

ALLOCATION OF ORGANS TO NON UK EU RESIDENTS

1. SETTING THE SCENE

- 1.1 There are not enough donated organs for all the people who need them in the UK. Against this background of scarcity, allegations in the media that organs from NHS donors were being given to patients from outside the UK, on a privately funded basis, caused widespread consternation. The allegations, made in a number of newspapers during 2008, and in early 2009, concerned liver transplants undertaken in two transplant centres in London, Kings College Hospital and the Royal Free Hospital. The patients were mainly from EU countries, principally Greece and Cyprus, and whilst it was acknowledged that the British hospitals and their surgeons were not breaking the law in entering into fee paying arrangements with the governments of these countries, there was nevertheless considerable disquiet about the practices. A number of important issues were raised.
- 1.2 The first issue was fundamental and extends beyond that of non-UK patients receiving NHS derived organs. In a system that relies on the generosity of organ donors, financial gain from the transplant of donated organs feels morally wrong. Even if the organs themselves are neither bought nor sold, they are essential to any transplant procedure. Without the organs, the procedures could not be offered privately or otherwise. Furthermore, if there is the possibility of financial gain, there may also be a perception that medical institutions and individuals will prefer private patients over others on the NHS waiting list, thereby casting doubt on the fairness of the UK transplant system.
- 1.3 The second issue relates to the assumptions of donors: transplants are only possible because of the free and willing donation of organs by people concerned to help others. There is an assumption that organs will be given to

people on the NHS waiting list. This is not to say that donors would have any objection to helping other potential recipients once their fellow citizen's needs had been met but, as we know, scarcity prevents this from being a realistic possibility.

- 1.4 The third issue related to a fact that was less well known: that under reciprocal EU law, citizens from other countries have a legal right under limited but defined circumstances to come to the UK for transplantation with UK donated organs within the NHS and to be treated with equal priority with UK based residents.
- 1.5 An overarching concern was that if these issues were not resolved, confidence in the integrity of the organ donation system on which so many lives depend could be eroded, potentially exacerbating an already critical shortage of organs.
- 1.6 In March 2009, the then Secretary of State, the Rt Hon Alan Johnson MP, commissioned me to undertake a review of the allocation of organs to non UK EU residents. I was assisted by a small team listed in Appendix 1 to this report which brought a variety of skills to the review process. The work of this review team built on the work of the Organ Donation Taskforce and its subsequent review on presumed consent which I chaired. The aims of the review were to optimise the availability of organs for transplant for NHS patients, provide clarity to the transplant community, provide a clear framework for transplant centres to review or agree their policies in relation to this area of healthcare, reassure the public about the integrity of the UK transplant programme and finally enable the UK to feed in findings, and make representations about any work being taken forward by the EU Commission as part of the implementation of its Organ Donation Action Plan.
- 1.7 The review considered solid organs only – primarily heart and lungs, liver and kidney.
- 1.8 Every adverse transplant story that appears in the media has the potential to affect lives. It may make people question whether they should go on the organ donor register or put doubt and anxiety in the minds of those families who are being asked to consider donation around the time of publication. This is why I

very much hope that when the media are considering running stories with a potential negative impact, they give it very careful consideration. However, in the case of the 2008/09 liver transplant stories, publication should be welcomed and regarded as providing an opportunity, once and for all, to investigate practice and ensure that the UK allocation system of organs for transplant is completely transparent and accountable. Only when this is done can the British public have complete confidence in the UK transplant programme. This is essential if the number of organs for transplant is to be increased and the deaths of patients on waiting lists reduced. It is a critical adjunct to the implementation work that has already begun following the recommendations of the Organ Donor Taskforce in 2008.

- 1.9 In January 2009, some months after the Taskforce recommendations were launched, the NHS Constitution was published. It set out the seven key principles which guide the NHS in all it does and these principles have been in the forefront of my mind when considering the complex issues involved in organ allocation. All of them are, to a greater or lesser extent, reflected in this review. For example, that access is based on clinical need, not the ability to pay, and that the NHS should be accountable to the public, communities and patients that it serves.
- 1.10 In the short time available to me I sought to ensure that all shades of opinion and practice within the transplant community were captured. I had a series of one on one and larger meetings with a wide variety of key clinical and management staff involved in transplantation across the UK. In order to ensure that staff could speak their minds, those who met me were given assurances that the confidentiality of these meetings would be respected. I have drawn on the broad outcomes of these meetings as several themes emerged consistently from these discussions. However, the exact details of what was said and by whom will remain confidential to me.
- 1.11 One immediate outcome of these discussions was a broad consensus amongst those consulted about the role of private medical practice using organs from NHS patients obtained after death. Private medical practice in this context means medical work, undertaken in an NHS hospital or in a non-NHS medical

establishment, which is not provided as part of NHS commissioned and funded treatment. The NHS makes access to medical services available to anyone physically present in the United Kingdom. Patients from overseas who are present in the UK are able to access NHS services. Unlike patients who are ordinarily resident in the UK they may be charged for the full cost of all their hospital treatment unless they receive NHS services under an E112 arrangement (see 2.11 below) or an exemption applies. Both NHS hospital trusts and NHS Foundation trusts are entitled to carry out private medical treatment. In addition NHS hospital patients are entitled to pay for additional non-medical “hotel” services such as a private room in an NHS hospital.

1.12 There are two broad groups of transplant patients who might be treated privately. Firstly UK citizens who are entitled to NHS treatment may choose to have an organ transplant in the UK as a private patient either in an NHS hospital or in a private hospital. Private transplant operations for UK citizens are rare but they can foster accusations of queue jumping. Also within this group are EU citizens who are resident outside the UK but who are entitled to NHS services through EU legislation. They are treated on the same basis as NHS patients but typically elect to be private patients, with the costs usually being met by their government through a direct arrangement with the hospitals involved. Secondly, there are some transplant operations for people from beyond Europe, typically from the Middle East or other more distant parts of the world, who have no entitlement to free NHS care. If such persons are in the UK they are entitled to access NHS services but would be obliged to meet the full costs of NHS hospital treatment¹. Such patients usually elect to be treated as private patients. In all these cases the transplanted organs would be likely to have been derived from NHS patients after death. These cases should however be distinguished from those involving live donors.

1.13 There are a growing number of private organ transplant operations in the UK however which do not use deceased organs donated within the NHS. The number of kidney transplants that are derived from live donors in the UK has

¹ Under the National Health Service (Charges to Overseas Visitors) Regulations 1989.

increased from 589 in 05/06 to 927 in 08/09. This latter figure represents more than one in three kidney transplants in the UK. There is also a small but increasing number of live donor liver transplants, mainly involving parent to child donation. Because of the great expertise that British surgeons have built in this area, some people from countries which do not have a transplant infrastructure come to Britain for live donor transplantation, usually with members of their family donating the organ. These are entirely privately funded and take place either in independent hospitals or as private operations within NHS hospitals.

1.14 All living donor transplants that take place in the UK are authorised by the Human Tissue Authority (HTA), an organisation established by the Human Tissue Act 2004. The HTA looks at each case on an individual basis to ensure that donors are not being paid, that they are not being coerced and that both parties fully understand the implications of surgery. I recognise that this activity is good for the individual patients from abroad in that it helps a large number of people who might otherwise die. It is also good for the NHS and the UK. It increases the attractiveness of the UK as a place for leading transplant surgeons to work, brings income to NHS Trusts and keeps the UK at the leading edge of medical practice. I saw no evidence that this work adversely affected the capacity of NHS surgeons to treat NHS patients. The capacity constraints in this field are driven primarily by a shortage of organs not a shortage of skilled surgeons.

1.15 The review revealed that there is almost no private practice involving organs donated after death through the NHS for UK residents. My enquiries showed that there are none in heart and lung transplantation and very limited private practice in renal transplantation and liver transplantation. For example about 0.2% of all renal transplantation takes place in the private sector and 3.9% in liver (at the two hospitals named by the media).

1.16 Typically, the institution receives a payment with an additional fee to the surgeon. Although these fees appropriately reflect the expertise and time of the doctor, they are nevertheless large sums running into tens of thousands of pounds.

