1994

RESEARCH
REPORT
18

A Question of Give and Take

Improving the supply of donor organs for transplantation

Bill New, Michael Solomon
Robert Dingwall, Jean McHale

King's Fund Institute

The University of Nottingham

No 18 in a series of research reports on current health policy issues

A Question of Give and Take
Improving the supply of donor organs for transplantation

Bill New, Michael Solomon
King's Fund Institute

Robert Dingwall, Jean McHale
University of Nottingham

ISBN 1 870607 35 X

Published by the King's Fund Institute
14 Palace Court, London W2 4HT

Design & print by Intertype

Contents

Boxes

Figures

Tables

Acknowledgements

A large number of people made this report possible, and contributed to improving its quality during drafting. Dr Roger Williams, Director of the Institute for Liver Studies at King's Medical School, initiated the project and provided invaluable encouragement and advice throughout the lifetime of the project. Particular thanks should also go to Stephen Brown, who provided essential research assistance during the early stages, and Karen Ho who managed the arrangements for a national conference which discussed many of the issues analysed in this report.

The arrangements for the conference were expertly guided by a steering group consisting of Professor Stuart Cameron, Ken Judge, Robert Maxwell, Dr Richard Thompson and Dr Roger Williams, all of whom also commented extensively on various drafts of this report.

The conference itself was held on 22 March 1993 and focused on ways of improving the supply of cadaveric donation. Interim findings from the King's Fund Institute/University of Nottingham research were presented by the authors, but the success of the day was ensured by an eminent group of speakers from the transplant community and academia: Professor Sir Roy Calne, Alison Crombie, Professor John Harris, Dr David Lamb, Professor Paul Michielsen, Hany Riad, Professor John Salaman, Robert Sells, Elizabeth Ward, James Wellbeloved and Dr Roger Williams. The conference was chaired by Robert Maxwell and Professor Albert Weale. Many thanks to all these individuals, many of whom also gave up much of their time to comment on this report.

Many others, in one way or another, provided the authors with information, comments, guidance, support and encouragement. Particular thanks go to: Dr Jan de Boer, Dr Bernard Cohen, Susie Gabbay, Dr Sheila Gore, Professor Arnt Jakobsen, Bill Kent, Melvin Madsen, Professor Ken Mason, Dr Guido Persijn, Rabbi Nisson E Shulman, Ann Sommerville, Julia Warren and colleagues at the UKTSSA, and Celia Wight.

Finally, material from the Omnibus Survey was made available through the Office of Population Censuses and Surveys and was used by permission of the Controller of Her Majesty's Stationery Office.

The authors

Bill New is a Senior Research Officer at the King's Fund Institute which he joined in 1988. His publications include *Too Many Cooks? The response of the emergency services to major incidents in London* and, co-authored with Anthony Harrison, annual reviews of health policy in *Contemporary Britain* and *The Public Services Yearbook.* He is currently studying for a PhD on issues relating to the rationing of health care.

Michael Solomon has been a Research Officer at the King's Fund Institute since 1991. His work has been in the areas of population health and public attitudes to health policy issues. His publications include *The Health Status of Londoners: A comparative perspective,* with Michaela Benzeval and Ken Judge, and a number of articles on public opinion and the NHS.

Robert Dingwall has been Professor and head of the School of Social Studies at the University of Nottingham since he moved from the Centre for Socio-Legal Studies at the University of Oxford in 1990. He has written on a wide variety of topics in health, social welfare and legal studies, including the training of health visitors, the young disabled, decision-making in child abuse, divorce conciliation, the history of nursing, asbestos disease litigation and medical negligence.

Jean McHale is a Lecturer in Law at the University of Manchester where she moved from the University of Nottingham in 1993. She has a particular interest in medico-legal issues. She has written a number of articles in this area and is the author of *Medical Confidentiality and Legal Privilege.*

Sources

Data in this report were collected directly from countries' organ donation registries, bodies which often undertake a host of other functions relating to organ procurement, allocation and research. Many thanks are due to all those who helped with supplying the international data. The title and location of the agencies for each of the countries included in the analysis is as follows:

Austria Belgium Germany Luxembourg Netherlands	**The Eurotransplant Foundation, University Hospital, Leiden, Netherlands**
Denmark Finland Norway Sweden	**Scandiatransplant, Department of Clinical Immunology, University Hospital of Aarhus, Skejby Sygehus, DK-8200 Aarhus N, Denmark**
Australia	**Australian Co-ordinating Committee on Organ Registries and Donation (ACCORD), Level 7, 73 Miller Street, North Sydney, New South Wales 2060, Australia**
Canada	**The Hospital Medical Records Institute, 250 Ferrand Drive, Box 3900, Don Mills, Ontario, M3C 2T9, Canada**
France	**France Transplant, Hopital Saint-Louis, 1 Avenue Claude Vellefaux, 75475 Paris, France**
Greece	**Hellenic Transplant Service, contact: National General Hospital 'Evangelismos', Ipsilandou 45-47, Athens 106 76, Greece**
Italy	**Nord Italia Transplant, Transplantation, Immunology and Blood Transfusion Service, Ospedale Maggiore Policlinico, via F. Sforza 35, Milano 20122, Italy**
New Zealand	**Anzdata Registry, Green Lane/National Women's Hospital, Green Lane West, Aukland 3, New Zealand**
Portugal	**Centro De Histocompatibilidade Do Sul, Campo Desantana 130, 1100 Lisboa, Portugal**
Spain	**Organizacion Nacional de Trasplantes, Central Organ Exchange Co-ordination Office, Sinesio Delgado 8, 28029 Madrid, Spain**
Switzerland	**Swiss Transplant, 24 rue Micheli-du-Crest, 1211 Geneve 14, Switzerland**
United Kingdom	**United Kingdom Transplant Support Service Authority (UKTSSA), Southmead Hospital, Southmead Road, Bristol, BS10 5ND**
United States	**United Network for Organ Sharing (UNOS), 110 Boulders Parkway, Suite 500, PO Box 13770, Richmond, Virginia 23225-8770, USA**

Summary

Transplanting organs from one human to another is increasingly constrained by a shortage of donors. The world-wide rate of kidney and heart transplantation has now reached a plateau, whilst the number of those waiting increases steadily. Although this phenomenon affects all the developed countries which utilise transplant technologies, there exist extremely wide variations between countries in the rate at which transplant activity takes place. These variations have been viewed by researchers as indicating that the UK could significantly improve its performance.

International comparisons need to be made with caution, however. One of the factors which constrains the supply of cadaveric donation is the number of individuals who die in 'appropriate' ways. Cadaveric organ donors will typically have suffered some form of catastrophic intracranial trauma, either as a result of a road accident or internal haemorrhaging. These mortality rates vary from region to region and country to country, and there is evidence that relevant mortality rates are positively correlated with donation rates. At least some of the variation between countries is therefore beyond the influence of the health service community.

Nevertheless, there is undoubtedly room for improvement in the UK. A two-year national audit of all deaths in English Intensive Care Units (ICUs) found that 30 per cent of those who were asked refused permission to donate the organs of the dead relative. This outcome is in part a consequence of the legal framework for donation in this country, colloquially known as an 'opting-in' system. Unless an individual has explicitly expressed a wish to donate, by carrying a donor card for example, the relatives must consent at the time of death. In practice, relatives are consulted in any case.

Reducing the impact of relatives' refusal is a key goal for improving the supply, and to this end some countries have adopted a different legal framework – 'opting-out' or 'presumed consent' – which allows the removal of organs without the consent of relatives. However, the medical profession and transplant community in the UK are split over the ethics and practicality of such a change. Public opinion is also divided. There is a danger that, by provoking acrimonious public debate, its immediate implementation in the UK might damage the reputation of organ transplantation more generally.

However, there are other reasons why potentially suitable donors may not donate organs. The national audit referred to above only considered those who died in ICUs. Other studies have found that many of those who die on general wards might be suitable, but because they are not ventilated in an ICU, the relevant tests are not undertaken. Clinicians in Exeter have developed a protocol for 'electively ventilating' those patients who would otherwise have died on general wards so that their organs become available.

An alternative source of kidneys is the live donor. In the UK a very small proportion of kidney transplants are from living donors, amounting to 1.5 per million population. Norway, for example, undertakes ten times that rate. The reasons for this relatively low level in the UK are manifold, but the outcome is that relatives are not routinely informed of the possibility of live donation and, indeed, there is no central guidance to clinicians on how this matter should be approached.

Conclusions

Methods to reduce the rate of relatives' refusal by voluntary means do not offer scope for significant improvement over current levels of donation.

Presumed consent legislation is not recommended for immediate implementation due to a lack of consensus among the transplant community on the ethics and practicality of the policy, and the impact public disagreement could have on the standing of the transplant technology.

Elective ventilation has provided initial evidence of a substantial impact on donation rates; implementation of this procedure is recommended if legal and ethical questions relating to the interests of the potential donor can be resolved.

There is substantial scope for improving kidney donation rates from live donors, but carefully formulated guidance will be essential if this opportunity is to be taken without falling into unethical practices.

Notwithstanding these initiatives, it is extremely unlikely that the supply of human organs will ever be sufficient to eliminate waiting lists. Medical advance offers the prospect of animal organs eventually replacing those of humans, but in the meantime, available organs will need to be allocated fairly.

Improved data collection and a more open discussion of allocation practices is necessary if organs are to be allocated in a socially just manner.

Introduction – the problem

1

The transplanting of organs from one human to another is a medical intervention which fifty years ago would have seemed a suitable topic for a science fiction novel. And yet, in the 1990s, kidney transplants are the treatment of choice for end stage renal disease, and heart and liver transplants offer the only chance of life for thousands of people across the world with chronic heart or liver failure. It is an operation which attracts intense media attention, particularly when children's lives are at stake. However, the reason for such attention is often particularly poignant, involving a race against time for a suitable donor.

Transplant activity is increasingly constrained by the shortage of organs, a phenomenon affecting every country which has developed the ability to undertake this form of surgery. Quite possibly uniquely, doctors and surgeons are prevented from alleviating suffering and avoiding death by the shortage of a particular physical resource – a human organ. Until medical science learns to replicate human tissue or replace organs with those from animals, the problem will remain: how can we maximise the supply of these organs by organisational or legal reforms without offending ethical principles?

Focus of the analysis

The focus of this report is on the supply of organs which, in the developed world at least, predominantly come from deceased, or 'cadaveric', donors who have been artificially ventilated in an Intensive Care Unit (ICU). Typically these individuals would have suffered some form of massive head trauma resulting in admission to ICU for diagnosis and treatment. Organ donation is only considered when recovery is impossible.

The principal organs concerned are the kidney, heart, liver and lung. Others, such as the pancreas, are also transplanted but in relatively small numbers. These are the so-called 'solid' organs: they are non-regenerative and are generally transplanted whole. Other organs and human tissue present somewhat different issues. The cornea has its own procurement system involving an 'eye bank' in Bristol which can store corneas for up to thirty days (Armitage *et al.*, 1990). They can be retrieved by non-medically qualified personnel under the Corneal Tissue Act 1986 and the vast majority of corneas come from donors who do not provide solid organs, since the donors do not need to be ventilated (UKTSSA, 1992). Regenerative tissue, such as blood or bone marrow, come exclusively from live donors. Issues surrounding these forms of transplantation will not be analysed in this report.

Solid organ donors, on the other hand, are almost always artificially ventilated, a process which preserves the organs until such time as the organ retrieval arrangements can be implemented. Artificial ventilation involves pumping air into the lungs, enabling the heart to continue beating. For this reason such donors are sometimes known as 'beating heart' donors. Whilst ventilated, a number of tests are undertaken on the patient, who is not yet considered a potential donor, to ascertain whether there is any hope of recovery. If the relevant criteria are satisfied – see Box 1 – then the individual is described as 'brain stem dead': the brain is no longer capable of sending or receiving the relevant neurological information via the brain stem, and recovery is impossible. Organ donation can now be considered.

'Brain stem death' is, in fact, the clearest point of death, more so than the cessation of cardiac or ventilatory function which can in some circumstances be reversed. The concept and diagnosis of brain stem death is central to cadaveric donation, and to intensive care in general, but it is one which is often difficult for the general public to understand, although it is no longer controversial among the medical profession. It is perhaps unfortunate that the terminology appears to imply that this is a 'special' form of death rather than simply its clearest manifestation.

Not all organs must come from a ventilated, beating-heart donor. For a limited period after cessation of the heart beat, kidneys can be donated from individuals who die without having been ventilated. Such donors are known as asystolic or 'non-heart beating' donors. Furthermore, kidneys, and less commonly sections of the liver and pancreas, can be donated from living individuals. In developed countries these procedures supplement cadaveric donation but do not provide the majority of organs.

This report will focus on what might broadly be termed the 'social' issues constraining the supply of organ donors. It is the organisational, legal and ethical issues which form the basis of the analysis and our recommendations. The report will not, by and large, investigate the medical or technical difficulties involved in procuring and transplanting organs. These differ in complex ways between the organs in question, and we cannot

1

BRAIN STEM DEATH

With the development of intensive care techniques it became increasingly common for ICUs to have deeply comatose and unresponsive patients with severe brain damage, maintained on artificial respiration by means of mechanical ventilators. It was clear that for many of these patients, even with a beating heart and functioning internal organs, there was absolutely no chance of regaining consciousness. Furthermore, the artificial ventilation could not be continued indefinitely – after a period the organs would deteriorate as a result of the absence of certain brain functions. The concern of medical practitioners was to develop sufficiently robust criteria for establishing no possible chance of recovery such that, upon their fulfilment, the ventilator could be switched off, thus sparing relatives prolonged emotional stress.

These criteria were developed during the 1960s, most significantly by the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death. Their report was published in 1968, and the 'Harvard criteria' for brain death gained world-wide recognition (Ad Hoc Committee, 1968). In the UK, criteria were formally accepted by the medical profession somewhat later, with the publication in the *British Medical Journal* and the *Lancet* of a statement from the Conference of Medical Royal Colleges and Faculties of the UK (1976). Subsequently the DHSS published a code of practice for the removal of cadaveric organs which included brain stem death criteria (the term 'stem' tends to be added in this country, although for the purposes of this report the concept is essentially the same). A revised version of the guidance still applies (Working Party on behalf of the Health Departments of Great Britain and Northern Ireland, 1983).

The Royal Colleges' statement identified three general conditions which have to be satisfied before brain stem death testing can be considered: the patient is deeply comatose, the patient is maintained on a ventilator because spontaneous respiration is inadequate, and there is no doubt that the condition of the patient is due to irremediable structural brain damage. If these conditions are satisfied then the following diagnostic tests for brain stem death should be undertaken:

- The pupils are fixed in diameter and do not respond to sharp changes in the intensity of incident light.
- There is no corneal reflex.
- The vestibulo-ocular reflexes are absent (a test involving injecting ice-cold water into the ear and observing eye movement).
- No motor responses within the cranial nerve distribution can be elicited by adequate stimulation of any somatic area.
- There is no gag reflex or reflex response to bronchial stimulation by a suction catheter passed down the trachea.
- No respiratory movements occur when the patient is disconnected from the mechanical ventilator for long enough to ensure that the arterial carbon dioxide tension rises above the threshold for the stimulation of respiration.

A further memorandum from the Royal Colleges in 1979 made it clear that they considered that these criteria established death, and not just a stage on an irreversible process toward death (Conference of Medical Royal Colleges and their Faculties in the UK, 1979). In fact they stated that these criteria established the clearest point of death, in contrast to the traditional cessation of the heart beat, which can often be reversed through resuscitation, for example. The last test outlined above clearly indicates how brain stem death differs from persistent vegetative state, during which respiration can continue, seemingly indefinitely, without the aid of a ventilator, and without the patient regaining consciousness.

Although these criteria were not 'invented' by the transplant community they were refined at a time of increasing transplant activity. Hearts and whole livers in particular can only be taken from the ventilated 'heart beating' donor, and although kidneys can be removed from an asystolic or non-heart beating donor the condition of the organ is likely to be better in the former case. It is not entirely coincidental that the Harvard criteria were first published in 1968 – a very busy early heart transplant year. The relative slowness of the criteria's adoption in the UK is one reason why heart and liver transplants lagged behind kidneys, other reasons being their cost and relative complexity (Jennett, 1991).

The suspicion that there was an 'ulterior' motive for developing the criteria resulted in some controversy. The consensus articulated by the Royal Colleges' statement was challenged by a small group of doctors who objected to death being defined as brain stem death (Evans and Lum, 1980). Their objection was followed by a now notorious Panorama television programme transmitted in October 1980 on the BBC: 'Transplants – Are the Donors Really Dead?', which caused a sharp reduction in the number of donors in the following months.

These controversies are now largely in the past. Denmark, one of the last countries in the world to accept brain stem death criteria, did so finally in June 1990 (Gabel, 1991). Only countries such as Japan, with strong cultural or religious objections, have continued to resist their adoption (Nudeshima, 1991), although the indications are that Japan will soon adopt a law bringing it into line with the international consensus. Many others have incorporated brain stem death into legal statute. Nevertheless, anecdotal evidence still suggests that members of the public find the criteria hard to understand and leave them suspicious that the medical profession might be encouraged to certify death and remove organs prematurely. The challenge remains to convince the lay population that brain stem death is, in fact, no different from death as commonly understood.

hope to contribute to the technological debate. However, one organ, the kidney, will be referred to more commonly than the others for a number of reasons.

First, kidney transplantation is the longest established and most widely practised of the transplant operations. As a consequence, the international data are the most complete and the most reliably available. Second, although it is the number of individual donors which is the key variable, such data are not readily available in a wide variety of countries over a long period of time. But, by the end of the 1980s, over 95 per cent of donors had suitable kidneys, and a similar proportion of these kidneys were transplanted (Gore *et al.*, 1992b; Cohen and Persijn, 1992); kidney transplantation activity is therefore now a reasonable proxy for donor rates, if the fact that each donor has two kidneys is accounted for. Third, as indicated above, kidneys have two special features – the possibility of asystolic and living donation – which deserve analysis in their own right.

Non-renal organs will not be ignored, however. Wherever possible the special problems and difficulties will be indicated in the text – such as those pertaining to the multi-organ donor – and the activity data for the kidney will be replicated for heart and liver. And it is worth noting now some of the reasons why non-renal organs are transplanted at a lower rate than kidneys.

First, and most obviously, only one liver or heart is available from each donor. Second, the incidence of kidney diseases suitable for transplantation is higher than equivalent diseases of the heart and liver, resulting in relatively higher demand for renal transplantation. Third, the non-renal technologies are more costly and complex and rely more heavily on robust brain stem death criteria, hindering their early development (Jennett, 1991). Fourth, many more non-renal organs are unsuitable: whereas 95 per cent of consenting donors have kidneys which are suitable for transplantation, the equivalent proportions for hearts and livers are 65 and 71 per cent (Gore *et al.*, 1992b).

Fifth, whereas over 96 per cent of suitable kidneys for which consent has been given are donated and transplanted, the respective figures for hearts and livers are 74 and 62 per cent. Reasons for these lower proportions relate to the complexity of the procedures and the relatively small number of non-renal transplant centres. They include: the deterioration of organs by the time of transplantation, lack of suitable recipients, non-availability of a transplant team, lack of theatre time, and shortage of intensive care facilities (Gore *et al.*, 1992b). Finally, there are 'restricted offers' whereby the kidneys alone are donated. All these factors have meant that kidney transplantation has outstripped non-renal transplantation, even though the latter involve saving life rather than simply improving its quality.

Table 1 Cost-per-QALY 'league table', 1990/91 prices

Intervention	**Cost per QALY (£)**
Cholesterol testing and diet therapy (all adults aged 40-69)	**220**
Neurosurgical intervention for head injury	**240**
Pacemaker implantation	**1100**
Hip replacement	**1180**
Coronary artery bypass graft (left main vessel disease, severe angina)	**2090**
Kidney transplant	**4710**
Breast cancer screening	**5780**
Heart transplant	**7840**
Cholesterol testing and treatment (all adults aged 25-39)	**14150**
Home haemodialysis	**17260**
Coronary artery bypass graft (one vessel disease, moderate angina)	**18830**
Continuous ambulatory peritoneal dialysis	**19870**
Hospital haemodialysis	**21970**
Erythropoietin treatment for anaemia in dialysis patients (assuming 10 per cent reduction in mortality)	**54380**
Neurosurgical intervention for malignant intracranial tumours	**107780**

Source: **Mason *et al.*, 1993**

Are transplants worth doing?

One criticism of attempts to improve the supply of organs is that transplant surgery may not be an appropriate use of publicly provided health care resources. Organ transplants have often been seen as expensive and rather 'heroic' procedures, draining resources from more effective and less costly procedures. This is an important point, and one we return to in chapter 6. However, before embarking on a detailed analysis of the shortage of organs, it is worth noting two possible justifications for the technology.

The first way of justifying a particular medical intervention is to investigate its cost-effectiveness – does it offer good value for money? An increasingly popular method of measuring effectiveness is the QALY or Quality Adjusted Life Year. This unit of measurement combines an assessment of the increased length and quality of life which results from an intervention. The extra QALYs which can be bought per pound of health care resources for a whole range of treatments can then be ranked in a league table such as that in Table 1.

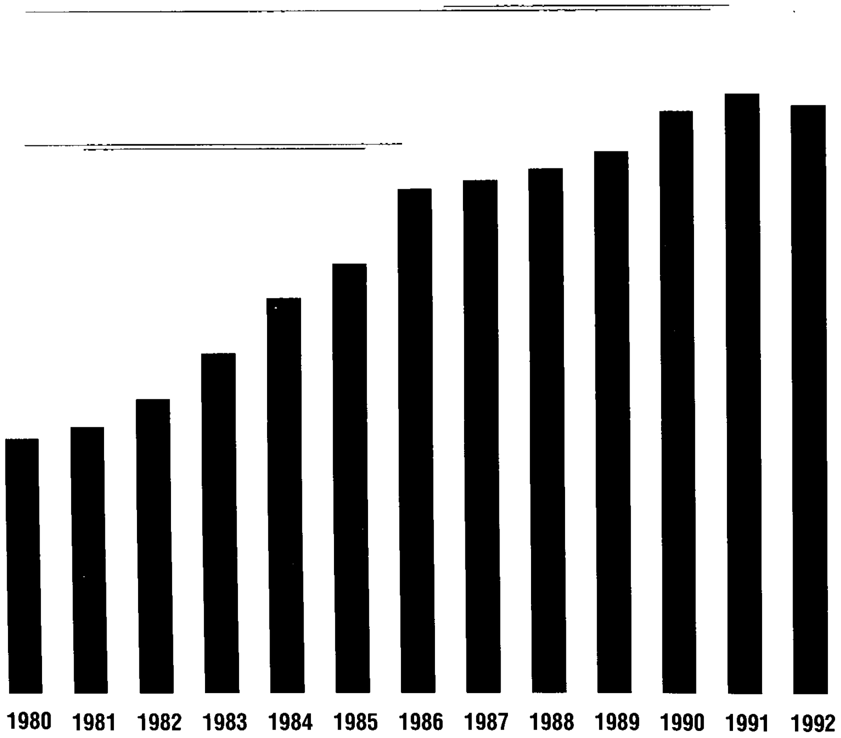
On these measures – and it must be emphasised they are still relatively crude – neither kidney nor heart transplantation appears to be an unduly inefficient use of NHS resources, and they both seem better 'value' than certain preventive measures. Kidney transplantation in particular is the most cost-effective form of renal replacement therapy, the alternatives involving various forms of dialysis.

The second way of assessing the appropriateness of an intervention is to invoke notions of social justice. We may not just be interested in the efficiency with which an intervention 'produces' health but with the distribution of these effects among the population. Heart and liver transplants are the only life-saving option for many diseases relating to these organs, and thus, whatever the cost, could be argued to occupy a position of high priority in allocating health care resources.

World transplantation activity during the 1980s and 1990s

The principal organs in terms of transplantation activity are the kidney, heart and liver. Figure 1 shows the rate of growth of kidney transplantation in the main cadaveric organ transplanting countries of the world between 1980 and 1992. The eighteen countries included were those with reliably available statistics over the period in question. Statistics were

Figure 1 Total kidney transplantation activity (cadaveric plus live) of the world's leading cadaveric transplant countries, 1980-1992



Notes:

1 Countries included in the total: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, New Zealand, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK and Eire, USA.

2 Figures for 1990-92 include ex-DDR patients; before that, data relate to West Germany.

3 Data for Greece unavailable before 1985 but negligible. Data for 1980 and 1981 for the USA, and for 1980 for Canada, were unavailable and estimates were included. Italy is a significant cadaveric transplanting nation but data were not available for a number of years and were therefore not included in the total.

Source: For all the Figures in this report, unless otherwise stated, data were collected direct from the countries' national co-ordinating registries.

provided directly by the relevant co-ordinating registry in each country so as to provide the most accurate picture possible. South American countries and India were excluded since most of their kidney transplants come from living donors, often procured by commercial means (Santiago-Delpin, 1991; Patel, 1988). Other countries such as Singapore undertake a very small annual number of transplants in absolute terms (Soh *et al.*, 1991). The aggregate is therefore a good approximation of the total kidney transplantation rates in the developed world during the 1980s and early 1990s.

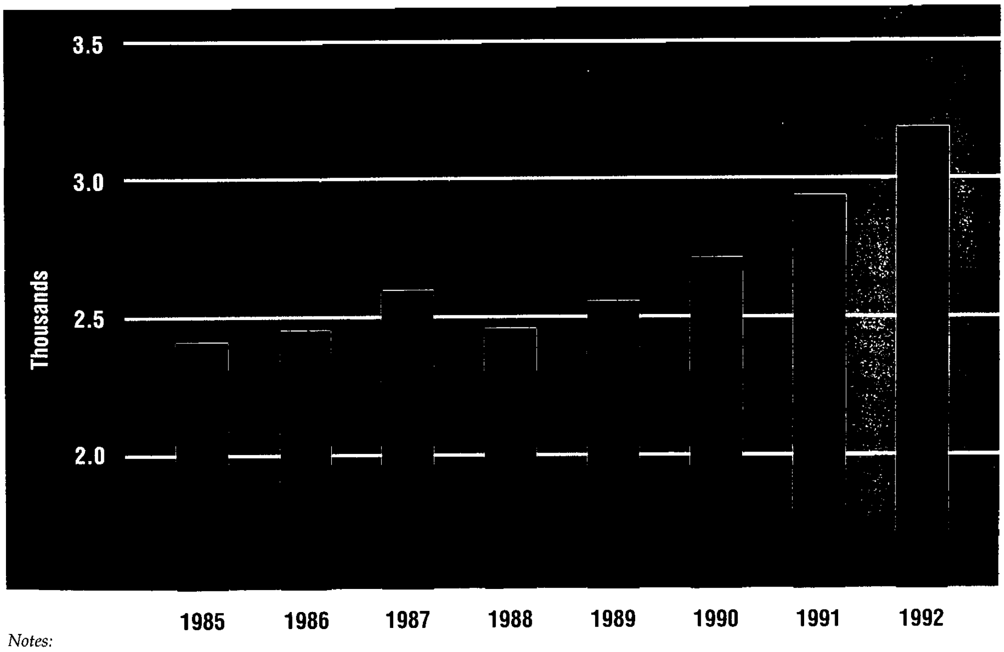
Kidney transplants were the first to be widely developed and therefore were already conducted at a relatively high rate in 1980. The increase in activity during the decade is clear, from just below 10,000 (16 per million population (pmp)) in 1980, to 21,500 (36 pmp) in 1992 – an improvement of 125 per cent. However, a plateau appears to have been reached in the early 1990s: 1992 was the first year which saw the total number of kidney transplants decrease over the year before. Few countries have managed to avoid this trend, and only two – Spain and Portugal – have transplant rates which are still clearly rising.

The same is not the case for live kidney transplants, shown in Figure 2. In 1983 the drug cyclosporin was introduced, significantly improving the survival of poorly matched cadaver organs. Data are less reliable before this date, but it is widely accepted that the proportion of living donors was higher in this pre-cyclosporin era, and that after 1983 the improved results from cadaveric donation led many countries to reduce the proportion of live transplants (Evans, 1990a). Whether this involved a reduction in the absolute numbers is less clear. At any rate, by the mid-1980s the number of kidneys donated in this way had stabilised at around 2,500. But between 1988 and 1992 the number had risen from 2,500 to almost 3,200 – an increase of 28 per cent.

Furthermore, this increase means that the number of live transplants as a proportion of the total has increased from approximately 13 per cent in 1988 to 15 per cent in 1992. Neither was this increase solely as a result of the activity in the USA, which constitutes about 75 per cent of all live transplants in the countries under analysis. Non-USA countries have increased their live donation rate by approximately 38 per cent. It may be no accident that these increases have occurred at a time of falling cadaveric donation rates.

Heart and liver transplants became widely performed rather later than kidneys and therefore

Figure 2 Total live kidney transplantation of the world's leading cadaveric transplant countries, 1985-1992



Notes:

1 Countries included in the total: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany (including ex-DDR patients), Greece, Netherlands, Norway, New Zealand, Sweden, Switzerland, USA.

2 Spain and Portugal undertake negligible numbers of live transplants. Data for the UK and Italy were unavailable for the period in question.

Source: As Figure 1.

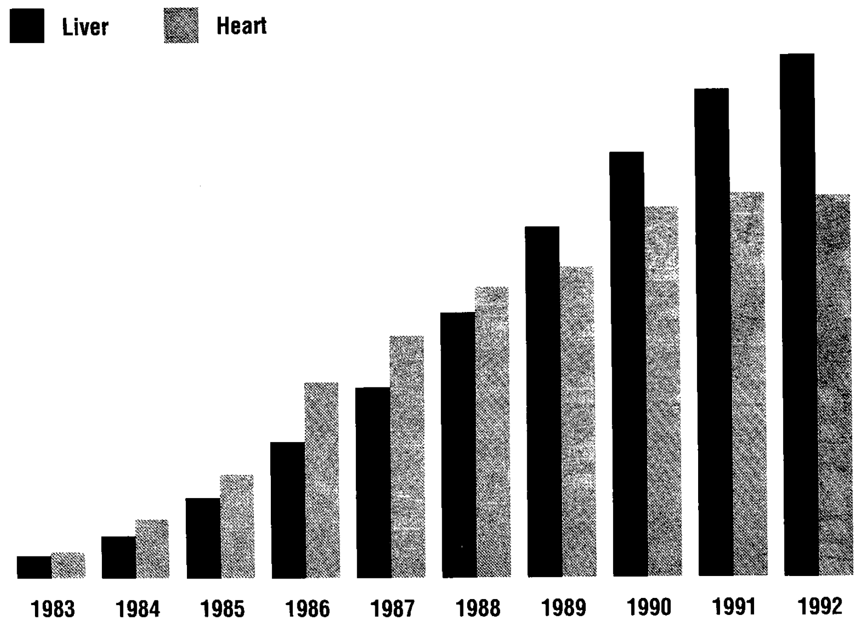
were undertaken at a lower rate in the early 1980s, even accounting for the fact that only one organ is available from each donor. Reliable data are available for a large number of countries from 1983. Subsequently, their trends have shown an interesting divergence, as shown in Figure 3. Heart transplants have followed the pattern set by kidneys, rising strongly during the 1980s before levelling off during the 1990s at a world-wide rate of about 4,500 per year. Liver transplants, on the other hand, despite starting off rather more slowly, have now overtaken heart transplants and are still rising strongly with over 6000 transplants undertaken in 1992.

The plateau in donor rates indicated by the kidney transplantation data is a cause of some concern. The reasons are likely to be manifold, but particularly significant may be the reduction in the size of the potential pool of donors – those who die in ways which lead to brain stem death and artificial ventilation. Clearly, this is in itself a most welcome development but with important consequences for the future of transplantation.

Cadaveric organ donors predominantly die from intracranial haemorrhage, or from head trauma caused by road traffic accidents. Each of these causes of death has dropped dramatically over the last twenty years, as shown in Figure 4. Road deaths in fourteen of the main transplanting countries have dropped by almost thirty per cent, from 124,000 in 1970 to 88,000 in 1990. Spain and Portugal have not been included in this total because their data were not available on a comparable basis over the period in question. However, these two countries were alone in reporting a steady upward trend in road deaths, as well as the only steady upward trend in cadaveric donation. These factors are likely to be related.

Deaths from intracranial haemorrhage are not available internationally, but in the UK deaths from these causes have dropped by almost seventy per cent over the same period, from just over 22,000 in 1970 to just over 7,000 in 1990. Even though the transplant community have attempted to widen the pool by, for instance, increasing the upper age limit for a donor to 70 years, they are swimming against a tide of reductions in the relevant mortality rates.

Figure 3 Total liver and heart transplants of the world's leading cadaveric transplant countries, 1983-1992



Notes:

1 Countries included are as for Figure 1.

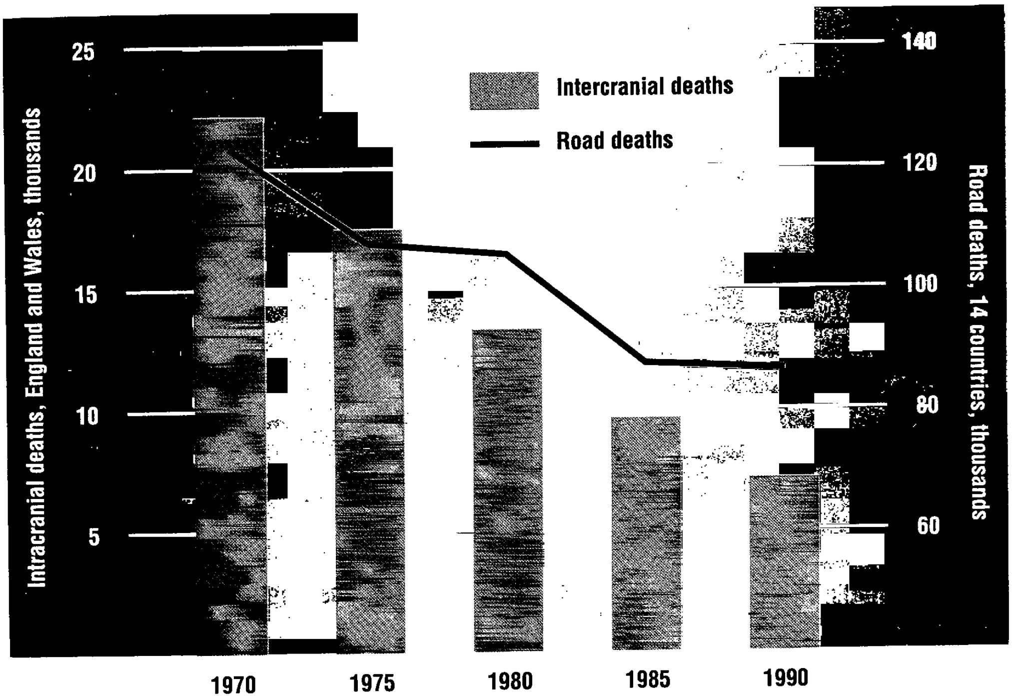
2 Figures from 1990-1992 include ex-DDR patients.

3 Some of the later heart transplants were 'domino hearts', donated by live patients who underwent combined heart-lung transplants themselves.

4 Some of the later liver transplants were live donations of a liver section from parent to child.

Source: As Figure 1.

Figure 4 Aggregate road deaths in 14 countries and aggregate deaths from subarachnoid and intracerebral haemorrhage, all ages, England and Wales, 1970-1990



Note:

Countries included in the road death total: Austria, Belgium, Canada, Denmark, Finland, France, West Germany, Great Britain, Italy, Netherlands, Norway, Sweden, Switzerland, USA.

Sources:

Department of Transport (1970-1990), *Road Accidents Great Britain – The Casualty Report,* HMSO, London.

Office of Population Censuses and Surveys (OPCS) (1970-1990), *Mortality Statistics: cause,* HMSO, London.

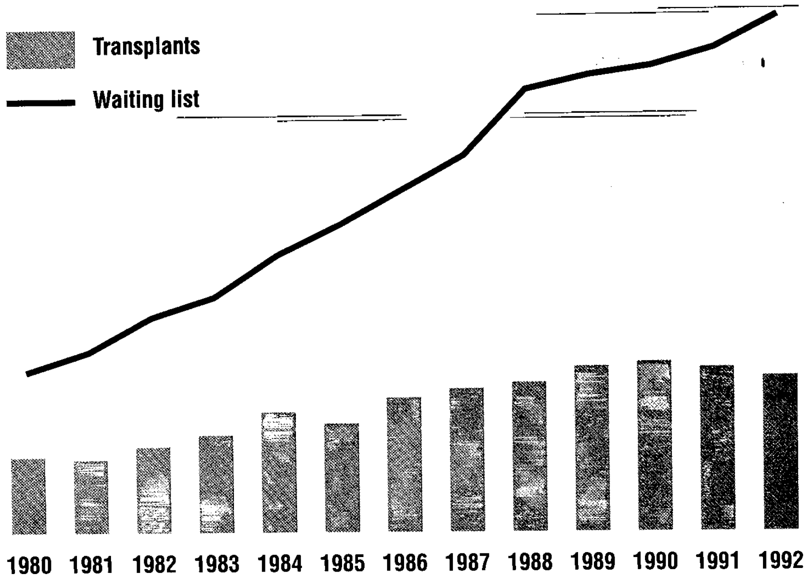
The gap between supply and demand

The increases in transplantation activity during the 1980s did not succeed in guaranteeing an organ for everyone who would benefit, and for the majority of people long waits, particularly for kidneys, were the norm. The plateau in kidney transplantation has now made this situation worse. International data for those waiting for a kidney transplant are less readily available than for transplants themselves, but good data are available for the UK and some European countries. Figure 5 shows the aggregate number of kidney transplants performed from cadaveric donors, and waiting lists at the year end, in the UK and Eurotransplant region – the area covered by the Eurotransplant Foundation for co-ordinating and promoting transplantation activity in Austria, Belgium, Germany, Luxembourg and the Netherlands. The number of transplants rose from 14.7 pmp in 1980 to 30.8 pmp in 1992, but the last two years have seen a decrease in activity and, overall, the trend echoes that of world activity. However, the number of those on waiting lists continues to rise steadily. Almost 15,000 were waiting for a kidney in the six countries at the end of 1992, with the gap between those waiting and those receiving a transplant growing ever wider.

Those waiting for a heart and liver do not face such a long wait, although the situation is getting worse and, of course, many die before an organ becomes available. Between 1987 and 1992 the number waiting for a heart in the Eurotransplant region has increased from 96 to 938, and for a liver from 95 to 344, though these figures include ex-German Democratic Republic patients from 1990 onwards. Transplants only increased from 392 to 753 for hearts, and from 273 to 780 for livers over the same period. Non-renal organ transplants are constrained by the availability of transplant centres and by technical aspects to a greater degree than kidneys. Ultimately, though, they depend on donors, and to that extent face the same constraint as kidney transplantation.

The problem facing the transplant community can therefore be simply stated: there are not enough organs to meet demand, and the situation

Figure 5 Total cadaveric kidney transplantation rates and waiting list figures in the UK and Eurotransplant region, 1980-1992



Notes:
1 Eurotransplant region consists of: Austria, Belgium, Germany, Luxembourg, Netherlands.
2 Figures exclude ex-DDR residents.
Source: As Figure 1.

is getting worse. Waiting times are long – in the UK the wait for an average patient for a kidney at the end of 1992 was two and a half years – and are getting longer. Up until recently the international transplant community might have consoled itself with the thought that at least more people were being treated, but this is, on an aggregate level, no longer the case.

Interestingly, it is not necessarily the lack of human and capital resources which is constraining kidney transplant activity. The United Kingdom had 36 centres undertaking transplantation activity during 1991 at an average of 49 transplants per centre. However, a recent review of specialist services in London recommended that to ensure a high quality of outcome transplant centres should each conduct at least 100 grafts annually, justifying a team of three or four surgeons and ensuring the economical use of nursing staff (Mallick, 1993). They suggested that this meant that London's regions' 14 centres should be reduced to five. Furthermore these recommendations were made with a view to a maximum throughput of 600 operations as opposed to the current 480. So a reduction in current capacity would still leave plenty of room for growth if only the organs were available.

