



Building on Progress:

Where next for organ donation policy in the UK?



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1 Introduction

The BMA's interest in organ donation

The British Medical Association is interested in all issues affecting doctors and patients and has campaigned for improvements in a range of public health measures. Organ transplantation is an area that has seen amazing medical achievements but has not yet reached its full life-saving and life-transforming potential. As doctors it is difficult to see our patients dying and suffering when their lives could be saved or dramatically improved by a transplant. It is even more difficult when we know that lives are being lost unnecessarily because of poor organisation, lack of funding or because people who are willing to donate organs after their death simply never get around to making their views known, resulting in relatives making a decision without knowing the individual was willing to donate. For this reason the BMA began in the 1990s to look at ways in which the organ donation system could be improved to reduce the number of avoidable deaths, increase the number of lives that could be transformed by a transplant and make maximum use of the high level of altruism in UK society.

This report focuses on organ donation. It is important to recognise, however, that another equally important and complementary way of reducing the number of unnecessary deaths is to focus on public health measures to reduce the incidence of chronic diseases that lead to the need for an organ transplant. The increasing incidence of obesity and diabetes in our society, for example, which can be partly attributed to changes in our diet and our sedentary lifestyle, is a major public health issue that needs to be addressed as a matter of urgency. Public health measures and early interventions to reduce demand for donated organs and practical steps to improve the organ donation system are both important; this report focuses on the latter.

Organ Donation in the 21st Century

The BMA's Medical Ethics Committee has discussed organ donation on many occasions and, in 1999, the BMA's Annual Representatives Meeting adopted a policy calling on the BMA to campaign for an opt-out system for organ donation. Following this policy decision the BMA published a report in 2000, *Organ Donation in the 21st Century – Time for a Consolidated Approach*. This emphasised that shifting to an opt-out system with safeguards would not make sufficient difference on its own but that this needed to be accompanied by a radical review of the organ donation system with new legislation and major changes to the infrastructure. Whilst undertaking the work for this report it became apparent that a number of other organisations were also calling for changes to the infrastructure, but on an individual basis with little co-operation or co-ordination. The BMA therefore established the Transplant Partnership, a coalition of 18 professional and patient groups all committed to improving organ donation rates in the UK. The Transplant Partnership undertook awareness-raising work with politicians and the public and liaised very effectively with the then leaders of UK Transplant and the policy team at the Department of Health. The Partnership lobbied on changes in legislation and for practical improvements. The BMA also continued to encourage and facilitate debate about an opt-out system with safeguards, as one part of this broader strategy.

What has happened since the last report?

There have been dramatic improvements in the organ donation system since the BMA's last report on organ donation was published in 2000.

- New legislation has been passed throughout the UK providing a clear legal framework within which organ donation can flourish. Legal uncertainties around consent and non-heartbeating donation (now referred to as donation after circulatory death), have been clarified and a new legal system has been established for living organ donation providing a more rational and streamlined approach (see section 3).
- A thorough and comprehensive review of the infrastructure within which organ donation takes place has been undertaken by an Organ Donation Taskforce (see section 4) established by the last Government. It believed that many of the problems were caused by the lack of a structured and systematic approach to organ donation. The Taskforce looked at the system as a whole identifying strengths and weaknesses with a view to designing a national system based on best practice around the country. The Taskforce also looked at international models, such as those in Spain and the USA to see what, if any, lessons could be learned.
- The Taskforce came up with 14 wide-ranging and far-reaching recommendations which, it believed, could increase donation rates by 50% by 2013 (an increase of 405 deceased donors by 2012/13 compared with the 2007/08 baseline of 809). It was adamant, however, that if the reform was to be successful it would require clear political commitment, financial investment and a willingness to change established practice.
- The Government and the Devolved Health Administrations accepted all of the recommendations and provided the full funding requested. An Organ Donation Taskforce Programme Delivery Board was established and Mr Chris Rudge, formerly Medical Director of UK Transplant, was appointed as the first National Clinical Director for Transplantation to manage and oversee implementation of the recommendations on a day-to-day basis.
- The Organ Donation Taskforce undertook a review of the impact of introducing an opt-out system in the UK. After a thorough review it decided against recommending such a shift at that time, for various reasons including the belief that the recommendations it had already made could make such a shift unnecessary. It recommended that the issue should be reviewed again in the future if necessary.

Why are we publishing this report?

The BMA has three main aims in producing this report.

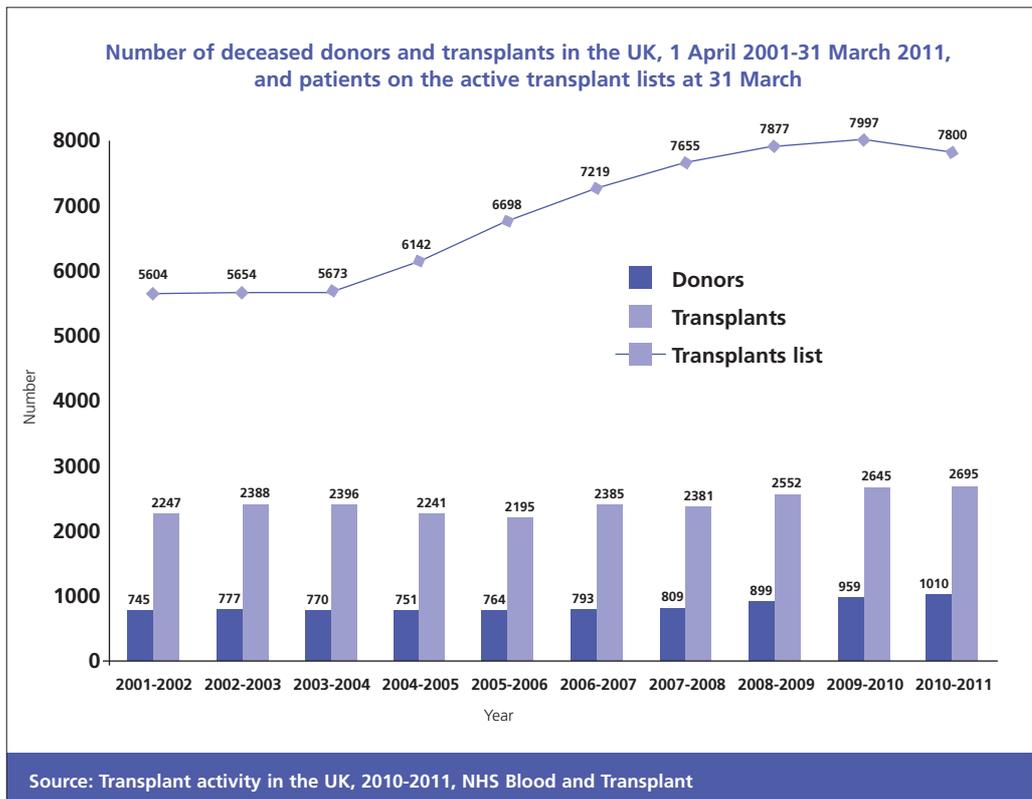
1. To acknowledge and celebrate the significant improvements that have been achieved and the considerable amount of work that has gone into this
2. To highlight the fact that, despite these achievements, people are still dying unnecessarily because of a lack of organs and
3. To encourage health professionals, policy-makers and the public to consider what more can and should be done.

Four years after the publication of the Taskforce Report, we have seen significant improvements in the infrastructure and increased donor rates. As the implementation programme reaches fruition and the new systems and arrangements are becoming settled, we need to decide, as a society, what the next steps should be. Now that we have a well-organised, well-funded, comprehensive infrastructure in place, is that enough? Can we say we have done all we can? Or, should we now look to go further and build on this progress by shifting our attention to new ways of increasing the number of donors and the number of lives saved?

We are at a cross-roads in terms of public policy on organ donation. Should we stop now? Or should we cautiously move forward? Nobody wants to undermine what has already been achieved, but nor do we want to stop too soon, before every reasonable avenue has been properly explored. The information provided in this report is aimed at encouraging debate about these important questions.

2 Donation rates and trends

For more than a decade significant attention has been given to addressing the large and increasing gap between the number of organs available for donation and the number of people requiring a transplant. For many years the waiting list increased while the number of donors remained fairly static. Since 2008, when the Organ Donation Taskforce Report was published (see section 4), there has been major investment, reorganisation and change. The latest published data (2010/11) show that over the last three years, donation rates from deceased donors have improved by 25% (compared with 2007/08).¹ More recent data provided by NHS Blood and Transplant (NHS BT) show that the total increase is projected to rise to 34% by April 2012 (based on donors up to 8 January 2012).² Much, although not all, of this increase is likely to be a result of the implementation of the Taskforce's recommendations although it is difficult to accurately judge the impact of specific changes. The Taskforce was confident that, with the changes it proposed, donation rates could increase by 50% within five years³ – an increase of 405 donors by 2013.



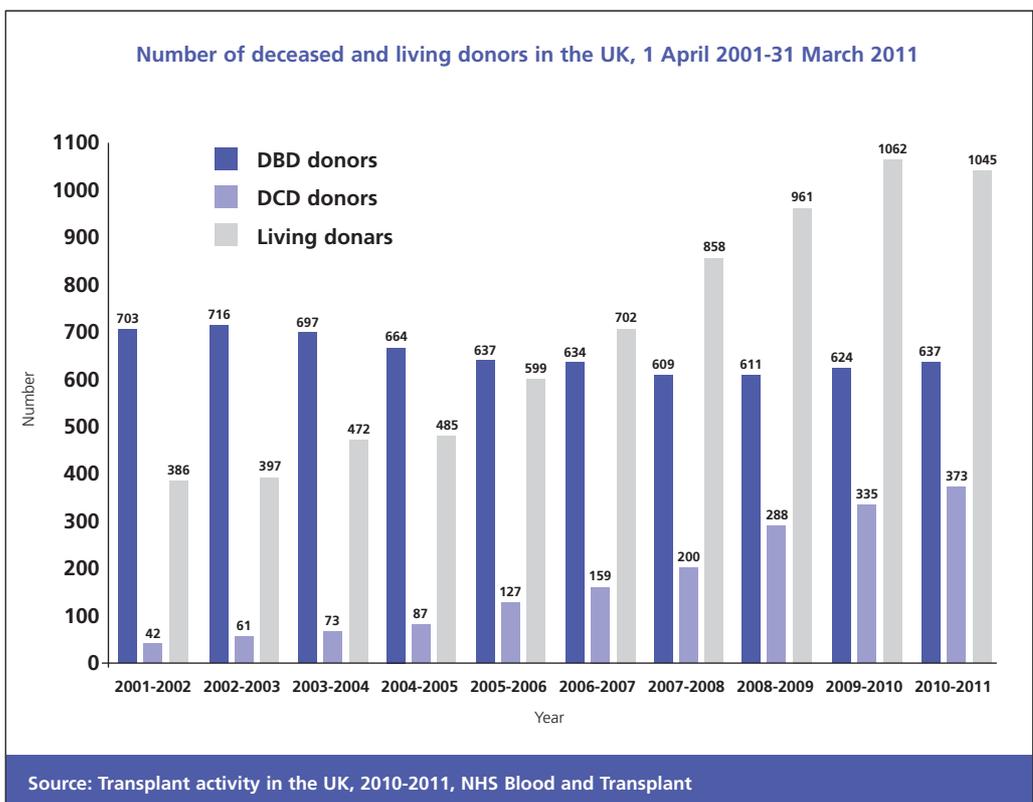
Graph reproduced with kind permission of NHS Blood and Transplant.

Transplant rates have also improved but not to the same extent as donation rates. A significant reason for this disparity is that fewer organs can be obtained from donors following circulatory death (DCD) who made up the majority of the increase in donors. NHS BT also acknowledges that a shift in the profile of donors has affected transplantation rates. With donors of higher age (30% were aged 60 or more in 2010/11 compared with 16% in 2001/02) and body mass index (20% were clinically obese compared with 12% in 2001/02⁴), the number and quality of organs retrieved

are reduced and so the growth in transplantation is proportionately lower than the growth in the number of donors.⁵ (The use of 'higher risk donors' is discussed in section 5.)

Types of donation

The graph below shows the way in which the type of donor has changed over the last decade. In 2001/02 the vast majority of donors (62%) were people who were on a ventilator and had been declared dead following brain stem testing (DBD donors). Only 42 (4%) were patients in whom treatment had been withdrawn and death diagnosed by cardiorespiratory failure (DCD donors – see section 3) and 34% were living donors. By 2010/11 the position had changed completely with the majority being living donors (51%) and DCD donors making up 18% of the total number of donors and 37% of deceased donors.



Graph reproduced with kind permission of NHS Blood and Transplant.

There are a number of reasons for this change. Much of the increase in living donation has resulted from a change in culture within the transplant community which has facilitated expansion and promoted awareness of the option of living donation. This has been aided by legislative changes which led, in 2006, to the introduction of a new, streamlined approval process for living donation and to paired and pooled donations (39 in 2010/11) and altruistic donation to strangers (28 in 2010/11)⁶ being allowed for the first time (see section 3). The increase in DCD donors can also be attributed, in part at least, to changing views and practice within the transplant community

and legislation which clarified the law on DCD donors,⁷ prompting significant investment in DCD programmes around the country. This shift in the type of donor can also be seen as the result of a deliberate attempt to promote and facilitate living donation and donation following circulatory death in recognition of the fact that the number of potential DBD donors was declining and would be unable to meet demand. It has been recognised that more patients are surviving their injuries, and also that because of improved diagnostic equipment and testing, it becomes clear at an earlier stage that recovery is not possible and so some patients are not being transferred to an intensive care unit (ICU).

Whilst the potential donor audit (see section 4) indicates some areas of practice that can be improved to increase the number of DBD donors, any resultant increase will never be sufficient to meet demand. As a result of considerable efforts, however, the number of donors following circulatory death has increased by 135% since 2006/07 (see graph above). The BMA has always supported the use of DCD donors both as a way of increasing the donation rate and also as a way of facilitating the wishes of those who want to donate but do not die in circumstances in which DBD is an option.

The transplant waiting list

At the end of March 2011, there were 7,800 people on the UK's active waiting list for a transplant and a further 2,783 were temporarily suspended from the list because they were unfit or otherwise unavailable for a transplant.⁸ Although still high, 2010/11 saw the first drop in the number on the waiting list (by 197 patients) for more than a decade. Whilst this is encouraging, NHS BT points out that this is unlikely to reflect a true reduction in demand for transplantation since if there were an unlimited supply of organs, many more people would go onto the waiting list.⁹ Similarly, although the data show 511 deaths of people on the waiting list in 2010/11,¹⁰ the true number of people who died because of the shortage of organs is likely to be much higher. The figure of 1,000 deaths – or three deaths per day – is usually quoted.¹¹

The NHS Organ Donor Register

The NHS Organ Donor Register (ODR) was originally established to measure the effectiveness of awareness-raising campaigns and has gradually, over a period of time, taken on the important operational role it currently fulfils – a role it was never designed to undertake. Following an independent review into its operation in 2010,¹² a number of changes have been implemented – and more are planned – to ensure the register is both robust and fit for its current purpose. The quality of the data held on the ODR has subsequently been independently reviewed and found to be 'of a reasonable level in comparison to other companies'.¹³

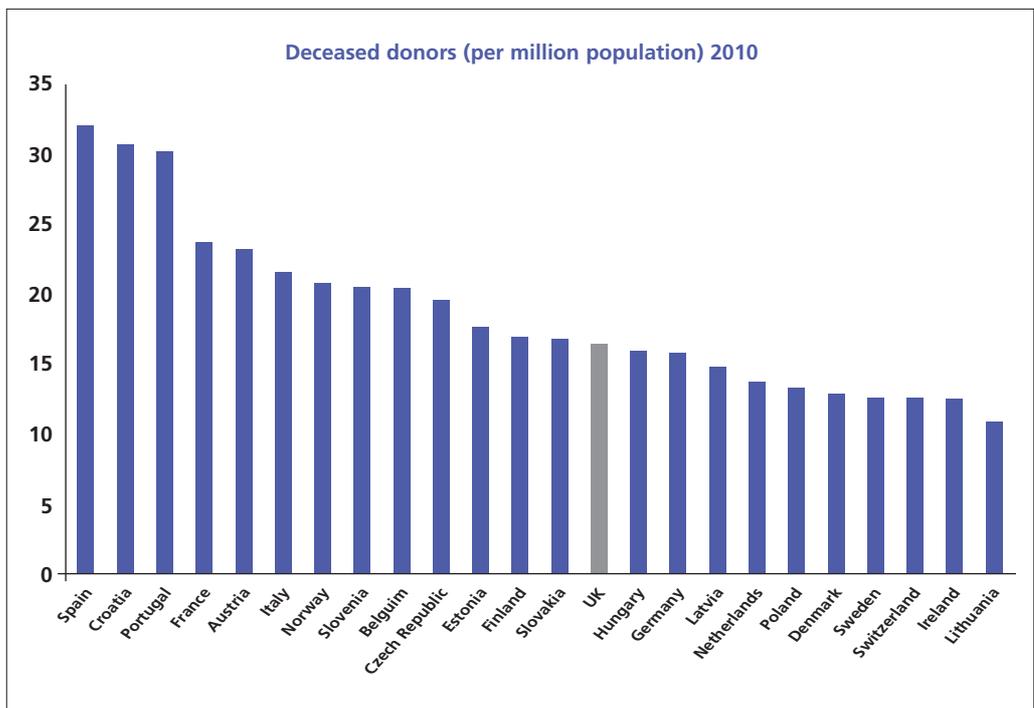
Over the last few years significant effort has been put into increasing the number of people on the ODR. By January 2012, more than 18.5 million people had signed up,¹⁴ compared with 8.3 million when the BMA's first report was published in 2000. This represents 29% of the UK population who have formally registered their wish to donate. This is encouraging, but there is still a significant gap between this figure and the 70-90% who say, when questioned, that they support organ donation. Efforts are continuing to increase the number of people on the ODR (see section 5).

The BMA supports these efforts, believing that anything that encourages individuals to think about, discuss and make known their views about donation is to be welcomed. Whilst there is not a direct correlation between the number on the ODR and donation rates (because it is often not those who sign up who die) the more people who join the register, the more likely it is that when people die their wishes will be known. In 2010/11, for example, 33% of deceased organ donors were registered on the ODR¹⁵ compared with only 19% in 2001/02. Nevertheless, this percentage increase is lower than the increase in the number of people on the register, supporting the idea that those who die and go on to donate are proportionately under-represented on the register.

Signing up to the ODR provides the legal consent (authorisation in Scotland) required to proceed with donation. Where the individual’s wishes are known, the approach to relatives is usually easier and in the majority of cases families are keen to fulfil their relatives’ wishes. The potential donor audit shows that the rate of family objection varies considerably according to whether the potential donor is on the ODR. It is unusual for families of potential DBD donors to object to donation if they know that is what the deceased wanted. Nevertheless, although they do not have a legal right of veto, where, despite encouragement, there is strong and sustained opposition from the family, donation is unlikely to proceed (see section 3). The message must, therefore, go out to those who wish to donate that it is essential that they inform their relatives of their wish to donate and that any disagreement is resolved before the situation arises.

What is it reasonable to expect in the UK?

The UK does not fare well in international comparisons of donation rates and, despite recent improvements, remains towards the lower end of European organ donor rates.



