

# Chapter 3

Supply and demand

## Chapter 3 - Supply and demand

### Chapter overview

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

### Introduction

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

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

**"It's not serious until it's you needing it. None of us need anything [now], so we don't have an issue." - participant at deliberative event<sup>264</sup>**

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

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

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

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

## Supply and demand in the UK: the current picture

### Blood

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

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

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

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

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

<sup>268</sup> World Health Organization (2010) *Sixty-third World Health Assembly: provisional agenda item 11.21 - human organ and tissue transplantation*, available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_24-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_24-en.pdf).

<sup>269</sup> *Ibid.*, paragraph 13.

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

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

## Organs for transplantation

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

<sup>270</sup> NHS Blood and Transplant (2011) *Small numbers, big hearts: annual review 2010/11*, available at: [http://www.nhsbt.nhs.uk/annualreview/pdf/nhsbt\\_annual\\_review\\_2010-2011.pdf](http://www.nhsbt.nhs.uk/annualreview/pdf/nhsbt_annual_review_2010-2011.pdf), p9.

<sup>271</sup> In the past five years, whole blood donor rates in the UK varied between 2.23 million donors in 2006-2007 to 2.33 million in 2008-9: NHSBT, personal communication, 12 January 2011; Scottish National Blood Transfusion Service (2010) *From giving to receiving: Scottish National Blood Transfusion Service - 2008-9*, available at: [http://www.scotblood.co.uk/pubdocs/SNBTS\\_Annual\\_Report\\_2008-09%5B1%5D.pdf](http://www.scotblood.co.uk/pubdocs/SNBTS_Annual_Report_2008-09%5B1%5D.pdf); Northern Ireland Blood Transfusion Service (2010) *Annual report 2009-10*, available at: <http://www.nibts.org/0910%20NIBTS%20Annual%20Report.pdf>; Welsh Blood Service, personal communication, 21 February 2011.

<sup>272</sup> NHS Blood and Transplant (1 January 2011) *Successful year for blood and organ donation*, available at: [http://www.nhsbt.nhs.uk/news/2011/newsrelease010111\\_2.html](http://www.nhsbt.nhs.uk/news/2011/newsrelease010111_2.html).

<sup>273</sup> For example, in 2010, the Department of Health issued a press release which urged people with Group O negative blood (so-called 'universal donors') to donate blood. See: Department of Health (20 December 2010) *Andrew Lansley urges people to give blood*, available at: [http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH\\_122978](http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_122978).

<sup>274</sup> Chief Medical Officer's National Blood Transfusion Committee (2009) *A plan for NHS Blood and Transplant and hospitals to address red cell shortages*, available at: [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/@ps/@sta/@perf/documents/digitalasset/dh\\_109118.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/@sta/@perf/documents/digitalasset/dh_109118.pdf).

<sup>275</sup> See: NHS Blood and Transplant (2010) *Who can't give blood?*, available at: [https://secure.blood.co.uk/c11\\_cant.asp](https://secure.blood.co.uk/c11_cant.asp).

<sup>276</sup> Advisory Committee on the Safety of Blood, Tissues and Organs (2011) *Donor selection criteria review*, available at: [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_129909.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_129909.pdf).

<sup>277</sup> NHS Blood and Transplant (8 November 2010) *ME/CFS sufferers permanently deferred from giving blood*, available at: [https://safe.blood.co.uk/PressRelease/MS033\\_081110\\_RG\\_ME\\_CFS\\_donor\\_deferral.pdf](https://safe.blood.co.uk/PressRelease/MS033_081110_RG_ME_CFS_donor_deferral.pdf).

<sup>278</sup> NHS Blood and Transplant (2010) *Who can't give blood?*, available at: [https://secure.blood.co.uk/c11\\_cant.asp](https://secure.blood.co.uk/c11_cant.asp).

<sup>279</sup> Diabetes UK (2008) *New guidelines for blood donors*, available at: [http://www.diabetes.org.uk/About\\_us/News\\_Landing\\_Page/2008/New-guidelines-for-blood-donors/](http://www.diabetes.org.uk/About_us/News_Landing_Page/2008/New-guidelines-for-blood-donors/).

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

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

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

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

<sup>281</sup> *Ibid.*

<sup>282</sup> Mr Keith Rigg, personal communication, 8 September 2011.

<sup>283</sup> NHS Blood and Transplant (2011) *Strategic plan 2011-14*, available at: [http://www.nhsbt.nhs.uk/strategicplan/pdf/nhsbt\\_strategic\\_plan\\_2011\\_14.pdf](http://www.nhsbt.nhs.uk/strategicplan/pdf/nhsbt_strategic_plan_2011_14.pdf), p12.

<sup>284</sup> NHS Blood and Transplant, personal communication, 20 July 2011.

<sup>285</sup> NHS Blood and Transplant (2011) *Strategic plan 2011-14*, available at: [http://www.nhsbt.nhs.uk/strategicplan/pdf/nhsbt\\_strategic\\_plan\\_2011\\_14.pdf](http://www.nhsbt.nhs.uk/strategicplan/pdf/nhsbt_strategic_plan_2011_14.pdf), pp11-3.

suggest solutions that would make more organs available (see paragraph 3.52). In its first report, the ODT concluded that a 50 per cent increase in organ donation after death was possible and achievable in the UK within the five years from 2008.<sup>286</sup> If this target were achieved, an additional 1,200 transplants could be carried out each year, 700 of which would be kidney transplants. By way of comparison, the ODT report notes the difference in donor rates between Spain – which has the highest organ donation rate in Europe – and the UK. In the former, there were 34 deceased donors per million of population in 2008, whereas in the UK, there were only 14 donors per million of population.<sup>287</sup> However, the ODT report notes that there may be many factors behind the difference in donor rates between countries, some of which may be influenced, whereas others cannot. These may include road traffic mortality rates, the incidence of deaths after brain injury, and the availability of intensive care facilities.<sup>288</sup>

- 3.10 The donation of organs – primarily kidneys – by living donors is becoming increasingly significant in responding to the need for organ donation. The rate of living organ donation has steadily risen in recent years: in 2010-2011, there were 1,045 living organ donors, compared with 1,062 in 2009-2010, 961 in 2008-2009, and 858 in 2007-2008.<sup>289</sup> Since 2007-2008, the number of living donors has exceeded the number of deceased donors.<sup>290</sup>

### **Gametes and embryos for treatment**

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

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

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

<sup>286</sup> 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](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf), p3.

