



Organ shortage: current status and strategies for improvement of organ donation A European consensus document – 1996.

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GLOSSARY

The following definitions will be used throughout this document:

Transplantation - The procedure, comprising a series of technical steps which need to be followed in a defined order, that enables the organs (or tissues) obtained from dead people (donors) to be transplanted into an appropriate live donor. It starts with the identification of all potential donors and ends with the transplantation (or storage) of the organs (and/or tissues) retrieved.

Brain Death - Complete and irreversible cessation of all cerebral and brain stem functions which, from the scientific, ethical and legal point of view is accepted as equivalent to the death of the individual. Strict testing according to agreed protocols is required to establish brain death beyond doubt.

Potential Donor - Any person diagnosed as brain dead, by means of clinical examination, following the elimination of any medical contraindications to donation, i.e. conditions representing a potential risk for recipients.

Effective Donor - A potential donor from whom at least one solid organ (or tissue) has been retrieved for transplantation.

(Potential and/or effective donor rates can be expressed either by reference to the catchment population (donors per million population - pmp) or by reference to hospital parameters (e.g. donors as a percentage of overall hospital mortality; of intensive care mortality or as a rate per hundred hospital beds, etc.)).

Retrieval - removal of an organ or tissue intended for transplantation whether subsequently transplanted or not.

Key Donation Person: A person responsible for organ donation in a specific area or hospital. He/She may or may not be the transplant co-ordinator.

Organ Sharing Office (OSO)*: Bureau responsible for the collection and management of data from donors and recipients and allocation of organs according to agreed criteria.

Organ Exchange Organisation (OEO)*: Organisation responsible for the organ +/- tissue allocation in a specific region/country.

Organ Procurement Organisation (OPO) *: A body or organisation responsible for organ donation and procurement in a specific region/country.

*In some countries one organisation may perform more than one or all of the above functions within a region or country.

1. SUMMARY

1.1 Organ transplantation is the best available established technique for the treatment of end stage failure of most essential organs (liver, heart and lungs). Corneal transplantation is similarly well established and tissue transplantation, particularly of bone but also of skin, tendons, etc., is growing very rapidly. Over 1 million people world-wide have benefited from successful organ transplantation. A number of transplant patients have survived well over 25 years and five years survival rates for most organ transplant programmes are around 70%. With modern techniques of organ preservation and advances in immuno-suppression, a significant proportion of patients can now expect to achieve long-term survival with a high quality of life.

1.2 Many more people could benefit from organ transplantation than receive transplants at present. There are currently nearly 40,000 patients waiting for a kidney in Western Europe. Mortality rates for patients waiting for a heart, liver or lung range between 15 and 30%, i.e. 400 plus die waiting for an organ each year. These figures do not represent the true position. Because of the chronic shortage of organs, some transplant clinicians are extremely selective about the patients they put on the waiting list. Currently only those patients most likely to benefit will be even considered for transplantation.

1.3 The critical factor is the supply of organs for transplantation. Only good quality organs are likely to function satisfactorily and there are strict limits on the time that can be taken to retrieve and transplant the organ. In practice this means that, for most organs, only relatively young donors are suitable who are admitted into intensive care units and subsequently declared brain dead so that organs can be retrieved while the donors heart is still beating. A typical donor has suffered either a road traffic accident or a severe cerebrovascular accident. Due to improvements in road safety in European countries, donors in the former group are in decline. Kidneys are somewhat less sensitive to ischaemia (shortage of oxygen).

1.4 In view of the potential for successful transplantation, it is considered essential that countries with an organ transplant service, take all possible measures to ensure that all potential donors are identified and as many as possible converted into effective donors.

1.5 The organ donation/transplantation process is necessarily complex. There is a number of important steps each of which needs to be recognised and an effective system put in place to manage that every part of the process if potential donor organs are not to be lost. The steps are:

i. **Donor identification** – all potential donors should be identified at as early a stage as possible. This will facilitate donor screening and donor management (see below).

ii. **Donor screening** – donors should not be used if there is a risk of transmission of serious disease (cancer, infection) to the recipient. Guidance has been prepared by the Council of Europe and some member states on the serological and other screening methods that should be used to minimise the risk of transmission of infectious or malignant diseases to the recipient. Whenever possible, screening should include a social history taken from the relatives to exclude recent high risk behaviour, which might indicate a risk of a transmissible disease which is at too earlier stage to be detected by serological screening.