- 1.17 The wider NHS may not be disadvantaged when payment is made for these transplant services. Indeed other service users may indirectly benefit from this income. However central to each procedure is the need for a donated organ which can be neither purchased nor sold yet must be available for it to take place. It could be argued that transplantation of a donated organ is equivalent to selling on a gift, even though no financial value attaches to the organ itself.
- 1.18 However, it is extremely difficult to insulate a donated organ from the taint of “private purchase” if it is transplanted into a fee paying patient by a surgeon who makes a financial gain in a hospital which also makes a profit from the procedure. It is equally difficult to assure potential donors that their organs will be allocated to the person who needs them most if it is widely known in a mixed health economy that private patients generally gain faster access to care. The perception, therefore, even if the surgeon and institution had no involvement in the allocation of organs, would be that private patients were paying to access an organ more quickly.
- 1.19 How things appear to potential donors is important because of its impact on their willingness to donate, but this is not the only consideration. In attempting to increase donation rates, considerable emphasis is placed on enabling people to expressly consent to donate their organs after death. For this consent to be real, people need to understand the terms of their donation. Transparency and clarity are essential to valid consent, and by being able to assure donors that their gift will be respected and allocated to a fellow citizen on the basis of need and clinical suitability, as opposed to ability to pay, the terms of the donation are clear and straightforward.
- 1.20 Although I found no evidence that private patients were receiving organs more quickly than NHS entitled patients, public response to media coverage has shown that undertaking transplant operations in the private sector with NHS donated organs can have a corrosive effect on public and professional confidence in the organ donation system. Given the importance of public confidence in the continued availability of donor organs, it is vital that the system is not subject to any perception of bias, preferment or queue jumping. Financial gain by either an institution or individuals inevitably creates this

perception. A strong view was also expressed to me that it is part of the “willing donation” given by an NHS patient and their family that the donated organ should stay within the NHS rather than being used to treat a private patient. For this reason, as far as organs obtained after death from NHS patients are concerned, I recommend that there should be no private clinical transplantation practice whatsoever in the UK for either NHS entitled patients or for those not so entitled. The work up and assessment of the patient from the point of referral to a transplant surgeon, the decision to list, the transplant procedure and post transplant care for the life of the graft should all be within the NHS and subject to the normal multi disciplinary team review. This recommendation is vital to maintain the integrity of the transplant system and the confidence of the public.

RECOMMENDATION ONE

That Secretary of State for Health should impose an immediate ban on all private clinical practice involving solid organs which have been donated after death within the NHS. This ban should include overseas visitors who are fee paying NHS patients under the 1989 Regulations.

- 1.21 There are some practical steps which I recommend to give effect to Recommendation 1. Whilst many transplant centres are in NHS Trusts, some of the most high profile are in NHS Foundation Trust hospitals to which the Secretary of State cannot give directions. I would hope however that NHS Foundation Trust Boards would want to endorse this policy for their own Trusts and suggest that, in the first instance, the Secretary of State should write to all Foundation Trust Boards to invite them to do so.
- 1.22 For those transplant centres which are within NHS Trusts, I recommend that the Secretary of State issues an amendment to the 2005 Directions to ensure that all NHS Bodies provide and use organs obtained after death within the NHS, only for NHS patients, within the scheme operated by the NHS Blood and Transplant Authority (NHSBT), and that NHSBT only allocate organs on that basis. I envisage that this would only require a small change to the 2005 Directions.

1.23 Transplant services are commissioned from NHS bodies by commissioners such as the National Commissioning Group. I recommend that they should change their commissioning contracts to give effect to Recommendation One. I also recommend that changes are made to the standard acute services contract for Foundation Trusts to the same effect. This would create a legal obligation on all Foundation Trusts to implement Recommendation One and it would therefore prevent prospective private patients having access to NHS derived organs within all NHS hospitals.

1.24 Commissioning arrangements for healthcare vary across the four countries in the UK. For clarity this report primarily describes arrangements in England, and I hope each of the Devolved Administrations will consider adopting the principles that underpin the recommendations. The National Commissioning Group (NCG) is the body in England that commissions NHS services for rare conditions and for rarely required or highly specialist medical procedures on a national basis. As part of this activity NCG commissions all NHS solid organ transplants, except for kidneys. Kidney transplants are commissioned regionally and the regional Specialised Commissioning Groups (SCGs) should continue to secure these services for their residents.

RECOMMENDATION TWO

I recommend that the Secretary of State issues amendments to the 2005 Directions, and proposes amendments by April 2010 to the standard form of NHS Acute Services Contracts including the National Commissioning Group contracts with Transplant Centres, to require all NHS bodies, including NHS Foundation Trusts, to ensure that an organ which is donated from an NHS patient after death is required to be processed under the NHSBT matching and allocation scheme and can only be used for NHS entitled patients receiving their clinical care as an NHS patient.

- 1.25 My enquiries have identified that alongside E112 arrangements, some governments of other EU countries, have contracted with NHS Trusts for transplant services to be provided on a private patient basis in the UK for their citizens. Financial arrangements have been established directly between those governments and certain NHS hospital Trusts. If Recommendation One is accepted, then these contracts could not continue with patients being treated as private patients. However they could continue with the patients being treated as NHS patients. I believe that it would be more appropriate and transparent for such contracts to be agreed nationally with NCG acting on behalf of the NHS. For livers this would mean that the funding of patients under E112 arrangements would be part of the annual contract agreed between the National Commissioning Group (NCG) and transplant centres.
- 1.26 In this way, NHS hospitals will receive reimbursement from commissioners such as NCG for all the transplant activity they undertake for NHS entitled patients not resident in the UK, as well as for all transplants for UK residents. Such an arrangement would ensure that there could be no perception of a financial incentive to Trusts or clinicians to favour patients from other countries.
- 1.27 There is potentially a separate issue where an individual patient may seek to exercise a right under Article 49 of the EU Treaty to have a transplant operation in the UK as an NHS patient without the prior approval of their national government. I am not aware that this has ever occurred but if it does happen I recommend that the transplant centre should refer the case to the Department of Health for specific advice.

RECOMMENDATION THREE

All arrangements for the provision of transplant services for EU based patients, where an entitlement exists under EU law, should be made between the national government concerned and NCG and, if approved, should be undertaken as part of the annual contract agreed with transplant centres.

2 WHO IS ENTITLED TO RECEIVE NHS DERIVED ORGANS?

- 2.1 One cannot fail to sympathise with the plight of a person who needs a transplant but dies for lack of facilities in their own country. If we were that person and had the funds to do so, we too would do everything we could to obtain a transplant elsewhere. But I return to the opening sentence of this review. There are not enough donated organs for all those in the UK who need them. Every organ donated to a person not resident in the UK means that a person on the NHS waiting list will not get the organ they need. And that can mean the difference between life and death for that person.
- 2.2 It would be wrong however to start with an assumption that UK donors should always and only benefit UK recipients, but it is fair to assume that NHS patients whose relatives have donated their organ would wish priority to be given to other NHS patients. Whilst it is unrealistic under present conditions to consider that we will ever have too many organs, we would surely want to argue for a system that would allow for spare organs to be used and not wasted once all people on the UK waiting list had benefited appropriately. For example, if a child with a rare blood group dies and parents consent to donation, that child's liver would only be suitable for a recipient of the same size and blood group. If no child on the UK waiting list is a suitable match and a recipient could be identified further afield, then it is right that it should be offered across borders, rather than be wasted.
- 2.3 Organ donation is sometimes characterised as 'helping our neighbour'; where that neighbour is assumed to be a fellow member of the society in which the act of generosity occurs. Whilst as a society we have taken steps to protect against discriminatory direction of organs by individual donors, organ donation cannot realistically be interpreted as an act of globally focussed compassion. However, we can and have taken steps to seek to ensure that donated organs are fairly and justly allocated.

- 2.4 Given the scarcity of organs, those who are resident in the UK are entitled to assume that, as potential donors and as supporters of a nationally funded health service, they would be seen as potential recipients in priority to those not resident in the UK, unless non-residents were part of a formal reciprocal scheme.
- 2.5 I know that some members of the public have been dismayed by media reports which seem to indicate that reciprocal healthcare arrangements in the EU entitles all those in EU countries to come to Britain for transplantation with a UK donated organ. In fact, this is not actually the case but the situation is complex and it is not surprising that people are confused. My enquiries revealed that there was also considerable professional confusion about who is and is not permitted to come to the UK to take advantage of NHS facilities, let alone who should or should not be entitled to NHS transplants in the UK.
- 2.6 It is important to recognise that there are some successful reciprocal arrangements for organ donation which operate to the UK's advantage, an example being the arrangement with the Republic of Ireland (RoI). Transplantation requires a critical mass of population to be viable. The RoI is too small to sustain a complete service and there is a long standing arrangement by which Irish citizens travel to the UK for liver, heart and lung transplants. In return, some organs donated in the RoI enter the NHS pool. The UK also provides the expertise of our clinical teams and supports liver, heart and lung teams in Dublin. Historically the UK is a net beneficiary of organs – see the table below. The position in relation to other countries is shown in Appendix 2.