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

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

<sup>289</sup> NHS Blood and Transplant (2011) *Transplant activity in the UK 2010-11*, available at: [http://www.uktransplant.org.uk/ukt/statistics/transplant\\_activity\\_report/current\\_activity\\_reports/ukt/activity\\_report\\_2010\\_11.pdf](http://www.uktransplant.org.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/activity_report_2010_11.pdf). See also: NHS Blood and Transplant (2011) *Statistics: transplants save lives*, available at: <http://www.uktransplant.org.uk/ukt/statistics/statistics.jsp>.

<sup>290</sup> NHS Blood and Transplant (2009) *Transplant activity in the UK 2008-9*, available at: [http://www.organdonation.nhs.uk/ukt/statistics/transplant\\_activity\\_report/current\\_activity\\_reports/ukt/2008\\_09/transplant\\_activity\\_uk\\_2008-09.pdf](http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/2008_09/transplant_activity_uk_2008-09.pdf), p7.

<sup>291</sup> Human Fertilisation and Embryology Authority (2010) *Fertility facts and figures 2008*, available at: [http://www.hfea.gov.uk/docs/2010-12-08\\_Fertility\\_Facts\\_and\\_Figures\\_2008\\_Publication\\_PDF.PDF](http://www.hfea.gov.uk/docs/2010-12-08_Fertility_Facts_and_Figures_2008_Publication_PDF.PDF), p3. In the UK, this equates to approximately 3.5 million people. The figure of one in seven couples related to couples who are unable to conceive after two years.

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

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

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

<sup>293</sup> *Ibid.*, p127.

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

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

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

<sup>297</sup> HFEA (2004) *Sperm, egg and embryo donation (SEED) policy review: findings of the clinic survey*, available at: [http://www.hfea.gov.uk/docs/Clinics\\_survey\\_Seed\\_review.pdf](http://www.hfea.gov.uk/docs/Clinics_survey_Seed_review.pdf), p7.

<sup>298</sup> *Ibid.*, paragraph 2.3. Ninety nine clinics were surveyed in total.

<sup>299</sup> *Ibid.*, paragraph 3.3.

<sup>300</sup> *Ibid.*, paragraph 4.1.

<sup>301</sup> Gamete donors are able to limit their donations by using a consent form for egg or sperm donation supplied by the HFEA where they are asked "do you have any restrictions that you would like to apply to your answers...eg, use for a named recipient?" See: Human Fertilisation and Embryology Authority (2009) *Your consent to the use and storage of your donated eggs*, available at: [http://www.hfea.gov.uk/docs/HFEA\\_WD\\_form\\_new\\_green\\_ver2\\_Sept\\_09\\_new\\_file.pdf](http://www.hfea.gov.uk/docs/HFEA_WD_form_new_green_ver2_Sept_09_new_file.pdf).

<sup>302</sup> Human Fertilisation and Embryology Authority (2009) *Code of practice*, available at: [http://www.hfea.gov.uk/docs/8th\\_Code\\_of\\_Practice%282%29.pdf](http://www.hfea.gov.uk/docs/8th_Code_of_Practice%282%29.pdf), guidance note 11.

- 3.14 Debate on the levels of supply for gametes has also focused on the removal of the donor's right to anonymity. As noted earlier (see paragraph 2.74), donor-conceived individuals now have the right at the age 18 years to approach the HFEA to obtain information to enable them to trace their donor and contact them directly.<sup>303</sup> The trigger for this change in the law was a High Court judgment in 2002 where it was held that Article 8 of the European Convention on Human Rights (which guarantees respect for private and family life) was engaged in a situation where a donor-conceived person sought to obtain non-identifying information (such as their hair colour or ethnicity) about the donor.<sup>304</sup> The government response extended beyond the scope of the judgment (which related only to *non*-identifying information) to specify that identifying information, too, should in future be provided.
- 3.15 There has been considerable dispute over the evidence as to the effect of the removal of donor anonymity on the supply of gametes for treatment. One approach to the evidence is through the examination of the number of *donors* who registered at an HFEA-licensed clinic for the first time before and after the removal of anonymity in 2005. The HFEA reports that in 2004, 224 sperm donors, and 1,032 egg donors registered; in 2006, the number of first-time sperm donor registrants rose to 287, but the number of egg donors dropped to 781; and in 2008, both sperm and egg donation registrants rose, with sperm donors totalling 396, and egg donors 1,150.<sup>305</sup> However, it has been suggested that the number of sperm donors had, in fact, already begun to decline before the legislative changes, because of concerns that any future changes regarding donor anonymity might be made to be retroactive (as had been the case with adoption legislation).<sup>306</sup> The number of treatments which use donated eggs has, moreover, fallen in recent years: figures published by the HFEA indicate that in 2005, 1,888 treatments used donated eggs, falling to 1,660 in 2006, 1,530 in 2007, and 1,444 in 2008.<sup>307</sup> There has been a similar decline in the number of embryos donated for other women's treatment: from 2001, when 326 embryos were donated, to 2006, when 200 embryos were donated.<sup>308</sup>
- 3.16 The HFEA has also published data on whether sperm donors limit their donation to one family (for example, where the family is known to them) or give permission for their donation to be used to found up to ten families. The number of sperm donors who stated that their donation should be limited to one family only has risen in recent years, with 20 donors stipulating a one family limit in 2007, 48 donors in 2008, and 67 donors in 2009.<sup>309</sup> Conversely, the number of UK donors who do not limit their donation to one family has fallen slightly during the same time period (293 donors in 2007, 290 donors in 2008, and 276 donors in 2009). However, when sperm imported into the UK from abroad is included in these figures, the total number of sperm donors who place no limit on their donation has risen slightly overall: in 2007, 340 sperm donors did not limit their donation to one family, rising to 346 donors in 2008, and 355 in 2009.