Source: Produced using data published by the Council of Europe.¹⁶

There are a very large number of variables that influence organ donor rates, some of which are more amenable to change than others. These include the level of wealth, religious beliefs, legislation, social norms, education, medical infrastructure, number of intensive care beds and the number of deaths following road traffic accidents and cerebro-vascular diseases. The fact that one factor seems to be favourable to organ donation in one country does not mean that it could or should be adopted in another. Countries with a high number of deaths following road traffic accidents, for example, may have a higher number of donors, but that is not something the UK would want to emulate. As a society we should be willing to look at other countries to see what can be learned but also to maintain a UK focus. The donation rate would, almost certainly, be higher if the UK had many more intensive care beds and we should continue to investigate areas, such as this, where further investment would be beneficial. We also need to focus on the true potential for donation in the UK at the current time, through the potential donor audit (see section 4) which has recently been improved and expanded. As long as this shows that there are a significant number of potential donors who are not donating, we must continue to strive for improvements.

3 The current legislative framework

Organ donation in the United Kingdom is governed by the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006. It is a criminal offence to use organs for donation without appropriate consent (referred to as authorisation in Scotland), to give or receive any reward in exchange for organs for transplantation or to transplant organs from a living donor without the necessary prior approval. In addition, the 2004 Act established the Human Tissue Authority (HTA) to regulate certain activities and to oversee the implementation of the legislation in England, Wales and Northern Ireland. The HTA also regulates living organ donation throughout the UK. Detailed information on the provisions of the human tissue legislation is available in separate guidance from the BMA.¹⁷ More detailed guidance for those in England, Wales and Northern Ireland can also be found in the HTA's Code of Practice on transplantation.¹⁸

The Human Tissue Authority was one of a large number of organisations included in the Public Bodies Act 2011. The Act established a mechanism through which the Government could transfer the functions of public bodies to other organisations. At the time of writing the Government's stated intention was to transfer most of the functions of the HTA to the Care Quality Commission and to abolish the HTA by 2015. Up-to-date information can be obtained from the BMA's website.

Consent for organ donation after death

In the BMA's previous report, there was a lot of criticism of the Human Tissue Act 1961 which regulated organ donation at the time. The 2004 and 2006 Acts addressed these concerns and clearly set out the legal requirements around consent (authorisation in Scotland) for donation after death. Donation may not proceed without the explicit consent (authorisation) of either the donor, given during his or her lifetime (usually by signing up to the Organ Donor Register), or someone else legally empowered to give it. In the absence of explicit consent from the individual, consent or authorisation may be given by someone nominated by the deceased (in England, Wales and Northern Ireland), someone with parental responsibility for a child who has died or other family members according to a specified hierarchy.¹⁹ In Scotland, the legislation explicitly states that third parties cannot give authorisation if they know the individual was unwilling for any part of the body to be used for that purpose. If it may be necessary for a coroner, or procurator fiscal in Scotland, to order the carrying out of a post-mortem examination, organs or tissues may be removed only with the specific agreement of those authorities. Guidance for coroners is discussed in section 4.

Under the new legislation the individual's own wishes take precedence and, legally, the relatives' wishes cannot override those of the deceased. The legislation is, however, enabling. It permits but does not require donation to proceed. Whilst the Human Tissue Authority advises that families should be 'encouraged' to respect the views of their loved ones,²⁰ in practice in 2010/11, 6% of families refused donation despite the individual having authorised donation during his or her lifetime.²¹ There are mixed views about the acceptability of this practice. In a survey of the general public, 56% said it was never acceptable for the family to override the known wishes of the individual to donate organs after death.²² The BMA takes a more pragmatic approach, recognising that the health care team also has a duty of care to the bereaved relatives. Insisting on donation in the face of their strong and sustained opposition is likely to add to their distress as well as, potentially, generating public hostility towards organ donation. It is also questionable whether all

individuals who sign up to the ODR would want their wishes followed if to do so would cause very significant additional distress to their families. For many families it is important to spend time with their loved one after death has been diagnosed. This can present difficulties, in terms of timing, if the individual wanted to donate organs. This dilemma should be discussed in advance with the family and wherever possible arrangements should be made for this wish to be facilitated whilst still allowing donation to proceed. Where it is not possible to achieve both of these aims, a decision will need to be made, based on the individual circumstances and after discussion with the family. In some circumstances – where it is evident that severe distress would be caused to the relatives – not proceeding with donation will be the right option. Individuals who have clear views about what they want to happen to their body after death, and do not want their relatives to override their wishes, should ensure that in addition to formally recording their consent they have also discussed the issue with their relatives during their lifetime.

Donation after circulatory death (DCD)

There are two different types of deceased donation: donation following brain stem death (DBD) and donation after circulatory death (formerly referred to as ‘non-heartbeating donation’ or ‘donation after cardiac death’). There is also an important distinction within donation after circulatory death between ‘controlled DCD’ (also referred to as Maastricht category III) where death follows the planned withdrawal of life-sustaining treatment, and ‘uncontrolled DCD’ (Maastricht category I/II) where death is sudden and unexpected. The contribution of each of these types of donation to the total number of donors in the UK has shifted over time. Originally when donation began in the 1950s all donation was uncontrolled DCD. Once guidelines were established for diagnosing death using brain stem tests, DBD became the most common form of donation with a small amount of uncontrolled DCD. By around 2005, uncontrolled DCD donor numbers had fallen and the number of controlled DCD donors had increased considerably so that 37% of all deceased donation comes from controlled DCD donors (and 63% from DBD donors).²³ It is likely that this will shift again over time and it is possible that some uncontrolled DCD programmes may be resumed.

This information is relevant to the legal framework because in 2000, when most of the DCD programmes used uncontrolled DCD, questions were raised about the lawfulness of taking the steps required to preserve the organs before consent for donation had been obtained. This issue was clarified in the 2004 and 2006 legislation and the law now clearly permits the taking of the minimum steps necessary to preserve organs for donation after death has been confirmed. These interventions may be undertaken before the register is checked or relatives’ consent (or authorisation) for donation is obtained but all steps must cease if it becomes known that consent (authorisation) has not, or will not, be given for donation.²⁴ Although this legal clarification was welcomed and coincided with the investment of significant sums by UK Transplant (now the Organ Donation and Transplantation directorate of NHS BT) into developing DCD programmes around the country,²⁵ by that stage uncontrolled DCD had already begun to decline for other reasons. In fact, at that stage controlled DCD had become the standard practice, where donation follows the controlled withdrawal of treatment and there is time to ensure that consent is obtained before the procedure takes place. This legal clarification will, however, be useful in the future should a decision be made to resume uncontrolled DCD.

Living organ donation

Donation of organs from living individuals requires prior approval by the Human Tissue Authority. The only exception to this rule is 'domino' donations where an organ is removed for the benefit of the donor him or herself. This arises, for example, where a kidney is removed for clinical reasons but is suitable for transplantation into another individual.

Where the donor is a healthy volunteer, the donor and recipient must be interviewed by an Independent Assessor who is accredited by the HTA. The Independent Assessor must be satisfied that the person giving consent to the donation has been given and has understood the necessary information, and that there is no evidence of reward or coercion or evidence that the individual has been subjected to pressure to consent. The Assessor then submits a report to the HTA which decides whether to authorise the donation. There are some cases where additional safeguards are in place, and each case must be considered by a panel of at least three members of the HTA before approval is given. These cases are:

- in England, Wales and Northern Ireland, where the donor is an adult who lacks capacity or a child who lacks capacity to consent (only adults with capacity can be living solid organ donors in Scotland, except where an adult who lacks capacity donates as part of a domino donation)
- 'paired' and 'pooled' donations which allow a donor and recipient to pair up with one or more other donor and recipient pairs in an organ exchange. For example, donor A's organ goes to recipient B, donor B's organ goes to recipient C and donor C's organ goes to recipient A. This system can be used by donors who are incompatible (by ABO blood group or HLA type) with their chosen recipient.
- donation to a stranger (referred to as 'non-directed altruistic donation').

The second and third of these categories are collectively referred to as National Living Donor Kidney Sharing Schemes (NLDKSS).

Mental capacity legislation

Although there is specific legislation covering organ donation there are other legislative provisions that are also relevant. Legislation relating to decision making for adults who lack capacity, for example (the Mental Capacity Act 2005 and Adults with Incapacity (Scotland) Act 2000) has had a significant impact on discussions about the clinical management of potential donors²⁶. The legislation requires that decisions taken on behalf of adults who lack capacity are made in their best interests (benefit in Scotland). Part of the assessment of best interests involves taking account of prior wishes and values; this includes taking account of any expressed wish to donate organs after death. This legislation, for example, provides the legal justification for taking some steps before death to facilitate donation, where it is known the individual wished to donate organs. This issue is discussed further in section 4.

EU Organs Directive

The EU Organs Directive aims to ensure high quality and safe standards for the donation, procurement, transportation, traceability and follow-up of human organs throughout the European Union.²⁷ The Directive, which requires that all transplant centres' compliance with the Directive is audited and controlled, must be incorporated into UK legislation by August 2012. The Human Tissue Authority has been nominated as the competent authority for the UK.²⁸ At the time of writing draft regulations were being considered that would lead to the development of a regulatory mechanism as well as setting standards for the quality and safety of organs for transplantation.²⁹ From August 2012 all organisations involved in the donation or transplantation of organs will need to be authorised by the HTA. It will be necessary to keep a record of living and deceased donors, put in place a reporting system for serious adverse events and develop and implement an effective and proportionate system of penalties for breaches of the Directive.

4 Developing the infrastructure

Strategies to improve organ donation rates require action on two fronts: developing the infrastructure within which donation takes place and increasing the number of donors. This section looks at the actions that have been taken, and the success that has been achieved, in the first of those areas.

The Organ Donation Taskforce

In December 2006 the UK Government set up an Organ Donation Taskforce charged with identifying barriers to organ donation and transplantation and recommending ways to overcome them, within the existing operational and legal frameworks. The Taskforce took an objective and strategic approach, looking in detail at every aspect of the transplant process, identifying problems or barriers to donation and recommending radical, comprehensive and far-reaching changes. A key finding of the Taskforce was the significant variability in performance between different regions in terms of brain stem testing, referral of potential donors and local engagement. This was seen as a reflection of the ad hoc way in which the system had developed and the lack of a coherent national strategy. The Taskforce recognised that donation should no longer be viewed as an 'optional extra' but must become a mandatory and usual part of the duty of care in every hospital and that this needed to be performance-managed. Furthermore, in order to be successful, Trust Chief Executive Officers (CEOs) or Chief Operating Officers (COOs) needed to take responsibility, and be accountable, for the identification and referral of potential donors within their hospital. The Taskforce report was published in 2008 with 14 recommendations (see below) which, it believed, would increase donation rates by 50% over a five-year period.³⁰ The Taskforce was adamant that the recommendations required both financial and political commitment and must be implemented in full; partial implementation was not an option.

Recommendations of the Organ Donation Taskforce

1. A UK-wide Organ Donation Organisation should be established.
2. The establishment of the Organ Donation Organisation should be the responsibility of NHS Blood and Transplant.
3. Urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice. Additionally, an independent UK-wide Donation Ethics Group should be established.
4. All parts of the NHS must embrace organ donation as a usual not an unusual event. Local policies, constructed around national guidelines, should be put in place. Discussions about donation should be part of all end-of-life care when appropriate. Each Trust should have an identified clinical donation champion and a Trust donation committee to help achieve this.
5. Minimum notification criteria for potential organ donors should be introduced on a UK-wide basis. These criteria should be reviewed after 12 months in the light of evidence of their effect, and the comparative impact of more detailed criteria should also be assessed.

6. Donation activity in all Trusts should be monitored. Rates of potential donor identification, referral, approach to the family and consent to donation should be reported. The Trust donation committee should report to the Trust Board through the clinical governance process and the medical director, and the reports should be part of the assessment of Trusts through the relevant healthcare regulator. Benchmark data from other Trusts should be made available for comparison.
7. Brain stem death (BSD) testing should be carried out in all patients where BSD is a likely diagnosis, even if organ donation is an unlikely outcome.
8. Financial disincentives to Trusts facilitating donation should be removed through the development and introduction of appropriate reimbursement.
9. The current network of donor transplant co-ordinators (DTCs) should be expanded and strengthened through central employment by a UK-wide Organ Donation Organisation. Additional co-ordinators, embedded within critical care areas, should be employed to ensure a comprehensive, highly skilled, specialist and robust service. There should be a close and defined collaboration between DTCs, clinical staff and Trust donation champions. Electronic on-line donor registration and organ offering systems should be developed.
10. A UK-wide network of dedicated organ retrieval teams should be established to ensure timely, high-quality organ removal from all heartbeating and non-heartbeating donors. The Organ Donation Organisation should be responsible for commissioning the retrieval teams and for audit and performance management.
11. All clinical staff likely to be involved in the treatment of potential organ donors should receive mandatory training in the principles of donation. There should also be regular update training.
12. Appropriate ways should be identified of personally and publicly recognising individual organ donors, where desired. These approaches may include national memorials, local initiatives and personal follow-up to donor families.
13. There is an urgent requirement to identify and implement the most effective methods through which organ donation and the 'gift of life' can be promoted to the general public, and specifically to the BME population. Research should be commissioned through Department of Health research and development funding.
14. The Department of Health and the Ministry of Justice should develop formal guidelines for coroners concerning organ donation.

Reproduced from: Organ Donation Taskforce (2008) Organs for Transplants. A report from the Organ Donation Taskforce. Department of Health, London.

The Taskforce's mantra was that organ donation should become 'a usual not an unusual event', emphasising that it should be seen as a standard part of end-of-life care for all suitable patients. It should be the norm that brain stem tests are carried out on every patient where brain stem death is a possible diagnosis, that all cases of brain stem death or treatment withdrawal are referred to the donor co-ordinator, and that the Organ Donor Register is checked and the relatives approached in every case where donation may be a possibility. The Taskforce recommended

considerable restructuring of the system, much of which had developed in an ad hoc fashion at a local level. NHS Blood and Transplant was to become the single national organisation responsible for organ donation and transplantation and would directly employ an increased number of donor co-ordinators. Clinical 'donation champions' and donation committees within every Trust would ensure that donation was considered on a Trust-wide basis and at Board level. To ensure high-level engagement and oversight, individual hospital donation rates, together with benchmark data from other Trusts for comparison, would be provided to the Trust Board and would be considered as part of the clinical governance process.

The UK Health Ministers accepted all of the Taskforce's recommendations and the UK Government appointed Mr Chris Rudge (formerly Medical Director of UK Transplant) as the first National Clinical Director for Transplantation in England to lead the day-to-day implementation of the recommendations and to chair a Programme Delivery Board that maintained oversight of progress across the UK. Similar appointments were made in Scotland, Wales and Northern Ireland. In Scotland, the Cabinet Secretary for Health & Wellbeing asked the Scottish Transplant Group to take responsibility for overseeing implementation in Scotland. In 2008/09, £16.5 million was allocated to the NHS for organ donation and transplantation (of which £11.5million was new money specifically related to the implementation of the Taskforce report). A further £26.5 million was allocated for 2009/10.³¹ The UK Health Ministers made clear, however, that it expected to see improvements and would be closely monitoring donation rates. In December 2011 the Organ Donation Taskforce Programme Delivery Board published its final report, announcing that all of the recommendations had been fully or substantially implemented.³²

Clinical leads, specialist nurses and donation committees

A fundamental aim of the Taskforce was that every acute Trust in the country should have a donation champion (subsequently renamed clinical lead for organ donation), an 'embedded' donor transplant co-ordinator (subsequently renamed specialist nurse – organ donation) and a donation committee, chaired by a non-clinical champion, acting as a link between the transplant team and the Board or senior management of the Trust.³³ These local 'collaboratives' would ensure that organ donation was always considered in appropriate cases, identify and remove barriers to donation within the Trust and raise awareness of organ donation within hospitals and amongst the local population. Thus a national system of local collaboratives – based on the successful model in Spain (see section 6) – was seen as key to maximising donation potential.

As part of its implementation policy, NHS BT developed and executed a 12-month professional development programme for clinical leads and donation committee chairs.³⁴ The programme aimed to provide participants with the skills necessary to implement the Taskforce's vision of making donation a normal part of end-of-life care. The training focused on achieving the 'six big wins':

1. Increased consent/authorisation rates
2. Increased diagnosis of brain stem death
3. Increased donation after cardiac death (now referred to as donation after circulatory death)
4. Increased rate of donation in emergency medicine

5. Increased referral according to minimum notification criteria
6. Increased quality and quantity of organs from improved donor management.

A final part of the programme was the development of 12 regional donation collaboratives in the UK to provide local teams with support, advice and a forum for the exchange of ideas.

Clinical leads for organ donation

The aim of the clinical lead posts is to have a senior clinician within each Trust (or equivalent in the devolved nations) who is responsible for ensuring that organ donation is seen as a priority, that the Taskforce's recommendations are implemented and that procedures are in place to optimise potential donor identification and management. The role is a strategic one, focusing on policies and process rather than on individual cases.

Clinical leads are employed by the Trust for one or two sessions per week with funding and training provided by NHS BT. The vast majority of clinical leads are consultants in intensive care. This initially gave rise to some concerns about a potential conflict of interest where intensivists are making decisions about withholding or withdrawing life-prolonging treatment, carrying out brain stem tests to diagnose death and, at the same time, have a formal position within the Trust relating to organ donation. Their goal, however, is not to maximise the number of donors – which could give rise to a conflict of interest – but to ensure that systems are in place so that the option of organ donation is always available for patients and their relatives. The BMA supports this goal and believes that all doctors who care for dying patients should see the offer of organ donation as part of their role. Nevertheless, Trusts may decide that introducing a formal system to protect against any perception of a conflict of interest is helpful, such as introducing a formal requirement for a second clinical opinion when clinical leads are making decisions to withdraw life-prolonging treatment from someone who may go on to be an organ donor.³⁵ This may simply be a matter of formalising existing practice under which, for example, the ICU consultant and the referring consultant liaise closely over such decisions.

Clinical leads have been appointed in all 226 donating hospitals in the UK.³⁶ Most are employed for one session per week but a small number have additional responsibilities and have two sessions. This may be because they work in a large Trust, because they have additional commitments on a national level or because they have taken on the role of Regional Clinical Lead for Organ Donation. The regional clinical leads, working with NHSBT regional managers, compile annual reports and donation plans and ensure co-ordination and collaboration within the region. A small number of extra clinical leads have been appointed in specialist areas such as paediatrics or emergency medicine. It is important that hospitals genuinely protect this time to enable clinical leads to fulfil their responsibilities.

Through the Professional Development Programme clinical leads were provided with leadership and change management training designed to encourage them to identify the barriers to the delivery of the six big wins within their region, to analyse the reasons for these barriers and to develop and implement a series of objectives to overcome them. Part of the role of the clinical lead is to ensure

the development of local educational and training opportunities for all staff likely to be involved with the care of a potential organ donor, in line with the Taskforce's recommendation 11. This has been approached in different ways around the country with some using e-learning resources, donor simulation training or face-to-face training provided by clinical leads or specialist nurses.

Specialist nurses – organ donation

In line with the Taskforce's ninth recommendation, specialist nurses (formerly called transplant co-ordinators) are now employed and trained directly by NHS BT. These individuals provide the vital link between the family of the deceased, the hospital where the donor died and the transplant centres retrieving and receiving the donated organs. Organ donation and transplantation are logistically complex, as well as emotionally demanding, and specialist nurses play a critical role in making them happen. The Taskforce assessed the way the system was organised and recognised that the workload and working methods of specialist nurses were unsustainable, with some working up to 24 hours without a break. It suggested that the role should be split into three distinct areas of work so that up to three individuals might attend each donor:

- discussions with the organ donor's family, covering consent and seeking a medical and social history of the donor;
- obtaining clinical information, registering the donor with NHS BT and making arrangements for the organ retrieval;
- participating in the retrieval process and liaising with NHS BT over the allocation of organs.