Outline of the report

This chapter has outlined the aggregate world position for kidney, heart and liver transplantation and established that there is a clear shortage of organs relative to the numbers waiting. Chapter 2 analyses transplant activity levels in the UK, and puts this activity into an international context. It concludes by outlining the limitations of what can be learned from international experience. Chapter 3 presents the legal and religious context in which this activity takes place in the UK, and analyses the state of public opinion on transplantation issues. Chapter 4 sets out the options for improving the supply of organs in the UK, and assesses the evidence for the efficacy of each. Chapter 5 turns to the ethical issues surrounding these options. An assessment is made of where policy needs the most careful formulation to accommodate ethical concerns. Chapter 6 considers issues relating to a fair allocation of organs and of resources to the transplant technology itself. Chapter 7 draws this analysis together and sets out the policy options.

Activity – the UK and beyond

2

Chapter 1 provided an indication of aggregate world transplantation activity. Such aggregation, however, hides a wide range of activity between countries. In this chapter these variations are analysed, as are the limits of what can be learned from the most successful countries. First, the situation in the UK is analysed in detail: the practical organisation of organ procurement and donation and the trends in transplantation activity and waiting list figures during the 1980s. Second, this analysis is placed in an international context, comparing the UK's experience with that of eighteen other countries from around the world. The chapter concludes with an examination of the pitfalls awaiting the unwary when making international comparisons.

The UK's procurement arrangements

The following describes a typical course of events involving the transplant of a cadaver organ into a recipient. Details will vary, as will the sequence of events, but the description offers a basic indication of how the system in the UK operates.

A typical transplantation

A potential donor will typically have suffered some form of massive cerebrovascular accident, such as intracranial haemorrhage or head trauma as a result of a road accident. Initially, they would be transferred to an intensive care unit (ICU) for ventilation, diagnosis and the hoped-for recovery. However, not all patients who suffer a cerebrovascular accident will be ventilated in an ICU. Some may suffer respiratory arrest after admission to a general ward and will not be ventilated if the prognosis looks hopeless. These patients can also be suitable as organ donors.

If recovery looks unlikely for those taken to ICU for diagnosis and treatment, the relatives are informed of this possibility by intensive care staff. Then the first of two sets of brain stem death tests are performed. If this test confirms death, and if there do not appear to be any general medical contraindications to donation, the ICU staff will make a formal request for organs. The transplant co-ordinators are notified and will typically travel to the donating hospital. The co-ordinators liaise with the relatives and the intensive care team, ensuring that the relatives are handled properly and – if donation is agreed – that the necessary organisational arrangements are taken care of. After a second set of brain stem death tests is performed, between six and twelve hours after the first, and if brain stem death is confirmed, the patient is proclaimed dead. The coroner must be informed if the death is 'reportable'; occasionally this will result in the coroner denying permission to go ahead with transplantation if a post-mortem examination is necessary.

Details differ depending on how many organs are being donated, with 'multi-organ' donors entailing the most difficult co-ordination (Wight, 1989; Crombie, 1993). For kidneys, tissue-type matching is an important part of the process and due to the number of those on national waiting lists a beneficially matched recipient will normally be available. A convention is that one kidney will usually be retained locally and the other distributed according to a national waiting list on the basis of beneficial matching. The local kidney transplant team will remove both kidneys and, if they co-operate with the convention (see page 74), send the second kidney to the relevant centre elsewhere in the country.

For a multi-organ donor, the non-renal surgical teams and transplant centre are selected on a national rota basis, depending on a suitable recipient being available – if the centre at the top of the list has a suitable recipient, then their team removes the organ and the centre is moved to the bottom of the list. A central element in the co-ordinators' practical role is to liaise with the UK Transplant Support Service Authority (UKTSSA) and non-renal teams to facilitate these processes. In general, organs are not removed unless it is believed that a suitable recipient is available.

The explantation – the surgical removal of organs – takes place at the donating hospital by the transplant teams when theatre time can be arranged. For multi-organ donation, the operation takes an average of about five hours. The transplant teams then take the organs back to their transplant units to complete the transplantation.

This brief outline essentially illustrates a 'best case'. At many points in the process potential donor organs can be lost: if brain stem death tests are not undertaken, or if relatives refuse permission to remove organs, or, as has been indicated, due to the difficulties of arranging for multiple donation. Partly to ensure that such losses were minimised, transplant co-ordinators were employed and these individuals are now an integral part of the transplantation process.

The transplant co-ordinators

The first transplant co-ordinators were introduced in the UK in the late 1970s. There are now approximately sixty posts, employed by Regional Health Authorities and working in proximity to a transplant unit. In part their role is educational: the aim is to keep all health care professionals involved in transplantation activity abreast of the best practice and latest developments relating to donor suitability and the donor referral process. Updates are provided on current successes and initiatives. Although a wide range of health professionals are targeted, it is the critical care specialists – intensivists, critical care nurses and anaesthetists – who are considered particularly important.

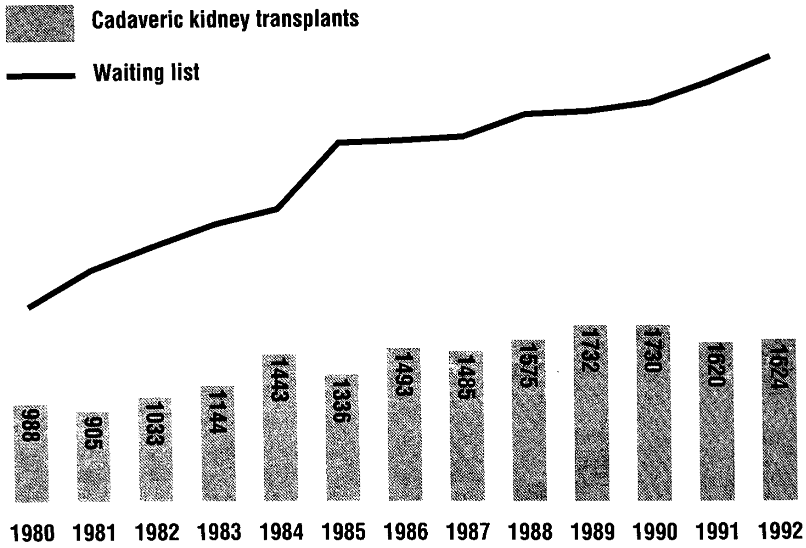
The educational role is complemented by practical support in the donating unit at the time of donation. It is now estimated that 70 per cent of the co-ordinators will facilitate the process in this way – the remainder liaise over the telephone (Crombie, 1993). Typically, co-ordinators arrive on the scene at some time between the two sets of brain stem death tests. They are not therefore directly involved in the initial elements of the transplant process – performing brain stem death tests, assessing for general medical contraindications and approaching the relatives with news of death and the initial request for donation – so it is these elements which constitute important parts of training and education. However, co-ordinators have a valuable practical role. They can provide support and advice for the families and ICU staff, organise the call up and arrival of transplant teams, liaise with UKTSSA over waiting lists and tissue-type matching, and arrange theatre time. Finally, the co-ordinators consider a vital element of their job to be the follow-up, both to the ICUs and to the families of the donors.

UK's transplantation activity

Between 1980 and 1991 the number of individuals in the UK with a functioning graft as a proportion of all those on renal replacement therapy increased from 44.0 per cent to 55.3 per cent – the highest in Europe (European Dialysis and Transplant Association, 1992). This increase in the proportion with a functioning graft was matched by a reasonably steady increase in the number of cadaveric transplants performed in the UK until the 1990s. Figure 6 shows, however, that since a peak of 1732 transplants in 1989 the number has dropped to 1624 transplants in 1992. The latest data from the UKTSSA show that this has dropped further to 1562 in 1993 (UKTSSA, 1994). Waiting lists have risen steadily, however, reaching a peak of 4361 people waiting for a kidney in the UK at the end of 1992.

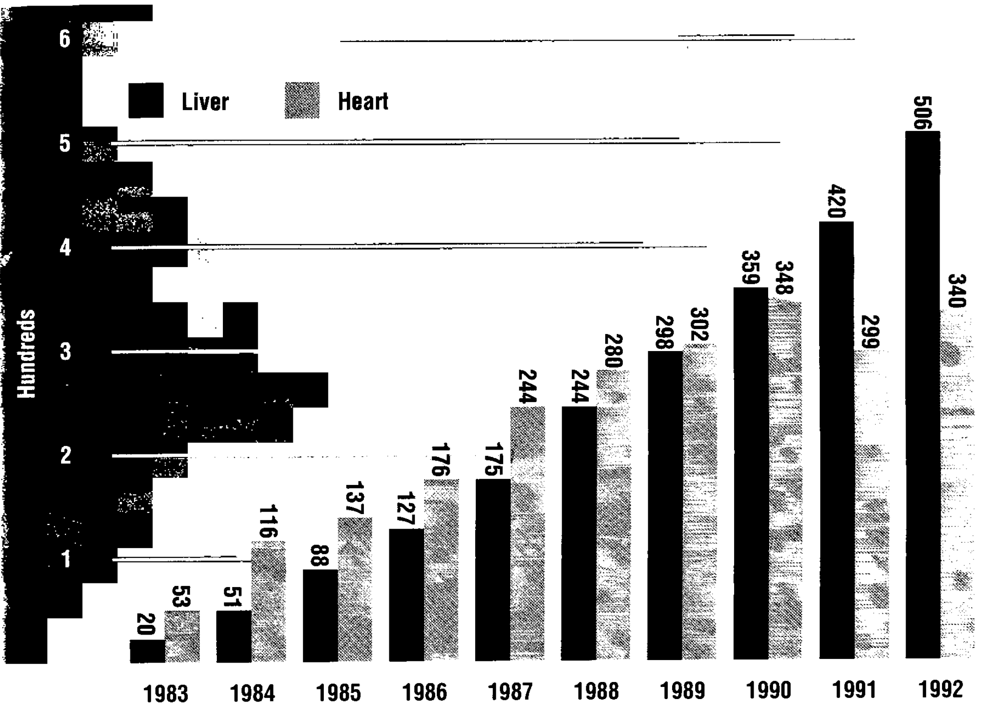
The UK has only a small proportion of reported transplanted kidneys from live donors, currently constituting about 5 per cent of the total.

Figure 6 UK cadaveric kidney transplants performed and numbers waiting at year end, 1980-1992



Note: Data do not include combined kidney and pancreas transplants
Sources: UKTSSA and Healthcare Parliamentary Monitor, 5 August 1991.

Figure 7 UK and Eire heart and liver transplants, 1983-1992



Note: Heart transplants include 'domino hearts' but not combined heart and lung.
Source: UKTSSA

Unfortunately, the United Kingdom Transplant Support Service Authority (UKTSSA) does not hold data on live donations prior to 1989, but estimates from surveys of individual transplant centres indicate that up until 1989 the proportion of all transplants from living donors was approximately 10 per cent (Donnelly *et al.*, 1989 and 1991). Certainly since 1989 the number of live transplants undertaken has dropped from 118 to 91 (UKTSSA, personal communication). This reduction is at odds with the world-wide trend described earlier.

Activity for liver and heart transplants are shown in Figure 7. Heart transplant activity has followed the trend observed for the world total: a steady increase until the 1990s when the rate levelled off at just over 300 transplants per year. The number of liver transplants has risen more steadily, again following the world trend, reaching 506 transplants in 1992. Waiting lists for both these technologies are relatively low when compared with those for kidney transplants: those waiting for a heart at the end of 1992 numbered 325, and those for liver only 83. In the UK these data are only available as a useful estimate of need from 1990, before which they included patients on European waiting lists. On this limited evidence they are both rising: the heart waiting list stood at 239 in 1990, that for liver at 57.

Comparative data analysis

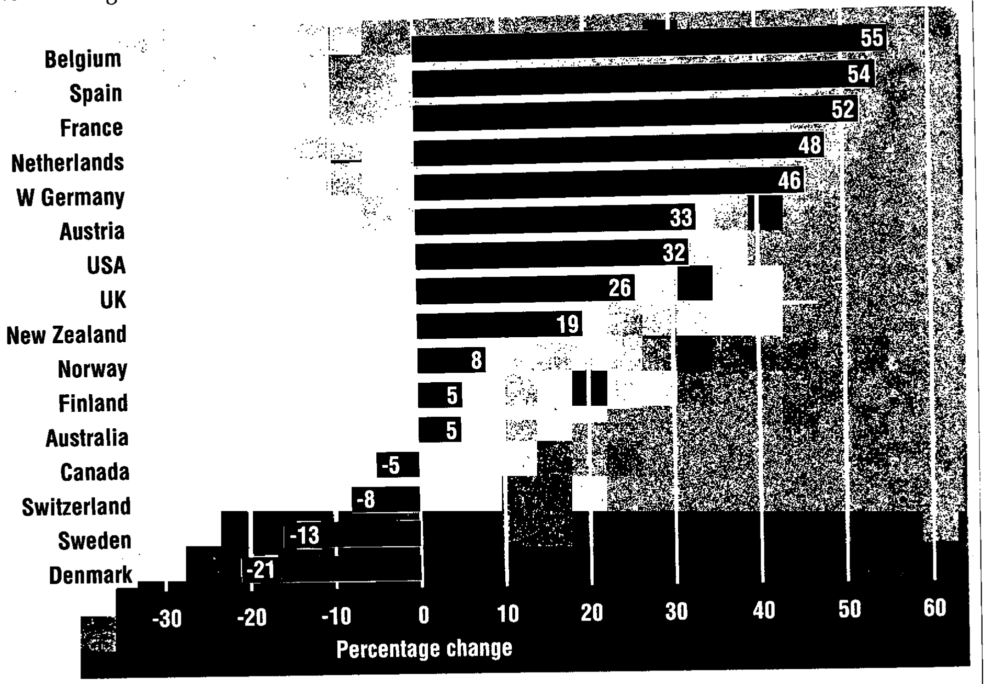
In this section we compare the UK activity with that in eighteen of the world's leading cadaveric transplant nations.

Rates of change in kidney transplantation, 1985-92

Figure 8 shows the rate of increase of cadaveric kidney transplantation for sixteen of the countries under consideration since 1985. Portugal and Greece are excluded as their exceedingly high rates of increase – 271 and 318 per cent respectively – are chiefly a result of starting from a low base in 1985, a consequence of their being rather late starters in the transplant field. Data were not available for Italy. All of the remaining countries undertook significant numbers of cadaveric kidney transplants in 1985.

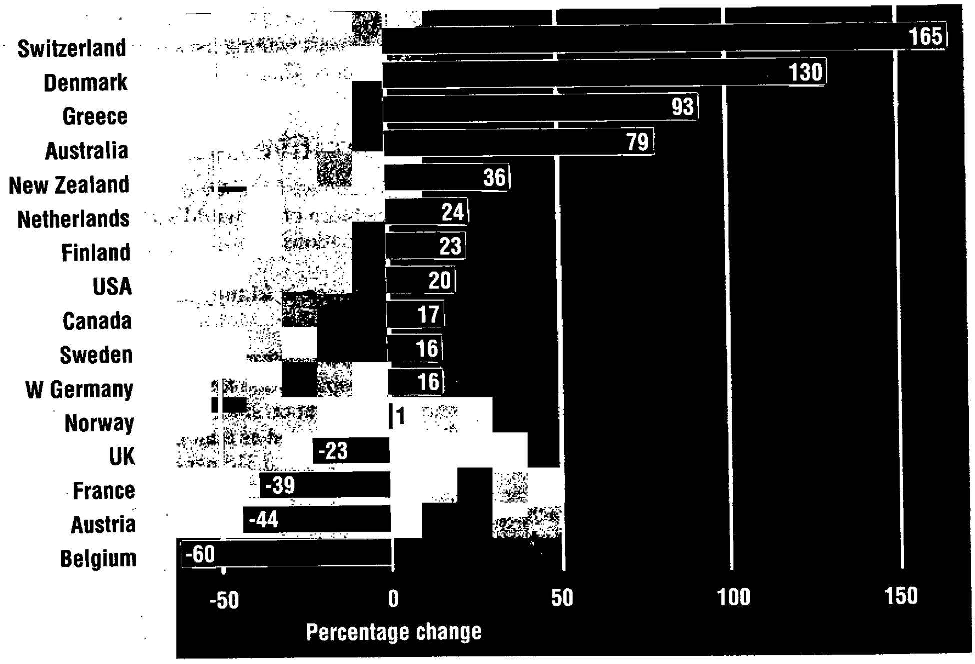
Caution should be exercised when interpreting the precise percentage increases, as these will depend on the particular circumstances prevalent during the respective base years.

Figure 8 Change in the number of cadaveric kidney transplants undertaken, 1985-1992



Source: As Figure 1.

Figure 9 Change in the average number of live kidney transplants undertaken, 1985-87 to 1990-92



Note: UK data available only from 1989-1992: rate of change relates to that period.
Source: As Figure 1.

However, it is worth noting that a group of countries – Switzerland, Canada, Australia and those comprising Scandinavia – have either increased their rate only marginally or have suffered a reduction in cadaveric transplantation over the period in question. The 'world' problem appears to have affected some countries significantly earlier than others.

Live kidney donation also shows significant variations between countries. Figure 9 shows the rate of increase of the mean values – taken to avoid large random statistical variations caused by the relatively low numbers involved – from 1985-87 to 1990-92. Four countries have significantly reduced their live donation activity: Belgium, Austria, France and the UK. Two others – Portugal and Spain – undertake negligible numbers of live transplants. These six countries have enjoyed reasonably large increases in cadaveric activity over the same period, although others, such as the Netherlands, the Federal Republic of Germany and the USA, have improved their cadaveric rate and have not chosen to restrict live donation. Two of those countries which suffered a reduction in cadaveric activity – Switzerland and Denmark – have increased their live transplantation by the greatest margin.

Rates of change in numbers waiting, 1980-1992

The increase in those waiting also varies considerably between countries. However, the use of 'numbers waiting pmp' as a comparator of how successfully 'need' is being addressed in various countries is problematic. Table 2 shows transplants undertaken, those waiting for transplants and the numbers accepted for renal replacement therapy. It is clear that although Austria, Belgium and Germany have high waiting lists, they also have high acceptance and transplant rates. In general, comparison of need is extremely difficult to make as 'acceptance for treatment' probably reflects national policies as much as variations in the incidence of a disease. For example, a recent review of policy for end stage renal disease in the USA reported that

> *the USA treatment rate [incidence] was 2.2 times higher than that in Canada and 3.8 times higher than the combined European rate. Only one European country, Austria, had a treatment rate more than half as high as that of the United States* (Iglehart, 1993).

The author indicates that this is partly a result of central government policy, the Medicare End Stage Renal Disease Program, which causes 'the criteria physicians' apply to the selection of patients [to be] considerably broader' than that in other industrialised countries. Comparisons are also complicated by the fact that waiting list figures in Austria and Belgium contain significant numbers of non-residents – approximately 40 per cent in both countries during 1991 (Cohen and Persijn, 1992).

However, given that countries have differing policies on the numbers admitted for renal replacement therapy, they nevertheless succeed to a varying extent in restricting the increase in numbers on waiting lists. Figure 10 shows the waiting list at year end for four Eurotransplant countries and the UK. Since 1988, Austria appears to have made a significant reduction in those waiting, from 146.8 pmp to 138.5 pmp. Belgium has had similar success, reaching a plateau of around 85 pmp, until 1992 saw sharp increase to 93.3 pmp. The UK, on the other hand, has witnessed a steady increase from 60.0 pmp to 75.7 pmp over the seven year period.

Variations in transplant activity, 1992

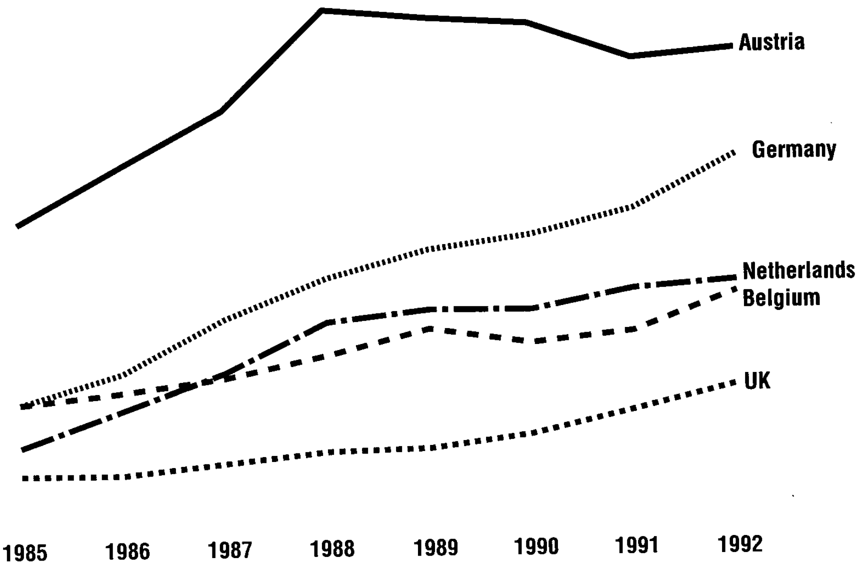
The rate of transplantation activity at any one point in time is the most significant of the indicators. The countries are ranked by their 1992 cadaveric

Table 2 Cadaveric kidney transplants undertaken, those waiting at end of year, and those accepted for renal replacement therapy in the UK and Eurotransplant region, 1991

Country	**Transplants performed**	**Waiting list**	**Accepted for renal replacement therapy**
		(per million population)	
UK	**28.2**	**71.6**	**59.7**
Austria	**51.2**	**136.8**	**105.3**
Belgium	**38.6**	**84.3**	**86.7**
W Germany	**31.8**	**107.9**	**94.1**
Netherlands	**28.4**	**94.1**	**60.0**

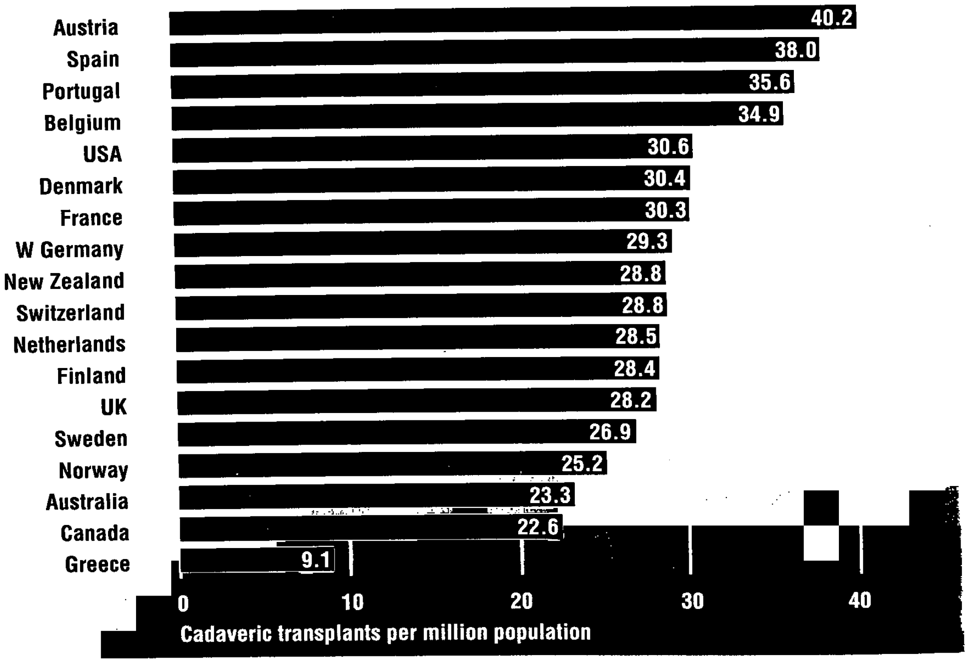
Sources: **Cohen and Persijn, 1992; European Dialysis and Transplant Association, 1992.**

Figure 10 Waiting list at year end for kidney transplantation in the UK and Eurotransplant region, 1985-1992 (pmp)



Note: Excluding ex-DDR residents, but including non-residents on Belgian and Austrian waiting lists.
Source: As Figure 1.

Figure 11 Cadaveric kidney transplantation rates (pmp) in the world's leading cadaveric transplant countries, 1992



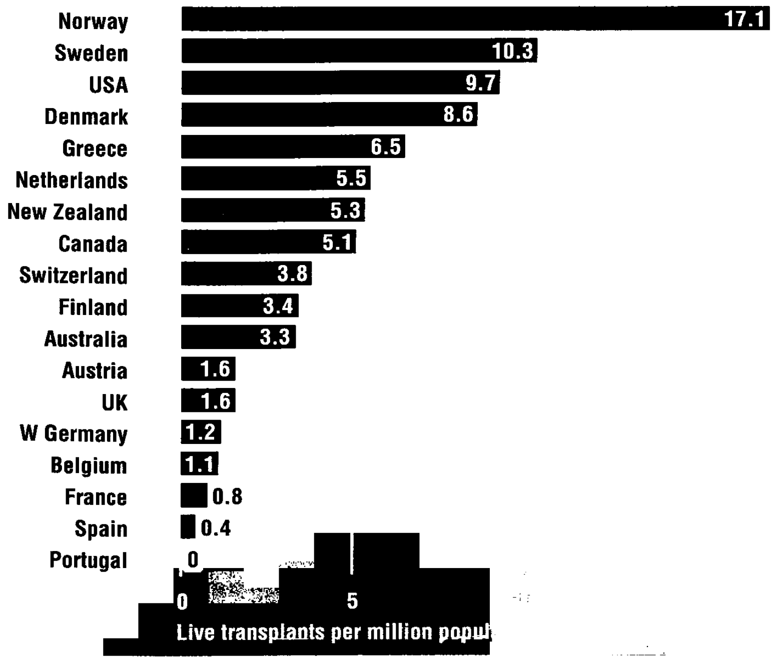
Note: Data for Italy not available for 1992.
Source: As Figure 1.

kidney transplantation rate in Figure 11. Austria, Spain, Portugal and Belgium display significantly higher rates than the others, ranging from 34.9 pmp for Belgium to 40.2 pmp for Austria. The following nine countries have similar rates, from 30.6 pmp in the USA to 28.2 pmp in the UK. The remaining countries lag behind somewhat. Greece was a relatively late starter in the transplant technology, and Italy has a particularly severe set of procurement problems which marks it out as something of a special case: data were not available for 1992, but in 1991 Italy undertook only 10.2 pmp (Pizzi *et al.*, 1990; Sirchia *et al.*, 1989). It seems clear that those countries which have stemmed the increase in waiting list numbers, namely Austria and Belgium, have also attained high levels of cadaveric transplantation activity in international terms.

Live donation also varies significantly between countries, as shown in Figure 12, but the Scandinavian countries, except Finland, and the USA appear to have a particularly positive attitude towards live donation. Norway has by far the highest rate, with 17.1 pmp transplants in 1992. Others – including the four leading cadaveric transplant countries – undertake relatively few. Portugal, for example, conducts no live transplants at all. Broadly speaking, the more successful a country appears to be at procuring cadaver organs the less its propensity to undertake live transplants, and vice versa.

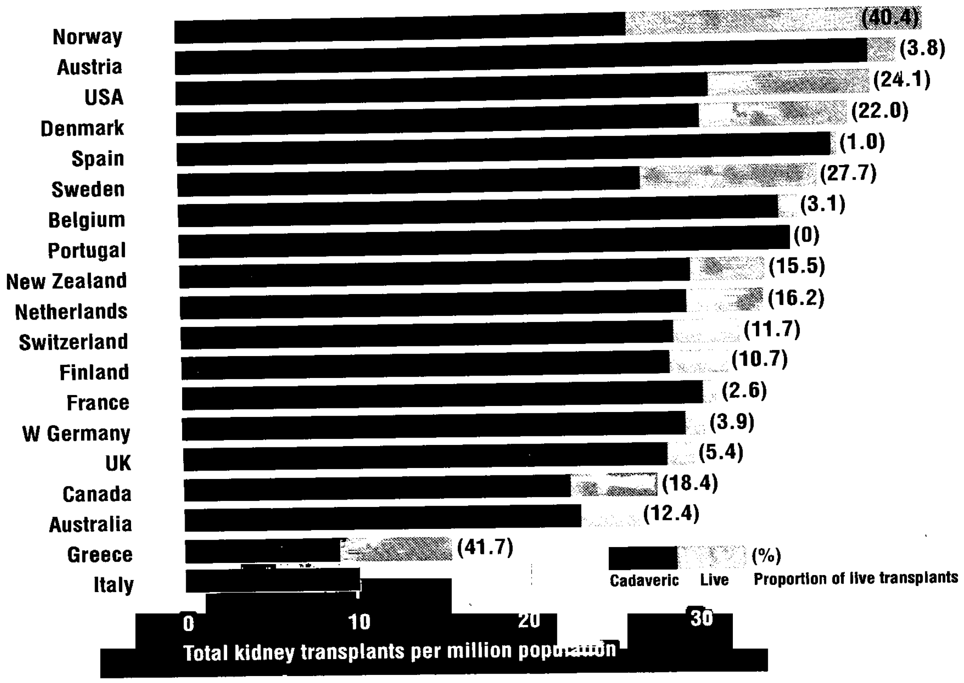
Figure 13 shows the total number of kidney transplants undertaken and the proportion of this total made up by live transplants. One can immediately see how a positive policy for live donation in Norway and Sweden moves them significantly up the international league table, with Norway becoming the world's leader with 42.3 pmp. These two countries have relatively low rates of cadaveric retrieval and so, in the light of the comment above, this high live donation rate is not surprising. But the proposed 'inverse relation' between live and cadaveric donation is not universally followed. Two countries in particular – the USA and Denmark – have reasonably high cadaveric retrieval rates, and yet have still chosen to undertake significant numbers of live transplants. This serves to indicate that live donation is a policy choice open to all the countries listed, including those who, like France, Germany and the UK, have reasonably successful cadaveric programmes but who nevertheless find themselves

Figure 12 Live kidney transplant rates (pmp) in the world's leading cadaveric transplant countries, 1992



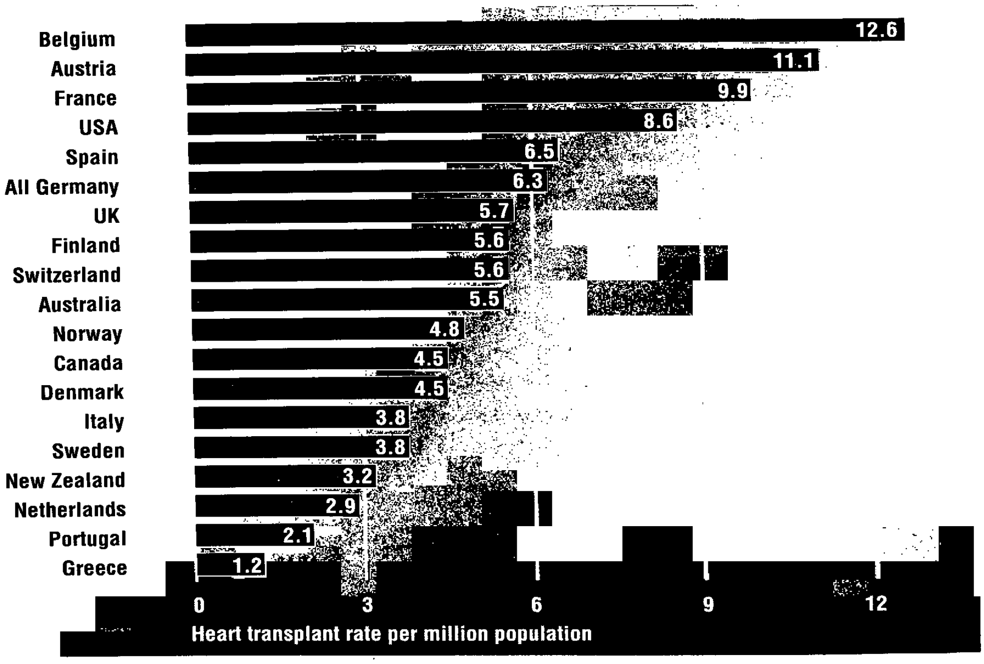
Note: Data for Italy not available. Remainder are the latest available for 1992, although live donation totals are subject to late notifications. Figures are therefore likely to be approximate.
Source: As Figure 1.

Figure 13 Total kidney transplant rates (cadaveric plus live) (pmp) and the proportion of live transplants, 1992



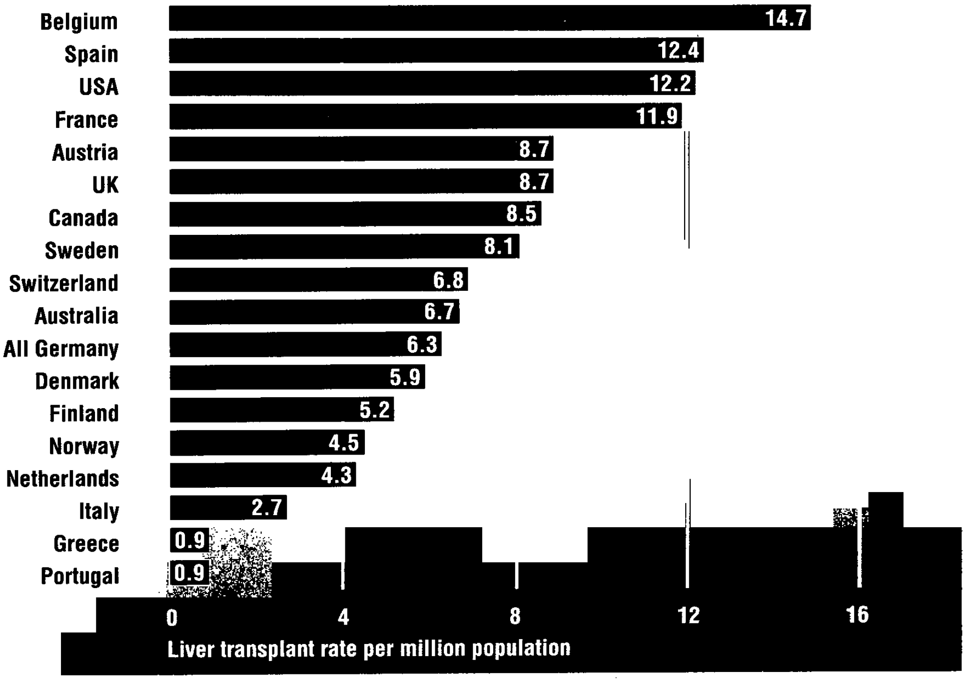
Note: Breakdown for Italy not available; the total for Italy relates to 1991.
Source: As Figure 1.

Figure 14 Heart transplant rates (pmp), 1992



Note: Italy's data are for 1991.
Source: As Figure 1.

Figure 15 Liver transplant rates (pmp), 1992



Notes

1 Italy's data are for 1991.

2 Australia's data includes those for New Zealand, whose patients are transplanted in Australia.

3 Data include living-related donation where countries undertake this procedure.

Source: As Figure 1.

near the bottom of the international aggregate league table.

Figures 14 and 15 replicate the pmp data for 1992 for heart and liver transplantation. A somewhat wider variation is indicated, in turn a reflection of the fact that these organs are restricted to a far greater degree by factors other than simply a shortage of donors. We will not investigate these factors further here, but turn our attention to the focus of our concern: the factors influencing the number of donors. How much can we learn from international experience?

Factors influencing variations in activity rates between countries

The immediate reaction of many who are presented with the data set out in Figures 8-15 is to isolate the most successful countries and investigate their legal or organisational practices. When a practice unique to a successful country or small group of countries is discovered, it is often then promoted as the cause of the high rate of activity – for example, the presumed consent legislation in Belgium, Austria and France (Roels and Michielsen, 1991; Roels *et al.*, 1991) and the national system of co-ordination in Spain (Matesanz and Miranda, 1992). Both these initiatives are discussed in some detail in chapter 4. But although it is widely acknowledged that there are numerous factors affecting a country's transplantation activity, it is not so often acknowledged that some of these factors may be beyond the control of the health care community. They may, in fact, prove to have a greater influence on transplant rates than the legal or organisational practices mentioned above.

In this section three factors taken from Box 2 on page 26 are analysed in some detail. All three – road death rates, intracranial deaths and population density – are effectively impossible to influence in favour of organ transplantation. Road traffic accidents and intracranial haemorrhage, in particular intracerebral and subarachnoid haemorrhage, are the main causes of death amongst organ donors. The *UKTSSA Annual Report 1991/92* estimated that 24 per cent of donors died from the former cause and 53 per cent from the latter. Population density indicates the ease, or otherwise, with which casualties (potential donors)

2

FACTORS INFLUENCING THE SUPPLY OF DONOR ORGANS

Death rates from relevant causes:

- ***road death rates*** **constitute 24 per cent of donors in the UK**
- ***deaths from various forms of intracranial haemorrhage*** **constitute over 50 per cent of donors in the UK**

Demographic and physical characteristics of a country:

- ***population density*** **affects the distances which need to be travelled between hospitals and transplant centres**
- ***age structure*** **influences the number of suitable donors**
- ***ease of travel*** **will be affected by mountainous or other inhospitable terrain**

Level of health care funding:

- ***number of ICUs and transplant centres*** **affects the ability to manage cadaveric donors, and to make full use of suitable donated organs**

Procurement arrangements:

- ***legal framework*** **affects, in particular, procedures for gaining consent to donation**
- ***co-ordinating arrangements,*** **such as the number and organisation of transplant co-ordinators, will affect procurement, particularly of the multi-organ donor**

Cultural factors:

- ***propensity for altruism*** **influences a country's rate of consent to donation**
- ***religious and ethnic composition*** **influences the possibility of certain organisational or legal policies**
- ***acceptance of brain stem death criteria*** **is necessary for large scale cadaveric donation**
- ***support of the medical profession*** **for transplant technology across medical disciplines affects co-operation in procurement**

can be reached and taken to hospital, and their organs transported thereafter. Could these factors vary significantly from country to country and explain some of the variation in activity rates?

Road death rates

Good international comparative data are available for road deaths per million population. Standardised figures (death within thirty days of the accident) are presented in Table 3 – the countries are ranked according to their cadaveric kidney transplantation rates. Alongside is given some indication of the legal system in operation. It is immediately clear that four of the seven highest transplanting countries also have presumed consent legislation. But it also appears as though these countries have relatively high road traffic deaths. The variation in road deaths between countries is high, with Portugal reporting 310 pmp and the UK 94 pmp, the latter being one of the lowest rates in the world. Could these road deaths 'confound', in statistical terminology, the observed association between the law and transplant rates?

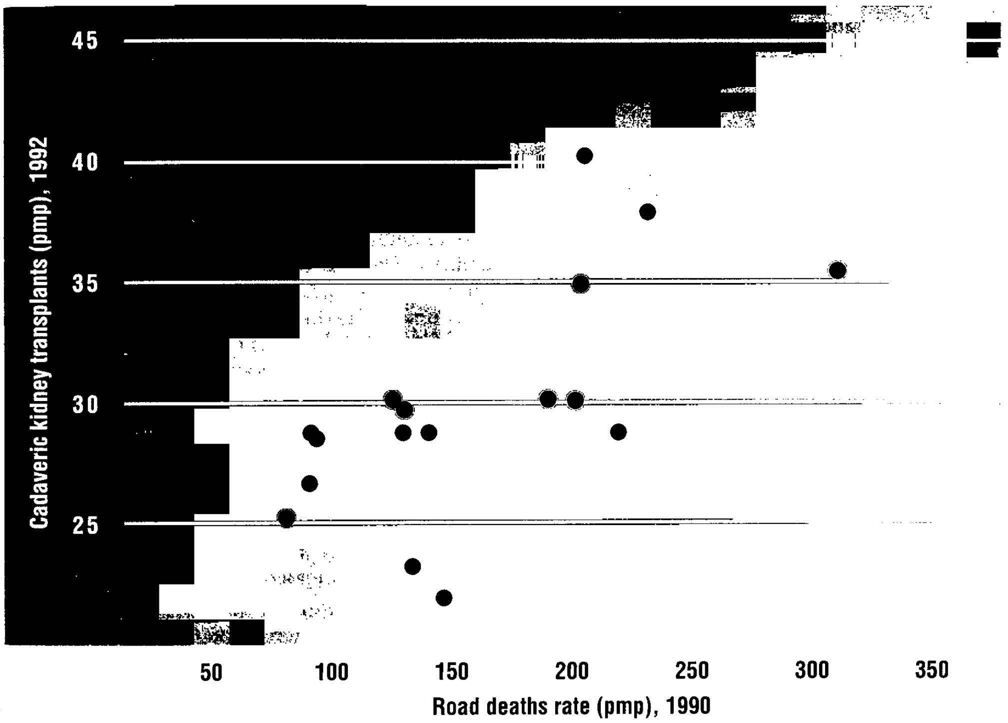
Table 3 Road deaths per million population (1990) and operation of presumed consent legislation in a selection of countries ranked by cadaveric kidney transplantation rates (1992)

Country	Road deaths pmp	Presumed consent/ opting-out legislation?
Austria	205	Yes
Spain	230	Yes
Portugal	310	
Belgium	202	Yes
USA	177	
Denmark	124	
France	200	Yes
Germany	130	
New Zealand	215	
Switzerland	140	
Netherlands	92	
Finland	130	Yes
UK	94	
Sweden	91	
Norway	79	Yes
Australia	136	
Canada	148	

Source: Department of Transport

There is some prima facie evidence that they do. Italy and Greece were omitted from the analysis because they are both special cases to a certain extent: Greece as a late starter and Italy with its particular set of organisational difficulties. Figure 16 shows a scatterplot of road deaths pmp by cadaveric kidney transplants pmp for the remaining seventeen countries. A simple bivariate regression reveals a significant relationship at the 95 per cent level of confidence – the hypothesised relationship is extremely unlikely to have happened by chance. Obviously, such statistical

Figure 16 Scatterplot of cadaveric kidney transplant rates (pmp), 1992, against road death rates (pmp), 1990, in seventeen countries



Note: Countries included: Austria, Spain, Portugal, Belgium, USA, Denmark, France, W Germany, New Zealand, Switzerland, Netherlands, Finland, UK, Sweden, Norway, Australia, Canada.

