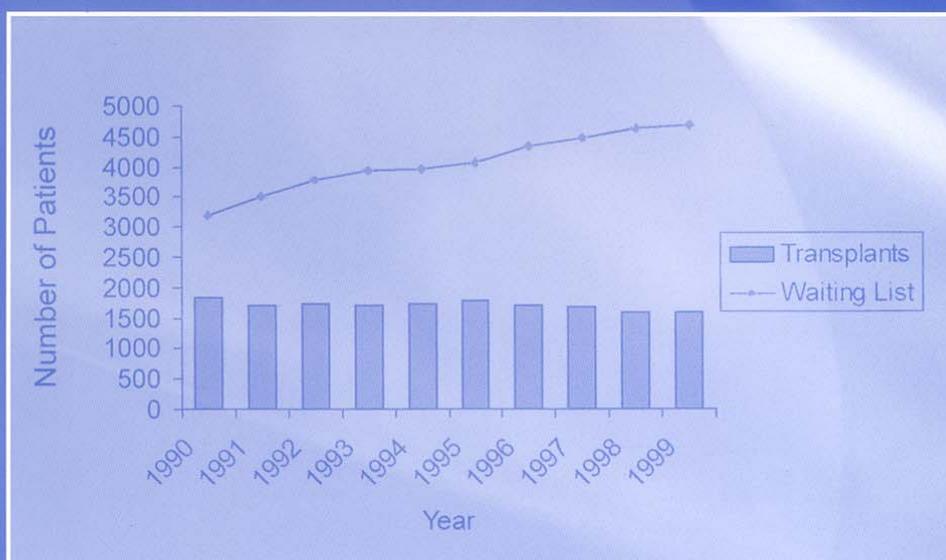


Organ Donation in the 21st Century

Time for a consolidated approach



Contents

Membership of the Medical Ethics Committee	iii
Editorial Board	iv
Acknowledgements	v
Introduction	1
Part One - The Current Situation	2
The Problem	2
The Legislative Framework	2
Cadaveric donors	2
Live donors	4
Practical Considerations	4
The Solution	4
Part Two - Increasing the Number of Donors	7
More Direct Appeals for People to Register as Potential Donors	7
Addressing common concerns	8
Facilitating registration on the NHS Organ Donor Register	9
Living Donors	10
Non-Heartbeating Donors	12
Presumed Consent	13
Assessing the success of presumed consent	13
The Belgian system	14
Presumed consent with safeguards	14
BMA policy	15
Registration for opting out	16
Adults lacking capacity to make decisions	16
Children and young people	17
Public support	17
Suggestions Requiring Further Consideration	17
Elective ventilation of patients close to death	18
Ethical and practical considerations	18
Safeguards	19
Living kidney exchange	19
Other Suggestions Rejected by the BMA	20
Part Three - Improving Co-ordination and the Infrastructure	22
National Co-ordination	22
The Spanish model	22
A National Transplant Service	22
Local Co-ordination	23
Routine referral	23
Screening criteria	24
Maintaining the viability of donor organs	24
Transplant co-ordinators	25
Improving the Infrastructure	26
Developing a "UK Model"	27
Part Four - A Consolidated Approach	28

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A publication from the BMA's Medical Ethics Committee (MEC) whose membership for 1999/2000 was:

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Organ Donation in the 21st Century Time for a consolidated approach

Introduction

Dramatic advances have been made in transplantation over the last twenty years but thousands of people are still dying from conditions that could be overcome by the transplant of a donor organ. This paper highlights the inability of the current system to meet the increasing demands placed upon it and considers various ways of overcoming the main problems. It focuses exclusively on increasing the availability of organs for transplantation. It does not consider the retention of tissue for diagnostic, research or other purposes.¹ This paper brings together a range of practical suggestions for increasing transplantation rates, for the benefit of those people whose lives could be saved or dramatically improved by a transplant. The BMA hopes that the publication of this paper will stimulate wide-ranging debate - amongst health professionals, policy makers and the public - and will encourage a concerted action for change.

Part One

The Current Situation

The Problem

In 1998 7% fewer organ transplants were carried out in the UK than in 1997; in the same period the waiting list increased by 3%.² This increasing gap between supply and demand appears to be a continuing trend. The statistics for 1999 compared with 1998 show no change in the number of transplants and an increase of 3% in the waiting list.³

At the end of March 2000, 5,354 people were on the active national transplant waiting list in the UK⁴ although it is widely acknowledged that waiting list numbers do not give an accurate reflection of overall need. Because of the shortage of organs available for donation, in most parts of the UK people are only placed on the waiting list when they are considered to have a reasonable chance of receiving a donated organ. Those who need a transplant but, because of the shortage of donors, are unlikely to receive one are not, therefore, included in waiting list figures.

Official statistics show that over the five year period 1995-1999, about a thousand patients died whilst on the waiting list for a heart, heart and lung, lung or liver transplant.⁵ In fact the actual number of people dying whilst awaiting an organ transplant is likely to be considerably higher. Many more will have died without even reaching the waiting list and this number does not include the thousands of patients who die because there are insufficient dialysis facilities to meet the demand. One must also remember those patients whose lives are dominated by the burden of dialysis.

This is not just a problem in the UK but worldwide there is a major and increasing shortage of organs for donation. A variety of strategies have been adopted around the world to seek to remedy this problem. This paper looks to practice at home and overseas to seek an appropriate strategy for the UK.

The Legislative Framework

Cadaveric donors

In the UK, the removal of organs from people after their death is covered by the Human Tissue Act 1961 (covering England, Scotland and Wales) and the Human Tissue Act (Northern Ireland) 1962. The Human Tissue Act states that:

“1(1) If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of his body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body of any part or, as the case may be, the specified part, for use in accordance with the request.

“1(2) Without prejudice to the foregoing subsection, the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for the said purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe-

- (a) that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or
- (b) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with”.

If it might be necessary to hold an inquest, or a coroner’s post-mortem examination, the Act states that organs or tissues may only be removed with the specific authorisation of the coroner. In Scotland, organs may not be removed in any case where the procurator fiscal has objected to their removal.

The Human Tissue Act is widely regarded as being unsatisfactory and in need of reform.⁶ The loose wording of the legislation, which has been referred to as simplistic and ambiguous, has led to difficulties which will inevitably increase with developments in communication technology. Fundamental questions remain unanswered by the law: who is “lawfully in possession of the body”? What is “such reasonable enquiry as may be practicable”? Does this include using the Internet and E-mail to try to contact every surviving relative? Should the view of a surviving relative, who has been estranged from the deceased for many years, have the power of veto over the donation? Methods of practice have developed, in spite of the unhelpful wording of the legislation, and generally a pragmatic approach has been adopted which has not, so far, been subject to legal challenge.

It is generally accepted, though not beyond doubt, that where a patient dies in hospital, the hospital management is “lawfully in possession of the body”, until the executors or relatives ask for the body to be handed to them. When the person dies elsewhere, the person lawfully in possession of the body is considered to be a close relative or long-term partner. A pragmatic approach has also been taken in interpreting the phrase “such reasonable enquiry as may be practicable” and in deciding which relatives’ views should be sought. In most instances, this will consist of discussing the matter with those relatives who have been in close contact with the deceased in the period leading up to the death. These people will be asked about their own views, those of the deceased patient and whether any other relative is likely to object. Many potential organ donors will have spent a short time in hospital before their death and the medical and nursing staff will already be in contact with the close relatives.

The wording of the legislation is also outdated and fails to reflect life in the twenty-first century. The use of the word “spouse” in the legislation would exclude from consideration the increasing number of couples who live together as long-term partners without marrying. In practice, long-term partners are, quite appropriately, consulted about donation but this is another example of where practice has developed in spite of the wording of the legislation.

It has also become standard practice to seek the consent of the relatives for donation even though the legislation merely requires that the person lawfully in possession of the body has made enquiries to ensure that the surviving relatives do not object to the donation. Thus, although the UK currently operates an “opt-in” system for organ donation (with explicit consent from either the individual or the relatives), these procedures have developed by custom and

practice rather than being a necessary requirement of the legislation. It would be possible to operate a form of presumed consent under the current legislation, simply by changing the way in which relatives are approached. The BMA, however, strongly believes that any such change must be made explicit and with the support of the public and health professionals.

The BMA calls upon Westminster and the Scottish Parliament to facilitate public debate about the shape of new legislation, to overcome these inherent problems with the existing law, and to provide a legal framework within which organ donation can prosper and more lives can be saved.

