form of dedicated webpages or electronic newsletters providing general information for donors on the progress of research.[688] However, we recognise that this form of 'broad' consent is likely to be more applicable to circumstances where the possibility of donation to a particular tissue bank is known at the time of donation. It may be less applicable where generic consent is sought in the context of a specific research project, with the aim simply of protecting the possibility of future use and avoiding waste.

- We also highlight the possibility of 'tiered' consent, where it is possible to categorise particular uses that are known to be controversial, and hence enable donors to consent to some, but not all, unknown future uses. Clearly, in order to offer this option to potential donors, researchers will need to be confident that information systems are in place that will accurately record the donor's preferences. While concerns are sometimes expressed as to the practicality of offering tiered consent options, we are aware of examples where they work well in practice.[689]

7.49 **We further endorse the funders' commitment "actively [to] develop and promote detailed guidance on seeking generic consent, incorporating views of patient and public groups".[690] We recommend that the process of developing the guidance should involve consideration of the 'broad' and 'tiered' approaches to consent outlined above**.

7.50 We also note here, that while patients who are asked to consent to the future use of their tissue appear very willing to give that consent, levels of knowledge among the general public about the

[688] See, for example, University of Bristol (2010) *Avon longitudinal study of parents and children: newsletters*, available at: http://www.bristol.ac.uk/alspac/participants/newsletter/. We distinguish here between generalised information about research projects and the much more onerous – and at times ethically difficult – question of feeding back information of personal relevance to the tissue donor.

[689] For example, the Manchester Cancer Research Centre Biobank, in seeking patient consent to the research use of excised cancerous material, specifically offers the opportunity for patients to 'opt-in' to research involving 'xenografts' (where tissue is transplanted into laboratory animals). Professor Chris Womack, personal communication, 14 July 2011.

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

research importance of tissue appear relatively low.[691] Improved awareness could only help to make the task of those responsible for seeking consent to the future research use of such tissue less onerous. **We recommend that the Medical Research Council and other research funders should work to increase public awareness of the key role of donated tissue in scientific and clinical research**.

7.51 On the question of **willingness to share samples** and associated data, we note that the use of tissue samples for research purposes in any setting, public or private, has the common goal of improving understanding of disease in order to improve patient care. In pursuit of that goal, there is a general acceptance that an appropriate approach is of fair and equitable access to samples that have been legally and ethically collected, based on scientific merit. In Spain, the requirement to share samples is enshrined in the legislation governing tissue banks (see paragraph 2.33). In the UK, a high-profile example of good practice is found in the UK DNA biobanking network, which provides biobank infrastructure to manage samples and data from investigators working throughout the UK, using a common set of agreed principles.[692] Networks of rare disease collections, such as those relating to childhood cancers, benefit from sharing through aggregated case numbers. However, ensuring what would be seen by the majority to be „fair access" appears to be difficult to achieve in practice. There are several reasons for this, but the most common is the reluctance of researchers to share samples and data that they have collected using funds and grants that they have acquired for the purpose, usually specifically to further their own (and their institution's) biomedical research activities. Historically, such collections may also be limited by the scope of the consent that has been given by donors, although the funders' recommendations in this area (see paragraph 7.47) should ensure that generic consent is routinely sought in the future.

7.52 **We conclude that where material is freely donated by patients or by members of the public, it is not acceptable for individual researchers or research groups to hinder, inhibit or refuse access to other researchers for scientifically valid research, unless there are sound reasons for doing so**. **Indeed, we take the view that where material has been donated for research use, there is an ethical imperative to make the most efficient use possible of it**. We note that the UK research funders' vision includes strong measures to promote better sharing of samples, with future funding to be dependent on applicants meeting a number of criteria, including: justifying why new tissue collections are necessary; describing how their collection and storage of samples complies with existing good practice; registering collections in a publicly accessible directory; and making appropriate arrangements for fair access. We endorse this approach. **We also welcome the funders' further commitment to ensuring that there is clear guidance on how the interests of investigators who invest time and effort in sample collections are recognised**.

