controversial topics in surgery

Presumed consent for organ donation

GEOFF KOFFMAN & INDERJIT SINGH AND SIMON BRAMHALL

My awareness of the plight of transplant surgeons and their patients was awoken by hearing the Transplant Czar on the *Today* programme. Britain is falling in the league of organ donation. An opt-out policy (presumed consent) would seem logical for a society to express its humanity towards its less fortunate citizens. Koffman argues for the benefits of this while recognising the many drawbacks and possible public abreaction associated therein.

Logic is, however, perverse and the effects on organ donation would be incalculable should presumed consent be tested in the courts. Bramhall, nonetheless, identifies countries that have enacted opt-out legislation yet this alone does not explain the superior rate of OD in those countries.

Both the public and medical profession need constant education on the benefits and *modus operandi* of OD. The annual opportunities are rare for OD from a typical district general hospital: it is all too easy to find an excuse *not* to call out the retrieval team.

A decade of PR campaigning is needed to embrace enhancing facilities for OD, education and legislation: only by these will the apathy and misinformation of profession and public be reversed.

TOM DEHN
Series Editor

Presumed consent: the way forward for organ donation in the UK

Geoff Koffman,¹ Inderjit Singh²

¹Consultant Surgeon, Renal Transplant Unit, Guy's Hospital, London

²RCS Post-CCT Fellow, Royal College of Surgeons; Addenbrooke's Hospital, Cambridge

CORRESPONDENCE TO

Geoff Koffman, Renal and Transplant Unit, 6th Floor, Borough Wing, Guy's Hospital, London SE1 9RT

T: +44 (0)20 7188 1544; E: geoff.koffman@gstt.nhs.uk

Introduction

We are justifiably proud of our national transplant service, which has delivered ever-improving outcomes and saved countless thousands of lives over the past 50 years. There is great respect for organ donors and their families and currently more than 90% of the UK population support organ donation.

The problem

Despite the best efforts of health professionals and the Department of Health there has been no significant increase in deceased organ donor rate over the past 10 years. The UK currently lies well down the organ donor league table with a rate of 14 donors per million population (PMP) in comparison with 34 donors per million in Spain,¹ 27 PMP in Belgium and 23 PMP in France.

The UK active transplant waiting list is expanding by about 8% a year and the increasing incidence of type-2 diabetes as well as the ageing population are likely to exacerbate the shortage of available organs.² This has resulted in rising mortality rates for patients awaiting a transplant, particularly for those needing heart, lung and liver replacement. It is estimated that approximately 500 patients die each year while waiting for a deceased organ. For kidney failure patients there has been a consequent dramatic rise in living donor transplants so that they currently represent about 50% of all kidney transplants in the UK.

There are many other factors responsible for the organ shortage in the UK. The most important of these are shortage of intensive therapy unit (ITU) beds, failure to recognise potential donors on ITU and failure to carry out brain-stem death tests. Refusal by relatives to allow donation is another common problem. It is not surprising that 40% of relatives

opt for the default position (non-donation) if they do not know their relative's wishes and they have only a very short time to make a decision.

The opt-in system

The donor card scheme was replaced by the National Organ Donor Register in 1994 (so called opt-in scheme) and currently approximately 17 million people have registered (approximately 25% of the UK population). There is a clear discrepancy between those supporting organ donation and those registering to opt in. The donors who have opted in are easily identifiable via the register should they suffer brain-stem or cardiac death.

Agreement by next of kin is always sought and only refused in about 10% of cases if the donor has opted in. If the potential donor is not registered (75% of cases) the relative refusal rate is much higher at 40% and even greater among some ethnic groups.⁵ This rate has increased from 30% in the last 10 years or so possibly due to diminished trust in the medical profession. This means that in total we currently retrieve about 60–65% of potential organs simply because of relative refusal.