### **Gametes and embryos for research**

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

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

<sup>304</sup> *R v Secretary of State for Health* (2002) EWHC 1593.

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

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

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

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

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

<sup>308</sup> Human Fertilisation and Embryology Authority (2008) *A long term analysis of the HFEA register data 1991-2006*, available at: [http://www.hfea.gov.uk/docs/Latest\\_long\\_term\\_data\\_analysis\\_report\\_91-06.pdf](http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_91-06.pdf), pp91-3.

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



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

- 3.17 Gametes and embryos may be used for a number of research purposes. Sperm is used primarily in research related to fertility, while eggs and embryos are used more widely: research uses include contributing to basic science research; increasing knowledge about fertility; contributing to knowledge about both heritable and non-heritable diseases; and research using embryonic stem cells. However, the number of eggs donated for research purposes has fallen significantly in recent years. Figures published by the HFEA indicate that in 2001, 2,016 eggs were donated for research, compared with 845 in 2006.<sup>310</sup>
- 3.18 Most embryos donated for research are donated by patients who have undergone IVF, and who do not want to cryopreserve (freeze) their 'spare' embryos.<sup>311</sup> The rate of embryo donation for research appears to have remained more stable than egg donation: HFEA statistics indicate that 4,193 embryos were donated for research in 2001, 3,639 in 2004 and 3,338 in 2006.<sup>312</sup>

### **Tissue for medical treatment**

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

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

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

<sup>310</sup> Human Fertilisation and Embryology Authority (2008) *A long term analysis of the HFEA register data 1991-2006*, available at: [http://www.hfea.gov.uk/docs/Latest\\_long\\_term\\_data\\_analysis\\_report\\_91-06.pdf.pdf](http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_91-06.pdf.pdf), pp91-3.

<sup>311</sup> Mounce G, Mardon H, Franklin S, and Turner K (2010) Who donates their embryos to research? *Human Reproduction* 25: 1278-1.

<sup>312</sup> Human Fertilisation and Embryology Authority (2008) *A long term analysis of the HFEA register data 1991-2006*, available at: [http://www.hfea.gov.uk/docs/Latest\\_long\\_term\\_data\\_analysis\\_report\\_91-06.pdf.pdf](http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_91-06.pdf.pdf), pp91-3.

<sup>313</sup> Meeting with NHS Blood and Transplant Tissue Services, 2 March 2010.

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

<sup>315</sup> NHS Blood and Transplant (2009) *Cornea transplantation*, available at: [http://www.uktransplant.org.uk/ukt/newsroom/fact\\_sheets/cornea\\_transplantation\\_fact\\_sheet.jsp](http://www.uktransplant.org.uk/ukt/newsroom/fact_sheets/cornea_transplantation_fact_sheet.jsp).

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

### **Blood and tissue for research**

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

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

- 3.21 Blood and tissue for research<sup>317</sup> are sought by a number of different parties. These include hospitals, universities, commercial organisations, publicly or charitably-funded tissue banks, national cancer banks, and historic collections. While some researchers experience difficulties in obtaining the bodily materials they need for their research, in many cases these difficulties may arise less as a result of shortages in stocks of the material itself, than from difficulties in *accessing* available material, for example because of inadequate systems in place for obtaining appropriate consent at the time the material is taken. Breakthrough Breast Cancer recently commented that "the main barrier to progress [is] a shortage of good quality tissue - the raw material for research."<sup>318</sup>
- 3.22 In order to access tissue samples, researchers need ethical approval for their research project from a REC and consent from the person providing the material (unless the material comes from a living donor and is anonymised - see paragraph 2.17). The premises where tissue is being removed from deceased donors, or after a post mortem, must be licensed under the Human Tissue Act (see paragraph 2.60). During a meeting with the Working Party about regulation, the HTA suggested that many of the cases where there *are* problems accessing tissue for research may arise from bureaucratic issues within an organisation, rather than as a result of the regulatory requirements of the Human Tissue Act itself.<sup>319</sup> Researchers have reported a lack of confidence in applying the provisions of the Act,<sup>320</sup> and a recent report by the Academy of Medical Sciences (AMS) cited the processes involved in obtaining permission for research to go ahead from individual NHS trust research and development (R&D) departments as a "major bottleneck" in health research.<sup>321</sup>
- 3.23 In the same meeting between regulators and the Working Party, problems arising out of reluctance to share research samples were also highlighted. These problems may be due in

<sup>316</sup> A deceased donor can donate 2,000-4,000cm<sup>2</sup> of skin, which takes 100 days to convert into a graft-ready tissue. The average adult patient with severe burns uses 2,000-9,000cm<sup>2</sup> per grafting, but may need 2-3 grafts with a 1-3 day gap between each operation. The London bombings resulted in requests for 31,090cm<sup>2</sup> to one hospital alone. See: NHS Blood and Transplant (2006) *Blood matters - issue 20*, available at: [http://www.blood.co.uk/pdf/publications/blood\\_matters\\_20.pdf](http://www.blood.co.uk/pdf/publications/blood_matters_20.pdf), p14.

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

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

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

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

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

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

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

### **Participants in first-in-human trials**

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

- Dr J. Reeve, consultation respondent

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

- 3.25 The number of phase I trials using healthy volunteers conducted in the UK appears to be relatively stable: 244 such applications were approved in 2008; 229 in 2009; and 222 in 2010.<sup>324</sup> During a meeting with the Working Party, a representative from NRES noted that the issue of shortage of volunteers was not raised during regular discussions the service holds with phase I trial units, suggesting that this was not a general problem.<sup>325</sup> It was however noted that, at times, there may be 'bottlenecks' in the supply of volunteers, although – perhaps surprisingly – after the events at Northwick Park, where several young men suffered severe adverse reactions to a drug being tested for the first time in man, levels of volunteering for trials reportedly rose. This may be due, in part, to the accompanying publicity which revealed the amount of money the young men were being paid to participate.<sup>326</sup>

### **Examples of factors influencing demand**

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

<sup>322</sup> Meeting with regulators, 23 June 2010.

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

<sup>324</sup> MHRA, personal communication, 7 September 2011.