This has proved difficult to achieve in practice. The Taskforce also recommended that work relating to donation and that related to recipient care should be separated.

At the time of the Taskforce Inquiry there were about 100 donor co-ordinators working in 18 teams. There were also 12 'in-house' co-ordinators based full-time within a single critical care unit or Trust. The Taskforce recommended that their number needed to be increased to around 250 and that all specialist nurses should be employed and trained by NHS BT. By November 2011 the target of 250 specialist nurses, and support staff, employed by NHS BT had been achieved and there were plans to appoint a further 20.³⁷ The intention has been that all specialist nurses would be embedded within the intensive care unit and at the time of writing the vast majority were already working in this way. Specialist nurses work in regional teams and have 24-hour support from regional managers who, in turn, have support from a range of experts to ensure that any challenging ethical or legal situations can be addressed. Applicants are required to have experience within emergency medicine or critical care and to have significant local management experience. They are also required to hold a post-basic qualification in critical care and must be able to demonstrate appropriate skills in communication and organisation. The training is both desk-based and practical and can take up to ten months to complete.³⁸

The specialist nurse's main priority is to manage the donation process. Another key aspect is the collection and interpretation of data for the potential donor audit (see below). They also have an important educational role at a local level. In addition, under the new local collaborative model,

the specialist nurse has a more clearly defined strategic role in developing organ donation locally, working with the clinical lead and the donation committee to identify any problems, review performance and seek solutions as well as raising the profile of donation both within the hospital and in the local community.

Donation committees

The Taskforce's fourth recommendation was that every acute Trust, and equivalent in the devolved nations, should appoint a donation committee chaired by a non-clinical 'donation champion'. By November 2011 this had been achieved with the establishment of about 200 committees. Committee chairs come from a range of backgrounds including organ transplant recipients, non-executive directors and retired clinical staff. Committee membership varies depending upon local need, and availability, but the clinical leads and specialist nurses are key members. Other members include members of the clinical team from emergency medicine, paediatric intensive care, neuro-intensive care and the palliative care service, the end-of-life care pathway lead, an operating theatre representative and a hospital chaplain.³⁹ Some Trust Medical Directors also sit on the committees. The committees are responsible for ensuring that donation is integrated into the core business of the hospital and report to the Trust Board on a regular basis. The level of involvement and engagement of Board members varies but overall appears to have improved significantly since the introduction of the new structures.⁴⁰

Part of the role of the donation committee is to assess the data from the potential donor audit to identify when, and why, potential donors have been lost or overlooked and to recommend solutions to any problems identified. Donation committees have also been involved with the development of local donation policies, raising awareness about donation locally and identifying appropriate ways of honouring donors.

Donor identification and referral

In line with the Taskforce's fifth recommendation, standard national donor identification and referral criteria have been established so that all patients who meet the criteria for brain stem testing (apnoea, coma from known aetiology and unresponsive, ventilated and fixed pupils) or where a clinical decision has been made to withdraw life-prolonging treatment should be referred to the specialist nurse. This appears to be working well for those who meet the criteria for brain stem testing but there is some anecdotal evidence that the criteria for donation following circulatory death are subject to differing interpretation and require further clarification.⁴¹ This is confirmed by the potential donor audit (see below) which shows a low donor identification and referral rate for these potential donors and so clarifying the referral criteria must be seen as a priority.

In December 2011 the National Institute for Health and Clinical Excellence (NICE) published a clinical guideline on improving donor identification and consent rates for deceased organ donation.⁴² The guideline states that the healthcare team should discuss the potential for organ donation with the specialist nurse in all cases where the following criteria are met:

- 'defined clinical trigger factors in patients who have had a catastrophic brain injury, namely:
 - the absence of one or more cranial nerve reflexes **and**

- a Glasgow Coma Scale (GCS) score of 4 or less that is not explained by sedation

unless there is a clear reason why the above clinical triggers are not met (for example because of sedation) and/or a decision has been made to perform brainstem death tests, whichever is the earlier

- the intention to withdraw life-sustaining treatment in patients with a life-threatening or life-limiting condition which will, or is expected to, result in circulatory death'.⁴³

The research data analysed by NICE,⁴⁴ showed that the use of clinical triggers and a requirement to refer according to standard criteria led to an increase in both referrals and donors. It is hoped that implementation of the NICE guideline will result in early and consistent donor referral. This, combined with the clinical lead and specialist nurse providing support and guidance to staff and the donation committee investigating all cases where potential donors are lost, should lead to an increase in referral rates and, subsequently, an increase in donors across the UK.

Clinical management of potential donors, before and after referral, is also an important issue. This includes decisions about the timing of withdrawal of treatment (which should take account of the individual's wish to become a donor where that is known), and the initial stabilisation and assessment of potential donors. Work is currently underway to develop and test an 'intensive care bundle' to help intensivists to provide clinical care to potential donors in a way that will maximise donation potential.⁴⁵

National Organ Retrieval Service

Another key change recommended by the Taskforce was the introduction of national organ retrieval teams. It recognised that the system in place since the 1990s, which required specialist teams from several different transplant centres to attend a single donor, was problematic and unsustainable. The teams varied in size, composition and level of experience. Most had other clinical commitments and so were often unable to respond at short notice and they relied heavily upon staff and facilities at the donor hospital. Organ retrieval had developed in an ad hoc fashion and was neither explicitly funded nor performance-managed. The Taskforce's proposal was that regional multi-organ retrieval teams should be established that were virtually self-sufficient and available 24 hours a day, seven days a week without other elective commitments during periods on call for organ retrieval. They would be able to provide early expert advice on donor management as well as providing an efficient, high quality retrieval service. It was envisaged that this change would increase capacity (to cater for the anticipated 50% increase in donors), increase the number of organs collected per donor and improve the quality of the organs available. The new multi-organ retrieval service has been in place since April 2010 and, under the new system, Trusts that support retrieval teams risk the imposition of financial penalties for non-retrieval caused by a lack of team availability.⁴⁶

In March 2010 NHS BT published national standards for organ retrieval from deceased donors.⁴⁷ The standards include that a retrieval centre point of contact must be available 24 hours a day, be able to dispatch the retrieval team within one hour of notification (unless the team is already

committed to retrieval elsewhere) and an on-call consultant surgeon must be available for the retrieval team to consult during the retrieval if necessary. The standards also specify that lead abdominal surgeons must be capable of accurately assessing and retrieving all abdominal organs and lead cardiothoracic surgeons must be capable of assessing and retrieving hearts and lungs. Where they are working together the two teams should agree, in advance, how the retrieval operation will proceed.

Review of the new system after one year, to 1 April 2011, highlighted a number of issues. It found that although teams were required to be available 365 days a year, individual cardiothoracic teams were only out retrieving organs on between nine and 28% of days and abdominal teams on between 19 and 59% of days.⁴⁸ This raised concerns about the effective use of resources which is currently being reviewed. Cardiothoracic retrieval is being considered as one part of a broader review of cardiothoracic transplantation led by the NHS National Specialist Commissioning Group.⁴⁹ Despite these logistical issues, some clinical leads have reported that the revised retrieval arrangements have had a major positive impact on the effectiveness of the system in their area.⁵⁰

The organ allocation and offering system

All organs that become available are allocated according to set criteria determined by advisory groups relating to specific organs. The blood group, age and size of both the donor and recipient and, in some cases, the tissue type are taken into account to ensure the best possible match for each patient.

The Taskforce recommended improvements to the process of allocation by the introduction of an electronic offering scheme which speeds up the matching and allocation process for donated organs. The web-based system enables specialist nurses for organ donation to input data allowing recipient nurses to see on-screen, in real time, the organs that are available, where they have been offered and when they have been accepted. This significantly reduces the time and work involved in the allocation process. The electronic offering system (EOS) has been trialled and widely adopted around the country. As a result of this review some improvements are being made to the system before its use is further expanded.

The British Transplantation Society (BTS) and the Intensive Care Society (ICS) have also called upon NHS BT to consider the way in which organs from DCD donors are currently offered to transplant units. They believe that the system would be streamlined and made more efficient if organs were offered to transplant units simultaneously rather than sequentially.⁵¹ At the time of writing this issue is under review by NHS BT.⁵²

The potential donor audit

It was recognised many years ago that a crucial part of the process of improving donation rates is to understand the true potential for organ donation from deceased donors and the reasons for non-donation. In April 2003 UK Transplant (now the Organ Donation and Transplant directorate of NHS BT) began routinely collecting data on all deaths in intensive care units throughout the UK. It identified the key points in the donation process: brain stem testing, considering donation, speaking to relatives and obtaining consent to donation. Through analysing these data UK

Transplant was able to identify where donors were lost and thus areas that required attention. The data were illuminating. From 1 April 2003 to 31 March 2005 2,740 individuals' deaths were diagnosed by brain stem tests (individuals who were therefore identified as potential donors), of whom only 1,244 (45.4%) went on to donate.⁵³ Donation was considered in 90% of cases and, of these, an approach was made to the next of kin for permission in 94% of cases. Confirming anecdotal evidence, the largest reason for non-donation was found to be relative refusal which stood at 41% of those approached (ranging from 35% amongst the white population to 70% for ethnic minorities). Another area where donors could have been lost was the failure to carry out brain stem tests. In 4,166 patients brain stem death was recorded as a possible diagnosis but in 1,309 (31.4%) of these, tests were not carried out. Although they are often linked, brain stem death testing was not introduced to facilitate organ donation but for the diagnosis of death in situations where there had been severe neurological damage yet other vital organs were being maintained by high level medical intervention. It should, therefore, be the norm for brain stem death testing to be carried out on every patient where brain stem death is a possible diagnosis unless there are there are clinical reasons why this is not appropriate.

The Organ Donation Taskforce stressed that, in addition to the actual number of donors, an important measure of success is the proportion of those suitable for donation who are identified and whose personal, or family's, wishes are ascertained and followed. The number of transplants is clearly also an important measure of success. The Taskforce welcomed ongoing work by NHS BT to collect more detailed data and to expand the potential donor audit to emergency departments. It recommended that the data for individual Trusts should be made publicly available and reviewed by the Trust Board.

Donation after brain stem death

The new enhanced and expanded potential donor audit has been in operation since October 2009. In the first full year (1 April 2010 to 31 March 2011), 1,141 patients' deaths in intensive care units were diagnosed by brain stem tests and there were no absolute contraindications to donation.⁵⁴ Of these 617 (54%) went on to donate. The family was approached about donation in 93% of cases (in 20% of cases where relatives were not approached this was because the family had already stated that they would not consent before a formal approach was made.) Overall the family refusal rate was 35%. Where the individual's wish to donate was known the refusal rate dropped to 6% but when the relatives did not know the individual's views it increased to 50%.⁵⁵ Ethnicity remains highly significant in respect of refusal rates with a rate of 29% amongst the white population and 77% amongst the non-white population.

As in 2003 there were a number of cases, 467 (28%), where all of the criteria for brain stem testing were met but the tests were not carried out; the reasons given for this varied but included that the patient was haemodynamically unstable and that there was family pressure not to test.⁵⁶ There were also cases, 258 (15%), where the referral criteria were met but the case was not referred to the specialist nurse.⁵⁷ In 30% of these cases the reason given was that the patient was not identified as a potential donor or donation was not considered.⁵⁸ In 91% of cases where consent was provided donation proceeded. Where it did not proceed the main reasons were that the organs were deemed medically unsuitable by the recipient centres (25%) or the coroner/procurator fiscal refused to give authorisation (17%).⁵⁹

It is difficult to make a direct comparison with the 2003 data because of the different way in which the data are presented but there have clearly been some improvements, including a welcome reduction in the refusal rate which decreased from 41% to 35%. Donation rates for individual areas continue to show significant variation although this could in part be due to factors such as the age, sex and ethnicity of the population.

Summary of key data for DBD 2010/11⁶⁰

		Yes %	No %
Total number of deaths in ICU and emergency departments	29,060		
Criteria for brain stem testing and referral met	1,672		
Referred to specialist nurse (% of those meeting testing criteria)	1,414	84.6	15.4
Brain stem tests carried out (% of those meeting criteria)	1,205	72.1	27.9
Death confirmed and no medical contraindications (ie. potential donors)	1,141		
Family approached (% of potential)	1,057	92.6	7.4
Consent/authorisation obtained (% of those where families approached)	682	64.5	35.5
Solid organs donated (% of those with consent)	617	90.5	9.5

Donation after circulatory death

Under the new system, data are also collected on donation after circulatory death (DCD) following the planned withdrawal of treatment. In 2010-2011, there were 2,875 potential donors whose imminent death was anticipated, treatment was withdrawn and there were no absolute contraindications to solid organ donation.⁶¹ With these potential donors, the non-referral rate was significantly higher at 56%.⁶² As with donation after brain stem death, in 32% of cases the reason given was that organ donation was not considered; the medical contraindications rate was also high amongst this group at 34%.⁶³ The relatives were approached about donation in 47% of cases and among these the relative refusal rate was 49% (where the individual's wish to donate was known the refusal rate dropped but only to 20% which is significantly higher than for DBD donors⁶⁴). Where consent (or authorisation) was provided, donation proceeded in 50% of cases. Of the cases where donation did not proceed, in almost half this was because there was a prolonged period between treatment withdrawal and death resulting in organ damage and in a further 21% of cases the organs were deemed medically unsuitable by the recipient centres.⁶⁵

Summary of key data for DCD 2010/11⁶

		Yes %	No %
Total number of deaths in ICU and emergency departments	29,060		
Referral criteria met (on ventilator, not BSD, imminent death expected)	7,192		
Referred to specialist nurse (% of those where referral criteria met)	3,188	44.3	55.7
Treatment withdrawn and no medical contraindications (ie. potential donors)	2,875		
Family approached (% of potential)	1,359	47.3	52.7
Consent/authorisation obtained (% of those where family approached)	691	50.8	49.2
Solid organs donated (% of those with consent)	345	49.9	50.1

Potential donor rate

Another important and interesting addition to the data set is information about the potential donor rates per million population in the UK.⁶⁷ This allows us to assess what is the absolute *maximum* rate of donation in the UK if *all* potential donors went on to donate (recognising, of course, that in practice this is unachievable). The data for 2010/11 show that over that period the rate of potential DBD donors was 18.4 per million population. The potential rate of DCD donors was 46.4 per million population. This is based on 2,875 potential DCD donors but it needs to be recognised that a significant percentage of those (probably around 43%) will be unable to donate because of an extended period between withdrawal of treatment and death. This reduces the potential DCD donor rate to 26.4 per million population, giving a total potential deceased donor rate of 44.8 per million population. The current donation rate in the UK is 16.3.⁶⁸

Clinical, legal and ethical guidance

Over the last few years a number of guidelines have been published on various aspects of organ donation with a view to improving practice and consistency throughout the UK. Some of these documents predated the Taskforce. Others were published in direct response to the Taskforce's third recommendation that outstanding legal, ethical and professional issues should be resolved so that professionals can work within a clear and unambiguous framework of good practice. This section highlights the main points in some of these key documents.

The process of seeking consent

In addition to identifying standard referral criteria (see above), the NICE guideline on organ donation⁶⁹ also provides detailed advice about the process of planning and seeking consent based on analysis of the published research. This includes the recommendation that the approach should be made by a multi-disciplinary team made up of the medical and nursing staff involved in the care of the patient led by an identifiable consultant, and the specialist nurse for organ donation. A local faith representative should also be included where that is likely to be the wish of the family. The guidance also states that the organ donor register should be checked, and the donor's potential to donate should be identified, before the relatives are approached. Families should be allowed sufficient time to understand and accept the inevitability of death and to spend

time with the patient before the issue of donation is raised unless the family initiates discussion about donation earlier. When the approach is made, it should be in positive terms and should avoid the use of negative or apologetic language (eg 'I am sorry to have to ask you...'). The guideline also lists the information that must be provided and the knowledge and skills required by those specialists approaching relatives.

The BMA supports these recommendations. It believes that information about organ donation should be given to families in a positive way that emphasises the huge difference donation makes to people's lives, and that families should be informed of the comfort that many families derive from the knowledge that their loved one's organs have been used for donation.

Diagnosis of death

In 2008 the Academy of Medical Royal Colleges published a code of practice for the diagnosis and confirmation of death.⁷⁰ This reviewed and updated the existing guidance on diagnosing death by brain stem tests in those over the age of three months and also, for the first time, included clear guidance on diagnosing death following cardio-respiratory failure. The increase in donors following circulatory death prompted the need for clear, nationally agreed guidance both about how death is diagnosed and also the necessary period between death being diagnosed and interventions commencing with the aim of preserving organs for donation. The code specifies that where a patient has suffered cardio-respiratory arrest and attempts to resuscitate are either inappropriate or have been unsuccessful, the individual should be observed for five minutes. After this time a set of basic tests should be undertaken to confirm that death has occurred (including confirming the absence of circulation using an arterial line or electrocardiogram (ECG)) and the legal time of death should be recorded as the time the tests are undertaken.

Brain stem testing has frequently been closely associated with organ donation but the code of practice emphasises that brain stem tests should be undertaken in *all* patients who might meet the criteria and that they should not be considered only in cases of possible organ donation. The same recommendation was made by the Taskforce. This is because it is good clinical practice to withdraw treatment that is no longer able to benefit patients. The Academy's code of practice restates the requirement that the diagnosis of death following brain stem tests must be made by at least two medical practitioners who have been registered for more than five years and are competent in the conduct and interpretation of brain stem testing, at least one of whom must be a consultant. The set of tests should be conducted on two separate occasions but the legal time of death is after the first set has diagnosed that the patient is dead.

Donation following circulatory death

Since around 2005 there has been a big increase in the number of units providing donation after circulatory death (see section 3) such that these donors now make up nearly 37% of all deceased donation.⁷¹ Yet this is one area highlighted by the Taskforce where there remained legal, ethical and clinical uncertainty and where additional guidance was required. Since the Taskforce report was published, three sets of guidance have been produced addressing different aspects of this type of donation: legal guidance (from the Department of Health and Welsh Assembly Government,⁷²

the Scottish Government⁷³ and the Department of Health, Social Services and Public Safety in Northern Ireland⁷⁴) ethical guidance from the UK Donation Ethics Committee⁷⁵ and clinical guidance from the British Transplantation Society and the Intensive Care Society.⁷⁶

Taking steps before death to facilitate donation

The BMA's Medical Ethics Committee (MEC) discussed, in 2004 and again in 2010, the question of what, if any, steps could be taken before death to facilitate organ donation. On both occasions the MEC concluded that some steps – such as continuing fluids or oxygen and taking a blood sample for virology screening – would be both legally and ethically justified where it was known that the individual wished to donate organs after death. The BMA therefore supports the view that where an individual wanted to be an organ donor, it is ethically acceptable to take steps to facilitate, or at least not to frustrate, the patient's wish to donate organs after death provided the steps are not contrary to the patient's interests. The legal test that must be satisfied, however, is a 'best interests' test; any interventions involving patients who lack capacity must be in their best interests. In order to assess this, every case needs to be considered individually to determine the individual's wishes and the risk of causing any harm or distress to the patient or those close to the patient.