iii. **Donor management** - it is essential that organs procured are in good condition prior to retrieval. The management of the potential donors physiological state while on intensive care and of the donor prior to and during retrieval can make a major difference to the condition of the organs. Poor donor management can make organs unusable.

iv. **Consent/authorisation** - appropriate consent or authorisation has to be obtained before organs can be removed. Countries have different legal requirements, in some consent is presumed while in others specific consent has to be sought from either relatives or some body. Whatever the system, it is advisable to discuss donation with any relatives as part of the screening process. There is evidence that the approach to the relatives can affect their willingness to agree to donation. Staff seeking to obtain the agreement of relatives should be appropriately trained.

v. **Organ retrieval** - the surgical technique for removing organs from the body and the way those organs are subsequently handled and preserved prior to and during transportation are critical to the successful outcome of the transplant. Each year a number of organs are damaged during removal and/or transportation. Some can be repaired but a few will have to be discarded.

vi. **Organ allocation** - for some organs, particularly kidneys, the successful long-term outcome of the transplant depends partly on appropriate matching between donor and recipient. A well-organised system for allocating and transporting donated organs to the most appropriate recipient is important. In some cases, optimum allocation will require exchange of organs or tissues between transplant organisations and countries. Co-operation between countries is increasingly important.

1.6 The purpose of this document is to provide a step-by-step guide to the most effective ways of procuring the maximum number of high quality organs for transplantation from cadaveric donors based on an analysis of the scientific data available and relevant international experience. Recommendations are made on the most effective ways of procuring organs from such donors and for monitoring the procurement process. In making the recommendations, local and national requirements and the legal, ethical and cultural frameworks within which individual countries have to operate have been taken into account.

1.7 If at each stage of the process and level of organisation, certain key objectives can be met, countries can maximise the rate of organ transplantation.

2. SUMMARY OF RECOMMENDATIONS

2.1 Organ procurement

i. The transplant process is long and complex and cannot be left to chance. Protocols should be developed for each step. A key person should be made responsible in each area/hospital for managing and monitoring the process with the power to determine where efforts and resources should be directed.

ii. Published figures cannot be extrapolated to provide local rates of potential versus effective donors (although marked differences from published rates for potential donors should be considered as suggestive of under detection). A donor detection gap should be established for each hospital/area and systems for monitoring the rates established.

iii. A means should be developed to evaluate the size and characteristics of the potential donor pool to measure and monitor potential donor detection rates. To ensure reliability, data should be collected prospectively and analysed retrospectively as recommended in the "Donor Action Programme".

iv. Proactive donor detection programmes should be instituted in every acute hospital using specially trained professionals (key donation persons) working to agreed protocols and ethical rules.

v. A "key donation person", independent from transplant teams, should be appointed in every acute hospital with a clearly defined role and responsibility for establishing, managing and auditing systems for donor identification and identifying potential areas for improvement.

vi. Protocols should be developed setting out the criteria for screening potential donors and their organs for the risk of disease transmission and potential viability. All appropriate steps should be taken to avoid the transmission of infectious and neoplastic diseases and primary organ failure.

vii. The incidence of irreversible cardiac arrest, sepsis and other contraindications to organ donation relating to donor management of potential donors should be monitored and audited to detect and correct any problems identified. Involvement of Intensive Care Unit staff in research and/or educational programmes on donor management should help raise standards.

viii. An appropriate legal framework for donation and transplantation is required which adequately defines brain death; the type of consent or authorisation required for retrieval (see below); the means of organ retrieval, which ensures traceability but maintains confidentiality and which bans organ trafficking.

ix. Law professionals should be fully aware of the transplant process and the co-operation of those most closely involved, i.e. judges and coroners, should be sought to reduce legal refusals to a minimum.

x. It is advisable to ascertain the opinion of the public and health professionals about presumed or informed consent for organ donation before considering legal changes that might be potentially detrimental. The key donation person appointed in each centre/area must be aware of all local legal criteria and should be responsible for meeting these requirements. There should be a system for the safe custody of all certificates and test results required by the law.

xi. Because both positive and negative messages can affect the public's willingness to donate organs, there is a need for a professional attitude towards, and support from experts in the field of, communications. They should help to minimise the impact of "bad news" on, and to maximise the communication of "good news" about transplantation to, health professionals, the media and the public. Special attention should be paid to both the content of the message and the best means of dealing with the most controversial topics. The preparation of specific briefing materials should be considered.