Organs transferred for transplant between Republic of Ireland and the UK, April 08 - March 09

organ	Retrieved in RoI, transplant to UK residents.	Retrieved in UK and transplanted to RoI residents.
kidney	3	0
heart	4	0
lung	5	5
liver	5	4
total	17	9

- 2.7 There are similar ‘pooling’ arrangements in other parts of Europe. Eurotransplant for instance is a federation of countries including Austria, Belgium, Germany, Luxembourg, the Netherlands and Slovenia. The Nordic Countries also have their own transplant federation, Scandiatransplant.
- 2.8 It is also worth acknowledging the special cases that can arise in relation to transplant procedures. For example, one or two babies are born in the UK each year without a thymus (a gland behind the sternum important in developing immune response). There is no shortage of thymus glands for transplant. But for surgeons to maintain the necessary skills to offer thymus transplant, they need to undertake at least four cases a year. For this reason, Great Ormond Street Hospital offers thymus transplant to several babies each year from other parts of the world. Any alteration in legal entitlements would need to ensure that this sort of practice could continue.

CURRENT ENTITLEMENT ALLOCATIONS

- 2.9 Under the 2005 NHS BT Directions², potential transplant recipients are allocated to one of two groups, Group 1 and Group 2. Full details are in Appendix 3.

PATIENTS IN GROUP 1

- 2.10 Group 1 patients always have priority over those in Group 2. Group 1 includes all people ordinarily resident in the UK, regardless of nationality. It should be noted that by choosing to live in the UK, foreign nationals become potential donors as well as potential recipients.

² The NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005.

- 2.11 Also in Group 1 are all those people who are entitled to assert a right to NHS treatment under EU Regulations 1408/71. These are the reciprocal healthcare arrangements which are familiar to all applying for an European Health Insurance card or EHIC before going away on holiday. They exist to ensure treatment is available for anyone in the EU (and are extended to the European Economic Area and Switzerland) who is taken ill while visiting the UK. In very rare cases, for example, those who have the misfortune to suddenly develop fulminant liver disease or myocarditis (very serious problems which have a rapid onset and lethal course), it might include a transplant. Regulation 1408/71 also provides for persons to be authorised by their home Member State for the purpose of receiving healthcare. Such healthcare is provided at the expense of the patient's home Member State.
- 2.12 This categorically does not mean that all EU or EEA citizens are in Group 1. However broadly we have to treat those ordinarily resident in Britain from the EU and indeed worldwide, for example those working or studying here for an extended period, on equal terms with residents of the UK³. Nor, save in very special situations we discuss below, does it cover people who have come to the UK for the specific purpose of seeking medical treatment.
- 2.13 Finally there are a number of countries listed in the Guidance to the 2005 Directions with which the UK has bilateral health agreements which allow them to refer their citizens or nationals to the UK for treatment for pre-existing conditions. This might include transplantation. Amongst them are British island populations, such as the Falklands and Gibraltar but also a number of very small Commonwealth countries in the Caribbean including Anguilla, Montserrat and the Turks and Caicos islands.
- 2.14 A more surprising listing are nationals of the former Yugoslavia, such as Croatia and countries of the former Soviet Union such as Ukraine, Uzbekistan and Georgia. In reality, referrals from all the territories mentioned in this paragraph are either extremely rare or non-existent. Some of these listings have their origin in history and are in need of review.

2.15 It is unclear to me why, under the 2005 Directions, the UK grants Group 1 status to nationals of certain non-EU and non-EEA countries. Nationals of many of these countries would not necessarily be entitled to free NHS care and thus would have to meet all the costs of treatment. The “right” to be treated as a Group 1 patient is therefore likely to be only a right for the tiny minority of nationals of those countries who could afford to meet the costs of their own medical treatment. In addition, the right to Group 1 status depends on residence in the UK or countries with defined reciprocal agreements, not on nationality. Permitting nationals from states such as Uzbekistan to be within Group 1 would mean that a UK national who was ordinarily resident in Uzbekistan would be in Group 2 even if that person had lived for many years previously in the UK, but a national of Uzbekistan who had no connection whatsoever to the UK would be in Group 1.

2.16 I recommend that an urgent review is conducted to consider whether the inclusion of nationals of the countries listed in Annex 2 of the Guidance to the 2005 Directions continues to be justified. I would suggest the only justification can be proved evidence of reciprocity of donated organs and/or services.

RECOMMENDATION FOUR

I recommend that the Secretary of State urgently reviews the reciprocal country arrangements in Annex 2 of the Guidance to the 2005 Directions and only continues to provide for nationals of other countries when there is evidence of the reciprocal transfer of organs and/or services.

WHAT IS THE PRESENT PRACTICE?

2.17 I asked transplant centres what checks they made of patient status (i.e. whether they were Group 1 or Group 2) before accepting them for transplant. All centres checked for NHS number and other details. Whilst transplant centres

³ Under for example the European Convention on Social and Medical Assistance.

were strongly in favour of only treating those who had NHS entitlement, they reported that they were unsure of the law in some cases regarding treatment of non-resident foreign nationals, particularly from EU states.

2.18 I asked specifically if there was evidence of people coming to Britain, for example as asylum seekers, in order to receive transplantation services (asylum seekers qualify for NHS treatment). Transplant centres acknowledged that there were a handful of asylum seekers who had received transplants over the last decade, but some had had fulminant liver disease after their arrival in this country, so had not entered the UK with a pre-existing need for transplant. A more likely scenario was acknowledged to be those asylum seekers who enter Britain knowing of their need for dialysis. Once they are on dialysis, they might then be considered for transplant.

2.19 There is widespread recognition that there is a need for tighter guidance to the transplant community about which patients who are based abroad or who have recently come to the UK are and are not eligible for transplant and what procedures Trusts should go through to check the entitlement of an individual patient. It is also important to clarify the rules for those NHS clinicians in related specialties who refer patients to transplant units. This is because transplant teams may assume that a patient is eligible for NHS treatment when they are referred to them from elsewhere in the NHS. However the rules for entitlement to a transplant are different from entitlement to other NHS services, so this may not be the case. I recommend that the Secretary of State issues guidance to clarify the legal position and to ensure that specific eligibility checks are carried out before a person is listed for a transplant operation.

RECOMMENDATION FIVE

The Secretary of State should issue clear guidance to transplant centres about the eligibility of patients who are resident abroad or who have recently come to the UK and the steps which should be taken by Trust to determine eligibility in an individual case. This guidance should stress the need for Trust to have effective corporate governance procedures in place so that the eligibility of every patient is clearly documented before any NHS transplant operation is carried out. The Department of Health should be able to provide timely advice in complex cases.

WHAT IS THE LEGAL POSITION FOR PATIENTS FROM ABROAD

- 2.20 I took advice from David Lock, a barrister with extensive experience of EU law as it affects the NHS, who advised on the legal position. This part of my guidance is based on that advice.
- 2.21 Anyone who is physically present in the UK is entitled to access general NHS services. However the NHS has a duty to impose charges for hospital services provided to visitors and, subject to obligations to provide immediate life saving treatment under Article 2 and or 3 of the European Convention on Human Rights, can refuse to provide those services unless advance payment is made by the patient. But there is also a system regarding organ allocation which is set out in 2005 Directions made by the Secretary of State. Thus even if someone who lives abroad can establish a general right to NHS treatment, that person may not be entitled to a transplant operation with an NHS donated organ.
- 2.22 The EU is committed to maintaining a single market, with EU residents having free movement for work. That can only be a reality if workers and their families who are resident in another EU state can access healthcare for themselves and their family in the EU state in which they are working. EU regulations provide that such persons must “enjoy the same benefits under the legislation of any Member State as the nationals of that State”.⁴ In theory, this could include transplantation.
- 2.23 Some patients choose to travel across borders to obtain quality assured healthcare from doctors based in other member states. Most continental healthcare systems are based on an insurance system where the insured has the right to seek healthcare from any doctor, and then charge the insurance company for the service that the doctor provides. A state based medical insurer cannot specify that payments from the national insurance fund will only be made to doctors based in their own state. The legislation is thus directed at the obligation of the home state or health insurance provider to pay, rather than

⁴ See regulation 3 of EU Regulation 1408 of 1971 (as amended).

being based on obligations on medical institutions in other states to provide such services. Some British patients have already exercised these rights to their advantage in order to have NHS funded medical treatment in other European countries. State owned medical services, such as NHS Trusts, may be acting in breach of EU law if they refuse to provide services to a patient solely based on a person's residency in another EU state.