In the BMA's view, the level of evidence available about the individual's wishes is an important factor in deciding what intervention is appropriate. For example:

- a) those donors who have stated, in advance, that they would be willing to undergo invasive procedures to enhance the prospect of a successful transplant;
- b) those donors who have indicated a wish to donate their organs – by joining the Organ Donor Register or signing a donor card;
- c) those donors where the relatives have authorised donation on the basis of the donor's known wishes and beliefs;
- d) those donors where the relatives have authorised donation on the basis of the donor's likely wishes and beliefs;
- e) those donors where there is no indication of the donor's wishes but where the relatives have nonetheless authorised donation as something they wish to see happen.

The further down this list one goes, the more difficult it is to justify invasive procedures on the basis of a 'best interests' test.

The first official guidance on this subject was published in November 2009, by the Department of Health and Welsh Assembly Government.⁷⁷ This document focused on the broad assessment of 'best interests' required under the Mental Capacity Act 2005, which takes account of medical, social, cultural and religious issues, focusing on the individual's own wishes and beliefs. It concluded that where it is known that the individual wanted to donate organs after death, some actions to facilitate donation could be in the person's best interests if they do not cause the person harm or distress (including causing distress to family and friends) and would therefore be lawful. The type of interventions considered included adjustments to the timing or place of death, maintenance or adjustment of existing treatments such as fluids or inotropes to maintain patient

stability and blood sampling for the purpose of tissue typing or virology screening. Where it is not possible to ascertain the individual's wishes the guidance states that clinicians would need 'a compelling reason' to take actions to facilitate donation in the individual's best interests. Parallel guidance was issued in Scotland, in May 2010, in relation to deciding whether actions to enhance the chances of a successful donation would be for the person's 'benefit' as required by the Adults with Incapacity (Scotland) Act 2000.⁷⁸ In March 2011 similar guidance was published in Northern Ireland based on the common law principle of best interests.⁷⁹

In December 2011, the UK Donation Ethics Committee (UK DEC) – set up in response to the Taskforce's third recommendation – published its first report, *An ethical framework for controlled donation after circulatory death*. In relation to this subject UK DEC took a similar position to the DH and BMA.⁸⁰ This report also provides a detailed ethical framework to guide practice throughout the donation process.

Clinical guidance

In June 2010 the Department of Health hosted a consensus meeting on donation after circulatory death, following which the Intensive Care Society (ICS) and the British Transplantation Society (BTS) published joint clinical guidance.⁸¹ The document highlighted the wide variation in practice in both the care of potential DCD donors and the retrieval and transplantation of organs, and sought to provide clear clinical guidance for practice. The guidance stated very clearly that a decision to withdraw treatment must be completely separate from, and precede, any consideration of organ donation. No measures to facilitate donation should be instituted before this decision has been made. The guidelines covered issues such as suitability criteria for donation after circulatory death, the process of treatment withdrawal, the definition of 'optimal' and 'sub-optimal' donors and the diagnosis of death and post mortem interventions. Some areas were identified where further debate was needed before agreement could be reached such as the possibility of continuing ventilation for a period of time in the belief that some of the patients will go on to fulfil the criteria for DBD rather than DCD.

Requested allocation of organs

In March 2010 the UK Health Administrations, together with NHS BT and the Human Tissue Authority produced a policy document on requested allocation of a deceased donor organ. This followed a small number of requests by individuals or their families for organs to be donated, after death, to a family member or close friend. At the time such requests were turned down because donations were required to be unconditional, following a case in 1998 where an individual's family stipulated that organs should be used only for white recipients.⁸² The type of case envisaged by the policy document was where a family member or close friend of the potential donor required a transplant and the donor, or the donor's family, requested that they should be given priority. It was pointed out, in debate on the issue, that living donors can direct their donation to a particular individual. In fact, in some of the cases considered, the patient was in the process of becoming a living donor for a family member or friend before the incident that led to death.

One of the fundamental principles of the UK's organ donation system is that organs are donated freely, voluntarily and unconditionally. In addition, the Human Tissue (Scotland) Act 2006 specifically prohibits individuals from attaching conditions to their donations.⁸³ When the BMA's Medical Ethics Committee (MEC) discussed this issue in 2007 it concluded that the basic principles, that donation should be unconditional and that organs should be allocated on the basis of clinical need, should be upheld. It believed, however, that there should be some flexibility to consider individual requests for directed donation in rare and exceptional cases. The MEC did not, however, support allowing donation to be *conditional* upon an organ going to a particular recipient. Rather it should be possible for families to request that consideration is given to allocating the organ to a particular person who is genetically or emotionally close to the donor. Whether that request is accepted would depend, at least in part, on the potential harms to others – for example, if there was someone on the 'super urgent' list who would die without the organ, the family should be informed that it was not possible to meet their request and that the organ would be allocated on the basis of clinical need. Consent (or authorisation) for organ donation must however be given irrespective of whether the request is accepted. To do otherwise, the MEC considered, would be to submit to a form of conditionality that is not acceptable for this type of public service.

The policy document, from the Health Departments and NHS BT, takes a very similar approach, stating that a request for directed donation can be considered where:

- consent, or authorisation, has been provided;
- the consent or authorisation is not conditional on the request being met;
- there are no others in desperately urgent clinical need of the organ who might be harmed by the organ going to the nominated individual (individuals on the urgent heart scheme or super urgent liver list will always be given priority);
- the individual, in his or her lifetime, or the family after death, had requested donation to a particular individual who is a family member or friend of long standing; and
- the potential recipient is on the transplant waiting list or meets the criteria for a transplant.

As a safeguard, NHS BT established a mechanism to consider and approve individual requests that fall within this framework. By November 2011, four requests had been made, three of which were approved (in the fourth case donation was conditional upon the request being met and so the agreed criteria were not met). For a variety of reasons none of these donations actually went ahead.⁸⁴

Guidance for coroners

One of the problems identified by the Taskforce was the significant variation in the decisions of coroners and procurators fiscal regarding whether donation could proceed in cases referred to them. It had been known for some time that some coroners refused permission for donation in all cases of sudden or unexplained death whereas others would allow donation of some organs where this would not interfere with their investigation. The Taskforce recommended that discussions should take place and national guidelines should be developed in order to ensure consistency and to minimise the number of cases where donation is prevented. As a result, in

March 2010, the Department of Health, together with the Ministry of Justice, produced guidance for specialist nurses on working with coroners⁸⁴ and an aide-memoire for coroners.⁸⁵ These documents emphasise the importance of the coroner or a deputy being available to make a decision in a timely manner and set out the information the coroner is likely to need prior to giving agreement to donation. They explain that it might be possible for the coroner to agree to the removal of organs from those parts of the body that are not likely to be significant in any subsequent post-mortem examination and that the coroner may ask for a forensic pathologist to be present during organ retrieval. Coroners are advised that they may wish to discuss the possibility of donation with the pathologist who will undertake the post-mortem examination and, where relevant, the police before making a decision. Awareness of organ donation will also be included in coroners' training. In spite of these developments there remains significant unexplained variation in coroner's refusals. Further work with coroners is ongoing in a further attempt to reduce the variation in practice and the number of donors lost.

In Scotland, there is a long-standing agreement between the Scottish Transplant Group and the Crown Office and Procurator Fiscal Service regarding organ donation. This is currently being updated to take account of the development of DCD programmes.

Living donation

In May 2011 the British Transplantation Society and the Renal Association produced the third edition of their *United Kingdom Guidelines for Living Donor Kidney Transplantation*.⁸⁷ The guidelines cover clinical, ethical and legal aspects of living donation providing up-to-date and robust guidelines for clinicians involved in this area of transplantation.

In addition, in January 2012 NHS Blood and Transplant published its *UK Strategy for Living Donor Kidney Transplantation* with the aim of increasing the number of living kidney donor transplants. The key aims of the strategy are to:

1. Increase transplant activity from living kidney donors for both adult and paediatric recipients, ensuring that donor safety is consistently promoted through best clinical practice.
2. Achieve optimum pre-emptive living donor kidney transplantation rates and equity of access for patients within each transplant centre across the UK.
3. Maximise the opportunities for donors and recipients who wish to participate in the National Living Donor Kidney Sharing Schemes, which include paired/pooled donation, non-directed altruistic donation and altruistic donor chains.⁸⁸

Considerable emphasis is placed on the importance of having appropriate, robust and transparent commissioning arrangements in place to facilitate and encourage living donation. In fact, NHS BT highlights the lack of streamlined commissioning arrangements across the UK as the primary risk to the successful implementation of the strategy.

What more can or should be done?

The last four years have seen momentous and significant changes to the infrastructure within which organ donation takes place. This has resulted in more donors and more transplants being undertaken. This is cause for celebration, but not complacency: people are still dying and as long as more can be done, more should be done. Whilst the 14 recommendations of the Taskforce have been fully or significantly implemented, some still require work over a longer period of time and other areas should also be explored. Set out below are some areas where further work is needed to maximise the efficiency of the system to ensure that all potential donors who want to donate are able to do so. Most, if not all, of these issues are already being investigated but the momentum and enthusiasm that has built up from the Taskforce report must be maintained in the longer term.

Increasing referrals

Some of the recommendations of the Taskforce require changes to clinical practice and in the way in which health professionals carry out their work. The reforms that have taken place have been aimed at changing the mindset of those working with dying patients, so that all health professionals see donation as part of their responsibility to their patients which will inevitably take time and require ongoing effort. This will include working with health professionals based in emergency medicine as well as those in intensive care where potential donors have traditionally been identified. It is hoped that in the future:

- all patients who meet the criteria for brain stem testing will have the tests undertaken, irrespective of whether they are considered likely to be donors;
- health professionals' acceptance and implementation of clinical triggers and/or clear and unambiguous referral criteria will ensure the specialist nurse is consulted and involved at an early stage in all possible cases; and
- there are no more cases where the potential donor audit reports that organ donation was simply not considered (failure to consider donation where a person was on the ODR should be reviewed at a senior level in the hospital).

Unlike most aspects of donation, this is an area that could be subject to targets and possibly reward schemes such as the Commissioning for Quality and Innovation (CQIN) payment framework in England. A hospital could, for example, receive payments for achieving a 100% referral rate for potential donors (based on clear and unambiguous referral criteria). Such an incentive would not result in a conflict of interest since it is not about donation rates, per se, but about giving all patients who are dying the option of donation where that is a possibility. One Strategic Health Authority has included organ donation indicators into its CQIN framework and this is reported to have led to greater scrutiny of organ donation within the Trust and also appears to be showing improvements in those areas monitored by the CQIN. NHS BT is considering how this initiative could be expanded to other parts of the UK.⁸⁹

One of the aims of the Taskforce was to remove disincentives to donation by recommending that hospitals are reimbursed for the cost of organ retrieval, reinstating a system that was abolished in the late 1990s. The rationale for its abolition was that paying hospitals' costs when they retrieved organs made it appear that this was an 'optional extra' rather than part of the core business of

acute hospitals. The money was, therefore, included in the overall hospital budget but, in practice, did not reach its intended destination. The reintroduction of the payment for reimbursement needs to be monitored to ensure the money is reaching the appropriate departments but, where it is working well, it is seen as welcome recognition of the work involved in donation.⁹⁰

Reducing the relative refusal rates

It has long been known that one of the major problems for organ donation is the high rate of relative refusals. In the 2003 Potential Donor Audit, it stood at 41%; by 2010 it had reduced to 35% for DBD donors but this is still too high. In producing its guidance, NICE reviewed the published literature including identifying the key factors that were associated with consent and with refusal.

*Factors associated with consent being given:*⁹¹

- 'understanding that transplantation was a proven procedure, had a high success rate, and knowledge of the benefits of organ donation
- an understanding of the term brain death
- acceptance of death, and confidence in the 'diagnosis of death'
- consideration and knowledge of the deceased's wishes (through carrying a donor card or discussion)
- earlier timing of request
- involving more family members with the decision
- the level of comfort with which the healthcare professional requested consent
- good relationships between the family and the healthcare professionals
- satisfaction with treatment (either of the family or the deceased)
- congruence between the views of healthcare professionals and the families at initial approach
- request for donation being initiated by a healthcare professional (not a physician) with further discussion with an organ donation professional
- request by different healthcare professionals
- more time spent with an organ donation professional
- knowledge of the impact of donation on other processes, such as funeral arrangements
- knowledge of the costs of donation
- choice of organs for donation
- families being able to discuss both specific and wider issues and getting answers to questions.'

*Factors associated with a decision to refuse consent:*⁹²

- feelings of pressure to consent
- feeling emotionally overwhelmed
- feeling of surprise on being asked about consent
- fear of causing more 'suffering' or disfigurement, and not wanting the deceased to have more medical intervention
- concern that donation may cause more distress to family members
- uncertainty about the deceased's wishes
- reluctance to accept the death
- social resentment
- lack of understanding and confidence in the concept of brain-stem death
- lack of family consensus and the family being 'upset'
- family reticence
- making the decision before information was provided by a healthcare or organ donation professional
- an absence of key decision makers
- the length of the process
- not liking the hospital or healthcare professionals
- feeling that the medical care was not optimal
- initial approach by a healthcare professional
- perception that the healthcare professional did not care or was not concerned, or the healthcare professional showing a lack of respect
- healthcare professionals stating that the request was required
- lack of knowledge of the impact of donation on other processes, such as funeral arrangements
- lack of detailed information on the process of organ donation, including the timing of retrieval and information on recipients
- initial perception of healthcare professionals that the family were likely to refuse.'

More research is needed in this area and careful consideration should be given to determining what more can be done to make relatives more likely to consent. This might include:

- continued attempts to raise awareness of organ donation and to encourage people to make their views known and to discuss the issue within families (in Scotland, where there have been ongoing promotional campaigns about organ donation the consent rate has risen to 86%.⁹³)
- more work with ethnic minority communities – where the refusal rate is particularly high – to understand the specific reasons for this and to identify factors that would motivate these groups to donate
- compulsory training in bereavement for those who are likely to approach relatives

- improved training about donation in both undergraduate and postgraduate education so that all health professionals feel confident in identifying potential donors and joining specialist nurses in discussing the issues with families
- considering whether there would be any advantage in giving the family a short death certificate, confirming that death has occurred, before organs are removed. Provision for short death certificates was made in the Coroners and Justice Act 2009 but has not yet been implemented.

The potential donor audit (see above) shows that the relative refusal rate is particularly high amongst black and ethnic minority populations. Work is ongoing to try to determine the reason for this and to ensure that this group is aware of the impact of their decisions on people within their community.⁹⁴ Black and ethnic minority groups are more likely to need a transplant but less likely to sign up to the organ donor register. Even where people have indicated their wish to donate, relatives are more likely to override their wishes. This is a very serious issue that needs to be addressed and work must continue to find innovative ways of reaching these groups.

Brain stem death testing in neonates

The Academy of Medical Royal College's code of practice on diagnosing death⁹⁵ applies only to those over the age of three months and there are currently no standard tests for diagnosing brain stem death in neonates. This means that neonatal hearts are not donated in the UK. There are brain stem death testing standards for neonates in other parts of Europe, however, and so currently neonatal hearts are imported.⁹⁶ This is an area that requires attention so that the diagnosis of death in neonates is brought into line with other countries.

Agreed acceptance criteria for organs

Consideration needs to be given to the development and consistent application of agreed acceptance criteria for organs. Currently different criteria are used by different transplant surgeons and physicians and many organs are refused without the surgeon seeing the organs. There may be good reasons why organs are refused but there need to be clear and consistent criteria to guide this decision. NHS BT is currently working to address this problem.⁹⁷

Organ donation in the NHS

There is a widespread view that the reforms that have taken place have been a major success and the BMA shares this view. It is also evident that those charged with implementing the reforms and taking things forward at a local level on a day-to-day basis demonstrate great enthusiasm and commitment. Over the last four years there have been considerable resources directed to implementing the Taskforce report, both in terms of time and money but things are changing. The Programme Delivery Board, established to oversee implementation of the Taskforce recommendations, has been disbanded and Mr Chris Rudge, National Clinical Director for Transplantation, who was responsible for the day-to-day management of the changes, retired at the end of August 2011 and will not be replaced. Some concerns have been expressed that, with the loss of this central driving force, changes in the Health Service in England, and reductions in public sector spending throughout the UK, the momentum that has been developed could be lost. As a response to some of these concerns a Transitional Steering Group has been established by

the Department of Health.⁹⁸ This group, chaired by Mr Chris Rudge, has membership from the four Health Departments, NHS BT and the key professional groups for intensive care, emergency medicine and transplantation. It is reassuring that many of those working within the system have stated strongly that the momentum that has built up can and should be maintained at a local level. They believe this can be achieved with strategic direction and input from NHS BT (which is leading the development of a post-2013 strategy) and support and encouragement via the structure of regional donation collaboratives.⁹⁹ Whilst there is uncertainty about the future, there is also tremendous optimism that what has been achieved can be maintained and developed.

At the time of writing the process for commissioning transplant services in England is unclear. The Organ Donation Taskforce advised that the commissioning of all transplant services should be undertaken on a national basis – a view the BMA supports. There are also questions about how maximum benefit can be derived from the work that has been done by, for example, linking commissioning to performance, such as whether commissioners of acute hospital services could make their contracts dependent upon NICE guidelines on referral and consent being followed. Whatever systems are put in place, organ donation must continue to be managed and co-ordinated in a coherent fashion and to be seen as an integral part of the end-of-life care pathway. It is only if these changes are protected that the major advances that have been made can be maintained and we can begin to build on the new infrastructure.

5 Increasing the number of donors

As we have seen over the last four years developing the infrastructure, as described in the previous section, can by itself increase the donation rate through better donor identification and referral, improved systems for organ retrieval and allocation and the expansion of new types of donation such as donation after circulatory death. Further improvement can be made by increasing the number of donors, in order to make maximum use of the infrastructure that is now in place. This section sets out a number of ways that have been suggested for achieving this increase either within the current opt-in system or by considering alternatives to it. Some of these initiatives are relatively uncontroversial such as expanding controlled DCD programmes to emergency departments and increasing publicity for the NHS Organ Donor Register. Others, such as the introduction of a regulated market, are more contentious. In fact the BMA does not support some of the options set out in this report but has included them on the basis that those considering how best to proceed should at least be aware of all of the options. The BMA's views are clearly set out below.

Expanding the pool of potential donors

Expanding controlled DCD programmes to emergency departments

The Organ Donation Taskforce emphasised that intensive care should not be the sole focus for organ donation and that all areas where end-of-life care is provided should be included. Attention has recently focused on emergency departments (EDs), where patients are admitted who are not expected to survive their injuries and donation after circulatory death may be possible. Currently, in many such cases treatment is withdrawn in the ED and organ donation is not considered. It is hoped that by raising awareness amongst those working in EDs (with the assistance of clinical leads, specialist nurses and donation committees) and providing clear clinical guidelines, donation could become an option for those admitted to the ED with no, or very little, hope of survival. Data collected via the potential donor audit show that the number of potential DCD donors in emergency departments has ranged between 155 and 207 in each of the three six month periods since April 2010. The actual number of DCD donors in each of these periods, however, ranged from only 5 to 11.¹⁰⁰ Work to increase the number of donors from this source is therefore considered a priority. In the longer term attention will focus on other areas such as acute stroke units, medical assessment units and general medical wards so that individuals treated in those facilities may also have the option of donation. It is also possible, in the future, that uncontrolled DCD from emergency departments might be considered (see section 3).

In October 2010, the Department of Health hosted a consensus meeting following which the College of Emergency Medicine and the British Transplantation Society published a report setting out ways of ensuring that the option of donation is available for those who die in the emergency department.¹⁰¹ In practice this would mean that, for example where patients have catastrophic brain injury that is not survivable, rather than withdrawing treatment in the ED, the clinical team would refer the patient to the specialist nurse and steps would be taken to establish the individual's wishes regarding donation. Wherever possible, potential donors would subsequently be transferred to a critical care setting for assessment, management and withdrawal of treatment.