Live donors

The Human Organs Transplant Act 1989 was introduced in direct response to the “kidneys for sale” scandal which exposed an international trade in human organs. Under the 1989 Act, the making or receiving of payment (except expenses) for the supply or offer of any organ is illegal. This applies both to live and dead donors. The legislation also applies restrictions on live donation of non-regenerative organs. Those who are closely genetically related must provide evidence of the relationship before proceeding. For unrelated donors, the donation may not proceed until approval has been received from the Unrelated Live Transplant Regulatory Authority (ULTRA). Although the definition in the Act of a close genetic relation is fairly broad - including uncles and aunts by half blood - donation between long-term partners, which makes up an increasing number of live donations, requires approval from ULTRA.

Practical Considerations

Public opinion surveys in the UK consistently report that around 70% of those interviewed would be willing to donate organs after their death but only 20% of these make their views known by carrying a donor card or being listed on the organ donor register.⁷ This may be because of an unwillingness to consider their own mortality, it may be something they meant to get around to doing but never seemed to have the time, they may not know how to register their wishes, it could be a result of apathy or simply because they have never been asked the question. But the importance of making known one’s views about organ donation cannot be overstated. Where an individual dies without expressing views about donation, relatives are approached and, in practice, the responsibility falls to them at what is a very difficult and emotional time. It is estimated that around 30% of relatives, when asked in these situations, refuse a request for organs to be used. In two studies undertaken in Spain, 30% of the families that refused consent would have changed their minds one year later.⁸ Experience from the UK, and elsewhere, shows that where the relatives know that the deceased was willing to be a donor, it is very rare for them to seek to override this wish. Where an individual carries a donor card, this gives a clear indication to the family that he or she is willing to donate organs after death. It also acts as a prompt to discussion about donation, within the family, which is to be encouraged.

The Solution

In the past many organisations, including the BMA, have attempted to identify “the” solution, with individual groups arguing for more direct appeals for people to register as potential donors, greater co-ordination and resources, a change to a system of “presumed consent” (see page 13) or the use of “elective ventilation” of people close to death to preserve their organs

(see page 18). In reality, no single change will have the desired effect and a multi-faceted approach is needed.

In the future the use of animal organs and tissue for transplantation (xenotransplantation⁹) and the use of cell nuclear replacement technology to develop compatible tissue for transplantation (sometimes referred to as “therapeutic cloning”¹⁰) may, at least partially, resolve the problem. Both of these developments are, however, still at the research stage and will then need to progress through a series of clinical trials; even if these trials are successful, it will be many years, if ever, before they are available routinely in clinical practice. In the meantime, serious consideration needs to be given to how to improve the present situation.

Contrary to popular belief, the organs of only a small proportion of people who die will be suitable for donation depending upon the manner, time and place of death. With a few exceptions (see page 12 on non-heartbeating donors), donation is only possible in the small number of cases where patients are being ventilated in the period leading up to their death. (In these cases, brain stem tests are needed to confirm death because the heart and lungs, cessation of which would normally be indicative of death, are maintained artificially.) The number of cases which fall into this category has declined over the last decade largely because of the overall drop in the number of deaths from head injuries caused by road traffic accidents and intracranial haemorrhages. This makes it essential that as many as possible of those who die in such situations, and who do not object to donation, go on to become donors.

An audit of deaths in intensive care units in England during 1989 and 1990¹¹ provides useful insight into where the system breaks down and thus, where change is needed. Of the total 24,023 deaths in the audit, 3,266 cases (13.6%) had a possible diagnosis of brain stem death and therefore might have been suitable for donation but only 1,232 of these became donors.

Potential donors:	3,266	
Potential donors resulting in donation:	1,232	37.7%
Potential donors not resulting in donation:	2,034	62.3%

Reasons for loss of potential donors	Number lost
Brain stem death test not carried out:	797
Cessation of heart before tests completed:	76
General medical contraindication to donation:	438
Relatives not asked about donation:	126
Relatives refused:	557
Organs offered but not retrieved:*	40

* Reasons for a failure to use organs offered for donation often include: non-suitability of the organs by the time of the donor operation, non-availability of a transplant team, lack of theatre time, shortage of intensive care facilities, lack of suitable recipients, and coroners' refusals.

This audit was carried out nearly a decade ago and although the continued relevance of its findings is confirmed by practical experience and anecdotal evidence, there would be considerable value in undertaking a further study to assess the current situation. Very similar results were obtained from a study undertaken in 11 hospitals in the Netherlands, Spain, the UK and Canada between 1994 and 1996 in which only 31% of potential donors went on to

become donors. In that study too, the main problems occurred in the identification and management of donors and family or coroner refusals.¹² The implication of these results is that there is scope for an increase in the number of potential donors reaching the stage of donation and, in order to maximise this potential, attention needs to focus primarily on these two areas:

- ▶ improving the identification and management of potential donors; and
- ▶ reducing the number of refusals by relatives.

Although the losses are smaller in number, attention also needs to be given to:

- ▶ ensuring that in all appropriate cases families are approached about donation; and
- ▶ ensuring that the loss of organs offered is kept to an absolute minimum.

Suggestions for increasing the overall rate of organ donation can be divided into two broad categories focussing on:

1. increasing the number of donors available; and
2. improving the co-ordination, infrastructure and training to ensure that the additional organs available translate into an increased number of transplants.

These two goals are inter-dependent and should be seen as two sides of a single coin. Increasing the number of donors available is only useful if the system is able to cope with the additional workload. Similarly, developing a system to cope with a greater workload will only bring about improvements if accompanied by an increase in donors. The rest of this paper considers a variety of suggestions for moving forward on these two fronts.

The BMA urges medical and nursing staff and other organisations - such as the relevant Royal Colleges, transplantation organisations and patient support groups - to work together to campaign for positive action to achieve these two goals.

Part Two

Increasing the Number of Donors

More Direct Appeals for People to Register as Potential Donors

Publicity campaigns have an important role to play in raising awareness of the need for more organ donors and encouraging people to make their wishes about donation known. In the past, this type of campaign has had some, but not overwhelming, success in increasing the number of people listed on the organ donor register. Despite prolonged, and expensive advertising campaigns since the NHS Organ Donor Register was established in 1994, less than 14% of the UK population are registered.¹³ Whilst, in theory, a central organ donor register should improve the efficiency of an organ donation programme, it is a matter of great concern that the current system in the UK is ineffective and has serious flaws. Most people who add their name to the register assume that in doing so, their wishes will be known if they die in a situation which would make their organs suitable for donation. In fact, the register is not routinely checked when a potential donor is identified and the onus rests with the family to make the patient's wishes known or to guess what the patient would have wanted; thus the benefit of the register is effectively limited to any discussion within the family which accompanies a decision to sign up. There are also practical problems with maintaining the register: there is no established mechanism for people to be removed from the register when they die or for reminding people to ensure that their names and contact details are up to date.

Regardless of any other changes which may be agreed, as a matter of urgency, attention needs to be given to ensuring that any central register, whether for people to opt in or opt out of organ donation (see page 13), is effectively managed and routinely consulted. It must allow people to add and remove their names and the details contained on it should be checked at regular intervals - perhaps every five years. The register must be quickly and easily accessible to authorised personnel in all hospitals. In order to maintain the clear separation between the treating and transplant teams, the responsibility for consulting the register, before the relatives are approached, should fall to the transplant co-ordinator. For this to work, the transplant co-ordinator would need to be informed routinely, by the intensive therapy unit (ITU) staff, of all impending deaths of people who might be suitable for donation; this would be facilitated by the introduction of a system of routine referral (see page 23).

Although some people carry organ donor cards, this system has also proved to be less effective than originally envisaged. Organ donor cards are only of practical benefit if the card is with the person at the time it is needed (many women, for example, carry their donor card in their handbag which may not be picked up by paramedics in the event of a serious car accident) or if relatives know the individual carried a card and inform the relevant health professionals accordingly. Any publicity needs to encourage those people who have not already done so, to think about donation and, for those who would be willing to donate organs after their death, to ensure that their relatives are aware of their views.