2.24 A patient who wishes to travel to another EU state under Regulation 1408/71 specifically to have a transplant operation is required to seek the prior approval of their home state healthcare system. If approval is granted, the home state healthcare system and not the individual patient pays for the treatment. There are restrictions in the EU regulations on the circumstances in which a home state healthcare system can refuse to provide such approval. The general test is whether the requested treatment can be provided within the home state within a time limit which is medically justifiable, taking into account the patient's current state of health and the probable course of the patient's illness. For example, Greece provides transplant services as part of its national health system. Thus if a Greek patient was not able to get an organ transplant operation in Greece, the Greek medical service could authorise that person to come to the UK to get treatment⁵. If a person is authorised by the government of their home state to come to the UK for a transplant operation, they are entitled to NHS treatment here on the same terms and with the same clinical priority as a UK based resident.

2.25 I am clear that an EU national does not have a "right to a transplant". The most that such a patient could establish is a right to be treated by the NHS on an equal basis to NHS patients resident in the UK. Guidance should make it clear that an EU based patient could be lawfully refused treatment in the NHS if he or she was not deemed clinically suitable or able to access follow up treatment. It should also make it clear that EU based patients should not be entitled to use EU legal rights to "queue jump" over UK residents.

⁵ See regulation 22(1)(c) of 1408 of 1971 EU.

- 2.26 If transplant services generally or for a specific medical condition are not part of the medical services offered by the patient's home state health service then there is no transferrable right which the patient can exercise under EU law to have the treatment provided abroad. The patient must have a right to treatment in their home state before the patient can claim a passportable right to have the treatment elsewhere in the EU. Thus, for example, if transplant services are not provided as part of an EU Member State's own healthcare system, it is difficult to see how that Member State could use EU law to access NHS treatment for a transplant because he or she would not have that right in their home state.
- 2.27 EU legislation however does not at present explicitly take account of situations where the limitations on the ability of a state to provide healthcare are not financial, nor due to lack of will to provide a particular treatment for their citizens such as in a small country where the size of the population prevents the establishment of a comprehensive donation and transplantation programme. However, given the shortage of donated organs and the large number of UK residents awaiting transplant, providing NHS transplant services to all EU patients would disadvantage UK patients and could have an adverse effect on donor recruitment.
- 2.28 Despite the law, and probably as a result of the EU wide shortage of donors, there is anecdotal evidence that some European member states interpret the European regulations in a way that generally favours their own nationals. Although such an approach technically leaves them open to legal challenge, there is no evidence of open EU borders for transplant services. I am told of one country for example, which only treats patients resident in that country, working on the principle that only those who have the possibility of being donors should receive transplants. Other countries have a quota of transplants, which they make available to non residents, or reciprocal arrangements whereby the number of organs received from a country prescribes the number of residents from that country who receive transplants in the following year.
- 2.29 Britain too could follow these examples. However the terms of this Review require that I look for solutions within the framework of European law,

suggesting the more cautious approach is to issue guidance to NHS bodies to ensure that only those who are genuinely entitled to exercise their rights under EU law are treated within the NHS with NHS donated organs. I consider that this is likely to be a smaller number than are presently provided with treatment.

2.30 The legal problem of an EU system which does not take account of non-financial capacity constraints in acute healthcare may be partly resolved by the forthcoming EU Directive on patient mobility. However, although there is a proposal to exclude organ donation from the patient mobility directive, this may not solve the uncertainty. I understand that the new directive will not replace 1408/71 and patients will still have the potential to exercise individual rights under Article 49 of the EU Treaty. Unlike patients who assert a right to come here with the support of their own governments under 1408/71, individual patients who assert a right to be treated under Article 49 are not placed in Group 1.

2.31 There is a possibility that it would be lawful for the UK to use the shortage of donated organs to restrict access to NHS transplant services even if a patient had an established right to come to the UK to seek medical treatment with the approval of their home state under regulation 1408/1971. However this is an area that would need a considerable amount of further legal work and which may, depending on the outcome of the negotiations on the Patients Rights Directive, not be necessary. I therefore recommend that there is clearer guidance provided on who is and who is not entitled under existing EU law.

CAPACITY ISSUES IN OTHER MEMBER STATES

2.32 EU patients currently asserting their legitimate rights under EU law to be considered for a transplant, with the prior authority and financial support of their governments, come predominately from two EU countries, Greece and Cyprus. With a population of less than a million, Cyprus is not big enough to sustain a comprehensive transplant service. It also has a greater prevalence of certain conditions which may require transplant, for instance, familial amyloid

polyneuropathy, a genetic disease whose treatment may include liver transplant. Greece does have a transplant service although, like the UK, there are not enough donors to support the numbers requiring transplanted organs.

2.33 Whilst individual patients benefit from the ability to come to the UK for transplant, it could be argued that taking them outside their own health care system for treatment is in fact a disservice to the Greek and Cypriot populations as a whole. Whilst Britain provides transplants, there is little incentive for such countries to develop the necessary capacity, or, in the case of Cyprus, to make suitable reciprocal arrangements with geographical neighbours. In addition to addressing the wider issues of passportable rights within the EU with regard to transplanted organs which may take some time, a practical interim alternative is to work with the EU and the appropriate national medical bodies to support those countries which have a transplant capacity problem, either by effecting reciprocal arrangements between smaller countries, or by helping develop capacity through training of their doctors in UK transplant facilities. I understand that this process has already begun with some countries.

RECOMMENDATION SIX

The Secretary of State should work with colleagues across the EU to encourage the building of donation and transplant capacity in those states where they are currently not provided, or to help develop formal reciprocal arrangements between neighbouring countries.

SHOULD FOREIGN NATIONALS HAVE ACCESS TO POOR QUALITY ORGANS?

2.34 Foreign nationals are classified as Group 2 under the Directions, unless the individual has a specific right to Group 1 status. Such patients are generally only entitled to NHS services if they agree to meet the full costs and are often required to pay costs upfront, or they can be treated in private hospitals. There are a relatively small number of such patients who come to the UK each year. These Group 2 patients only have access to organs, primarily livers, which are not deemed to be of sufficient quality for NHS patients. I understand the

principle is that, even if an NHS donated organ is of too poor quality to be used within the NHS, it should not be discarded if it has the potential to offer some hope to a foreign patient.

- 2.35 Those who support this practice say that no organ is lost to NHS patients because of it, but it still raises some serious ethical concerns. Firstly, whether it is right to offer desperate patients procedures which, because of the poor quality of the organ, are considered too risky to be offered to NHS patients. Secondly, whether someone should in effect be allowed to buy the opportunity that many NHS patients might be willing to take but are not offered; the choice to be transplanted with a far from ideal organ when the alternative is death, on or off the waiting list.
- 2.36 While there are foreign Group 2 patients waiting for private liver transplants in the UK there will always be a suspicion that the quality of organs could be misrepresented for financial gain. Given that improved surgical techniques now mean that the outcome for Group 2 patients transplanted with NHS-rejected livers is likewise much improved, it is understandable that suspicions have increased.
- 2.37 Overall I consider that the process by which livers are designated as unfit for Group 1 but fit for Group 2 is disquieting and should cease. There is a strong view amongst the transplant community that if the organ is fit for use there will always be sufficient Group 1 patients who should be offered the choice to have a transplant with that organ. I believe that if an organ is genuinely of such poor quality that no NHS patient should be offered the chance to have it, then I consider that it follows that it is not ethically fit for use and should be destroyed. This practice should be addressed by the recommendations we have made regarding the use of NHS donated organs in private practice but it should also extend to Group 2 patients who are treated as fee paying NHS patients.
- 2.38 There is a particular practical problem in relation to the live donation liver transplant programme for patients who come from abroad. If a previously healthy donor of a liver for living transplant develops liver failure as a consequence of liver donation surgery, the current procedure is that this donor is immediately listed as a 'super urgent' case on the liver transplant list, no

matter what their country of origin. As explained earlier, many people come from all over the world to the UK for live donation procedures. If there were not more recipients waiting than donors available, one would want to continue to support the selfless altruism of foreign live donors by making transplant available to the donor in cases of live donor liver failure. However, a liver offered to a foreign resident patient in such circumstances is one which cannot be offered to a UK resident person who may then die. It is a harsh consequence of scarcity but in these situations the foreign resident voluntary donor who, as a result of their donation needs a liver transplant, remains a Group 2 patient. Under the current system such a person should therefore not be listed for transplant as if he or she were in Group 1. We support this classification. Counselling for such patients should make clear not only the risks of the procedures they are considering, but ensure that they understand that, should the consequence be liver failure for them, there can be no rescue available in the form of a liver transplant from a UK donor.