7.53 The question of sharing samples is thus closely connected with the issue of **funding.** In the context of individual research projects where new sample collection is necessary, we highlight the practical difficulties that may arise in connection with maintaining a tissue resource when funding for a particular project comes to an end, and hence the difficulty in some cases of ensuring that samples remain available to the research community. **We note that the UK funders make reference to the importance of ensuring that "funding mechanisms for long-term storage and curation are considered", and recommend that particular attention should be given to this issue in initial funding decisions**.

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[691] For example, at the Working Party"s deliberative event in Bristol, just one person out of 43 attendees mentioned research without being prompted by facilitators. See also: Academy of Medical Sciences (2011) *A new pathway for the regulation and governance of health research*, available at: http://www.acmedsci.ac.uk/index.php?pid=47&prid=88, which reported that a patient and public involvement workshop it organised jointly with the Association of Medical Research Charities and INVOLVE highlighted the importance of public communication about the different types of health research.

[692] Yuille M, Dixon K, Platt A *et al.* (2010) The UK DNA banking network: a "fair access" biobank *Cell and Tissue Banking* **11**: 241-51.

7.54 A more fundamental question of principle arises in connection with the funding of major tissue resources. Issues of sample collection aside, tissue was considered in the past as financially neutral: as a 'free good'. Now, attention to sample quality, as well as sample storage, processing, distribution and governance requirements in a regulated environment, have all added to research costs. Indeed, securing and maintaining funding for sample collection has been cited by a series of experts as a significant challenge to tissue banks in the next three to five years irrespective of whether they are in the public or private sectors.[693]

7.55 Money for biomedical research in the UK comes from government via a number of routes (including the Department of Health, the Higher Education Funding Councils and the Research Councils), from charities and from the private sector. Access to samples is similarly sought by those working in the public, charitable and private sectors. The samples themselves are donated almost entirely from within the public sector (the NHS), and, as we note above, tissue resources may be conceptualised as a 'public good', with donors providing their material as an act of public benefit (see paragraph 7.19). The question therefore arises as to whether it is appropriate for the commercial sector to contribute in some additional way to the costs of maintaining tissue banks, to reflect the fact that their one of their ultimate aims, unlike that of public and charitable sector researchers, is to make profit for shareholders.

7.56 The majority of tissue banks operate on a cost-recovery basis, although commercial tissue suppliers exist to make a profit. Non-profit-making banks may recover their costs either by including an element of infrastructure costs in the fee charged for each item they supply, or by seeking separate contributions to the costs of making samples available, for example through block contracts or start-up grants. Many public sector tissue banks charge a premium to researchers from the private sector, effectively using the private sector to subsidise researchers from the public and charitable sectors. On the one hand, it might be considered that such an arrangement effectively renders the tissue bank itself a commercial institution, charging 'commercial' fees to the private sector; on the other, that such higher fees simply reflect an appropriate return on the part of the private sector for access to 'public goods'.

7.57 If the aim is for commercial companies to make – and be seen to make – a specific contribution to the costs of maintaining tissue resources in return for access to the public good of freely donated tissue, then it is certainly the case that one-off contributions, or block contracts, provide a more transparent way to achieve this aim than through differential pricing. However, a number of factors, including the changing nature of the biotechnology sector (with researchers seeking tissue increasingly working in small start-up companies, for example)[694] and fiscal pressures in the pharmaceutical and biotechnology sectors,[695] suggest that it may become increasingly difficult for public sector tissue banks to find partners willing to make major one-off contributions. Moreover, enhanced, transparent measures for corporate finance and accounting responsibilities, introduced in response to high profile accounting scandals a decade ago, mean that it is now more difficult for companies simply to donate money to assist setting up of tissue banks, although such accounting requirements do not preclude charitable donations.[696]

7.58 The Council"s 1995 report *Human tissue: ethical issues* specifically recommended that tissue banks should operate on a not-for-profit basis, a recommendation which we support. We also repeat our earlier observation, that bodily material donated freely by NHS patients and the general public should be understood as a public good. **We conclude that it is appropriate for commercial companies to make an explicit, and additional, contribution, in some way, to the costs of maintaining these public goods to reflect the value of the public's donation. We therefore recommend that any prospective sample collection for research (whether**