A detailed analysis of the scientific data and international experience of organ donation, carried out by the Council of Europe,¹⁴ found that the most cost-effective way of increasing the public's willingness to donate was by improving the knowledge of health professionals not directly involved in transplantation - particularly those involved in identifying potential donors and approaching the relatives - and through the media. In Spain, for example, the national

transplant organisation runs a 24-hour 7-day-a-week telephone helpline to answer any questions related to organ donation from journalists, health professionals or the general public.¹⁵ A similar service could be established in the UK. The Council of Europe concluded that the key messages to get over are:

- ▶ transplants are very effective and well-established procedures;
- ▶ they can offer long-term survival and a high quality of life for increasing numbers of patients with no other hope of cure;
- ▶ organ donation is the only current way to save such patients' lives;
- ▶ organ shortage is the main limitation to saving the lives of more such patients; and
- ▶ any of us might need an organ.¹⁶

Addressing common concerns

A common concern, which needs to be recognised and addressed, is that organs might be removed before the patient is dead. This is predominantly caused by confusion around the term “brain stem death”. As the King’s Fund Institute Report¹⁷ remarked, it is unfortunate that the use of this term has been taken to imply a “special” form of death rather than simply its clearest manifestation. Use of the phrase “death confirmed by brain stem tests” instead of “brain stem death” may help to overcome this difficulty and to focus attention on the fact that the brain is no longer capable of sending or receiving the relevant information via the brain stem and thus recovery is impossible. Death confirmed by brain stem tests should therefore be seen as the clearest indication of what is commonly understood as “death”, more so than the stopping of the heart, or of breathing, both of which can, in some circumstances, be reversed. An explicit statement in the legislation requiring best current practice to be followed in determining death before organs are removed, may help to alleviate this fear. Current guidance includes the requirement that the death should be confirmed by “at least two medical practitioners who have been registered for more than five years, are competent in this field and are not members of the transplant team, at least one of the doctors should be a consultant.”¹⁸ It is common practice in some hospitals for the death certificate to be issued before organs are removed and wherever this is possible it would help to reduce such anxiety. Sometimes the time of death is recorded on the death certificate or in the patient’s medical record. Although death is not pronounced until the second set of tests have been completed, the legal time of death, and that which should be recorded on any official record, is the time of the first set of brain stem tests that established death.¹⁹

Another reported area of concern among the relatives of deceased patients is a suspicion that a DNR (do not resuscitate) order might have been placed on their loved one in order to provide organs for donation. Such concerns reflect a failure of communication about the nature and purpose of cardio-pulmonary resuscitation and a common, but overly optimistic, view that modern medicine can delay death indefinitely. The expression of such concerns also reveal a lack of knowledge about the transplant procedure itself since, as stated on page 5, with a small number of exceptions, once the patient’s heart has stopped beating the organs are no longer suitable for donation. Such concerns are not restricted to issues around organ donation and are indicative of a need, more generally, for improved communication, information and support at the time of bereavement. Whilst it is important to raise awareness of organ donation, this must not detract attention from the fact that the primary role of intensive therapy units is to save lives; transplantation is only an option when all efforts to achieve that aim have failed.

Some people have expressed concerns that their organs, given freely after their death, may be used to benefit those who can afford to pay for their treatment in preference to those waiting for treatment within the NHS. The idea that a patient may “jump the queue” for organs by seeking treatment in the private sector may deter some people from agreeing to donate their organs after death. In fact, only 0.16% of all transplants carried out over the three year period 1997-1999 were carried out in private hospitals.²⁰ (The precise number of private patients receiving transplants, however, is unknown because the data collected do not differentiate between private and NHS treatment carried out within an NHS hospital.)

Everyone who is entitled to NHS treatment has the same opportunity to receive a donated organ, irrespective of whether they have opted to have their treatment in private facilities. It is only where there is no suitable recipient from that group that the organs are offered to those who would not be eligible for treatment within the NHS. Details of all people, entitled to NHS treatment, who are waiting for a transplant are included on a database and when organs become available they are allocated to the next suitable person on the waiting list. Where there is more than one suitable recipient, an agreed formula is used to decide who should receive the organ. The formula varies between organs but for the allocation of kidneys, a priority list of recipients is created by a points system taking into account factors such as the patient’s tissue type, time on the waiting list, age and any previous transplants as well as geographical distance from the donor.²¹ Ability to pay for treatment plays no part in the selection process for any organ.

Facilitating registration on the NHS Organ Donor Register

In addition to greater understanding of the issues, it needs to be made as easy as possible for people to register their wishes in order to overcome the apathy which often hinders registration. New registrations come from a variety of sources. In 1999, 50% were from driving licence applications and reminders, 44% from patients registering with a general practitioner, 3% were on the registration leaflet issued by the Department of Health which is available in various places in the community and 3% from other sources.²² Another potential source of donors would be for general practitioners to ensure that all of their existing patients had been asked their views about donation. It would be inappropriate and insensitive to broach this issue at a time of illness, but other opportunities should be utilised such as at the time of registration, routine medical examinations and “well woman” and “well man” clinics. In the past the role of the general practitioner has been simply to seek their patients’ views about donation and record them. The BMA considers that health professionals should actively encourage their patients to agree to donate organs after their death. This will need to be very carefully handled, however, to ensure that patients do not feel pressured to agree to donation and that long-term patients do not misinterpret the request and suspect their doctor is withholding information from them about a serious illness. General practice surgeries, and hospitals, should also be encouraged to display prominent posters about organ donation. Solicitors consulted by people making wills could routinely ask their clients whether they have made their views known about organ donation. An information pack produced for schools would also be worthwhile.

Various campaigns and initiatives have also led to increased numbers of registrations. For example, in August 1999 Taunton Deane Borough Council included, with every electoral registration form, a letter from the Mayor appealing for residents to register as organ donors. From the 44,000 households who received the letter (at a cost of less than ,3,000), over 11,200 new donors were recruited to the register.²³ Although attempts to make it easier for people to

register their willingness to donate are to be applauded, great care must be taken to ensure that people understand what they are signing and that registration is optional. There are also legal restrictions on the use of public funds. The BMA has no ethical objection to this type of proactive approach provided that such initiatives can be shown to be both effective and lawful. Attempts over many years to persuade the population to carry an organ donor card or sign up to the register, however, have not solved the shortage of organs for donation. Whilst these efforts should undoubtedly continue, the BMA does not believe it is acceptable to postpone consideration of other options in the vague hope that further attempts to facilitate registration will solve the problem.

Living Donors

There are two different types of living donors. The first type, and the one considered in this paper, is altruistic donation from healthy donors. This type of donation has traditionally formed only a very small part of the overall transplant programme in the UK and, at the present time, is almost exclusively restricted to kidneys. Although segments of liver and lung are sometimes transplanted from healthy living donors, these are not currently routine procedures and are considered justified in only a small number of cases. The second type of live donation, which is not considered here, is where an organ becomes available as a result of a procedure carried out primarily for the benefit of the donor. The most common scenario is what is known as a “domino” transplant where a patient needing new lungs has heart and lungs removed and replaced by organs from a cadaveric donor. The patient’s own heart is then available for transplantation to another person.

Data from 1998 show a large increase (40%) in the number of live kidney donations from healthy donors compared with the previous year, representing 14% of the total kidney transplant programme for that year.²⁴ This increase continued during 1999, with a further 8% increase in the number of live kidney donations, representing 16% of the total kidney transplant programme for 1999.²⁵ Some people within the transplant community have called for serious consideration to be given to encouraging more live donations as a way of overcoming the shortfall of kidneys for donation. They argue that whilst, traditionally, attitudes toward living kidney donors in the UK has been, understandably, cautious, evidence from other countries indicates that the procedure is generally very safe, with few risks for the donor and a high chance of success for the recipient. Major complications for the donor are rare and the mortality rate is about 0.03%.²⁶ There are clear advantages to the donation of kidneys from healthy living donors. Higher success rates have been achieved both from related and unrelated donors compared with cadaveric donors.²⁷ The use of living donors also has other advantages: it permits pre-emptive transplantation for someone with progressive renal failure, so avoiding the need for dialysis; it allows the transplant to proceed at the optimal time for the donor and recipient; and for those with end stage renal failure, it allows them to escape the long and tortuous wait for a kidney from a cadaveric donor.

Any use of healthy living donors must be subject to strict safeguards. Guidance issued by the British Transplantation Society and the Renal Association²⁸ states that living donor kidney transplantation should only be undertaken if four essential conditions are met:

- ▶ the risk to the donor must be low;
- ▶ the donor must be fully informed;

- ▶ the decision to donate must be entirely voluntary and not due to coercion or the offer of an inducement; and
- ▶ the transplant procedure must have a good chance of providing a successful outcome for the recipient.

The BMA endorses these restrictions and also considers that only competent adults should be considered as live organ donors.

Part of the reported increase in the number of live donations in the UK is accounted for by the increasing number of donations from unrelated living donors, the majority of which were between married couples or long-term partners (32 of the 38 cases in which the relationship was reported); the remainder of donors were step-parents and friends of the recipient. In all such cases the donation would require the prior approval of the Unrelated Live Transplant Regulatory Authority (ULTRA) under the terms of the Human Organs Transplant Act (see page 4). This safeguard was clearly intended to prevent vulnerable individuals being coerced, or offered incentives, to donate. Its restriction to unrelated donors, however, ignores the very real pressures that could be placed on individuals to donate to another member of their family. It is possible that, at the time the legislation was passed, it was anticipated that unrelated donors would be unknown to the recipient and this would raise concerns about the donor's motivation. In reality, those living donors who are not related to the recipient are, nonetheless, emotionally close to them and are acting from altruistic motives. In the BMA's view, there do not appear to be legitimate grounds for making a distinction between related and unrelated donors.