xii. The most cost effective means of increasing the public's willingness to donate seems to be improving the knowledge of health professionals (not directly involved in transplantation) and the media about transplantation issues. Continuing education should

form an essential element of any communication strategy. A transplant hot line manned by appropriately trained professionals should be considered.

xiii. People should be encouraged to speak about organ donation and transplantation and to communicate their wishes to their relatives. As a donor's wishes will not always be known, staff in a position to make requests for agreement to organ donation to relatives should be properly trained for the purpose. If such requests are well handled the rate of donation refusals can be reduced.

xiv. Organ retrieval procedures should be well planned to minimise delay and disruption to donor hospital. Retrieval teams should be lead by experienced surgeons trained, where appropriate, in multi organ retrieval. Organ damage during retrieval should be reported and monitored and further training provided as necessary to minimise damage during retrieval or transportation.

xv. An organ sharing/allocation organisation is essential but its roles and responsibilities must be clearly defined, particularly if it is to have a role in organ donation and procurement (see below).

xvi. Attention should be paid to ensuring that hospitals are properly resourced and, if necessary, reimbursed for maximising organ procurement.

xvii. In order to optimise organ donation there is need for a supra hospital transplant organisation, appropriate in size and structure to the local situation with specific responsibilities for the whole process of organ procurement.

xviii. The most effective organisational approach is one which balances the requirements for effective organ procurement (small, local) with those for organ allocation (large, national/multinational) (see below). The aim should be to optimise organ procurement whilst ensuring the most clinically effective allocation of organs and tissues.

xix. Health Administrations are responsible for ensuring that there is proper organisational support for organ donation and distribution and should guarantee the fairness, transparency and safety of the whole system.

2.2 International co-operation

xx. International co-operation on the promotion of organ donation is desirable to help maximise organ donation and equalise access to transplantation between countries. Governments should actively promote such co-operation.

xxi. Priority should be given to international co-operation which improves standards of training, exchange of experience, and which helps guarantee the safety of organs and the ethical standards by which they are retrieved and transplanted.

3. INTRODUCTION

After four decades of experience, progress in transplantation medicine and surgery has been impressive. Advances in technique and the development of new immunosuppressive drugs have made it possible to transplant successfully several major organs, i.e. kidney, heart, heart/lung, lung and liver, into an increasingly large number of patients. Transplants of the pancreas and small bowel are also being performed. Over 1 million people world-wide have received an organ transplant and some have already survived more than 25 years. Five-year

survival rates for most organs are now at least 70%. Transplantation of parts of organs or tissues including corneas, heart valves, bone, tendons, etc. are also well established and in some cases like bone, demand is growing very rapidly.

However, a severe shortage of cadaveric organ donors remains a major obstacle preventing the full development of transplant services and imposes a severe limit to the number of patients who benefit from this form of therapy. Although organ transplants save thousands of lives and transform the quality of life of thousands more, many people will die or remain on renal replacement therapy because the organ supply falls drastically short of demand. Nearly 40,000 patients are at the moment waiting for a kidney in Western Europe whilst the number of cadaveric donors remains stable at around 5,000 each year.⁽¹⁾ This is also the case in USA where the gap between the number of available organs and patients on the waiting list is also very high. They have more than 30,000 patients on the waiting list and the number of cadaveric donors is around 5,000 each year.⁽²⁾ Mortality rates while waiting for a heart, liver or lung transplant generally range between 15% and 30% but are even higher in some reports depending on the type of the organ needed.^(1,2) In 1994 there were no suitable livers for some 400 European citizens and around a further 400 died while waiting for a heart.⁽¹⁾

These figures do not reveal the true levels of unmet need for such organs. The potential need for the different organs is much higher.⁽³⁾ The shortage of organs means that only the patients most likely to benefit are put on the waiting list for an organ transplant. To put patients on a waiting list who have no hope of receiving an organ is both pointless and highly questionable ethically.⁽⁴⁾

The increasing demand for organs with no increase in the supply poses problems for many countries, particularly countries in which regulation of live donation is non-existent or poorly regulated, as the risk of organ trafficking increases. In some countries outside Europe, adults have voluntarily sold one of their kidneys in exchange for money or some other kind of compensation. There have been rumours of kidnapping and coercion to force the donation of a kidney although these are fortunately mostly unfounded. Organ trafficking not only poses major ethical problems, but also makes it more difficult to guarantee the quality and safety of the organ. Organ donation, properly regulated, allows the safety and quality of the organs to be properly assessed. For this reason there is now a strong international consensus that, until or unless some alternative such as xenotransplantation becomes available, the only acceptable course of action is to make every effort to maximise the procurement of cadaveric organs for transplantation. Member states of the Council of Europe and the European Union and their respective transplant organisations have taken steps to eliminate the possibility of coercion or organ trafficking. Specifically, Article 21 of the Convention on Human Rights and Biomedicine states "the human body and its parts shall not, as such, give rise to financial gain".