The report included the following recommendations:

- all emergency departments (EDs) should consider the identification of a lead clinician with an interest in donation who should be represented on the Trust/Health Board Donation Committee
- the potential for donation should be reviewed after each death in EDs and data from the Potential Donor Audit (see section 4) should be reviewed every six months
- local organ donation policies should be developed for EDs, including the care of a ventilated patient and the transfer of patients to intensive care for further assessment and management
- existing training and education programmes for ED staff should be supplemented by incorporating organ donation into Emergency Department induction programmes and local/regional study days.

The BMA supports these recommendations but recognises that due to resource constraints it may not always be possible for patients to be transferred from the emergency department to ICU when donation is being considered. This may be because there are no beds available or because the patients do not meet the admission criteria. This is an issue that needs to be explored further both to determine the number of donors lost because of the lack of ICU facilities and to identify solutions. This might involve seeking additional funding to increase the number of intensive care beds and/or increased flexibility in terms of admission criteria or identifying other suitable locations for assessment and management of those patients who are not being treated in ICU but wish to donate organs after their death.

Expanding the type of organs used from DCD donors

The vast majority of organs transplanted from donors following circulatory death (DCD) are kidneys although some pancreases, livers and lungs have also been transplanted.¹⁰² The possibility of heart donation from DCD donors has also been raised following three cases from the United States reported in 2008. The mean age of the donors was 3.7 days and the cause of death of all three was birth asphyxia. Decisions to withdraw life-prolonging treatment were made by the intensive care team with the consent of the families. Treatment was withdrawn in the operating room where cardiac function was monitored. When cardiorespiratory function ceased, the first patient was observed for three minutes before the organ donation process was initiated. On the advice of the ethics committee the observation period was reduced to 75 seconds with the other two patients. The hearts were then removed and transplanted into other babies. All three recipients survived.

In the UK, the Academy of Medical Royal Colleges' guidance on diagnosis of death (see section 3)¹⁰³ states that the minimum period of observation, before death is declared, should be five minutes following cessation of cardiorespiratory function. (This guidance applies only to those over 3 months of age, however; there are no UK guidelines for diagnosing death in neonates.) In 2009 a team from Papworth Hospital reported that they had recovered cardiac function in a human DCD donor by using extracorporeal perfusion 23 minutes after cardiorespiratory arrest.¹⁰⁴ The paper's authors suggested that this represents a potential source of increased donor supply for heart transplantation.

The fact that an individual is declared dead following cessation of cardio-respiratory function but the heart is subsequently restarted and transplanted into another person is a difficult concept and one that requires careful explanation. Discussing this apparent contradiction, the UK Donation Ethics Committee's consultation report says:

'Some people feel uneasy about restoring cardiac function, given that irreversible cessation of cardiac function is a key component of the diagnosis of death in the donor. In physiological terms, cardiac function cannot be restored within the original biological system (ie the donor) without artificial support. The diagnosis of death applies to that person as a whole, not to their individual organs. There is therefore no ethical inconsistency if the heart is re-started and transplanted to a recipient.'¹⁰⁵

Some intensivists have expressed concerns about this practice however, questioning whether frustration over the falling number of DBD donors has resulted in 'interventions that could jeopardise professional and public confidence in all forms of donation' and arguing that such practices are 'at the very edge of acceptability.'¹⁰⁶

The BMA's Medical Ethics Committee (MEC) considered this issue in October 2010 and concluded that this was an acceptable and important area of research to pursue with a view to informing developments in clinical practice. DCD donors are patients in whom treatment has been withdrawn following a clinical decision that attempts to prolong life are no longer able to achieve any therapeutic goal and are not, therefore, in the patient's best interests. In principle, the MEC considered there was no difference between transplanting hearts from donors whose death had been diagnosed by brain stem tests (DBD donors) and those whose death was diagnosed by cessation of circulatory function (DCD donors). Nevertheless, the BMA believes that the principle of heart donation following circulatory death will need very careful explanation, both to families and, more generally, to the public. A careful explanation of the way in which death is diagnosed will be needed and an explanation that a heart that has stopped beating can be restarted after the person has died and used for transplantation. It might also be helpful to refer to fact that the first heart transplant, under Christian Barnard, was from a DCD donor.

More research is needed before this can be introduced into clinical practice but it represents a possibility of both increasing the number of hearts available for donation and also of facilitating the wishes of more people who wish to be donors, although the numbers are likely to be small for the foreseeable future.

Expanding living donation

As described in section 2, the number of living organ donors has increased dramatically over the last decade and the number of living donors is now higher than the number of deceased donors. The vast majority of living donors donate a kidney (1,020) but in 2010/11, 25 living donors (2.4%) donated part of their liver.¹⁰⁷ It is also possible for living donors to donate lung lobes to those with end-stage lung disease although this is not current UK practice.

With any form of living organ donation the donor undergoes major surgery and is exposed to risk of complications for the benefit of another person. It is now widely accepted that the risk to which kidney donors are exposed is within acceptable levels. With liver and lung donation, however, the risks are significantly higher and this is likely to be a key factor in the low uptake of living donation. Nevertheless, NICE has reviewed the evidence of living liver¹⁰⁸ and lung¹⁰⁹ donation and has concluded, in both cases, that the evidence on efficacy and the safety profile 'appears adequate to support the use of this procedure' for suitable recipients. Whilst there may be scope for more living liver and lung donations, because of the level of risk associated with donation this is not an ideal solution to the organ shortage problem. For some people awaiting a transplant, however, who have a friend or relative willing to donate, this may be an option. As with all living donation, those individuals considering living liver or lung donation need to be aware of the risks and complications and must be acting voluntarily and free from pressure. All cases of living donation need to be approved, in advance, by the Human Tissue Authority following review by an independent assessor.

Although already established, there is also considerable scope to extend living kidney donation through expansion of the National Living Donor Kidney Sharing Schemes. This includes paired/pooled donation, non-directed altruistic donation and altruistic donor chains. Altruistic donor chains are where a non-directed altruistic donor opts to donate into the paired/pooled scheme instead of directly into the national donor pool. The kidney is then matched with someone in the paired/pooled scheme and the donor registered with that recipient then donates to another recipient and so on.

Many people are not aware that they could donate a kidney to a stranger and so more work raising awareness about this option could help to extend the scheme. A YouGov survey in November 2011 found that 32% of people surveyed did not know that it was possible to donate a kidney altruistically to a stranger but that 8% would consider it.¹¹⁰ Clearly not all of these would go on to donate but even a small number could have a significant impact. The BMA supports moves to raise awareness about altruistic non-directed donation but recognises that care is needed to ensure that individuals do not feel pressured to donate.

Use of 'higher risk' donor organs

No transplant is without risk but there are a number of factors that affect the level of this risk.¹¹¹ These include factors that might affect the graft function, such as the age of the donor, cause of death, type of donor (DCD or DBD), body mass index and length of stay in ICU prior to donation. There are also some factors that increase the risk of a transmissible disease being passed on to the recipient such as previous use of intravenous drugs, high risk sexual behaviour or previous history of malignancy. These risks can be reduced by limiting the criteria for donor acceptance (by age, body mass index, existing medical conditions etc) but every restriction applied reduces the number of organs available for transplantation. Conversely extending the acceptance criteria (by allowing older donors or those with existing malignancy for example) would increase the pool of potential donors but also increase the level of risk to which some recipients would be exposed. Introducing wider acceptance criteria would also increase the likelihood of donors going through the donation

procedure and none of the organs being suitable for transplantation. An appropriate balance therefore needs to be reached between risks and benefits when setting exclusion criteria for donation. NHS Blood and Transplant has developed a list of absolute contraindications for donation and has advised that all potential donors who have none of these contra-indications should be referred even if the likelihood of any organs being accepted appears low.¹¹² The BMA supports this approach but believes that where there is a reasonable possibility that none of the organs will be suitable for transplantation, this should be discussed in advance with the donor family.

NHS BT has also, jointly with the British Transplantation Society, provided guidance on the information that should be provided to those who need a transplant both before they go on the waiting list and once an organ is offered. It makes clear, in relation to the offer of an organ, that 'where the risks exceed those that are accepted within current guidelines (for example where the donor has a primary intra-cranial cancer or a recent history of malignancy such that there is a possibility of tumour transmission), this should be discussed with the potential recipient when the organ is offered.'¹¹³

Elective ventilation

Once a patient has been diagnosed as dead using brain stem tests, artificial ventilation is usually continued for a period of time to allow the family time to say goodbye or, if organ donation has been authorised, for arrangements to be made for the organs to be retrieved. Elective ventilation is different in that it involves *starting* ventilation, once it is recognised that the patient is close to death, with the specific intention of facilitating organ donation. This system was introduced, with strict controls, in Exeter in 1988 and led to a 50% increase in the number of organs suitable for transplantation. It was stopped abruptly in 1994, however, when the Department of Health advised that the practice was unlawful.¹¹⁴

The law requires that, when patients lack the capacity to consent, procedures or interventions must be in their best interests. The use of elective ventilation is not intended to be for the clinical benefit of the individual but to facilitate donation. The Mental Capacity Act 2005, however, takes a broad approach to 'best interests' (and a similar broad approach to 'benefit' is likely under the Adults with Incapacity (Scotland) Act 2000) and there has recently been a formal recognition that taking some steps before death to facilitate donation could be in an individual's best interests (see section 4). The BMA has long argued that where an individual had expressed a wish to donate organs after death, some steps to facilitate that wish may be seen as in that person's best interests or benefit (or at least not contrary to his or her interests). Individuals who are sufficiently informed may also wish to give specific, advance consent, to permit elective ventilation to take place. The UK Donation Ethics Committee has called for further debate on this issue, to more clearly define the appropriate balance between benefits and harms and the type of interventions that could reasonably be undertaken.¹¹⁵ The BMA would also welcome further clarification on this issue. From an ethical perspective one of the major concerns with elective ventilation is the level of the risk to which the incapacitated adult may be exposed. Fears have been expressed that, in theory at least, elective ventilation could induce a persistent vegetative state (pvs). Although the chance of harm occurring is considered to be very low, inducing pvs would be a very significant harm and,

if elective ventilation were to be permitted, very careful safeguards would be needed to minimise this risk. This might include, for example, restricting elective ventilation to those patients dying of spontaneous intracranial haemorrhage (since these patients rarely, if ever, develop pvs)¹¹⁶ and stating that artificial ventilation must not be started until natural respiratory arrest has occurred.¹¹⁷ There are also practical difficulties associated with the lack of ICU beds and competing demands for limited resources. In the BMA's view, priority would always need to be given to the use of intensive care facilities for those who have a chance of recovery rather than for those who are being ventilated to facilitate donation.

Elective ventilation is not an easy option but it has been shown to increase donation rates, and to facilitate the wishes of a group of patients who want to donate and would otherwise be unable to do so. The BMA is not calling for the law to be changed to permit elective ventilation but believes this may be an issue that would benefit from debate both to assess the clinical, legal and ethical issues raised and to assess public opinion about its use.

Ensuring individuals' wishes are known

The potential donor audit (see section 4) demonstrates that where an individual's wishes are known the relatives, under the current opt-in system, are less likely to refuse consent to donation. With DBD donors in 2010/11, the overall refusal rate was 35% but this dropped to 6% where the individual's wishes were known (where the individual's views were not known the refusal rate was 50%). With donors following circulatory death, the overall relative refusal rate was 49% but this dropped to 20% where it was known that the individual wanted to donate (the refusal rate was 61% when the individual's views were not known).¹¹⁸ While there are still cases where the individual's known wishes are overridden by relatives, the knowledge that relatives are less likely to refuse in these circumstances provides impetus to find ways of encouraging people to think about donation and make their views known.

More publicity about the NHS Organ Donor Register

The clearest way to record a wish to donate is to sign up to the NHS Organ Donor Register (ODR). The register is available to authorised individuals 24 hours a day, 365 days a year which means that when the family are approached they can be informed that their relative wanted to donate organs after death. Over the years a lot of effort has gone into promoting the ODR with high profile campaigns involving celebrities and emphasising the real difference transplants make to people's lives. There are currently 18.4 million people registered, representing 29% of the UK population. Whilst this is an impressive number, it does not compare with the 70-90% who say they support donation.

NHS BT has undertaken a number of campaigns, including in 2009 one aimed specifically at the group of people who would be willing to receive an organ if they needed one, but have not thought about signing up to the register – 'if you believe in organ donation, prove it'. Although such campaigns are principally aimed at encouraging people to sign up to the register, another benefit is encouraging people to think, and talk about, their wishes regarding organ donation. Such promotional campaigns have, however, been significantly restricted in England over recent

years whereas in Scotland, the Government has continued to fund high-impact national advertising and publicity campaigns. Indeed there is a statutory duty on Scottish Ministers, under the 2006 Act, to promote information and awareness about organ donation. Scotland currently has the highest consent rate in the UK at 86%.¹¹⁹

A number of campaigns have been targeted at black and ethnic minorities where the shortage of donors is particularly acute. Around 16% of people on the waiting list for a donor organ are from Asian communities but these communities make up only 1.4% of people on the Organ Donor Register.¹²⁰ Similarly, 8% of people on the waiting list are from black communities, but these make up only 0.4% of those on the Register.¹²¹ Research has found high levels of support for organ donation amongst African-Caribbeans and South Asians but a lack of awareness of the specific need for organs within their community.¹²² NHS BT has tried to address this problem by emphasising the way in which people within their own community are suffering because of a lack of suitably matched donors. It also provides a series of leaflets on different faiths' perspectives on organ donation to correct some of the myths and misunderstandings about religious perspectives on donation.¹²³ These targeted campaigns appear to be working¹²⁴ but more work is required to determine how to produce and disseminate this information to maximum effect and also to identify barriers that are 'cultural' rather than 'religious'.

The BMA has, for many years, supported an opt-out system with safeguards for organ donation and is best known for its work in this area. It has also undertaken, or supported, many campaigns aimed at raising awareness of organ donation generally and encouraging people to sign up to the Organ Donor Register. It ran campaigns encouraging people to 'have a heart on Valentine's Day' and to 'sign one more card this Christmas' as well as using various mechanisms to encourage its own members to lead by example and make sure their own wishes about donation were known.

Encouraging people to sign up to the ODR is an important component of a broader strategy to improve donation rates but is not *the* answer to the organ shortage. There is not a direct link between the number of people on the ODR and the number of donors. One reason for this is that the people who register are not wholly representative of the people who die and go on to donate. It will never be possible to get everyone who is willing to donate organs to sign up to the ODR but encouraging as many people as possible to do so is important. It needs to be acknowledged, however, that as publicity for, and awareness of, the register increases – and with no formal mechanism to record an objection to donation – there is a possibility that the relatives of those who have not signed up might interpret that fact as a sign that the individual did not wish to donate. This could have a negative impact on attempts to reduce the relative refusal rate.

'Prompted choice'

In December 2010 the Cabinet Office published a paper, *Applying behavioural insight to health*, identifying areas where what has been termed 'prompted choice' or 'nudge theory' could help to address significant health issues within the population. The idea is to understand people's behaviour and develop ways to 'prompt people to make choices that are in line with their underlying motivations'.¹²⁵ One of the examples used in the document was organ donation.

From 1 August 2011 people who wish to apply for a new, or renewed, driving licence online have been required to answer a question about organ donation.¹²⁶ Under the previous scheme, through which more than 8.5 million people signed up, a question about signing up to the ODR was included but it was possible to skip over it. Under the new scheme, the question must be answered before the applicant can move on. The options given are:

- Yes, I would like to register
- I do not wish to answer this question now
- I am already registered on the NHS Organ Donor Register.

The Nuffield Council on Bioethics, whilst supporting the use of such a pilot scheme to assess the effectiveness of prompted choice, was concerned that applicants were given no opportunity to object to donation. Its report argued that failure to give the option of expressing objection 'significantly undermines commitment to following the wishes of the deceased and even, arguably, fails to comply with the spirit of current legislation with its central focus on consent'.¹²⁷ Clearly, if the option to say 'no' is to be included, there must be a clear and robust mechanism in place for those objections to be registered and acted upon. This would involve either modification of the ODR to include the option to opt out of donation or a new organ donor register designed specifically to allow people to either opt into or out of donation.

The use of driving licence applications as a form of prompted choice is not new. In the late 1990s, for example, licensed drivers in Texas and Virginia were required to state their views about donation before obtaining a licence. In Texas, where the choice was between donation or non-donation, the system was abandoned after 80% registered as non-donors leading to an overall reduction in the number of donors.¹²⁸ In Virginia, the options were donor, non-donor or undecided. In the first six months of the programme, approximately one million Virginia drivers were asked to declare a preference. Of these, 31% registered as donors, 45% as non-donors and 24% were undecided.¹²⁹

In spite of the negative response to its first attempt, Texas introduced a new law in January 2010 requiring clerks in the Department of Public Safety to ask all driver's licence and ID card applicants whether they would like to register as organ donors. After six months it was reported that nearly 70,000 donors a month had joined the register.¹³⁰ There have been similar news reports of a positive effect from a similar initiative in Illinois.¹³¹ In addition, the New Jersey Hero Act 2008 states that, from 2013, individuals who apply for, or renew, their driving licence or ID card will be required to consider whether they wish to become a donor. Two options are offered: to sign up as an organ donor or to 'review information about the life-saving potential of organ and tissue donation, and the consequences when an individual does not make a decision to become an organ donor and does not register or otherwise record a designated decision-maker.'¹³²

We await with interest the outcome of the UK experience of this form of prompted choice. If successful, this model could be repeated with other official documents such as applying for a passport, completing tax returns, registering with a GP or, subject to legal reform, electoral registration.

Mandated choice

Mandated choice is a system whereby all adults are required, by law, to decide in advance whether they wish to donate their organs for transplantation after death, with penalties imposed on those who refuse to state a view. Prompted choice (see above) is a modification of mandated choice and the boundaries between the two can sometimes be blurred. Mandated choice and a soft opt-out system with safeguards are the two alternatives to the status quo that are most frequently discussed and supported. There are a number of variations on the theme. Traditionally, it was suggested that everyone would be asked about donation and must decide 'yes' or 'no' or face some penalty (whether a fine, inability to obtain a driving licence, rejection of tax returns or ineligibility for inclusion on the electoral register and therefore ineligibility to vote). A more recent proposal is that individuals should be given the choice of three options – 'yes', 'no' or 'I want my family to decide'.¹³³

The principle behind mandated choice is to increase donation rates whilst enhancing individual autonomy by allowing individuals themselves to make the decision and ensuring that all individuals' wishes are known and respected. It aims to overcome the problem of apathy whereby a large majority of individuals express willingness to donate when asked, but do not make their wishes known by signing up to the Organ Donor Register or informing their relatives. Making it compulsory for individuals to decide and record their wishes also gets over the problem of people not wishing to think about their own mortality.

A further aim of mandated choice is to transfer control from the family to the individual.¹³⁴ Under this system, the views of the individual are usually binding and so the relatives would have no right of veto¹³⁵ (unless the individual specifically asked them to choose), thus also overcoming the high relative refusal rate, which currently stands at 35% (and 50% for those whose views are not known). The intention of most advocates is that this would apply in practice, as well as in law, as opposed to the current system whereby the relatives have no legal right of veto but, in practice, organs are not removed against the strong and sustained wishes of the family (although some have suggested that the discretion for allowing family refusals in some cases should remain¹³⁶). Although the binding nature of the individual's stated wish to donate is usually a key strand of mandated choice, it is difficult to see how this would work in practice, since it is highly unlikely that most surgeons would be willing to remove organs in the face of strong family objections. The BMA believes that while attempts should be made to persuade the family to follow the individual's previous wishes, the retrieval team should have the discretion not to retrieve organs in this situation (see section 3). When assessing mandated choice, therefore, it must be recognised that this part of the system may be difficult to uphold in practice.