Before ULTRA approves an application for donation by a living unrelated donor, it must be satisfied that:

1. no payment has been, or is to be, made;
2. the person referring the case for consideration is the doctor with clinical responsibility for the donor;
3. a doctor has explained to the donor the nature of the procedure and the risks involved in the removal of the organ in question;
4. the donor's consent was not obtained by coercion or the offer of an inducement;
5. the donor understands that his or her consent can be withdrawn at any time; and
6. the donor and the recipient have been interviewed separately by a suitably qualified independent person, who is not part of the transplant team, and that person is satisfied that the above conditions have been met.²⁹

These conditions are equally important whether the donation is from a relative or from an unrelated donor. The current mechanism was established as an immediate response to a scandal about the sale of human kidneys and this fact is reflected in the limited scope of ULTRA. Whilst it may succeed in preventing exploitation caused by financial pressures, its failure to consider other types of pressure appears illogical. If such a regulatory body is considered necessary, it should have the broader role of protecting all live donors from exploitation and pressure. The BMA considers that all live donations should be subject to the same rigorous assessment, either

by ULTRA or by some other mechanism, to ensure that the potential donation is truly voluntary and free from pressure.

Non-Heartbeating Donors

It is possible for some organs and tissue to be removed for transplantation from non-heartbeating donors for a short period after death (predominantly kidneys, corneas and heart valves but some success has also been found with liver grafts). This means, in practice, that patients who die of cardiac arrest in general wards or accident and emergency departments, or those who are declared dead on arrival at hospital, may still be donors. Clinicians in the Netherlands, in the early 1990s, made a concerted effort to increase the number of kidneys available for donation by using this method. Once the family had agreed to donation, a catheter was inserted into the body to cool the kidneys, in order to preserve the organs for transplantation. Over a nine year period, 21% of transplanted kidneys at the University Hospital, Maastricht came from non-heartbeating donors.³⁰

In Leicester, a non-heartbeating donor programme has been established that provides 25% of the kidneys for the transplant unit.³¹ In the vast majority of cases this is where the relatives have been approached and given their consent to the use of the procedure. Many relatives welcome the additional time this gives them to make a decision about organ donation. In a small number of cases, where the staff believe they may be able to trace the relatives in time to seek their views about organ donation but not in time to gain their permission to the insertion of the catheter, the coroner may agree to the procedure being carried out. It would not be appropriate for any procedure to be carried out where the death is reportable (because there is reason to suspect that the death was violent or unnatural or with sudden deaths of unknown cause) without seeking the permission of the coroner or procurator fiscal.

There has been some debate about both the legal and ethical acceptability of inserting a catheter into the body of the patient shortly after death, particularly if this is done at a time when it may not be known whether the individual has expressed views about donation. The Human Tissue Act provides for the use of the body after death for therapeutic purposes which could include inserting a catheter into the body to cool the kidneys as an integral part of the transplantation process. Arguably, therefore, where the death does not fall into one of the categories of reportable deaths, then the decision as to whether to proceed is a clinical one. The timing of the procedure is crucial, however. The legislation states that donation may proceed if the individual has previously expressed a wish to donate and this has not been withdrawn or if, having made “such reasonable enquires as may be practicable”, there is no reason to believe that any surviving relative objects. The ambiguity of this phrase is discussed on page 3 and is particularly relevant in the context of non-heartbeating donors. It has been suggested that whilst there has been no ruling on what constitutes “such reasonable enquiry as may be practicable”, “it seems safe to conclude that an enquiry which incurred such delay as to render the organs therapeutically useless would be considered unreasonable”.³² If this assumption is correct, it implies that a catheter could be inserted to preserve organs for donation in cases where the relatives could not be contacted in time and without necessarily seeking the consent of the coroner or the procurator fiscal. Clarification of the law in this area is urgently required.

The most recent statistics from the Leicester programme indicate that comparative success rates can be achieved using non-heartbeating donors. In an assessment of transplant activity between 1992 and 1999 no significant difference was found in the one or five year graft survival rates

between non-heartbeating and heartbeating cadaveric donors.³³ The BMA believes that consideration should therefore be given to ways of facilitating the increased use of non-heartbeating donors. Accident and emergency departments must be aware of the potential use of kidneys from these patients and the need to notify the transplant co-ordinator without delay when potential donors are identified. A system of presumed consent (see page 13) where the opt-out register was quickly and easily accessible, would also facilitate the increasing use of non-heartbeating donors. If it were possible to find out, within the necessary timescale, that the individual had not registered an objection to donation, a catheter could be inserted to preserve the organs on the grounds that consent to organ donation could be presumed. Regardless of the type of consent system operated, it will also be essential that steps are taken to raise awareness among the population, and particularly the relatives of those concerned, that this action may be taken if the circumstances of the patient's death suggest that the kidneys might be suitable for donation.

Presumed Consent

Much of the debate around organ donation has centred on the consent needed to remove organs for transplantation after the individual's death. The main distinction made is between those countries which have an "opt-in" system - whereby individuals are asked while they are alive to register their intention to be a donor - and an "opt out" or "presumed consent" system - whereby it is assumed that the individual wished to be a donor unless, when alive, he or she had registered an objection. In practice, very few countries operate at either of these extremes and most countries have at least some scope to take account of the views of close relatives. The Belgian Law on the Procurement and Transplantation of Organs 1986, for example, which is often held up as a model for presumed consent legislation, states that donation cannot proceed if there is objection from a first degree relative or a spouse living with the donor, unless that objection is contrary to the deceased patient's stated wishes. In reality, the difference is one of emphasis rather than one of substance. In Belgium, the relatives are not asked to consent to donation but are informed of the intention and may register an objection. The wording of the UK legislation is not substantially different from the Belgian legislation, although a practice has developed in the UK whereby relatives are asked to give explicit consent, rather than being given the opportunity to object, to donation.

Assessing the success of presumed consent

Meaningful data on the success of presumed consent in other countries are difficult to achieve because this is only one of a number of factors that will influence donation rates. In addition to the form of consent required for donation, these factors include:

- ▶ the predominant cause of death (such as the number of road traffic accidents);
- ▶ the availability of ITU beds and staff;
- ▶ the number, responsibility and organisation of transplant co-ordinators;
- ▶ the number of transplant surgeons;
- ▶ the number of specialised units in the region;
- ▶ the number and characteristics of the patients on the waiting list (such as which organs they need); and
- ▶ the availability of training programmes for Intensive Care Unit staff (such as the European Donor Hospital Educational Programme (EDHEP)³⁴ and Donor Action³⁵).

Although straightforward comparison of the rates of donation between countries has shown a general tendency towards higher rates in those countries with a presumed consent system, because of the confounding factors this does not provide sufficient evidence to confirm a causal link. A comparison is often made between the transplantation rates at two centres in Belgium which have many of these factors in common: Antwerp, which retained an opt-in system accompanied by enhanced public and professional education and Leuven, which adopted the new law³⁶. The rates in Antwerp remained the same, whereas in Leuven, rates rose from 15 to 40 donors per year over a 3-year period³⁷.

Although these comparative data appear to indicate a causal relationship, this has not been proved and it is quite possible that other factors contributed to the increase. The consistently high donation rates in Spain, for example, is widely acknowledged to be a result of the new mechanism for transplant co-ordination (see page 22) rather than the introduction of a version of presumed consent.³⁸

Unless a more sophisticated analysis of the data is carried out, which controls for other factors, or more effort is put into analysing the rates in individual countries before and after the introduction of presumed consent, meaningful data will remain elusive. Even if a causal link were to be established in those countries with presumed consent, that does not necessarily mean that it would have the same effect in the UK and direct extrapolation needs to be treated with caution. Acceptance by the public and the profession is a crucial issue. In Belgium, the new legislation was introduced without public disquiet but the legislation did not represent a major change in practice. It merely formalised the existing practice of teaching hospitals throughout Belgium which, for more than 20 years, had removed organs for transplantation without explicit consent, without legal challenge.³⁹ The legislation therefore brought more openness and gave doctors a legal framework within which to work.