Sources: Department of Transport and as Figure 1

evidence cannot be conclusive. Nevertheless, there is a strong suggestion that road death rates have a significant influence on transplant rates, although other factors taken together are more important in explaining variations.

Intracranial deaths

A similar analysis could, in principle, be applied to the other main cause of death amongst organ donors – intracranial deaths. Unfortunately, international comparative data are less readily available for this form of mortality and, in fact, only allow for comparisons of all forms of cerebrovascular accident, including stroke. Stroke is a very large cause of mortality but seldom results in organ donation.

However, the relevant causes of death – intracerebral and subarachnoid haemorrhage – are available for regions within the UK. If there is an association between deaths from haemorrhage and donor rates at the regional level, then this would indicate that a similar effect is likely at the international level. In fact, in a regional analysis it is possible to pick a more appropriate dependent variable – donors pmp rather than cadaveric kidney transplants pmp. The former is the true variable of interest, since transplants can be affected by logistical factors.

Data were obtained from the Office of Population Census and Surveys (OPCS) for intracerebral and subarachnoid haemorrhage rates, and from the UKTSSA 1991-92 annual report for donor retrieval rates. The relationship between English Regional Health Authority intracranial death rates and donor retrieval rates was tested using the same statistical technique as that described above for road death rates. There was a significant relationship between the two variables at the 95 per cent confidence limit. Again, it should be emphasised that although significant, other factors taken together explain a greater proportion of the variation.

Nevertheless, it is not easy to demonstrate statistical significance with a small number of cases, since observed relationships are increasingly likely to have occurred by chance the fewer the number of cases involved. In both of these tests, however, statistical significance was demonstrated, indicating that the influence of intracranial and

Table 4 The leading cadaveric kidney transplanting nations ranked by their rate of activity pmp (1992), and population density

Country	**Population density (number per square km)**
Austria	92
Spain	77
Portugal	113
Belgium	322
USA	27
Denmark	120
France	103
W Germany	249
New Zealand	13
Switzerland	164
Netherlands	406
Finland	15
UK	235
Sweden	19
Norway	13
Australia	2
Canada	3

Source: *The Economist Pocket World in Figures 1994 Edition,* Hamish Hamilton Ltd.

road deaths on donor rates is probably quite strong.

The conclusion to be drawn from this analysis is an important one. International comparisons of success in achieving cadaveric transplantation rates should be made with extreme caution. Variations are at least in part due to differences in countries' 'pools' of potential donors. Furthermore, the sizes of these pools are falling due to medical advance. All that can be hoped for is to make the best use of the pool of donors available in any given country.

Population density

However, making the best use of the pool will also be influenced by at least one factor entirely beyond the influence of the medical profession – population density. In general, the less densely populated a country the longer the average distance between hospitals, transplant centres, and those suffering from a cerebrovascular accident. All these factors will make it harder to reach and transport patients to ICU, and more difficult and time consuming to collect and transport organs without affecting their suitability. Cadaveric organ procurement, it could be argued, is therefore more problematic in less densely populated countries.

The statistical test applied above does not confirm this hypothesis. However, this may be because a relationship only exists at low levels of population density. Although it is hard to test this proposition, it is to some extent supported by the evidence in Table 4, with the countries again ranked in order of their kidney transplantation rate in 1992.

Although there is no clear pattern, it does seem that population densities of less than 20 per square km have a significant impact on a country's ability to procure cadaveric kidneys, particularly Finland, Sweden, Norway, Australia and Canada. Of course, as has been emphasised, this is only one of many factors, but nevertheless will be important for a minority of countries. It is not, however, a factor restricting the UK's procurement ability.

Utilising potential donors in the UK

The best estimate of how well the 'pool' is utilised in the UK is provided by the work of Sheila Gore and colleagues from the MRC Biostatistics Unit, as a result of a recommendation from the Hoffenberg committee (Hoffenberg, 1987). The study – henceforward referred to as the 'national audit' – undertook a confidential audit of all deaths in intensive care units in England in 1989 and 1990. It does not, therefore, include potential donors on general wards, but nevertheless provides the best evidence of how effectively potential donors in ICUs are managed in England. A brief summary of the results is presented in Table 5.

One finding from the audit not reported in Table 5 was the regional variation in confirmed brain stem deaths. The researchers recommended increasing the number of brain stem death tests, but it was acknowledged that much of the variation in the number of tests undertaken could be explained by variations in the incidence of deaths from non-cranial causes. This supports the findings reported above: variations in donor rates will be due in part to variations in intracranial haemorrhage rates.

Although a significant proportion of potential brain stem deaths are not tested (perhaps indicating that potential donors are lost), it has been noted that 'possibly' brain stem dead individuals can show clear general medical contraindications to organ donation, thereby rendering formal testing redundant (Smith *et al.*, 1992). Furthermore, only six per cent of potential donors' families were not formally approached with a request for donation. Rather more significant is the number of relatives who refused permission for donation to go ahead – 30 per cent (301 from 989) of those with whom organ donation

Table 5 Estimated numbers of ICU deaths per year in various categories based on the national audit of ICUs in England, 1989 and 1990

Category				**Estimated numbers**	**pmp**
ICUs account for approximately 84 per cent of cadaveric solid organ donors. Estimated number of deaths in ICUs per year				**13,000**	
Number of deaths considered to 'possibly' satisfy brain stem death criteria				**1,768**	**37.0**
Number of brain stem deaths undertaken				**1,339**	**28.0**
Brain stem death confirmed				**1,287**	**26.9**
Confirmed and no general medical contra-indications				**1,054**	**22.1**
Organ donation offered to relatives?	**No**	**no known relatives**	**6**		
		not discussed	**59**		
	Yes	**donation refused**	**301**	**989**	
		offered but not retrieved	**22**		
		relatives consented	**666**		
Became donor of transplanted solid organ				**650**	**13.6**

Note: **figures are estimates, adjusted for lack of 100 per cent ICU compliance**

Source: **Gore *et al.*, 1992b**

was discussed. Reducing this proportion should clearly be an important policy goal. However, it would require this proportion to be reduced to close to zero for the UK to approach the transplantation rates of Belgium, Spain and Austria. Clearly this is highly unlikely, even under a reasonably strict interpretation of presumed consent legislation.

Concluding comment

All the practical and legal options for making better use of the donor pool – both cadaveric and living – will be analysed in chapter 4. Nevertheless, it should be clear that, with cadaveric donation at least, there are constraints on the total number of transplants which an individual country can hope to undertake. The transplant community in the UK should not be seduced into thinking that they can necessarily emulate the achievements of the world's most successful transplanting nations.

3 Context – the law, religious perspectives and public opinion

Transplantation activity takes place within a broad social context. In this chapter the analysis turns to a detailed examination of three aspects of this context in the UK. First, the legal framework within which organ procurement takes place is crtically assessed. Second, the religious perspectives of certain important faiths are outlined. Third, the current state of public opinion is reported, drawing on evidence from three of the most recent surveys.

The law relating to organ donation in England

In this section we analyse the English law relating to organ donation in some detail.

Cadaver transplants

The current legislation concerning cadaver transplantation is the Human Tissue Act 1961. The traditional view is that English law does not recognise ownership of the cadaver (Dr. Handasyde's case (C.18) 1 Hawk P.C.148; R v. Sharpe (1857) Dears. & Bell 160,163; Williams v. Williams (1882) 20 Ch.D. 659,662-3,665; R v. Price (1884) 12 Q.B.D. 247,252; Hamps v. Darby (1948) 2 K.B. 311, 319, 320, 322, 328.) (Matthews, 1983). The crucial issue is rather who has lawful possession of the body. The Human Tissue Act 1961 provides that organs from the deceased may be used for transplantation if removal is authorised by the person who is lawfully in possession of the body. It has been suggested that the person who has actual physical possession of the body has lawful possession for the purposes of the Act (Meyers, 1991). This may be the next of kin. However if the body is lying in hospital, nursing home or other institution, authority for transplantation may be given on behalf of the person having control or management (s1(7)).

The person in lawful possession may authorise the removal of an organ from the deceased in one of two possible situations. First, the deceased may have expressed a wish that his or her organs be used in this manner. S1(1) of the 1961 Act provides that the deceased must have made a request that his organs be used either in writing, on a donor card, for example, or orally in the presence of two witnesses during his last illness. There is no age limit stipulated for such a declaration (Lanham, 1971). If a declaration has been made then the organs may be used for transplantation, unless there is reason to believe that the deceased has withdrawn the request before death.

If no declaration has been issued then the person lawfully in possession may still authorise transplantation. However, the statute provides that he or she must make such reasonable enquiries as are practical to ensure that the deceased has not expressed an objection or that the surviving relatives do not object to the organs being transplanted (s1(2)). What enquiries must be made? No definition is given in the statute. Skegg (1984) suggests a reasonable enquiry would be simply to enquire of spouse or close relative as to whether they have expressed an objection or another person has objected.

If the organs are needed urgently can they be used even though no enquiry has taken place? S1(2) may, on one view, require that at least some enquiry should be made before the person lawfully in possession of the body authorises the removal of an organ for transplantation (Dworkin, 1970). On another view, an enquiry need only be made if reasonable and practical to make it. This approach can be contrasted with that taken in other jurisdictions: for example, in the United States the Uniform Anatomical Gift Act contains a prioritised list of persons who can authorise donation in the absence of the deceased's explicit consent.

Transplants must usually be undertaken by a registered medical practitioner who is satisfied, from an examination of the body, that life is extinct. However there are certain special provisions which concern the removal of eyes (Inserted by the Corneal Tissue Act 1986). These may be removed by a person who has been suitably trained and qualified acting under the supervision of a registered medical practitioner. Where there is reason to believe that an inquest may have to be held on a body or a post-mortem will be required, the Act provides that no authority for use of the body can be given without the consent of the coroner (s1(5)). Since delays by coroners could lead to organs being rendered useless the Home Secretary has issued guidelines which stress that consent should only be refused where there might be later criminal proceedings in which the organ might be required as evidence, or if the organ is (or might be) the cause (or partial cause) of death, or if its removal might impede further inquiries. Mason (1992) has suggested that the Scottish approach could be adopted allowing the coroner to be present at the transplant operation and this would then constitute the post-mortem.

Death

One potential difficulty facing transplant surgeons is the fact that there is no statutory definition of death in English law. The medical profession in the United Kingdom have long departed from the view that the failure of the heart, the traditional last gasp, is the end of the patient's life (cf M. Evans, 1990; Lamb, 1991). Today most medical practitioners accept that death is brain stem death (Pallis, 1987; cf Wainright *et al.*, 1986).

The courts have not expressed a precise view on the legality of brain stem death. In two cases in which the Court of Appeal had the opportunity to consider the issue they decided the case on other grounds (R v Cunningham and R v Malcherek and Steel (1981) 2 All ER 442 CA.). In a more recent case Re A (a minor) ([1992] 3 Med L.R. 303) in the family division of the High Court Johnston J accepted the claim that death had occurred at the point at which the patient was pronounced brain dead. If the courts are prepared to accept a definition of brain stem death then is there really any need for a definition to be included in statute?

The Criminal Law Revision Committee in their 14th Report (1980), rejected a statutory definition. They said that it would amount to fixing an expression of present medical opinion in statute and could become outdated. They also saw problems with disagreements as to the scope of such a definition. The Committee declined to examine the issue further arguing that it went beyond their terms of reference. It has been suggested by Kennedy (1973) that a law defining death could have the effect of adding to public unease and operating against the future interests of transplant surgery. Others have argued that a statutory definition is necessary in the interests of clarity and certainty for the medical profession (Skegg, 1976 and 1984). Jennett (1977) argues that a statutory definition is necessary to ensure that doctors do not face criminal charges. The argument that a statutory definition of death may be unresponsive to changes in medical practice can perhaps be overstated. It is possible for the definition of death to be enshrined in regulations which can then be altered if there are such dramatic changes in medical science to warrant it.

Cognitive death

One point that needs to be stressed is that death as generally accepted by medical practitioners is brain, or brain stem, death. Some discussion has been generated as to whether or not death for these purposes includes or should include cognitive or 'higher brain' death.

Considerable discussion of the issue of cognitive death has taken place in the context of anencephalic infants (Davis, 1988; Walters and Ashwall, 1988; Shewmon *et al.*, 1989; Ethics and Social Impact Committee Transplant Policy Centre, Ann Arbor, 1988). These are babies born with the cerebral hemispheres of the brain missing and with little or no brain function above the brain stem. It has been suggested that such infants are a potentially useful source of organs for both child and adult recipients (Rosner *et al.*, 1988). Anencephalics have been used as organ donors in this country. In 1986, for example, Magdi Yacoub carried out the first British neonatal heart transplant from an anencephalic donor. In 1988 a working party of the Royal Medical Colleges issued guidelines providing that anencephalic infants were to be treated as dead after two doctors had certified that spontaneous breathing had stopped (Working Party on Organ Transplantation in Neonates, 1988). In the case of beating heart donors organs should not be removed within the first seven days of life in view of the uncertainty surrounding diagnosis of brain stem death in the anencephalic. If a cognitive definition of death is accepted this would be to go one step further and may be tantamount to saying that such infants are 'dead' when born.

Ultimately, recognising cognitive death in order to access organs from anencephalic infants may be an unnecessary extension of the law. The number of anencephalic infants available is already small and is decreasing due to better screening; there are also fewer infants born with neural tube defects (McGillivray, 1988). But if anencephalic infants are recognised as potential organ donors should other individuals with brain damage be available as organ donors? When the supply of blood to the brain ceases it is the higher levels of the brain that are damaged first. These areas of the brain control faculties of alert awareness, perception, reasoning, problem-solving memory and decision-making. Patients may have brain damage to such an extent that they are in a persistent vegetative state. In addition some older children are hydrancephalic. They lack the cerebral cortex and have fluid in the cerebral cavity. Should they be regarded as dead in the eyes of the law?

Recognising cognitive death has advantages from the point of view of organ donation in that the pool of potential donors may be increased. However some would regard use of such persons as donors as morally abhorrent, arguing that they are in need of respect because of their status as human persons. There is also the danger of misdiagnosis. While the diagnosis of death may be relatively straightforward for those patients in coma which is the result of a chronic disorder in which there has been a steady deterioration in the patient's condition, diagnosis may be acutely difficult in relation to a patient who is suffering from a coma of traumatic origin.

One solution advanced is that rather than enter into difficult questions regarding the scope of cognitive death the anencephalic should be treated as a special case for the purposes of organ donation (Ethics and Social Impact Centre, Arbor, 1988; Truog and Fletcher, 1989; Walters, 1989; Winslow, 1989). However, due to the vast literature on this subject, and the relatively small impact anencephalic donation would have on transplantation rates, this issue will not be discussed further in this report.

Liability for failure to enforce the statute

There is no specific criminal offence included within the Human Tissue Act 1961 penalising those who fail to follow its provisions. In the past the courts were prepared to find that those who failed to comply with the legislation would be liable under a general common law offence of disobedience to a statute (*R v Lennox Wright* [1973] *Criminal Law Review* 67). However, this offence was criticised by the Law Commission (1976). They saw it as obsolete and said that without an express statutory provision there was almost always no intent by Parliament to penalise the conduct. In the more recent case of *R v Horseferry Road Justices exp IBA* [1987] the court held that if an express criminal offence for breach of a statutory provision was not included in a modern statute the common law would not fill the void. It appears most unlikely that the courts would today be prepared to follow the approach taken in *Lennox Wright.*

It has been suggested that where a death is the subject of a coroner's enquiry, if organs are removed without the authorisation of the coroner a doctor would be obstructing the coroner in the execution of his or her duties (Mason, 1992). But, to constitute an offence the action must actually cause an obstruction. Mason (1992) suggests that this is unlikely if, for example, the organs removed are the patient's kidneys.

It is uncertain as to whether a doctor who had removed an organ for transplantation without making enquiries would be held to have committed a civil wrong or tort and would be required to pay compensation to the deceased person's relatives. It has been argued that if nervous shock to the relative could be foreseen then damages may be recovered (Kennedy, 1988; Norrie, 1985). But ultimately, perhaps, as has been suggested by Mason, 'the most potent sanction lies with the General Medical Council' (1992).

Commercial dealing in organs

Until 1989 there was no legislation regulating commercial dealing in organs. However, in that year the Human Organ Transplants Act 1989 was passed. This piece of legislation was a response to the 'kidneys for cash' scandal. Individuals had been brought from Turkey and paid to donate their organs which were then transplanted into waiting patients. This incident led to disciplinary action before the General Medical Council. The Council's guidelines provided that doctors could not give treatment if donors were being paid. Three UK doctors were charged and after a 35 day disciplinary hearing they were found guilty of serious professional misconduct. The name of one was struck off the Medical Register.

The Human Organ Transplants Act 1989 provides that a person is guilty of an offence if he or she makes or receives payment for supplying or agreeing to supply organs for transplantation. Those who initiate organ dealing also commit an offence whether this is undertaken by an individual or an organisation.

An organ for these purposes is defined in section 7(2) of the Act as being any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body. The Act also makes it an offence to publish advertisements inviting people to supply organs for payment (Section 2). It was envisaged that payment refers not only to money but also to reimbursement in a non-financial form such as promises of promotion or of a better job (Department of Health, 1989). While the Act forbids payment for supply of organs, payments are allowed for defraying/reimbursing the cost of removing transplanting organ or any expenses on loss of earnings incurred by a person so far as reasonably and directly attributable to the supply of an organ from his or her body (S1(3)).

The 1989 Act reflects the concern expressed regarding commercial dealings in organs on a world-wide basis. The World Health Organisation has come down strongly against commercial dealing, declaring in 1988 that such trade is inconsistent with the most basic of human values and contravenes both the Universal Declaration of Human Rights and the spirit of the World Health Organisation Constitution (WH40.13).

Non-commercial live organ transplants

After the 'kidneys for cash' scandal there was considerable discussion as to whether live organ donation should be regulated. Today the law concerning live organ donation is consequently a combination of statute law and common law developed by the courts.

Can an adult consent to live organ donation?

At common law there is a principle that no one can consent to being killed or seriously injured (R v Brown [1993] 2 All ER 75; Dworkin, 1970). A transplant operation could, in theory, constitute serious injury. However a former Law Lord, Lord Edmund Davies, has stated extra judicially that he would be surprised if a surgeon was successfully sued for trespass to the person or convicted of causing actual bodily harm to one of full age and intelligence who freely consented to act as a donor (see Brazier, 1992). But he added the proviso that the operation must not represent an unreasonable risk to life or health. Where a kidney has been removed from a consenting adult it is highly unlikely that a court would strike this down on the grounds that it is contrary to public policy, since such an operation would usually only pose a minimal risk to the donor (Skegg, 1984).

It has been argued that there are practical limits to donation. A person could not, for example, decide to donate his or her own heart as

> *the risk-benefit ratio would be manifestly to the consenter's disadvantage ... At present, for practical purposes, this limits living donation to a single kidney or portions of the pancreas. It may well be that living donation of a lobe or segment of the liver or lung will become the norm in paediatric, or even adult, practice* (Mason, 1992).

Secondly, Mason suggests that it will be unlawful to accept an organ which one realises will almost certainly be rejected – for example, an animal organ. But the fact that the procedure is experimental does not necessarily mean that it is unlawful. There may be a risk that the organ might be rejected but the possibility of failure exists in the development of most medical technology. Adults are able to participate in many risky activities such as motor racing and hang gliding; likewise they can volunteer to take part in medical experiments. Moreover the risk here is undertaken with the laudable aim of saving life.

The use of vulnerable groups such as children and the mentally incompetent as organ donors is highly controversial. The law on this point is unclear. As far as the mentally incompetent adult is concerned the House of Lords has affirmed that while no one can consent on the behalf of such an adult to medical procedures (Re F [1990] 2 AC 1), a doctor may treat a patient where it is in the best interests of the patient. However it is unclear as to how far the power to act in the best interests extends. A transplant operation performed for therapeutic reasons on an incompetent adult may be in that patient's best interests. Difficulties arise in those situations where it is proposed to use a mentally incompetent adult as a donor. It may be argued that such a donation may be of therapeutic benefit. This type of argument was used in a famous US case, Strunk v. Strunk (1969) 35 ALR (3D) 683. In this case the donor was an adult with a mental age of six. He was chosen to donate a kidney to his brother who was critically ill. The court came to the conclusion that it would be in the best interests of the donor for his brother's life to be saved after they had heard evidence of the close relationship between the two brothers (Schwartz, 1985). The argument that the donation is therapeutic is one which should be examined with care. It is important that the rights of the mentally impaired be safeguarded.

In some jurisdictions the issue of whether prisoners and members of the armed forces should be able to donate has been the subject of some controversy (Adams, 1987). This issue has not arisen in this country. Prisoners are competent to consent to medical treatment (Freeman v Home Office [1984] 2 WLR 430). An American commentator, Adams (1987) has suggested that the only fair approach to donation by such groups is a system by which independent and institutional checks could be introduced. He recommends that the donor be required to seek independent and non-medical advice as to the wisdom of donation prior to giving consent. The donor's case should then be reviewed by an institutional board, perhaps along with a psychological evaluation of the donor's suitability.

Children as donors

Are children capable of consenting to their involvement in an organ donation programme? In Re W (A Minor) [1992] (3 WLR 758 at p772) the Court of Appeal suggested that the Family Law Reform Act 1969 which authorises children over 16 to consent to medical treatment does not apply to donation of organs or blood. At common law a child can consent to medical treatment as long as that child is deemed competent to do so by the medical practitioner treating that patient (Gillick v West Norfolk and Wisbeach AHA [1986] AC 112) and it is suggested that this common law position also applies in relation to organ donation. If a child is incompetent to consent to medical treatment that treatment may be authorised on their behalf by their parents, or where there is a disagreement between parent and children – as to the giving of, for example, life saving treatment – by application to the court. The extent to which a donation by an incompetent child would be lawful is at present unclear. As in relation to an incompetent adult the court may decide that the child derives some therapeutic benefit from acting as an organ donor (Norrie, 1985).

At a European level transplants from minors and other incompetents have been allowed. The Council of Europe Resolution on the Harmonization of Transplantational Legislation provides that the removal of organs from minors and other legally incapacitated persons should be allowed if the donor and his or her legal representative is given information about, for example, the medical, social and psychological consequences of donating (Resolution (78) 29 Art. 6). In France living donation between minor siblings is recognised if consent to organ removal is given by the donor's legal representative and authorised by a committee of three experts. Two of these experts must be doctors, one of at least twenty years standing. Refusal in the case of a mature minor must be respected in all cases (Mason, 1992).

At present the question of live donation by a minor appears to be of more theoretical than practical interest. Brazier (1992) has suggested that it is unlikely that English courts would sanction such a major procedure as the removal of a kidney from a child, although she notes that bone-marrow donations are routine. Mason (1992) comments that he has not come across any British surgeon currently practising who would accept a live child as an organ donor.

Mental incapacity and organ donation

The issue of whether a mentally incapacitated adult should be allowed to donate his or her organs for transplantation is presently under consideration by the Law Commission (Law Commission, 1993). The Commission has suggested that certain major decisions concerning mentally incapacitated adults be referred to a 'judicial forum' (Para 4.4) and the donation of organs and tissue would come within this category (Para 6.21). This is a welcome suggestion. The decision to transplant an organ from a mentally incapacitated person is a serious step and all possible safeguards which can be introduced are to be welcomed. The Commission invites debate as to whether any additional criteria other than that contained the Human Organ Transplants Act 1989 should be included before transplantation is authorised.

It seems reasonable that only in the most exceptional cases should a mentally incapacitated adult be even contemplated as an organ donor. A mentally incapacitated adult who is not a relation or does not have some close personal bond with the proposed recipient of an organ should not be used for transplantation. If the donor does fulfil these criteria then the operation should only be undertaken where the risk to the donor is minimal, where the recipient requires the transplant to save his or her life and, after taking all reasonable steps, another suitable donor cannot be found.

Can donation ever be forced?

It appears highly unlikely that an English court would ever compel a person to donate an organ without their consent. This issue was the subject of discussion in the case of McPhail v Shimp (1978) in the United States. Robert McPhail was suffering from a rare bone disease and the prognosis for his survival was slim unless a comparable donor could be found. After a search was made it was found that the defendant's first cousin was the only suitable donor. While his cousin had originally agreed to a first test to determine suitability he later did not want to go ahead with the transplant. In the Pennsylvania court, Flaherty J said that the common law had consistently held to the rule which provides that no human being is under a legal compulsion to give aid to another human being or to rescue that human being. He commented that forcible extraction of living body tissue causes revulsion to the judicial mind raising the spectre of the swastika and the Inquisition.

It appears undesirable for one person to be forced to benefit another in the general good at a time when English law does not impose any general obligation to behave as a good Samaritan. This argument would appear to apply equally in the case of a child donor. While there are recent statements which have been made by the Court of Appeal that parents may consent to treatment even when a competent minor refuses, it is submitted that the facts of those cases are significantly different from the transplantation question and a court would be unlikely to sanction organ transplants from an unwilling minor (Re R [1991] 4 All ER 177; In Re W (a minor) [1992] 3 WLR 758).

Genetically unrelated live donation

Alongside the common law is the Human Organ Transplants Act 1989. The need to prevent commercial dealing is reflected in the encouragement given to donation between relatives and the obstacles placed in the way of donation between those not genetically related. The Act makes it an offence, unless certain safeguards are complied with, for a person who lives in the UK to remove an organ intended to be transplanted into another person or to transplant an organ from one living person to another living person unless the person into whom the organ is to be transplanted is genetically related within a prescribed class of individual (s2(1)). Those relatives included are parents, children, brothers and sisters, aunts and uncles, nephews and nieces. Genetic relationships for the purposes of the Act are established by use of genetic fingerprinting tests (Human Organ Transplants (Establishment of Relationship) Regulations 1989 SI No 2107). Unrelated donors were seen as being especially likely to donate because of a commercial motive.

The Act does not stop transplants between unrelated persons but it imposes various safeguards before such transplants may go ahead (s2(6)). The regulation of unrelated live donation is governed by an independent body ULTRA – the Unrelated Live Transplant Regulatory Authority (ULTRA,1992). Two types of transplant between genetically unrelated persons are regulated by the Authority. First, those transplants which occur when an organ becomes available as a result of a procedure undertaken primarily for the donor's treatment, and second, all other transplants. In the case of the first type of transplant the Authority must be satisfied that no payment has or will be made in contravention of section one of the Act and that the application to the Authority has been made by a registered medical practitioner. In relation to the second category transplants may take place if the Authority is satisfied that no unauthorised payment has been made and the donor has been referred to the Authority by a registered medical practitioner who has clinical responsibility for him. An additional five criteria have to be considered in relation to this second category (Human Organ Transplants (Unrelated Persons) Regulations 1989 SI No. 2480).

1 The medical practitioner must give the donor an explanation of the medical procedures and the risks involved in the removal of the organ.

2 The donor must understand the nature of the medical procedure and the risks as explained by a registered medical practitioner, and give consent.

3 The donor's consent to the removal of the organ must not have been obtained by coercion or offer of an inducement.

4 The donor must understand that he or she is entitled to withdraw consent if so desired, but that he or she has not done so.

5 Donor and recipient must both have been interviewed by a person who appears to the Authority to have been suitably qualified to conduct such interviews and who has reported to the Authority as to whether the above conditions have been satisfied and has included in their report an account of any difficulties in communication with donor/recipient and an account of how these were overcome.

In practice these interviews are undertaken by a hospital consultant or someone of equivalent standing. There is an appeal structure. In non-urgent cases appeals are considered at the Authority's next meeting. In urgent cases a case committee is set up to approve such applications.

Between 1st April 1990 and 31st March 1991, 304 transplants were approved: 289 concerned domino heart transplants – those where the donor is the recipient of a heart and lung – and cardiac and pulmonary valve grafts. Six corneal transplants were approved, under conditions whereby the donor needs major surgery to the face. Nine were renal transplants, but no mention was made of how many of these donors were spouses.

In its first annual report, the Authority commented that it was not aware of any illegal transplants being undertaken in the UK, although it took the view that there is always scope for abuse where kidneys and other organs are removed from living persons outside the UK and brought into the country (ULTRA, 1992).

One criticism of the 1989 Act is that while it provides safeguards with the aim of ensuring that unrelated donations are bona fide, there are no such safeguards provided for related donors. It can be argued that those who are close relatives of the patient needing a transplant have special need of counselling in view of the pressure which may put upon them to donate.

> *In our Judeo-Christian society, in which self-sacrifice is a working ethic, more courage may be required to resist organ donation than to accept it* (Starzl, 1985).

We may, on the other hand, be in danger of undervaluing altruism by unduly restricting non-related donation.

> *Any 'genetic-relative' restriction clearly debars virtually the whole of humanity from the opportinity of such fraternity and love in any given case of need for an organ* (M. Evans, 1989).

Individuals may be motivated to donate to persons other than those to whom they are genetically related. But this analysis is developing into an ethical debate which will be explored more fully in chapter 5.

Conclusion

At present, while statute does provide some regulation of organ donation and transplantation, the cover provided is by no means comprehensive and the existing law relating to both cadaver and live donation presents those engaged in transplantation with considerable problems. A thorough overhaul of the existing legislation covering organ donation would be helpful, irrespective of the merits of changing the law to one of 'presumed consent', or of the specific concern relating to elective ventilation – these issues are discussed in chapters 4 and 5. However, a general review of legislation should be undertaken as part of a wider overview of both tissue and organ donation – encompassing questions such as the ownership of tissue, recently examined by the Nuffield Foundation on Bioethics. Such an undertaking would be a major task which goes far beyond the boundaries of this report.

Religious perspectives

In a multi-cultural society it is important to pay respect to the views of different cultural and religious groups. A number of spokespersons for various religious denominations were contacted and asked directly their opinion on organ donation and changing the law to one of presumed consent. Most groups contacted had no defined policy regarding an alteration in the law. They stressed that the decision on whether an organ should be removed was essentially for the individual concerned. Some groups provided a fuller response than others.

Christianity

As far as the Christian faith is concerned, the Church of England have no defined policy on organ donation. However the Archbishop of York indicated in correspondence that the Church would probably wish to stress that while organs were needed and an automatic system would avoid the stresses involved in obtaining consent from relatives, consent is nevertheless one of the foundation stones of medical ethics. This somewhat ambiguous position is echoed by other writers:

> *... the prior consent, implicit or explicit, of the donor while alive and/or of the donor's next of kin is essential* (Scorsone, 1990).

These rather broad conditions leave open the possibility of presumed consent being acceptable, though with a certain nervousness. Respect for the corpse is also central to the Christian and many other faiths. This could operate against organ donation, particularly through schemes such as elective ventilation, discussed later in this report (see page 55). It is acknowledged, however, that there is no single correct means of respecting the dead; times may change and in the future there may be a social assumption that to use dead bodies as a means of life for others is to pay them respect. At present there is no such assumption.

Other groups, such as the Mormons and Jehovah's Witnesses, have put forward the view that the decision regarding donation is simply a matter for the conscience of the individual believer. The Greek Orthodox Church emphasises the importance of ascertaining carefully the time of death, and would not regard transplantation from a body being kept 'alive' on life support systems as justifiable. This may partly explain the relatively low level of cadaveric donation in Greece.

Islam

There is divergence among Islamic commentators as to whether donation is allowed under Islamic law. Some authorities have emphasised the requirement that the cadaver is not mutilated, including cremation, and that the most appropriate and religiously required act is to bury the dead as soon as possible:

> *both religious beliefs regarding bodily resurrection and cultural norms about the treatment of the dead with respect and consideration make the donation of bodily organs loathsome to Muslim sensibilities* (Sachedina, 1988).

On the other hand, it has been noted that certain principles of Islamic law can be interpreted as allowing cadaveric donation: justifiable exceptions occur for established rules, for example allowing blood transfusions to save life, and choosing the lesser of two evils (Sahin, 1990).

Nevertheless, this ambiguity may have contributed to past difficulties in getting members of the Asian community to donate organs. In this community there is much dependence upon the role of the head of the family in decision-making which can present considerable problems when the head of the family is still in their country of origin. In Leicester, despite making a video in an Asian language and a substantial publicity campaign, the transplant co-ordinator has commented that in 10 years she has had only one Asian donor in the area. This is in the face of considerable kidney failure among the Asian community. Many Leicester Muslim groups have directly opposed donation. The Department of Health, with support from Muslim leaders, has made another video in support of organ donation but this has apparently had little impact. It is likel that the introduction of presumed consent legislation may lead to objections from this religious group, as was the case in Singapore (see page 58).

Shinto

The Shinto religion is presumed to be as old as Japanese culture. The

> *vague and 'primitive' ideas and concepts expressed in the classic literature, all of which had been written or edited before the 11th century, are still accepted by modern Japanese society* (Namihira, 1990).

There have been problems in obtaining consent to donation from those of the Shinto religion because the followers of this faith believe that there are grave consequences in not according respect to the dead. The relatives expect to see the deceased before or shortly after death and doctors will often refrain from pronouncing death until relatives are present. This means that the organs may be rendered useless for transplantation. If the itai, or remains, is harmed by an accident or crime then the soul of the dead is believed to be unstable and unhappy and has capacity to bring misfortune to the deceased's relatives.

> *To this day it is difficult to obtain consent from bereaved families for organ donation [...] even in cases where individuals had indicated willingness to offer their dead body after death [...] Most Japanese think injuring the itai makes the dead person's soul more miserable than ignoring the person's living will* (Namihira, 1990).

A policy of presumed consent would therefore be likely to provoke opposition from those of the Shinto faith.

Judaism

Orthodox Judaism is not opposed to the removal of organs from cadavers, according to one leading authority (Shulman, 1993), although individual Jews often object and Jewish teaching is not clear cut, particularly with reference to brain stem death. It is part of Jewish teaching that death should not be hastened and the law prohibits the hastening of death of one individual to save another (Weiss, 1988). Heart transplants, in particular, are a source of some controversy with the extreme Orthodox (Era Haredit) community. It has been argued that heart and liver transplants constitute murder because the heart is beating until it is removed. These objections are in opposition to the fundamental principle of organ donation and thus apply to both opting-in and presumed consent systems. The Jewish position regarding a change in the law to presumed consent is unclear.

Three major principles emerge in the context of Jewish medical ethics. First, there is the supreme sanctity of human life, second the dignity of the person as a creation reflecting God, and third the need to reduce suffering and meet the needs of the sick and their families. While Jewish law provides that the dead may not be mutilated, profit may not be obtained from their remains and death may not be hastened nor burial deferred, these criteria may be outweighed once the life of the prospective recipient is at stake.

> *While these issues have been debated among Rabbinic authorities, the general consensus is that the saving of life, limb or function is of paramount importance and effectively overrides these concerns* (Bulka, 1990).

There has also been a shift in Jewish opinion towards acceptance of brain stem death criteria (Weiss, 1988). Nevertheless, it is quite clear from this discussion that presuming consent would not be acceptable to at least some members of the Jewish community, since they do not readily sanction donation under any circumstances.

Live donation may be undertaken even if there is a major risk to the donor, if otherwise the death of the recipient is certain.

Other religious groups

There appears to be no religious objection to organ donation from Buddhists. The position regarding Hindus is slightly less clear. It has been suggested that in the case of Hindus donation is allowed if they expressly request prior to death that their organs be used. However, in general

> *There is nothing in the Hindu religion indicating that parts of humans, dead or alive, cannot be used to alleviate the suffering of other humans* (Trivedi, 1990).

Finally, two smaller groups oppose transplantation in all its forms: Rastafarianism and Christian Science (Andrews and McIntosh, 1992).

Conclusion

A significant minority of the major religious denominations have reservations about organ donation. Although views on the issue of presumed consent have rarely, if at all, been formulated, it seems clear that its provisions have the potential for offending some Muslims or Orthodox Greek or Jewish believers, as well as some smaller groups. Drafting of such legislation would need to take these concerns seriously.

Public opinion and organ donation

People's attitudes have long been recognised as precursors to behaviour. In the area of organ donation specifically, public attitudes have been identified as playing a crucial part in the procurement process. By the mid-1980s it was acknowledged that 'attitudes toward organ donation are often cited as an impediment to the procurement of organs for transplantation' (Manninen and Evans, 1985).

The recognition that 'the availability of organs for transplantation is affected … crucially by public attitudes' (Wakeford and Stepney, 1989) has increased awareness of the importance of investigating people's views regarding all aspects of the organ donation process. This has been recognised in the USA, where in 1991 it was felt that 'much of the present debate about these controversial issues went on without serious consideration of the opinion of the general public' (Kittur *et al.*, 1991).

While there have been surveys of public opinion in Britain concerning organ donation, notably those commissioned by the Department of Health and the British Kidney Patient Association, it was felt that a discussion of the particular issues contained within this report would benefit from an investigation and analysis of public opinion as it relates to the same specific issues. There were three main reasons for doing so.

First, as already discussed, 'people's attitudes are an important aspect of organ procurement, and certainly serve as the basis of human behaviour' (Manninen and Evans, 1985). If future donation behaviour is the focus of discussion, serious consideration must be given to investigating the attitudes of the general public. As has been starkly realised in the USA, 'the success of organ procurement depends on the altruism of the

3

PUBLIC OPINION QUESTIONNAIRE

Introduction

You may know that hospital doctors sometimes carry out transplant operations. These operations involve removing an organ, such as a kidney or a heart, from a person who has just died and giving it to another person. This can sometimes save the life of the person who is given the new organ. The person who gives their organ is called a donor. Here is a list of some of the organs that can be donated after death: heart, lung, kidney, liver, pancreas.

Question 1

Some people's organs are not always suitable for using in a transplant operation, *but if we assume your organs were suitable,* would you agree to donate your organs after your death? Can you read this card and tell me which answer applies to you?

Yes, definitely
Yes, possibly
No, because of religious reasons
No, because of other reasons
I don't know

Question 2

You may know that people can carry a 'donor card' which they can fill in to say which organs they would like to donate after their death. Will you look at this next card and tell me which answer applies to you?

I have a donor card, and I usually carry it with me
I have a donor card, but I don't usually carry it with me
I don't have a donor card, but would think about getting one
I would probably not get around to carrying a donor card
I don't think it's worth me carrying a donor card
I would not want to carry a donor card
I am not sure

Question 3

At present, organs are normally taken from someone who has just died only if their relatives agree at the time.

I'd like to describe two different situations to you and ask you what you think you might do.

Supposing you had a relative, aged between 16 and 50, who was in intensive care in hospital, and who the doctors unfortunately thought was unlikely to survive, and you were their nearest relative.

Firstly, if your relative was not carrying a donor card and had never made their views clear, would you agree that their organs could be used after their death? Please choose your answer from the card.