3 ORGAN ALLOCATION

3.1 Discussions about entitlement to NHS derived organs have revealed a number of specific practices, particularly in the liver transplantation community, which need to be addressed. It is helpful to show where transplants take place in the UK and also outline, in broad brush terms for a non specialist audience, the clinical procedures in place for the allocation of organs. It may also help to understand why liver transplantation has been the focus of questions about the allocation of organs to non UK EU residents.

UK hospitals where liver transplants are carried out

Birmingham	Diana, Princess of Wales Children's Hospital
Birmingham	Queen Elizabeth Hospital
Cambridge	Addenbrooke's Hospital
Edinburgh	Royal Infirmary
Leeds	St James University Hospital
London	King's College Hospital
London	The Royal Free Hospital
Newcastle	Freeman Hospital

3.2 The system of allocation differs according to the type of organ whether it is a heart, lung, kidney or liver, but there are some guiding principles. When an organ becomes available anywhere in the country, the duty office at NHS Blood and Transplant (NHSBT) is notified immediately. Staff first identify whether there are any super urgent cases with blood group or age compatibility in any of the transplant centres before allocating it to a person on the transplant list or relevant transplant centre. Organs donated from children generally go to child patients to ensure the best match in size but when there are no suitable child recipients, organs from young people are given to adults. If there are no suitable patients for a donated organ anywhere in the UK, reciprocal arrangements within the European Union allows donor organs to be offered to other EU countries. This is extremely unusual however.

- 3.3 The Advisory Groups within NHSBT have devised clear criteria for adding patients to the waiting list to help give patients across the UK equitable access to transplant. The NHSBT database contains a record of all those listed as waiting for a transplant. It is not a record however of all those who might benefit from a transplant which is a much greater number. Because of the shortage of donated organs, access to the waiting list is carefully managed and many people who would benefit from a transplant are not put on the list. For all organs, demand far exceeds supply and about 1,000 people each year will die while on the waiting list or have to be taken off the list because they have become too sick for surgery. For example, up to a third of young people with cystic fibrosis waiting for a transplant will die whilst waiting.
- 3.4 Clinical staff usually specialise in the transplant of one particular organ. The communities involved have different characteristics as do the organs themselves. It is worth detailing these, once again in broad brush terms for the non specialist, so that there can be a greater appreciation of the issues involved.

KIDNEYS

- 3.5 A kidney is easily transportable and will survive in good condition for up to 24 hours if appropriately packed. For a kidney transplant to have the best chance of success, donor and recipient should be as closely matched as possible, including tissue type and then by blood group, age and size. The National Kidney Allocation Scheme, introduced in 2006, is run by NHSBT and matches the details of donor organs against the details of patients registered on its centrally held waiting list.
- 3.6 There are currently some 7,000 people registered on the active waiting list for a kidney transplant and approximately 2,500 people received kidney transplants in 08/9 of which about two thirds come from deceased donors and one third from live donors.
- 3.7 A computer based five tier national allocation system is used with a score based on time on the waiting list (favouring those waiting longest), tissue match

and age (favouring good matches for younger patients), age difference between donor and recipient, location of donor in relation to recipient (favouring minimal transport times for the donated organ) and a number of other factors such as blood group. Thus for kidneys, matching is based on objective science and although tissue matching is not as important as it once was for some patients, basically for a good outcome, a match is a match. The national allocation system seems to be working well and our investigations did not identify any major problems.

- 3.8 It is worth saying that the public is familiar with the concept of matching and understands that if a kidney does not match someone on the waiting list in the UK it should be offered elsewhere rather than be wasted. A very small number – 1 in 2008/09 - of NHS derived kidneys are therefore offered to EU patients outside the UK and vice versa.
- 3.9 A patient with failing kidneys requiring a transplant can be kept alive with dialysis, perhaps even for some years, until a donor organ becomes available, although quality of life is likely to be poor. This availability of dialysis is also to some extent a transplant safety net. A marginal donor kidney can be transplanted in the hope that the patient will do well, but in the knowledge that if it fails, dialysis is still an option. This is not the case for liver or heart. Almost all of those on the kidney list will be suffering from chronic conditions, with very few having experienced sudden organ failure.

HEARTS AND LUNGS

- 3.10 There are approximately 100 people on the waiting list for a heart and around 130 heart transplants are performed each year. For heart transplantation, quality is the dominant issue. To remain viable for transplant, a heart must be appropriately transported and transplanted within 4 hours. This is a major logistical exercise which may for instance involve chartered flights. The success of heart transplants is not predicated on tissue typing, as it is with kidneys, but is heavily dependent on the quality of the organ transplanted. Key factors are its state at donation and time elapsed since removal. Marginal

hearts cannot be used as the survival rate is very poor. This means hearts for transplant are more likely to come from the young and previously fit and hence a smaller donor pool. Because time is of the essence, the geographical location of donor and recipient is also a major issue.

- 3.11 At any one time, around 5 or 6 people (approximately 6%) on the waiting list for a heart transplant are critically listed, that is, they will die within days without a new heart. These are usually people in previously good health but who have suddenly become acutely ill, usually because of infection or trauma. Whilst there is a 'fallback position' for kidney patients in dialysis, the equivalent for hearts, ventricular assist devices (VADS), can only be used at most for a year and may not be suitable for all patients awaiting transplant. In addition, they have significant side effects including blood infection and blood clots. Therefore patients waiting for a heart who are classified as urgent are given priority.
- 3.12 If there are no urgent patients on the waiting list, the organ is offered for patients on the non-urgent list within the retrieving centre who are nearest in size and blood group to the donor and then to those in other centres on a rotational basis. Location of donor and recipient is therefore an influential factor.
- 3.13 The same principles apply to the allocation of lungs for transplant, although there is no national system for offering to the most urgent patients. Each centre makes the decision as to which patient is to receive a lung, depending on size, blood group and severity of illness. A rotational process is used for offering the lung to patients in other centres if it cannot be used in the local centre. There are 250 patients on the waiting list for lungs in the UK and about 150 transplants are performed each year.
- 3.14 Recent data show that there were 5 lung transplants in patients from the Republic of Ireland using organs from UK donors in 2008/09. In the first three months of 2009/10, the Freeman Hospital in Newcastle has transplanted one lung and one heart into Rol patients with organs from UK donors.

LIVERS

- 3.15 Livers are transported on ice in a similar way to kidneys, hearts and lungs and remain viable for transplant for about 12-18 hours.
- 3.16 There are about 300 people on the waiting list for a liver transplant at any one time (although this represents a small fraction of those who would benefit from transplant) and about 650 liver transplants were undertaken in 08/09.
- 3.17 Livers do not require detailed matching like kidneys (just size and blood type) and, by contrast to heart and lungs, there are more available for transplantation. This is partly because some of the conditions that most commonly cause donor organs to be made available, such as cerebral haemorrhage, damage the heart but will not have affected the quality of the liver.
- 3.18 In lay terms, livers are more 'forgiving' in that, unlike hearts, good results can be obtained with less than perfect organs. Also, the liver can regenerate to some extent and a large, good quality liver can be split into two, particularly if one of the recipients is a child. Poorer quality livers are not split as this may have a greater impact on success. The demand for liver transplant is so high that livers previously thought poor quality or rejected for other reasons, such as the lifestyle of the donor, are now used routinely. That this is possible is also due to the great skill of liver surgeons in advancing surgical techniques.
- 3.19 The majority of those requiring transplantation of the liver have chronic conditions but some have what is called fulminant liver disease; that is they were previously healthy but something - typical examples are infection with hepatitis viruses or paracetamol overdose – suddenly precipitates very rapid, widespread and irreversible liver damage. This liver failure causes a chain reaction in the body and death usually follows very rapidly, often in days. Because of this acute situation, these patients are classed as 'super urgent'. About 130 patients are listed this way across the UK each year. They are notified to NHSBT and placed on a national waiting list and take absolute priority whenever donor livers become available.
- 3.20 When a donated liver becomes available, it is retrieved by the zonal centre (that is the centre allocated to collect all donor livers within a particular geographic

zone). The liver is first offered to those listed as super-urgent on the national list anywhere in the country. A decision about whether to accept it is made by a surgeon at the centre where the patient is listed. If the liver is suitable for splitting, the left lateral lobe (the smaller one) is offered to a child recipient. The retrieving centre is allowed to keep the right lobe. If not needed for a super-urgent patient, or suitable for splitting, the liver is used by the zonal, ie the retrieving centre. If the liver cannot be used in the zone because there is no suitable recipient, it is offered to the national pool via each of the transplant centres, in a set sequence held by the NHSBT duty office. Once a centre has accepted a liver, it will go to the bottom of the offering sequence the next time a liver becomes available from another centre. Thus for liver transplants there is not a national patient allocation system, but a centre allocation system.