[693] Betsou F, Rimm DL, Watson PH *et al.* (2010) What are the biggest challenges and opportunities for biorepositories in the next three to five years? *Biopreservation and Biobanking* **8**: 81-8.
[694] CellCentric (2009) *What biotech companies want*, available at: http://www.walescancerbank.com/documents/What_do_Biotech_companies_want-Nessa_Carey.pdf.
[695] See, for example, Archibald K, Coleman R, and Foster C (2011) Open letter to UK Prime Minister David Cameron and Health Secretary Andrew Lansley on safety of medicines *The Lancet* **377**: 1915.
[696] See, for example, the Bribery Act 2010.

national or local) should be underpinned by a business plan that includes funding contributions from the full range of public, charitable and private sources, depending on where research users for the particular collection are likely to be located. Any such business plan should ensure that the financial value of the materials that patients and members of the public have freely donated should be recognised as being on the 'public' side of the balance sheet. We note that there are a variety of ways in which this may be achieved, particularly given the current climate in which collaborations between industry, the NHS and the academic sector are encouraged.[697]

7.59 Finally, we address the issue of **governance** arrangements. Particular criticisms have been raised by researchers whose work is subject to more than one regulatory regime, leading to what are experienced as duplicatory and bureaucratic inspection arrangements.[698] The HTA and MHRA have recently been exploring the possibility of joint inspections and have announced plans to continue with such joint arrangements in the future.[699] A memorandum of understanding between the MHRA and HFEA concerning inspections is also under development.[700] Cooperation of this kind between regulators, that seeks to meet statutory requirements while minimising administrative burdens for the organisation being inspected, is clearly to be welcomed.

7.60 Licensing issues under the Human Tissue Act may lead to specific difficulties in accessing tissue for research. The HTA"s Code of Practice states that tissue cannot be removed from a deceased person for the purposes of research without a licence being held by the institution where it will take place.[701] Similarly, if bodily material removed for the purpose of transplantation is subsequently used for research, rather than transplantation, the material must be stored on licensed premises, unless it is for a specific research project that has been approved by a research ethics committee.[702] However, many hospitals where bodily material is removed – either for the purpose of transplantation, or other medical treatment – do not hold an HTA licence, as removing organs for transplantation is explicitly excluded from the licensing requirements. Such hospitals are unable to use any bodily material they remove for research purposes, regardless of the wishes of the deceased person or their relatives. **The Working Party emphasises the need for ongoing dialogue between the Human Tissue Authority and the transplant and communities to find a proportionate way forward**.

7.61 **We reiterate here our view that good governance systems, accompanied by transparency of process, are an essential requirement if potential donors are to have the trust necessary for them to contemplate donation in the first place** (see paragraph 5.74). Patients and the public are only likely to give generic consent for research, for example, if they are able to trust in the integrity, not only of the individual professionals involved, but in the organisational systems that will be required to ensure that their consent is properly recorded,

[697] See, for example, the announcement of a model agreement between pharmaceutical and biomedical industries, universities, and the NHS in order to streamline research contracting processes. The model agreement aims to support clinical collaborations, and is supported by a guidance document setting out how the agreement should be used in developing contracts for specific clinical research collaborations: Department of Health (23 February 2011) *New agreement launched to streamline research collaboration between life sciences industry, universities and the NHS*, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_124576. See also: National Institute for Health Research (2011) *Model industry collaborative research agreement (MICRA)*, available at: http://www.nihr.ac.uk/infrastructure/Pages/micra.aspx.

[698] Human Tissues Group, responding to the Working Party"s consultation.

[699] Human Tissue Authority (2010) *HTA review of the year event 2010*, available at: http://www.hta.gov.uk/newsandevents/htaevents.cfm/859-Review-of-the-year.html.

[700] The House of Commons Science and Technology recommends that the HFEA should be included in a memorandum of understanding with both the MHRA and the HTA: House of Commons Science and Technology Committee (2010) *Bioengineering*, available at: http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/220/220.pdf, paragraph 118.