Transplantation comprises the processes of organ donation and subsequent implantation or grafting. The two parts are totally interdependent. However, historically, the techniques of organ implantation have received far more attention from the scientific community in terms of both research effort and resources than organ and tissue procurement. Until very recently, only 2-3% of papers submitted to International transplant meetings were devoted to organ donation, procurement and preservation. Most transplant professionals now recognise the

severity of the organ shortage and the need to address the problems posed. Editorials in specialist journals have recently addressed the problem,^(5,6) but there are still few research papers in this field.

Increasingly, national health departments, international working groups and meetings of experts are seeking to develop a closer co-operation between health professionals and administrations. Private companies and foundations are also now dedicating financial resources to support the development of educational or research programmes relating to organ procurement. The programmes of all international transplant meetings now include sessions devoted to organ procurement. However, organ procurement is not just a matter for transplant teams. The whole medical community needs to be aware of the problem and become involved either indirectly or directly in the process of organ procurement. Indirectly health care professionals can educate others about the problem, allay fears and encourage a positive attitude to donation. Directly, all health care staff can help identify potential donors and ensure that such patients are recognised and assessed. As in any other medical activity, the overall success of transplantation is ultimately the responsibility of all health care professionals.

This document provides an analysis of the steps necessary to achieve an effective process for organ procurement taking into account the available scientific evidence and describing relevant international experience. The document focuses on the technical and organisational aspects of cadaveric organ donation.

It should however be remembered that the deceased's wishes and the sentiments of his/her family have to be treated with respect. The communication established with the deceased's family and the consideration given to their wishes are essential elements in the process of procurement itself.

Recommendations are made wherever opportunities exist for improving the process.

This document does not discuss living donation.

It does not discuss organ retrieval from non-heart beating donors (NHBDs) either, since such techniques are not currently universally accepted due to additional ethical, legal, technical and organisational problems.

4. ORGAN PROCUREMENT

4.1 The Transplantation Process

4.1.1 Overview

Transplantation is a complex process involving a number of discrete but interconnected steps. Before considering the practicalities of the process, it is important to recognise the context within which it takes place. The use of substances derived from one human being for the treatment of others imposes unique ethical questions for society, particularly when, in the case of organs and most tissues, those substances are not renewable. Society now demands this type of treatment and itself benefits from the results. As Arthur Caplan testified before the US congress in 1990 *"What is truly distinctive about transplantation is not technology or cost, but ethics. Transplantation is the only area in all of health care, which cannot exist without the participation of the public. It is the individual citizen who while alive,*

or in the case of vital organs, after death, who makes organs and tissues available for transplantation. If there were no gift of organs or tissues, transplantation would come to a grinding halt."⁽⁷⁾ Essentially, any acceptable organ transplant service depends totally on altruistic organ donation by either living or cadaveric donors. However, the Convention on Human Rights and Biomedicine states that "Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and when there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic methods of comparable effectiveness." When considering aspects of the transplant process, these important societal principles have to be taken into account.

Health professionals are essential to transplantation, as transplants are medical procedures. Such factors as economic benefit, institutional or individuals reputations, surgical ego, municipal pride or chauvinism, however, should never be the *raison d'être* for a transplant programme ⁽⁸⁾. The overriding aim of any transplant programme should be to minimise the donor organ and tissue shortage by optimising the levels of altruistic donation of organs and tissue and ensuring their allocation to the most clinically appropriate recipient. The system should be based on strict adherence to widely accepted ethical rules.⁽⁹⁾ Any practice contravening such principles is to be deprecated.