The presumed consent or opt-out system

The presumed consent or opt-out system allows people to register their unwillingness to donate after death. If there is no registered opt-out the default or presumed position is that they wish to donate their organs. There are many misconceptions regarding this system that would require a change in the law. The most frequently quoted is that this would take away the next of kin's input into the donation process.⁵ This is not so. The system proposed would still allow relatives to veto donation if they felt it was against the expressed but unregistered wishes of the donor or it would cause the relatives themselves undue suffering. However, the default position would be donation whereas with the current legislation it is non-donation.

Clearly the practice and interpretation of the new law would be in the hands of medical and paramedical staff who would interact with the families and there could be potential for conflicts of interest. Nevertheless, this 'soft' application of the presumed consent law has been shown to work well in other European countries.⁴

The second misconception is that the system would automatically increase donation rates significantly and rapidly. This is unlikely to take place unless there is acceptance by the general public that the system is fair and workable. The presumption of consent does not mean that the potential donor has consented and therefore, although donation is for the good of society it is still vital that the role of the donor family remains clearly defined. Such law can only be effected by a sympathetic relationship between family and transplant coordinators and failure to understand this could lead to adverse publicity and an increase in opting out. Education of the public as to how the law would work is clearly most important. Given the above caveats it is reasonable to question whether presumed consent would deliver an increased rate of donation.

Potential benefits of presumed consent

It is likely that about 5–10% of the population would opt out and that family discussions at the potential donor's bedside would exclude a further 10%, giving a total donation rate of 80–85%. This is an increase in donation of about 20% but may take several years to achieve. This figure is in line with the results of presumed consent legislation in other countries.⁵ Presumed consent countries have 25–30% higher donation rate than informed consent countries⁶ although it is difficult to prove absolutely a causal relationship between donation rates and a particular determinant. There is a strong belief that over time with a good educational framework both opting out and relative refusal would be reduced and donation would be the norm. Recent polls have indicated that a majority of UK citizens (64%) are now in favour of a presumed consent system in the UK.⁷

The Spanish model

It is important that this legislation is not seen as a panacea for organ donation. In Spain, which has the highest donation rate in the world, presumed consent legislation is only part of the reason for success. The other vital factors are the expansion of transplant coordinator teams,⁸ better availability of ITU beds and high rates of road traffic accidents. Here the presumed consent legislation is not primarily responsible for the impressive donor rates but creates the right framework.

Organ Donor Taskforce

Despite the potential benefits the proposed scheme has not had consistent support from the medical profession although it has been championed by the Chief Medical Officer and the British Medical Association. In 2008 Gordon Brown, then Prime Minister, asked an Organ Donor Task Force to investigate the potential effect of the opt-out system in the UK. This group examined the many factors influencing donation rates and concluded that the case for a change in the law was not proved. They recommended the establishment of a UK-wide organisation to identify and allocate organs, a doubling of the number of transplant coordinators embedded in hospital trusts, having an organ donor champion in each hospital and improving the identification of potential donors as well as monitoring donation activity in all hospitals.

Clearly these changes need now to be given time to produce improved rates and there is evidence to suggest improvement in some regions.⁹ The taskforce unfortunately rejected clear evidence of the potential benefit of presumed consent, which it had itself commissioned. An analysis of 28 countries showed consistently higher donation rates with presumed consent. Research also showed a 25% higher donation rate with presumed consent even when other determinants were excluded. Perhaps other factors such as cost and risk of adverse publicity may have influenced the decision.

Summary

Since Kennedy *et al* proposed a change in the UK organ donation law¹⁰ there has been a reluctance to make this leap of faith. All other attempts to make significant impacts into the donor deficit have proved disappointing. It seems likely that we could expect a significantly higher donor rate with presumed consent and that this would be sustained because we would create a default position to donate and produce a more positive attitude to donation. A law change would require huge publicity and educational initiatives, which are likely to increase donation.

The new system would allow families of opted-out patients not to be questioned about donation and would allow presumed consent donors the right to donate without high-level relative refusal. To maximise donation we need to consider other radical proposals such as increasing ITU beds, incentivising hospital trusts and possibly deceased families.