- 3.21 If, for some reason, an allocated retrieval team cannot retrieve an organ in their zone, another centre can retrieve it if they have capacity to do so. Retrieval zones are allocated by the NHSBT Liver Advisory Group on which every Liver Transplant Centre is represented. In this way every centre is party to the regular reviews of activity to ensure allocation is as fair as possible.
- 3.22 Centres have local autonomy of decision making about the recipient of livers that they retrieve or are offered. Every liver centre has a weekly multidisciplinary team (MDT) meeting at which decisions are made about the priority order of patients for liver transplants that may become possible during the coming week. Where a patient's condition deteriorates rapidly during the week and a transplant is done in an order different from that agreed the MDT reviews the decision the following week.
- 3.23 There is no evidence to suggest that there has been a difference in waiting time between private and non-private patients but nevertheless, this system of allocation via centres, some of which have substantial private practice, might have contributed to public unease that private patients received an organ in preference to NHS patients.
- 3.24 A national allocation system for livers has been under discussion for some time. It would do much for transparency and it would also break the link between retrieval zone and transplant activity. Some liver transplant centres have argued

forcefully that a national allocation system would not take into account local clinical judgement which some feel plays an important part in a successful transplant. It is recognised that a national allocation system is not a panacea and there are clear difficulties to be resolved. However it would bring a greater transparency to the system and improved public confidence.

3.25 In the United States a scoring system called MELD (Model for End stage Liver Disease) is used to calculate the survival probability of a patient with end-stage liver disease and to allocate organs to patients. A UK version, UKELD, has been developed since 2005 which is used to ensure equity of access to the waiting list for liver transplantation so that only patients above a certain UKELD score can be registered (apart from special cases) but it is not being used nationally for allocation. In both the US and UK systems there is room for clinical adjustments, which can lead to a lack of confidence in its application on a national basis. A more transparent and rigorous system of allocation would help further collaboration between centres and would also assure greater public confidence.

3.26 I recognise that such a system would need to blend rules with clinical judgement. If a system were too 'rules based' it could work against the patient's best interests. An example of this was the lung allocation system introduced in the US which prioritised those patients who had been on the waiting list longest. An unintended consequence was that some of the very sickest patients were those who had only been on the list a short time and they were the ones most disadvantaged by this system.

RECOMMENDATION SEVEN

The Secretary of State should encourage officials to work with NHSBT with advice from the Liver Advisory Group to implement a universal allocation process for liver transplants, and to expedite an equitable allocation process based on objective parameters.

3.27 A further difficulty raised in liver transplantation was in relation to the quality of the liver being offered. This has allowed some organs to be used for Group 2 patients. As mentioned earlier, evidence seems to suggest that Group 2

patients now do quite well and this has added weight to the belief that the quality of the liver may have been misrepresented. Whilst I have been unable to verify if this has ever occurred in practice, the possibility of such a practice breeds distrust and this can be corrosive. This situation would be avoided with the implementation of the two recommendations I have already made, namely adherence to a universal allocation process and no private practice for transplants involving NHS derived organs.

3.28 There can be a genuine practical difficulty however in appraising the quality of livers being offered. A centre might, for instance, not want to accept a marginal liver for a patient who had particular clinical problems whilst wanting to accept it for a patient in better health. A digital imaging service called NORIS has recently been trialled which allows surgeons to inspect livers on-line before accepting them. I understand that this service has three year funding from NHSBT during which its effectiveness will be assessed.

CLARITY OF RESPONSIBILITY

3.29 Pioneering areas of medicine, such as liver transplantation, seem to attract strong characters. Whilst these individuals can put relationships with colleagues, management and other transplant centres under strain, it should not be forgotten that patients may benefit from their determined and driven nature, their willingness to take risks for their patient's benefit and their supreme technical skill. It is because these individuals have been prepared to push surgical boundaries that liver surgery has been advanced, to the extent that there has been a demonstrable global impact in terms in the number of people who now survive liver transplantation. British liver transplant surgeons have been a major part of this global success story.

3.30 However if the actions of these strong characters damage public confidence in the organ donor system, resulting in a significant fall in donor organs from an already low base, they may cause more harm than good.

3.31 Individual doctors are formally accountable to their employing trust and to their professional regulator, the General Medical Council. As far as Trust

governance is concerned, there may be a perceived conflict of interest if a surgeon's activities are deemed unacceptable by the rest of the transplant community but are beneficial financially to that Trust. I have reached the strong view that the tensions in this very difficult area mean that governance and accountability arrangements need to be clearer.

3.32 A number of bodies have governance responsibilities for transplant services overall and this review has identified areas where accountability is not as clear cut as it should be. As a result, action has not been taken to address areas of concern when it was required. This lack of clarity has arisen over time and with the best intentions, as a series of interim arrangements evolved to address emerging questions. However, this review has created the opportunity to address any confusion and identify clear responsibilities and boundaries for the bodies involved. Greater accountability and clarity of responsibility would be of benefit both to the transplant community and to wider society.

3.33 I recommend that guidelines should be introduced to ensure compliance with the organ allocation systems and that these guidelines should be built into the commissioning contracts between NCG or regional SCGs and the transplant centres. It should then fall to Commissioners to monitor the performance of transplant centres against those guidelines and to encourage both compliance and improvement. If a breach occurs, it would then be for Commissioners to determine whether the breach warranted intervention and, in extremis, whether to remove the designated status of the transplant centre for that activity.

3.34 NHSBT has a wealth of knowledge about NHS transplant activity, and is able to connect all parts of the donation and transplant system together in order to ensure the greatest benefit from donated organs. It should also have an important role in supporting proper governance throughout the NHS transplant system. At present, NHSBT has organ specific advisory groups each of which have a membership representing all the relevant transplant centres. Currently these Advisory Groups' guidance, which is made in NHSBT's name, is directed towards the donation and transplant centres. In view of the tensions uncovered by this review, which are specific to liver transplantation, I recommend that, while continuing to provide advice to transplant centres, the

Advisory Groups should be accountable to the NHSBT Board. As the statutory body the Board has responsibility for decisions made in its name. In turn, the NHSBT Board should advise the board of the National Commissioning Group, the regional SCGs and those of the devolved administrations who should not commission services which are not compliant with NHSBT guidelines.

3.35 Audit of practice and outcomes across donation and transplantation are undertaken by a number of bodies: NHS Trusts providing services; NHSBT; and the Royal College of Surgeons of England. Robust data should be gathered and used for commissioning as it is a vital tool in monitoring the quality of activity and in driving improvement.

RECOMMENDATION EIGHT

There should be greater clarity established about the roles of Commissioners and NHSBT for ensuring governance within the NHS transplant system. Clear lines of accountability should be established for commissioning, provision, monitoring and audit of NHS transplant services.

3.36 Good leadership is necessary to pull the liver transplant community together and develop new methods of working. NHSBT's Liver Advisory Group has an important role and I suggest that the Group should be streamlined to facilitate decision-making, increase its influence and assist it in recommending improvements to the allocation and transplant programme. Greater transparency would be assured if the reasoning behind decisions as well as minutes of meetings were placed online. There should be an opportunity for meaningful patient involvement, including via open meetings at which patient concerns could be raised.

CONCLUSION

- 3.37 The UK is currently engaged in a five year programme of activity aimed at increasing donation rates by at least 50%. This increase would enable an estimated 1200 extra people to benefit from an organ transplant. In order to achieve this goal and maintain and improve transplantation services in the future, the public must be engaged with and confident in donation and transplant processes. Even if donation rates increase significantly in coming years the demand for donated organs will also increase and sadly, some UK citizens will still die for want of a donated organ. In the face of continuing scarcity, the NHS has a moral responsibility to allocate organs in the interest of the people on its own waiting list. It has a further responsibility to ensure that those who benefit from a donated organ do so on the basis of need and clinical suitability as opposed to ability to pay for a transplant operation. Genuine reciprocal arrangements which benefit those seeking a transplant in the UK should also be encouraged and developed further.
- 3.38 Basic moral instincts support a duty of rescue of non UK citizens legitimately resident in this country who unexpectedly and urgently require an organ for transplant in the same way that UK citizens would hope to be treated if they fell into such a dire situation when they were abroad. Pragmatic considerations (and removal of the constraint of scarcity) also support the donation of rarely required tissues such as paediatric thymus.
- 3.39 The UK must work within the framework of European law which allows non-UK EU residents from countries which have their own transplant services in place to receive organs donated within the NHS but we must ensure that hospitals and individual clinicians do not prioritise such patients over other NHS patients and that the systems are in place to show that such priority cannot be given to such patients.
- 3.40 This is not because we wish to discriminate against non UK citizens but rather because, in a situation of scarcity, their interests are trumped by those who are part of the system within which the resources exist – the NHS. The resources in this case being not only the transplant services but more importantly, the donated organ.