4.1.2 The six steps

The donation/transplant process should start with the identification (donor identification) of all individuals with brain death being ventilated in intensive care units (ICUs). Such potential donors should be carefully assessed to exclude contraindications to donation (donor screening) pending the necessary clinical and legal procedures required to establish and certify brain death. During this phase, the haemodynamic stability of the potential donor must be maintained (donor management) to preserve the viability of the organs. The legal or social requirements for authorising the removal of organs or tissues have to be met. The relatives will have to be approached and interviewed either to obtain formal consent or to obtain a social history about the potential donor. Adequate support for the family from trained staff at this time is essential. The existence of the donor has to be notified to a transplant co-ordinator or appropriate transplant organisation to ensure that an appropriately trained person takes charge of the process of organ removal. Arrangements, both within and outside the hospital, for (multiple) organ retrieval (and/or tissue) must also be made. Organ retrieval, preparation, preservation and packaging preparatory to transportation are a difficult process, which requires significant expertise if organs are not to be damaged and rendered unusable. The organs retrieved should be allocated (organ allocation) according to previously agreed criteria preferably by an organisation, which holds a common waiting list and can co-ordinate the distribution and transport of organs. Organs will normally be transplanted within a few hours of retrieval, although kidneys can be stored for up to 24 hours. Many tissues may be stored for much longer periods but may require further processing.

The whole process can take many hours and involve a large number of staff with very different skills and from many backgrounds. Such a process cannot be left to chance. Protocols or operating procedures are needed for each step and the staff involved needs to be properly trained and adequately experienced in their respective roles. Even in the best centres with the most complete infrastructure, difficulties sometimes arise and there is a risk that either the donor or the organs will be lost. It is important to have a means of auditing the procedures to identify problems and modify procedures accordingly, if the continued effectiveness of the process is to be ensured. Ideally, one key (donor) person should be appointed in each area/hospital with the specific role of managing and monitoring the transplant process.

Recommendation: The transplant process is long and complex and cannot be left to chance. Protocols should be developed for each step and a key person should be made responsible in each area/hospital for managing and monitoring the process with the authority to determine where efforts and resources should be directed.

4.2 Donor Detection: Potential and Identification

4.2.1 Scope of the problem

Detecting potential donors is the starting point of transplantation and is possibly the most difficult to subject to standard protocols. The only way to be sure that donors are not missed is to have a means of identifying and monitoring the potential and effective donor pools within relevant hospitals or areas. To do so requires collecting information about the total number of people certified as brain dead and the reasons, including relatives refusal, why some did not become donors. Reasons other than strict medical contraindications need to be examined including non-admission to an ICU. This in turn depends on the physicians in charge of patients identifying potential donors. The question remains how to monitor rates of potential and effective donation in such a way as to identify hospitals or areas where rates are low because of poor organisation or reluctance on the part of health care staff or relatives.

There are a number of possible indicators which depend on calculating rates of donation either in relation to the population of a specific area, or based on hospital indices such as the rate of donation compared to the hospital death rate, ICU death rate, or number of hospital beds, etc. The advantage of using indices based on large areas, e.g. a population of 10 million plus, is that rates are more reliable and stable over time. Data based on smaller populations or units may be affected by many factors.

Several studies using different methods suggest that rates of over 50 potential donors per million population per year (pmp/yr)⁽¹⁰⁻¹⁷⁾ can be achieved. None of the studies achieved 100% donor detection rates (Table I). Studies of hospital indexes⁽¹⁸⁻²⁰⁾ have suggested that 2% to 3% of all people dying in a hospital and around 14% of those dying in the intensive care units, will suffer brain death. Of these, between 17% and 20% will have a medical contraindication to organ donation. Such studies suggest that rates of effective donation of well over 30 pmp/year, can be achieved. (Such rates cannot apply to all organs. Suitable donors for heart and lungs, for example, need to be younger and fitter). In contrast the mean

organ donor rate in the European Union during 1995 was 14 donors pmp/yr. The cadaveric kidney transplant rate over the same period was 27.3 pmp/yr.⁽¹⁾

Such studies give an estimate of the possible “donor detection gap” between current donor rates and potential rates if this first step of donor detection were to be fully effective. It is, in theory, possible that in some countries the transplant rates could be more than doubled. However, it is difficult to extrapolate from such studies to provide expected local rates as these will vary due to local factors such as road death rates, intracranial haemorrhage prevalence, population density, number of ICU beds, age structure, etc.^(21, 22) It is preferable to establish the donor detection gap for each hospital/area. Steps can then be taken locally to analyse the causes of the gap and implement measures to improve performance.

Recommendation: Published figures cannot be extrapolated to provide local rates of potential versus effective donors (although marked differences from published rates for potential donors should be considered as suggestive of under detection). The donor detection gap should be established for each hospital/area and systems for monitoring the rates established.

