



# postnote

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## ORGAN TRANSPLANTS

**People awaiting organ transplants considerably exceeds the organs available. This POSTnote describes the 'organ gap' – the extent to which demand for organ (and tissue) transplantation exceeds the availability of transplantable organs. It examines the pros and cons of various options for increasing donation rates including 'opt-in' (the current UK scheme) and 'opt-out' (presumed consent) and considers the use of these systems in other countries. Potential alternative treatments for the future, such as stem cell therapies, will not be discussed in this note.**

### Background

Organ transplantation is the established treatment for the failure of vital organs such as the kidneys, pancreas, liver, heart or lung. Kidneys are by far the most common type of organ transplant. Of the several million people in the UK with chronic kidney disease, a small proportion, currently about 37,000,<sup>1</sup> will develop end stage renal failure (ESRF), when regular dialysis or transplantation are the only treatments to prolong life. The current cost of treating these people has been estimated at 1-2% of the total NHS budget, although they comprise only 0.05% of the adult population. A successful kidney transplant is the most clinically-effective and cost-effective treatment for many ESRF patients. At the end of the last financial year 6,592 people were on the kidney transplant waiting list. During that year only 1,838 kidney transplants were performed. Future demand for organ transplants is likely to continue to increase due to the rapid rise in some diseases, such as diabetes and hepatitis C, together with an ageing population.

### Improvements in transplants

A major issue with organ transplants is preventing the patient's natural defence mechanism, the immune system, from rejecting the transplanted organ. Tissue matching, which matches blood group and tissue type (important for kidney transplants) between donor and recipient, reduces the likelihood of the patient's immune system rejecting the transplanted organ. Anti-rejection

treatments, usually based on drugs that suppress a patient's immune system, are also used. The development of more effective immuno-suppressive drugs, better understanding of tissue matching, improvements in surgical techniques, advances in post-operative care and developments in organ preservation methods have all contributed to improved outcomes for transplant recipients. Future developments are targeted at minimising the extent of immune suppression needed.

### Where do organs come from?

The manner, time and place of death determine whether a person's organs are suitable for donation. The most common source of organs is from patients who have died in intensive care but whose vital organs other than the brain are being maintained by medical support. Death is confirmed by brain stem death tests. These patients are referred to as heart beating donors (HBD). Numbers in this category have declined over the last decade due to improvements in paramedical care, neuro-surgical practice and preventative medicine (such as treatment of hypertension) and a simultaneous decrease in the number of deaths from road traffic accidents. Transplant programmes are thus turning to other sources of organs. More emphasis is being placed on living donation (usually a kidney). Organs can also be retrieved from patients shortly after death and in subjects who die from critical illness in hospital settings. These patients are referred to as non-heart beating donors.

### Organ transplants in the UK

The UK has an 'opt-in' approach to organ donation. This requires potential donors and/or relatives to indicate their willingness for organs to be removed for transplantation (see box 1). Individuals can indicate their wishes in a number of ways – by making their wishes known to relatives and those closest to them, by registering on the NHS Organ Donor Register (ODR), or by carrying a donor card. Approximately 11.6 million people (19% of the UK population) are registered on the NHS ODR.

**Box 1 Regulating organ transplants**

The Human Tissue Act 1961, covering England, Scotland and Wales and the Human Tissue Act (Northern Ireland) 1962 govern the removal of organs from people after their death in the UK. Consent from relatives is not required by statute but in practice this is always established prior to organ donation. The Human Tissue Bill will repeal current transplant legislation in England, Wales and N. Ireland. Separate but complementary arrangements will be made in Scotland. The fundamental premise of the Bill is that consent must be obtained from potential donors and/or from their relatives to use human organs and tissue. In addition, the Bill will clarify that it is lawful to use procedures for maintaining organ viability after death and whilst consent is sought, to protect organs in the period leading up to the transplant.

The Department of Health (DH) is responsible for organ transplant policy. This is implemented through UK Transplant (UKT), which replaced the UK Transplant Support Service Authority in 2000. UKT is responsible for all aspects of the donation, matching and allocation of organs for transplantation across the UK and for increasing the number of transplants.

Even so, the number of people awaiting transplantation greatly exceeds the number of organs available (see graph). On 31 March 2004, 7,236 people were waiting for organ transplants in the UK while only 2,867 transplant operations were performed during that financial year. This shortage of organ donors means that some 400 patients, mainly those waiting for life-saving heart, liver or lung transplants, die each year before a suitable donor can be found. Some have thus suggested that the UK's approach should change.