Yes, definitely
Yes, possibly
No, for religious reasons
No, for other reasons
I don't know

Question 4

Secondly, if this time your relative was carrying a donor card and had made it clear that they were willing to donate their organs, would you agree that their organs could be used after their death?

Yes, definitely
Yes, possibly
No, for religious reasons
No, for other reasons
I don't know

Question 5

From what you have heard or read, do you think that: there is usually a shortage of donor organs for transplant or are there usually enough available when they are needed?

I don't know

Question 6

When there is a shortage of donor organs, do you think that some sort of incentive should be given to a person to encourage them to agree to donate organs?

Yes. In Britain we tend not to pay people for being a donor; for example, people donate blood free. Do you think people should be given money as an incentive to donate organs?
Yes, money
No, not money but other
Don't know if money, but other
No, no incentives
Don't know

Question 7

As I mentioned earlier, at present, organs are normally taken form someone who has just died *only* if their relatives agree at the time. In some countries one way which is used to increase the numbers of donor organs is to say that organs could *always* be taken from adults who had just died, *unless* they had specifically forbidden it. The person's relatives would not need to be asked. Can you look at this card and tell me whether you would be in favour of this in Britain or not?

Yes, definitely
Yes, possibly
No, for religious reasons
No, for other reasons
I don't know

Question 8

Lastly, if you were advised by a doctor that you really needed a transplant operation, would you accept the transplant? Can you read this next card and tell me which answer applies to you?

Yes, definitely
Yes, possibly
No, because of religious reasons
No, because of other reasons
I don't know

American people' (Prottas and Batten, 1991).

Second, it is important to explore variations within national data, so that any policy recommendations which emerge may be focused towards particular sub-groups of the population. 'An understanding of sociodemographic variations in attitudes and behaviour may facilitate organ procurement efforts by identifying target groups for information dissemination' (Manninen and Evans, 1985).

Third, information about public opinion is crucial in the context of the current policy debate concerning suggested changes to present practice. One useful tool for choosing certain policy options from a range of alternatives is to gauge the popularity of the suggested possibilities. This is particularly important for organ donation, which relies so heavily upon public confidence in and co-operation with statutory procedures. National surveys are useful 'to assess public attitudes about alternative methods to increase donation and to see whether any of these methods offend the sensibilities of the general public' (Kittur *et al.*, 1991).

Method

Given the significant role of public attitudes in the process of organ transplantation, it was important to obtain some indication of the views of people in Britain concerning some of the issues discussed specifically in this report. The most effective way of eliciting people's views on a large scale was to conduct a national survey. The Office of Population Censuses and Surveys (OPCS) was commissioned to include a number of questions relating to organ donation in their Omnibus Survey in September 1992. A representative sample of 2035 adults in England, Wales and Scotland was obtained through the household survey conducted over two weeks. Respondents were told that the survey was concerned specifically with kidney, heart, lung, liver and pancreas donation. The issues addressed by questions in this survey can be found in Box 3.

Information concerning these issues provides a picture of public knowledge of, and orientation to, organ donation in general, people's actual and envisaged behaviour under the present system, and an indication of the level of popularity of future policy options.

Comparative data

In describing the findings of this survey, it is possible to make comparisons with information from other sources, both British and international. In Britain, national household surveys of public opinion regarding organ donation were commissioned by the Department of Health (DoH) and the British Kidney Patient Association (BKPA) in 1992. The DoH commissioned Research Surveys of Great Britain (RSGB) to include relevant questions in their July 1992 Omnibus Survey, which obtained a nationally representative sample of 2000 adults. Since 1988, the BKPA has annually commissioned Gallup to ask questions concerning kidney donation to a nationally representative sample of 1000 adults. While the results of the survey conducted in April 1992 are presented here, the results from the October 1993 BKPA/Gallup survey were not significantly different. For consistency, therefore, findings are compared for surveys conducted in 1992. International comparisons are possible where there are appropriate data.

Findings

In this section the main findings from the OPCS Omnibus Survey are presented.

Awareness

In establishing the extent of awareness of the issue among the British public, it was found that 90 per cent thought that 'there is usually a shortage of donor organs for transplant'. This may represent a permanently high level of awareness among the British public generally, or it may reflect the publicity given to organ donation in the media in 1992 as a result of the plight of four year old Laura Davies.

Applicability

Nearly nine out of ten (86 per cent) of respondents thought that they would accept a transplant if they had been advised that they 'really needed' one, while 7 per cent didn't know. Another 7 per cent thought that they would refuse a transplant, including 1 per cent of the sample who said that they would refuse for religious reasons. This gives an indication of the proportion of people for whom organ donation and donation policy are not personally relevant. A similar result was obtained from a survey of nearly 1500 people in 1987, when just over 5 per cent said that they would refuse to accept a transplant for themselves (Wakeford and Stepney, 1989). These findings are supported by anecdotal evidence from some transplant surgeons. Thus while the overwhelming majority of the population would accept a transplant, it is important to recognise that a small but significant number of people in Britain indicate that the option of transplantation would not be considered for religious, moral or other reasons.

Attitudes to donation

In order to ascertain people's views about donation in principle, respondents to the OPCS Omnibus Survey were asked whether they would agree to donate their own organs after death. Similar questions were also asked in the DoH and BKPA

Table 6 Attitudes to donating own organs after death

%	OPCS	DoH	BKPA
In favour	**70**	**70**	**72**
Against	**13**	**12**	**18**
Other (neutral or don't know)	**17**	**18**	**10**

Sources:
- **OPCS Omnibus Survey, September 1992;**
- **RSGB Omnibus Survey, July 1992;**
- **Gallup Poll, April 1992.**

surveys. The results from all three surveys are shown in Table 6.

The findings of all the surveys are very consistent. Seven out of ten people in Britain would agree to donate their organs after death. This indicates widespread positive attitudes in favour of donation, even after recognising the possibility of 'social desirability bias' (Edwards, 1957). In wishing to give a 'desirable' response, some people may have reported willingness to donate without being completely certain. Bearing this in mind, however, a majority of people in Britain are in favour of donating their organs after death.

In comparison, surveys in the USA during the 1980s found that only between 45 and 50 per cent of Americans were willing to donate their own organs (Evans and Manninen, 1988). More recently, while 79 per cent of Americans reported no objection to organ donation in general, only 36 per cent 'claimed to be potential organ donors' (Kittur *et al.*, 1991). In Holland an equivalent figure of 38 per cent has been found (Kokkedee, 1992).

These international comparisons highlight the relative willingness of people in Britain to consider donating their own organs after death. The subsequent issue is, therefore, the extent to which this widespread support in principle translates into potential donating behaviour.

Table 7 Donor card holders

%	OPCS	DoH	BKPA
Card holder, usually carry	**19**	**23**	**25**
Card holder, don't usually carry	**8**	**7**	**7**
Not card holder	**73**	**67**	**67**

Source: As Table 6.

Donor cards – ownership

Given the present system in Britain, how do both public awareness of a shortage of donor organs and widespread public support for donation in principle translate into the carrying of organ donor cards in practice? Table 7 shows that approximately one in five people in Britain usually carry an organ donor card. About 7 per cent have a donor card but do not usually carry it with them. Approximately 70 per cent do not have a donor card.

While one in five may appear to be a low rate of card carrying, two positive features emerge. In a comparison of the Department of Health's data over time, the proportion of all people with donor cards, including those who do not usually carry them, has risen from 21 per cent in 1988 to 30 per cent in 1992. Second, the British situation can be compared favourably with rates of card ownership in other European countries. In Holland 18 per cent have donor cards, although only 9 per cent always carry them, while in Germany only 2 per cent of the population have cards (Kokkedee, 1992). The American situation appears to be more similar to Britain, where in 1987 an estimated 25 per cent of the population carried organ donor cards (Evans and Manninen, 1988).

Nevertheless, there is a clear disparity between the proportion of people with favourable attitudes towards donation and the proportion who carry donor cards. Approximately one half of the OPCS survey sample reported that they would be in favour of donating their organs after death but did not carry a donor card. Of those, however, about one half (27 per cent of the total sample) stated that they 'would think about getting one'.

However, while there may be some scope for increasing donor card ownership, it is not clear whether this would have any impact on donation rates. Indeed evidence from 1988-92, during which time card ownership increased with no corresponding rise in donations, suggests that the impact might be minimal. This is discussed further below.

To be successful, the whole system of procurement and distribution of organs must inspire public confidence. It is not clear that the public are wholly confident in the system, if 'folk tales' such as that described in Box 4 are to be believed.

However, one way of addressing the issue of public uncertainty is to use survey data to examine variations in the rate of donor card ownership and in attitudes to donation within the population. One

4

'URBAN FOLK MYTH'

There are various sources of evidence about public perceptions of social issues. One which has received some attention is the contemporary legend or 'urban folk tale'. As with the traditional myth, the contemporary legend survives because it possesses three elements: a strong story-line, a foundation in actual belief and a popular moral (Brunvand, 1983). During 1992, the following story was in circulation in the city of Nottingham:

> *A 17 year old went to a (named) night club in the city one Friday. He did not come home, so his mother called the police, who were not very interested. He did not come back all weekend, but rang his mother from a call box on Monday, saying he was unwell. She drove to pick him up and found him slumped on the floor of the call box. He said that he had passed out after a drink in the club and remembered nothing of the weekend. There was a neat, fresh scar on his abdomen. She took him to the hospital, where doctors found that he had had a kidney removed. The police were called again and showed much more interest. A senior officer spoke to the mother and said that there was a secret surveillance operation going on in this club and others in the region because they had had several cases of the same kind and they thought that the organs were being removed for sale.*

A few days later the story was picked up by the *Nottingham Evening Post* (23 July 1992) as a response to many calls from members of the public. The local police had also been inundated with calls. Both they and the renal specialist at the City Hospital said that the account had no basis in fact and the reporter wrote the story up as a contemporary legend. A slightly different version of the story was covered by the local BBC radio station in their morning news magazine on 4 August 1992. An appeal among sociologists elicited a number of reports of the story from other cities and countries.

This story clearly has a strong plot and is founded on a detailed factual structure. The moral is also fairly obvious: young people ought to be careful about night clubs or, more generally, about any activity which takes them out of a circle of family and friends. Stated like this, the thematic descent from a traditional folk tale like that of Hansel and Gretel should be apparent.

Such internal characteristics, however, can only partially account for the dissemination of the story. The folk tale draws its strength as much from the receptivity of audiences as from the skill with which it is told. In the modern world, we may no longer believe in witches who roast children in their ovens. However, it seems that large numbers of people in widely scattered locations are ready to believe that there is a market in stolen organs, supplied by unscrupulous surgeons and their accomplices. The plausibility of this story is indicative of a wide ranging, if low level and imperfectly articulated suspicion of organ transplantation and the means by which its demands are met. Paradoxically, the more emphasis is placed on the crisis in supply, the more plausible becomes the notion of an underground trade.

It is, of course, important not to place too much emphasis on one folk tale told on different occasions for different purposes. Nevertheless, it would be equally inappropriate to dismiss it as an item of evidence of popular disquiet which may need to be addressed in any proposal for policy change.

criticism made of previous investigations into organ donation has been that variations in the willingness to donate have not been addressed (Prottas and Batten, 1991).

Donor card ownership varies by sex, age and social class. Twice as many women as men carry cards. People in their thirties are most likely to carry donor cards while those over the age of 60 are least likely to do so. People in higher social classes are far more likely to carry cards than people in lower classes. Previous analyses have attributed this to 'unequal visibility of card displays and in their general distribution' (Lewis and Snell, 1986).

More importantly, perhaps, willingness to donate varies by the age and social class, though not sex, of the respondent. People up to their mid 50s and those in higher social classes are more likely to have favourable attitudes to donating their organs after death.

Donor cards – impact

As mentioned above, it is essential to attempt to assess the potential impact of donor cards on donation rates. In an effort to estimate the effect on the next of kin of the deceased, respondents to the OPCS survey were presented with two scenarios, both in the context of the present practice of asking for relatives' consent to donate organs. These were included to address the criticism that research into opinions about organ donation has not clearly distinguished between giving permission when the deceased's views are, and are not, known. It is also important to elicit specific rather than general attitudes if the purpose is to provide some indication of specific behaviour (Ajzen and Fishbein, 1980).

People were asked the following question in the survey:

> *Supposing you had a relative, aged between 16 and*

> *50, who was in intensive care in hospital, and who the doctors unfortunately thought was unlikely to survive, and you were their nearest relative.*
>
> *Firstly, if your relative was not carrying a donor card and had never made their views clear, would you agree that their organs could be used after their death?*

Over half (58 per cent) stated that they would be likely to agree to donation. Almost a quarter (23 per cent) reported that they would refuse to give permission. These findings compare closely with equivalent figures of 56 per cent agreement in Holland (Kokkedee, 1992), and 53 per cent of an American sample asked in 1984 (Prottas and Batten, 1991).

The reported refusal rate of 23 per cent can also be compared with the actual rate of relatives' refusal of 30 per cent found in the national audit of organ donation in England (Gore *et al.*, 1992b). While the opinion question appears to underestimate slightly the rate of refusal, it can be seen as a roughly valid predictor of behaviour, given the extremity of a situation which is impossible to imagine exactly without experience.

However, it should be noted that this question does not elicit refusal rates in circumstances when the deceased does not have a card but has previously declared their wishes about donation.

Respondents were then asked:

> *Secondly, if this time your relative was carrying a donor card and had made it clear that they were willing to donate their organs, would you agree that their organs could be used after their death?*

Given these circumstances, 95 per cent of respondents stated that they would agree to donation. Only 2 per cent stated that they would refuse. The equivalent figure for Americans in 1984 was 92 per cent agreement (Prottas and Batten, 1991). It is clear, therefore, that the overwhelming majority of people would act upon the wishes of a deceased relative in such circumstances. One limitation of this question should be noted, however, namely that the refusal rate is unknown for the situation when the deceased is carrying a card but has not previously declared their wishes to the next of kin.

The comparison between attitudes in the two given circumstances is illustrated in Table 8. Together, the two questions assume people with a card have made their views known to their relatives, and that people without a card have not. They do not elicit data concerning other scenarios. Acknowledging this limitation, the data point to the potential impact which card ownership combined with a declaration of the wishes of the deceased in favour of donation can have on relatives' refusal.

Within the existing framework of arrangements for organ donation, the exact extent of the scope for improvements in donation rates is unclear. The results presented suggest that there is potential for far greater numbers of people than at present to carry donor cards. However, it remains to be seen whether this would lead to an actual reduction in the rate of relatives' refusal to consent to donation. It may well be that the majority of extra cards would be carried by people whose relatives would have given consent anyway.

Table 8 Potential impact of donor cards

... Would you agree that their organs could be used after their death ...'

	... without a donor donor card and no prior declaration?	**... with a donor card and prior declaration?**
		per cent
Yes	**58**	**95**
No	**23**	**2**
Don't Know	**19**	**3**

***Source:* OPCS Omnibus Survey, September 1992.**

Changing existing arrangements

Most people in Britain have favourable attitudes to organ donation. However, there may be limited scope for increasing further the proportion who would consider themselves to be potential donors. Given such constraints, pressures are mounting for changes in existing arrangements. Respondents to the OPCS survey were asked for their views about two alternatives in particular. People were asked for their attitudes towards incentives aimed at increasing the number of potential donors, and for their views about introducing a system of presumed consent for organ donation in Britain.

Incentives

If people stated that they thought incentives should be offered 'to a person to encourage them to agree to donate organs', they were then asked whether or not they thought that this should be in the form of money. While only 7 per cent supported the idea of giving money to potential donors, 30 per cent thought that some kind of (unspecified) non-financial incentives should be offered. In contrast, over half (53 per cent) of respondents were opposed to any form of incentives.

Those in middle age were most likely to oppose incentives of any kind, while the young and old were least likely to express opposition. Controlling for both age and gender, there were significant class differences in opposition to incentives. While two thirds of people in higher social classes expressed opposition to incentives of any kind, less than half of those in lower social classes did so.

The level of opposition to incentives contrasts with one survey result from the USA, in which 52 per cent of those asked were in favour of some form of financial or non-financial compensation for potential organ donors (Kittur *et al.*, 1991). The influence of cross-cultural differences, such as the long-established practice of commercial blood donation in the USA, may well account for the difference between the results in the two countries.

Another finding in Britain, however, is less easy to explain. When respondents to the BKPA survey were asked for their views about offering a grant for funeral expenses to the family of a deceased organ donor, 52 per cent stated that they were in favour, and only 33 per cent were opposed. It may be that this specific question focuses more on compensation for the donor's family and thus elicits sympathy for their situation. On the other hand, questions about the principle of offering incentives focus on their instrumental role in encouraging more people to become potential donors, and thus provoke less sympathy.

While people are inclined to feel sympathy for a grieving family, British people seem to be more opposed to the idea of offering financial incentives as 'carrots' to increase the numbers of potential donors. For the moment at any rate, the majority of the British population want organ donation to remain a voluntary action.

Presumed consent

In view of the current debate about the possibility of a change to a system of presumed consent, three British surveys in 1992 asked people for their views about this proposal. A summary of the results is shown in Table 9.

One in five of respondents to the OPCS survey were 'definitely' in favour of introducing presumed consent in Britain. A similar proportion was 'possibly' in favour. However, slightly more people (48 per cent) were against the proposal than in favour. The DoH survey, on the other hand, found slightly more people were in favour of the suggestion than against, although the difference was minimal. Overall, the small differences between the numbers for and against in these two surveys suggest that public opinion in Britain is split roughly evenly over the issue of presumed consent.

Table 9 Attitudes to presumed consent

%	OPCS	DoH	BKPA
In favour	**40**	**46**	**61**
Against	**48**	**43**	**30**
Other (neutral or don't know)	**12**	**11**	**10**

Source: As Table 6.

However, the result from the BKPA survey, suggesting that twice as many people in Britain favour 'opting-out' (as it was termed in this survey) than oppose it, appears to paint a different picture. One possible explanation of this difference is the precise wording of the question. In both the OPCS and DoH surveys, the proposed new arrangements were described and contrasted with the present system. People were then asked the question whether they were for or against the new system just described. In contrast, respondents to the BKPA survey were simply asked:

> *Would you approve or disapprove if the kidneys of anyone who had just died could be used unless they had 'opted-out', that is, stated that this must not be done?*

The emphasis in this question is more on the use of organs, as opposed to the actual process of registering an objection to 'opt-out'. By describing the situation of someone 'who had just died', the question may tend to prompt people to imagine a scene in a hospital. In this case, therefore, respondents might be more likely to be in favour of any proposal which increased the likelihood of actual donation. In contrast, the questions in the other two surveys focus on the process of 'opting-out' while the potential donor is still alive, and make more explicit the change from the existing system. It might be argued, therefore, that responses to these questions are slightly more considered and based on a more complete account of the proposed change and its implications for potential donors. It may also be the case that responses specifically for kidney donation differ from those regarding organ donation more generally.

It is possible to make comparisons with opinions in two other countries. In the USA, 39 per cent of respondents were in favour of presumed consent and 52 per cent were against (Kittur *et al.*, 1991). This is broadly similar to the balance of opinion in the OPCS survey. In Holland, 24 per cent of respondents preferred changing to a system of 'opting-out', while 75 per cent wanted to keep their present system of 'opting-in' (Kokkedee, 1992). So it seems that British people, in their collective ambivalence, are not as opposed to presumed consent as the Dutch.

In summary, public opinion in Britain appears to be divided over the issue of presumed consent. However, it is difficult to predict exactly how public opinion might change after the introduction of any new legislation in the future.

Implications

Public opinion is important for conferring some degree of legitimacy on policy decisions. Information about the state of public opinion concerning policy options is a useful guide to their popularity and the ease with which any changes would be accepted. Organ donation relies upon the co-operation, trust and confidence of the general public, and whatever arrangements are in place must have widespread support.

The findings presented in this section provide information concerning two key aspects of the current debate. These are the extent of the scope for improvement in donation rates under the present arrangements, and public attitudes to any change in those arrangements.

Scope for improvement under current arrangements

The vast majority of people in Britain are aware of the shortage of donor organs. Most are in favour of donating their own organs after death. Moreover, while one fifth of the population usually carry donor cards, a further one quarter report that they would consider getting one.

The findings show that the overwhelming majority of people would respect the wishes of a deceased relative if the desire to be a donor had previously been stated in discussion and recorded on a donor card. However, gaps in the current state of knowledge remain. More information is needed about the attitudes of next of kin in scenarios where the wishes of the deceased are not known with such certainty. Furthermore, a better understanding is needed of the relative importance of card carrying and previous declarations of wishes, and the separate effect of each upon relatives' decisions.

In addition, one approach now is to encourage widespread discussion of donation. The aim would be to prompt the small number of people who 'don't know' whether they would want to donate their organs after death but who might consent after more careful consideration, to think about the issue and make their views known.

One method of trying to achieve such aims which has been used in recent years is national publicity campaigns. One example of their potential influence can be seen in the 42 per cent increase in the number of kidney donations in Britain in 1984, at the same time as an advertising campaign conducted by the Department of Health and Social Security (Lewis and Snell, 1986). Such publicity can affect card carrying directly, but can also have indirect effects on donation by provoking wider public discussion and raising awareness generally.

This was also the aim of the publicity campaign conducted by the Department of Health in March 1993. A television advertisement was broadcast throughout the month, urging people to discuss organ donation with their relatives. A leaflet accompanying the campaign addressed some of the specific concerns which can cause relatives to refuse consent. A donor declaration box was also included on all new driving licenses. However, evaluation suggested that there were no significant differences in attitudes to donation and in the extent of discussions before and after the campaign, although there was a huge increase in the demand for donor cards and publicity leaflets. Furthermore, no impact on actual donation rates has been demonstrated. Futher discussion of the effectiveness of publicity campaigns can be found in chapter 4.

In seeking to improve donation rates, it is vital to understand the reasons for relatives refusing to give permission for donation. These include fears that doctors may not try as hard to save the life of a potential donor, concerns about prolonging the suffering of a dying relative, and feelings of intimidation about the supposed complexity of the donation process (Prottas and Batten, 1991). Of course, another reason for refusal may well be that prior discussion has taken place with the deceased, and that views against donation are already known. Indeed, it may be the case that publicity campaigns aimed at prompting discussion might lead to people deciding against wanting to donate their organs. A national survey in the UK of the reasons for relatives' refusal to give consent to donation is currently being conducted by transplant co-ordinators, critical care nurses and MORI, funded by the Department of Health, and is due to report the findings of the two year study at the end of 1994.

Having discussed the potential significance of the findings for organ donation under existing arrangements, the implications for possible changes to present practice are now considered.

Attitudes to change

People in Britain appear to be quite guarded about some suggested changes in transplantation policy. This may reflect a natural tendency of opinion to be conservative and resistant to change generally. However, as discussed below, some possible changes are more popular than others, and there are important messages about the receptivity of the public which should not be ignored.

Taking incentives first, the vast majority of people in Britain oppose the idea of offering financial incentives to potential organ donors. In this respect the British public appears to be supportive of Richard Titmuss, who argued that 'no money values can be attached to the presence or absence of a spirit of altruism in a society' (1970). In a discussion of blood donation specifically, he argued that 'the commercialisation of … donor relationships represses the expression of altruism'. In particular, the payment of less affluent donors is seen as coercive and constraining, eroding people's 'right to give'.

It has also been argued, again regarding blood donation, that the introduction of payment in a previously gift-based system reduces the amount given voluntarily (Collard, 1978). More generally, one consequence of reward is to 'overjustify' an act, reducing the intrinsic motivation to perform the previously voluntary act. In considering whether or not to offer inducements to potential donors, 'it is important to realize that incentive need not be the only effect of reward' (Lea *et al.*, 1987).

While the fact that nearly one third of respondents were willing to contemplate offering (unspecified) non-financial incentives to potential donors suggests that this option could possibly be explored further in the future, nevertheless it is clear that people in Britain are overwhelmingly opposed to financial incentives for donation.

Turning to presumed consent, public opinion appears to be divided. This may reflect widespread reservation about any form of change in existing arrangements. However there is evidence which examines attitudes to various alternative suggested systems of consent and suggests that these other arrangements are more popular than presumed consent.

The DoH survey in 1992 asked about attitudes towards the present British system and to a suggested 'opting-in' register where the wishes of potential donors are recorded centrally on computer (as in the Lifeline Wales scheme discussed in the next chapter), as well as views about presumed consent. The proportions in favour of the present system and an 'opting-in' register (70 and 71 per cent respectively) far exceeded the 46 per cent who were in favour of presumed consent.

Two other British studies have compared attitudes to alternative proposals. In a national survey of almost 1500 people in 1987, a register of those opting-in was found to be more popular than one of 'opting-out', with 77 per cent favouring the former while 56 per cent supported the latter (Wakeford and Stepney, 1989). In a poll of over 600 out-patient attenders in two district general hospitals in the south west of England in 1990, 79 per cent supported the present donor card system and 69 per cent approved of computer records of 'opting-in', while only 15 per cent were in favour of the idea of an 'opting-out' card (Riad and Banks, 1990).

It would appear, therefore, that the existing arrangements or an alternative system of 'opting-in' are consistently more popular in Britain than a system of presumed consent. However, as the analysis in the next chapter demonstrates, there are severe doubts about the effectiveness of an 'opting-in' registry for improving donation rates. As far as presumed consent is concerned, it is only possible to state with any certainty that there is no clear consensus amongst the British public.

Conclusions

Public opinion is important for organ donation. Any system of organ procurement depends crucially on public confidence in the established arrangements. The findings of the national OPCS Omnibus Survey show that people in Britain are aware of the shortage of organs for donation. While this may be personally relevant to most people, however, there is a minority of the population who would not consider receiving a transplanted organ.

Other findings from the survey generate possibly as many questions as they do answers, highlighting gaps in existing knowledge and understanding of current arrangements. In particular, this discussion suggests three outstanding areas of uncertainty.

One important gap in current knowledge is the likely net effect of publicity campaigns aimed at promoting discussion of organ donation. Findings have consistently shown that about 70 per cent of people in Britain are in favour of donating their organs after death. Of the remainder, about half are not sure. It may be that there is scope for reducing the rate of relatives' refusal by encouraging people who are uncertain to consider the issue if they have not already done so, and to make their views known to their next of kin. However, it is not certain whether more widespread discussion would lead to more decisions being made to become potential donors than definite decisions against wanting to donate. The effectiveness of publicity campaigns are discussed further in the next chapter.

Second, there remains uncertainty about the relative importance of the presence of a donor card and knowing the views of the deceased, when each is present without the supporting evidence of the other. We have seen that the combination of both has a highly significant effect on the decisions of next of kin, but the separate effects of the donor card and knowledge of the deceased's wishes on relatives' decision whether or not to give consent remain unclear.

A third area of uncertainty is the reasons for relatives' refusal to give consent to donation. While it has been acknowledged that they are vitally important to discover and address, comparatively little is known about them. The hope is that, as more is understood about the precise reasons, there might be more scope for addressing some particular issues and doubts by specific educational measures.

These points of discussion suggest that it is not clear to what extent the rate of relatives' refusal to give consent to donation can be reduced below present levels. While it is important to maximise the number of potential donors by measures which prompt discussion and to address specific doubts and questions, there may well be a 'saturation point' at which the numbers of people not wishing to donate their own or their relatives' organs cannot be reduced any further.

This analysis has also presented information about the state of public opinion concerning possible changes to the present arrangements for donation. The British public are overwhelmingly against financial incentives being offered to potential donors. Opinion is divided over the issue of whether to change to a system of presumed consent. It would be difficult for either supporters or opponents of a change to presumed consent to cite the present state of public opinion as supporting evidence for their position.

Options – how can the supply be improved?

4

In this chapter the options for improving the supply of donors in the UK are analysed. Some of the proposals have been specifically designed with the UK in mind; others originate overseas and appear to contribute to effective organ procurement in other countries. However, in light of the analysis of chapter 2, simply displaying a high rate of transplantation activity is insufficient evidence for adopting that country's procurement methods or legal arrangements. Specific initiatives from abroad should demonstrate some evidence that they have actually influenced the rate of activity in the country in question.

Methods to increase the supply of donor organs can be organised into one of four broad categories:

- **Improving practice:** proposals which aim to improve current practice:
  - relating to cadaveric donors,
  - relating specifically to kidney donors;
- **Significant innovations:** initiatives which would substantially change practice, but which remain within the current legal framework for gaining consent;
- **Changing the law:** policies which advocate changes to the law on gaining consent;
- **The future:** technological innovations involving the use of animal organs – xenotransplantation.

Issues relating to commercial dealing and financial incentives, and those relating to cognitive death, have been analysed in the context of the UK's legal framework and public opinion. Given the highly unlikely possibility of legalising payment as an incentive for donation, and its unpopularity with the public at large, such an option is not discussed further in this chapter, although it is considered in chapter 6 in the context of issues relating to allocation.

Improving practice – cadaveric donors

In this section the analysis focuses on some of the methods by which current practice could be improved for cadaveric donation. The options are organised into three parts: improving technical and logistical procedures, reducing relatives' refusal rates, and enhancing the co-ordinator network.

Improving technical and logistical procedures

It has been suggested that technical and logistical procedures can be improved by:

- increasing the number of brain stem death tests;
- reducing the number of general medical contraindications; and,
- improving the organisation of multi-organ donation.

Brain stem death testing

The first possibility – suggested by the findings of the national audit – is to increase the number of individuals who undergo brain stem death tests when they 'possibly satisfy' brain stem death criteria. Researchers have estimated that by reducing the non-performance of these tests the number of offered donors could be increased by a modest proportion (Gore *et al.*, 1992b). However, it is likely that the audit picked up many 'possible' brain stem deaths in a technical sense – they would have satisfied the particular criteria involved – but because ICU staff were aware of overwhelming medical contraindications the tests were not actually undertaken (Smith *et al.*, 1992). If this is true, then the potential for improvement may be rather limited. Nevertheless, it is clearly important for brain stem death tests to be undertaken whenever there is the possibility of a suitable donor.

The more likely means of achieving increased brain stem death tests is not to concentrate on those already in ICUs, but to test those potential donors who would have died outside the ICU on general and surgical wards or in the Accident and Emergency department, by 'electively' admitting them to an ICU and placing them on a ventilator. Such a system of elective ventilation is discussed further below.

Medical contraindications

A second potential improvement involves a better understanding of the general medical contraindications to donation. Whereas it is undoubtedly true that overwhelming septicaemia, for example, will clearly indicate unsuitability, intensive care staff may not always be aware of the precise range of contraindications. In an interim report of the national audit it was found that, of 47 potential donors with specified general medical contraindications, only 10 donors were discussed with the transplant team and the co-ordinators (Gore *et al.*, 1989). As transplantation techniques improve, so the range of potential donors widens. For example, extremes of age are often no longer considered to be general contraindications.

However, in a follow-up to the national audit, transplant surgeons considered that in only 6 per cent of cases where a brain stem dead patient was listed as having general medical contraindications, were the kidneys actually transplantable. The liver was transplantable in only 1 per cent of these cases, and in no cases were the heart or lungs considered transplantable. The follow-up study concluded that it was 'reassuring that ... so few transplantable organs were missed' (Gore *et al.*, 1992a).

Improving arrangements for the multi-organ donor

A final set of improvements to current practice relate to logistical difficulties, or circumstances which lead to the non-use of otherwise suitable organs. Such difficulties apply more to the non-renal organs, with kidneys almost always successfully transplanted into a suitable recipient. For other organs, the situation is rather more problematic. Non-renal organs deteriorate faster than kidneys and many more are unsuitable by the time of the transplant operation; suitable recipients are fewer in number; non-renal transplant units are less common and transplant teams are occasionally not available or have to travel long distances; and lack of theatre time may also militate against non-renal explantation.

One example of how some of these problems can be addressed is provided by an initiative from Addenbrooke's Hospital, Cambridge, which seeks to simplify the multi-organ donor procurement process (Wight, 1989). Traditionally, each organ requires its own team, often requiring large distances to be travelled by the teams and entailing feats of organisation by the co-ordinator. Under the scheme, a combination of staff from liver and heart transplant centres form a single surgical team trained and available for the removal of all solid organs. Once stored, the organs are shipped to their allotted destinations. Not only does this reduce the possibility for losing organs due to logistical difficulties, but it should significantly reduce the inconvenience caused to the donating hospital by large numbers of medical personnel arriving with little warning, and the

> *possibility of five separate surgical teams in the operating theatre, sometimes unknown to one another and speaking different languages* (Wight, 1989).

It has been suggested that the impact of this practice has had a deleterious effect on the whole process of organ donation, and may even have had an influence on the levelling off of donation rates. A single case of insensitivity from a travelling surgeon could be enough to provoke resistance among ICU staff to future co-operation in the procurement and management of donors. The Cambridge scheme is now to be implemented throughout the UK.

Reducing relatives' refusal and non-discussion

A second set of improvements to current practice relates to methods aimed at reducing the extent to which relatives' consent is withheld. As discussed earlier, this is by far the most significant cause of the non-use of otherwise suitable organs. Three options present themselves:

- improved dissemination of donor cards;
- reductions in the refusal rate of those with whom discussion takes place;
- reduction in non-discussion with relatives.

Improved dissemination of donor cards

The first option involves improved dissemination of the donor card. Initiated in 1971 as a private enterprise, and relating at first only to kidneys, it was soon adopted by the DHSS and developed as a national policy. Since its inception it is estimated that an average of 10 million cards have been distributed every year. Little is known about the precise destination of the cards – they are supplied to charities, GPs' surgeries, libraries, police stations and hospitals – but at least three million per year are issued with the driving licence by DVLC.

The impact of the card operates in two ways. First, it is a direct signal to those who are in possession of the body, and to relatives, that the deceased individual wanted to donate their organs. Second, it acts indirectly: as an instrument of publicity, a focus for debate and a symbolic indication to family members of an individual's intention whilst alive.

For the card to have a direct impact, it must be found on the body of the deceased at or shortly after the time of death. Although 70 per cent of the UK population are actively in favour of donating their own organs, only 20 per cent or so usually carry a donor card, as the discussion of public opinion in chapter 3 indicated. It is reported that significantly less than 20 per cent of potential donors have cards which are actually found on their person at the time of death. Unfortunately, such evidence can only be anecdotal since data on possession of a donor card at death are not recorded, and neither was this information sought in the national audit. The fact that there are no recorded cases of relatives refusing donation in the face of a donor card (a legally unnecessary, but nevertheless universally observed, practice), might lead one to think that substantially increased possession of the card would improve donation rates.

The achievement of such a goal, however, would require significant improvements in the card-carrying habits of the British public, and, furthermore, among those members who would otherwise have organ donation refused by their relatives. Merely increasing the carrying of cards among those members of the public whose families already approve donation is of relatively little value. So, since 70 per cent approval is reported for organ donation it is tempting to expend resources in an attempt to ensure that this proportion of the population always carries a card. But if they are the same proportion who already consent to donation – 70 per cent of potential donors' families consented to donation in the national audit – then this increased card carrying could quite possibly have no impact at all on the donation rate.

The task is to achieve card carrying by those members of the public whose families would otherwise have refused consent, a far more difficult proposition, and one for which it is particularly hard to design an appropriate dissemination strategy. The Departments of Health and Transport have arranged for all new and renewed driving licences to contain a box to record the holder's willingness to donate, which will go some way toward solving the problem of lost or mislaid cards. This is a laudable strategy but does little to overcome the problem of targeting the appropriate groups.

Irrespective of these difficulties, the second, indirect, way in which the card has an impact – as a means of raising public awareness – should not be underestimated. The policy of voluntarism as exemplified by the donor card may have reached the limits of its potential as a direct means of influencing refusal rates. But it is still a valuable symbolic reminder of the shortage of organs, and probably lies behind the high degree of public awareness of this issue.

Reducing refusal rates by other means

The second option, notwithstanding the donor card, is to reduce the rate at which relatives refuse permission. Within the current legal framework, one means of reducing refusal rates is to encourage a more skilled, sympathetic and persuasive contact with the deceased's relatives by intensive care staff. The chief difficulty is the stressful and emotional context in which such an approach has to be made. The intensive care staff will almost invariably make the first contact once it is suspected that brain stem death is a possibility, and so their training is of the utmost importance. Prompt utilisation of transplant co-ordinators is also desirable. The extent to which such improvements can contribute to a significant reduction in the 30 per cent refusal rate is open to debate, however.

Another strategy has demonstrated rather more measurable benefits. Publicity campaigns have long been associated with attempts to improve donation rates, and there is some evidence of their success. Ironically, the most infamous example is of adverse publicity: the fall-off in donation rates after the Panorama television programme of October 1980 entitled 'Are the donors really dead?'. Other campaigns have appeared to have a positive impact. Lewis and Snell (1986) reported a 42 per cent increase in donation rates which coincided with a six month campaign by the DHSS in 1984 to advertise the merits of the kidney donor card. Gore *et al.* (1991) reported a significant drop in refusal rates by relatives – from 30 to 22 per cent – during a period of 'intense, positive publicity about transplantation' during October-November 1989.

The evidence is not conclusive, however. The 1984 campaign coincided with the introduction of the drug cyclosporin which greatly improved the effectiveness of transplantation and certainly would have encouraged greater activity regardless of donation rates. A recent television campaign conducted by the Department of Health during March 1993 appears to have had no effect on donation rates, according to provisional data from the UKTSSA (1994), even though a preliminary evaluation of the campaign reported improved discussion within families (Department of Health communication, 1993). The data show that the number of cadaveric kidney transplants have dropped to their lowest level since 1987, and the number of donors is 4 per cent lower than in 1992.

Furthermore such campaigns are expensive – the March 1993 event cost £1.5 million (UKTSSA, 1993b) – and temporary in their impact – the refusal rates recorded by Sheila Gore and colleagues soon returned to their pre-campaign level of around 30 per cent. Although useful in sustaining public awareness of the issues at stake, it does not appear that publicity campaigns are a cost-effective means of improving on current levels of donation in the long-term.

Reducing non-discussion

A small number of relatives are not asked if they are willing to agree to donation at all. Although small – only 6 per cent of contacted families had no discussion – such a proportion is still significant. Indeed, it has been suggested that some form of required request legislation – whereby doctors would have to make a request for every suitable potential donor – may be appropriate, and this is discussed later in this chapter. However, apart from the emotional burden this places on the medical staff, it is likely that many of those who were reported as having no discussion either clearly objected without prompting, or it was brought to the attention of the medical staff in some other way that they would refuse.

Extending the co-ordinator network

The final means of improving current practice in relation to all organs is to extend the transplant co-ordinator network. There appear to be two approaches. In the UK the transplant co-ordinators are organised at the regional level, work in proximity to transplant centres and consist of full-time staff predominantly from a nursing background. Similar systems operate in the Eurotransplant countries, although Germany has a majority of doctors (Wight, 1993). One could simply expand the number of co-ordinators employed in this way. A rather more ambitious alternative would be to adopt the approach utilised in Spain, and described in Box 5. The evidence for the effect such a system has had on transplant activity is not conclusive, but nevertheless strongly suggests a positive impact. As indicated in the box, the system was fully implemented as late as 1990. Since then the number of co-ordinator teams increased from 56 to 118. Figure 18 shows the Spanish kidney transplant activity from 1980 until 1992. It appears that after a steady increase until the mid-1980s, activity levelled off between 1986 and 1989. From 1990 until 1992, however, there has been a remarkable increase. It certainly looks as though the implementation of the national network of co-ordinators and their expansion was accompanied by a substantial increase in transplantation activity.

Such evidence cannot be conclusive – there may well have been other factors at work, such as improved publicity or worsening road traffic accident rates. Furthermore, caution should be exercised in assuming that the UK would be able to emulate the overall transplant rate for similar reasons – this country already has a national co-ordinating system and our road death rate is low and falling. It should also be noted that ICU staff trained for the needs of the transplant community would constitute a break with the tradition of clear separation between the curative/therapeutic role of ICU staff and the procurement role of the co-ordinators. It would be vital that no confusion of these roles should result, leading to ethical concerns as to the motivation of the ICU staff.

Nevertheless, the arrangements in Spain, quite possibly designed with the benefit of being able to observe the failings of other systems, appear worthy of close attention and, if nothing else, they certainly allowed the Spanish transplant community to take full advantage of the opportunities presented to them. Spain now has the second highest rate of cadaveric kidney transplantation in the world. The introduction of such a policy would not necessitate a wholesale reform of the UK's co-ordinator network. If further resources were to become available they could be spent on part-time co-ordinators in local hospitals with major ICUs. Where more than one co-ordinator now works full-time in a single centre, individuals could be redeployed.