[701] Human Tissue Authority (2009) *Human Tissue Act code of practice 2*, available at: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm, paragraph 142.

[702] Ibid, at paragraphs 144-5. However, no licence is required for organ transplantation, see paragraph 135.

their donated material is properly stored and handled, and the research they wish to support is appropriately facilitated.

7.62 In response to widespread concerns about the fragmented nature of research regulation, the Academy of Medical Sciences recommended in early 2011 that a new overarching „Health Research Agency" (HRA) should be established to oversee the regulation and governance of health research.[703] **We endorse the overarching aim of simplifying and clarifying research regulation, with particular reference both to the points of difficulty highlighted above and to the ethical requirement of good and responsible governance. We do not take a stance on what particular form such governance ought to take; we do, however, commend the ethical approach taken in this report to those responsible for regulation of this area in the future**.

Research infrastructure

7.63 Finally, we highlight the central importance of ensuring the necessary **infrastructure** is in place before people are actively encouraged to donate. The point was made repeatedly to the Working Party that it can be very distressing to offer to donate material, but for the system to be unable to meet the expectations it has raised. This issue arises specifically in the context of seeking material from deceased donors for possible future research use. We recognise that this is a complex issue, but make the following observations with respect to ways forward:

- Tissue from deceased donors is potentially very useful for research, particularly given the difficulties in obtaining some forms of tissue from living donors. All forms of donated tissue (fresh tissue, frozen tissue and fixed tissue[704]) require an efficient infrastructure to be in place in order to ensure that material can be retrieved and processed in the necessary short time-frame.[705] Additional issues arise in the case of fresh tissue, where potential *users* must be willing to accept the material as soon as it becomes available, as the window for the research may be as short as a few hours. It is not acceptable to establish systems whereby patients or their relatives are invited to agree to donate tissue, unless there is a realistic chance that the tissue will, in fact, be used.

- The infrastructure for identifying donors and triggering the process of donating tissue for research potentially exists in the form of the organ donation system. However, discussing the possibility of donating tissue for research may not be uppermost in the minds of health professionals who are primarily concerned with the donation of organs for transplant – a much more obvious and immediate need.

7.64 **We recommend that the National Institute for Health Research and the Medical Research Council should take a lead in discussing with research organisations in both the academic and commercial sectors, and with NHSBT Tissue Services, whether there is sufficient demand for a more structured approach to access to tissue from deceased donors for research purposes around the country**. One possible output of such discussions could be the creation of model guidance on acceptable procedures to follow should individual NHS trusts, companies or universities wish to set up local arrangements to support local research.

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[703] Academy of Medical Sciences (2011) *A new pathway for the regulation and governance of health research*, available at: http://www.acmedsci.ac.uk/index.php?pid=47&prid=88, chapter 9.

[704] Tissue may be used immediately for research purposes („fresh"); or it may be preserved for later use, either through freezing or through being „fixed" in some form of preservation material (usually formaldehyde solution).

[705] See, for example, Department of Health (2011) *The Ministerial Advisory Group on Dementia Research: headline report*, available at: http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_127904.pdf, p7, where the importance for dementia research of the prospective recruitment of brain donors and more effective coordination of brain tissue donation is emphasised.

Gametes

Therapeutic use

7.65 In Chapter 6, we highlighted the striking contrast between the national infrastructure established to maximise blood and organ donation, with the absence of any similar coherent structure in respect of gametes. We recognise that there are significant differences between these forms of donation that may have led to these differences of approach: first, that blood and organ donation have much greater public acceptance than gamete donation; and second, that both blood and organ donation take place firmly within the NHS, while infertility treatment and gamete donation take place predominantly (although not solely) in the private sector. However, we do not accept that these differences are sufficient to justify such a wholesale difference of approach. We have argued above (see paragraph 7.7) that fertility treatment and gamete donation are accepted as having 'public' features, which are recognised in particular through the creation of regulatory structures to govern them. Treatment using donated gametes is available, albeit on a patchy basis, on the nationally-funded NHS. The donation of gametes through regulated fertility clinics is not purely a private matter. There is a public interest in ensuring that gamete donation services are efficiently managed, that the welfare of donors is seen as a matter of public concern, and that best possible use is made of those willing to donate.