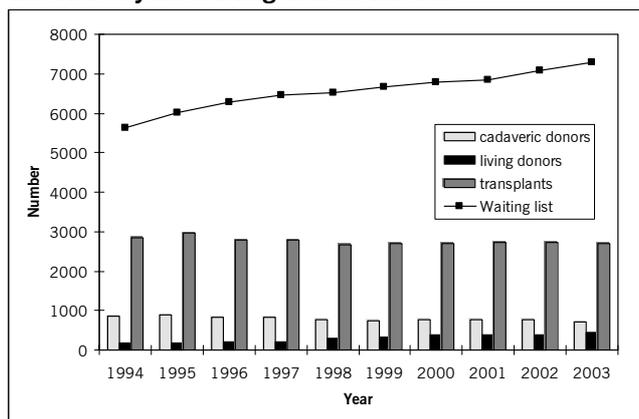
**Legislation**

There are several legislative options for regulating organ donation and transplantation (see box 2, page 3). The Human Tissue Bill aims to ensure that removal of organs/tissues for retention and transplantation happens only with consent of patients or relatives. However it has been suggested by some MPs that a system of presumed consent (or 'opt-out') should be introduced. Such a system assumes all adults would wish to be a donor unless, when alive, they had registered an objection. Some argue that the introduction of this system in other countries has resulted in higher donation rates.<sup>2</sup> An opt-out system was debated recently during the report stage of the Human Tissue Bill in the House of Commons and rejected by members (a free vote was not allowed).<sup>3</sup> The Bill is now passing through the House of Lords.

**How does the UK compare with other countries?**

A wide range of organ donation rates is observed in different countries (see table). Spain has the highest at nearly 34 per million population (pmp) compared with the UK rate of about 12 pmp. Higher donation rates are often attributed to having opt-out legislation in place. However other factors such as how efficiently potential donors are realised and the number of intensive care beds are also important. For example, one study which looked at 28 European countries, excluding Spain,

**Number of organ donors, transplants and patients on the end of year waiting lists in the UK**



Source: UK Transplant.

**Legislation, practice and donor rates**

Country	Legislation (see box 2)	Actual practice	Donors (pmp) annual rate 2003
Spain	Presumed consent	Informed consent	33.8
Belgium	Presumed consent	Presumed consent and family informed	24.4
Austria	Presumed consent	Presumed consent	23.3
US	Informed consent with required request	Informed consent with required request	22.1
Ireland	Informed consent	Informed consent	21.1
Norway	Presumed consent	Informed consent	19.2
France	Presumed consent	Informed consent	18.3
Netherlands	Informed consent	Informed consent	14.9
Germany	Informed consent	Informed consent	13.8
Sweden	Presumed consent	Varies, recent changes	12.8
UK	Informed consent	Informed consent	12.0
Greece	Presumed consent	Informed consent	6.4

Source: Council of Europe; National Transplant Organisation (ONT).

identified the following factors as being associated with high donation rates:<sup>4</sup>

- an opt-out policy
- a large number of transplant centres pmp
- a high percentage of the population enrolled in university education
- and a high percentage of Roman Catholics (the Roman Catholic church had been previously cited for its support of donation).

In Spain the high donation rate is thought to be mainly due to the way organ transplantation is co-ordinated.<sup>5</sup> While the legislation (presumed consent) has remained unmodified since 1979, organ donation rates increased during the 1990s. This followed the formation in 1989 of a National Transplant Organisation and a national network of specially trained and dedicated hospital physicians in charge of the whole process of organ donation. The new 'hospital-centred' approach now covers nearly all major Spanish hospitals. A proactive donor detection programme, systematic death audits in hospitals, economic reimbursement for hospitals and the social climate all contribute to the high donation rate. Spain also has a high number of road traffic accident deaths which raises potential donor numbers.