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

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

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

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

<sup>327</sup> Pfeffer N (forthcoming) *Insider trading* (London: Yale University Press).

<sup>328</sup> Professor Naomi Pfeffer, personal communication, 27 July 2011.

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

3.27 As we noted at the beginning of this chapter, demand is partly a response to scientific innovation: there was no 'demand' as such for transplants before they became technically possible, or for donor eggs before the development of IVF procedures or stem cell research. This is clearly not to suggest that needs that could not be met before the expansion of innovation are thereby insignificant: indeed, such an argument would deny value to much medical progress. It should also be noted that consumer-driven demand cannot simply be ignored, as it is likely to emerge elsewhere (see paragraph 3.83).<sup>330</sup> However, recognition of the main influences steering demand is a necessary step in seeking to formulate an appropriate response. Below, we summarise some of the scientific and social<sup>331</sup> factors that have been both driving and reducing demand for human bodily material for treatment or for research. Where relevant, we note where these factors seem likely to be amenable to change, for example demand reduction through public health measures, and we return to the question of an appropriate ethical response to imbalances between supply and demand in terms of bodily material in Chapter 5.

3.28 Demand may not be spread evenly over the population. There are ethnic communities where organ donation is not a regular practice yet where need is higher than the national average. In addition to factors such as age and underlying patterns of health, the ethnic origin of potential recipients of donated material is of relevance because people are more likely to find an immunologically compatible donor among others of similar origin. Thus, South Asian and African Caribbean people wait on average twice as long as white people for a kidney transplant, both because of lower donation rates in these communities, and because of higher levels of need. Differences in genetic predisposition, increased prevalence of other underlying medical conditions, and poorer access to, and uptake of, services lead to greater risks of developing organ failure.<sup>332</sup> It is important to note, however, that lower rates of donation in such communities are not easily accounted for by simple cultural or religious factors. On the contrary, some researchers have argued that there can be a very active sense of charity and sacrifice where the suffering of others is recognised. Research suggests that reluctance may be attributed to factors such as uncertainties about what is, and is not, sanctioned by religious doctrine, a general lack of trust and confidence in health services, and specific anxieties about the management of death and disposal of the corpse where donation after death is concerned.<sup>333</sup> Similar observations have been made in relation to assisted conception in British South Asian communities. A study of gamete donation found that doubts about third-party

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

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

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

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

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

assisted conception reduced both the numbers seeking treatment and the likelihood of donation.<sup>334</sup>

### **Scientific factors increasing demand**

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

<sup>334</sup> Culley L and Hudson N (2006) *Public perceptions of gamete donation in British South Asian communities*, available at: [http://www.dmu.ac.uk/Images/GAMDON%20final%20report\\_tcm6-11021.pdf](http://www.dmu.ac.uk/Images/GAMDON%20final%20report_tcm6-11021.pdf).

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

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

<sup>337</sup> Human Genome Project (2008) *About the Human Genome Project*, available at: [http://www.ornl.gov/sci/techresources/Human\\_Genome/project/about.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml).

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

<sup>339</sup> Directive 2010/63/EU, Article 47.

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

### **Scientific factors reducing demand**

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

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

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

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

<sup>343</sup> See, for example, NHS Blood and Transplant (2007) *Comparison of survival rates among kidney transplant centres*, available at: [http://www.uktransplant.org.uk/ukt/statistics/centre-specific-reports/pdf/comparison\\_of\\_survival\\_rates\\_among\\_centres.pdf](http://www.uktransplant.org.uk/ukt/statistics/centre-specific-reports/pdf/comparison_of_survival_rates_among_centres.pdf).

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

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

- 3.38 **Developments in stem cell science** include the production of 'induced pluripotent cells' (iPSCs) directly from skin or other adult cells using viruses to introduce 'stemness' factors (deduced from study of ESCs).<sup>348</sup> The source of iPSCs makes them a less controversial option than ESCs, while their ability to produce cells to match the genetic makeup of a patient means that they may be less likely to suffer rejection (though this has been challenged).<sup>349</sup> The technology to create iPSCs is rapidly being improved and expanded. However, this is not to say that iPSCs are free of ethical concerns and policy challenges, for example with regard to whether tissue donors should be specifically informed about the possibility of their donated material being subsequently used for the creation of iPSCs.<sup>350</sup>
- 3.39 Research is also progressing into the use of ESCs, with the establishment of clinical trials to test their application to a number of treatments: it is however still at an early stage, with the world's first clinical trial using ESCs announced in October 2010.<sup>351</sup> It has recently been reported that blood platelets – which are used to repair damaged tissue and blood vessels – have been produced from human ESCs. This advance, if applied to general patient populations, could supplement supply from blood donors.<sup>352</sup>
- 3.40 Another potential application of stem cells is in drug development, where tissue created out of human stem cells might reduce the use of experimental animals, and provide a more specific model for testing efficacy and safety. As well as efforts by individual pharmaceutical companies and academic centres, a PPP (public-private partnership) has been set up by the UK Government and pharmaceutical companies – Stem Cells for Safer Medicines (SC4SM) – to take this forward.<sup>353</sup> Stem cell research may also be valuable in producing cell models for

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

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

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

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

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

<sup>350</sup> See, for example, Journal of Medical Ethics Editorial (2008) Time to reconsider stem cell ethics: the importance of induced pluripotent cells *Journal of Medical Ethics* **34**: 63-4. In addition, it has also been suggested that iPSCs may raise safety issues, depending on how they are generated as the risk of integrating retroviruses will be greater for iPSCs than ESCs. See: Gene Therapy Advisory Committee (2010) *Points to consider for UK clinical trials involving cell therapy*, available at: [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@ab/documents/digitalasset/dh\\_119086.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_119086.pdf).