Evidence of effectiveness

There is very limited evidence available to assess the effectiveness of mandated choice in increasing donation rates since no country has adopted this model. 'Prompted choice' can be seen as a form of mandated choice, although applied to only small sections of the population and without penalties. The first attempt at prompted choice in Texas (see above) could indicate that when people are forced to make a decision – 'yes' or 'no', they are more likely to take a negative

approach. It is unclear, however, whether the same model was used in the later, more successful, attempt and so it is difficult to draw any firm conclusions from this. More evidence may become available when data from the UK's DVLA system are published.

By including an option not to decide, or to leave the decision to the family, as has been suggested, there is less risk that people who are unhappy about being forced to choose will say 'no', but if large numbers take this option, the situation may be no better than currently. There is even a chance that the refusal rate could increase if families infer from their relatives' decision not to sign up to the register, when given the option, that they were not committed to donation.

Ethical considerations

There are clear benefits of knowing every individual's wish about organ donation rather than seeking views from relatives, at a time of great distress and anxiety, or making assumptions about what a person is likely to have wanted. In order to achieve this situation, however, an element of coercion is required and compelling people to make choices can be seen to undermine, rather than enhance, their autonomy. There are precedents for requiring people to make a choice, where it is felt there is a responsibility to do so, such as mandatory voting in Australia. In the same way, Chouhan and Draper argue 'it may be seriously irresponsible of people not to decide about organ donation when the lives, and quality of life, of so many people depend upon this decision.'¹³⁷ Furthermore, they argue, interfering with individual liberty, by mandating choice, can be justified by the benefit that is likely to accrue from increasing the number of donors available and thus the number of transplants that can be undertaken. There is very little effort, harm or inconvenience to the individual, they argue, but considerable potential benefit to others.

The Organ Donation Taskforce expressed some support for mandated choice but raised concerns about some of the practical difficulties and the costs which it considered would be higher than implementing and maintaining an opt-out system (see below).¹³⁸ It also expressed concerns that the imposition of a penalty on those who did not comply risked losing public goodwill and challenged the concept of donation based on a 'gift relationship'.¹³⁹

Practical considerations

A number of practical issues would need to be addressed such as when individuals would be contacted, who would contact them, how people would express a view and what the punishment should be for failing to respond, as well as how they can change their mind once their view is registered. It would not be possible just to add the names of those who say 'yes' to the existing Organ Donor Register, since there would be no way to differentiate between those who said 'no' and those who asked for the decision to be left to family members. This could lead to families being unwilling to consent to donation, in case their relative had chosen the 'no' option, and a subsequent increase in the relative refusal rate. A specific database would, therefore need to be developed, containing the views of every adult within the UK; this is a major and costly task.

Public opinion

Mandated choice received considerable public support in the deliberative events organised by the Organ Donation Taskforce. Of eight options discussed, it was ranked fourth overall but was put in the top three options by 44% of participants and was ranked first by 22%.¹⁴⁰

BMA view

The BMA accepts that the principle behind mandated choice, that everyone's views should be known and acted upon, is a good one. It does not, however, have confidence that the system would work in practice, and has some concerns about the level of coercion that would be required. If individuals are to be 'mandated' to make a choice, there must be some punishment for those that do not do so. Giving people the option not to make a choice, whilst superficially reassuring, is unlikely to lead to any improvements over the status quo. In particular, the BMA has concerns about:

- the coercive nature of forcing people to make a decision at a particular time
- the risk that if people are required to make a choice when they do not want to, they may be more likely to say 'no'
- the situation being no different than the status quo if people are given the option of not deciding
- the type of 'punishment' that might be appropriate or reasonable if individuals refuse to choose
- the lack of any evidence showing a positive association between mandated choice and donation rates.

Opt-out with safeguards

The BMA has long advocated an opt-out system with safeguards and continues to believe that this is the best option for the UK. Under an opt-out system everyone would be assumed to want to donate organs after their death unless, having received information about the system, they had chosen to opt out of donation during their lifetime. Most supporters of this type of system, including the BMA, support what is often called a 'soft' system of opt-out. This system has built-in safeguards, so that the family is always consulted and asked about any unregistered objection and there is scope not to proceed with donation if this would cause severe distress to the family. (In practice the family needs to be involved in order to provide information about medical history etc and donation is highly unlikely to proceed if the family is not available.) A few countries, such as Austria, operate a 'hard' opt-out system whereby unless an individual has opted out of donation during his or her lifetime organs can be used for donation after death, with no role for the family. This system has not been proposed for the UK.

The principle behind an opt-out system is that the default position should be to save lives and that, unless an individual objects to donation their organs should be used after death to benefit others. Under such a system individuals have exactly the same choice as under an opt-in system – to donate or not to donate – but the way that choice is registered differs, to give priority to donation in the absence of objection. The system would work as follows.

- Before the new system is introduced there would be extensive and high profile publicity to ensure all members of society were aware of the forthcoming change and to encourage them to consider their own wishes about donation after their death.
- A database would be established with mechanisms for people to easily and quickly opt out if that is their wish.
- Once implemented, when someone over the age of 16 dies and donation is a possibility, the opt-out register must, by law, be checked and if the individual had opted out, donation could not proceed.
- As an extra safeguard, if the individual had not opted out, family members would be asked if they were aware of any unregistered objection.
- If the relatives were not aware of any objection, they would be informed that donation would proceed. There would, however, be scope not to proceed if it became evident that to do so would cause severe distress to the relatives.

Those under the age of 16 and those who have not had capacity since the system was introduced, and therefore would not have had the opportunity to opt out, would be excluded from the system and specific consent from a qualifying relative would continue to be required.

The main practical change would be in the approach to relatives. Rather than asking them to make the decision (as currently happens when the individual's views are not known), relatives would simply be asked if they were aware of any unregistered objection. The broader change would be to the philosophy around donation, making donation the usual and expected thing to happen when someone dies. This is an outcome that has been widely championed including by the Organ Donation Taskforce (making donation a usual not an unusual practice) and NHS BT (to promote organ donation as 'expected behaviour' amongst UK citizens)¹⁴¹ although different strategies have been recommended to achieve that outcome.

Terminology

This system is often referred to as 'presumed consent' and this is the term the BMA has traditionally used. This term is, however, controversial with people arguing that 'presumed consent' is not 'consent' at all but something rather different. The BMA has found that this has resulted in debate focusing on the terminology and thus detracting from the important debate about the merits, or otherwise, of the system itself. Another term that is frequently used, and which is a simple description of the system is 'opt-out' – individuals who do not wish to donate need to opt out. In order to differentiate between those versions of opt-out that involve the family and those that do not, the former is referred to as either 'soft opt-out' or 'opt-out with safeguards'. In France the term 'presumed solidarity' has been used. The BMA's preferred terminology is 'opt-out with safeguards'.

Evidence of effectiveness

It is notoriously difficult to assess the impact of opt-out legislation on donation rates, because of the problem of separating out the effect of opt-out from other factors that are known to affect donation rates. When analysing the data to assess the impact of opt-out legislation, there are two main types of research that can be undertaken, comparisons between countries with an opt-out

system and those without, and comparing donation rates within countries before the introduction of an opt-out system and afterwards. It is not possible to do an experimental study or controlled trial, where other factors – such as the number of deaths from road traffic accidents – are manipulated or controlled, so it will never be possible to obtain a result showing a clear cause and effect. The best result that can be obtained from this type of research is a positive association or correlation between an opt-out system and donation rates.

With support for an opt-out system being expressed by England's Chief Medical Officer¹⁴² and the then Prime Minister, Gordon Brown,¹⁴³ the Government in 2007 asked the Organ Donation Taskforce to undertake a review of opt-out and consider the potential impact of introducing such a system in the UK. As part of this review the Taskforce commissioned the University of York to undertake an independent systematic review of all published studies. The review identified:

- eight studies comparing countries with an opt-out system and those without, four of which were 'of sufficient methodological quality to provide reliable results.'¹⁴⁴ All four of those studies found that opt-out law or practice was associated with increased rates of donation and, in all except one of these, the results were statistically significant.
- five studies of countries before and after the introduction of opt-out legislation which were methodologically sound. All of these studies reported an increase in donation rates following the introduction of an opt-out system.

The authors of the review concluded that:

'The available evidence suggests that presumed consent legislation is associated with an increase in organ donation rates, though the size of the association varied between studies. A number of other factors also appear to be associated with organ donation rates, such as transplant capacity, GDP and health expenditure per capita.'¹⁴⁵

This confirms the findings of studies conducted previously,¹⁴⁶ and since the Taskforce's report was published,¹⁴⁷ that having an opt-out system is one of a number of factors that are associated with higher donation rates. The presence of that positive association in all the studies which met the criteria for the systematic review is, in the BMA's view, the most convincing evidence that could be obtained from such a literature review, because these studies could not control for possible confounding factors.

The Taskforce interpreted the York findings rather differently however, concluding that 'we found no convincing evidence that it would deliver significant increases in the number of donated organs' and the report concluded that an opt-out system could 'negatively impact on organ donation numbers'.¹⁴⁸ This interpretation of the data was not universally shared.¹⁴⁹

The BMA accepts that it is not easy to demonstrate a direct causal link between opt-out and donation rates, because with observational studies it is difficult to exclude other factors that might have had an impact. Nevertheless, after reviewing the evidence available the BMA concludes that

there is a positive association between the two – that is to say that those countries that have an opt-out system tend to have higher donation rates although it cannot be said for certain what causes them.

A study which did not meet the criteria of the York review looked at the differential rates of organ donation between hospitals in Belgium which adopted the opt-out system and those which in the short-term did not. This was thus a ‘before and after’ study which did control for factors such as increased publicity surrounding the law change. It showed no increase where the system was not changed and a significant increase where it was changed.¹⁵⁰

Ethical considerations

Any system that has the potential to increase the number of organs available for donation, and therefore the number of lives that can be saved, has strong moral arguments to support it but there are other factors that need to be taken into account.

As mentioned above, the central principle behind opt-out is that the default position should be to save lives. If people do not object, it is right that their organs should be used for the benefit of others. That is not to say that we have a moral obligation to donate, or that we have no interest or rights in relation to what happens to our bodies. Rather, if individuals have not indicated any objection to donation, it is appropriate to assume they would want to act in an altruistic manner and help others.

The organ donation system in the UK is based on altruism and the notion of a gift relationship. The ‘gift’ element of donation can be important to those families who consent to donation, and to those who receive organs. It has been suggested that if the individual does not personally, or via his or her family, pro-actively ‘volunteer’ the organ, it is no longer a gift. Under an opt-out system, however, individuals go through exactly the same thought process to decide not to opt out as they do in deciding to opt in. Given the option to donate or not, a decision is made to act to help others, by not opting out of donation; this is no less of a gift than an organ donated under an opt-in system. Undoubtedly some will think more about this than others and some people will choose not to think about it at all. Under an opt-out system, there is no way of knowing which of those who have not opted out would have taken positive steps to donate under an opt-in system. Some people will see the loss of this positive action to donate as a cause for concern. Whilst it may be seen as preferable for individuals – or their families – to take active steps to give organs, we need to acknowledge that under the current system, organs are being lost that could have saved lives when that would not have been the wish of potential donors. In the BMA’s view families should be encouraged to see the whole process of organ donation as a ‘gift’ which has the potential for very significant benefit to another person.

A central question around opt-out systems for organ donation is whether they enhance or reduce autonomy. Those who oppose such schemes suggest that the decision is being taken out of the hands of individuals and the government is taking and using organs without consent. Individuals, and their families, are thus denied the right to make a personal decision and so their autonomy is undermined. It is important to recognise, however, that under an opt-out system individuals have

exactly the same decision to make – to donate or not to donate – and so the decision clearly still rests with the individual.

In practice, although the current system is referred to as an opt-in system, the majority of people who donate organs have not given consent. In 2010/11, 33% of donors had signed up to the ODR; in the remaining cases consent (authorisation in Scotland) was given by family members. Some family members will have known what their relative wanted from previous discussions, but the majority of decisions will have been based on their 'best guess' of the views of the deceased. This makes the process particularly difficult for families who may struggle to make the 'right' decision at a time of immense pressure and distress. It is possible that in some of those cases where the families gave consent, the individual – had he or she expressed a view – might have objected to donation, and vice versa. Under an opt-out system this is less likely to happen because there is a formal mechanism for those who oppose donation to record their wishes and for ensuring that those wishes are respected. The publicity that will precede the change is also very likely to increase discussions within families about donation. Where the individual's views are known the situation is less difficult for the family. Furthermore Michielsen, who operates within an opt-out system in Belgium, observes that '[f]rom the emotional point of view, there is a fundamental difference between having to take the responsibility for permitting organ removal and not making use of the right to oppose removal.'¹⁵¹ In addition, given that 70 to 90% of individuals who take part in surveys say they support donation, statistically it is more likely that someone who dies will be in the majority who wish to donate than in the minority who do not.

Practical considerations

One of the major concerns about introducing an opt-out system is the risk of a backlash; the fear that people will object to the new system and opt out of donation as a means of protest. There is a precedent for this. Brazil introduced an opt-out system in 1998 without public support and against a background of public mistrust in the government. The system had to be abandoned after large numbers of people opted out.¹⁵² The BMA has always argued that an opt-out system must have public support before it is introduced (see below). If there is widespread support for the system, the chance of people opting out in protest is significantly reduced; other countries that have introduced such systems have not experienced this problem.

The success of an opt-out system depends to a very large extent on the way in which it is implemented. It is essential that there is widespread, high-profile publicity, well in advance of the new system coming into effect. Particular efforts must be made to contact hard-to-reach groups and the publicity will need to be repeated at regular intervals. There must be quick, simple and convenient ways for people to opt out, if that is their wish, and a robust and accurate database must be maintained. The database would need to give people the option of opting out of donating different types of organs, such as heart or corneas, or the option to opt out completely. This could be based on the current opt-in register which is already established and tested, with the names of those who wish to opt in replaced by those who wish to opt out. Because it is so important to the success of the venture that this work is undertaken properly, sufficient time – perhaps as much as two to three years – would need to be built into the proposals for this preparatory work.

During the Taskforce review of opt-out, some intensivists raised concerns that patients might be afraid that efforts would not be made to save their own lives if they were considered to be potential organ donors. This is a concern that we know is already held by some people under the current system,¹⁵³ and so it is not exclusive to opt-out. It could equally be argued that if people are on the Organ Donor Register – and thus indicate a willingness to donate – they might be seen as potential donors rather than as patients. The important point – irrespective of the consent system in place – is to ensure that patients and the public are aware of the clear separation between the treating team and the transplant team and that patients and relatives are given sufficient information about what is happening and why, to reassure them that all treatment decisions are made in patients’ best interests.

Public opinion

Public support is crucial for an opt-out system to work. In 1999 the Department of Health commissioned a survey of public opinion in which 28% supported a shift to an opt-out system with 50% opposed and 22% undecided.¹⁵⁴ Since then, however, a number of surveys have shown increasing support for such a shift. In October 2007 a YouGov survey commissioned by the BMA showed that 64% of respondents would support an opt-out system with safeguards.¹⁵⁵

The most recent and most comprehensive survey of public opinion was undertaken in 2008 by the Organ Donation Taskforce which organised seven one-day workshops around the UK each with about 50 participants.¹⁵⁶ Participants were polled at the beginning of the event and again after receiving information, watching video clips presenting arguments for and against opt-out and having the opportunity to ask questions and discuss the issue with a panel of experts. Before the event 65% supported a change in legislation to opt-out. After receiving information and having the chance to consider the issue carefully, this increased to 72% in favour of this change. The number who expressed ‘strong support’ for such a change nearly doubled after the event from 25% to 43%.¹⁵⁷

The Organ Donation Taskforce Report

The Organ Donation Taskforce, which reported in 2008, did not recommend a shift to an opt-out system at that time.¹⁵⁸ One of its concerns was the cost of implementing the new system. It estimated set-up costs for the database of at least £10 million and £2 million per annum running costs. The Taskforce also estimated that publicity around the new system would cost a further £25 million for a sustained three-year campaign. (This compares with £12.1million spent in the financial year 2007/08 in connection with the ban on smoking in public places.¹⁵⁹)

The Taskforce concluded that the changes to the infrastructure it had recommended in its first report (see section 4) should be tried first and might make opt-out unnecessary. It therefore adopted a ‘wait and see’ strategy. The expert working groups established by the Organ Donation Taskforce to consider the legal and ethical implications of changing to a system of presumed consent advised, however, that there were ‘no fundamental legal or ethical barriers to introducing a ‘soft’ opt out system, in which, as a safeguard, family members would be consulted about donation.’¹⁶⁰

In spite of the report's conclusion the Welsh Assembly Government has pledged to introduce an opt-out system with safeguards in Wales and a White Paper was published in November 2011.¹⁶¹

BMA view

The BMA has supported a change in legislation to opt-out with safeguards since 1999. This policy has been reaffirmed on many occasions since. The main reasons for the BMA's support can be summarised as follows.

- We believe that, as one part of a broader strategy, a shift to an opt-out system will have a positive effect on donation rates.
- Studies show that a large majority of people would be willing to donate but only 29% of the population are on the NHS Organ Donor Register or carry a donor card. While this level of apathy exists despite people's good intentions, people will continue to die while waiting for donor organs.
- The BMA supports the principle behind an opt-out system – that if people do not object to their organs being used after death, they should be used to save lives.
- Under an opt-out system individuals have exactly the same choice as in an opt-in system – to donate or not to donate.
- The decision not to opt out of donation is as much of a gift as a decision to opt in.
- An opt-out system gives added protection to those who do not wish to donate and makes it more likely that those who are willing to donate will be able to do so.
- Organ donation becomes the default position which, with public support, changes cultural expectations in society. This represents a more positive view of organ donation which is to be encouraged.
- Overall an opt-out system is better for recipients (because more organs will be available) better for donors (because it is more likely their wishes will be respected) and better for relatives (because it is more likely that the individual's own wishes will be known).

Reciprocity

Under a system of reciprocity, those who donate organs, or sign up to donate after their death, receive priority should they themselves require a transplant. One of the aims of this system is to overcome the problem of so-called 'free-riders' – those who would be willing to accept an organ, should they need one, but are not willing themselves to donate (although, in practice, most people have simply not made a decision rather than actually being 'unwilling' to donate). NHS Blood and Transplant highlighted this in its advertising campaign launched in 2009 following surveys that showed that while 96% would accept an organ if they needed one, only 27% had signed up to the Organ Donor Register.¹⁶² This lack of reciprocity is not just an issue with organ donation; NHS BT's surveys also found that 55% of those questioned would accept a lift without offering one in return and half would borrow books but haven't lent their own.

In 2008 Israel became the first country to pass legislation incorporating a system of reciprocity into its organ donation system.¹⁶³ Under the new system, which came into effect in January 2010, priority is still given to those in urgent medical need of a heart, lung or liver. Where two candidates have equal clinical need, however, priority will be given to:

- individuals who consent during their life to donate organs following death and their first degree relatives
- first degree relatives of people who donated organs following their death
- individuals who become non-directed living donors (ie to strangers) and their first degree relatives.