7.66 **We conclude that there should be a coherent and managed infrastructure for egg and sperm donation, on the lines of the structures currently in place for organ donation**. Indeed, we note that in 1998 the HFEA proposed that "serious consideration" should be given to the idea of a "national donor service" (or several regional donor services) to provide a coordinated approach to the development of recruitment methods and help maximise the numbers of donors available.[706]

7.67 As we suggest in Chapter 6 (see paragraph 6.62), such an infrastructure would be well-placed not only to manage the kind of co-ordinated information campaigns envisaged in the first rung of our Intervention Ladder, but also to develop and share best practice in recruiting, retaining and 'recognising' donors (rung 2). **We recommend that the Department of Health, in consultation with the HFEA and its successor body/bodies, should initiate consultation with clinics as to how such an infrastructure could best be created**, drawing as appropriate on the lessons of recent initiatives such as the 'hub and spoke' model piloted in Manchester.[707] We emphasise that by 'infrastructure' we do not necessarily mean a new organisational entity. The precise shape or legal status of the infrastructure will be of much less importance than its overall aim of creating an organisational framework able to develop the best possible practice in handling all aspects of the recruitment of donors on behalf of clinics.[708]

Research use

7.68 In Chapter 6, we recommended the establishment of a pilot scheme to evaluate the effects of offering financial compensation for time and inconvenience (that might also be understood as remuneration) to those willing to come forward as egg donors for research (see paragraph 6.81). In coming to this conclusion, we noted that the physical risks of egg donation are currently regarded as acceptable in the context of altruistic donation, and that the possibility of

[706] Human Fertilisation and Embryology Authority (10 December 1998) *Paid egg sharing to be regulated, not banned*, available at: http://www.hfea.gov.uk/986.html.

[707] The central hospital 'hub' provided the majority of donor management, while local 'spoke' centres provided easier access for potential donors: Royal College of Nursing (2010) *Hub and Spoke scheme aims to boost sperm donation*, available at: http://www.rcn.org.uk/development/communities/rcn_forum_communities/midwifery_fertility_nursing/news_stories/hub_and_spoke_scheme_aims_to_boost_sperm_donation.

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

reward does not affect this. However, the risks of repeated egg donation are unknown, and potentially of greater concern. We therefore commented that if reward were to be offered for egg donation, very clear procedures would need to be in place to ensure a clear limit on the number of possible donations. The 2011 ESHRE guidance on cross-border reproductive care also sets out further procedural safeguards that should be followed to avoid the inappropriate targeting of donors from abroad (see paragraph 6.68). **We recommend that an essential part of the pilot scheme should be the development of protections both to limit the number of times a woman may donate eggs for research purposes, and to guard against the inappropriate targeting of potential donors in other countries**.

First-in-human trials

7.69 We begin consideration of the role of 'intermediaries' with respect to first-in-human trials by noting that the role of healthy volunteers in such trials has been considered in this inquiry primarily as a source of comparison with the donation of bodily material, and that the extent to which we are in a position to offer specific recommendations in respect of this issue is thus correspondingly limited. However, we make the following observations with respect to two themes that have arisen earlier in this report: partnership and governance.

7.70 We have noted earlier (see paragraphs 5.68 and 7.61) the importance in some contexts of the role of partnership between the donor of bodily material and the future user of that material, particularly in the context of research. The notion of partnership may be especially valuable in long-term studies, where participants may, at repeated intervals, provide samples and information, and where there will be regular information to share about the progress of the study. We suggest here that the concept of partnership may also be of some value in conceptualising the relationship between healthy volunteers in first-in-human trials and the researchers and institutions running the trial. The nature and extent of that 'partnership' may, of course, differ considerably from what is possible and meaningful in a longitudinal study: in some first-in-human trials, for example, participants may only receive one dose of the trial compound, and the only information about the progress of the trial may be that a certain number of patients received the drug with some side effects and that it will not proceed any further. In other cases, of course, there will be further progress, to Phase II and III and beyond, and hence more to report. While recognising that in some cases the 'partnership' may be short, we consider that the approach still has value, because it emphasises the mutual nature of the relationship: the contribution of the volunteer is recognised not only in payment but also through an acknowledgment that she or he has an interest in the outcome of the project. We note with interest the MRC's 'Help make history' website, which seeks to create a network of healthy volunteers interested in participating in HIV vaccine trials, as an example of how such a partnership approach may seek to create a different form of relationship from that traditionally envisaged between healthy volunteers and pharmaceutical companies.[709]