The Belgian system

A central registration of non-donors was established in Belgium in 1987. Citizens of all ages can express their objection to organ or tissue donation at their town hall. Parents may register objections for those who are too young to make a decision for themselves and a legal representative may register an objection on behalf of an adult who lacks the mental capacity to do so. At the end of 1995, 1.75% of the native Belgian population and 3.23% of the foreign population had registered their objections to donation. Higher levels of objections were found among young children, whose parents had “opted out” on their behalf, and the level of objections decreased with age such that only 0.5% of people over 69 years of age were on the register.⁴⁰ It is mandatory that the register is checked before any organs are removed. Although the Belgian law does not require the family to be consulted about donation, this is encouraged in practice. The lower rates of family objection, compared to the UK, may indicate that while families are reluctant to take a personal decision about the removal of organs, they find it easier in a system where failure to register an objection while alive can, legitimately, be understood as implicit consent to donation. Where donation is seen as the norm, rather than the exception and where, in the absence of evidence to the contrary, consent is presumed, grieving relatives are relieved of the burden of making the decision about donation.⁴¹

Presumed consent with safeguards

Because of the need to obtain information about the potential donor, as part of the donor screening process, it will in practice always be necessary to discuss donation with the relatives. Health care teams also have a responsibility to family members and must be sensitive to, and as far as possible not add to, their distress. A system of presumed consent, such as that which operates in Belgium, which would allow close relatives to object to donation where the individual's wishes were not known, would represent a shift of emphasis in favour of donation without major changes to practice; it would respect both the wishes of the potential donors and the sensitivities of their families. Such a system would allow organs to be removed for donation after the individual's death if:

- ▶ consent can be presumed because there is no evidence from the register, or volunteered by the family, that the individual objected to his or her body, or any specific part of the body, to be used for such purposes after death.

But:

- ▶ if the individual has not expressed any views about donation while alive but it is apparent that to proceed with the donation would cause major distress to a first degree relative or a long-term partner, the donation should not proceed.

The crucial difference would be in the approach to the relatives. Close relatives would not be asked to give permission for the organs to be used for donation. Instead, they would be informed that the individual had not registered an objection to donation while alive and, unless they object - either because they are aware of an unregistered objection by the individual or because it would cause a close relative or long-term partner major distress - the donation will proceed. Thus, donation becomes the default position.

BMA policy

The BMA at its Annual Representative Meeting in Belfast in 1999 expressed overwhelming support for the introduction of a system of presumed consent with safeguards. The BMA's reasons for supporting presumed consent are set out below.

- ▶ It is reasonable and appropriate to assume that most people would wish to act in an altruistic manner and to help others by donating their organs after death.
- ▶ Studies show that the majority of people would be willing to donate but only a small number of these are on the NHS Organ Donor Register or carry a donor card. While this level of apathy exists, people will continue to die while waiting for donor organs.
- ▶ Given that the majority of people would be willing to donate, there are good reasons for presuming consent and requiring those who object to donation to register their views.
- ▶ A shift to presumed consent would prompt more discussion within families about organ donation.
- ▶ It is more efficient and cost-effective to maintain a register of the small number who

wish to opt out of donation than of the majority who are willing to be donors.

- ▶ With such a shift, organ donation becomes the default position. This represents a more positive view of organ donation which is to be encouraged.
- ▶ Despite the acknowledged difficulties of obtaining meaningful data about the success of presumed consent in other countries, the BMA believes that, as one part of a broader strategy, a shift to presumed consent is likely to have a positive effect on donation rates.

Registration for opting out

The BMA supports a system of presumed consent, in which close relatives' views are also taken into account (see page 15), accompanied by adequate safeguards to ensure that those who do not wish to donate are given a genuine opportunity to opt out. This means that there must be extensive and high profile publicity given to the new procedures and mechanisms must be in place to ensure that all sections of the public are informed and can register their objections easily and quickly. This would need to be given careful consideration but might include, for example, individuals being able to opt out through their general practitioner - as part of the GP registration card for new patients or routine enquiries for existing patients - by inclusion on electoral registration forms, on passport applications, tax returns or by registration at a post-office.

A central computerised register of those who wish to opt out would be required along the lines of that used in Belgium. This must be properly designed and maintained to ensure that it is kept up-to-date and that effective mechanisms are in place for removing people when they die or changing an individual's details as necessary (this could be audited by checking the information contained on the register at 5-yearly intervals). It should permit people to add or remove their name at any time. The register must be quickly and easily accessible to authorised personnel in all hospitals, 24 hours a day, 365 days a year. Checking the register should be mandatory before any organs are removed and, if the individual had not registered an objection, this information should be passed on to the relatives. If a member of the close family volunteers information about an unregistered objection, the donation should not proceed.

None of the major religions represented in the UK are opposed to organ donation (Buddhist, Christian, Jehovah's Witness, Hindu, Sikh, Jewish and Muslim)⁴² although some communities are. Under Islamic Law bodies should be buried as quickly as possible after death and, for this reason, organ donation has sometimes been refused by Muslims. In 1995, however, the Muslim Law (Shariah) Council UK issued a directive supporting organ donation and transplantation. This official acceptance of organ donation, removes the need for Muslims to be considered as "presumed objectors" in any system of presumed consent, as originally suggested in the 1994 Kings Fund Institute report.

Adults lacking capacity to make decisions

Under any system of presumed consent, provision must be made for those adults who lack the capacity to make an informed decision about organ donation. This may be by facilitating individual decision making where this is possible or by the use of an authorised proxy or legal representative, as provided in the Adults With Incapacity (Scotland) Act 2000 and the Government's proposals for legal reform in England and Wales.⁴³ Recognising the spectrum of

ability of those who are broadly described as having learning difficulties or lacking mental capacity, steps should be taken to facilitate individual decision making to the greatest extent possible. It should not be assumed that all people with learning disabilities are unable to make decisions about these issues, nor should it be assumed that they would not wish to donate organs after their death. Information should be provided in a way individual patients are able to understand and to allow them the opportunity to express their own views about organ donation.

Some patients, however, either lack all capacity - because they are in a coma for example - or do not have sufficient capacity to make a decision about organ donation. In the Kings Fund Institute report, it was suggested that adults lacking mental capacity might be considered “presumed objectors” in a system of presumed consent.⁴⁴ The BMA does not support this view. The rationale behind presumed consent is that it is reasonable and appropriate to assume that most people would wish to act in an altruistic manner and to help others by donating their organs after death. Those who lack mental capacity should be given the same opportunities to perform altruistic acts and it should not be assumed that they would not wish to donate. There must, however, be established mechanisms for a proxy, or legal representative, to opt out of donation on behalf of someone who is not mentally competent to make a personal decision. Whatever type of consent system is in place for organ donation, it is essential that those who lack mental capacity must be given the same opportunities as other patients to become recipients of donated organs. Decisions must be made on the basis of clinical need and people must not be excluded because of their lack of capacity.

Children and young people

The BMA believes that the system of presumed consent should apply only to those over the age of 16. Those under that age should be given information and encouraged to opt in to organ donation and to discuss their views with their parents or others close to them. Where a child dies, the parents should be asked whether the child had expressed any views about organ donation and the parents’ own views about donation should be sought.

Public support

For any change to the system of organ donation to be successful, the support and confidence of the public and health professionals will be crucial. The BMA would like to see genuine debate and discussion around the country about the relative merits and drawbacks of the different systems. Informed debate about the issues would give society an opportunity to change its philosophy and would provide the information necessary to permit an informed judgement about the system best suited to the UK. In May 1999 the Department of Health commissioned a survey of public opinion on preferences between the status quo and a change to a system of presumed consent. Overall 50% expressed a preference for the current system, 28% supported a shift to presumed consent and 22% expressed no preference.⁴⁵ These results were, however, obtained before there had been any major publicity or debate about the benefits and workings of an opt-out system. A more recent poll carried out in Scotland found a majority of those interviewed were in favour of a change to presumed consent (50.4% in favour, 36% opposed, 10% neither actively supporting nor opposing a change and 4% did not know).⁴⁶ With further debate and information about the way such a system would operate, the BMA believes that a majority of the public throughout the UK would support a change.

Suggestions Requiring Further Consideration

Some suggestions have been put forward that the BMA is not able to support at the present time but that require further debate and consideration.

Elective ventilation of patients close to death

One suggested way of increasing the number of organs available for donation is by the use of elective ventilation.⁴⁷ There are, however, a number of both practical and ethical difficulties with elective ventilation that has led the BMA to conclude that it is not a viable option at the present time. Nevertheless, the BMA would like to see the subject kept under review and this section highlights some of the difficulties and the type of safeguards that would be needed if it were to be permitted in the future.

Elective ventilation would involve ventilating a selected group of patients, who are in deep coma and close to death with no possibility of recovery, for a short period (usually only a few hours) before death is confirmed, to preserve their organs for long enough to prepare for their removal after death. Elective ventilation was introduced in Exeter, with strict controls, in 1988 and led to a 50% increase in the number of organs suitable for transplantation but the practice was stopped abruptly in 1994 when the Department of Health declared it unlawful.⁴⁸ The law, which is designed to protect people who are not competent to make decisions for themselves, declares that procedures may only be undertaken which are necessary and intended to be in the patient's best interests; any other intervention is unlawful. The use of elective ventilation is not intended for the benefit of the patient, because there is no possibility of the individual recovering, but is undertaken, for a short period before death is confirmed, in order to enable organs to be used for the benefit of others.