4.2.2 Improving donor detection

Knowledge of the environmental characteristics in the catchment area, e.g. health resources, infrastructure of the hospitals, location of neurosurgery teams and trauma centres, mortality rates, incidence of traffic accidents, cerebrovascular accidents, cerebral tumours, bullet wounds, etc. will help estimate the likely overall size of the donor detection pool. However, the best means of improving donor detection rates require an effective system for the early identification and follow up of all patients admitted to acute hospitals that may eventually be diagnosed as brain dead. The Donor Action Programme⁽²³⁾ advises that information on potential brain death patients should be recorded prospectively but analysed retrospectively by means of a review of the medical record. This type of analysis will identify localities or hospitals with both an underdetection problem⁽¹⁷⁾ and failure to convert detected potential donors into effective donors.

Recommendation: A means should be developed to evaluate the size and characteristics of the potential donor pool to measure and monitor the potential donor rates. To ensure reliability, data should be collected prospectively and analysed retrospectively as recommended in the "Donor Action Programme".

4.2.3 Donor Detection Programmes

The best means by which potential donors are detected and rates monitored is a proactive system of donor detection every acute hospital for which a person of sufficient authority is given responsibility. Ideally a key individual (key donation person) should be given the responsibility for:

- i. development of a protocol for identifying potential donors which includes events to be recorded and clarifies the roles and responsibilities of hospital professionals in donor identification;

- ii. educational programmes for health staff about transplantation;
- iii. auditing donor procurement and problems on a regular basis.

Recommendation: Proactive donor detection programmes should be instituted in every acute hospital using specially trained professionals (key donation persons) working to agreed protocols and ethical rules.

4.2.4 The role of the "Key Donation Person"

The key donation person needs to be a member of the hospital staff, well respected and closely related with the intensive care units. He/She should work in close relation, but independent from any transplant team(s) and report directly to the medical director of the institution and the OPO/OEO, who are accountable for overall performance. The role of the key donation person is now considered by many to be fundamental to improving donor detection rates. It is he/she who will be responsible for integrating the actions noted above; for development of donor detection programmes and specific protocols, etc., and for defining local benchmark figures and targets for improvement. The appointment of such a person will make the difference between a successful and a non-successful donation programme.

Recommendation: A "key donation person", independent from transplant teams, should be appointed in every acute hospital with clearly defines roles and responsibilities for establishing, managing and auditing systems for donor identification and identifying potential areas for improvement.

4.3 Donor Screening: acceptability of Organs

It is important to ensure that, as far as possible, any organs retrieved from a donor are of acceptable quality and do not pose an unacceptable risk to the recipient. The major risks to the recipient are the transmission of infectious or malignant disease with the organ. Advice on microbiological screening has been prepared by the Council of Europe⁽²⁴⁾ and others and guidance on screening donors for malignancy has also been published by the Council of Europe.⁽²⁵⁾ Standard protocols for screening potential donors should be developed locally.

The risk factors which determine the suitability of potential donors change from time to time and include not just the risk of transmission but the quality of the organ in terms of its viability. Improvement in donor management, organ preservation and transplant experience have meant that increasingly transplant teams can use organs which were considered marginal a few years ago.⁽²⁶⁾ Protocols to assess the suitability of donor and each of their organs should be developed but will need to be reviewed from time to time to maintain the balance between minimising the risk of organ transplantation for the recipient and maximising the supply of organs.

Recommendation: Protocols should be developed setting out the criteria for screening potential donors and their organs for the risk of disease transmission and potential viability. All appropriate steps should be taken to avoid the transmission of infectious and neoplastic diseases and primary organ failure.

4.4 Donor Management

4.4.1 Scope of the Problem

There is time further to evaluate and screen the potential donor. After completing brain death certification, obtaining appropriate consent; fulfilling legal requirements (see below) and organising the retrieval procedure (see below), it is necessary to maintain the potential donor in a medical condition which will maximise the viability of the organs. Depending on time necessary to complete the above processes, donor management may be critical over a period of 24 hours or more during which time the donor's condition could deteriorate sufficiently to prevent the use of some or all of the organs. Prevention of severe sepsis, maintenance of haemodynamic stability and avoidance of cardiac arrest are examples of good donor management. In a five-year study performed in a hospital in Barcelona, 14% (55/399) of otherwise acceptable organ donors suffered from either a cardiac arrest or uncontrolled sepsis which were contraindications to retrieval.⁽²⁷⁾ In a Madrid study,⁽¹⁸⁾ 9.5% (107/1137) of all brain death subjects suffered a cardiac arrest at some point in the process. Similarly, a 1993 Basque study⁽¹⁶⁾ reported cardiac arrest in 11 of 131 potential donors (8.4%). In a multicentre Spanish audit performed during 1995, the figure had been reduced to 4%.⁽²⁰⁾ In another study, an aggressive approach to donor management resulted in the transplantation of 44 donor hearts that might otherwise have been turned down.⁽²⁸⁾