3.41 To remain true to the donation process we need to be able to assure potential donors that principles of justice and fairness are embedded within the organ allocation system. We also need to recognise what can be realistically assumed about the motivation and expectations of donors. Given the concern that potential donors may be deterred by any possibility of financial gain or unfair allocation being associated with their gift, the use of donated organs should remain firmly within traditional NHS structures with every organ being donated freely and allocated within the NHS family.

Appendix 1: Terms of Reference and Advisory Group

Terms of Reference

In order to optimise the availability of organs for transplant for NHS patients and ensure public confidence in the fairness and transparency of the organ allocation system in the UK, to examine policy and practice in the UK, within the framework of European law, on the use of organs from UK deceased donors in respect of the referral, acceptance and transplantation of non UK EU residents including the different funding arrangements and to report findings to the Department of Health by June 2009.

Review led by

Elisabeth Buggins CBE, Chair of NHS West Midlands

Advisory Group

John Dark, Professor of Cardiothoracic Surgery Newcastle

Bobbie Farsides, Professor of Clinical and Biomedical Ethics Brighton and Sussex Medical Schools

David Lock, Barrister

Vivienne Parry, Writer and Broadcaster

Appendix 2

Deceased organ transplants in UK NHS hospitals, organs donated from UK hospitals into patients

recorded as resident overseas (excluding RoI)

Apr 04 - Mar 09 by NHS group and financial year of transplant

NHS group	2004/05	2005/06	2006/07	2007/08	2008/09
1	27	17	17	26	22
2	25	20	6	5	4
total	52	37	23	31	26

Organs offered from non-UK hospitals into UK hospitals, by year and organ (excluding RoI)

Apr 04 - Mar 09 by financial year of transplant and organ

Year	Kidney	Heart	Liver	Pancreas	Lung	Total
2004/05	1	3	5	0	2	11
2005/06	3	9	11	1	2	26
2006/07	0	6	4	0	1	11
2007/08	0	3	2	0	0	5
2008/09	0	2	0	0	0	2
Total	4	23	22	1	5	55

There was one further organ (liver) offered from outside the EU (Norway) in 2004/05.

UK organs offered to other countries (excluding RoI) for transplant, Apr

08 - Mar 09

organ offered	number offered*
kidney	1
heart	13
single lung	1
lung pair	8
heart/lung block	2

* NB some of these organs were offered overseas more than once

Appendix 3

NATIONAL HEALTH SERVICE

NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005

The Secretary of State for Health, in exercise of the powers conferred on her by sections 16D(1), 17 and 126(4) of the National Health Service Act 1977⁽⁶⁾, and all other enabling powers, makes the following Directions—

Citation, commencement, interpretation and application

1.— These Directions may be cited as the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005 and shall come into force on 1st October 2005.

(1) These Directions apply in relation to England.

(2) In these Directions—

“the Act” means the National Health Service Act 1977;

“NHS body” means a Strategic Health Authority, a Special Health Authority, an NHS trust, an NHS Foundation Trust and a Primary Care Trust;

“NHSBT” means the Special Health Authority known as NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG)(7); and

“the Schemes” means the following Donor Organ Sharing Schemes⁽⁸⁾:

(a) Operating Principles for Pancreas Transplant Units in the UK, prepared by the UKT Kidney and Pancreas Advisory Group, first published in August 2003;

(b) Operating Principles for Renal Transplant Units in the UK, prepared by the UKT Kidney and Pancreas Advisory Group, first published in May 1999;

(6) 1977 c.49; section 16D was substituted by section 12(1) of the Health Act 1999 (c.8) (“the 1999 Act”) and amended by sections 1(3) and 3(1) and (2) of, and paragraphs 1 and 6(a) of Part 1 of Schedule 1 to, the National Health Service Reform and Health Care Professions Act 2002 (c.17) (“the 2002 Act”); section 17 was substituted by section 12(1) of the 1999 Act and amended by section 1(3) of, and paragraphs 1 and 7 of Part 1 of Schedule 1 to, the 2002 Act and section 67(1) of, and paragraphs 5(1) and (3) of Part 1 of Schedule 5 to, the Health and Social Care Act 2001 (c.15) (“the 2001 Act”); section 126(4) was amended by section 65(2) of the National Health Service and Community Care Act 1990 (c.19), by paragraph 37(6) of Schedule 4 to the 1999 Act, by paragraph 5(13)(b) of Part 1 of Schedule 5 to the 2001 Act, by sections 6(3)(c) and 37(1) of, and paragraphs 1 and 10(a) of Schedule 8 to, the 2002 Act and by section 184 of, and paragraph 38 of Schedule 11 and Part 4 of Schedule 14 to, the Health and Social Care (Community Health and Standards) Act 2003 (c.43).

(7) Established by NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Establishment and Constitution) Order 2005, S.I. 2005/2529.

(8) Copies of the Schemes are available on the website www.uktransplant.org.uk

- (c) Operating Principles for Liver Transplant Units in the UK and Republic of Ireland, prepared by the UKT Liver Advisory Group, first published in July 1999;
- (d) Operating Principles for Cardiothoracic Transplant Units in the UK and Republic of Ireland, prepared by the UKT Cardiothoracic Advisory Group, first published in May 1999; and
- (e) Operating Principles for Ophthalmic Transplant Units in the UK and Republic of Ireland, prepared by the UKT Ocular Tissue Advisory Group, first published in July 1999.

Functions in relation to blood, stem cells and tissue

2.— In this paragraph, “blood, stem cells and tissue” means blood, blood components, blood products, plasma, stem cells and other tissue.

(1) In order to promote or secure the effective supply of blood, stem cells and tissue for the purposes of the health service, the Secretary of State directs NHSBT—

- (a) to provide a collection, storage and delivery service for blood, stem cells and tissue;
- (b) to provide a screening, testing and processing service for the preparation of blood, stem cells and tissue;
- (c) to conduct or commission research into the uses of and development of blood, stem cells and tissue;
- (d) to provide diagnostic and other services in connection with the collection and use of blood, stem cells and tissue and treatments depending on or requiring their use (including, for example, reagent preparation and provision, patient pathology and therapeutic services, histocompatibility and immunogenetic services, platelet and granulocyte immunology);
- (e) to promote, by advertising, marketing and otherwise, the donation of blood, stem cells and tissue, with a view in particular to maintaining an adequate supply of blood, stem cells and tissue;
- (f) to prepare, store and distribute plasma fractions and other products for therapeutic, diagnostic and other purposes;
- (g) to promote, through advice and guidance, the appropriate use of blood, stem cells and tissue (having regard in particular to the need to promote the effective use of blood) and, as it considers appropriate, to provide a reference laboratory for donors and patients; and
- (h) to establish and manage a register of blood and bone marrow donors and any associated services necessary for the effective treatment of patients.