Even if these developments were not to influence greatly the effectiveness of current practice in the UK, they may still have an

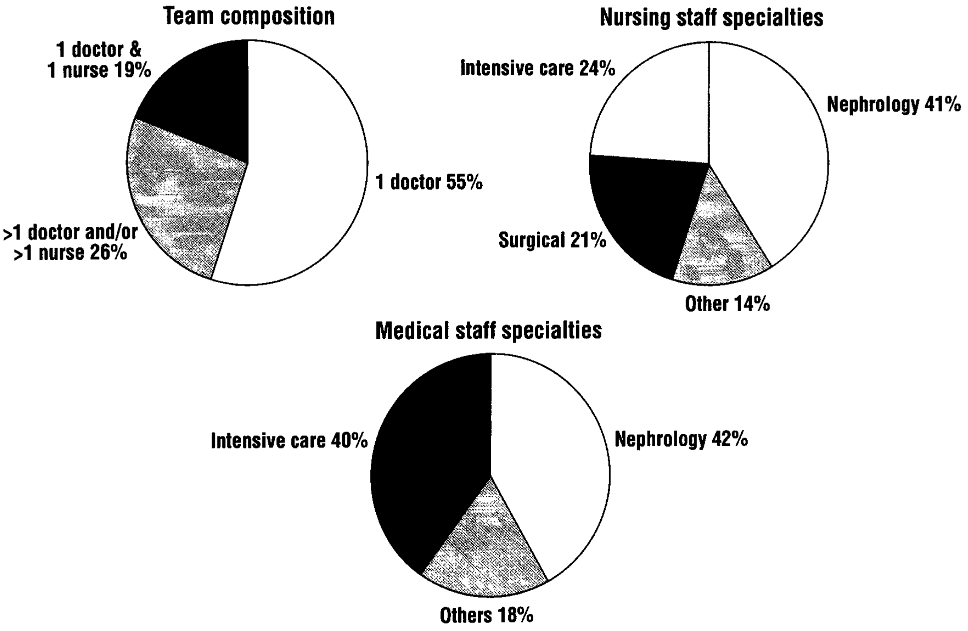
5

THE SPANISH TRANSPLANT CO-ORDINATOR NETWORK

The Spanish national co-ordinating organisation, ONT (Organizacion Nacional de Trasplantes), and the system of co-ordinators was only 'consolidated' in 1990 (Matesanz, 1991). Transplant co-ordinators are organised on a two tier basis with a regional co-ordinator in each of the fifteen regions, and 118 teams working at the local donating hospital level. This means that every major hospital with ICU facilities has a co-ordinating team attached. The team may have one, two or three members, consisting of a combination of doctors and nurses. All the doctors and one third of the nursing staff on these teams are part-time, the rest of their time is spent working in their specialty – see Figure 17.

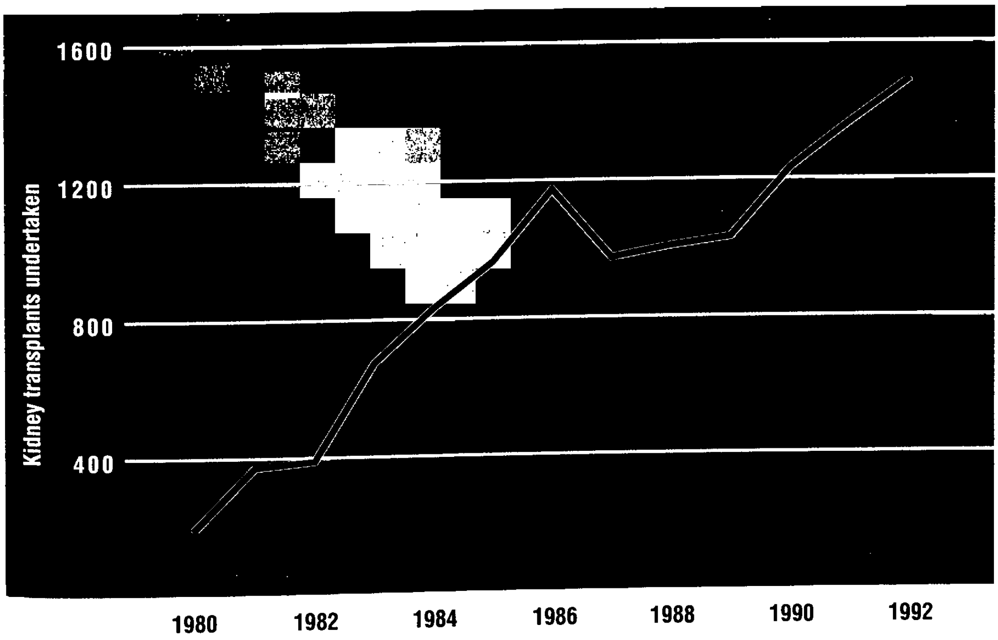
The most important element of this system is that the co-ordinators, key agents in the procurement process, are employed at all the donating hospitals and not just those which have a transplant unit. Furthermore, the majority of the local co-ordinators work only part of their time as co-ordinators, the remainder of their time spent in specialty work, predominantly in intensive care or nephrology. The combined effect is for intensive care and nephrological work in Spain to be directly integrated into the organ procurement process. As indicated by the discussion of the UK transplant co-ordinators, education and liaison with intensive care staff is of prime importance. In Spain this process can be more or less continuous with units having dedicated part-time or whole time staff on site. Under such a system, local hospitals without transplant units are likely to be sympathetic and well-informed as to the needs and importance of the transplant procurement process.

Figure 17 Spanish transplant co-ordinator teams, 1992



Source: Organizacion Nacional de Trasplantes.

Figure 18 Spanish kidney transplant activity, 1980-1992



Source: Organizacion Nacional de Trasplantes.

important function in supporting future reforms. The closer integration of the transplant community and the major donating hospitals is likely to be an important precondition for the potential for success of many of the proposals outlined below. Many of these options rely on non-transplant staff being particularly well motivated and instructed in the particular procedures concerned.

Improving practice – kidney donors

Kidney procurement and transplantation is a somewhat more flexible process than that involving the non-renal organs. More of the organs are suitable, and as a result of the large national pool of those waiting it is relatively easy to find a beneficially matched recipient. They also withstand a longer 'cold ischaemic' time – the period during which the organs are stored whilst transported from donor to recipient – than other organs. But, in particular, human kidneys are suitable for two procurement policies which are not in general suitable for other organs: live donation and asystolic or 'non-heart beating' donation.

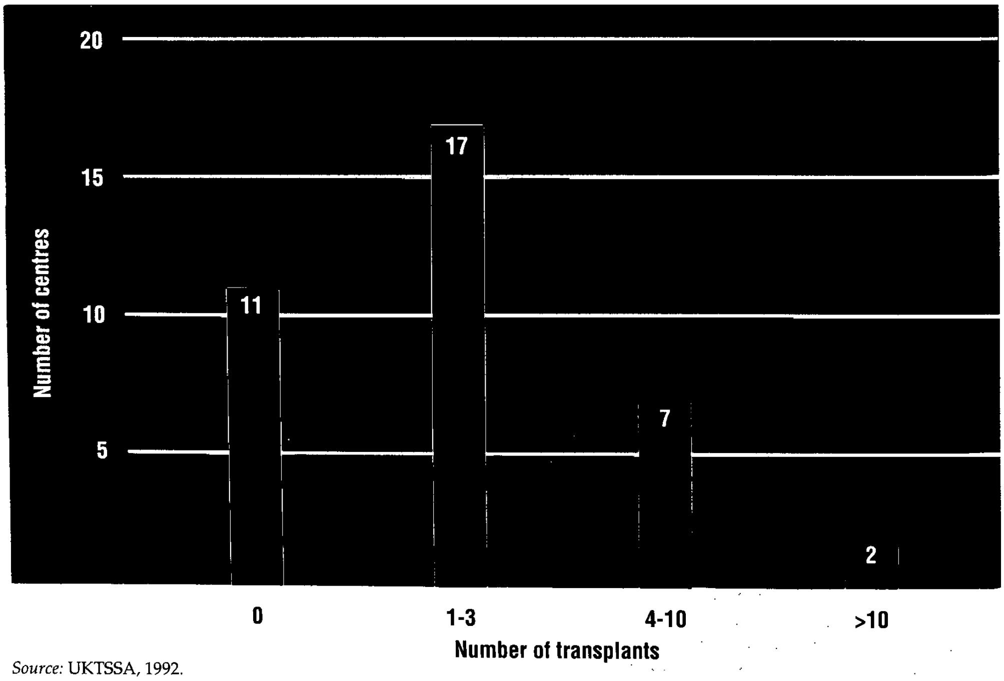
Increased use of the live donor

Living relatives, and occasionally non-genetically-related partners, can donate one of their two kidneys and continue to live a healthy life. Sections of a living parent's liver can be transplanted into a child, although, as yet, in very small numbers. Live donation offers some profound ethical dilemmas, analysed in the next chapter, but many countries undertake a much higher proportion of kidney transplantation in this way than the UK. What might the UK achieve by a more systematic attempt to increase donation from this source?

There is currently no Department of Health guidance on genetically-related live donation. Partly as a result of this, the history of live donation in the UK has been one of falling activity and inter-regional variation. Evidence presented earlier suggested that the proportion of live donation in the UK has dropped from 10 per cent during the 1980s to 5 per cent in 1992. Absolute numbers have also fallen since reliable records began in 1989. However, a survey of 32 transplant centres revealed that there were wide variations: some centres did none, whilst others reported 20 per cent of their transplants coming from living donors (Donnelly *et al.*, 1989). In 1991, 37 centres undertook kidney transplants with variations in the number of live transplants shown in Figure 19.

Without central guidance, policy is left to the individual clinical teams who must decide whether or not the possibility of live donation will be communicated to the patient or to their family. The result is an inconsistent approach which probably contributes to the UK's low live transplant rate by international standards.

Figure 19 Live kidney donation in the UK, 1991



Source: UKTSSA, 1992.

Precisely who is responsible for these decisions is less clear. The survey cited above asked transplant centres whether or not live donation should be expanded, and 60 per cent thought it should. This would seem to indicate that surgeons are willing to undertake more transplants of this type, and that it is the nephrologists with the responsibility for placing patients on the transplant waiting list who have the most significant influence. Surgeons can have a dramatic effect, though: some of world renown, such as Thomas Starzl, publicly admit to doing none at the present time (Bonomini, 1991). Other countries, such as Norway, have a far more systematic approach and achieve far higher rates – see Box 6.

What could be achieved in the UK? It is reasonable to take the Norwegian experience as a theoretical maximum. Norway has achieved up to 20 pmp over the past few years, and in 1992 undertook 17.1 live transplants pmp. The UK may not wish, or need, to adopt such an aggressive approach. A threefold increase over the UK's rate of 1.6 pmp has been achieved by eight of the countries analysed. The exact level will be a function of how rigorously the option of live donation is offered to patients, and on the clinical acceptability of tissue mismatches and older donors. But there is no reason to believe that the UK's population and family structure are so different from other countries that there will be many fewer suitable donors. A significant increase is likely by simply making a systematic offer to patients or their families. The manner in which this is done is important, however, and the ethical questions associated with such a policy are discussed in the next chapter.

Unrelated donation was discussed in the context of the English law in chapter 3. In the UK in 1991 only nine kidney transplants were undertaken from unrelated living donors. There is substantial scope for increase here too, but it would seem prudent to develop genetically-related donation first, given the nervousness which many have over the possibility of widespread unrelated donation encouraging commercial dealing.

Increased use of the non-heart beating donor

One of the reasons for the relatively fast development of kidney transplantation compared with heart and liver is that it was not necessary first to establish brain stem death criteria. Kidneys have been removed from a non-heart beating donor up to 110 minutes after cessation of heart beat (Kootstra *et al.*, 1991). This is known as the 'warm ischaemia' time. Ideally, the kidneys should be cooled as quickly as possible, before explantation, by means of the insertion of an irrigation tube into the cadaver so that the kidneys can be protected by cold perfusion until the

6

NORWAY'S LIVE KIDNEY DONATION PROGRAMME

There are a number of reasons for Norway's high proportion of live donation, including improved outcomes compared with cadaveric transplants and low population density (Jakobsen *et al.*, 1991). Although the first of these influences is important, it applies to all the developed countries undertaking cadaveric transplant programmes and so is not sufficient to explain Norway's high rate. More significant is the fact that Norway has a small population living in a large country, resulting in a population density of only 13 per square km compared with, say, the UK's 234 per square km. This has had a number of implications for renal transplantation in Norway.

First, travelling to and from dialysis centres is costly and time consuming, making the dialysis procedure particularly arduous for patients. It is a rather more unpleasant alternative to a transplant than in most countries. Second, the large distances between donating hospitals, and between donating hospitals and the single transplant centre in Oslo, has meant that cadaveric procurement is difficult, resulting in low rates by international standards. The result is that live donation has continued to be a positive policy choice for the Norwegian medical profession in the post-cyclosporin era, when some other countries reduced the proportions and relied more heavily on cadaveric donation. The element of positive policy choice is important, since other low population density countries, such as Finland, Canada and Australia do not undertake such a high number of live transplants.

The procedure in Norway involves the nephrologist at the dialysis centre investigating the possibility of live donation as soon as it becomes clear that transplantation is indicated for renal failure. Relatives are screened for suitability – normal kidneys and blood pressure, absence of cardio-pulmonary disease, and so on – and then the option of live donation is suggested as a matter of course. Patients are in fact not placed on a waiting list for a cadaveric kidney if a suitable live donor is willing to donate (Jakobsen, 1993). Siblings, parents and occasionally grandparents or related uncles or aunts are involved – over 50 per cent are siblings and 35-40 per cent parents. About 10 per cent of the living donor transplants carried out over the past few years are non-genetically related, and they have all, except in one or two cases, been between spouses. Since the advent of cyclosporin, all types of tissue mismatch have been accepted (Jakobsen *et al.*, 1991). If it is suspected that a relative is reluctant to donate, but apparently feels an element of moral or emotional pressure, the medical profession will always 'find the donor not medically fit which gives the reluctant potential living donor a clean face' (Jakobsen, 1993).

relatives can be found and donation requested (Rapaport, 1991). Such procedures allow for those who suffer a fatal cardiac arrest, for example, to nevertheless donate their kidneys. In the UK, however, the national audit only found ten such donors out of 1,200 identified donors from ICUs. It may be that more organs were retrieved by this method outside the ICU, but the proportion is still likely to be extremely small.

A concerted effort has been made to increase the number of non-heart-beating donors by clinicians in the Netherlands (Kootstra *et al.*, 1991). Over a nine year period, 21 per cent of transplanted kidneys at the University Hospital, Maastricht, came from non-heart beating donors. With this type of procedure it is essential that those concerned act as fast as possible once it is clear that resuscitation is hopeless. It is particularly important for those in A&E departments to understand the principles and potential benefits to be gained from such a procedure.

The experience in a University hospital, with transplant surgeons, co-ordinators, and emergency room staff all on one site, and with experienced professionals offering best practice, is not an easy one to replicate in a large number of general hospitals with little or no experience of these procedures. Nevertheless, a 20-25 per cent increase is highly significant and deserves wider discussion. One scheme is already being proposed by Mr Maurice Slapak, a transplant surgeon at St Mary's Hospital, Portsmouth (Pallot, 1993). However, at the time of writing, the proposals are being considered by the hospital's ethical committee, thus indicating that the procedure is not without its critics. The ethical problems will be discussed in the next chapter.

Two significant innovations

Two proposals are described here, both of which are claimed could provide significantly increased numbers of donor organs. Neither require a change in the law relating to consent of the relatives, although the second – elective ventilation – is currently of doubtful legality for reasons discussed below. Both, however, would require a substantial change in current practice at some point in the transplantation process. The first involves the development of a centralised opting-in registry, and the second the use of elective ventilation for those dying on general medical wards.

Opting-in registry

An opting-in registry operates on the same principle as the donor card: it is an explicit statement of consent by a potential donor while he or she is still alive. Such an explicit statement is in accordance with Section 1(1) of the Human Tissue Act 1961, the difference being that it would take the form of a record on a centralised computer register to which all relevant hospital units could have instant access. Such a proposal is claimed to hold significant advantages over the donor card. Once the statement is made, it cannot be 'lost' nor can the statement fail to be found simply because the donor did not have it about his or her person at the time of death. A computer register should be cheaper to administer, involving only electronically recorded information (although the publicity needed to achieve a substantial response may be expensive). And it would be extremely flexible, with anyone able to add or remove their name from the registry at any time.

The UK already has some experience of such a scheme, as do other European countries, with rather disappointing results. The UK scheme, 'Lifeline Wales', was established in Cardiff in 1986. A computer database is held at the Cardiff Royal Infirmary and ICU units can phone in to see if a brain dead patient is on the registry. Donor cards in Wales are distributed with a tear off portion which can be mailed, free of charge, back to the registry. It is currently claimed that about 300,000 names are held on the computer, from a population of approximately 2.8 million. Although donor rates improved significantly in the year following the introduction of the scheme – to approximately 20 pmp – it was suspected that this was due in large measure to the publicity surrounding its launch. Donor rates have now settled back to their pre-1987 levels of around 14 pmp. Furthermore, those who run the scheme report that no donors have been obtained via the scheme in circumstances when the donor's family would otherwise have refused consent 'because [every registered person] who died had been carrying a donor card and his or her views were already known' (Salaman *et al.*, 1994).

The Belgian presumed consent law also provides for an 'opting-in' registry. Individuals can make an explicit statement of consent if they are not satisfied with 'presumed consent' at death, since the law allows for relatives to initiate an objection which must then be respected. However, three years after the new law was introduced – in March 1990 – only 0.02 per cent of Belgians had expressed explicit consent, and only 1.8 per cent explicit objection. The remainder were presumably either content with the 'default' position, or unaware or incapable of understanding what was at issue.

The UK Health Departments are currently considering the possibility of setting up such an opting-in register in England. A feasibility study has been conducted and the results are due soon. It is possible that such an initiative would involve utilising the existing NHS central register which is used for recording individuals' NHS numbers. Nevertheless, the results in Wales do not indicate that an opting-in scheme such as this will serve to increase significantly the supply of donors.

Elective ventilation

Intracranial deaths account for over 50 per cent of organ donors in the UK. If respiratory arrest occurs before or on arrival at the hospital, then these patients will typically be intubated and ventilated in the Accident & Emergency department before being transferred to ICU for diagnosis and treatment of unexplained coma.

However, some of those who die of intracranial haemorrhage and might otherwise be suitable for donation do so in general or geriatric wards. The only difference in many of these patients is the time of onset of respiratory arrest. If the diagnosis is confirmed by CT scan to establish that the prognosis is poor, and death is predicted to occur within hours, then elective transfer to ICU can take place for artificial ventilation to be undertaken only when respiratory arrest occurs. These patients would not be considered as having any chance of survival, and so such a transfer would only be to preserve the donor organs until brain stem death can be established. Such practice is quite contrary to the traditional use of ICUs, which are considered to be solely for the saving, or at least extension, of life.

The Exeter Protocol

A protocol has been developed at the Royal Devon and Exeter Hospital, designed to ensure that patients dying of cerebrovascular accident are managed by transfer to ICU so that their organs could be retrieved – see Box 7. The protocol began on 1st May 1988 and over the next 19 months the team estimated that eight patients who would otherwise have been missed became donors. When these individuals were added to those who had become donors without reference to the protocol the study team estimated that the donor rate (individual donors) pmp per year increased from 19.8 to 37.5 – or 75 kidneys pmp, more than two and a half times the national average (Collins, 1992; Feest *et al.*, 1990). Since then, the team members have reassessed their estimate downwards, with, over a four year period, 13 from 39 donors coming from the protocol (Riad, 1993). This still represents an increase of 50 per cent over a non-protocol system.

It may be that this increase would not be easy to reproduce nationwide. Furthermore, the number of extra donors is small in absolute terms and therefore the reported increases are likely to be outside confidence limits for statistical significance (Routh, 1992), although this claim has been challenged. Nevertheless, even if the national increase were substantially less than that estimated by the Exeter team, it would still represent a significant increase in donor rates. A study similar to the English national audit but undertaken in Wales and including deaths outside the ICUs, came to similar conclusions about the opportunities presented by elective ventilation:

> *the supply of donor organs ... could be increased by altering the management of patients aged 50-69 dying in general medical wards, in particular by increasing the number ventilated* (Salih *et al.*, 1991).

7

THE EXETER PROTOCOL

There is no age limit for organ donation, patients over the age of 70 years may be suitable.

Criteria for identification of patients with intracranial vascular accidents as potential organ donors:

- **Characteristic mode of onset: sudden with rapid development of coma**
- **Progressive decline in conscious level**
- **Deep coma: lack of withdrawal response to painful stimuli**
- **Intracranial vascular accident confirmed by CT scan is desirable**

THE ICU REGISTRAR SHOULD BE INFORMED WHEN A PATIENT IS ADMITTED IN DEEP COMA

Exclusions:

Reversible causes of coma

Procedure – this sequence of events must be strictly observed:

- **Junior medical staff discuss case with consultant concerned**
- **Consultant or nominee discuss suitability of patient with member of transplant team**
- **If patient is suitable, discuss with consultant in charge of ICU**
- **If all are agreed, consultant physician or nominee should approach relatives**

Approach to relatives

Discussion with the relatives will need to include:

- **The physician's belief that the patient is unlikely to recover**
- **A request for organ donation**
- **The need for transfer to ICU as the appropriate place for management of organ donation**
- **The possibility of the patient being removed from ICU to a ward if he or she ceases to be suitable as a donor**

Management in ICU

Degree of intensive treatment is for discussion between consultant physician and consultant in ICU

Sources: **Feest *et al.*, 1990; Collins, 1992**

Effect on ICU workload

The protocol is not without its critics. The most common criticism is that elective ventilation would cause a large increase in the workload of ICUs which they would not be able to accommodate, and possibly make it more difficult for those in immediate danger of losing their life to gain access to a bed (Routh, 1992). How much strain is, in fact, likely to be placed on ICUs?

The best estimate of the current availability of ICU facilities – namely, the ratio of occupied to staffed ICU beds – comes from a census survey conducted in 1989 over two days: Sunday 5th and Tuesday 7th of November (Gore, 1992). 187 of the 226 ICUs contacted responded. The survey found that, at 3pm on Tuesday 7th November, the mean number of staffed beds was 4.4 and the mean number of occupied beds was 3.6. In yearly terms, this translates into an average of 1314 occupied bed days out of 1606 staffed bed days. ICUs are clearly under pressure and have little leeway for admitting increased numbers of patients, a proposition supported by a more recent audit (Stoddart, 1993). Furthermore, 40 per cent of the units had fewer than four staffed beds, and only a third of these were able to accept new admissions. Of the larger units, only just over one half were able to do the same.

But what difference would a national policy of elective ventilation make? At Exeter – and this is likely to be an over-estimate – the team found on average three donors per year from the protocol from a population of 303,000. This translates into 10 donors pmp per year. The 277 ICUs in England (Stoddart, 1993) serve a population of 47.8 million, which means that, at best, there would be 478 extra donors to be found nationwide, an average of just under two per unit. Let us assume an upper limit of three per unit for the purposes of this discussion.

How long would these donors spend in an ICU bed? No electively ventilated donors should spend more than 48 hours in the ICU according to the Exeter experience, and this can be written into the protocol. Thus if donors turn out not to be suitable or do not continue to respiratory arrest, then they should be removed from the ICU. One donor in Exeter spent 127 hours in the ICU, but personal communication with staff from the hospital has confirmed that this would not be normal practice and only occurred because there was no pressure on ICU beds at the time. Indeed, all but two of the donors in the initial report of the protocol were in the ICU for less than 24 hours (Feest *et al.*, 1990). Let us estimate two bed days per donor as the highest likely average length of stay.

Thus, on the most extreme estimate, units will, on average, have to accommodate three electively ventilated donors per year spending a total of six bed days in the unit. This would be in addition to the current mean occupancy rate of 1,314 bed days – an increase of 0.46 per cent. 470 extra donors constitutes an increase of 66 per cent on the English donor rate for 1991, but is likely to increase ICU workload by less than 1/100th of that proportion. Whilst it is acknowledged that these average figures hide the fact that some units will be at full capacity, and therefore entirely unable to contribute to the policy, this analysis draws attention to the relatively small impact such a policy would have on the intensive care community, whilst having a potentially enormous impact on transplant activity.

Conclusion

Further evidence on the potential effectiveness of elective ventilation is required notwithstanding the results reported above. The Exeter study was small and involved clinicians from a number of different specialties collaborating successfully on a single site. These conditions would not be the norm nationally, since, for example, most ICUs occupy a site without a transplant unit.

To resolve these issues a national study has been proposed – PIVOT (the Potential of Interventional [elective] Ventilation for Organ Transplantation) – to be undertaken in two phases. The first 'documentation' phase would analyse the effect of introducing an elective ventilation protocol into a large number of hospitals, both with and without transplant units and with various sizes of ICU. This phase would not involve actual implementation of the procedure, merely a study of its potential from records collected at the hospitals involved in the study.

The second 'randomisation' phase of the study would involve implementing the procedure itself, in order to establish whether or not any deleterious effects result from elective ventilation in comparison with control groups. The reasons behind this proposed element of the research are discussed in more detail in chapter 5, along with why, for legal reasons, the study has had to be postponed.

Changing the law on gaining consent

Of particular interest to policy makers has been the various legal frameworks within which procurement takes place. The UK, along with Germany, the Netherlands, Italy, Canada, Australia and New Zealand, have what might broadly be termed 'opting-in' legal systems. Two other systems have generated much interest in the literature: presumed consent – also known as opting-out – and required request.

Presumed consent

Presumed consent schemes have been introduced into many countries, although attempts to enact such legislation in the UK have always failed, the latest being the Transplantation of Human Organs Bill 1993. The international legislation falls into several categories. The purest version of the law allows automatic removal except in a situation in which the deceased has expressed an objection during his or her lifetime. This 'strict' type of presumed consent procedure applies in Austria where organs can be removed

> *provided in his or her life, the person concerned has not expressed an objection. The views of close relatives are not taken into account* (Conference of European Health Ministers, 1987b)

A slightly less strict version of presumed consent operates in Belgium where, if there is no explicit objection by the deceased, the relatives are allowed to object but the medical profession are under no obligation to seek their views. The relatives must initiate the process under these circumstances (Michielsen, 1992a, b).

Other, still weaker, schemes allow removal unless the deceased has made an explicit or informal objection at any time. Such a formulation of the law effectively requires that the relatives are consulted in order to glean the wishes of the deceased. Although it is formally the views of the deceased whilst alive which are being sought, such schemes allow the relatives to object on the deceased's behalf. France and Spain operate presumed consent legislation of this kind (Hors *et al.*, 1992; Matesanz and Miranda, 1992).

Finally, a scheme in operation in Singapore provides for the automatic exclusion of certain categories of potential donor, including non-citizens and Muslims (Soh *et al.*, 1991). Muslims can, however, donate their organs if they wish, by pledging their organs whilst alive or if their relatives consent.

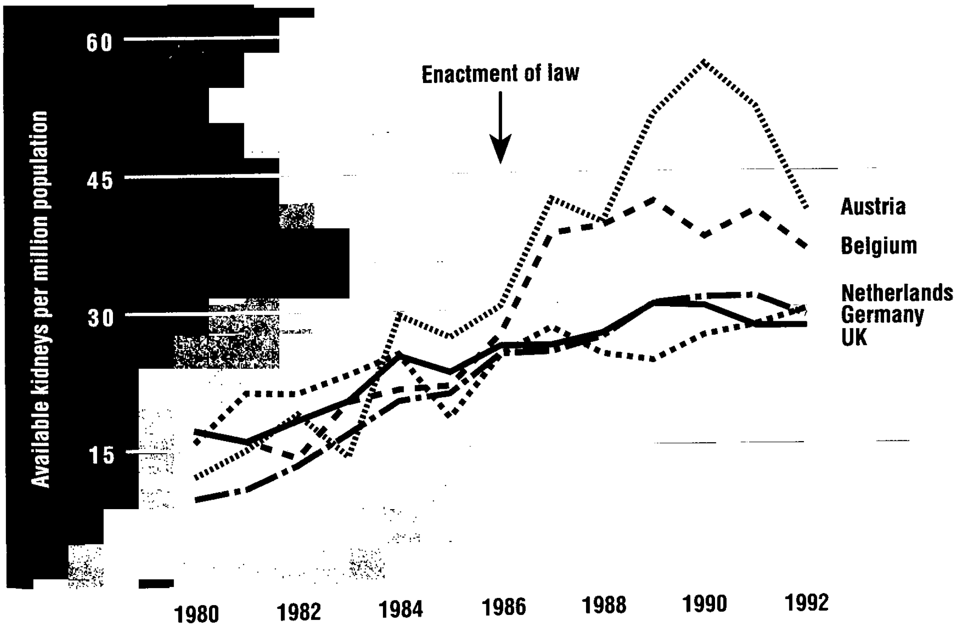
In this chapter the evidence for the law's efficacy will be examined. Since the hypothesised effect of presumed consent laws in high transplanting nations can be confounded by road deaths, for example, a more appropriate approach is to examine the affect of introducing a law on the trend of procurement activity in a single country.

Does presumed consent work? Belgium

Belgium enacted presumed consent legislation in June 1986 in the middle of a period of sustained and steady growth in kidney transplantation across Europe. Figure 20 shows the number of available kidneys (equivalent to the number transplanted by country of origin, thus adjusting for import and export flows) between 1980 and 1992 in the UK and four Eurotransplant region countries.

Belgium did increase the number of available kidneys by a significant margin during 1987 – a rise of 37 per cent over the year before – and this does

Figure 20 Available kidneys in the UK and Eurotransplant region, 1980-1992 (pmp)



Note: 'Available kidneys' refers to the number of transplanted kidneys derived from a particular country, but possibly transplanted abroad.
Source: As Figure 1.

not seem to be simply the continuation of an earlier trend. Furthermore, neither the UK, Germany nor the Netherlands experienced a similar increase in the same year. On the other hand, Austria did experience a similar increase, drawing attention to the fact that the effect experienced in Belgium could have been as a result of other factors (Austria did not introduce similar legislation in the same year having done so in 1982, formalising a 200 year tradition of routinely utilising the corpse for medical purposes). For instance, the publicity devoted to the organ donation issue whilst the law was being debated could itself have promoted a greater willingness to donate on the part of the public and a more informed attitude on behalf of ICU staff. It has also been noted that the number of transplant co-ordinators increased at around this time, and that the law formalised systems of reimbursement so that donating hospitals could be sure that they would receive the appropriate payment for managing the donor.

These objections are inconclusive, however. One would expect a 'publicity effect' to subside. The increase in the number of co-ordinators was likely to be as much a result of the increased number of donors as the cause of it. And the law merely formalised payment systems which operated successfully for the majority of hospitals beforehand. But perhaps the best evidence is provided by Figure 21. The chart shows the difference between centres which always asked permission, and the centre which 'followed the law'. It is clear that the influence of publicity, co-ordinators and payment systems had no effect in those centres where relatives' permission is always sought. It certainly seems as though the law had an independent effect on kidney retrieval where its provisions were adopted.

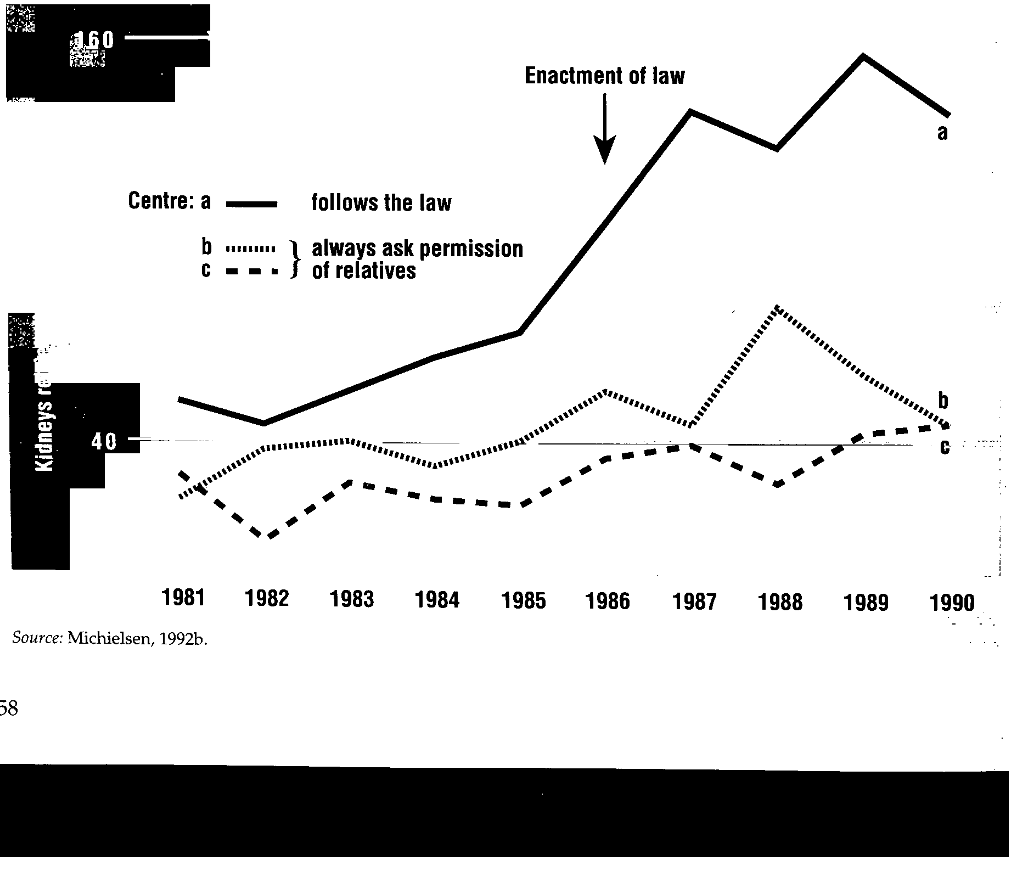
In any time-series analysis 'concurrent interventions' such as those described above will always make it difficult to prove the causal influence of the intervention in question, in this case a law. On balance, though, the evidence suggests that the introduction of presumed consent in Belgium had a significant impact on the availability of organs.

Does presumed consent work? Singapore

Singapore also introduced presumed consent legislation after a long period of transplant activity under an 'opting-in' system. The number of transplants undertaken in Singapore are relatively small and so were not included in the international analysis. Nevertheless, the development of kidney transplantation over time has some interesting features as shown in Figure 22.

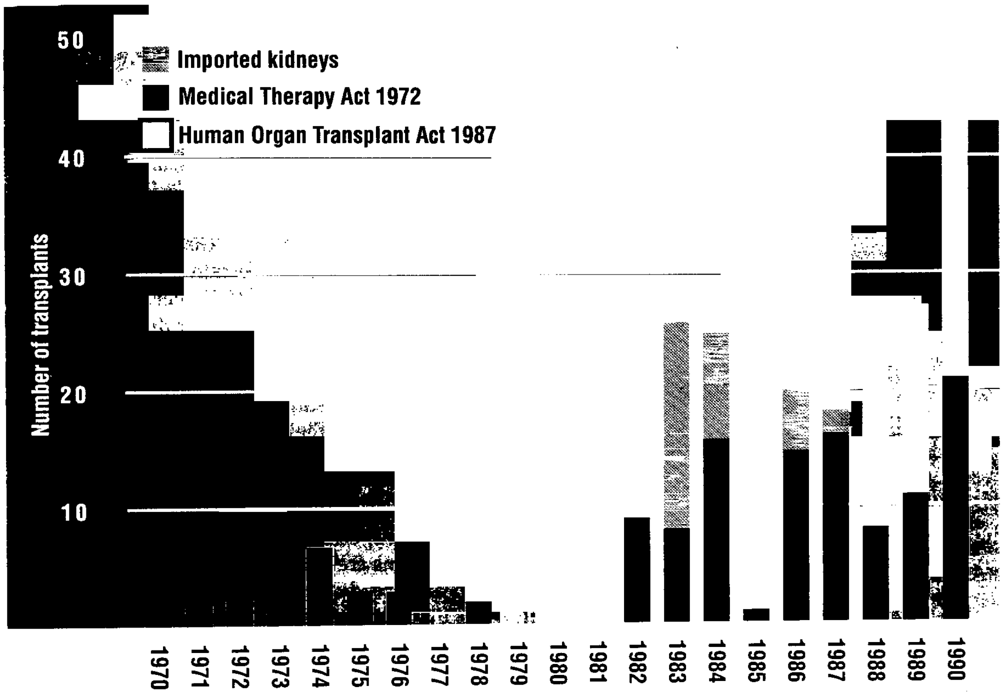
Between 1970 and 1982 only 30 cadaveric kidneys were transplanted, constituting an average of approximately 0.9 pmp per year, clearly inadequate by any international standards (Lim *et al.*, 1990). In an attempt to increase this level of activity, kidneys were imported from Europe and North America – transplants from this source are shown by the light shaded area. The initial success

Figure 21 Kidney retrieval in three different centres in Belgium, 1981-1990



Source: Michielsen, 1992b.

Figure 22 Cadaveric kidney transplants in Singapore, 1970-1990



Note: All cadaveric transplants performed in Singapore are displayed. This includes voluntary donation of kidneys under the Medical (Therapy, Education and Research) Act 1972 (opting-in), kidneys imported from Europe and North America and kidneys procured under the Human Organ Transplant Act 1987 (presumed consent).
Source: Soh *et al.*, 1991.

of this policy was short lived when it became clear that the one-year graft survival of these kidneys was poor, probably as a result of the prolonged 'cold ischaemia' times involved.

In 1987, the Human Organ Transplant Act was introduced incorporating the provisions described above. The number of transplants undertaken in 1988-90 increased significantly over the 'non-import' total of the previous years, imports being discontinued in 1988 (Soh *et al.*, 1991). Some analyses – including that represented in Figure 22 – have attempted to isolate exactly the number of kidneys procured under the new law compared with the number obtained under the old opting-in legislation, which still applied for those wishing to pledge their organs. However, such an analysis will underestimate the number of voluntary pledges, since it cannot be known for certain how many families would have consented given the chance (Teo, 1991). Nevertheless, the evidence from Singapore adds to that from Belgium as to the efficacy of presumed consent legislation.

Required request

Required request and routine enquiry are used extensively in the United States with the aim of increasing the supply of organs. The Uniform Anatomical Gift Act 1987, which forms the model for many state statutes, makes provision for required request and routine enquiry. The development of required request policies by hospitals was encouraged by the Omnibus (Budget) Reconciliation Act 1986. This Act provides that failure on the part of hospitals to adopt routine enquiry or required request policies will lead to the denial of Medicare and Medicaid reimbursements from the Health Care Finance Authority.

Required request is a procedure in which enquiries must be made of the families of potential donors to see whether they would allow their relatives' organs to be used. Twenty six US states have this type of policy. The legislation in some states incorporates exceptions to the general duty of enquiry where, for example, the wishes of the deceased are already known, or the medical staff are unable to locate the family in a timely manner, or where enquiry would exacerbate mental or emotional distress.

Routine enquiry is the procedure of informing individuals and families of the option of organ donation. Eighteen states have legislation of this kind. Some states do not require hospitals to approach families directly but stipulate that they must establish organ and tissue donation committees to design policies which would result in prompt identification of donors and prompt referral to the Organ Procurement Agency.

How successful have the required request and routine enquiry schemes been? While there was an initial increase in the availability of organs, over time the schemes do not appear to have had a major impact (Mozes *et al.*, 1991; Ross *et al.*, 1990). One reason for this, it is suggested, is the lack of institutional commitment to ensuring that the required request procedures are followed. The United States experience illustrates that simply to enact required request legislation is not enough. It is vital to have adequately trained and qualified personnel.

As one organ procurement official observed:

> *if you simply ask relatives about organ donation by simply citing the law the consent rate is zero* (Caplan, 1988).

Another reason suggested for the lack of dramatic impact of required request is that doctors find organ procurement time consuming and emotionally demanding. It is questionable whether statutory enactment of required request would have a significant impact. The national audit found that only 6 per cent of relatives in the UK are not approached when an otherwise potential donor is on a ventilator, and many of these would probably have communicated their unwillingness to consider donation by other means.