**Box 2 Options for organ transplant legislation**

Policy options for organ transplantation include:-

- *Opt-in.* Potential donors and/or relatives express their wish to donate organs after death.
- *Presumed consent or opt-out.* At death a person's organs could be taken for transplantation unless he or she had registered their desire to opt-out. In practice many countries operate informed consent (or presumed consent with permission) where although an opt-out law is in place, relatives are asked if they are in favour of donation and their wishes are respected (see table).
- *Required request.* In the US a policy of required request or referral is operated where it is illegal not to enquire whether a person's organs can be used for transplantation. This ensures opportunities for donation are less likely to be overlooked. The UK Transplant Co-ordinators Association would support a requirement that every intensive death be referred to a donor co-ordinator.
- *Required response or mandated choice.* This places an obligation on all adults to consider whether they wish to donate their organs, for example requiring people to tick a box on their tax return or driving licence forms.
- *Incentive schemes.* Giving financial rewards or priority for medical treatment to patients willing to be donors.

**Issues**

Over the past few years there has been debate on changing legislation. Most agree that other changes or improvements to the UK's system, discussed below, also need to be made.

**Changing legislation**

Opinions on whether there should be a change in legislation differ. The British Medical Association, The British Transplantation Society (BTS), the Royal College of Surgeons and some patient groups, such as the National Kidney Research Fund (NKRF), consider the UK should adopt a system of presumed consent with permission (see box 2). They argue that although this system may make little difference to existing procedure it will affect the culture and framework within which discussions about donation take place, with the strong assumption being that the answer will be yes. NKRF has also suggested there should be a system of mandated choice which obliges everyone to consider whether they wish to donate their organs.

However, DH is not in favour of presumed consent. DH found no evidence that the public would overwhelmingly support presumed consent from responses to its *Human Bodies, Human Choices* consultation.<sup>6</sup> It considers changing legislation to be a high-risk strategy. Without clear public support, presumed consent may be counter-productive, leading to reduced donation rates. The Royal College of Nursing, the British Organ Donor Society (BODY) and some patient groups also agree. BODY is concerned that under presumed consent the concept of altruism and organ donation as a gift would be lost.

**Public attitudes**

At present the level of public support for changing legislation is unclear. In an opinion poll carried out by DH in 1999, 50% of respondents favoured the current

system, 28% supported a shift to presumed consent and 22% expressed no preference. A survey conducted by the NKRF in September 2000, showed that 57% of the British population supported presumed consent. Although repeated surveys for the British Kidney Patient Association have shown nearly 75% of the UK population favour their own and their families' organs being used for transplantation, this sentiment is not reflected by the number of people registered on the ODR or in relatives' refusal rates.

**Relatives' refusal rate**

While public support for organ donation is high, in practice many relatives refuse authority for donation. During 2003/4 a potential donor audit was established by UKT in nearly all intensive care units in the UK. The results, published in autumn 2004,<sup>7</sup> confirmed that intensive care teams were appropriately referring the majority of potential donors but showed that 42% of relatives refused when asked. This rate is significantly higher than the refusal rates of 30% found in studies in the early 1990s. It is likely that there are many causes for this increase, including the Alder Hey scandal in 1999 where organs were kept without consent. UKT has instigated further investigations into relatives' refusal rates to consider possible solutions.

**Organisation of transplant services**

Heart, lung, liver, pancreas and small bowel transplant services are commissioned at national level by the National Specialist Commissioning Advisory Group. Renal (kidney) services used to be commissioned by 90 Health Authorities but following the recent re-organisation of the NHS, are now commissioned by 303 primary care trusts (PCTs). Some commissioning, particularly strategic planning, is done by PCTs grouped together in Specialised Commissioning Groups. Despite kidneys being the most frequently transplanted organs, there are not enough patients for commissioning to work effectively at PCT level. DH is encouraging PCTs to form consortia to commission renal services jointly. The National Kidney Federation is concerned this might mean it is unclear who is responsible for taking the lead on renal services.

Provision and co-ordination of an organ retrieval team, rapid access to operating theatres and intensive care beds, and staffing are all necessary for a successful transplant operation to take place. Although medical advances have prolonged the period an organ can be kept outside the body, delays in transplanting it can affect its subsequent performance and the outcome for the patient. The lack of 'transplant culture' and transplant co-ordinators in hospitals is also an issue. Over the past few years, UKT has increased the number of transplant coordinators (see box 3). This has been welcomed but may need to continue if the UK is to increase its organ transplants. Spain, which has a smaller population than the UK, has twice as many transplant co-ordinating teams.