7.71 Along with the sharing of information, another aspect of such a partnership must be acceptance of responsibility on the part of trial organisers for the clinical follow-up of participants after the trial. Again, what is required in terms of follow-up will vary considerably according to the nature of the trial: volunteers taking doses of a new antibiotic or diuretic are unlikely to need the same kind of stringent follow-up as will be required for new drugs that, for example, target the immune system or have a novel mechanism of action.[710]

7.72 Finally, we consider the role of governance. Much has been written about the question of payment for healthy volunteers in clinical trials: whether such payment is exploitative in being offered at all, being too low or being too high; whether the potential volunteer is vulnerable and risks making choices they might later regret; and what information they might need to make their

[709] See: MRC Clinical Trials Unit (2010) *Help make history*, available at: http://www.helpmakehistory.mrc.ac.uk/about_us.aspx.
[710] Department of Health (2006) *Expert scientific group on phase one clinical trials: final report*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_073165.pdf, terms of reference.

decision. Such debates, however, focus very much on the role of how the individual should be approached and what factors steer their decision. We suggest that an alternative approach might be to consider the issue from the position of the responsibilities of the intermediaries concerned. If the review in question has been subject to ethical and scientific review and found to be satisfactory, then the key question for intermediaries is not whether it is appropriate to recruit participants at all, but rather whether there are particular ethical concerns about particular participants, or categories of participant. One class of participant about whom there could, legitimately, be professional concern would be those who 'over-volunteer' for paid research, either by volunteering for more than one trial at once, or by participating in serial trials (or both).

7.73 We suggest that a key element of governance will be for trial organisers to take responsibility for actively ensuring that potential participants are not 'over-volunteering'. One way in which this might be achieved would be through compulsory use of the TOPS database (see paragraph 2.54): trial organisers could be required both to register details of all participants on the database, and to check it closely when recruiting to a new trial. **We welcome the voluntary accreditation scheme for units conducting phase 1 trials, established in 2008 by the Medicines and Healthcare products Regulatory Authority (MHRA), which requires that accredited units must have a procedure in place to address over-volunteering.[711] We recommend that the MHRA should monitor closely any units that do not apply for accreditation, with a view to making requirements to guard against over-volunteering compulsory if necessary**.

7.74 We note that, in its current guidance to the pharmaceutical industry, the ABPI provides advice against over-volunteering, recommending a 'washout period' between studies: in general this is of a minimum of three months but dependent on the compound being studied and its mode of action.[712] However, concerns about 'over-volunteering' relate not just to the potential risks to the individual's health from the particular studies, but more subtly to the notion that 'loaning one's body' through first-in-human trials should not be regarded as a long-term low-paid job.[713] One way of dealing with this wider concern about the nature of participation would be to restrict the total number of trials a person may ever participate in, regardless of 'washout' periods in between. **We recommend that the National Research Ethics Service (NRES) should consult on the possibility of limiting the total number of first-in-human trials in which any one individual should take part**.

[711] Medicines and Healthcare products Regulatory Agency (2007) *Phase I accreditation scheme*, available at: http://www.mhra.gov.uk/home/groups/is-insp/documents/websiteresources/con2033097.pdf, p7. The majority of commercial phase 1 units in the UK are currently accredited by the scheme: MHRA, personal communication, 28 July 2011.

[712] Association of the British Pharmaceutical Industry (2007) *Guidelines for phase 1 clinical trials*, available at: http://www.abpi.org.uk/our-work/library/guidelines/Documents/phase1-trial-guidelines.pdf, p17.

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