Within these categories a weighting system is applied such that first degree relatives of those who have signed a donor card have half the priority given to those who have signed a donor card themselves. Those who have a first degree relative who donated after death and those who were non-directed living organ donors have one and a half times the priority of those who have signed a donor card.

The introduction of the new system was preceded by a 'massive, multilingual, multimedia educational campaign designed and aimed at all levels of education in the public'¹⁶⁴ with the aim of encouraging people to sign an organ donor card. The new policy applies to everyone, including those who have religious objections to donation (on the basis that if they oppose donation they should neither give nor receive organs). The policy is due to be reviewed after two years.

A system of reciprocity also operates under United Network for Organ Sharing (UNOS) guidelines in the United States, whereby any living donor is given priority for organs from deceased donors should they need them at any stage in the future. This could be seen as acting as an incentive to people to donate or it could be seen as removing a counter-incentive. If fear of failure of the remaining kidney deters people from acting as living donors, then assuring them that they would be given priority for an organ, should they need one in future, might increase the number of donors and therefore the number of lives saved and transformed by a transplant.

Evidence of effectiveness

As mentioned above, it is very difficult to obtain data showing the impact of any individual factor or initiative on organ donation rates. A news article in the *BMJ* in 2011, for example, reported that the number of transplants fell by 20% in Israel in the previous year and that the number of people dying while waiting for an organ increased.¹⁶⁵ The reason given for this fall, however, was the legal changes to the definition of death in 2008. No mention was made of the number of living donations or donor registrations as an indicator for how well the 'reciprocity provisions' in the Act have been received.

In addition, part of the measure of the success of this scheme is the number of people carrying donor cards and it is likely to take some time before any increase in people signing up for donation is reflected in increased donation rates. The publicity surrounding the introduction of the scheme, however, could reasonably be expected to have itself had a positive impact on donation rates. It is therefore difficult to judge how much any improvements have been offset by the reduction in donors resulting from changes to the definition of death.

Ethical considerations

The notion of rewarding those who contribute to the public good has many attractions, not least because its focus is not simply on increasing donation rates but also on making the system fairer. Nevertheless, the offer of an incentive for donation is seen by some as undermining the 'gift relationship' whereby an individual, as an act of solidarity, donates an organ to another person for no personal gain. With systems of reciprocity, donors are encouraged to give in order to receive some (actual or potential) benefit, therefore emphasising self-interest over pure altruism. A significant, but perhaps not the only, reason for donating is to gain some personal advantage – in terms of priority for an organ in the future should one be needed. The difference between these schemes and payment per se, however, is that the reward is not immediate and the individual may never need an organ and so never gain any benefit.

Offering incentives is frequently considered to be coercive but it has been argued that any coercion in a reciprocity scheme for organ donation must be minimal given that 'all the benefits accrue to the individual while s/he is alive while the costs are exacted exclusively after his/her death'.¹⁶⁶ This, of course, only applies to systems that relate solely to deceased donation. Even where the scheme includes living donation, however, there is no guarantee of benefit since the donor may never be in the position of needing an organ so the lack of any immediate benefit would appear to reduce, if not eradicate, concerns about coercion.

Such schemes also introduce allocation based partly on social, rather than solely clinical, factors. Those who act in a way we consider to be in the public good – by agreeing to donate – get the possibility of some future benefit, whereas those who do not, risk being penalised by having a lower priority in the event of needing an organ. Although in practice clinical need would continue to be the principal factor in allocating organs, and donation status would only be considered where two individuals have the same clinical need, introducing any moral element to these judgements by considering donor status could be seen as a step towards allocation based on social worth or just deserts. Gillon warns that '[i]f past or present fault [thus] became an accepted criterion for distributive justice for scarce medical resources, a very steep 'logical slippery slope' would have been created.'¹⁷⁷

Practical considerations

In establishing a system of reciprocity, there would need to be some time-limits on registration to gain entitlements. If not there would be nothing to prevent those who are told they need an organ transplant from signing up to the register in order to gain immediate priority access to organs. If this were possible, the incentive for those not requiring a transplant to sign up would be removed – they could simply wait and see if they need an organ. In development of the Israeli law it was agreed that people should be registered for three years prior to their need for a transplant being identified in order to receive the benefit. As a transitional arrangement for the first year, anyone on the register would be given priority over those not on the register.

Thought would need to be given to how children and adults lacking capacity would fare within such a system. The most logical option would be to exclude them from the scheme and to reach

a fair position about how their priority would be determined relative to those within the scheme. Alternatively, proxy advance decisions could be made by parents on behalf of children too young to make a personal choice. Similarly carers could make proxy decisions on behalf of adults lacking capacity on the basis that it is clearly in their best interests to receive priority access to organs, should they need it, without causing them any significant harm.¹⁶⁸

One of the practical difficulties of the scheme relates to the relative weight given to registration on the Organ Donor Register and clinical needs. If greater weight is given to signing up to the Organ Donor Register, the incentive for people to sign up is large and the increase in donors is likely to be significant. This means, however, that those who do not sign up are unlikely to receive organs despite having far greater clinical need than other people who have volunteered to be donors after their death. This is a very harsh punishment for people who may have failed to sign up because of apathy, because they are disorganised or because they do not want to confront their own mortality for example. This appears to contravene a central principle in medical ethics that medical care should be provided, and scarce resources allocated, on the basis of clinical need and not on the actual or perceived blameworthiness of the patient.¹⁶⁹ If priority is given to clinical need, however, as in Israel, and it is only when two people have exactly the same clinical need that their donor status becomes relevant, there is less of an incentive to donate and therefore less likelihood of the scheme having a significant impact on donor rates. Some balance would need to be reached between these two factors in order for the system to be fair but also to be effective.

A key aim of reciprocity systems is to increase fairness by giving priority in terms of allocation to those who are themselves willing to donate. It is suggested that, since so-called ‘free-riding’ is a ‘morally precarious position’, it is reasonable to counteract that by disadvantaging those who choose not to sign up for donation.¹⁷⁰ This may be seen as fair in relation to the majority, but some thought needs to be given to those whose organs are not suitable for donation – because of current illness, or past medical history, for example. This group will be unfairly disadvantaged because it is not that they are unwilling to donate but that their organs are simply not suitable.

Public opinion

In a 2004 survey of 336 adults in Greater London (118 Asian, 112 African-Caribbean and 106 white), participants were asked to rate the impact of a series of initiatives on their willingness to sign up to donate organs after death.¹⁷¹ The options included gaining priority access to organs, as well as cash payments at the time of signing up to the organ donor register, reduced insurance premiums, ability to influence the characteristics of organ recipients and formal recognition of donation. Amongst all groups the alternatives that were deemed most important on average were priority access to organs should the need arise and upfront cash payments.

A survey of 1,009 Scottish adults in 2004 found mixed opinions regarding reciprocity schemes with 42% in support, 43% neither agreeing nor disagreeing and 12% opposed to such schemes.¹⁷²

BMA view

The BMA supports the approach of NHS BT in drawing attention to the moral disparity of those who are not willing to donate organs after their death but would be willing to accept an organ if they needed one. It is appropriate to encourage people to think about this but the BMA does not support the type of reciprocity system introduced in Israel because it breaches two fundamental principles that the BMA values, namely that:

- donation should be a gift freely and voluntarily given and therefore individuals should not be given an incentive to donate and
- organs should be allocated on the basis of clinical need and social or moral factors should not be taken into account.

A regulated market

Most of the discussion in this paper has focused on donation after death but an increasing number of transplants are from living donors. Currently the law permits living donation – including to strangers (see section 3) – but prohibits the sale of, or trade in, organs. Intermittently, however, calls are made for the organ shortage to be addressed by allowing people to sell their organs. In August 2011, for example, a paper in the *BMJ* recommended that healthy individuals should be offered about £28,000 – the average annual income in the UK – to donate a kidney to enable people to ‘do a kind deed and make enough money to, for instance, pay off university loans.’¹⁷³ Whilst some supporters of paid organ donation advocate a free market approach to organ sales,¹⁷⁴ others believe that most of the concerns about the potential harmful effects of allowing people to sell their organs can be overcome through a regulated market.

In one possible model for a regulated market in the UK, the NHS would be the sole authorised purchaser and would buy organs and tissue, for a fixed price, from willing sellers in the same way as it does other goods such as dialysis machines or drugs.¹⁷⁵ Only those living within the geographical area covered by the scheme, who may therefore also benefit by receiving an organ, should be eligible to sell. The NHS purchaser would ensure appropriate screening, matching and allocation of organs – to prevent the rich gaining an unfair advantage at the expense of the poor. Allocation would continue to be on the basis of need. John Harris, a strong advocate for such a scheme, argues that those who agree to sell their organs should be given priority in the allocation of organs if they become patients in need of a transplant in the future.¹⁷⁶ He also argues that any payment made to sellers should not be liable to tax or reduction of welfare benefits, as an added incentive to individuals to sell their organs and thus benefit both themselves and others.

Evidence of effectiveness

Although it is widely recognised that the illegal sale of organs is endemic in some parts of the world,¹⁷⁷ Iran is the only country to legally permit a market in human kidneys.¹⁷⁸ The system, in operation since 1988, is run by the Dialysis and Transplant Patients Association (DTPA), a voluntary patient group. Potential vendors contact DTPA and are referred to a transplant centre for evaluation according to the same medical criteria as living donors who are not financially compensated. The Iranian government provides a fixed compensation of approximately US\$1,200

plus health insurance cover for one year for conditions directly related to the surgery. The vendor also receives remuneration either from the recipient, the recipient's family or one of a number of charitable organisations: this amount is usually between US\$2,300 and US\$4,500. Vendors must be aged between 20 and 35 years of age and must also have the consent of their next of kin.¹⁷⁹ Analyses of the Iranian system¹⁸⁰ have found that:

- by 1999 the waiting list for kidneys had been eliminated (subsequent reports, however, have claimed that this is only true for those who can afford to pay for a live donor, with others still being placed on a waiting list for a deceased donor¹⁸¹)
- the long-term outcome for recipients does not appear to be significantly different whether the kidney came from a paid donor or a living related donor
- the regulated market has not reduced altruistic donation; living related donation rates have remained static and altruistic donation after death has increased over this period.

It has also been found, however, that:

- organ vendors are disproportionately impoverished and uneducated
- the data on long-term outcomes for organ vendors are conflicting and incomplete.

Hippen, an advocate of such a scheme for the United States, suggests that lessons can be learned from the Iranian experience, to introduce an ethical market in human organs. He argues that altruism can persist and even flourish alongside a kidney market, as it does in Iran. Donors can still choose to donate altruistically and recipients can have the choice of an organ from someone who was paid or who was donating altruistically. Long-term outcomes would need to be assessed and this would need to be built into the system and careful attention would need to be given to the selection of vendors and to ensuring that they are properly informed of the risk. Hippen rejects the argument that impoverished individuals are coerced by the offer of a financial incentive on the grounds that 'an offer cannot be coercive if the relationship is initiated by the person in danger of being coerced'.¹⁸²

Ethical considerations

Central to the debate about permitting a regulated market are arguments around consent, coercion and exploitation. It is argued that autonomous individuals should be free to do whatever they wish with their own bodily material, including selling it, provided that they are sufficiently informed, have given consent and are not harming anyone else. Society does not usually prevent individuals from making their own decisions about where the balance of benefits and harms lies for them. Prohibiting payment, in the absence of significant harm to the individual or others, could therefore be seen to infringe the freedom and autonomy of individuals. Kidney donation involves major surgery with a small, but inherent, risk of harm. The fear is that the people who are more likely to take up the option of selling organs are those who are poor, impoverished or in serious financial difficulties and who have few, if any, other options. Essentially, those who need the money will be more likely to expose themselves to these risks and may be tempted to dismiss or minimise any concerns they have about it in order to gain the money they need. This raises

the scenario of donors acting contrary to their better judgement because of their financial circumstances and the financial incentive offered, leading to claims of exploitation and coercion.

Although the offer of an incentive is not, in itself, exploitative, individuals may be exploited if, under different financial circumstances, or with full information, they would not have chosen to donate. Arguably, however, the coercion in such cases is caused by their financial situation; prohibiting payment for donation will not improve their situation and limits the options open to them. The idea that adults with capacity need to be protected from making the 'wrong' decisions by restricting the options open to them has been challenged in other areas, including in the debate around women participating in egg-sharing arrangements.¹⁸³ If people consider that selling an organ is the best option for them, and there are safeguards built into the system so that the risks and payments are controlled and the rich cannot pay for preferential treatment at the expense of the poor, are there legitimate grounds to prevent individuals from taking this action? The International Forum for Transplant Ethics has pointed out that vendors themselves are willing to sell their organs and see this as the best option open to them; their position may be worse if the option of selling a kidney is removed from them. They argue that:

*'[i]f the rich are free to engage in dangerous sports for pleasure, or dangerous jobs for high pay, it is difficult to see why the poor who take the lesser risk of kidney selling for greater rewards – perhaps saving relatives' lives – should be thought so misguided as to need saving from themselves.'*¹⁸⁴

A further ethical consideration stems from the ancient professional obligation to intervene only for a patient's net benefit and to impose harm or risk of harm only for the intended net benefit of the patient. While it is widely accepted that, with appropriate consent, minimal harm may be imposed by doctors for the benefit of others, contemporary as well as ancient medical ethics would draw the line at imposing substantial harm for the benefit of others, even if appropriate consent were given. Donation of a heart for the benefit of a loved one would be an obvious example. In the case of kidney donation, however, this concern would apply equally to unpaid living donation as to paid donation. The current acceptance of living kidney donation implies that the level of harm and risk of harm for donors is morally acceptable whether paid or unpaid. Conversely, if the level of harm to paid kidney donors is too great to be ethically acceptable then the same conclusion should exclude unpaid kidney donors.

Moving from a system based on altruism to one based on commerce, however, would represent a fundamental shift, raising the question of whether altruism is a 'good' in itself which we should strive to maintain irrespective of the practical outcome of that shift. The Nuffield Council on Bioethics stresses the importance of altruism 'as underpinning important communal values that express something very significant about the kind of society in which we would wish medicine and research to flourish.'¹⁸⁵ There is also a principled argument that donation and altruism are central to the NHS, which operates the organ donation system. If we accept a move to commerce in this area, this could be viewed as one step towards an overall reduction in altruism in society, with people less willing to help others unless there is some personal gain. It has been argued for

example, that if a financial motivation is introduced 'the value of donation would be undermined, because it would no longer stand for selfless motivation or sacrifice on the part of the donor, and nor would it express a sense of shared obligation, of solidarity, to provide that which is essential for life or health'.¹⁸⁶ Linked to this is concern about the way we perceive ourselves and others as human beings. Allowing payment for an organ can be seen as treating that part of our bodies as a mere commodity to be traded. This could be seen to undermine the notion of human dignity and the moral obligation to show respect for persons.

Practical considerations

Proponents have suggested that introducing a regulated market in human organs would be a pragmatic solution to the serious problem of the lack of organs which is resulting in unnecessary deaths. We may consider voluntary donation, with its emphasis on altruism, human dignity and minimisation of exploitation, as far preferable. If that fails to maintain supply, however, as a society a decision is needed about whether to uphold the principle of altruism and accept the consequences or to take a more pragmatic approach and take steps, such as the use of payment or incentives, to meet the shortfall. Some would argue that given the benefits that accrue from donation, payment (if it were found to increase donations) may be justified on utilitarian grounds. The consequence of not maintaining the supply of organs is not simply the unnecessary loss of life. It is well known that some patients, in desperation, use unlawful, unregulated and sometimes unsafe arrangements in other countries. This not only puts their life at risk but also has a knock-on effect on others, when limited NHS resources are required to deal with the consequences. A patient who was not at the top of the waiting list for a transplant would, nonetheless, receive urgent medical treatment for complications arising from sub-standard surgery undertaken in other countries. From the donor's perspective, it has been suggested that the continued shortage of organs in developed countries, and the failure to take action to address it, provides a market for, and thus sustains, the harmful and clearly exploitative practice of trafficking organs from developing countries.¹⁸⁷ Introducing an ethical market in organs, it is suggested, may therefore help to prevent the greater harms of trafficking as well as addressing the urgent need for more donors.

One of the practical arguments that is frequently used against payment for organs is that paid donors would transmit more diseases than voluntary donors because of the type of person the payment would attract and the possibility that they would lie about any illnesses or risk factors in order to get the money. Data from blood donation surveys appear to add weight to the argument that, at a global level, incentives might affect the quality of the donation or lead to more potential donors being rejected for blood donation. The World Health Organization's 2007 Blood Safety Survey found that donors who gave blood voluntarily, and for altruistic reasons, had the lowest prevalence of HIV, hepatitis viruses and other blood-borne infections, as compared to people who donate for family members or in return for payment.¹⁸⁸ In practice, however, with routine screening of donors for communicable disease it is unclear how big an issue this would be in the UK although it may still be a problem in countries that are not able to undertake full screening. One effect in the UK, however, could be that more potential donors are rejected because of infectious diseases and therefore the expected increase in actual donors could be smaller than anticipated.

Any payment for organs, from living or deceased donors, is specifically prohibited by the EU Organs Directive, which the UK has signed up to. It limits reimbursement to that which is 'strictly limited to making good the expenses and loss of income related to the donation'¹⁸⁹ (This contrasts with the EU Tissues and Cells Directive – which applies, for example, to gamete (egg or sperm) donation – which also permits payment to make good 'inconveniences related to the donation'.)

Public opinion

A survey of third-year medical students in Switzerland found that 27% would consider selling a kidney but 73% would not, under any circumstances. Of those who would consider selling, 66% would sell only to overcome a particularly difficult financial situation.¹⁹⁰ In this study, the median amount of money expected for donation of a kidney was £20,500. In a 2004 survey of the Scottish public only 24% said the offer of payment for living donation would make them more likely to donate (51% said it would make no difference and 21% said it would make them less likely to do so).¹⁹¹ The author points out, however, that payment of only £2,000 was suggested and the results may have been different had the figure been higher. (Figures of up to £100,000 have been suggested.¹⁹²)

BMA view

The BMA believes that organ donation should be a gift, freely and voluntarily given and does not support incentives or direct payment for donation. The shift away from altruism and social solidarity in organ donation could have a broader impact on societal attitudes and contribute to an overall reduction in altruism within UK society. In addition, living kidney donation carries a small but significant health risk; introducing payment could lead to donors feeling compelled to take these risks, contrary to their better judgement, because of their financial situation.

Payment of funeral expenses

The offer of financial incentives for organ donation has also been proposed as a way of increasing the number of deceased donors. In its report, *Human bodies: donation for medicine and research*,¹⁹³ the Nuffield Council on Bioethics advocates a system whereby the NHS offers to meet the funeral expenses of those people who sign up to the Organ Donor Register during their lifetime and subsequently become donors. This is based on the system in place for those who donate their bodies to medical schools for educational purposes where cremation fees are often paid. In these cases a medical school arranging cremation is seen as an acknowledgement of the donor's contribution to medical science and teaching and has not proved controversial (although it is not clear how aware people are of this arrangement). The Nuffield Council proposes that payment of funeral expenses would similarly be seen as recognition of the contribution a person and his or her family have made in allowing donation to proceed. The offer of funeral expenses may also act as a trigger to important conversations within families which would remove uncertainty around donation and, in turn, help families to fulfil their loved one's wishes. Although it is not widely reported, and few details are available, a contribution towards funeral expenses is offered to organ donors in some regions in Spain.¹⁹⁴ Payment to families for donors' burial costs also formed part of the Israeli organ donation law which came into force in 2010 (see above).