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

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

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

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

- 3.41 **Regenerative medicine** aims to restore the function of diseased, degenerating or damaged organs or tissues.<sup>355</sup> There are several approaches this field of medicine may take in 'regenerating' organs or tissue, some of which have already been carried out for a number of years, such as the use of bone marrow transplants to treat leukaemia. It is, for example, possible to transplant a person's stem cells back into the same person, which avoids the risk of their immune system rejecting the transplant, and reduces the need for an allogeneic transplant. This technique has been used on an experimental basis to try to repair the donor's heart and other organs and involves taking bone marrow cells from the hip of the patient; these are concentrated or partially purified, and then injected into the damaged organ. Bone marrow transplant for organ repair is still at the stage of small clinical trials, with around 1,000 people in total treated in the course of the trial so far for heart disease.<sup>356</sup> Small safety trials for adult heart cells also began in 2010, with cells taken from heart biopsies and grown in the laboratory to provide larger numbers, then re-injected.<sup>357</sup>
- 3.42 Scientific advances have also offered the possibility of developing **artificial bodily material**. This may include artificial muscle where protein-based materials have been found to be able to adopt similar conformations to biomolecules in muscle,<sup>358</sup> and artificial corneas.<sup>359</sup> The first transplant of an organ formed in a laboratory was carried out in 2011, when surgeons successfully transplanted a trachea that had been grown from the patient's own stem cells and seeded onto an artificial scaffold.<sup>360</sup> So-called 'artificial gametes' are brought about from the successful derivation of egg<sup>361</sup> and sperm<sup>362</sup> precursor cells from ESCs, primordial germ cells, or other human cells. This technique has had success using mouse models, but the HFEA's Scientific and Clinical Advances Advisory Committee estimates that while research teams might be able to produce sperm from stem cells in the next few years, the production of eggs from stem cells could take longer. The Committee thought that it would be at least 5-10 years before eggs or sperm could be produced that could potentially be used in treatment.<sup>363</sup> Such developments, like other aspects of research in reproductive medicine, are likely to be controversial.
- 3.43 **Xenotransplantation** refers to organ transplants between animals and humans and was the subject of a Nuffield Council on Bioethics report in 1996.<sup>364</sup> This advance offers non-human alternatives to donated bodily material and there have been several widely-publicised studies involving animal-to-human transplants, mainly involving organs from pigs.<sup>365</sup> However, the promise of this technology has not yet been realised, with few advances in recent years. This

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

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

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

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

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

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

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

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

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

<sup>363</sup> Human Fertilisation and Embryology Authority (2009) *Committee paper: update on in vitro derived gametes*, available at: [http://www.hfea.gov.uk/docs/In\\_vitro\\_derived\\_gametes.pdf](http://www.hfea.gov.uk/docs/In_vitro_derived_gametes.pdf).

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

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



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

- 3.44 In the field of **reproductive technology**, developments in IVF treatment have enabled demand for sperm to be reduced in some circumstances. For example, advances in the use of intracytoplasmic sperm injection (ICSI) have increased the fertility potential of men who have very low numbers of sperm available, or whose sperm have very poor motility or 'swimming ability'. ICSI is a process whereby a single sperm is injected directly into a woman's egg *in vitro*, enabling some men with a low sperm count or who have had a vasectomy to father a child when, in the past, they would have had to consider donor sperm if they wished to have children.<sup>368</sup>
- 3.45 Technical improvements in egg freezing may also offer women an alternative in some cases to the use of donor eggs. The technique of egg freezing was developed primarily to preserve the fertility of young women with cancer who faced possible sterility as a result of chemotherapy or surgery. Eggs (oocytes) for future use may be harvested and frozen as primordial follicles taken from the ovarian cortex by biopsy, as immature oocytes to undergo *in vitro* maturation, or as mature oocytes following stimulation, as in conventional IVF. Where ovarian cortical strips are taken – for example, where a woman has cancer and there is no time to stimulate her ovaries, collect her eggs, and freeze the resulting embryos<sup>369</sup> – they may be re-transplanted back on to the ovarian pedicle in the hope that spontaneous conception will occur. Alternatively, they may be transplanted on to another site altogether (such as under the skin in the forearm).<sup>370</sup> IVF procedures would then be required to achieve a pregnancy. Egg freezing is also used by couples who have ethical objections to the freezing of embryos. There is also a growing (but still small) demand for 'social' or 'elective' egg freezing, where a woman has her eggs frozen for her own future use, if required.<sup>371</sup>
- 3.46 Other procedures that have influenced the demand for donor gamete treatment include pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS). These techniques may enable some couples, who previously would have had great anxieties about conceiving children with a high risk of genetic abnormality, to be reassured that only embryos that are free of the specific disorder or abnormality will be transferred to the woman's womb. They may therefore be reassured about the possibility of conceiving using their own gametes, rather than seeking donor gametes.

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

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

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

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

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

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

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

## Social factors increasing demand

### Public health factors

- 3.48 Increasing demand for some organs, in particular livers, hearts and kidneys, arises from the increase in chronic diseases, with four such diseases accounting for 60 per cent of deaths worldwide: cardiovascular disease, cancer, diabetes, and chronic respiratory disorders. The largely preventable behavioural risk factors associated with these diseases include use of tobacco, harmful alcohol consumption, unhealthy diet, and physical inactivity.<sup>376</sup> The importance of reducing these risk factors has been recognised by the World Health Organization which has emphasised that the "highest priority" should be given to prevention and health promotion "in order to reduce the diseases that lead to the need for transplants in the first place."<sup>377</sup> Effective interventions to reduce the number of people living with these conditions include regulation of marketing and fiscal measures to increase the prices of alcohol and energy-dense foods, alongside individually targeted behavioural programmes and mass media campaigns.<sup>378</sup> The failure to implement such programmes has recently been described as a failure of political will.<sup>379</sup> It is hoped that an international framework for the prevention of chronic, non-communicable diseases will be drawn up at a high level meeting of the General Assembly of the United Nations (UN) planned for September 2011.<sup>380</sup>
- 3.49 Infertility may be caused by a number of avoidable risk factors, such as tubal damage from sexually transmitted disease. Smoking and obesity are also contributory factors to impaired reproduction.<sup>381</sup> The average age of a first pregnancy in the UK has risen in recent years, and

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

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

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

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

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

<sup>377</sup> World Health Organization (2010) *Sixty-third World Health Assembly: provisional agenda item 11.21 - human organ and tissue transplantation*, available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_24-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_24-en.pdf), paragraph 17.