Xenotransplantation

The future of transplantation is exciting. The continuing improvement in immunosuppressive drugs and surgical techniques will increase graft survival and reduce the need for retransplantation. But further into the future lies the possibility of eliminating the need for human cadaveric organs altogether by using animals' organs instead – xenotransplants.

The procedure is by no means a new one. The first heart transplanted into a human was taken from a chimpanzee in 1964 because in the absence of brain death criteria the medical staff concerned felt unable to proceed with explanting a heart from a ventilated donor. The recipient died after one hour (West, 1991). A more successful attempt at heart xenografting involved 'Baby Fae' who received a baboon's heart in 1984 but still survived only 20 days. In the early 1960s attempts to transplant kidneys from chimpanzees and baboons into human adults failed in the vast majority within two months, with only one case lasting 9 months (Drugan *et al.*, 1989). Liver transplants have been no more successful: in 1992 a baboon's liver was transplanted into a 35 year-old patient with little success (Ballantyne, 1992).

Nevertheless, these experiences have led researchers to a better understanding of the nature of the rejection process. In particular, species appear to fall into two groups: discordant and concordant species, first identified by Sir Roy Calne in 1970 (Najarian, 1992). Concordant species are closer genetically to humans, and include apes. The rejection process in these species was not 'hyperacute', although a slower process of rejection inevitably soon followed. In discordant species, such as pigs, a violent rejection process sets in within minutes or hours. However, concordant species, while appearing to offer the best hope for future xenotransplants, suffered from often not having large enough organs to support human life, and from the resistance of animal rights groups who argued that their relatively high form of cognitive development made them unsuitable for farming for 'spare parts'.

For these reasons attention has reverted to discordant species, and the pig in particular. The pig's organs are similar in size to human's, and pigs are already farmed intensively for food. While this may not draw a line through the ethical objections, pigs certainly have clear advantages over concordant species. The problem of hyperacute rejection remained, however, until recent advances in genetic engineering. Researchers at the University of Cambridge have succeeded in breeding pigs with a critical human gene incorporated into their DNA (James, 1993). The idea is to 'trick' the human immunological response into thinking the pig's heart is its own. So far 37 transgenic pigs, as they are known, have been born. Other genes also need to be incorporated into these pigs, which may mean cross-breeding three pig lines. Clinical trials could start anywhere between three and seven years' time – that is, between 1996 and the year 2000 (White, 1993).

However, the period between first clinical trial and regular medical use could be a long one. The problems of rejection are likely to remain in some form or another. Xenotransplantation as a regular medical intervention is unlikely until well into the 21st century. However, there is a real possibility that issues surrounding the shortage of cadaveric organs and live donation will only persist into the 'medium term' future – successful xenotransplants will put an end to these debates. Nevertheless, such developments are not so imminent that the transplant community can close its eyes to today's difficulties. Policies must continue to be promoted to alleviate current shortages. These policies, and indeed those of xenotransplants, involve fundamental ethical questions, and these are the subject of the next chapter.

Ethics – are the options morally defensible?

5

The options analysed in the previous chapter are associated with a number of ethical issues. In this chapter the analysis will focus on ethical objections, but it is important to stress at the outset that an initiative which increases the supply of organs will, *ipso facto,* have one very important ethical argument in its favour: the potential to avoid death and relieve suffering. This point is often neglected in the ethical literature on organ donation. A genuine ethical drawback to a policy to improve the supply of organs does not mean that the policy should be abandoned. A judgement must be made on whether the drawback outweighs the good to be done through a life-saving procedure.

Morals, ethics and value clarification

Moral or ethical theories are concerned with right and wrong – with what constitutes good and bad behaviour or policy. An ethical analysis of policies to increase the supply of donor organs will do just that: assess whether or not the policy appears to be the right thing to do. An ethical analysis must be based on the best possible empirical evidence, but it will also involve making a judgement on issues which are beyond quantification. These issues might include the implications of presuming that someone would have wished to donate their organs, or whether it is appropriate to subject people to traumatic decisions such as those relating to live donation. Although not quantifiable, judgements about such issues still need to be made and they should be based on as clear and impartial an analysis as possible. The approach adopted in this chapter is to outline the ethical issues surrounding each policy, assess which are the most serious and suggest how we might devise means of avoiding their worst consequences. Ethical analysis provides a framework for thinking rather than simple solutions; nevertheless, a clear understanding of the values at stake can only serve to improve decision-making.

Presumed consent legislation

Article 10 of the Council of Europe's recommendations on organ donation issued in 1978 provided that:

> *no removal must take place where there is explicit or presumed objection on the part of the deceased, in particular taking into account his religious and philosophical convictions* (Council of Europe (78) 29).

In 1987 another Conference of European Health Ministers came down in favour of the promotion of cadaver organ donation. However, Article 10 of the earlier resolution was rewritten to provide that removal may take place only where there is consent on behalf of the deceased – although this consent could be 'presumed' in the absence of express objection. This change in emphasis left the question of whether a presumed consent or an opting-in policy was to be adopted to the individual nation.

There appear to be four ethical issues relating to implementing presumed consent legislation relating to:

the wishes of the individual;

the sensibilities of the relatives;

trust in the medical profession;

good medical practice.

The wishes of the individual

The first concern would be most serious in the context of 'routine salvaging', a system whereby one could not 'opt-out'. Should routine salvaging be allowed? It has been noted that in many areas of legislation the general public interest takes priority over the wishes of the individual (Dukeminier, 1969). There is a public interest in ensuring an efficient supply of organs. Once dead, why should a person's wishes be respected? This type of argument is open to the objection that it is insensitive to the wishes of deceased. In our society the wishes of the dead are respected by, for example, giving legal force to the declarations made in their last will and testament.

More commonly, individuals are given the opportunity to 'opt-out' under presumed consent legislation. Although less serious, the concern remains that individual wishes would be ignored. The Hoffenberg Committee commented that there was a danger that organs would be removed when this was not the wish of the person whilst alive (Hoffenberg, 1987). Persons may feel pressurised into not opting-out because it might be seen as socially unacceptable (Veatch, 1987). Others may be ignorant of the law or unable to understand it – vulnerable groups would be most at risk. In a multi-cultural society, the risk of ignoring the implicit wish of individuals with strong religious beliefs is particularly serious. No presumed consent legislation can possibly guarantee that the wishes of all concerned will be respected.

The sensibilities of the relatives

If concern would be felt by those now living with strong beliefs about the proper procedure for their body after death, distress could certainly be caused to family members who wished to grieve without the knowledge or suspicion that the body of a loved one was being 'mutilated' – particularly if donation was conducted only under a 'presumption' that the deceased had given consent. The Conference of European Health Ministers commented that,

> *the role of the family in deciding on organ removal is much more important in cases of presumed consent than in cases of express consent. In the latter case the sentimental objections of the family have to be weighed against the legal rights of the deceased who has willed the organ donation. In the case of presumed consent the family's express objection weighs more heavily against the presumed consent of the deceased ... In practice therefore whether consent is express or presumed, the final decision rests to a very large extent with the family of the deceased* (Conference of European Health Ministers, 1987c).

It is worth noting, however, that the sensibilities of families are not taken into consideration in the case of a coroner's autopsy. In England in the early 1980s 'some 20 per cent of persons dying ... [were] subject to a medico-legal autopsy' (Mason, 1983). In other words, a large number of deceased individuals are subjected to invasive surgery, without the need for consent, to satisfy social imperatives. What is more, society sanctions such investigations only as a means of establishing cause of death or to help in the solving of a crime – lives are not directly at stake. The ethical distinction which supports the coroner's autopsy but denies the donation of organs unless consent is provided, is by no means clear (see the arguments of Professor John Harris, quoted in Meek, 1992).

Trust in the medical profession

Both these possible consequences – ignoring individual rights and offending the family's feelings – could have an impact on trust and respect for the medical profession. Whilst presumed consent may, in the short run, furnish more organs for transplants, in the long run its systematic effect on the institutions of medical care could be depressing and corrosive of that trust upon which doctor-patient relationships depend. And, even in the short run, public controversy can adversely affect donation rates (Patel, 1993). Furthermore, doctors may be unwilling to override the wishes of nearest relatives regarding organ donation, blunting the impact of the schemes.

Good medical practice

There may also be certain medical risks in removal without consent. In October 1979 a woman who died suddenly in France had her corneas transplanted (Redmond-Cooper, 1984). Unfortunately, the recipient contracted rabies. It was later revealed that the donor had contracted rabies when bitten by a dog in Egypt shortly before her death. Her family knew this and had they been asked they would have been able to pass on this information to the medical team.

Can presumed consent legislation be ethical?

If a presumed consent scheme were to be introduced certain questions would need to be addressed. Would all organs be covered by a presumed consent scheme? Should organs be made available simply for clinical transplant or also for experimentation purposes? Should certain vulnerable groups of patients be excluded from routine removal? The 1969 Renal Transplantation Bill, an attempt to introduce a limited form of presumed consent, provided exclusions for persons who, at the time of death, were suffering from mental illness or mental handicap, minors, those over 65, prisoners and permanent residents in institutions for the aged, disabled or handicapped.

It may also be necessary for a statutory definition of death to be enacted. This would, as was noted earlier, prove a difficult and controversial task. Presumed consent would also have to be accompanied by massive publicity in order that members of the public were made aware of their opportunity to opt out. In addition the legislators would need to address themselves to the question of who should have ownership and control of the cadaver and of the organs.

However, it may be that many of these ethical objections can be overcome by sufficiently carefully drafted legislation – see Box 8. Individual rights can be safeguarded by means of computer registries and exclusions of certain categories of individual. The sensibilities of the relatives can be safeguarded by allowing them to initiate an objection which must be respected. The position of the medical profession is protected by allowing the individual clinician to decide how and when to utilise the law's provisions. Such a law would also allow for donation under circumstances whereby the relatives, at a moment of grief, do not wish to discuss the possibility, but would otherwise normally be in favour of donation.

Nevertheless, unless the medical profession broadly supports the implementation of presumed consent legislation there is a serious danger that transplantation will be brought into disrepute by the controversy which would ensue (see, for example, Patel's (1993) account of recent controversies in France in relation to the removal of organs without

8

AN ETHICAL PRESUMED CONSENT LAW FOR THE UK?

A mixture of the Belgian presumed consent legislation of 1986 and that instituted in Singapore in 1988 could provide an ethically acceptable legal framework for the UK. Such a law would have to include the following elements, in the light of the discussion in the text.

- **The opportunity for individual members of society to register their objection and to 'opt-out'. This should be made as easy as possible, and be accompanied by substantial ongoing publicity so that future generations would be aware of the 'default' position.**
- **The opportunity for sections of society to be automatically excluded – to be 'presumed objectors'. These might include religious groups, such as Muslims or orthodox Jews, as well as the mentally ill or handicapped and other vulnerable groups.**
- **The family should be provided with the right to initiate an objection and withhold donation in the absence of explicit pledges on behalf of the deceased. This would protect the sensibilities of those families with particularly strong feelings. Doctors would not be obliged to request permission, however.**
- **The medical profession should be given clear responsibility for implementing the law in the way they see fit on a case by case basis. No compulsion or penalty for failing to act should be involved.**

These comprise the broad principles which should guide any presumed consent legislation; the details would obviously need careful debate and drafting. Nevertheless, the Belgian and Singaporean experience has provided us with valuable guidance on workable, ethical legislation.

consent). This in turn may corrode the public's trust in doctors and medicine. The best way forward is for the debate to continue until those who would have to work within a new law are satisfied that their reservations have been addressed.

Required request legislation

Arthur Caplan (1984;1988) has been one of the strongest advocates of the required request procedure. He argues that institutional required request means that opportunities for obtaining consent will not be missed. Required request standardises enquiry and thus places less strain on health care professionals and family members at a time of great stress and emotional upheaval. It also preserves the right of the individual to refuse consent since voluntary choice remains the ethical foundation upon which required request is based.

However, others disagree, making a number of criticisms of the required request procedure (Martyn *et al.*, 1988). Doctors and relatives may find the system distressing, though for rather different reasons than those relating to presumed consent. Doctors may be put under pressure to find that donors are suitable candidates for donation with implications for the diagnosis of brain stem death. Unlike presumed consent legislation, required request prescribes actions. It does not in general allow for the doctor to decide on a case by case basis the proper approach. In some circumstances it may be quite clear that requesting organ donation may be insensitive to the needs of the family. To suggest to relatives that organ donation is a gift of life is to play upon their emotions and guilt feelings at the time of their loved one's death.

There is also a danger that respect for donors may be eroded in the constant search for organs and this may have long term implications for public confidence in the medical team and the organ donation process. In general it seems clear that required request's prescriptive nature, and the associated problems of enforceability, mean that it is ethically unsustainable. There is also little evidence that it would be effective in improving the supply.

Elective ventilation

Before discussing the ethical aspects of elective ventilation, it should be noted that recent opinion has questioned whether the procedure is lawful (Sommerville, 1993). The reason for such an opinion is outlined below, followed by the ethical discussion, and finally a conclusion on whether the legal position should alter the ethical assessment.

The law and elective ventilation

The ventilation procedure is clearly being used for the benefit of the recipient of the transplanted organs and not for the patient. Currently, in law, a patient must consent to all medical treatment whether or not it is in their best interests. If one is not in a position to consent, due to being in a coma, for example, then one's relatives cannot give that consent on one's behalf. Decisions as to whether to treat in circumstances of mental incapacity are made by clinicians, only when in the patient's best interests. In the case of cadaveric donation, in circumstances where the individual concerned is dead, the relatives can authorise removal of organs. Elective ventilation does not satisfy any of these conditions. If a patient is electively ventilated prior to brain stem death being established then it is submitted that the use of elective ventilation will constitute a battery in civil and in criminal law.

If the use of this procedure is to be continued then its legality will have to be established through express statutory enactment. To introduce an exception it would have to be argued that the need for transplanted organs is such that public policy would dictate the use of such a procedure even though it was not in the interests of the (potential) donor. In view of the furore over the use of persons who are cognitively dead as organ donors – particularly the problems surrounding anencephalics – such an exception would prove exceedingly controversial.

Nevertheless, no-one would suggest that the clinicians who have promoted this procedure have anything but the best intentions for their patients. The possibility that the procedure is unlawful does not automatically imply that it is unethical. Ethical objections deserve analysis in their own right, and they have been arranged under three headings. Elective ventilation:

- impedes traditional ICU work;
- is against the best interests of the patient;
- offends the dignity of the dying process.

Impedes traditional ICU work

The first criticism stems from the fact that 'a policy to initiate supportive care of a patient when it is known that it will not benefit that patient in any way is very different from the traditional approach' (Routh, 1992). The objection appears to be that ICU resources should be solely devoted to the saving and prolongation of life, and that their use for any other purpose, such as the preservation of cadavers for organ removal, should only be undertaken when the initial purpose was one of rescue and life extension.

Let us first assume that there is an unlimited supply of intensive care beds. Is there an ethical case for resisting the use of ICU facilities under these circumstances? To do so would be to make an ethical distinction between the direct and indirect saving and extension of life, and this does not seem reasonable. An electively ventilated patient is quite clearly a means of saving other lives and reducing other suffering, albeit only as the first link in a chain which results in a transplanted organ. However, specialties in a health service should not operate parochially. If the skills of intensivists can be used to save life in ways which happen to differ radically from previous practice, then this is in itself not sufficient reason for resisting that change.

If it is appropriate in principle to use intensive care facilities purely to expedite organ retrieval, why in practice is it still resisted? Unlike the debate surrounding changing the law to one of presumed consent, where the individual concerned is already occupying a bed in the ICU, electively ventilating a potential donor would mean that an accident victim with a good chance of survival might be denied treatment. This is highly unlikely in practice; more likely is a situation whereby

> *a decision has to be made whether or not to discontinue ventilation on the potential donor when the family have agreed to and expect him to become a donor* (Routh, 1992).

Notwithstanding the evidence cited earlier that the average increase in an ICU's workload would be small, cases such as that described above are bound to occur if elective ventilation becomes a national policy. Is it ethical to allow for the possibility of such an event?

The question is, rather, whether it is reasonable to allow for the possibility of unpalatable choices. As things stand, any reasonably busy ICU may not be able to cope with a sudden influx of two or three seriously injured individuals – choosing between those who can benefit from care is a common problem for those working in the NHS. Having to decide to remove an electively ventilated patient to free a bed will certainly not be welcomed by ICU staff. But it is a circumstance made necessary by an attempt to provide potentially life-saving organs for others. The alternative is to leave an available bed potentially unused when it could be providing the means for securing additional organs. This would seem harder to defend ethically.

Against the best interests of the patient

There is a perception among some in the intensive care community that elective ventilation causes death to be 'postponed' when there are no clinical grounds for so doing:

> *deliberately prolonging a patient's dying is unacceptable for any reason* (Park *et al.*, 1993).

Such procedures constitute poor medical practice and erode the confidence which the public has in the medical profession. Relatives may be forgiven for being confused and distressed by a process which simultaneously informs them that a loved one is sure to die whilst taking the individual in question to a department which is devoted to attempts at saving life. Perhaps the most serious scenario involves a prospective donor failing to satisfy brain stem death criteria and remaining in a persistent vegetative state after ventilation is stopped (Routh, 1992). This scenario is one which is recognised by proponents of elective ventilation as deserving serious consideration (Collins, 1992). It offers the prospect of a real prolongation of a 'living death' and all the associated grief of the relatives.

Leaving aside the possibility of misdiagnosis for a moment, the accusation that death is being prolonged is strongly refuted by doctors who developed the Exeter protocol. They argue that the point of death is no different whether one adopts the protocol or not:

> *... such patients die when breathing ceases; elective ventilation does not prolong the act of dying, for one is ventilating a corpse* (Nicholls and Riad, 1993).

The difference between the electively ventilated patient and those dying on general wards is twofold. First, the electively ventilated patient is transferred to ICU whilst still alive. Second, the official confirmation of death, after the second set of brain stem death tests, is made somewhat later than if the patient died on the general ward. The actual point of death, however, will have been the same in either case, since artificial ventilation is only initiated once respiratory arrest has taken place (although there is a view that death may be postponed for a short period of time). The legal controversy stems from the fact that this intervention is not in the patient's interests, and he or she is in no position to consent to it.

But is this situation ethically unacceptable? The Exeter protocol only considers those patients in deep coma with 'lack of withdrawal response to painful stimuli' (see page 55). Even though the patient is placed on a ventilator when this is not for their own benefit, the procedure does not cause distress. Even if the moment of brain stem death can be shown to have been postponed for a short period in the electively ventilated patient, this does not automatically indicate that the patient's interests have been abused. And the fact remains that other patients stand to benefit.

However, a mistaken diagnosis is another matter. Although there are no reported cases, it is possible that respiratory arrest coupled with elective ventilation could result in the patient remaining in a persistent vegetative state. Brain stem death would not have occurred in such a patient and the concern is that in some way elective ventilation confounds the original diagnosis. Patients in a persistent vegetative state do not recover, and so such an outcome would clearly not be in the patient's interest. This assessment was recently reinforced by the high court ruling on Tony Bland, left in a persistent vegetative state after the Hillsborough football stadium disaster (*Airedale NHS Trust v Bland* [1993]). If elective ventilation directly caused significant numbers of such patients, it would render the procedure unethical.

The only way to establish whether this possibility is a real one is to undertake a large-scale randomised study. PIVOT, the proposed research mentioned in chapter 4, includes a randomisation element which would allow an assessment of the validity of this concern. But before this element of the study can go ahead the legal position must be resolved; as matters stand, the law prevents such research.

Offends the dignity of the dying process

The desire for a painless, dignified and peaceful death is deeply rooted into many of the world's cultures. Respect for the corpse is of symbolic importance, and the funeral constitutes a fundamental rite of passage. Intensive care staff must deal with these issues more than most and it is perhaps unsurprising that views such as these are commonly heard:

> *I take exception to the idea ... that we should scout around the wards, look for patients about to die and take them to the Intensive Care Unit, intubate them and ventilate them until they are brain dead so that their organs can be used for the purposes of transplantation* (Bihari, 1993).

There is a belief that the 'good death' is becoming a thing of the past, and that we are in danger of undermining the dignity of the dying process. Although the passage quoted above from an eminent intensivist may somewhat caricature the process described by clinicians in Exeter (Feest *et al.*, 1990), it has a serious message. Moving individuals with no hope of recovery from one department to another and attaching ventilatory equipment could well be viewed as deeply undignified.

Those who developed the Exeter protocol were quite clear that the process should not be initiated without the relatives' understanding and agreement. This should clearly apply in all units where elective ventilation is introduced.

But it may still be argued that such procedures prevent the 'good death' in a more fundamental sense, regardless of how the relatives feel. A peaceful and dignified departure of the spirit and soul, whatever one's religious beliefs, is simply not possible if one's mortal remains are being moved from pillar to post. Such an assertion is not, in the final analysis, refutable. But we should remind ourselves that acceptable modes of dying change with changing cultures and technologies. A century ago the notion of dying whilst attached to various forms of machinery would no doubt have seemed undignified to some. As the rationales for new practices are understood, new contexts for dying become acceptable. It may not be long before actively managing death to save other lives is as 'good' and dignified a form of dying as any other.

Concluding comment

The only significant ethical concern with elective ventilation relates to the possibility of increased numbers of patients in a persistent vegetative state. A study which would resolve this issue has been postponed because the procedure appears to be unlawful. However, the ethical grounds for this unlawfulness can only be established by conducting the study. This 'Catch-22' situation is clearly unsatisfactory and requires resolution.

The non-heart beating donor

Although a relatively neglected area in the literature, the non-heart beating donor offers the prospect of significant improvements in donation rates. However, it is not without ethical drawbacks. As discussed earlier, one solution, developed in the Netherlands, is to insert a tube into the cadaver before permission is granted in order to cool the kidneys *in situ* (Rapaport, 1991). The procedure is minimally invasive, but nevertheless involves a small incision in the groin. Does this constitute an unreasonable and unethical mutilation of the cadaver? After all, society sanctions the coroner's autopsy and the embalming process, both of which involve cutting into a corpse.

Clearly, in one sense the procedure does not go as far as that under presumed consent legislation: no organ or any other part of the body will be removed without the consent of the next of kin. However, it does involve cutting open a corpse without consent, solely for the purpose of the possibility of organ donation. Whether or not this is justified seems to rest on similar arguments to those discussed in relation to presumed consent, but in the context of a less 'significant' presumption – that the individual and/or the family would not object to minimally invasive surgery.

Such a small scale procedure may prove ethically acceptable. But if presumed consent legislation proves unacceptable, the precise ethical distinction between inserting a catheter and removing an organ should be clarified. Such a distinction is not obvious – both involve cutting into a corpse without consent. There is a danger of inconsistency here. Ultimately, the ethical issues revolve around consent in both cases, and not the nature of the act to which consent is, or is not, presumed.

Live donation

As we have seen, a potentially large proportion of those who present with renal failure could benefit from a live donation. However, even though virtually all the developed nations which predominantly use cadaveric donors have legalised this form of donation, only a very few have actively pursued it as a means of making inroads into waiting lists. Two reasons given by a clinician from a UK transplant centre were 'the excellent survival of patients with grafts from cadavers after treatment with cyclosporin ...and the expectation that most patients would get a kidney soon after starting dialysis' (Donnelly *et al.*, 1989). Implicit is an assumption that cadaver donation is ethically preferable. However, it is now clear that cadaveric organs cannot match the demand. Are the ethical drawbacks to live donation too severe for its use as an alternative?

There appear to be three main ethical concerns with live donation, arranged under the following headings:

- *primum non nocere* – it offends the fundamental medical ethic;
- **voluntarism** – it may not involve a decision freely made and with a full understanding of the consequences;
- **commercialism** – it runs the risk of encouraging a trade in organs.

Primum non nocere

The principle of 'first, do no harm' is, when one looks closely at medical practice, often breached (Moore, 1988). Throughout history medical interventions have caused untold harm – many drugs have extremely harmful side effects, and surgery can leave a patient disfigured and often risks death. Nevertheless, these procedures were defended, and still are, on the basis of 'expected net benefit' to the patient. We now acknowledge that we cannot always be sure that an intervention will do good, but accept that certain probabilities of success make a 'cure' defensible. There is an 'expected' or probabilistic benefit. On the other hand, drastic surgery such as amputation undoubtedly does harm in one sense, but is defended on the grounds that doing nothing would result in a worse situation. The 'net' benefit is positive. Such justifications are not uncontroversial, since individual patients will still on occasion be harmed, but risks are broadly accepted for the overall benefits provided.

In these circumstances the principle *primum non nocere,* though stretched a little, could still be said to guide practice. However, with live donation the moral context shifts drastically: actual harm, in the form of a surgical incision and explantation, is done to one individual to benefit another. Blood transfusion and caesarian births provide similar examples, but are less clear cut. Caesarian sections are often for the benefit of the mother as well the child, and blood transfusions eventually became entirely harmless to the donor. The extent of the harm done in a live explantation is small, but it exists, if only of the kind present for all surgery and anaesthesia. No surgeon or nephrologist feels entirely comfortable about putting healthy individuals 'under the knife'. There would seem to be absolutely no expected net benefit in so doing.

However, although doctors' reluctance can be appreciated, can we be sure that there is no benefit at all to the donor? Recent conceptualisations of health include many more dimensions than simply the absence of symptoms, or the adequate functioning of limbs and organs. Psychosocial health is also important and there is evidence that health as measured on these less objective grounds is improved by the act of donation (Bonomini, 1991). Indeed, it would be surprising, and worrying, if this were not the case for it would imply that the donors were not doing what they really wanted. If they are, then it seems that the original principle, though stretched a little more, is still intact. But the question of voluntary consent leads on to the second issue.

Voluntarism

Regardless of whether harm is done to the donor, there is general agreement that an individual should not be forced into donation. Individual liberty to act as one chooses within the law is a highly valued principle. Coercion can, of course, operate in insidious ways and it is these covert mechanisms, rather than overt physical ones, which are the concern of the transplant community. More specifically, there are two possible elements obstructing a 'free' choice to donate: emotional pressure and insufficient knowledge of the consequences.

The first of these elements is exemplified most clearly by the following case, involving a partial liver transplant from parent to child:

> *for a parent whose child is dying ... it is hard to imagine that there would not be enormous pressure – proportionate to the amount of time the child had spent on the waiting list and the grimness of the prognosis – to serve as the source of a lobe of liver* (Caplan, 1993).

Not to offer the donation may stigmatise the parent as selfish and heartless. Other familial relations could also be at risk: a brother who refuses to donate a kidney may be ostracised by the remaining family members. These potential donors may be said to be under 'emotional blackmail' from those who do not have to bear the full weight of the costs of the decision. It is all too easy to express moral indignation at another's actions or inactions when we ourselves do not have to bear the consequences. We should not pursue a policy which places parents, or other relatives, under such a burden.

However, it is not so clear that an individual should be protected from making such a decision under any circumstances. For example, simply being told that live donation is an option, and to consider coming forward for the relevant tests, would seem a defensible policy. In this way potential donors would be obliged to consider what they could do for a family member before anyone knows who is or is not medically suitable. Emotional coercion would be avoided, but personal responsibility encouraged. If the potential donors feel unable to go through with the operation, then the doctors must find them medically unfit. The crucial point involves medical suitability: potential donors should not have this information conveyed to those who might then be able to exert improper pressure.

Some might argue that such a situation is still unfair: merely by virtue of being presented with the option the individual is immediately placed under an unwarranted moral burden. However, if this were accepted it would be tantamount to denying that we ever have a duty to face up to difficult decisions relating to the welfare of others. Indeed, there is a strong case for systematically informing relevant family members of the option. This is the only way of ensuring that those individuals who would genuinely have no difficulty in choosing to donate are not denied the opportunity through lack of knowledge.

But if we can ensure that donation is not as a result of emotional pressure, can we be sure that true risks involved are properly understood? As has been strongly argued by one nephrologist, medical textbooks themselves disagree about the risks which the donor will incur (Michielsen, 1991). How can the donor make a properly informed choice under such circumstances?

Clearly, much responsibility lies with the presiding clinician to make clear the extent and limit of medical knowledge of the consequences of the removal of a kidney. It is certainly not true that nothing is known: there is much evidence relating to surgical mortality rates, for example (Bonomini, 1991; Jakobsen, 1990). And it certainly seems prudent to advise on the basis of the worst possible case.

But ultimately we, as potential donors, and not doctors must decide whether we wish to proceed. Many activities in society – from living in polluted urban environments to eating saturated fat – have risks attached the levels of which are unclear. Nevertheless we do not attempt to proscribe the activity. An uncertain level of risk is insufficient reason to deny people the opportunity to donate, as long as this uncertainty is properly communicated to the donor.

Commercialism

This type of objection, chiefly directed towards genetically-unrelated donation, argues that it will ease the way for the unacceptable practice of commercial dealing. The response of the European Health Ministers was clearly in favour of Germany's answer:

> *"despite the prohibition on fees many people hold the view that the donation from living persons among non-relatives leaves the door open to perverting the intended purpose of transplantation" [...] this answer perhaps provides the outline of a solution to this fundamental problem:* ***a ban on the removal of non-regenerative organs from a living human who is not closely and genetically related to the recipient*** *(emphasis in original)* (Conference of European Health Ministers, 1987a).

This report has not considered in detail the arguments for and against a market in organs. Essentially, though, they rest on the possibilities of exploitation and profit-making or 'trafficking' (M. Evans, 1989). The 'slippery slope' argument, such as that used by the Council of Europe, rests on the notion that by allowing unrelated donation, one condition for commercialisation is thereby satisfied. This must make the possibility of commercial dealing more likely.

The first point to note is that genetically-related family members could also be faced with surreptitious exploitation, as discussed above, even if it is not always monetary. If this is accepted it would, on the 'slippery slope' line of argument, necessitate banning all live donation, something for which no government has demonstrated a desire. As for encouraging profit-making, this would seem to be a case of throwing the baby out with the bathwater:

> *the moral evil of trafficking stems not from the donation of an organ from a non-relative, but from the profit directed commercial arrangements ... Thus the proper response is to attack the exploitation of the act of donation, not the act itself* (M. Evans, 1989).

Unrelated donation and profit motivated organ brokering are sufficiently different activities for it to represent a high degree of timidity to outlaw a potentially beneficial act to both donor and recipient. With any form of live donation there will always be the chance that someone, somewhere will be tempted to donate an organ for a less than ethically healthy reason. This will be despite the best attempts of regulators or doctors to protect people from improper persuasion. But can these possibilities really deter policy-makers from encouraging acts of altruism and beneficence?

Concluding comment

The most serious ethical concerns about live organ donation relate to the possibility of improper pressure to donate. Detailed guidance is necessary to ensure that the opportunities for increased donation are not jeopardised by unethical practices. Current guidance from the General Medical Council (UKTSSA, 1993c) is both unduly negative about about promoting live donation and insufficiently detailed concerning the necessary safeguards. There is now a case for guidance from the Department of Health to accompany the existing documentation on unrelated donation.

Xenotransplantation

The prospect of transplanting parts of animals into our own bodies may seem somewhat distasteful to many. Not only does it make us feel uncomfortable in the sense that we are perhaps 'watering down' our humanness, but there is also the fear that we are 'playing God' with nature. Are these simply ill-considered emotional responses, or are they symptomatic of fundamental ethical concerns?

Much of the ethical debate has concerned itself with speciesism (Caplan, 1992; Kushner and Belliotti, 1985). Is it possible to establish morally relevant differences between ourselves, as humans, and 'closely related' species such as primates? The reason for such debates was the fact that primates appeared to offer the best prospect of successful xenotransplants. But the medical profession foresaw ethical difficulties. The prospect of farming chimps and baboons, the expense of breeding and the possibility of transferring animal viruses to humans – all these factors led to a belief that the future lay with discordant species (Najarian, 1992). Most interest now focuses on the genetically engineered pig.

The ethical issues surrounding the transgenic pigs are twofold:

is there a danger of 'playing God' with genetic engineering techniques?

can animals be used for 'spare parts'?

'Playing God'

The debate surrounding the opportunities and dangers of genetic engineering is too complex for any useful discussion here. Two points can be made, however. First, it should not be incumbent on the transplant community alone to address these problems, even if their technology brings the issues into particularly sharp relief. Many other areas of scientific enquiry use more painful and distressing experiments on animals than transplant research. Genetic experimentation on pigs may elicit headlines, but it is not the only, nor even the most common, focus for such research.

Second, the ethical debate must be conducted in the full glare of public scrutiny, uninformed though much of this scrutiny might be. If, to the frustration of the scientific community, progress is slowed because of 'unfounded' public concern, then this is nevertheless preferable to progress in a climate of fear and uncertainty.

'Spare parts'

Assume the pigs suffer no harm in the research and breeding stages. Genetic engineering is monitored and conducted to the satisfaction of the general public. Proven benefit to humans is demonstrated. Is the farming of these animals now justified? Do not animals have rights which deny us the authority to kill them for our own benefit?

If so, it would seem that the same logic must be applied to the farming of pigs for human consumption. Otherwise public policy would reject the killing of pigs for donor organs, whilst accepting their death for the production of food. This is not only inconsistent, but perversely so. For whilst it is generally believed to be morally acceptable to kill animals for food, this is under circumstances which offer us alternatives. No one has to eat pork to survive – on the contrary, it would often be much cheaper and healthier to rely on other sources of sustenance. With organs for transplantation, however, particularly hearts and livers, there is no alternative for a significant proportion of people who would otherwise die. Under these circumstances, those who wish to deny the use of animal organs for transplantation must provide even more compelling arguments than those who would wish to deny their use for food.

Concluding comment

Ethical discussions cannot resolve the issues they raise. They can only hope to clarify choices and guide decision-making. In this chapter the ethical issues raised by various proposals for improving the supply of organs have been set out. The concerns which warrant the closest attention, and those which seem the weakest, have been outlined. Inevitably, though, their final resolution must remain a matter for political and professional judgement.

6 Rationing – are resources being allocated fairly?

In previous chapters the factors affecting donor organ supply and demand have been reviewed. It is clear that there are no magic answers to the problems involved. All the trend data suggest that demand is likely to continue to outstrip supply, whatever measures may be taken in the short term. Wider social and economic changes, such as the long-term decline in road accident and intracranial haemorrhage deaths, will tend to erode any gains from introducing elective ventilation or a greater use of live donors.

There are vigorous debates about the morality of rationing elsewhere in the health care system. Should a civilized society meet the costs of any and every treatment that may bring some benefit to an individual or should a limit be set, reflecting the priority attached to health relative to other desired private or social goals? The predicament of the organ transplantation community poses these questions even more sharply. Transplantation faces an ultimate constraint in the actual supply of organs which is not faced by other areas of medicine. The necessity of rationing cannot be avoided by claiming that, in a perfect world, all relevant expenditures on health care would be incurred. Beyond a fairly modest point, extra investment in transplantation cannot increase the supply of organs.

The transplant community, then, is having to learn how to live with a problem that most other areas of health service delivery are likely to face over the next few years. The community's answer to the question – 'How do we deal fairly and justly with rationing a limited supply of health-improving treatment?' – is likely to have a much wider significance than the special case of organ transplantation might suggest.

This penultimate chapter explores the implications of rationing from two perspectives. First, it considers the issues involved in establishing the priority of this intervention relative to others – the problem of macro-allocation, the share of health care expenditures, if any, that should be allotted to this particular group. Having set a global sum, the system then needs to find a way of ranking individuals – the problem of micro-allocation, of deciding whom among the pool of potential beneficiaries actually gets the benefit. These are complex issues and the debates are still not clearly formulated within the UK transplant community and lack some of the data that would help to clarify the consequences of different choices. On the other hand, if we cannot procure all the organs which may be needed, professional time and public energy may be better used in seeking a consensus on what will constitute a socially and ethically defensible system for allocating those which are available.

Macro-allocation

What priority should organ transplantation have relative to other possible social expenditures? As Mooney and McGuire (1988) note, this involves a set of problems which have been relatively neglected by the literature on medical ethics, which has tended to concentrate on the micro-relationship between individual doctors and patients. In particular, it raises concerns about the efficiency with which resources are used and the equity with which they are distributed.

Macro-allocation has a number of features which distinguish it from the micro-allocation problems which we deal with later. Typically, the decisions are made at some distance from the clinical environment, by legislators, civil servants, insurers or health care managers. This gives the process an impersonal character: the decision-maker is rarely dealing with identifiable individuals or their advocates. The decisions bear on an entire class of individuals over a wide area and the constituency to whom the decision-maker is accountable is similarly wide – all taxpayers or policyholders rather than a specific cluster of patients. Finally, the decision-making is less urgent, less constrained by time and the immediate pressures of the life or death of specific people. Of course, macro- and micro-allocation cannot be wholly separated. The macro-decision provides the frame which constrains the micro, while micro-claims may be the rallying point for attempts to influence the macro- decision-makers (Note, Columbia Law Review, 1969. See also Kennedy, 1988; Frommer, 1987; Schwartz, 1985; Dossetor, 1988). Nevertheless, the distinction seems to be a useful one, not least because it reminds us that every organ transplant programme involves a decision not to use resources in some other way. Yadav (1990), for example, notes the hard choices facing Indian health policymakers. Can a transplant programme be justified if the basic health needs of the population are not being met?

The allocative efficiency of a particular pattern of welfare expenditure is an important issue for economic analysts. It involves a ranking of the returns from investments designed to enhance individual or collective well-being. A specific distribution of health care investment, for example, can only be considered efficient if the least valuable thing that is currently being done is still more valuable than the next most valuable thing that could be done with those same resources (Williams, 1978; Donaldson and Gerrard, 1993). While this may sound relatively straightforward in theory, there are many practical difficulties.

Are transplants cost-effective?

One of the most obvious difficulties is the way in which the returns to an individual or to society are measured. Economists find it easiest to reduce everything to a single type of measurement. They use money as the most general and abstract unit capable of summarizing the variety of specific social or psychological benefits, each of which may be measured in its own unique fashion. The conversion processes involved here are complicated and leave a good deal of room for argument about the way in which improvements in well-being can be identified, measured and valued. Nevertheless, the resulting ranking may help decision-makers to think about the relative value of different investments, calculated by the same crude processes, even if we should be cautious about treating them as statements of absolute value.

The most common ranking measure in the UK is the Quality Adjusted Life Year (QALY). This involves looking at the extension to the expectation of life that is likely to result from some procedure and weighting this by the average gain in quality of life that the procedure should confer. This figure can then be used as a denominator to assess the relative cost of achieving an increment of one QALY from different investment decisions. We have seen in chapter 1 how kidney transplants appear to be more effective at producing QALYs than other forms of renal replacement therapy. This would imply that it is more efficient for a decision-maker to invest in transplants than in dialysis and that, where possible, dialysis should be provided at home rather than in hospital. It must be remembered, though, that these are average results and they do assume that the groups of patients being compared are identical. In fact, patients selected for transplants tend to be younger and fitter with scope for greater improvements in the quality and quantity of life, as measured by the standard instruments used by economists.

This cost-effectiveness analysis would also need to be concerned with the cost/QALY ratio of transplants relative to all possible interventions directed at other conditions. In this ranking transplants may not appear particularly good investments. The State of Oregon, for instance, using a QALY-type methodology decided not to fund liver, heart or lung transplants for poor and elderly people seeking treatment under the Medicaid programme (Welch and Larson, 1988). However, a patient with private means or private insurance covering transplants would still be able to get this treatment. We shall look in more detail at the distributional effects of QALYs shortly.

If benefits are difficult to measure in a standard and consistent fashion, so too are costs. Buxton *et al.*'s (1985) study of the heart transplant programmes at Harefield and Papworth hospitals is a good example of the difficulty of deciding what should be included and how it should be charged. Many of the resources consumed in the programmes would have been there and used in an alternative fashion if the transplants had never been carried out. Should the costing embrace these or should it only cover the extra costs imposed by this new activity? Buxton and his colleagues also note the difficulty of deciding at what point in the evolution of a procedure costs should be measured. They note that the average cost of a transplant fell as the team gained experience so that, for instance, average lengths of in-patient stay declined considerably (cf Deitch, 1984). Conversely, staff seem to have been willing to absorb additional workload in their enthusiasm for innovation which would need to be costed into a permanent programme. A further point that might be mentioned is the discontinuous nature of some kinds of investment. Where there is a high start-up cost, as with CAT scanners, the average cost per patient falls rapidly as the volume of patients increases. Once the programme is fully loaded, though, the introduction of extra capacity can lead to a sharp increase in average costs, which then decline as the new resources are brought fully into use.