### Box 3 Transplant Framework

Since 2001, the Government has invested nearly £7 million, administered through UKT, to support initiatives to boost organ donation rates including 35 new donor liaison nurses, 11 regional transplant co-ordinators, 25 living donor co-ordinators and 14 NHS trusts funded to increase non heart-beating donations. In 2003, DH published its key aims for organ and tissue transplantation in *Saving Lives, Valuing Donors. A Transplant Framework for England*. It aims to:-

- increase the number of people on the NHS ODR to 16 million by 2010 by raising public awareness
- increase the number of potential organ and tissue donors and the number of organs and tissues for transplantation by optimising donation through NHS trust-wide procedures and protocols
- save as many lives as possible through transplantation and maximise quality of life of transplant patients by effective planning, commissioning and delivery of transplant services.

### Staffing organ transplant units

Several organisations, including BTS and the Royal College of Surgeons, are concerned about the current shortage of transplant surgeons. This leaves individual consultants facing long hours and unpredictable shift patterns and makes this career unattractive to young doctors. Potentially it could lead to transplant units not being operational and the possibility that organs will not be used. The situation is most acute in renal surgery where services are commissioned at the PCT level.

### Increasing the number of potential donors

Since 2001, UKT has increased the number of people registered on the ODR from 8 million to 11.6 million through awareness campaigns. The budget available to UKT for this (£774,000 per year) has restricted its options. Most new registrants have come from driving licence applications, reminders through the Driver and Vehicle Licensing Agency, general practitioner registration and Boots Advantage Card applications. One effective campaign was "Vote for Life" where organ donor registration forms were sent out with the electoral roll canvas. In 2002, 41 councils participated and it was the third largest source of new ODR registrants for that financial year. However it has been discontinued as it might be an unlawful use of the electoral roll canvas.

Other options for improving donation rates are increasing the number of living and non-heart beating (NHB) donors. UKT has invested in 14 NHB donor programmes and 25 living donor programmes both of which impact mainly on kidney donation. Between 2002/03 and 2003/04, the number of NHB donors rose from 61 to 73, an increase of 20%. The number of living kidney donors rose by 21% from 380 to 461. The introduction of the Human Tissue Bill should help NHB programmes by making it clear that doctors may start the necessary treatment for organ preservation while consent for donation is sought. Improvements in procedures between transplant units and accident and emergency wards also may increase NHB donor numbers. Further investment in NHB donor programmes will mainly be down to individual PCTs (or commissioning consortia).

Elective ventilation has also been suggested as a way to increase donor numbers - patients close to death would be transferred to intensive care and put on a ventilator to preserve organs for retrieval at death. In 1994, the DH advised this was unlawful on the grounds that the process was not intended for the patient's benefit (a common law requirement in medicine). This option has not received much support and was rejected during the report stage of the Human Tissue Bill in the House of Commons.

### UK Transplant

In its recent review of DH sponsored organisations,<sup>8</sup> the Government announced that a new national Blood and Transplant Authority (BaTA) will replace UKT and the National Blood Authority (NBA). UKT, which was established only in 2000, is widely regarded as a success, having maintained organ donation rates and increased the number of people on the ODR. Concern has been expressed that merging UKT, which is small (121 staff with a budget of ~£10 million per year), with the larger NBA (~6000 staff with a budget of ~£364 million per year) may make it difficult to maintain focus on achieving the UK's transplant targets.

### Overview

- The waiting list for organ transplants exceeds the number of transplants performed. In future, organ shortage, particularly for kidneys, is likely to increase.
- This shortage and comparison with other countries has led to the suggestion that UK legislation should change to a system of presumed consent. Such a change is not supported by the Government and was recently rejected (not a free vote) by the House of Commons.
- Other factors also affect transplant rates. Issues that need to be considered include organisation of transplant services, high relatives' refusal rates, and a shortage of transplant surgeons.

### Endnotes

- 1 *Sixth Annual Report* (2003). UK Renal Registry.
- 2 Kennedy et al. (1998). *The Lancet* 351:1650-2.
- 3 *Hansard* vol. 423, part no.109, columns 26-96
- 4 Gimbel et al. 2003. *Progress in Transplantation* 13:15-23.
- 5 Matesanz et al. 2002. *Journal of Nephrology* 15:22-28.
- 6 *Human Bodies, Human Choices. Summary of responses to the consultation report* (2003). Department of Health.
- 7 *Further results from the Potential Donor Audit, Paper presented to Meeting of the Board of the Special Health Authority: September 2004*. UK Transplant.
- 8 *Reconfiguring the Department of Health's Arm's Length Bodies* (2004). Department of Health.

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