4.4.2 Potential for improvement

The medical management of a potential donor is primarily the responsibility of the physician in charge of the ICU. However, at this stage the time for which such a doctor can be expected to keep and maintain a potential donor is limited, particularly given the pressure on ICU beds. Once death has been declared, donor management should transfer to the retrieval team leaving a potential gap. Therefore, the "key donor person" should also have responsibilities for donor management and particularly for overcoming problems, which can slow down the process.

The audit of potential donors, proposed in section 4.2 above, should also enable any complications arising in potential donors to be identified and analyzed. Evidence of poor donor management which resulted in a loss of donated organs should be analyzed and steps taken to avoid such complications in the future.

Research programmes into, and educational courses for, donor management have an important place improving our understanding of the problems and will help minimise the risk of complications, which will affect the acceptability of donors. New techniques or therapies that could help should be widely disseminated. Donor management training programmes for clinicians and nurses working with organ donors have proved very successful.⁽²⁹⁾

Recommendation: The incidence of irreversible cardiac arrest, sepsis and other contraindications to organ donation relating to donor management of potential donors should be monitored and audited to detect and correct any problems identified. Involvement of ICU staff in research and/or educational programmes on donor management should help raise standards.

4.5 Brain Death

4.5.1 Legal Requirements

Most countries have laws or codes of practice that define the brain death. Ideally, the means by which brain death is established and certified and its relation to transplantation should be explicit and agreed nationally. However, there are still some countries, which do not have a comprehensive legal framework covering all aspects of transplantation. Countries are strongly advised to review, and where necessary enact, laws that should cover as a minimum:

- i. an adequate definition of brain death which enables organ and tissue retrieval from donors after diagnosed brain death;
- ii. the form of consent or authorisation required to enable organ and tissue donation;
- iii. a requirement to register both the donor and recipient in such a way that donation is traceable but which maintains confidentiality;
- iv. bans absolutely any form of trade in organs or tissues (organ trafficking);
- v. the terms on which hospital staff and/or Health Authorities are permitted to retrieve and transplant the organs and tissues.

Recommendation: An appropriate legal framework for donation and transplantation is required which adequately defines brain death; the type of consent or authorisation required for retrieval (see below); the means of organ retrieval, traceability, confidentiality and which bans organ trafficking.

4.5.2 Diagnosis and Legal Certification

The clinical criteria to be met to establish a diagnosis of brain death are well recognised and accepted world-wide. They are discussed and explained in specialised publications.⁽³⁰⁾ Where differences in practice exist, this is normally a result of the necessary legal criteria to be met in a particular country.

If there is any doubt about the cause of death, then a judge or a coroner must be informed. This requirement is not necessarily a bar to donation. Such deaths represent some 40% of all donations in Spain or the USA. The impact of judge's/coroner's practices on organ recovery has not been widely investigated but is thought to be variable. For example, between 1991 and 1994 in the Madrid region, judges refused organ removal from some 3.5% of all such cases.⁽¹⁸⁾ In the USA from 1990 to 1992 organs retrieval was refused in between 7% and 11.4% of coroner's cases.⁽³¹⁾

4.5.3 Potential for improvement

There are no internationally agreed criteria by which judges or coroners can decide in which cases it is appropriate to allow organ retrieval. Depending on the legal system and the nature of the suspect death (e.g. trauma or sudden death versus suspected murder), some lawyers will see no reason to refuse organ removal whereas others may believe that it could prejudice full investigation, particularly in a suspicious death. It is advisable not just to keep such professionals fully informed about the benefits of transplantation, but to actively involve

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them in discussions about how best to minimise the loss of organs as a result of necessary legal procedures.

Recommendation: Law professionals should be fully aware of the transplant process and the co-operation of those most closely involved, i.e. judges and coroners, should be sought to reduce legal refusals to a minimum.