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

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

<http://www.nice.org.uk/nicemedia/live/13001/48984/48984.pdf>; National Institute for Clinical Excellence (2010) *Prevention of cardiovascular disease at population level*, available at: <http://www.nice.org.uk/nicemedia/live/13024/49273/49273.pdf>.

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

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

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

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

### The role of consumerism

- 3.50 The emergence of a so-called 'buyer's market' in recent years has arguably had an impact on the level of expectation people have of medical treatment: with it may come the attitude that, if a treatment is technically feasible, then it is also a right, as patients come to expect more of their health services.<sup>384</sup> Such an attitude may be reinforced in the UK by recent health policy developments, such as the increasing emphasis on the role of the public and patients in influencing not only their own care<sup>385</sup> but also the future direction of the health service.<sup>386</sup>

### Examples of factors influencing supply

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

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Medical Association (2007) *Smoking and reproductive life: the impact of smoking on sexual, reproductive and child health*, available at: [http://www.bma.org.uk/images/smoking\\_tcm41-21289.pdf](http://www.bma.org.uk/images/smoking_tcm41-21289.pdf).

<sup>382</sup> Office for National Statistics (2010) *Fertility: UK fertility remains high*, available at: <http://www.statistics.gov.uk/cci/nugget.asp?id=951>. The number of women over 40 years of age who have IVF treatment using their own eggs has also risen. In 1991, the number of women in this group numbered 6,457 which increased to 20,718 in 2001. See: Human Fertilisation and Embryology Authority (2007) *A long term analysis of the HFEA register data 1991-2006*, available at: [http://www.hfea.gov.uk/docs/Latest\\_long\\_term\\_data\\_analysis\\_report\\_91-06.pdf](http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_91-06.pdf).

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

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

<sup>385</sup> General Medical Council (2011) *Good medical practice: doctor patient partnership*, available at: [http://www.gmc-uk.org/guidance/good\\_medical\\_practice/relationships\\_with\\_patients\\_partnership.asp](http://www.gmc-uk.org/guidance/good_medical_practice/relationships_with_patients_partnership.asp).

<sup>386</sup> See, for example, Department of Health (2010) *Secretary of State for Health's speech: 'my ambition for patient-centred care'*, available at: [http://www.dh.gov.uk/en/MediaCentre/Speeches/DH\\_116643](http://www.dh.gov.uk/en/MediaCentre/Speeches/DH_116643); Department of Health (2005) *Creating a patient-led NHS: delivering the NHS improvement plan*, available at: [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4106507.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4106507.pdf).

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

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

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

### **Action currently taken at organisational level to facilitate donation or volunteering**

#### **Improvements in donation infrastructure (deceased organ donation)**

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

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

#### **Changing the consent defaults (deceased organ donation)**

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

<sup>389</sup> Directgov (31 January 2008) *25th anniversary of seatbelts - 60,000 lives saved*, available at: [http://www.direct.gov.uk/en/N11/Newsroom/DG\\_072333](http://www.direct.gov.uk/en/N11/Newsroom/DG_072333).

<sup>390</sup> Taken from introduction to ODT report 'Organs for Transplantation': Department of Health (2008) *Organs for transplants: a report from the Organ Donation Taskforce*, available at: [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_082120.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf).

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

<sup>392</sup> Working Party meeting with regulators, 23 June 2010.

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

- 3.54 In 2008, the ODT was specifically asked to consider whether it would recommend an opt-out system in the UK, and rejected the proposal at the present time.<sup>394</sup> It concluded that such a system would potentially undermine the concept of donation as a gift; erode trust in NHS professionals and the Government; and negatively impact on organ donation numbers. The Taskforce noted that it would review the position again if the situation had not significantly improved by 2013. However, the Welsh Assembly Government is currently seeking to introduce a 'soft opt-out' system where those dying in a Welsh hospital would be considered to have consented to organ donation unless they had specified otherwise, or unless their relatives refuse their consent.<sup>395</sup>
- 3.55 Another approach to the issue of consent would be the introduction of a system of '**mandated choice**', which would actively require everyone to register in advance their views on providing material for treatment or research after their death. In 2009, Professor John Saunders, chairman of the Committee for Ethical Issues in Medicine of the Royal College of Physicians (here writing in a personal capacity) advocated such a system, but emphasised that the choice should not be simply 'yes' or 'no' to the option of donation, but should also include the option that the person would prefer to leave the decision to their family.<sup>396</sup> Mandated choice for organ donation has been tried and abandoned in Texas and Virginia in the US in the past 20 years, but in both states it was restricted to a 'yes' or 'no' answer.<sup>397</sup> Moreover, in Texas, anyone who did not respond stating their preference was automatically defaulted to the 'no' cohort, which may have significantly influenced the outcome of the policy change. In Illinois, however, a significant increase in registration was observed after the introduction of such a policy in 2008.<sup>398</sup> The policy of mandated choice will be further tested in 2013 when New Jersey introduces the New Jersey Hero Act into its State law, which will require individuals who apply for or renew their driver's licence or personal identification card to consider whether they wish to become an organ donor.<sup>399</sup>

<sup>393</sup> 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).

<sup>394</sup> Department of Health (2008) *The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce*, available at: [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_090303.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090303.pdf).

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

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

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

<sup>398</sup> Illinois has stated that, since 2008, its organ donor register has grown from 38 per cent to 60 per cent of state residents. However, the quoted growth arises in part from the movement of donors from its old register to its new register. See: NHS Blood and Transplant (2011) *Prompted choice*, available at: [http://www.nhsbt.nhs.uk/downloads/board\\_papers/jan11/r11\\_04b\\_ODR\\_Prompted\\_Choice\\_Board\\_Paper\\_Jan11\\_v5.pdf](http://www.nhsbt.nhs.uk/downloads/board_papers/jan11/r11_04b_ODR_Prompted_Choice_Board_Paper_Jan11_v5.pdf).

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

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

### Box 3.1: Consent terminology

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

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

#### Mandated choice

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

#### Prompted choice

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

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

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

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

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

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

[http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH\\_128847](http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_128847).