Evidence of effectiveness

The Nuffield Council's report acknowledges that there is no evidence of the effectiveness of its suggestion and so proposes a pilot study in order to assess both public acceptance and its ability to contribute to increased donation rates. An analysis of the impact of this model in Spain, undertaken some years ago by the Director of Organización Nacional de Trasplantes (ONT), found no evidence that it led to increased donation rates although there are no published data about this.¹⁹⁵ At the time of writing there has been no published analysis of the impact of this provision in the Israeli law.

The outcome measures for a pilot scheme would need to be carefully considered and structured in order to obtain meaningful results. It would be difficult, for example, to identify an increase in relatives' authorisation because the refusal rate, where the individual is on the ODR, is only 6% so it would take a long time and would need to be a wide pilot area for enough cases to be included to identify a statistically significant difference. Another outcome could be increased donor registrations, or the rate of increase before and after the scheme is announced but, as mentioned above, there is not a direct correlation between the number on the register and the number of deceased organ donors. Another option would be to conduct follow-up interviews with relatives and the requesting staff to see what impact the availability of funeral expenses makes.

Ethical considerations

Many of the concerns that are raised in relation to providing incentives for living organ donors – around consent, coercion and exploitation (see above) – do not apply where the benefit is received after death. The donor is not undertaking any risk and does not benefit personally from the money. Whilst this represents a shift from the current system, which is based solely on notions of the common good (where the benefit is to unknown others), it can be argued that it nonetheless retains an altruistic focus because the action (ie signing up to the ODR) is still motivated by a desire to benefit others – the donor's family and heirs who will benefit from the payment after the individual's death, as well as potential recipients of the organs. Although not suggested by the Nuffield Council on Bioethics, the altruistic nature of the system could be increased further by offering families the option of donating the money to a charity of their choice, if they felt they did not need the money to cover the costs of the funeral.

The Nuffield Council on Bioethics uses a 'ladder of intervention' as a tool to analyse various ways of promoting and encouraging donation. It sets out six levels of intervention:

1. providing information about the need for donation
2. recognition of, and gratitude for, donation
3. removal of barriers to donation amongst those already inclined to donate
4. an additional prompt or encouragement for those already inclined to donate
5. benefits in kind to encourage those who would not otherwise donate
6. financial incentives that leave people better off by their decision to donate.

It refers to levels 1-4 as 'altruist-focused interventions' which act to 'remove disincentives from, or provide a spur to, those already inclined to donate' and to levels 5 and 6 as 'non-altruist-focused interventions' where 'the reward offered to the potential donor is intended alone to be sufficient to prompt action'.¹⁹⁶ The report makes clear that the step from altruist-focused to non-altruist-focused interventions should not necessarily be seen as moving from ethical to unethical although non-altruist-focused interventions may require more careful consideration.

A regulated market, as discussed in the preceding section, would clearly be a level 6 intervention. The Nuffield Council suggests that the offer of funeral expenses to family members could be viewed as a level 4 intervention, acting as an additional prompt to those who are already inclined to donate, but acknowledges that it could be placed higher up the ladder.¹⁹⁷ It could be argued, for example, that the payment of funeral expenses is a financial incentive that leaves people better off by their decision to allow donation to proceed – a level 6 intervention. Or, it could be seen as a benefit in kind (level 5 intervention) although it might be said that offering benefits in kind for something that is a necessity – such as funeral expenses – is equivalent to giving money, whereas a benefit in kind that is for a luxury or optional item is not.

In any event, using this mechanism the Nuffield Council concludes that '[s]ystems based on altruism and systems involving some form of payment are not necessarily incompatible'¹⁹⁸ even though they are normally seen as opposing approaches.

The BMA agrees that an individual donor's motivation could, under such a scheme, be both altruistic and financial, and that the system would still be based on altruism – in terms of being motivated by a desire to benefit others (including the financial position of one's relatives). Nevertheless, there would be a shift away from pure altruism in the sense of an act of social solidarity, where the motivation is to help unknown recipients, to one where the motivation is to provide financial benefit to specific members of one's family and heirs. The notion of donating to strangers as a common good, which is inherent in the current system, engenders considerable public support. It is unclear whether this type of shift in the concept of altruism would affect this support, but there is a risk that organ donation might increasingly be seen as less of a 'worthy cause' if part of the motivation is to benefit one's own family rather than to benefit society more generally. Donating organs after death is seen as a good and positive thing that people choose to do out of a sense of moral duty or a genuine concern for other members of society. This public recognition of the selfless act of donation could be damaged in a system that offers financial reward to the donor's family, even where those rewards are declined or, where accepted, were not the donor's principal motivation. On a societal level, however, the system could be particularly beneficial for the poor, who are most anxious about covering their funeral costs, and so could be seen as another form of solidarity.

There is no empirical evidence about the likely effect of shifting to a system where motivation is based on both altruism and reward. It is possible that those who currently feel a strong moral obligation to donate organs after death for the benefit of others may feel their gift is undermined in some way by the offer of payment. Those who do not qualify for the reward (because their

loved one had not signed up to the register for example) may feel less moral compulsion to consent and could possibly even feel aggrieved that others are receiving payment for donation when they are not. Such reaction is not inevitable, however, and those who are already motivated to donate but, for reasons of apathy have not signed up to the ODR, may see the offer of funeral expenses (and the possibility of benefitting their family and heirs) as the necessary prompt. Or, they may view it simply as appropriate public recognition of their altruistic act.

There is also a broader issue about what, if anything, the offer of payment to families in return for donated organs would say about our society's perception of the importance of social solidarity and whether, in reality, that matters. As a society, we benefit from notions of 'the common good' and selflessness. An important consideration must therefore be whether the introduction of payment to the families of organ donors would represent a significant shift that could undermine notions of social solidarity within society or whether it is a small step in the direction of commerce, reflecting the reality of a changing society in which behaviour can be heavily influenced by incentives, whilst maintaining its overall altruistic focus.

Practical considerations

Although the report does not go into details, there would need to be a maximum contribution to prevent individuals seeking elaborate funerals, way beyond their personal means, at public expense. The offer of unlimited funds would be unaffordable and unfair and could tip the balance significantly in favour of people donating for financial rather than purely altruistic motives. A moderate, standard grant towards funeral expenses as a form of public recognition of the altruistic act of donors would be preferable. Even so, with a basic funeral in the UK costing around £2,500 to £3,000,¹⁹⁹ the cost could be quite significant, raising legitimate questions about whether this is the best use of resources. (On the basis of 1,000 donors per year, for example, of whom 33% were on the ODR, the direct cost would be around £1 million). If it were evident that this would make a significant difference to donation rates, it might be cost-effective but much more work is needed in this area.

A relevant factor in the cost-benefit analysis is that the system is aimed at encouraging people to sign up to the Organ Donor Register, rather than being aimed at encouraging families to donate once a relatives' death has occurred. As mentioned above, there is not a clear correlation between increasing numbers on the ODR and increasing numbers of donors and so this type of incentive may not produce significant improvements in donation rates, at least in the short term. An alternative would be to offer the grant to any family that agrees to donation irrespective of whether the deceased was on the ODR. Having the type of two-stage approach recommended by the Nuffield Council, however, provides a level of protection for the patient. If families receive the grant for agreeing to the donation of organs, there would be a clear incentive for the family to authorise donation even if they knew that was not what their loved one would have wanted.

The introduction of such a system would also need to be carefully managed to ensure that people are not given false reassurance. The public generally has very little awareness that the majority of people do not die in situations where they would be able to donate organs: people who die at

home or at the scene of an accident, or even on a general ward in hospital, are most unlikely to be able to donate solid organs. Others will be unable to donate for medical reasons. Research shows that around 46% of people have made no financial provision for their funeral.²⁰⁰ If people believe it is unnecessary to make such provision because they have signed up to the ODR, this figure could be much higher.

Thought would also need to be given to whether it is the offer of donation or the fact of donation that would trigger payment. If an individual was on the ODR and the family did not object but the organs, once retrieved were not suitable for donation, it is unclear whether the donor's family would be eligible for payment. To make payment conditional upon organs suitable for donation being retrieved could be interpreted as payment for the organs themselves, rather than a payment in recognition of their donation. On the other hand, the cost of the system could increase significantly if the payment were made on the basis of the offer of donation, irrespective of whether donation proceeded or organs suitable for transplantation were received.

Public opinion

In 2004, the offer of a cash payment of £2,000 for funeral costs was included in a survey of the Scottish public on factors likely to influence their decision to donate.²⁰¹ Overall 39% said the offer would make them more likely to donate, 49% said it would make no difference and 9% said it would make them less likely to donate.

As part of its work on donation the Nuffield Council on Bioethics set up a deliberative workshop with 43 members of the public to establish their views on the range of issues under consideration.²⁰² Overall the public expressed strong support for altruism in donation and to the extent that incentives were supported, this was limited to those where altruism remained the primary reason for donation. Offering a contribution towards funeral expenses was seen as appealing because it was aimed at helping the family, rather than the individual, and because it was seen as recognition of their contribution rather than payment per se.

A YouGov survey undertaken in the immediate aftermath of the publication of the Nuffield Council on Bioethics' report in 2011 found mixed views about the general acceptability of the proposal.²⁰³ Of the 2,640 people questioned, 47% supported the suggestion, 32% were opposed to it and 21% said they did not know. Asked whether they thought it would make people more or less inclined to sign up to the ODR, 56% said they thought it would increase registrations, 1% said it would decrease registrations and 32% thought it would make no difference (11% did not know). Interestingly, however, of those who were not on the register, 58% said it would make no difference to them personally (28% said it would make them more likely to do so and 3% less likely).

BMA views

There are undoubtedly ethical issues, practical problems and cost-implications of this proposal that need to be thoroughly investigated. Nevertheless, the BMA does not have major ethical concerns about offering funeral expenses to those on the Organ Donor Register who go on to donate organs although we question the likely effectiveness of such a venture in increasing donation rates. Moving away from a system based solely on altruism would only be worthwhile if there is good reason to believe that it will achieve this aim. Whilst recognising the difficulty of devising a sufficiently robust study, if a pilot scheme could be devised that would measure the effectiveness of such a scheme, this would be worth exploring further. Any research would also need to address public support and, if possible, the broader implications, if any, of introducing a system based on financial as well as altruistic motivation.

6 The way forward for policy

What can we learn from Spain?

Spain consistently has the highest donation rate in the world at around 34-35 donors per million population (compared with 16 in the UK). It is therefore reasonable, when developing our own system, to look at the Spanish model to see what lessons can be learned.

How does the Spanish system work?

The law in Spain permits organs to be taken for transplantation with the consent of the family or in the absence of any known objection by the deceased. It is technically an opt-out system although there is no opt-out register and families are relied upon to report any objection to the transplant co-ordinator. In practice, consent is sought from relatives and the system therefore operates more in line with an opt-in system.²⁰⁴ Donation rates increased slightly after this legislation was introduced in 1979 but did not begin to increase significantly until what has become known as 'the Spanish model' was introduced in 1989. The Organización Nacional de Trasplantes (ONT) was established in that year as part of the Spanish Department of Health and undertook a programme of 'professionalisation' of organ donation through a network of professionals working at national, regional and local level. When this programme started there were 25 transplant co-ordinating teams, but by 1999 this had increased to 139 with one in each hospital with the potential for organ donation.²⁰⁵ Most transplant co-ordinators are medically qualified, usually intensivists, working part-time in the transplant co-ordinator role for two to three years at a time in order to avoid 'burnout'; after this time they return to other jobs.²⁰⁶

The system is designed to ensure that the transplant co-ordinators feel a sense of involvement and accountability for performance. They are responsible for all aspects of the organ donation process within the hospital, including donor identification which, given their positioning within the ICU, they are ideally placed to undertake. As part of the Spanish model all professionals directly or indirectly involved in organ donation receive regular training courses; it has been reported that since 1991 more than 11,000 professionals in Spain have undertaken this training.²⁰⁷ Communication with the public is also a large part of the strategy developed by ONT with a 24-hour telephone information line for the press, public and professionals in order to generate trust in the system and a positive overall view of organ donation.

Spain is an example of a country that has increased its donor rate, without implementing its opt-out law. It is possible that the background of an opt-out system – which potentially leads to a more positive view of donation within society – could have had some indirect impact on the success of the new model. Abadie and Gay have suggested, for example, that the defaults in legislation might affect decisions made by families, even if they are not enforced.²⁰⁸ It is, however, generally accepted, including by the BMA, that Spain's success is not due to its legislation but its organisational model. For many years the UK has been looking to the Spanish model to see how it could be adapted to the UK situation and a number of the initiatives suggested by the Organ Donation Taskforce are based on practice in Spain. The answer, however, is not simply to adopt more of the Spanish system. In fact, there are some aspects of the Spanish system that the UK either could not, or would not wish to, adopt.

Some of Spain's performance, compared with the UK, can be put down to differences in resources or clinical practices between the two countries. These include:²⁰⁹

- the higher number of intensive care beds in Spain – 87.5 per million population compared with 27 per million population in the UK (excluding coronary care, neonatal and burns units);
- different admission criteria for ICU – with far fewer beds in the UK, those with a poor prognosis, who are therefore more likely to be potential donors, are less likely to be admitted to ICU;
- end-of-life practices – in the UK it is considered good practice to withdraw life-sustaining treatment before brain stem tests are carried out if treatment is no longer benefitting the patient, whereas this is less common in Spain. This results in a far lower number of potential DBD donors in the UK. (Spain has a donor rate of 34-35 per million population, 95% of whom are DBD donors²¹⁰ whereas the maximum number of potential DBD donors identified in the UK potential donor audit was 18.4 per million population). This situation could change with recent Spanish legislation on withdrawal of life support which could make patient and family requests to withdraw ventilation more common.²¹¹
- the use of 'higher risk donors' (see section 5). In 2009, 45% of Spanish donors were over 60 years of age, compared with 30% in the UK. In 2009 no organs could be transplanted from 206 of the 1,606 donors (12.8%) in Spain.²¹²

Some aspects of the Spanish system have been subject to criticism although there is a significant level of ambiguity about how the system works in practice, such that it is difficult to know whether this criticism is justified. If the interpretation is correct there would appear to be some practices in Spain that would conflict with the general culture of care in the UK.

- The training for transplant co-ordinators includes informing them how to challenge the most common reasons families give for refusing donation. As a result of this the role of the co-ordinator has been interpreted as to explicitly and actively 'persuade' the family to agree to donation.
- Transplant co-ordinators are paid variable amounts based on the hours worked and so they are paid more when there are donors. This arrangement has been widely interpreted as incentive bonus payments for organ donation, although those responsible for the system have reacted strongly to 'ill-informed' criticism of this aspect of the Spanish model. In commenting on this the ONT has, nonetheless, acknowledged that variable payment is a 'favourable condition' for organ donation.²¹³ It explains that, unlike in other countries, in Spain 'there are many doctors with low basic pay but with the prospect of a significant increase linked to objectives.'²¹⁴
- The transplant co-ordinator may also have clinical responsibility for the patient's treatment in intensive care as well as identifying potential donors and approaching the family. This could be perceived as a conflict of interest, particularly if the transplant co-ordinator then receives additional payment as a direct result of any donation that proceeds.

A number of other countries have adapted the Spanish model with great success. Modifications of it can be found in parts of the United States of America²¹⁵ and in Italy.²¹⁶ In Italy, both organisational change, based on the Spanish model, and an opt-out system were introduced in 1999. It has been reported that not all regions implemented both aspects of the legislation but those that showed the greatest sustained increase in deceased donor activity rates are those that implemented both structural reform and an opt-out system for deceased donation.²¹⁷ The BMA has always argued

that an opt-out system alone could not achieve the type of donation rates we need and that this must be accompanied, or ideally preceded, by the development of a well-funded, well-organised infrastructure.

Where next for public policy?

The Organ Donation Taskforce and those who have worked so hard to implement its recommendations deserve congratulations and considerable credit for their work. For the first time in the UK, the organ donation system has been subject to rigorous review with a comprehensive, radical and logical approach and significant financial investment. The key principle underpinning the Taskforce's work – that donation should be a usual part of end-of-life care – has been translated into practical changes that have made, and will continue to make, a significant difference. Living donation has also continued to expand and a strategy has been developed to promote further growth. These changes will result in lives being saved and transformed. We have much to celebrate but we cannot afford to be complacent.

The Organ Donation Taskforce believed its reforms would lead to a 50% increase in deceased donors over the five year period to 2013, taking the UK to 19.6 donors per million population. The first three years saw an increase of 25%, and it is projected that this increase will rise to 34% in the fourth year to April 2012.²¹⁸ Although good progress has been made, it will be a significant challenge to achieve the target of 50% by 2013. Even if a 50% increase is achieved it will not solve the problem and people will still be dying unnecessarily. In its strategic plan for 2011-14, NHS BT acknowledges that with a changing donor profile, and increasing demand for donation, 'the need to deliver the targets of the ODTF, and be able to sustain further increases beyond the time period that was set, become even more challenging'.²¹⁹

As a society we need to consider whether, having developed the infrastructure, we should be satisfied that we have done all we can and accept that we have reached the limit of our potential for donation in the UK, or whether we should seek to build on what has already been achieved by shifting our attention to additional ways of increasing the number of organ donors.

In the BMA's view, as long as more can be done, more should be done. We recognise that any significant policy change will only succeed if it has public and professional support and must be pursued carefully. But we must not shy away from this debate. Doing nothing is not a neutral act. Where lives are at stake a positive decision not to pursue further gains is one that needs justification. We also cannot keep delaying the issue. Given the significant time that would be needed to implement any major change, lost time will inevitably result in lost lives.

We welcome debate on the range of possible options including systems based on reciprocity, mandated choice or the payment of funeral expenses but the BMA remains firmly convinced that a system of opt-out with safeguards is the best option and the one that is most likely to have a positive effect.

The BMA hopes that the publication of this report will encourage and facilitate debate – amongst health professionals, policy-makers and the public, with a view to reaching broad agreement about the way forward.

7 Summary of key points

- Since the Organ Donation Taskforce report was published in January 2008 there have been major changes and significant improvements to the organ donation system in the UK.
- The latest published data (2010/11) show that over the last three years, donation rates from deceased donors have improved by 25% (compared with 2007/08). More recent data provided by NHS BT show that the total increase is projected to rise to 34% by April 2012 (based on donors up to 8 January 2012).
- The Organ Donation Taskforce believed that, with the changes it proposed, deceased donor rates would increase by 50% by 2013. Although good progress has been made it will be a significant challenge to achieve this target.
- Whether or not the target of 50% is reached, people will still be dying unnecessarily while waiting for an organ transplant.
- Work must continue to maximise the impact of the changes that have taken place and to explore further avenues for improvement. This will include increasing organ donation from emergency departments, extending the use of living donors, increasing referrals, attempting to reduce the relative refusal rate and targeted campaigns for black and ethnic minority groups.
- As a society we now need to consider whether, having developed the infrastructure, we should be satisfied that we have done all we can or whether we should seek to build on what has already been achieved by shifting our attention to additional ways of increasing the number of organ donors.
- A range of options have been suggested, including a system of opt-out with safeguards, mandated choice, reciprocity or some form of incentive or compensation for donors.
- The BMA remains firmly convinced that a system of opt-out with safeguards is the best option for the UK and the one that is most likely to be effective.
- The BMA hopes that this report will encourage and facilitate informed debate amongst professionals, policy-makers and the public about how we take forward public policy on organ donation in the UK.

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