Assessing innovative treatments

Buxton *et al.*'s comments also point to the problem of assessing innovation (Dossetor, 1990). There is a certain conservatism to the cost-benefit approach to health care expenditure, when it comes to comparing existing treatments with new ones. This has been a more obvious problem in the USA where the costs have been more directly revealed for a long time and decision-makers have had to grapple explicitly with the issue of when a new procedure or treatment stops being resourced as research or experimentation and when it should pass into general use and be treated as a routine claim on private health insurance or state-funded schemes like Medicare and Medicaid (Mande, 1988; Gleeson, 1988; Anthony, 1988; Evans, 1985). One way to approach this might be to argue for separate welfare budgets for health care provision, which would be restricted to providing treatments of proven efficacy delivering benefits in excess of some cut-off point, and for health care innovation where funds might be allocated on some mixture of peer-reviewed scientific quality and national assessments of need. This would not solve the problem of choice within each budget or of deciding the size of each relative to the other but it would make the decision-making process more transparent and protect the place of innovation in the system.

This has, in effect, if not necessarily in intention, been the outcome of the policies of both the UK and US Federal Government in seeking to concentrate funding for transplants in recognized centres (Deitch, 1982, 1984; Simmons and Marine, 1984; Prottas, 1991). It has, however, been difficult to make this implicit policy stick. Prottas (1991) notes that the US Organ Procurement and Transplantation Network had lost its power to regulate entry by denying Medicare reimbursement to unapproved centres. Sir Terence English from the Royal College of Surgeons noted at a Department of Health seminar (1989) that three undesignated centres were doing heart transplants and one was doing livers. All fell outside the regulatory reach of the UKTSSA.

Does transplantation accord with notions of social justice?

The decision-maker, then, is presented with some difficult challenges in determining the efficiency of allocating health care resources to transplantation relative to other possible objects of investment. But these decisions also have considerable equity implications. Most welfare expenditure involves some sort of transfer from one group in the population to another. A socially efficient decision may confer advantages on one group which it may be difficult to justify in moral terms.

A sharp presentation of this issue can be found in Harris's (1987) attack on the QALY as a measure of the value of life. Because QALYs are based on units of time rather than on individuals, they will tend to favour the young at the expense of the old because, on average, the young have more potential life-years available to them. In theory, a treatment which saves a small number of young people a large aggregate number of life-years will always outweigh a treatment which saves a large number of old people a modest aggregate number of life-years. Harris also points out that a QALY-based approach can also discriminate on the basis of race and gender, where conditions restricted to members of a particular gender or ethnic group do not have QALY-efficient treatments available. People suffering from disabling conditions or injuries may find themselves in double jeopardy because their individual quality of life is assessed on a lower scale so that it may not merit treatment that would be QALY-efficient for an able-bodied person. Finally, Harris notes that a QALY-based approach tends to favour life-enhancing rather than life-saving treatments, a value-judgement which he regards as questionable.

Harris argues, against the economists' notion of allocative efficiency, that life-saving resources should be distributed on a basis of equality, which weights each individual's entitlements and needs at the same value as any other's. All lives are equally valuable and should attract the resources necessary to treat them. If the resources are insufficient, the problem must be turned back on national budgetary decision-making rather than assuming that it sets a finite limit for welfare investments. This claim lies at the heart of the difference between Harris and the economists, who start from the assumption that, in the short term, resources are scarce and that the problem for practical men and women is that of deciding how to get the most benefit from them. As Williams (1987) remarks, in his pithy reply to Harris, this is an irreconcilable difference. If you believe that resources are limited and should be used where they will do most good, then you have to accept that the fall-out may be discriminatory as between individual citizens.

This does not, of course, entail that they are denied civic status in other respects. It is on this point that the QALY can be considered as an improvement on some of the earlier attempts to measure benefit which concentrated on the patient's return to work and their wage-rate as an index (Evans, 1985, 1990b). Since both the chances of employment and the income earned are strongly affected by class, race and gender, these measures could be directly discriminatory. The QALY values a given level of suffering equally, whoever experiences it, and, as Williams stresses, its advocates would argue that treatments meeting the test of QALY-efficiency should be provided without further discrimination.

The implication of Harris's argument is that all needs for those replacement organs whose transplantation has progressed beyond the experimental stage, should be met without further question. A life-saving treatment is available which should not be denied to anyone who can benefit. If health care resources are inadequate to achieve this without cutting back on some other life-saving treatment, then other welfare expenditures must be cut or money diverted from private consumption through some form of taxation. While this may be an important political claim, it does not provide much assistance to the health service decision-maker who has to allocate a given budget, nor does it satisfactorily account for why we should treat life-saving as an overriding goal relative, let us say, to improving the quality of education or alleviating poverty at home or overseas or sustaining national defence forces capable of saving lives elsewhere through their contribution to international peace-keeping (Evans, 1990b).

As Englehardt (1984) observes, our lives are shaped by the tickets we draw at birth in two lotteries: one natural and one social. The natural lottery represents the biological endowments which influence whether or not we lead long and healthy lives and die peaceful deaths. The social lottery represents our social inheritance, the tracking which leads some to wealth and some to poverty. A winning ticket in one draw may, of course, improve the chances of winning in another. Wealth may compensate for a poor health endowment and vice versa. However, there are limits to which any state can intervene to insure individuals against the lot which is cast to them. Respect for individuals and their autonomy compels states to limit their interventions and to seek to draw a line between outcomes which are unfortunate and unfair and those which are merely unfortunate. It is only in the former category that state-sponsored compensation for misfortune becomes justifiable.

> *People, insofar as they have private property in that sense, have the secular moral right, no matter how unfeeling or uncharitable such actions may appear to others, not to aid those with excessive burdens...* (Engelhardt, 1984).

The unfortunate may be an object of private charitable impulse: they do not necessarily have an enforceable claim against other citizens.

> *To live with circumstances we must acknowledge as unfortunate but not unfair is the destiny of finite men and women who have neither the financial nor the moral resources of gods and goddesses.* (Engelhardt, 1984).

We live in a world of hard choices.

A further consideration which arises in this case is, of course, that to provide the resources for everybody who could benefit from a donated organ may represent an inefficient outcome if a matching supply of organs does not exist. In theory, this could mean doctors, nurses, theatres and beds standing idle when they could be providing treatment for some other condition. Harris might argue that the victims of that other condition would be receiving treatment anyway, but we come back again to the extent to which investing for unusable resources denies other possible uses of that investment, even if it is in the form of lower taxation and higher private consumption. As some critics of the cost-benefit approach have pointed out, there is no guarantee that a rational investment decision will result in perceptible resources being released for other uses or in a noticeable reduction in taxation (Centerwall, 1981). However, there is still an arguable moral case that those involved in the administration of compulsory measures of redistribution should strive to minimize the extent to which the gainers need to call upon the resources of the losers consistent with the achievement of the programme's objectives.

Allocating organs between populations

Harris's comments should, however, alert us to the need to understand the general nature of the flows inherent in organ transplantation. Organ donation is rather different from the classic case of blood donation discussed by Titmuss (1970) because it involves relatively small numbers of people, a highly differentiated product and little prospect of reciprocity. Even where a live donor is giving a kidney to a close relative, for example, there can be no element of exchange. Once I give you a kidney, because both of yours have failed, there is no way in which you can give me one back! Blood, however, goes into a large pool from which any of us may realistically expect to draw at some stage in our lives. Given the free availability of blood, relative to solid organs, it has not been thought necessary to develop explicit rationing rules. With the restricted supply of solid organs, however, most countries which perform transplants have developed some sort of national clearing house and allocation rules.

In general, cadaver organs are distributed partly on a basis of tissue compatibility and partly on a basis of geography. Details vary, but priority is normally given to potential recipients waiting at the harvesting centre, followed by those on the national waiting list, followed by those who can be contacted through international pooling schemes (UKTSSA, 1992; Schwartz, 1985; Prottas, 1991). The UK's scheme is described in detail in Box 9.

There are debates about the status of non-nationals who have come to a country for medical treatment and whether they should be included on a single waiting list or whether countries should run a two-tier list favouring their own nationals (Prottas, 1989; Kleinig, 1989). In order to encourage active harvesting of organs, allocation schemes usually contain some sort of sanction on centres which run up an 'overdraft' or offer incentives to those who make high deposits. In the UK, for example, a centre which has a positive balance of ten or more kidneys need not put additional, newly available organs into the national pool unless its Director so chooses.

If we establish that this approach, which accords precedence to biology, geography and, to some extent, nationality, leads particular social groups to experience a disproportionate ratio of donors to recipients, then this might lead us to review the equity of the system and to consider whether there should be some sort of compensation flowing in the other direction (cf Katz and Capron, 1975; Prottas, 1991).

9

THE UK'S DONOR ORGAN SHARING SCHEME

The following protocol was drawn up by the UKTSSA's Kidney Advisory Group at the end of 1991 (UKTSSA, 1992). The group's members come exclusively from the medical profession and, although the agreed protocol is published in a public document – the UKTSSA Annual Report 1991/92 – the deliberations of the group were not widely publicised, nor were the principles publicly debated. Not all centres participate in the scheme: those in the South East and South West Thames Regions (except St. Thomas' prior to September 1991) do not. In this sense it is voluntary, although those who join the scheme are bound by its rules. The following sets out the main operating principles.

- **All potential kidney donors will be notified prospectively to the UKTSSA with sufficient tissue-type information to determine whether there are beneficially matched recipients on the national waiting list. If so, the donor unit will offer one kidney unconditionally.**
- **Beneficially matched recipients which are on the donor unit's own waiting list will be given priority over beneficially matched recipients elsewhere.**
- **Where only one beneficially matched recipient is identified on a donor unit's waiting list, the second kidney will be made available nationally.**
- **Where a donor unit's balance of exported against imported kidneys is ten or more, offers to beneficially matched recipients on the national waiting list will be at the discretion of the donor unit's Director.**
- **A unit's 'balance of trade' will be the factor used to determine priority in the offering sequence where there are equally matched patients.**
- **UKTSSA may offer surplus kidneys for non-beneficially matched patients by request of the donating unit/region.**

The UKTSSA publishes some information on the characteristics of donors and recipients in the UK. Typically, transplants involve a flow from those under 40 to those aged between 40 and 55. There is evidence of an increasing use of organs from older donors, and a declining use of organs from 16-25 year olds which appears to be related to a decline in deaths from traumatic causes, mainly road traffic accidents (UKTSSA, 1992). No data have been published on the sex or ethnic background of donors and recipients. However, the UKTSSA has commented on the limited supply of organs from minority groups. Because tissue types are inherited, a good match is more likely to be found with an organ from the same ethnic group, although compatible donors and recipients will occur across ethnic groups. There is no evidence of the problem which has attracted some comment in the US (Ayres *et al.*, 1991; Prottas, 1991), where traumatic deaths among the young occur disproportionately in minority populations while end-stage renal disease in otherwise healthy recipients occurs mainly in the white population. It has been suggested that this imbalance should be remedied by loosening the tissue-matching requirements within minority groups, in order to allow them to take a more proportionate share of the available organs.

Within the UK, the only published figures on the regional 'balance of trade' relate to cadaveric kidneys. For the calendar year 1991 these suggest a flow towards London, which imported 63 kidneys from the rest of the country. If the other south-eastern centres, Cambridge, Oxford and Portsmouth, are included, the inward flow rises to 78 kidneys. Against this, the four Scottish centres exported 21 organs with another 8 coming from Cardiff and 19 from Belfast (UKTSSA, 1992). In the context of 1766 operations, these discrepancies are not large and would, in any event, need to be judged against the extent to which some of the London centres may recruit patients on a national basis. However, it should also be noted that there were no heart or liver transplant centres outside England so that the other nations of the United Kingdom are necessarily net exporters (Department of Health, 1989). Scotland established a heart and liver transplant centre just before the 1992 General Election.

If we are thinking rigorously about territorial justice, then we might argue that the normal place of residence or the main social ties of the donors should be more important factors than where they happen to die. If a sales representative born in Sunderland and living in Watford is killed in an accident on the M4 outside Cardiff, should her organs be considered as an input from the North East, the South East or Wales? Nevertheless, if this were established as a persistent pattern, even on a small scale, perhaps we might consider whether investment should be so directed as to allow the remainder of the UK to make greater use of the organs which it generates.

The macro-problem of organ transplantation is, then, primarily about the extent to which this group of patients should be considered to have a stronger claim to health care resources than others. Whether we seek to measure this in the currency of QALYs or in some other fashion or whether we wish to argue for the priority of expenditure on health relative to other worthwhile social expenditures, organ transplants have an opportunity cost. They represent one particular use of societal resources and their claims need to be appraised on that basis. To the extent that they are accepted, the issue then becomes one of the extent to which they can and should be met and the broad distribution of investments to yield a just result for different population, demographic or territorial groups. At this point, macro-problems start to intertwine with the micro-problem of allocation: which of the possible candidates gets the next available organ?

Micro-allocation

Moving on from the high-level questions about the allocation of national resources to transplantation programmes, we come to the micro-questions about which specific individual should receive an available organ. As we have seen, current UK policies favour inheritance and, to some extent, location. These, however, do no more than define broad groups of eligible recipients. It is still likely to be necessary to decide between recipients whose tissue-types are equally compatible and who live in the catchment of recognized transplant centres. Much of the literature about this choice is American, reflecting the particular challenge which the scarcity of organs implies for a medical culture, both popular and professional, which has tended to adopt a need-driven approach to health care, assuming that all resources necessary to the saving or prolongation of life should be provided to each individual. Although this assumption may seem difficult to reconcile with the abundant evidence of massive inequalities in health insurance coverage and access within the US, it has been a significant force in, for example, the development of the Medicaid programme covering the costs of dialysis to a rate of provision in the US three times that in the UK (Aaron and Schwartz, 1984).

It is also arguable that the more active US debate reflects a much greater sensitivity to the importance of the right of citizens to treatment which does not discriminate unjustifiably on the basis of age, race, gender or handicap. As Aaron and Schwartz note, much of the discrimination within UK medicine goes on in covert ways and there has been much less pressure for a critical examination of unconscious or inadequately theorized rationing principles. The costs of care may be contained by limiting access to renal dialysis or transplants among those over 55: the clinical grounds seem flimsy (Fehrman *et al.*, 1989; Howard *et al.*, 1989; Cardella *et al.*, 1989; Murie *et al.*, 1989) and the charge of ageism seems plausible in the absence of any explicit moral argument to the contrary.

Utilitarianism versus deontology

What moral arguments might be made for and against limiting transplants to certain groups in society? Traditionally, philosophers have divided these into two broad categories. Utilitarian arguments start from claims about the private or social benefit that will result from some particular action. We should do X rather than Y because it will be better for us as individuals or as a society. An example might be an assertion that we should give priority for organ transplants to young employed people whose death would result in a greater loss of productive life-years than if the same organ were given to an older retired person. Deontological arguments claim that we should prefer X to Y because it is morally right, even if not socially or economically efficient. For instance, we might argue that all lives are equally valuable as a matter of moral principle and that we should not take any actions or make any judgements which assume that one is less worthy than another. If a 30 year old and a 70 year old both need a transplant, they should have an equal opportunity to receive any available organ.

In practice, of course, most human judgements involve elements of both. Resources are not infinite so that utilitarian concerns are not negligible. At the same time, we are clearly unhappy with an approach that implies that we and our fellow-citizens should be considered only as productive units. We must also recognize, as a purely philosophical approach does not, that the persuasive force of a moral argument will depend upon the forms of reasoning which are accepted as legitimate in a given society. That evaluation is not independent of the distribution of political, economic and cultural power. In the Anglo-American world of the 1980s and 1990s, utilitarian arguments have gained an ascendancy which they have not enjoyed for many years. Nevertheless, there are still important deontological criticisms which can be made of their effects. The debate between Alan Williams and John Harris over the use of QALYs in macro-allocation, described earlier, is a good example of this clash of approaches.

What distributive principles can be identified in the debates about micro-allocation? In a useful summary, Dossetor (1988) lists nine which seem to be current – see Box 10. As we move down the list, the considerations of micro- and macro-allocation begin to merge. It should also be clear that the list jumbles utilitarian and deontological elements.

Need

As Dossetor notes, the first two factors in Box 10 are generally assigned the greatest weight, because they enable allocators to avoid the more controversial social choices implied by considering the worth, wealth or connections of patients. Medical need is essentially a deontological principle: the sickest should have the first claim on

10

PRINCIPLES OF MICRO-ALLOCATION

Dossetor lists nine principles or 'allocative factors' which could be referred to in deciding 'who gets the kidney?'. The final two, however, relate more to macro-allocation than to micro.

- **Need: this principle claims precedence for, in effect, the sickest patient;**
- **Outcome: this principle allocates organs so as to maximise the health benefit or improvement in health status, and is a utilitarian approach;**
- **Random selection: this principle suggests that who receives the organ should be decided by lottery;**
- **Queuing: this principle favours giving the organ to those who have been waiting the longest: 'first come first served';**
- **Ability to pay: this principle favours those with the most money, or those most willing to spend what they have;**
- **Social worth: this principle gives priority to those who provide the most value to society, or on whom most people in society depend, such as breadwinners in large families;**
- **'Squeaky wheel': organs are transplanted to those who lobby – 'shout the loudest' – most effectively;**
- **Programme politics: precedence is given to those who benefit the most, not for their own sake, but because of innovators' desire to make their enterprise look good during political funding decisions;**
- **Public policy: decisions are made with reference to the trade off between transplantation and other national goals.**

health care resources. However, it is vulnerable to utilitarian objections. The sickest patients are not necessarily the optimal candidates for transplants, since their debilitated conditions may compromise the prospects for a successful outcome. Is it right to prefer patient A whose condition gives them a 30 per cent chance of 6 months extra life at a heavy personal cost to the fitter patient B whose condition gives them a 60 per cent chance of 5 years extra life with a capacity for playing as full a role in society as they have ever done?

Even on its own terms, the priority claimed for medical need poses problems because of the way in which the recognition of need is bound up with access to health care, with the recognition of a transplant as an appropriate form of intervention, with the primary care physician's connection to relevant referral networks and with the quality of advocacy which the case attracts. The definition of need is a product of complex social processes of recognition, formulation and articulation (Smith, 1980). A system which is driven purely by expressed medical need will tend to discriminate against those groups with limited access to high-quality medical care and in favour of the very young and the old, whose health status is likely to be further compromised by a complex of comorbid conditions.

Outcome

A preference for outcome as an allocative principle is basically a utilitarian position. Organs should be allocated to those recipients who are likely to live longest. Even without entering the debate on QALYs and the question about whether the expected length of life should be weighted by the expected quality of life, we can see that this principle has consequences which raise deontological concerns. Post-operative survival in transplant patients is associated with their psychiatric status, their domestic circumstances, their economic situation and their compliance with long-term immunosuppressive therapy. It seems to be fairly routine for all of these matters to be taken into consideration by US transplant teams (for example, Copeland *et al.*, 1987; Caplan, 1987a, 1987b, 1989; Davis, 1987; Kilner ,1988; Starzl *et al.*, 1988; House and Thompson, 1988; Nieminen, 1990). These factors, however, are themselves associated with the broader social structures of a society.

This can be seen most clearly in the literature on compliance. A major cause of late rejection is thought to be a failure by patients to comply with the strict life-long requirements of immunosuppressive therapy (Didlake *et al.*, 1988; Rodriguez *et al.*, 1991). Non-compliant patients seem to be disproportionately black and Hispanic males, although the ethnic differences disappear once economic status is controlled (Rovelli *et al.*, 1989). The direct cost of medication was not a barrier in the last study, but the authors suggest that factors such as child care, housing, transportation and the loss of earnings from time off work to attend clinics need to be investigated. As Stimson (1974) pointed out some years ago, most compliance research operates on the assumption that non-compliance results from the defective rationality of the patients rather than seeking to understand the costs and troubles which compliance imposes on them. There has been little work since that might cause this judgement to be revised.

Health care professionals are poor predictors of non-compliance in individual cases (Meichenbaum and Turk, 1987), but an uncritical reliance on probability data to assess the odds of failure on a particular occasion can easily lead to a systematic bias in the aggregate decisions. The effects have certainly been sufficiently marked for the American Society of Transplant Physicians to direct its Patient Care and Education Committee to review the imbalance between the higher incidence of end-stage renal disease among the black population and their lower incidence of transplantation. The Committee's conclusions indicate that socioeconomic factors are as important as biological ones in explaining the low rate of renal transplantation in black populations, that these factors are likely to have an even bigger effect in the transplantation of solid organs and that there should be concern about the position of non-black minorities (Kasiske *et al.*, 1991). There is no evidence as to whether the same concerns should be felt in the UK, but the dominance of US research in the clinical literature is likely to have its effect on British decision-makers.

Another example to consider is the position of the mentally or physically handicapped. US law prohibits discrimination against the handicapped in any programme receiving Federal funds. This has generated some interest in the way patient selection criteria can set tests that the handicapped are differentially able to meet. Merrikin and Overcast (1985) set the discussion of allocation rules within the broad framework of anti-discrimination legislation in a way which may be helpful for policy discussion. In effect, the problem can be posed as that of distinguishing between direct discrimination – no patient in class X is eligible – and indirect discrimination – the test of eligibility is one which applies to all, but patients in class X are less able to meet it than are other classes. If the discrimination is indirect, does it result from a relevant clinical consideration which is so compelling that the failure of class X to qualify cannot but be condoned? Alternatively, does the discrimination result from factors which are either irrelevant or which are not so strong that they could not be balanced against the exclusionary effects?

Direct discrimination against the handicapped would clearly be unlawful. However, it would not be unlawful to discriminate against a specifically-defined group like severe insulin-dependent diabetics on the grounds that no member of that group could expect a positive outcome. Equally, it would not be unlawful to refuse access to transplantation to a handicapped person on a criterion which applied equally to the non-handicapped population. For instance, it might be argued that all patients with cardiac problems should be considered ineligible for liver transplants as poor surgical risks. A person with Down's Syndrome including cardiac anomalies would be excluded alongside an otherwise able-bodied person with angina.

However, the situation becomes more problematic when we turn to psychosocial criteria which the handicapped are less able to meet as consequence of other forms of discrimination. If preference is given to economically-active people with dependent relatives and a stable domestic environment, handicapped people may find themselves excluded, because their opportunities to satisfy these criteria are more limited, although their individual psychosocial functioning may be entirely consistent with the prospects of a successful outcome. Indeed, one might argue that a demonstrated capacity to handle the continuous self-management tasks faced by many physically-handicapped people is a particularly good indicator of their likelihood of being able to sustain long-term immunosuppressive therapy. Merrikin and Overcast argue that it is essential that programme providers distinguish clearly between these types of exclusion and that they should ensure that psychosocial exclusions rest on facts particular to the individual rather than on general rules which bear differently on different groups. Although these general rules may reflect outcome probabilities, they are of limited use in dealing with specific cases.

A final example, discrimination on the basis of age, may be particularly relevant to debate in the UK which is, at least among US authors, notorious for its reluctance to offer transplants to patients over the age of 55. This does not seem to be as a result of the organ exchange criteria, so much as of the decisions made by those responsible for admitting patients to the waiting list. There is a growing body of evidence that transplants can be performed with considerable success on patients well into their seventies who are otherwise in reasonable health (Medical News and Perspectives, JAMA, 1990; Fehrman *et al.*, 1989; Howard *et al.*, 1989; Cardella *et al.*, 1989; Murie *et al.*, 1989; Amrein *et al.*, 1990). Once again, this group seem likely to fall victim to apparently neutral tests. Their economic position and social integration may be compromised as a result of other forms of age discrimination but these do not necessarily influence outcome in the way that they would in younger patients. Perhaps the sternest challenge, however, is to the simple utilitarian analysis that would suggest withholding treatment on the grounds that there is a greater productive gain to be achieved by investing in younger members of the society. Against this, however, one might note the more equivocal evidence of the ability of the very young to benefit from unrelated donor transplants (Koffman *et al.*, 1989; McMahon , 1989). A deontologist would necessarily be unhappy with the notion that the old should be excluded from a life-extending and enhancing therapy solely on the grounds of age.

The fact that such issues can be raised is, of course, in some senses a tribute to the maturity of transplant surgery. In the early days of innovation, as Merrikin and Overcast concede, the medical team may be excused for making whatever arbitrary selections seem most likely to enhance the success of their programme. Once a procedure has become established, however, questions of access and social justice cannot be avoided. As we have seen claims that either need or outcome prospects can be separated from social judgements are unsustainable. The claim that a distributive system can rest solely on the technical logic of human biology is at best naive and at worst a deliberate refusal to engage with the utilitarian and deontological questions about the relative claims of different individuals under different environmental contingencies. Organ allocation in such circumstances becomes a way of uncritically perpetuating prior inequalities.

Random selection

A lottery is perhaps the one system that removes all element of judgement, once the right to enter has been established. However, it is clear that, in practice, the factors which generally influence access to medical care would influence the process by which cases were evaluated and entry tickets assigned. This is not a draw which anyone can enter for the anonymous cash purchase of a ticket. Need and benefit must be established, unless we are prepared to allow for the possibility that, say, those suffering from Munchausen's syndrome should be permitted to join the lottery, although they have no clinical need for the treatment. Conversely, self-certification of need would tend to discriminate against the less articulate and sickest patients.

Queuing

These sorts of problems would also afflict a queuing system. Jonasson (1989) points out that US waiting lists are also open to abuse: affluent and sophisticated patients may contrive to get onto lists at more than one centre and the point at which people get listed may vary between centres. This latter phenomenon is far from unknown in the NHS. Both a lottery and a queuing system are also open to the objection that the person who comes first may not be the most compatible recipient. As a result an organ may be wasted which might have saved someone assigned lower priority under these rules, although some US centres have developed scoring protocols which seek to balance clinical and temporal claims (Starzl *et al.*, 1987, 1988). Nevertheless, there may be something to be said for using one or other mechanism within a group of candidates who are reasonably homogeneous with respect to tissue type as a way of limiting the impact of simple normative judgements and we shall look more closely at the case for this when we consider the means by which decisions can be made.

Ability to pay

Relating access to transplants to the ability to pay has clear distributive implications. The first priority would go to the rich or to those in employments which offered generous health insurance cover. There is, however, a serious intellectual case for the development of a market which should not lightly be dismissed, although it does not seem to have received much attention in the literature (But see Andrews, 1986; Schwindt and Vining, 1986; Wight, 1991; Kevorkian, 1992). This should not be confused with the separate question of whether donors or their next of kin should be paid for giving up their organs, which was discussed earlier. The argument is essentially that used by Landes and Posner (1978) in their seminal article on adoption, 'The Market for Babies'. In brief, they argue that present Western adoption laws are inefficient, ineffective and confer an unacceptable degree of paternalism on social workers and courts. Couples who want to adopt babies face long waits while their lifestyles are minutely scrutinized by professionals who have no real knowledge of what makes for a successful placement in the long-term. Landes and Posner argue that auctioning babies would be a better test of the commitment of the adoptive parents, would provide stronger insurance against maltreatment, because of the investment that had been made, and would eliminate the abuses of professional paternalism. There would be no insidious moral judgements, merely the impersonal lottery of the market.

In the same way, one might argue that competitive bidding for organs would allow the value of the organ to the recipient and to society to be more clearly expressed and to eliminate the discretionary role of the medical profession or other allocators. The ability to bid would reflect the patient's own means, the extent to which next of kin or other interested parties were willing to contribute or the extent to which loan institutions regarded the candidate as a good risk. Although there might be large elements of moral judgement in the mind of the decision-makers, the outcome would reflect the aggregate of a number of decentralized choices by people with a direct personal knowledge and stake in the case rather than the specific preferences of a clique controlling the supply of the organs. The implied commitment involved might also be a better guarantor of long-term compliance than if the organ is treated as a free good.

This argument arouses strong passions and it should not be thought that we are advocating it here. Clearly, some of the claims that could be made are unsustainable: in a society where resources are differentially distributed between groups in the population on non-economic criteria, the outcome of market allocation of organs for transplant is likely to discriminate in ways which most people would find morally unacceptable. While it may be proposed that a society organized more fully on market principles would eliminate these other forms of discrimination as obstructions to the optimal use of labour and skills, the thinking here is essentially Utopian. In an imperfect society, the results of auctioning organs would necessarily be imperfect.

It is also arguable that there might be a knock-on effect on organ supply, if organs were being removed from rich and poor alike, but only going to the rich (Caplan, 1989). A number of studies have suggested, for example, that the low rates of organ donation among black and Hispanic groups in the US result from a perception that these groups do not benefit proportionately from transplant surgery (Dominguez *et al.*, 1991; Davidson and Devney, 1991; Creecy and Wright, 1990). Where there has been a deliberate effort to give organs to patients from these groups and to encourage the recipients to take part in programmes to encourage giving, donation rates have increased (Callender *et al.*, 1991). There is, then, a distinct possibility that the allocation of organs through the market would inevitably involve the introduction of some form of payment for donation, to ensure that the gains are shared between providers and donors or their estates, even if the converse is not necessarily true.

Lobbying

We have already noted the problems with relating transplant priority to ability to pay. The same considerations affect the influence of lobbying. Again, it is not difficult to imagine environments where organs were treated as a resource for patronage, much as voluntary hospital admission tickets used to be. However, this does not seem compatible with the notion of solid organs as a freely donated resource or the general distrust of patronage systems in the UK. We try to limit the extent to which public officials can confer private benefits other than through formal and accountable processes of decision-making and it seems unlikely that organ supply would be acceptable as an exception. Caplan (1989) discusses an example of a US government official pressurizing a transplant centre to make a kidney available for a relative of an important Middle Eastern figure. As he notes, this is a reasonable political trade-off with a clear utilitarian justification. However, its deontological merit is questionable. Should we allow those with connections to jump the queue for organs?

Social worth

Considered from the perspective of donors, we must recognize that lobbying again becomes bound up with notions of social worth. The young, the articulate, the good-looking and the compliant are always likely to make more attractive cases for media coverage or to engage the efforts of other advocates. Several US commentators discuss the case of Baby Jesse, turned down by a transplant centre because of their doubts about her parents' ability to comply long-term with therapy but whose parents built a media campaign presenting this as discrimination against non-married couples. The result was a prioritization of the case ahead of other babies whose parents were less assertive and sought to be more protective of the family's privacy (Caplan, 1987a). Similar concerns surround the case of Laura Davies, who died toward the end of 1993 after a series of multiple transplant operations. The large sums of money required for the operation to take place in the US were obtained in part due to the immense public popularity of the family, and to the parents' untiring willingness to promote their child's cause. The suspicion remains that the intense media interest in the case ensured that as soon as a suitable donor became available, Laura was first in the queue for the organs.

One might argue by analogy with willingness to pay that willingness to shout or lobby is a reasonable test of parental or recipient commitment. Against this, if it is unacceptable to buy organs because of the discrimination expressed in a pure market, it seems unlikely to be acceptable that organs should be allocated on the basis of influential connections or media tear-jerking.

What is to be done?

In the last analysis, it seems that we cannot entirely avoid some form of social judgement as the basis for the selection of recipients. As Held *et al.* (1988) have demonstrated very clearly for the USA, an ostensibly neutral set of criteria have produced a pattern of outcomes which favours whites over blacks, higher income groups over lower income groups, men over women and the young over the old. Comparable data have not been published for the UK, but this exercise would certainly be worth undertaking.

A better question to ask, then, might be about the procedures by which these judgements are made. Discriminatory outcomes may be acceptable, if the process which gives rise to them is seen as fair (Caplan, 1989; see also Tyler and Lind, 1988). Some American commentators (for example, Childress, 1987) have suggested that the reluctance to carry donor cards or to agree to requests for donation may reflect a lack of confidence in the decision-making process. This may apply both to the process of determining death and the availability of the organ for transplantation and to the process of determining who should actually receive the organ.

In fact, the literature is surprisingly opaque on the methods by which allocation decisions are made. The lack of documentation suggests that ethnographic research on the process could make a useful contribution to increasing public confidence. However, a close reading of the literature suggests that three main approaches can be identified: allocation by transplant surgeons, allocation by a 'God Committee', and allocation by protocol.

The first of these seems to be the most prevalent in the US and to be the dominant mode in the UK at the local level. There are minor variations: some sources imply that it is a team decision, where we might imagine discussion at a clinical meeting or rounds where candidate cases are reviewed by the doctors, or at least the senior ones, working on the unit; others suggest that the decision may be reserved to the clinical director or chief of the service. Whatever the specific form, the key point is that this is a professional decision made within the medical community (Lee, 1992). It might be argued that this is, at least in part, what professionals are for – to make difficult decisions in areas of moral uncertainty. Historically, professionals have enjoyed considerable discretion to make life and death choices in a fairly unexamined and essentially paternalist fashion.

While this is not necessarily wrong, it is a mode of decision-making whose legitimacy has become more contested in recent years. Throughout the developed world, we have heard increasing calls for greater social accountability and seen the proliferation of legal and ethical specialties concerned with the elaboration of justifications for particular decisions and of mechanisms for calling the decision-makers to account for the choices they have actually made. Transplant surgery cannot expect to be immune from this. Some centres have responded by broadening the interests in allocation decision-making to include other professions or lay representatives, the so-called 'God Committee' approach (Benjamin, 1988). These committees vary considerably in their composition and procedures but generically provide a means of involving a wider spectrum of interests in deciding who is to receive an available organ at an available centre. It must be stressed that the outcomes may not always be judged superior to those of medical paternalism: there are indications that consensus decision-making may tend to favour utilitarian criteria and to produce results which are even more closely tied to existing structures of inequality. However, in the absence of good data on the rhetorics used by participants, this can only be inferred from the pattern of outcomes, which may be generated by other variables.

One way to deal with this problem, which has already been mentioned, is the scorecard approach (Starzl *et al.*, 1989; Singer, 1990). The virtue of this is the advance specification of the criteria which are to be used and the relative weights to be afforded to different factors. These can be an object of debate without being tied to the emotive circumstances of particular cases. In the process, the point at which social criteria become relevant between candidate recipients of comparable clinical status and the choice of social characteristics to be examined can be clarified and set out for potential donors or consent-givers (cf Annas, 1985; Caplan, 1989; Robertson, 1989). It would be naive to suppose that this approach will eliminate all the difficulties: modern sociology has shown that rules and criteria always require elaboration to fit particular cases and that some element of discretion and interpretation is inescapable. However, a more public framework sets limits on this discretion and provides a background against which grossly unreasonable decisions can be identified and challenged. To the extent that a lack of public confidence in the system may be a limiting factor on the supply of organs, a more explicit discussion of the allocation process around a scoring system, which might be mandated by the UKTSSA or DoH regulations, could make a significant contribution to enhancing the willingness of some donors or next of kin to agree to the use of relevant organs. Before opening such a debate, though, it would be desirable to improve the information about the way in which this process works at present and to see whether a codification of existing practice might be a better foundation than *a priori* philosophical debate. It would certainly have more chance of operating successfully.

Concluding comments and recommendations

7

Organ transplantation provokes passionate debate. This is not surprising, since the technology depends on one of two highly unpalatable processes: death, or the surgical invasion of a perfectly healthy individual. Recommending how to improve the supply of organs in such an emotionally charged context is no easy task, as evidenced by the lack of unanimity amongst those debating the options.

The debate is mainly conducted within a relatively small community of interested parties: clinicians, interest groups, ethicists, lawyers and social scientists. But their lack of consensus is reflected in a somewhat ambivalent attitude to organ transplantation amongst the public at large. Although 70 per cent of people broadly support the notion of donating their organs after death, a smaller but still significant proportion are either unwilling or unsure. Anecdotal evidence suggests that this may be due to a fear that 'signing up' for organ donation will encourage the medical profession to pronounce death prematurely. In any event, transplantation technologies suffer from a double-edged sword: their high-profile image as life-saving techniques is also associated with death and dying. Clearly, proposals to improve the supply of organs cannot rely on an entirely confident and supportive general public.

Furthermore, for religious or personal reasons, many individuals simply oppose their own or a close relative's body being 'mutilated' after death. The perceived interference with a key rite of passage lies at the heart of the intense ethical disagreements over initiatives such as presumed consent legislation and elective ventilation. Recommendations must be made with caution in such circumstances.

The ethical debate surrounding live donation could hardly be more different. Because the procedure involves the healthy living rather than the recently dead, surgeons are often reluctant to operate on the donor and thereby offend the fundamental medical ethic, *primum non nocere.* There are also dangers of improper familial pressures to donate. However, failing to apprise relatives of the possibility of live donation, or even resisting it altogether, raises questions about the extent to which the medical profession can act in the interests of increasingly well-informed and assertive 'consumers' of health care.

Cultural values relating to death and live donation vary from country to country, thereby in part explaining why international comparisons of transplant activity reveal such wide variations. Laws, organisational practices and spending levels also differ between countries, but it is hardly surprising that a country such as Austria, with a two hundred year tradition of utilising the corpse for medical purposes, has found it easy to adopt presumed consent legislation. It is also likely that researchers have been overly eager to isolate 'successful' countries' experience and use it as evidence that their practices should be adopted. Cadaveric transplantation relies on mortality rates from specific causes which vary from one country to another. There is nothing the transplant community can do about the limit on organ donation set by the number of people who die in 'appropriate' ways.

Furthermore, medical and social advance is steadily reducing aggregate mortality rates from these causes. This, coupled with the growing number who are able to benefit and who therefore swell the world's waiting lists, makes it increasingly unlikely that the shortage of organs from human donors will be eliminated. Consequently, two final issues must be raised. First, there is a need to consider alternatives to human organs, and the debate must widen to include the appropriateness of using animals for 'spare parts' or expensive mechanical substitutes. Second, it is inevitable that all countries will continue to be faced with the problem of allocating available organs between individuals able to benefit from them. This undertaking is currently conducted by the medical profession, partly on the basis of non-explicit criteria. Such allocations must be made fairly, an outcome for which there are currently insufficient data to judge.

Recommendations

Reducing non-consent

There are three broad strategies for reducing non-consent: wider dissemination and carrying of the donor card, an opting-in registry to complement the donor card, and improved publicity of the need for organs. There is insufficient evidence to recommend increased reliance on any of these methods.

Increasing card-carrying will not necessarily translate into increased donation, since it is likely that new carriers will be those whose family would consent in any case (pp. 48-49). Opting-in registries have not demonstrated effectiveness in increasing donation. The Lifeline Wales scheme failed to provide a single donor who would otherwise have been 'missed' (p. 54). These findings cannot support the implementation of a national initiative such as that being considered by the Department of Health. Increased publicity does appear to have a limited effectiveness in reducing non-consent, although the effect is unpredictable and temporary, and its implementation costly (p. 49). The findings of this report do not support increased reliance on this method.

However, it should be noted that the donor card and intermittent publicity provide an invaluable public education role. The donor card, in particular, provides a focal point for national debate and a clear indication of individuals' wishes to their next of kin. They do not, however, provide a realistic means of permanently improving the supply of organs from the present level.

> ***Recommendation:*** *No <u>increased</u> reliance on the donor card or publicity as a means of improving supply; no implementation of national opting-in registries.*

Changing the law on consent

The most radical means of addressing the issue of non-consent is to remove the right of relatives to withhold consent in the absence of an explicit statement of the deceased's wishes. This would require the enactment of 'presumed consent' legislation. There is good evidence for the effectiveness of such legislation in other countries, notwithstanding the possibility of variable mortality rates and cultural differences confounding the picture (pp. 57-59). Furthermore, countries such as Belgium and Singapore have implemented carefully drafted legislation to avoid many of the ethical difficulties (p. 63).

Nevertheless, the medical profession, the transplant community and public opinion are split over the ethics of such a law, and so it would be inappropriate to recommend an immediate change in the law. If such a change provoked an acrimonious public debate it could damage the reputation of, and public confidence in, the transplant technology as a whole. The issue of changing the law should not be abandoned, but should continue to be debated until something closer to a consensus emerges. Meanwhile, other avenues such as those discussed below should be pursued.

Required request legislation has less to recommend it, offering little evidence that it will increase donation rates, as well as being ethically questionable due to its prescriptive nature (p. 63).