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

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

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

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

[http://www.organdonation.nhs.uk/ukt/statistics/transplant\\_activity\\_report/current\\_activity\\_reports/ukt/activity\\_report\\_2009\\_10.pdf](http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/activity_report_2009_10.pdf), paragraph 3.3.

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

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_109864.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_109864.pdf).

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

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

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

- 3.60 A 'paired' or 'pooled' donation occurs when a living kidney donor is fit and able to donate, but is found to be biologically incompatible with the proposed recipient, who may be, for example, the donor's friend, relative, or partner.<sup>408</sup> In order to facilitate donation in such cases, the option of 'pairing' the organs with another donor and recipient, or 'pooling' them into a group containing more than one other donor/recipient pair, has been developed. If the donor and recipient decide to go ahead with the paired or pooled donation, they will then be 'matched' with one or more compatible donor/recipient pairs who remain anonymous. The proposed paired or pooled donation must be approved by a panel of three or more members of the HTA before the transplants can take place.<sup>409</sup> Where approval is given, the kidney transplants for each of the recipients take place simultaneously.<sup>410</sup>
- 3.61 Eighteen paired living kidney transplants took place between 1 April 2010 and 31 March 2011.<sup>411</sup> The first instance of a three-way 'pool' in the UK took place at the end of 2009,<sup>412</sup> and, in 2010-2011, there were 38 pooled organ donations.<sup>413</sup> The number of people who may actually benefit from paired or pooled living organ donation, however, is only likely to be 20-30 per cent of those who go into the pairing and pooling system, as the circumstances where the exchange may be appropriate are limited, mainly because of the distribution of recipient blood groups.

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

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

<sup>407</sup> Human Fertilisation and Embryology Authority (2010) *Scientific and Clinical Advances Advisory Committee paper: maximum age limit for sperm donation*, available at: [http://www.hfea.gov.uk/docs/2010-05-13\\_SCAAC\\_paper\\_-\\_maximum\\_age\\_for\\_sperm\\_donation.pdf](http://www.hfea.gov.uk/docs/2010-05-13_SCAAC_paper_-_maximum_age_for_sperm_donation.pdf).

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

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

<sup>410</sup> Human Tissue Authority (2010) *Paired and pooled donations*, available at: [http://www.hta.gov.uk/db/documents/Paired\\_and\\_pooled\\_donation\\_flow\\_chart.pdf](http://www.hta.gov.uk/db/documents/Paired_and_pooled_donation_flow_chart.pdf).

<sup>411</sup> Human Tissue Authority (2011) *Annual review 2010-11: exercising efficiency*, available at: [http://www.hta.gov.uk/db/documents/Annual\\_Review\\_2011\\_FINAL.pdf](http://www.hta.gov.uk/db/documents/Annual_Review_2011_FINAL.pdf), p15.

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

<sup>413</sup> Human Tissue Authority (2011) *Annual review 2010-11: exercising efficiency*, available at: [http://www.hta.gov.uk/db/documents/Annual\\_Review\\_2011\\_FINAL.pdf](http://www.hta.gov.uk/db/documents/Annual_Review_2011_FINAL.pdf), p15.

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

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

#### Box 3.2: Streamlining access procedures: examples

- The HTA and NRES have jointly taken action to reduce bureaucratic hurdles to accessing material stored in tissue banks for research purposes. **HTA-licensed tissue banks may obtain generic ethical approval for research using stored tissue**, within terms and conditions agreed with the REC, obviating the need for individual researchers to apply to their local REC for approval of each project. The REC will approve the documentation used to seek generic consent from donors as part of the ethical review. Approved tissue banks may then release non-identifiable samples to other researchers without further ethical approval provided that satisfactory scientific scrutiny has been obtained. Around 200 tissue banks have received approval on this basis to date since 2006.<sup>419</sup>
- **A network of 12 brain banks** established by the MRC, 'UK Brain Banks', is currently developing a system to make it easier for people to donate brain tissue for research.<sup>420</sup> One of the banks (the Sudden Death Brain and Tissue Bank in Edinburgh) has conducted a trial of a system in which the bank is notified of a sudden death – which requires a post mortem examination – by the procurator fiscal, who decides whether the bank should be given permission to approach the family of the deceased. If permission is given, the bank telephones the next of kin, explaining their reason for calling, and providing an opportunity for the family to make a donation for research. The phone call is then followed-up with a letter, before authorisation forms are sent out to the next of kin, should they wish for a tissue donation to be made. After authorisation is given, a letter of thanks is sent to relatives, and an audit questionnaire is posted to them six months after their relative's death. During the trial, 215 families were approached, 206 of which agreed to authorise post mortem tissue for research. The final number of tissue requests fulfilled was 110.<sup>421</sup> The study concluded that the majority of families are willing to support research use of tissues donated after death even in the context of sudden bereavement and despite previous adverse publicity.

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

<sup>415</sup> Meeting with regulators, 23 June 2010.

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

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

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

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

<sup>419</sup> NRES, personal communication, 26 July 2011.

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

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

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



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

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

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

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

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

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

<sup>423</sup> Jane Hair, personal communication, 25 March 2011.

<sup>424</sup> European Commission (2009) *Assessment of the functioning of the 'Clinical Trials Directive' 2001/20/EC: public consultation paper*, available at: [http://ec.europa.eu/health/files/clinicaltrials/docs/2009\\_10\\_09\\_public-consultation-paper.pdf](http://ec.europa.eu/health/files/clinicaltrials/docs/2009_10_09_public-consultation-paper.pdf). It is foreseen that the proposal for a revision of the Directive will be adopted in 2012. See: European Commission (2010) *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Commission work programme 2011*, available at: [http://ec.europa.eu/atwork/programmes/docs/cwp2011\\_annex\\_en.pdf](http://ec.europa.eu/atwork/programmes/docs/cwp2011_annex_en.pdf).

<sup>425</sup> European Medicines Agency (2007) *European Commission-European Medicines Agency conference on the operation of the Clinical Trials Directive (Directive 2001/20/EC) and perspectives for the future: report on the conference*, available at: [http://www.eortc.be/services/doc/EUCTD/EC-EMEA\\_report\\_CT\\_20071003.pdf](http://www.eortc.be/services/doc/EUCTD/EC-EMEA_report_CT_20071003.pdf).