Ethical and practical considerations

The primary goal of medical treatment is to benefit the patient by restoring or maintaining the patient's health as far as possible, maximising benefit and minimising harm. The BMA has stated elsewhere that "if treatment fails, or ceases, to give a net benefit to the patient ... that goal cannot be realised and the justification for providing the treatment is removed. Unless some other justification can be demonstrated, treatment that does not provide a net benefit to the patient may, ethically and legally, be withdrawn".⁴⁹ Elective ventilation does not provide a net benefit to the patient and some people, including many working in intensive therapy units, argue that it would be unethical to subject a patient, who is unable to consent, to such an invasive procedure. Others contend that elective ventilation, whilst of no direct benefit to the patient, is not contrary to the patient's interests and has the potential to benefit others.

Similar questions have been asked in relation to the use of incompetent adults for non-therapeutic research⁵⁰ and genetic testing for the benefit of others.⁵¹ When assessing these issues, considerable emphasis is, appropriately, placed on the level of risk to the incompetent patient. "Minimal risk" can, however, be understood in different ways. It can mean a procedure which might involve a small amount of pain but no serious harm to the donor - as with bone marrow donation - or a procedure which involves no pain to the donor but carries a small risk of a great harm. Elective ventilation, it could be argued, falls into the latter category since there is a theoretical risk that a patient may show signs of clinical improvement when placed on a ventilator which might lead to the patient living, but in a profound coma or persistent vegetative

state (pvs).⁵² Although the chance of this occurring is considered to be very small, the severity of this potential harm is very high.

Many hospitals would not wish to use elective ventilation even if it was lawful and for others the practical difficulties of the lack of ITU resources and staff are likely to prevent its use. It is also unclear how relatives would respond to such requests particularly once they had been informed of the theoretical possibility of inducing pvs.

Safeguards

In the past the BMA has supported, in principle, a change in the law to permit elective ventilation. Having reviewed this issue, however, the BMA has concluded that there are too many ethical and practical difficulties for a change in the law to be recommended at the present time. If elective ventilation were to be permitted at some time in the future, however, strict safeguards would be needed. Each unit would need to have a comprehensive protocol reflecting the views of all relevant groups within the hospital. The protocol should:

1. confirm that priority would *always* be given to the use of intensive care facilities for those who have a chance of recovery;
2. require a detailed explanation to be given to the family to:
 - ▶ make it clear that there is no chance of recovery;
 - ▶ inform them of the small, but unquantifiable, risk of pvs; and
 - ▶ warn them to anticipate an improvement in the appearance of the patient but assure them that this does not mean that the patient's condition has, or is likely to, improve;
3. specify that patients will be considered for elective ventilation only where those close to the patient, or a patient's advocate, gives consent;
4. restrict elective ventilation to those patients dying of spontaneous intracranial haemorrhage, diagnosed by a senior consultant with the aid of modern imaging techniques, since these patients rarely, if ever, develop pvs;⁵³
5. state that artificial ventilation must not be started until natural respiratory arrest has occurred, in order to minimise the risk of pvs;⁵⁴
6. specify a time limit, of a few hours only, for maintaining donors on ventilation; and
7. establish an effective monitoring system to ensure that the outcome of each case is carefully assessed so that the level of risk associated with elective ventilation is kept under review in the light of emerging evidence.

Living kidney exchange

Some people requiring a kidney transplant, have a relative or friend who is willing to become a live donor but is unable to do so because of ABO (blood group) incompatibility, which means that the transplant would be rejected. It has been proposed that an exchange system could be established so that a donor who is incompatible with the intended recipient could donate to another person whose own donor would provide an organ in return.⁵⁵ Whilst recognising that

such a system would increase the number of willing donors who are able to donate, the BMA believes there are potential difficulties which need to be explored fully before such a scheme could be established. The BMA does not support the introduction of such a system at the present time, but would like to see further discussion about this option.

As with any live donation, it is essential that donors are permitted to change their minds at any time before the procedure has taken place. It has been suggested that, with an exchange system, the operations should be carried out simultaneously to avoid the situation where one donor drops out but the other proceeds. If that situation occurred, one donor would go through the operation but his or her friend or relative would not receive an organ in return. This scenario highlights one of the key differences between exchange programmes and direct donation; the donation is made with the expectation of receiving some benefit in return. It is precisely this fact that renders the procedure currently unlawful in the UK under the Human Organ Transplants Act which prohibits any payment “in money or money’s worth”. Although the motivation for donation is still altruistic, there are commercial overtones that need to be carefully explored. Indeed such arrangements have been described as involving a “hidden’ type of organ sale”.⁵⁶

One of the central ethical questions is whether the risk of coercion is any greater with kidney exchange than with direct kidney donation. Some people who feel a desire or duty to donate a kidney to a relative, partner or close friend may, nonetheless, be relieved to learn that they are ineligible because of ABO incompatibility. The exchange programme would eliminate this basis for not proceeding and could, potentially, make it more difficult for potential donors to say no. Advocates of the exchange system have identified this risk and have argued that potential donors must, at each stage, be given the opportunity to withdraw without any pressure to disclose the reason.⁵⁷

It is also unclear what the level of benefit would be from introducing such a scheme. There have been conflicting reports about the number of people in need of donation who could benefit from such an exchange based on the ability to identify sufficient numbers of suitable matched pairs.⁵⁸ One suggestion for overcoming this difficulty, is the development of an international registry of donors in order to identify compatible pairs for exchange⁵⁹ although there could be difficulties with co-ordinating the exchange of organs between countries. Another option would be to establish a pooling system whereby an ABO incompatible donor would donate an organ into a pool thus giving his or her relative or friend priority for the next suitable organ available. In the latter case, although the relative or friend would be given a higher priority for treatment, there is no guarantee that a suitable organ will become available and thus the benefit is less direct.

The BMA has some sympathy with the view that “the continued elimination of so many physically eligible and willing volunteer kidney donors on the basis of immunologic grounds is no longer acceptable, in view of the current acute need for organs”,⁶⁰ but believes that concerns about coercion and commercialisation need to be resolved before a change in the law is recommended to permit live kidney exchange.

Other Suggestions Rejected by the BMA

Organ donation is a subject of frequent debate in the media and in the academic literature. A number of other suggested ways of increasing the number of organs available for donation have been considered by the BMA but rejected. These are not considered in detail here but are listed

below with references for those who wish to consider them in more detail.

- ▶ The offer of payment or other incentives to live donors.⁶¹
- ▶ Bodies become automatically available for donation and organs may be used regardless of the individual's wishes.⁶²
- ▶ Mandated choice whereby every adult must decide and register their views about organ donation.⁶³
- ▶ Required request whereby doctors are required to ask all relatives of potential donors about donation.⁶⁴
- ▶ Conditional donations whereby individuals may choose to donate only to a recipient from a particular ethnic origin or religion. The BMA strongly supports the Government's view that hospitals should not accept organs offered on a conditional basis.⁶⁵

Part Three

Improving Co-ordination and the Infrastructure

National Co-ordination

The transplant process is long and complex involving at least six separate stages:⁶⁶

1. Donor identification: to identify all potential donors at as early a stage as possible.
2. Donor screening: to exclude those donors where there is a risk of transmitting a serious disease.
3. Donor management: to ensure that the organs are maintained in good condition prior to retrieval.
4. Consent/authorisation: to comply with the legal requirements before organs can be removed.
5. Organ retrieval: the removal of organs from the body and their preservation and transport to the recipient hospital.
6. Organ allocation: the allocation of organs, including matching between donor and recipient.

The Spanish model

Good co-ordination is central to the success of any transplant programme as has been demonstrated by the Spanish experience. In 1989, Spain established a national transplantation organisation, Organización Nacional de Trasplantes (ONT), the main purpose of which was to improve organ donation rates. This led to the establishment of a nationwide transplantation co-ordination system, with regional co-ordinators in each of the 17 regions and a co-ordinator at every hospital. Whilst many lessons can be learnt from the Spanish experience, as with presumed consent, direct comparisons need to be treated cautiously, and the Spanish model would need to be modified in order to be acceptable and effective in the UK situation. A variation on the Spanish model has proved very effective, however, in South Australia where the rate of donors increased to 19.6 donors per million population in 1999 compared with a national average of 8.6.⁶⁷

A National Transplant Service

The Royal College of Surgeons⁶⁸ has recommended the establishment of a National Transplant Service for the UK in order to ensure that organ donation and transplantation is viewed as a national service rather than being governed and operated at a local level. The proposed new Service, to work with established regional structures, would take over the existing work of the UK Transplant Support Service Authority (UKTSSA) and, in addition, would take on responsibility for:

- ▶ a national strategy for the delivery of transplant services;
- ▶ designation of transplant units;
- ▶ evaluation and maintenance of standards;
- ▶ organisation of multi-organ retrieval;
- ▶ recruitment, training and administration of donor transplant co-ordinators;

- ▶ development of initiatives to increase cadaveric donors;
- ▶ development of patient protocols;
- ▶ encouragement and facilitation of multi-centre trials;
- ▶ independent audit and the determination of policies concerning practice;
- ▶ co-ordination of education and publicity; and
- ▶ national representation.