Functions in relation to the transplantation of organs and tissues

3.— In order to promote or secure the effective transplantation of organs and tissues for the purposes of the health service, the Secretary of State directs NHSBT—

- (a) to provide an organ and tissue matching and allocation service, having regard to the need to ensure the—
 - (i) maximum and most effective use of organs and tissues;

- (ii) safety of persons and their survival rates; and
 - (iii) equity and integrity of the organ sharing system;
- (b) to maintain a list of persons who are in need of or are considered suitable for an organ or tissue transplant and to determine the criteria for inclusion on such list;
 - (c) to consider and advise the Secretary of State and NHS bodies on ethical, legal and clinical issues which arise out of the organ and tissue donation and transplantation service;
 - (d) to lead the development of donation and transplant standards and monitor the maintenance of such standards by NHS bodies;
 - (e) to acquire, record, update and keep information about potential and actual donors and recipients of organs and tissues which are or may be available for transplantation and other related matters, and, having regard to the law relating to data protection and confidentiality, to make such information available;
 - (f) to analyse and audit the information acquired, recorded, updated and kept under sub-paragraph (e) above;
 - (g) to promote, by advertising, marketing and otherwise, the donation of organs and tissues with a view to maintaining an adequate number of organs and corneas for transplantation;
 - (h) to commission organ and cornea donation programmes in the health service;
 - (i) to give advice about, or make arrangements for, the transport of organs;
 - (j) to secure the provision of such education and training in any matter related to its functions under this paragraph as NHSBT considers appropriate, both to NHS staff and others;
 - (k) to conduct or commission such research in connection with the field of organ donation and transplantation as NHSBT considers appropriate; and
 - (l) to work within agreed reciprocal arrangements with other established organ exchange organisations in other countries, for the exchange of organs, where appropriate.
- (2) For the purposes of sub-paragraph (1)(a), NHSBT may—
- (a) match and allocate organs and tissues from outside England; and
 - (b) to the extent that NHSBT carries out an equivalent service in relation to Scotland, Wales or Northern Ireland, in carrying out the organ and tissue matching and allocation service, have regard to the need to ensure the maximum and most effective use of organs and tissues, the safety of persons and their survival rates and the equity and integrity of the organ sharing system.
- (3) The list maintained under sub-paragraph (1)(b) may be a list which includes persons in Scotland, Wales and Northern Ireland provided that the list indicates where the person is from.
- (4) The information recorded, updated and kept under sub-paragraph (1)(e) may be recorded, updated, kept, analysed and audited with information about potential and actual donors and recipients of organs and tissues in Scotland, Wales and Northern

Ireland provided that information indicates where the potential or actual donor or recipient is from or to which country the information relates.

Functions in relation to the allocation of organs for transplantation

4.— Subject to sub-paragraphs (2), (3) and (4) of this paragraph, the allocation of organs by NHSBT for the purposes of transplantation shall be in accordance with the Schemes.

(1) No person in Group 2 shall receive an organ for which there is a clinically suitable person in Group 1.

(2) Group 1 shall comprise—

(a) persons ordinarily resident in the United Kingdom;

(b) persons who are—

(i) members of Her Majesty's United Kingdom Forces serving abroad;

(ii) other Crown servants employed in the right of Her Majesty's Government of the United Kingdom having been recruited in the United Kingdom and who are serving abroad;

(iii) employees, recruited in the United Kingdom, of the British Council or the Commonwealth War Graves Commission and who are employed abroad; or the spouse or any child under the age of nineteen of any person falling within sub-paragraphs (i) to (iii) above;

(c) persons who are entitled under Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to medical treatment in the United Kingdom;

(d) persons entitled by virtue of a bilateral reciprocal health agreement or the European Convention on Medical Assistance 1954 to medical treatment in the United Kingdom.

(3) Group 2 shall comprise persons who do not come within the categories of persons listed in Group 1.

General functions of NHSBT

5.— NHSBT may exercise functions under—

(a) section 23 of the Act (voluntary organisations and other bodies); and

(b) section 2(b) of the Act (Secretary of State's general powers as to services) to do anything whatsoever which is calculated to facilitate, or is conducive or incidental to, the discharge of NHSBT's functions.

(2) NHSBT, in performing the functions described in paragraph 2, 3 and 4 above, may provide advice and make recommendations to the Secretary of State on any matter connected with its functions.

Exercise of functions

6. NHSBT, in exercising its functions, shall have regard to any guidance issued by the Secretary of State.

Land transactions

7.— Subject to sub-paragraphs (2) and (3) of this paragraph, NHSBT shall exercise the functions of the Secretary of State under section 87(1) and (2) of the Act in so far as is necessary to enable it to secure and maintain such accommodation as it requires for the proper discharge of its other functions.

(1) The functions mentioned in sub-paragraph (1) do not include the powers of the Secretary of State to acquire land compulsorily.

(2) NHSBT shall not, without the prior approval of the Secretary of State, exercise the functions mentioned in sub-paragraph (1) so as to—

(a) acquire or dispose of any land, or any interest in land, the value of which exceeds £1 million; or

(b) acquire a leasehold interest where either—

(i) the term of the lease is less than one year and the rent payable exceeds £1 million; or

(ii) the term of the lease is not less than one year and the product of multiplying the number of years in the term by the amount of rent payable in the first year of the term exceeds £1 million.

(3) In sub-paragraph (3)(a) above “value” means the value on a disposal by sale with vacant possession on the open market.

(4) In sub-paragraph (3)(b) above “the term” in relation to a leasehold interest acquired by way of assignment means the unexpired term.

(5) Any function of the Secretary of State, under section 87 of the Act, shall be exercised in accordance with the procedures and instructions for the time being in force and issued by the Department of Health in the document entitled “Estatecode”(9), except in so far as such procedures and instructions are inconsistent with these Directions.

(6) Subject to NHSBT obtaining approval as and when required under sub-paragraph (3) above, where the exercise by NHSBT of any function to which these Directions apply requires—

(a) the execution under seal of any document, NHSBT shall execute such document on behalf of the Secretary of State under its own seal; or

(b) the execution of a document otherwise than under seal, NHSBT shall make arrangements for one of its officers who has been duly authorised for the purpose to sign the document for NHSBT on behalf of the Secretary of State.

Accounts

8.— NHSBT must prepare and keep annual accounts in respect of each financial year which shall give a true and fair view of the income and expenditure and cash flows of NHSBT for the financial year, and the state of affairs as at the year end.

(1) The accounts shall be prepared in accordance with—

⁽⁹⁾ Copies of this document are available on the website www.dh.gov.uk/estates

- (a) the Resource Accounting Manual⁽¹⁰⁾;
- (b) the Department of Health Special Health Authority Manual for Accounts⁽¹¹⁾;
- (c) any other requests made by the Secretary of State,

except where agreed with the Secretary of State in which case the exception shall be disclosed in the notes to the accounts.

Annual report

9. The Secretary of State directs NHSBT to produce an annual report in respect of each year from 1st April to 31st March, covering its activities and finances (including officers' remuneration) and to submit that report to the Secretary of State by no later than 30th September each year, or by such other date as the Secretary of State may direct.

Revocation

10. The following directions are revoked—

- (a) The National Blood Authority Accounts Direction given on 19 March 1993;
- (b) The National Blood Authority Directions in relation to Powers of Income Generation given on 29 March 1993;
- (c) The National Blood Authority Directions in relation to Building and Engineering Functions given on 29 March 1993;
- (d) The National Blood Authority Directions in relation to Financial Management given on 5 April 1993;
- (e) The National Blood Authority (Land Transactions) Directions 1997 given on 23 July 1997;
- (f) The Directions on the Allocation of Human Organs for Transplantation given on 12 February 1996 in so far as they apply to United Kingdom Transplant⁽¹²⁾.

Signed by authority of the Secretary of State for Health

Member of the Senior Civil Service

(10) This document is published by HM Treasury and is available on the website www.resource-accounting.gov.uk/current/frames.htm

(11) This document is available on the website www.info.doh.gov.uk/doh/finman.nsf

⁽¹²⁾ United Kingdom Transplant was established by the United Kingdom Transplant (Establishment and Constitution) Order 1991, *see* S.I. 1991/407 as amended by S.I. 1996/971, 1998/1577 and 2000/1612, and abolished by the National Blood Authority and United Kingdom Transplant (Abolition) Order 2002, *see* S.I. 2005/2532.

Date:

NATIONAL HEALTH SERVICE

NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) (Amendment) Directions 2009

The Secretary of State for Health makes the following Directions in exercise of the powers conferred by sections 7, 8, 272(7) and 273(1) of the National Health Service Act 2006⁽¹³⁾.

Citation and commencement

11. These Directions may be cited as NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) (Amendment) Directions 2009 and shall come into force on 1st May 2009.

Amendment of paragraph 4 of the 2005 Directive

For paragraph 4(3)(d) of the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005(b) substitute—

“(d) persons entitled by virtue of a bilateral reciprocal health agreement or the European Convention on Social and Medical Assistance 1954 to medical treatment in the United Kingdom;

(e) persons ordinarily resident in the Channel Islands.”.

Signed by authority of the Secretary of State for Health

Date

Name
Member of the Senior Civil Service
Department of Health

⁽¹³⁾ 2006 c.41. By virtue of section 271 of the Act the powers conferred on the Secretary of State by those sections are exercisable only in relation to England.

(b) The 2005 Directions came into force on 1st October 2005 and are annexed to the Department of Health Guidance, “Guidance on the allocation of organs for the purposes of transplantation”, available at www.uktransplant.org.uk.