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

<sup>427</sup> *Ibid*, p44 and 46.

<sup>428</sup> NHSBT Tissue Services, personal communication, April 2011.

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

### ***Actions aimed at changing individuals' behaviour***

#### **Forms of encouragement**

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

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

<sup>430</sup> BioNews (29 November 2010) *UK clinic granted permission to buy 'Russian eggs'*, available at: [http://www.bionews.org.uk/page\\_83109.asp](http://www.bionews.org.uk/page_83109.asp).

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

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

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

### Increasing public awareness (blood, organs, gametes)

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

#### Box 3.3: Promotional campaigns

##### Blood donation

###### Video media

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

###### 'Amazing Stories'

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

###### 'Give and Let Live'

- An educational website was also established by NHSBT in 2007.<sup>435</sup> It provides students aged 14 years and over "with the knowledge and understanding of key issues relating to donating parts of their body, either in life or after death, to help others." Several of the case studies used on the website tell the story of people whose lives have been saved or extended through the use of donated blood. These include Adrian Turner, a former Olympic swimmer who had to have his spleen removed as a teenager and needed a blood transfusion. The website also focuses on those who still need blood, such as James Baffoe, a young man with sickle cell anaemia. In a video interview, he notes that "if I don't receive red cell exchanges, I would have a lot more crises; a lot more stays in hospitals, and I hate hospitals."

###### Give Blood Scotland

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

###### Campaigns aimed at black and minority ethnic (BME) communities

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

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

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

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

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

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

## Organ donation

### NHSBT campaign

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

### Donate Wales

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

### Scottish Government

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

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

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

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

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

<sup>438</sup> NHS Blood and Transplant (2010) *NHS Blood and Transplant: adverts and video*, available at: [http://www.organdonation.nhs.uk/ukt/adverts\\_and\\_video/adverts\\_and\\_video.jsp](http://www.organdonation.nhs.uk/ukt/adverts_and_video/adverts_and_video.jsp).

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

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

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

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

<sup>443</sup> See, for example, Parkinson's UK (2009) *Parkinson's brain donor appeal supporters*, available at: [http://www.parkinsons.org.uk/support\\_us/parkinsons\\_awareness\\_week/brain\\_donor\\_appeal\\_supporters.aspx](http://www.parkinsons.org.uk/support_us/parkinsons_awareness_week/brain_donor_appeal_supporters.aspx).

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

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

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

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

### The introduction of financial incentives

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

### Benefit sharing

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

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

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

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

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

<sup>450</sup> 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](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf), p17.

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

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

<sup>453</sup> HUGO Ethics Committee (2000) *Statement on benefit sharing* (Singapore: HUGO).

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

### Permitting 'benefits in kind'

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

### Encouragement of living organ donation (primarily kidneys)

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

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

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

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

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

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

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

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

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

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

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

donation has increased significantly over the last decade, with a rise in the number of living organ donors each year for the past ten years.<sup>464</sup> While the decision to donate an organ as a living donor is an intensely personal one, usually motivated by the need of someone very close to the potential donor, NHSBT has taken active steps to encourage and support living donors: examples include the establishment in 2005 of a 'Renal Taskforce' to support living donation<sup>465</sup> and the creation in 2010 of the new role of 'Lead Nurse – Living Donation' within NHSBT itself.<sup>466</sup>

- 3.80 So-called 'stranger' living organ donation or non-directed donation, occurs when a healthy person donates an organ to the general pool, so that it goes to someone they do not know.<sup>467</sup> Figures published by the HTA highlight an increase between 2009-2010 and 2010-2011 in people donating kidneys to strangers, although the number of people who are given approval to become stranger donors in this way remains relatively small, having increased from 23 to 40.<sup>468</sup>

### **Action taken directly by individuals**

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

#### **Personal advertising for donors**

- 3.82 Direct advertising for donors is used for a range of bodily materials, from couples placing advertisements for egg donors in local newspapers<sup>469</sup> to appeals on charity websites for bone marrow donations for named individuals.<sup>470</sup> Individuals may seek the help of an intermediary in such searches: for example a recently-established website offers to manage the recruitment of egg donors for potential recipients.<sup>471</sup> Such 'personal action' (especially when undertaken via charities) may potentially have a beneficial effect on general public awareness, especially in relation to bone marrow donation.<sup>472</sup> However, concerns have also been expressed that direct recruitment of donors in this way may potentially lead to the prohibition on financial reward for donors being subverted in some cases.<sup>473</sup>

<sup>464</sup> NHS Blood and Transplant (2009) *Transplant activity in the UK 2008-9*, available at: [http://www.organdonation.nhs.uk/ukt/statistics/transplant\\_activity\\_report/current\\_activity\\_reports/ukt/2008\\_09/transplant\\_activity\\_uk\\_2008-09.pdf](http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/2008_09/transplant_activity_uk_2008-09.pdf), figure 2.2.

<sup>465</sup> NHS Blood and Transplant (2010) *Could I be a living kidney donor?*, available at: [http://www.uktransplant.org.uk/ukt/how\\_to\\_become\\_a\\_donor/living\\_kidney\\_donation/living\\_kidney\\_donation.jsp](http://www.uktransplant.org.uk/ukt/how_to_become_a_donor/living_kidney_donation/living_kidney_donation.jsp). However, this scheme has now ended and has been subsumed into NHSBT's other activities: NHSBT, personal communication, 9 August 2011.

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

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

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

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

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

<sup>471</sup> Altrui (2010) *Altrui: seeking the altruistic donor*, available at: [www.altrui.co.uk](http://www.altrui.co.uk).

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

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

### Cross-border care (fertility treatment and organ transplants)

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

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

<sup>475</sup> Human Fertilisation and Embryology Authority, (2008) *Authority paper: cross-border fertility treatment*, available at: [http://www.hfea.gov.uk/docs/AM\\_Item3\\_Dec08.pdf](http://www.hfea.gov.uk/docs/AM_Item3_Dec08.pdf), annex D.

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

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

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

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

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

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

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



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

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

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