The BMA supports this proposal and is disappointed that the Department of Health's review of the activities of the UKTSSA⁶⁹ dismissed this as a serious option.

Local Co-ordination

In addition to national co-ordination, it is also crucial that a network of trained local co-ordinators is in place to ensure that the procedure runs smoothly and that the maximum number of organs are retrieved for transplantation. The Council of Europe has recommended the appointment of a "key donation person" in every acute hospital who may, but need not necessarily, be the local transplant co-ordinator. This person would be responsible for:

- ▶ establishing, managing and auditing systems for donor identification and identifying potential areas for improvement;
- ▶ ensuring appropriate donor management and identifying and overcoming any problems; and
- ▶ making the arrangements for organ retrieval, alerting the transplant centres to a possible donation, providing information necessary for the identification of the most appropriate recipient and ensuring packaging and transport is available to take the organs to the recipient hospital.

Part of this role is undertaken, in the UK, by "link nurses". This system was established in Sheffield in 1992 and has now been extended throughout the country. In most ITUs and, increasingly, in theatres, general wards and accident and emergency departments, one or more of the nurses is identified as having a special interest in organ donation. These nurses attend courses and meetings and are provided with educational material and donation protocols; they act as the main point of contact between the treating team and the transplant team. Their role, as link nurses, is to ensure that organ donation is considered in appropriate cases, and to act as an information resource to the rest of the team.

Routine referral

Timely and routine referral is crucial to the overall success of any organ donation service. For example, in 24.4% of potential donors (797 patients), in the audit referred to on page 5, brain stem tests were not carried out. There may be good reasons why the test was not appropriate in each of these cases, for example there may have been clear contra-indications to donation, but it is also possible that at least some of them would have provided suitable organs for donation. The establishment of a system whereby staff routinely consider the possibility of organ donation in all deaths and imminent deaths in ITU could help to reduce the loss of potential donors. The establishment and use of protocols in each unit, setting out the criteria for donation and the contact details of the transplant co-ordinator, could help to facilitate a change of practice so that it becomes the norm for organ donation to be considered.

Since August 1998 Federal Regulations have required all Medicare certified hospitals in the United States to contact their local Organ Procurement Organization (OPO) about all individuals who die or whose death is imminent in the hospital.⁷⁰ This applies to all patients regardless of their age or medical history. The OPO will then determine the individual's suitability for donation. The introduction of these Regulations followed the success of the same provisions in Pennsylvania Act 102 which was implemented in 1995. As with other initiatives, the introduction of the routine referral system in Pennsylvania was accompanied by training and education and so a direct causal link is difficult to establish, but following its introduction, the number of medically suitable referrals increased by 25% and the number of organ donors increased by 24%.⁷¹ The early indications, however, are that the introduction of the Federal Regulations has not had a significant impact on the number of organs available for donation throughout the United States.⁷²

The BMA does not support legislation on routine, or required, referral but would like to see local protocols developed and regularly referred to so that all suitable deaths are referred to the transplant co-ordinator. The Intensive Care Society has produced a manual on the establishment of local guidelines⁷³ which includes the recommendation that any patients who meet the following criteria should be considered for organ donation:

- ▶ age 0-75 years;
- ▶ has suffered complete and irreversible brain stem damage resulting in brain stem death;
- ▶ is maintained on a ventilator;
- ▶ has no malignancy (except certain primary brain tumour);
- ▶ has no major systemic sepsis;
- ▶ has no known social or medical high risk factors for HIV.

The BMA hopes that local protocols will be developed and used in all units.

Screening criteria

Some potential donors will always be lost because they fall outside the screening criteria established by the Department of Health.⁷⁴ Although it is clearly important to have stringent controls to avoid the transfer of disease, the current list of contraindications for donation, which is based on the contraindications for donating blood, may be too restrictive. Automatically excluding from donation, for example, people who have lived in Africa in the past and all men who have ever had sex with another man, when diagnostic tests are carried out before transplantation to test for HIV, may be unfairly denying patients on the waiting list the option of a transplant. Although there may be a residual chance that the patient was in the window period before seroconversion when he or she died, many people urgently needing a transplant would be willing to accept that small risk. The potential recipient must, of course, be made aware of the residual risk and be given the choice of whether to proceed or wait for another donor. The BMA believes that consideration should be given to whether there are grounds for making the list of exclusions less restrictive.

Maintaining the viability of donor organs

Another crucial area for maximising the number of potential donors who donate, which often falls within the responsibility of the nursing staff, is adequate "donor management" after death

has been confirmed by brain stem tests. This includes attempts to ensure adequate fluid intake, electrolyte balance, normal blood pressure, the monitoring of urine output by catheter collection and the use of other therapeutic agents;⁷⁵ this is a crucial part of the transplant procedure and it is important that specific education and training is provided. The role of the transplant co-ordinator, and the treating team, in donor management is central to the success of the transplant service. The 1999 report from the Council of Europe identified donor management as one of the key stages of a successful transplant programme, stating:

”After completing brain death certification, obtaining appropriate consent; fulfilling legal requirements ... and organising the retrieval procedure ... it is necessary to maintain the potential donor in a medical condition which will maximise the viability of the organs. Depending on time necessary to complete the above processes, donor management may be critical over a period of 24 hours or more during which time the donor’s condition could deteriorate sufficiently to prevent the use of some or all of the organs. Prevention of severe sepsis, maintenance of haemodynamic stability and avoidance of cardiac arrest are examples of good donor management”.⁷⁶

Transplant co-ordinators

Transplant co-ordinators are crucial to the success of the transplant service yet their role has developed, in an ad hoc fashion, over the last twenty years in response to local needs. There are no nationally agreed education and training requirements, job descriptions or any formal career structure. The UK Transplant Co-ordinators’ Association has called for a national body to be established with responsibility for developing national standards for continuing education and training and to ensure consistency in the quality of service delivery across the country.⁷⁷ The Royal College of Surgeons has also recommended that all transplant co-ordinators should be employed, recruited and trained by the proposed National Transplant Service (see page 22) and have a common career structure, salary scales, job description and standards of practice. An expansion of their number, working to nationally agreed standards and responsibilities, could have a major effect on donation rates. The Royal College of Surgeons’ report called for a *minimum* of one full-time donor co-ordinator per million of the population covered by the regional service and for on-call rotas for transplant co-ordinators to be no more onerous than 1:4.⁷⁸ The UKTCA believes that a higher number of co-ordinators will be needed and is undertaking a detailed analysis to establish a more appropriate target⁷⁹.

The introduction and expansion of the link nurse system is a positive step since better co-ordination between hospital staff and transplant teams is likely to increase the effectiveness of the organ donation programme. In Spain and South Australia, part-time hospital co-ordinators work for the remainder of their time in the ITU or in renal units, ensuring an integrated approach. Such an arrangement in the UK, however, would break the tradition of ensuring a clear separation between treating staff and transplant staff and could raise fears about the motivations of those providing treatment. Whilst it is important to maintain this distinction, between the ITU staff and the transplant team, it is, nevertheless, important for treating staff to be aware of the procedures for identifying possible donors and to be aware of the appropriate steps to take when potential donors are identified. The link nurse programme provides this liaison between the transplant co-ordinators and the treating staff. The use of detailed written protocols and the provision of specific, on-going training for health professionals who are not part of the transplant team would also help to achieve this goal.

The hospital co-ordinators in Spain are given detailed guidance about their approach to families. Their role is not merely to seek the relatives' views about donation but, explicitly, to try to persuade the relatives to allow organs to be used for transplantation. The interview with relatives is carefully structured and planned. It stresses the arguments in favour of organ donation, emphasising first the interest of the donor (the generous nature of donation) moving on to the importance for the group (encouraging group solidarity) and finally emphasising the social interest (the waiting list and the need for donors). A list of ten reasons are given explaining why relatives commonly object to organ donation and for each of these counter-arguments are provided to try to overcome the family's objection.⁸⁰ Whilst a more consistently positive approach to organ donation should be encouraged (which would tie in with a system of presumed consent), the BMA would not condone the use of any pressure by those approaching relatives. The proposed National Transplant Service, in conjunction with other relevant professional bodies, should be responsible for developing a detailed protocol and ongoing training for discussion with relatives.