References

1. Transplant Committee of the Council of Europe. *Newsletter Transplant* 2008; **13**: 23–25.
2. Organ Donation Taskforce. *Organs for Transplants: A report from the Organ Donation Taskforce*. London: Department of Health; 2008.
3. Potential donor audit. *UK Transplant Bulletin* 2008; **68**: 11.
4. Rithalia A, McDaid C, Suekarran S *et al*. Impact of presumed consent for organ donation on donation rates: a systematic review. *BMJ* 2009; **338**: a3,162.
5. Directorate-General for Health & Consumers. *Key facts and figures on EU organ donation and transplantation*. Brussels: EC; 2007.
6. Bird S, Harris J. Time to move to presumed consent for organ donation. *BMJ* 2010; **340**: c2,188.
7. Crombie IK. *The Pocket Guide to Critical Appraisal*. London: BMJ 1996.
8. Miranda B, Vilardell J, Grinyó JM. Optimizing cadaveric organ procurement: the catalan and Spanish experience. *Am J Transplant* 2003; **3**: 1,189–96.
9. NHS Blood and Transplant. *Transplant Activity in the UK: 2008–2009*. London: NHSBT; 2009.
10. Kennedy I, Sells RA, Daar AS *et al*. The case for “presumed consent” in organ donation. International Forum for Transplant Ethics. *Lancet* 1998; **351**: 1,650–52.

Presumed consent for organ donation: a case against

Simon Bramhall

Consultant Liver Transplant Surgeon, Liver Unit, Queen Elizabeth Hospital, Birmingham

CORRESPONDENCE TO

Simon Bramhall, Consultant Liver Transplant Surgeon, Liver Unit, Queen Elizabeth Hospital, Birmingham B15 2TH
T: +44 (0)121 627 2346; E: Simon.Bramhall@uhb.nhs.uk

Introduction

The number of organ donors in the UK is approximately 13 per million population (PMP) per year and has been gradually reducing for most of the last decade. Attempts have been made by transplant surgeons to improve rates of transplantation by using more marginal donors, splitting livers for two recipients and the increasing use of deceased after-cardiac-death donors; the only success has been with the use of living related transplantation and this is largely confined to the recipients of kidneys. For the majority awaiting solid organ transplantation the number of donated organs remains the limiting factor in the number of transplants performed in the UK.

The UK donation rate is now one of the lowest in the developed world while the US consistently achieves organ donation rates of in excess of 25 PMP and Spain approximately 35 PMP. At the same time the need for solid organ transplantation is growing, with rises in the number of patients on the waiting lists of at least 8% per year. Evidence suggests that the UK population is supportive of organ donation, with 90% in favour during a UK survey carried out in 2003, and there are currently more than 16 million people signed up to the organ donor register.

The UK, however, was not always lagging behind and in 1989 organ donation rates in the UK were leading the world at 16 PMP but between 1989 and 2009 the rates of donation

in the UK have declined while elsewhere in Europe and the rest of the world they have raced ahead.

US and Spanish approach

The US and Spain have used different approaches to increase their rates of organ donation.

In the US the Surgeon General introduced new legislation on to the US Federal Register that meant that each hospital had a legal duty to identify and refer every potential donor to the organ donor organisation (ODO). Potential donors are identified using clinical triggers that are very often present in patients who are likely to be diagnosed as brain-stem dead (BSD). Hospitals failing to comply are financially penalised. The US already had a well-staffed and extensive network of organ donor coordinators and systems in place to reimburse hospital costs. In addition to the improvement in referral arrangements the ODOs around the US invested heavily in training of coordinators in consent processes that are very specific to families of potential organ donors. The coordinators in the US approach families to obtain consent and this has led to a significant increase in family consent rates.

In 1989 the Spanish government invested heavily in the organisational structure of organ donation. They radically increased the number of donor coordinators and ensured