> ***Recommendation:*** *No change in the law relating to obtaining the consent of the next of kin at present, but contined debate around concerns relating to presumed consent legislation.*

Transplant Co-ordinators

The UK transplant co-ordinators have proven themselves to be an invaluable addition to the transplant procurement system. However, many of the ICUs in England do not have staff with any specific training in the transplant field, and this might cause difficulties for the introduction of radical policies into an environment not familiar with them. Elective ventilation and the use of the non-heart beating donor, for example, have been shown to be effective policies only under conditions involving experienced and motivated staff. If they are to succeed, intensive care, A&E and transplantation expertise need good integration.

The Spanish model of transplant co-ordinator organisation offers an example of such integration, with many ICU staff acting as part-time co-ordinators (pp. 50-52). The result is that every major donating hospital in Spain has at least one part-time member of staff with specific training in the latest techniques and needs of the transplant procurement system. Further investigation of this system is advised in order to ascertain its potential as a model for expansion of the system in the UK.

> ***Recommendation:*** *Further investigation of the Spanish system of transplant co-ordinators as a basis for UK development.*

Elective ventilation

The elective ventilation protocol developed by clinicians at the Royal Devon and Exeter Hospital offers the best prospect of a workable policy which initial results suggest would significantly improve cadaveric donation rates (pp. 55-56). However, uncertainties remain as to whether these findings can be generalised to the whole of the UK and whether the procedure would cause an increase in the number of patients in a persistent vegetative state (pp. 64-65). Research to resolve these issues (PIVOT, see p. 56) has been postponed because legal opinion has warned that the procedure is in all likelihood unlawful (pp. 63-64).

Two courses of action are recommended. First, the documentation phase of PIVOT should go ahead to establish beyond reasonable doubt that the procedure is effective. Second, assuming that the results from the first stage are positive, the legal position must be resolved so that the second randomisation stage can take place. This is the only means of establishing that the procedure will not result in increased numbers of persistent vegetative state patients and is therefore ethical. Specific provision in a Bill to be presented to Parliament on behalf of the Law Commission relating to mental incapacity and consent, would be one means of resolving the current impasse.

Whilst it is clear that elective ventilation must not be implemented whilst the legal position is in doubt, the analysis of this report finds the procedure ethically defensible as long as fears relating to the persistent vegetative patient are unfounded (pp. 64-66).

> ***Recommendation:*** *Positive consideration of elective ventilation subject to satisfactory research findings, resolution of the legal position and agreed protocols.*

Genetically-related live donation

Genetically-related live donation offers significant potential for improving the supply of kidneys (pp. 52-53). Expansion of this procedure is ethically defensible as long as certain safeguards are adhered to (pp. 66-68). Indeed, it could be argued that the current *ad hoc* and unsystematic process unfairly denies the opportunity for donation to some who may be unaware of the possibility. Furthermore, those genetically-related live donations which already occur are not subject to detailed guidance and may fail to satisfy ethical standards.

Clinicians will continue to be the key agents in the process, and Department of Health guidance is essential if the supply is to be improved whilst avoiding the ethical pitfalls. The guidance should include appropriate mechanisms for making relatives aware of the possibility of live donation, and ensure that safeguards are adopted to protect the potential donor from improper emotional pressure.

> ***Recommendation:*** *Increased use of genetically-related live donors if backed by new Department of Health guidance.*

Allocating organs

Notwithstanding these initiatives, it is unlikely that the supply of human organs will ever be sufficient to eliminate waiting lists entirely. Under these circumstances choices will continue to be made regarding who is to receive available organs. Currently, kidneys are allocated by a combination of a nationally agreed protocol based on medical outcome, and locally based implicit decision-making by clinicians. Such a state of affairs may, first, unjustly militate against certain social or ethnic groups and, second, result in decisions between potential recipients being made on inappropriate criteria.

Two initiatives are required to rectify these deficiencies. First, improved data on the socio-economic and demographic characteristics of organ donors and recipients are necessary to assess whether allocation based on medical outcome results in a socially unjust distribution. Second, there needs to be public debate about the criteria which should, and those which should not, be taken into consideration when choosing between individual recipients.

> ***Recommendation:*** *Routine recording of socio-economic variables of donors and recipients and open debate on recipient selection criteria.*

The future

The future of the transplant technology will continue to provide controversial issues. Although xenotransplantation promises the eventual elimination of waiting lists, the genetic engineering revolution enabling it will need open discussion if it is to retain the public's confidence. Furthermore, providing pig's organs may eventually be cheap, but transplantation for vastly increased numbers of patients will not be. Technological advance may shift the terms of the debate in the future: as the physical resource constraints disappear, financial ones will take their place. And, as elderly patients' organs fail in circumstances where replacements are always available, at what point will we consider that transplantation is merely delaying death rather than saving life, and who will decide that such a threshold has been crossed?

References

H.J. Aaron and W.B. Schwartz (1984), *The Painful Prescription: Rationing Hospital Care,* Brookings Institution, Washington DC.

Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death (1968), 'A Definition of Irreversible Coma', *Journal of the American Medical Association,* 205, 85-88.

R.K. Adams (1987), 'Live organ donors and informed consent: a difficult minuet', *The Journal of Legal Medicine,* 8(4), 555-586.

I. Ajzen and M. Fishbein (1980), *Understanding Attitudes and Predicting Behaviour,* Prentice-Hall, Englewood Cliffs, NJ.

C. Amrein *et al.* (1990), 'Is heart transplantation a valid therapy in elderly patients?', *Transplantation Proceedings,* 22, 1454-1456.

I. Andrews and V. McIntosh (1992), *Patient's Charter Standard: Respect for religious and cultural beliefs,* Mount Vernon Hospital, London.

L.B. Andrews (1986), 'My Body, My Property', *Hastings Center Report,* October, 28-37.

G.J. Annas (1985), 'The Prostitute, the Playboy and the Poet: Rationing schemes for organ transplantation', *American Journal of Public Health,* 75, 187-189.

C.R. Anthony (1988), 'Federal financing of transplantation', *Transplantation Proceedings,* 20, 1047-1050.

W.J. Armitage, S.J. Moss, D.L. Easty and B.A Bradley (1990), 'Supply of corneal tissue in the United Kingdom', *British Journal of Ophthalmology,* 74, 685-687.

I. Ayres, L.G. Dooley, and R. Gaston (1991), 'Unequal Racial Access to Kidney Transplantation', *American Bar Foundation Working Papers,* No. 9111, American Bar Foundation, Chicago.

A. Ballantyne (1992), 'Donor pigs to be bred for human organ swaps', *Sunday Times,* 5 July, p. 9.

M. Benjamin (1988), 'Medical ethics and economics of transplantation', *Health Progress,* March, 47-52.

D. Bihari (1993), personal communication.

V. Bonomini (1991), 'Ethical aspects of living donation', *Transplantation Proceedings,* 23(5), 2497-2499.

M.A. Bos (1991), *The Diffusion of Heart and Liver Transplantation Across Europe,* King's Fund Centre, London.

M. Brazier (1992), *Medicine, Patients and the Law,* Penguin, London.

J.H. Brunvand (1983), *The Vanishing Hitchhiker: Urban legends and their meanings,* Picador, London.

R.P. Bulka (1990), 'Jewish perspective on organ transplantation', *Transplantation Proceedings,* 22(3), 945-946.

M. Buxton, R. Acheson, N. Caine *et al.* (1985), *Costs and benefits of the heart transplant programmes at Harefield and Papworth hospitals,* DHSS Research Report no. 12, HMSO, London.

C.O. Callender *et al.* (1991), 'Organ donation and blacks: a critical frontier', *New England Journal of Medicine,* 325(6), 442-444.

A.L. Caplan (1984), 'Ethical and policy issues in the procurement of cadaver organs for transplantation', *New England Journal of Medicine,* 311(15), 981-983.

A.L. Caplan (1987a), 'Equity in the selection of recipients for cardiac transplants', *Circulation,* 75, 10-19.

A.L. Caplan (1987b), 'Organ transplantation rationing: a window to the future', *Health Progress,* 68, 40-45.

A.L. Caplan (1988), 'Professional arrogance and public misunderstanding', *Hastings Center Report,* 18(2), 34-37.

A.L. Caplan (1989), 'Problems in the policies and criteria used to allocate organs for transplantation in the United States', *Transplantation Proceedings,* 21, 3381-3387.

A.L. Caplan (1992), 'Is xenografting morally wrong?', *Transplantation Proceedings,* 24, 722-727.

A.L. Caplan (1993), 'Must I be my brother's keeper? Ethical issues in the use of living donors as sources of liver and other solid organs', *Transplantation Proceedings,* 25, 1997-2000.

C.J. Cardella, M.E. Harding, G. Abraham *et al.* (1989), 'Renal transplantation in older patients on peritoneal dialysis' *Transplantation Proceedings,* 21, 2022-2023.

B.S. Centerwall (1981), 'Cost benefit analysis and heart transplantation', *New England Journal of Medicine,* 304, 901-903.

J.F. Childress (1987), 'Some moral connections between organ procurement and organ distribution', *Journal of Contemporary Health, Law and Policy,* 3, 85-110.

B. Cohen and G. Persijn (eds.) (1992), *Eurotransplant Foundation Annual Report 1991,* Eurotransplant Foundation, Leiden, Netherlands.

D. Collard (1978), *Altruism and Economy,* Martin Robertson, Oxford.

C.H. Collins (1992), 'Elective ventilation for organ donation – the case in favour', *Care of the Critically Ill,* 8, 57-59.

Conference of European Health Ministers (1987a), *First Report: Ethical and socio-cultural problems raised by organ transplantation,* Council of Europe, Strasbourg.

Conference of European Health Ministers (1987b), *Current legislation in council of Europe member states and Finland and results of European co-operation,* Council of Europe, Strasbourg.

Conference of European Health Ministers (1987c), *Third Report: Legislative measures in relation to organ transplantation and to European co-operation,* Council of Europe, Strasbourg.

Conference of the Medical Royal Colleges and Faculties of the UK (1976), 'Statement issued by the honarary secretary of the Conference of Medical Royal Colleges and Faculties of the UK on 11 October 1976', *British Medical Journal,* ii, 1187-88.

Conference of the Medical Royal Colleges and Faculties of the UK (1979), 'Memorandum on the diagnosis of death', *British Medical Journal,* i, p. 332.

J.G. Copeland, R.W. Emery, M.M. Levinson *et al.* (1987), 'Selection of patients for cardiac transplantation', *Circulation,* 75, 2-9.

R.F. Creecy, and R. Wright (1990), 'Correlates of willingness to consider organ donation among blacks', *Social Science and Medicine,* 31, 1229-1232.

Criminal Law Revision Committee (1980), *Fourteenth Report: Offences Against the Person,* Cmnd. 7844, HMSO, London.

A. Crombie (1993), personal communication.

M.N. Davidson and P. Devney (1991), 'Attitudinal barriers to organ donation among black Americans', *Transplantation Proceedings,* 23, 2531-2532.

A. Davis (1988), 'The status of anencephalic babies: should their bodies be used as donor banks?', *Journal of Medical Ethics,* 14(3), 150-153.

F.D. Davis (1987), 'Co-ordination of cardiac transplantation: patient processing and donor organ procurement', *Circulation,* 75, 29-39.

R. Deitch (1982), 'Government support for heart transplantation', *Lancet,* ii, p. 942.

R. Deitch (1984), 'The Government's present line on cardiac transplantation', *Lancet,* i, 407-408.

Department of Health (1989), *Improving the Voluntary Donation of Organs: a seminar organised by the Department of Health, 16 November 1989,* Department of Health, London.

R.H. Didlake, K. Dreyfus, R.H. Kerman, C.T. Van Buren, and B.D. Kahan, (1988), 'Patient noncompliance: a major cause of late graft failure in cyclosporin-treated renal transplants', *Transplantation Proceedings,* 20, 63-69.

J.M. Dominguez *et al.* (1991), 'Knowledge and attitude about organ donation in a Hispanic population', *Transplantation Proceedings,* 23, 1804-1806.

C. Donaldson, and K. Gerrard (1993), *The Economics of Health Care Financing,* Macmillan, London.

P.K. Donnelly, D.G. Clayton, A.R. Simpson (1989), 'Transplants from living donors in the United Kingdom and Ireland: a centre survey', *British Medical Journal,* 298, 490-493.

P.K. Donnelly, A.R. Simpson, D.G. Clayton (1991), 'Living Donor Kidney Transplantation in the UK and Ireland: does donor-recipient age difference matter?', in W. Land and JB. Dossetor (eds.) *Organ Replacement Therapy: ethics, justice and commerce,* Springer-Verlag, Berlin.

J.B. Dossetor (1988), 'Ethical issues in organ allocation', *Transplantation Proceedings,* 20, 1053-1057.

J.B. Dossetor (1990), 'Discussion', *Transplantation Proceedings,* 22(3), 933-938.

A. Drugan, W.J. Evans and M.I. Evans (1989), 'Fetal organ and xenograft transplantation', *American Journal of Obstetrics and Gynecology,* 160, 289-293.

J. Dukeminier, Jr. (1969), 'Supplying organs for transplantation', *Michigan Law Review,* 68, 811-866.

G. Dworkin (1970), 'The law relating to organ transplantation in England', *Modern Law Review,* 33, 353-378.

A.L. Edwards (1957), *The social desirability variable in personality research,* Dryden, New York.

H.T. Englehardt (1984), 'Shattuck Lecture – Allocating Scarce Medical Resources and the Availability of Organ Transplantation', *New England Journal of Medicine,* 311, 66-71.

Ethics and Social Impact Committee Transplant Policy Center Ann Arbor (1988), 'Anencephalic infants as sources of transplantable organs', *Hastings Center Report,* October/November, 28-30.

European Dialysis and Transplant Association (EDTA) (1992), *Report on Management of Renal Failure in Europe, XXII, 1991,* Oxford University Press.

D.W. Evans and L.C. Lum (1980), 'Cardiac transplantation', *The Lancet,* ii, p. 934.

M. Evans (1989), 'Organ donation should not be restricted to relatives', *Journal of Medical Ethics,* 15, 17-20.

M. Evans (1990), 'Death in Denmark', *Journal of Medical Ethics,* 16, 191-194.

R.W. Evans (1985), 'The socioeconomics of organ transplantation', *Transplantation Proceedings,* 17, 129-136.

R.W. Evans (1989), 'Money matters: should ability to pay ever be a consideration in gaining access to transplantation?', *Transplantation Proceedings,* 21, 3419-3423.

R.W. Evans (1990a), 'Organ donation: facts and figures', *Dialysis and Transplantation,* 19(5), 234-240.

R.W. Evans (1990b), 'The private sector vis-a-vis government in future funding of organ transplantation', *Transplantation Proceedings,* 22, 975-79.

R.W. Evans and D.L. Manninen (1988), 'US public opinion concerning the procurement and distribution of donor organs', *Transplant Proceedings,* 20(5), 781-785.

T.G. Feest, H.N. Riad, C.H. Collins, M.G.S. Golby, A.J. Nicholls and S.N. Hamad (1990), 'Protocol for increasing organ donation after cerebrovascular deaths in a district general hospital', *The Lancet,* 335, 1133-1135.

I. Fehrman, C. Brattstrom, F. Duraj and C.G. Groth (1989), 'Kidney transplantation in patients between 65 and 75 years of age', *Transplantation Proceedings,* 21, 2018-2019.

P.L. Frommer (1988), 'High tech for the few or low tech for the many?', *Proceedings of the Second International Congress on Ethics in Medicine, 1987,* Beth Israel Medical Center, New York.

H. Gabel (1991), 'Organ Procurement in Scandinavia 1990', in L.U. Lamm and F. Pedersen (eds.) *Scandiatransplant 1990,* Aarhus, Denmark.

S. Gleeson (1988), 'Organ transplant coverage and reimbursement', *Transplantation Proceedings,* 20, 1044-1046.

S.M. Gore, C.J. Hinds and A.J. Rutherford (1989), 'Organ donation from intensive care units in England', *British Medical Journal,* 299, 1193-1197.

S.M. Gore, R.M. Ross Taylor and J. Wallwork (1991), 'Availability of transplantable organs from brain stem dead donors in intensive care units', *British Medical Journal,* 302, 149-153.

S.M. Gore (1992), 'Intensive care unit funding: survey of staffing and bed occupancy in November 1989', *Care of the Critically Ill,* 8, 79-80.

S.M. Gore, W.J. Armitage, J.D. Briggs *et al.* (1992a), 'Consensus on general medical contraindications to organ donation?', *British Medical Journal,* 305, 406-409.

S.M. Gore, D.J. Cable and A.J. Holland (1992b), 'Organ donation from intensive care units in England and Wales: two year confidential audit of deaths in intensive care', *British Medical Journal,* 304, 349-355.

J. Harris (1987), 'QALYfying the value of life', *Journal of Medical Ethics,* 13, 117-123.

P.J. Held, M.V. Pauly, R.R. Bovbjerg, J. Newmann and O. Salvaterria Jr. (1988), 'Access to kidney transplantation: has the United States eliminated income and racial differences?', *Archives of Internal Medicine,* 148, 2594-2600.

R. Hoffenberg (1987), *Report of the Working Party on the Supply of Donor Organs for Transplantation,* DHSS, London.

J. Hors, P. Kormann, M. Busson, S. Kocon and E. Vaille (1992), 'France-Transplant', in R. Matesanz *et al.* (eds.), *Transplant,* vol. 4, Council of Europe, Paris.

R.M. House, and T. Thompson (1988), 'Psychiatric aspects of organ transplantation', *Journal of the American Medical Association,* 260, 535-539.

R.J. Howard, W.W. Pfaff, D. Salomon, J. Peterson, J.C. Scornik, E. Frederickson and R.S. Fennel (1989), 'Kidney transplantation in older patients', *Transplantation Proceedings,* 21, 2020-2021.

J.K. Iglehart (1993), 'The American health care system: the End Stage Renal Disease Program', *The New England Journal of Medicine,* 328(5), 366-371.

A. Jakobsen (1990), 'A second opinion: In defence of the living donor transplant', *Health Policy,* 16, 123-126.

A. Jakobsen (1993), personal communication.

A. Jakobsen, D. Albrechtsen, P. Fauchald, T. Leivestad, G. Sodal, A. Flatmark (1991), 'Allowing relatives to bridge the gap: the Norwegian experience', in W. Land, J.B. Dossetor (eds.) *Organ replacement therapy: ethics justice and commerce,* Springer-Verlag, Berlin.

A. James (1993), 'Transplants with transgenic pig organs?', *The Lancet,* 342, p. 45.

B. Jennett (1977), 'Diagnosis of brain death', *Journal of Medical Ethics,* 3, 4-5.

B. Jennett (1991), 'Heart and liver transplantation in the United Kingdom', in M. Bos, *The Diffusion of Heart and Liver Transplantation Across Europe,* King's Fund Centre, London.

O. Jonasson (1989), 'Waiting in line: should selected patients ever be moved up?' *Transplantation Proceedings,* 21, 3390-3394.

B.L. Kasiske, J.F. Neylan , R.R. Riggio, G.M. Danovitch, L. Kahana, S.R. Alexander and M.G. White (1991), 'The effect of race on access and outcome in transplantation', *New England Journal of Medicine,* 324, 302-307.

J.M. Katz and A.M. Capron (1975), *Catastrophic Diseases: Who Decides What?,* Russell Sage, New York.

I.M. Kennedy (1973), 'The legal definition of death', *Medico-Legal Journal,* 41, 36-41.

I.M. Kennedy (1988), *Treat me Right: Essays in Law and Medical Ethics,* Clarendon Press, Oxford.

J. Kevorkian (1992), 'A controlled auction market is a practical solution to the shortage of transplantable organs', *Medicine and Law,* 11, 47-55.

J.F. Kilner (1988), 'Selecting patients when resources are limited: a study of US Medical Directors of kidney dialysis and transplantation facilities', *American Journal of Public Health,* 78, 144-147.

D.S. Kittur, M.M. Hogan, V.K. Thukral, L.J. McGaw and J.W. Alexander (1991), 'Incentives for organ donation?', *The Lancet,* 338, 1441-1443.

J. Kleinig (1989), 'Organ transplants: the just and human expectations of nonresidents', *Transplantation Proceedings,* 21, 3430-3431.

C.G. Koffman *et al.* (1989), 'Renal transplantation in children less than five years ofage', *Transplantation Proceedings,* 21(1), 2001-2002.

W. Kokkedee (1992), 'Kidney procurement policies in the Eurotransplant region: 'opting in' versus 'opting out'', *Social Science and Medicine,* 35(2), 177-182.

G. Kootstra, R. Wijnen, J.P. van Hooff and C.J. van der Linden (1991), 'Twenty per cent more kidneys through a non-heart beating program', *Transplantation Proceedings,* 23, 910-911.

T. Kushner and R. Belliotti (1985), 'Baby Fae: a beastly business', *Journal of Medical Ethics,* 11, 178-183.

D. Lamb (1990), *Organ Transplants and Ethics,* Routledge, London.

D. Lamb (1991), 'Death in Denmark: a reply', *Journal of Medical Ethics,* 17, 100-101.

E.M. Landes, and R.A. Posner (1978), 'The economics of the baby shortage', *Journal of Legal Studies,* 7, 323-347.

D. Lanham (1971), 'Transplants and the Human Tissue Act 1961', *Medical Science and Law,* 11, p. 16ff.

Law Commission (1976), *Report on Conspiracy and Criminal Law Reform,* HC Papers 1975/76, no. 176, p. 140, para 6.1.

Law Commission (1993), *Mentally Incapacitated Adults and Decision-Making: Medical Treatment and Research,* Consultation Paper No. 129, HMSO, London.

S.E.G. Lea, R.M. Tarpy and P. Webley (1987), *The Individual in the Economy: a survey of economic psychology,* Cambridge University Press, Cambridge.

R. Lee (1992), 'Doctors as allocators: the bald facts', in S. Wheeler and S. McVeigh (eds.), *Law, Health and Medical Regulation,* Dartmouth, Aldershot.

A. Lewis and M. Snell (1986), 'Increasing kidney transplantation in Britain: the importance of donor cards, public opinion and medical practice', *Social Science and Medicine,* 22(10), 1075-1080.

S.M.L. Lim, P. Soh, K.T. Wooh and A. Rauff (1990), 'Organ donation in Singapore', *Transplantation Proceedings,* 22, 2179-2180.

B.C. McGillivray (1988), 'Anencephaly – the potential for survival', *Transplantation Proceedings,* 20(4), Supp.5, 9-11.

B.C. McGillivray (1988), 'Discussion', *Transplantation Proceedings,* 20(4), Supp.5, 12-16.

Y. McMahon (1989), 'Is kidney transplantation in the very small child worth it?', *Transplantation Proceedings,* 21, 2003-2005.

N.P. Mallick (1993), *Report of an Independent Review of Specialist Services in London: Renal,* HMSO, London.

J.R. Mande (1988), 'Who pays for organ transplantation?', *Transplantation Proceedings,* 20, 1041-1043.

D.L. Manninen and R.W. Evans (1985), 'Public attitudes and behaviour regarding organ donation', *Journal of the American Medical Association,* 253(21), 3111-3115.

S. Martyn, R. Wright and L. Clark (1988), 'Required request for organ donation: moral, legal and clinical problems', *Hastings Center Report,* 18(2), 27-34.

J. Mason, M. Drummond and G. Torrance (1993), 'Some guidelines on the use of cost-effectiveness league tables', *British Medical Journal,* 306, 570-572.

J.K. Mason (1983), 'Coroners from across the border', *Medical Science and Law,* 23(4), p. 271.

J.K. Mason (1992), 'Organ donation and transplantation' in C. Dyer (ed.), *Doctors, Patients and the Law,* Blackwell, London.

R. Matesanz (1991), 'Organizacion Nacional de Trasplantes', in J. Hors *et al.* (eds.), *Transplant,* vol. 3, Council of Europe, Paris.

R. Matesanz and B. Miranda (1992), 'Organizacion Nacional de Trasplantes', in R Matesanz *et al.* (eds.), *Transplant,* vol. 4, Council of Europe, Paris.

R. Matesanz, J. Hors, G. Persijn, C. Thayer and J.M. Dupuy (eds.) (1992), *Transplant,* vol. 4, Council of Europe, Paris.

P. Matthews (1983), 'Whose body? People as property', *Current Legal Problems,* 36, 193-239.

C. Meek (1992), 'Organ crisis', *BMA News Review,* November, 16-17.

Medical News and Perspectives (1990), 'Successful liver transplantation in older patients raises new hopes, challenges, ethical questions', *Journal of the American Medical Association,* 264(4), 428-31.

D. Meichenbaum and D.C. Turk (1987), *Facilitating Treatment Adherence,* Plenum, New York.

K.J. Merrikin and T.D. Overcast (1985), 'Patient selection for heart transplantation: when is a discriminating choice discrimination?', *Journal of Health Policy, Politics and Law,* 10, 7-32.

D.W. Meyers (1991), *The Human Body and the Law,* 2nd Edition, Edinburgh University Press, Edinburgh.

P. Michielsen (1991), 'Medical risk and benefit in renal donors: the use of living donation reconsidered', in W. Land, J.B. Dossetor (eds.) *Organ Replacement Therapy: ethics, justice and commerce,* Springer-Verlag, Berlin.

P. Michielsen (1992a), 'Organ shortage – what to do?', *Transplantation Proceedings,* 24, 2391-2392.

P. Michielsen (1992b), 'The introduction of an opting-out law in Belgium doubled organ retrieval', in G. Sirchia *et al.,* (eds.) *Proceedings of the Second International meeting on Organisational Aspects of Transplantation,* Ospedale Maggiore Policlinico di Milano, Milan.

G. Mooney and A. McGuire (1988), *Medical ethics and economics in health care,* Oxford University Press.

F.D. Moore (1988), 'Three ethical revolutions: ancient assumptions remodeled under pressure of transplantation', *Transplantation Proceedings,* 20(1), supp. 1, 1061-1067.

M.F. Mozes *et al.* (1991), 'Impediments to successful organ procurement in the 'required request' era: an urban center experience', *Transplantation Proceedings,* 23(5), p. 2545.

J.A. Murie, G. Lauffer, D. Gray, A. Ting and P.J. Morris, (1989), 'Renal transplantation in the older patient', *Transplantation Proceedings,* 21, 2024-2025.

J.S. Najarian (1992), 'Overview of in vivo xenotransplantation studies: prospects for the future', *Transplantation Proceedings,* 24, 733-738.

E. Namihira (1990), 'Shinto concept concerning the dead human body', *Transplantation Proceedings,* 22(3), 940-941.

A. Nicholls and H. Riad (1993), 'Organ donation (letter)', *British Medical Journal,* 306, 517-518.

M.S. Nieminen (1990), 'Evaluation and selection of the heart transplant patient', *Transplantation Proceedings,* 22, 186-187.

K.Mck. Norrie (1985), 'Human tissue transplants: legal liability in different jurisdictions', *International and Comparative Law Quarterly,* 34, 442-469.

Note (1969), 'Scarce medical resources', *Columbia Law Review,* 69, 620-92.

J. Nudeshima (1991), 'Obstacles to brain death and organ transplantation in Japan', *The Lancet,* 338, 1063-1064.

C. Pallis (1987), 'Brain stem death – the evolution of a concept', *Medico-Legal Journal,* 55, Part 2, 84-107.

P. Pallot (1993), 'Organs may be preserved without permission', *Daily Telegraph,* 21 June, p. 4.

G.R. Park, K.E Gunning, M.J. Lindop and P.G. Roe (1993), 'Organ donation (letter)', *British Medical Journal,* 306, p.145.

C.T. Patel (1988), 'Live renal donation: a viewpoint', *Transplantation Proceedings,* 20(1), supp. 1, 1068-1070.

T. Patel (1993), 'France's troubled transplant trade', *New Scientist,* 3 July, 12-13.

C. Pizzi *et al.* (1990), 'Organ donation in the North Italy Transplant Program', *Transplantation Proceedings,* 22(2), 333-334.

J.M. Prottas (1989), 'Nonresident aliens and access to organ transplant', *Transplantation Proceedings,* 21, 3426-3429.

J.M. Prottas (1991), 'Human tissues as medical treatment', *Southern California Law Review,* 65, 445-460.

J.M. Prottas and H.L. Batten (1991), 'The willingness to give: the public and the supply of transplantable organs', *Journal of Health Politics, Policy and Law,* 16(1) (Spring), 121-134.

F.T. Rapaport (1991), 'Progress in organ procurement; the non heart-beating cadaver donor and other issues in transplantation', *Transplantation Proceedings,* 23, 2699-2701.

R. Redmond-Cooper (1984), 'Transplants opting out or in – the implications', *New Law Journal,* 134, p. 648.

H.N. Riad and R.A. Banks (1990), 'Recording patients' views on organ donation: when to ask them and how to record the answer', *British Medical Journal,* 301, p. 155.

H.N. Riad (1993), personal communication.

J.A. Robertson (1989), 'Patient selection for organ transplantation: age, incarceration, family support and other social factors', *Transplantation Proceedings,* 21, 3397-3402.

A. Rodriguez, M. Diaz, A. Colon and E.A. Santiago-Delon (1991), 'Psychosocial profile of noncompliant transplant patients', *Transplantation Proceedings,* 23, 1807-1809.

L. Roels *et al.* (1991), 'Three years of experience with a 'presumed consent' legislation in Belgium: its impact on multi-organ donation in comparison with other European countries', *Transplantation Proceedings,* 23(1), 903-904.

L. Roels and P. Michielsen (1991), 'Altruism, self-determination, and organ procurement efficiency: the European experience', *Transplantation Proceedings,* 23(5), 2514-2515.

F. Rosner *et al.* (1988), 'The anencephalic fetus and newborn as organ donors', *New York State Journal of Medicine,* 88(7), 360-366.

S.E. Ross, J. Nathan and K.F. O'Malley (1990), 'Impact of a required request law on vital organ procurement', *Journal of Trauma,* 30(7), 820-824.

G. Routh (1992), 'Elective ventilation for organ donation – the case against', *Care of the Critically Ill,* 8, 60-61.

M. Rovelli, D. Palmeri, E. Vossler, S. Bartus, D. Hull, and R. Schweizer (1989), 'Noncompliance in renal transplant recipients: evaluation by socioeconomic groups', *Transplantation Proceedings* , 21, 3979-3981.

A.A. Sachedina (1988), 'Islamic views on organ transplantation', *Transplantation Proceedings,* 20(1), supp. 1, 1084-1088 .

A.F. Sahin (1990), 'Islamic transplantation ethics', *Transplantation Proceedings,* 22(3), 939.

J.R. Salaman, P.J.A. Griffin, W. Ross and J. Haines (1994), 'Lifeline Wales: experience with a computerised kidney donor registry', *British Medical Journal,* 308, 30-31.

M.A. Salih, I. Harvey, S. Frankel, D.J. Coupe, M. Webb and H.A. Cripps (1991), 'Potential availability of cadaver organs for transplantation', *British Medical Journal,* 302, 1053-1055.

E.A. Santiago-Delpin (1991), 'Organ donation and transplantation in Latin America', *Transplantation Proceedings,* 23(5), 2516-2518.

H.S. Schwartz (1985), 'Bioethical and legal considerations in increasing the supply of transplantable organs: from UAGA to Baby Fae', *American Journal of Law and Medicine,* 10(4), 397-437.

R. Schwindt and A.R. Vining, (1986), 'Proposal for a Future Delivery Market for Transplant Organs', *Journal of Health Politics, Policy and Law,* 11, 483-500.

S. Scorsone (1990), 'Christianity and the significance of the human body', *Transplantation Proceedings,* 22(3), 943-944.

D.A. Shewmon *et al.* (1989), 'The use of anencephalic infants as organ sources', *Journal of the American Medical Association,* 261(12), 1773-1781.

Rabbi Nisson E. Shulman (1993), personal communication.

R.G. Simmons, and S.K. Marine (1984), 'The regulation of high cost technology medicine: the case of dialysis and transplantation in the United Kingdom', *Journal of Health and Social Behavior*, 25, 320-334.

P.A. Singer (1990), 'A Review of Public Policies to Procure and Distribute Kidneys for Transplantation', *Archives of Internal Medicine*, 150, 532-537.

G. Sirchia, M. Scalamogna, L. Mascaretti, F. Poli, C. Pizzi and G. Bossi (1989), 'The North Italy Transplant Program's organization and activity: problems and proposals for the 1990s', *Tissue Antigens*, 34, 78-83.

P.D.G. Skegg (1976), 'The case for a statutory "definition of death"', *Journal of Medical Ethics*, 2, 190-192.

P.D.G. Skegg (1984), *Law, Ethics and Medicine*, Clarendon Press, Oxford.

G. Smith (1980), *Social Need*, Routledge and Kegan Paul, London.

G.B. Smith, G.L. Masters and C. Moss (1992), 'Organ donation from intensive care units', *British Medical Journal*, 304, p. 916.

P. Soh, S.M.L. Lim, E.C. Tan (1991), 'Organ Procurement in Singapore', *Annals of the Academy of Medicine*, Singapore, 20, 439-442.

A. Sommerville (1993), *Medical Ethics Today: Its Practice and Philosophy*, BMA, London.

T.E. Starzl (1985), 'Will live organ donations no longer be justified?', *Hastings Center Report*, 15, p.5.

T.E. Starzl, T. Hakala, A. Tzakis *et al.* (1987), 'A multi-factorial approach for equitable selection of cadaver kidney recipients', *Journal of the American Medical Association*, 257, 3073-3075.

T.E. Starzl, R.D. Gordon, A. Tzakis, S. Staschak, V. Fioravanti, B. Broznick, L. Makowka, and H.T. Bahnson (1988), 'Equitable allocation of extrarenal organs: with special reference to the liver', *Transplantation Proceedings*, 20, 131-138.

T.E. Starzl, R. Shapiro and L. Teperman (1989), 'The point system for organ distribution', *Transplantation Proceedings*, 21, 3432-3436.

G.V. Stimson (1974), 'Obeying Doctor's Orders: A View from the Other Side', *Social Science and Medicine*, 8, 97-104.

J.C. Stoddart (1993), *National ITU Audit 1992/1993*, The Royal College of Anaesthetists, London.

B. Teo (1991), 'Organs for transplantation: the Singapore experience', *Hastings Center Report*, November-December, 10-13.

R.M. Titmuss (1970), *The Gift Relationship: From Human Blood to Social Policy*, Allen and Unwin, London.

H.L. Trivedi (1990), 'Hindu religious view in context of transplantation of organs from cadavers', *Transplantation Proceedings*, 22(3), 942.

R.D. Truog and J.C. Fletcher (1989), 'Anencephalic newborns: can organs be transplanted before death?', *New England Journal of Medicine*, 321(6), 388-391.

T.R. Tyler and E.A. Lind (1988), *The Social Psychology of Procedural Justice*, Plenum Press, New York.

United Kingdom Transplant Support Service Authority (UKTSSA) (1992), *Annual Report 1991/1992*, UKTSSA, Bristol.

UKTSSA (1993a), *Annual Report 1992/93*, UKTSSA, Bristol.

UKTSSA (1993b), 'Organ donation: Department of Health publicity launch', *User's Bulletin*, No. 7 (Spring), p. 5.

UKTSSA (1993c), 'General Medical Council Guidance for Doctors on Transplantation of Organs from Live Donors', *User's Bulletin*, No. 7 (Spring), p. 8.

UKTSSA (1994), 'Transplant Statistics: 1 January – 31 December 1993', *User's Bulletin*, No. 10 (Winter), p. 3.

Unrelated Live Transplant Regulatory Authority (ULTRA) (1992), *Annual Report 1990/91*, ULTRA, London.

R.M. Veatch (1987), *Death, Dying and the Biological Revolution*, Yale University Press.

D. Wainwright, D.W. Evans and L.C. Lum (1986), 'The ethics of cardiac transplantation', *British Journal of Hospital Medicine*, July, 68-69.

R.E. Wakeford and R. Stepney (1989), 'Obstacles to organ donation', *British Journal of Surgery*, 76(5), 435-439.

J.W. Walters (1989), 'Anencephalic infants as organ sources: should the law be changed? Yes', *Journal of Pediatrics*, 115(5), Part 1, 825-828.

J.W. Walters and S. Ashwal (1988), 'Organ prolongation in anencephalic infants: ethical and medical issues', *Hastings Center Report*, October/November, 19-23.

D.W. Weiss (1988), 'Organ transplantation, medical ethics and Jewish law', *Transplantation Proceedings*, 20(1), Supp. 1, 1071-1075.

H.G. Welch and E.B. Larson (1988), 'Dealing with limited resources: the Oregon decision to curtail funding for organ transplantation', *New England Journal of Medicine*, 319, 171-173.

R. West (1991), *Organ Transplantation*, Office of Health Economics, London.

D. White (1993), personal communication

C. Wight (1989), 'Role of the transplant co-ordinator and multiple organ donation in the UK', *Transplantation Proceedings*, 21, 1398-1399.

C. Wight (1993), personal communication.

J.P. Wight (1991), 'Ethics, commerce and kidneys', *British Medical Journal*, 303, p. 110.

A. Williams (1978), 'Efficiency and welfare', in D. Black and G.P. Thomas (eds), *Providing for the Health Services*, Croom Helm, London.

A. Williams (1987), 'Response: QALYfying the value of life', *Journal of Medical Ethics*, 13, p. 123.

G.R. Winslow (1989), 'Anencephalic infants as organ sources: should the law be changed? No', *Journal of Pediatrics*, 115(5), Part 1, 829-832.

Working Party on behalf of the Health Departments of Great Britain and Northern Ireland (1983), *Cadaveric organs for Transplantation: a code of practice including the diagnosis of brain death*, DHSS, London.

Working Party on Organ Transplantation from Neonates (1988), *Report of a Working Party on Organ Transplantation in Neonates*, Conference of Medical Royal Colleges and their Faculties in the UK.

R.V.S. Yadav (1990), 'Transplantation as a health priority in India', *Transplantation Proceedings*, 22, p. 909.

Other recent King's Fund Institute publications include:

Seamless Care or Patchwork Quilt? Discharging patients from acute hospital care, Research Report 17, Linda Marks, 1994, £12.00.

Reshaping Mental Health Services: Implications for Britain of US experience, Research Report 16, Judy Turner-Crowson, 1993, £12.00.

Primary Health Care in London: Quantifying the challenge, Seán Boyle and Chris Smaje, 1993, London Initiative Working Paper 13, £12.00.

Too Many Cooks? The response of the health-related services to major incidents in London, Research Report No 15, Bill New, 1992, £9.95.

Through a Glass Darkly: Community care and elderly people, Research Report No 14, Melanie Henwood, 1992, £8.95.

Flexibility or Fragmentation? Trends and prospects in nurses' pay, Briefing Paper No 13, James Buchan, 1992, £8.95.

Ethics and Health Care: The role of research ethics committees in the United Kingdom, Research Report No 13, Julia Neuberger, 1992, £7.95.

A Foothold for Fundholding, Research Report No 12, Howard Glennerster, Manos Matsaganis and Pat Owens, 1992, £8.95.

Evaluating the NHS Reforms, Edited by Ray Robinson and Julian Le Grand, 1994, £9.95.

Health Care UK: An annual review of health care policy, edited by Anthony Harrison (published annually since 1984: back copies available).

Copies of this and other reports are available either:

Over the counter:
King's Fund Centre Bookshop
126 Albert Street
London NW1 7NF

By post:
Bournemouth English Book Centre
(BEBC)
PO Box 1496
Poole
Dorset BH12 3YD

By telephone:
Telephone 0202 715555
Fax 0202 715556

Cheques should be payable to BEBC Ltd.
All publications are delivered post-free.

3572 020000 04857

KING'S FUND INSTITUTE

The King's Fund Institute is an independent centre for health policy analysis. Its principal objective is to provide balanced and incisive analyses of important and persistent health policy issues and to promote informed public debate about them.

Assessing the performance of health care systems is one of the Institute's central concerns. The Institute is also concerned with health policy questions which go wider than health services proper. These centre on the scope of public health policy and on social and economic determinants of health.

The Institute is independent of all sectional interests. Although non-partisan it is not neutral and it is prepared to launch and support controversial proposals.

The Institute publishes a range of documents which include occasional papers, briefing papers and research reports. A publications list is available.

ISBN 1 870607 35 X
£15.00