The hospital co-ordinators in Spain are paid on a sessional basis for the work they undertake. This means that in centres where there are a large number of donors, the hospital co-ordinators are paid more than in smaller units. This has been interpreted by some as a system of "bonus payments" depending upon the number of organs they manage to achieve for donation⁸¹ but is, in fact, designed to pay for the extra work undertaken rather than acting as an incentive.

Spain has achieved consistently high donation rates and this is usually attributed to the introduction of the ONT, and specifically to the system of co-ordination. As with presumed consent, however (see page 13), care needs to be taken about direct extrapolation between countries because of the large number of confounding factors. There are some aspects of the Spanish model that would not be appropriate for the UK. Certain parts of that system, however, such as the emphasis placed on the role, training and organisation of the transplant co-ordinators, could usefully be incorporated into a new "UK model".

Improving the Infrastructure

The Royal College of Surgeons has undertaken a detailed review of the current organ transplantation system in the UK and has made a number of practical suggestions for improving the infrastructure to enable the system more effectively to meet the increasing demands made upon it.⁸² In addition to methods for achieving improved national and local co-ordination, the report also recommended:

- ▶ that action is taken to overcome the current shortage of transplant surgeons by changes to current training and staffing arrangements;
- ▶ the development of consultant-led multi-organ retrieval teams working in zones;
- ▶ improved support and reimbursement for donor hospitals; and
- ▶ the establishment of courses along the lines of the European Donor Hospital Educational Programme (EDHEP).

The BMA supports these proposed changes.

The number and use of critical care beds in the United Kingdom has been the subject of recent

review and action has been promised by the Government to ensure that, in the future, critical care services are better able to cope with increasing pressures.⁸³ The BMA welcomes this development, primarily for the benefits it will bring to those who have a chance of recovery but also, as a knock-on effect, the possibility that more facilities will become available for transplantation.

Developing a “UK Model”

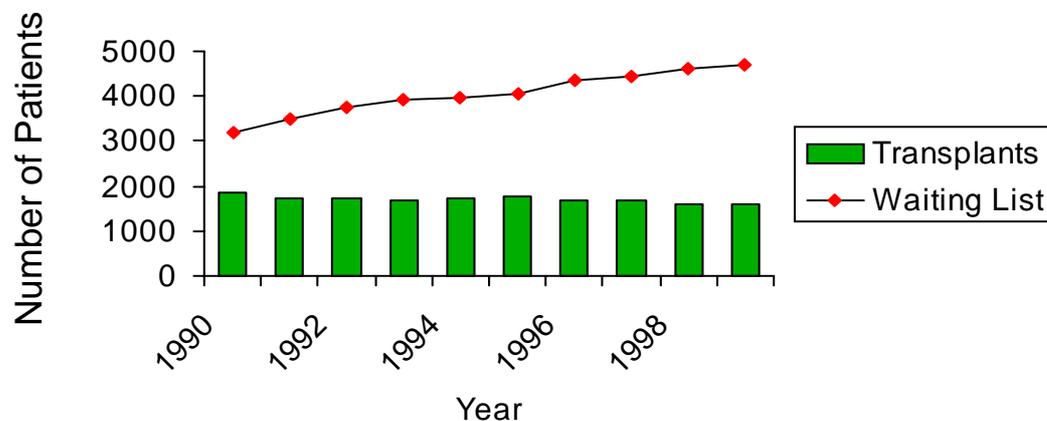
The major challenge is to develop a “UK model” for organ donation in the 21st century. This is not simply a matter of importing the procedures that appear to work in other countries. It is about building on existing good practice in the UK and learning from experiences overseas - modifying some aspects and rejecting others - in order to develop a model that suits the particular demands, challenges and structure of organ donation in the UK.

Part Four

A Consolidated Approach

Each year many people die waiting for an organ transplant. At the same time, bodies are buried or cremated complete with organs that could have been used to save lives, not because the deceased objected to donation but simply because they never got around to carrying a donor card or informing their relatives of their wishes. This is not a new problem. The gap between the number of people waiting for a transplant and the number of organs available for donation has been steadily increasing over the last decade, as illustrated by the graph below.

The number of patients on the active kidney waiting list and the number of patients who have had kidney transplants (cadaveric and live) in the UK



Graph reproduced with kind permission of the UKTSSA

By doing nothing, we allow this situation to continue and more people will die unnecessarily. Or, at the beginning of the new millennium, we can take positive action to reverse that trend.

The BMA invites other organisations to join it in campaigning for change. The shortage of organs for donation in the UK is a serious problem requiring serious action. The Government's response to-date has been piece-meal with a series of reviews recommending minor changes to the existing system. This "tinkering at the edges" will not and cannot solve the problems. A radical review of the whole system is urgently needed. Building on experience in the UK and other countries, we must develop a modern, efficient and effective service for the twenty-first century. The BMA recognises the dedication of those working within the transplant service and the difficulties they face because of the severe shortage of organ donors and pressures on the system. The responsibility for addressing these problems does not rest solely with the transplant community but is a matter for society as a whole.

Some of the changes proposed in this paper are likely to be controversial and need to be debated thoroughly before being implemented. Recognising the risk of alienating some sections

of the public by appearing to move too quickly, the BMA nonetheless considers that there are good arguments for seeking change. Furthermore, it believes that with careful explanation, these proposals will win the support and backing of a majority of health professionals and the public. The BMA hopes that those organisations with an interest in organ donation and transplantation will work together, with the media, to present information in a clear, sensible and balanced way to gain support for a radical review of the organ donation system.

The BMA would like to see a thorough review of the existing legislation and some changes to the existing organisational structure and established practice. In particular, we are calling for:

1. The introduction of a single, comprehensive, piece of legislation covering all aspects of organ donation - from both live and cadaveric donors:
 - ▶ to provide a clear and unambiguous framework within which organ donation may take place;
 - ▶ requiring that the most up to date guidelines are followed in determining death by brain stem tests before organs are removed;
 - ▶ to remove the distinction between related and unrelated live altruistic donors. All live donations should be subject to the same rigorous assessment, either by ULTRA or some other mechanism, to ensure that the potential donor is acting voluntarily and free from pressure;
 - ▶ to give legal authorisation to the use of invasive procedures, after death, to protect organs in the period leading up to the transplant in order to facilitate greater use of non-heartbeating donors; and
 - ▶ to introduce a system of presumed consent, with safeguards, for adults which allows doctors the discretion not to proceed if the potential donor's wishes are not known and it is clear that the donation would cause major distress to a first degree relative or long-term partner.
2. Changes to the organisational structure of the organ donation programme, including:
 - ▶ the development of a 24-hour 7-day-a-week telephone helpline to answer any questions related to organ donation from journalists, health professionals or the general public;
 - ▶ the development of a National Transplant Service to take over and expand on the work of the UK Transplant Support Service Authority;
 - ▶ consideration to be given to whether there are grounds for making the list of criteria for exclusion of donors less restrictive;
 - ▶ the development of an expanded network of organ donor co-ordinators, employed and trained by the National Transplant Service.
 - ▶ changes to current training and staffing arrangements to overcome the shortage of transplant surgeons;

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- ▶ the development of consultant-led multi-organ retrieval teams working in zones and improved support and reimbursement for donor hospitals, as recommended by the Royal College of Surgeons;
 - ▶ the establishment of additional critical care beds;
 - ▶ the establishment of training courses along the lines of the European Donor Hospital Educational Programme (EDHEP); and
 - ▶ the development of a “UK model” for organ donation building on existing good practice in the UK and borrowing, where appropriate, from practices overseas modified as necessary to suit the UK situation.
3. Changes to the established practice of organ donation, so that:
- ▶ the organ donor register is routinely consulted by the transplant co-ordinator when potential donors are identified in order to ascertain the potential donor’s expressed wishes before any approach is made to the family;
 - ▶ wherever possible, the death certificate is issued to the family before organs are removed for transplantation;
 - ▶ the term “brain stem death” is replaced with “death confirmed by brain stem tests”; and
 - ▶ the establishment and use of protocols in each unit, setting out the criteria for donation, so that it becomes the norm to consider organ donation and all suitable deaths are referred to the transplant co-ordinator.

Additional resources will be needed to fund these changes, both in terms of developing the infrastructure and resources to fund the increasing number of organ transplant operations which could be undertaken. Although in theory a proportion of this could be offset by a reduction in the costs of caring for those awaiting donations, in reality there will be others waiting to make use of the resources freed up. The BMA therefore believes that additional funding is needed in order to maximise the number of lives that can be saved.

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