4.6 Authorisation or Consent to Organ Donation

4.6.1 Legal considerations

Most countries have laws relating to consent or authorisation required for organ and/or tissue donation for transplantation purposes. In many the consent of the relatives prior to organ procurement is required (Table II). However, (see below), there is a debate between authors about the relative merits of laws which presume consent (unless the individual has opted out) and those which require either the positive consent of the donor (via donor card or register) or the consent of relatives. Presumed consent laws, when fully accepted, seem to benefit donation,⁽³²⁾ but, in practice, are often not applied mainly because of reluctance within the medical and legal communities to enforce donation.⁽³³⁾ The King's Fund Report did not recommend immediate implementation of presumed consent legislation in the UK on the basis that it could lead to public disagreement between professionals which would have an adverse impact on transplantation.⁽²¹⁾ If countries wish to apply a presumed consent law strictly, they need to develop a non-donor register which requires a significant infrastructure. Even then unfortunate misunderstandings are possible if the information about organ donation is not kept up to date or given out by untrained or under-trained staff.

In spite of the support organ donation receives in Spain, a recent survey showed that most people are against a change in current practice. Only 6% believed that organ removal should be performed without first consulting the wishes of the relatives.^(34,35) Reasons given by the general public in support of this attitude include the view that strict presumed consent represents an abuse of authority and/or that it is an offence against the relatives. Only one in five respondents to an UK survey in 1992 were in favour of the introduction of presumed consent whereas 50% were against the proposal.⁽²¹⁾

In practice, because of the need to take a social history from available relatives, even in those countries with presumed consent laws, clinicians are reluctant to retrieve organs if the relatives object for fear of adverse publicity. It is essential that good records are kept of all consents or authorisations obtained for each donor.

Recommendation: It is advisable to ascertain the opinion of the public and health professionals about presumed or informed consent for organ donation before considering legal changes that might be potentially detrimental. The key donation person appointed in each centre/area must be aware of all local legal criteria and should be responsible for meeting these requirements. There should be a system for the safe custody of all certificates and test results required by the law.

4.6.2 Obtaining authorisation or consent

The approach to the relatives of a potential donor is another of the key steps in the transplant process and one of the most sensitive given that it necessarily coincides with the distress and trauma surrounding any death, particularly if that death is sudden or unexpected as is so often the case when the patient is young. Together with the initial identification of potential donors, refusal by relatives to consent to organ retrieval remains one of the major causes of loss of potential donor and a serious obstacle to improving organ donation rates.

4.6.3 Factors affecting willingness to allow organ donation

There is evidence⁽¹⁹⁾ that relatives will rarely refuse to allow organ donation if the donor has previously made clear his/her willingness to donate. A few people and/or their relatives will have strongly held beliefs, which will make them unwilling to donate organs under any circumstances. The majority of the people are "neither for or against" transplantation. The key questions are, therefore:

- i. what factors will influence people to willingly agree to organ donation in advance and to make their wishes known to relatives and friends?
- ii. what factors will influence relatives to agree to donation when the views of the potential donor are not known in advance?

As noted above, although the legal position could, in theory, be a major factor, in practice it is not. The underlying public and professional attitudes to donation/transplantation are more important. One of the key factors influencing the willingness of individuals and their relatives to agree to organ donation, is the public attitude to transplantation at the time. Consideration should be given to how public and professional perceptions about transplantation can be positively influenced.

4.6.4 Public attitudes: impact of the media

As surveys have shown,^(21,35,36) there is significant public support for organ donation. One recent Spanish national survey shows a significant link between the public's predisposition to organ donation and their view that transplantation is a "good" health care service. This suggests that bad publicity about important matters such as brain death, organ trafficking, or fairness of access to transplantation, can have an adverse effect on the public's predisposition to agree to organ donation.

Many transplant professionals believe that adverse publicity about transplantation generates an increase in refusals to consent by lowering the image of transplantation among both the public and health care workers not specifically involved in transplantation. The impact of positive or negative publicity is usually underestimated by the scientific community. There are some classic examples of negative effects. In 1980, after a prime time TV current affairs programme in the UK had questioned the validity of brain-death criteria (Panorama BBC), it took 15 months for donor referral rates to recover. France and Belgium, both countries with traditionally high organ donation rates, have recently experienced significant drops, attributed at least in part to negative publicity. In France it was revealed that there had been

a failure to fully inform relatives of procurement procedures. In Belgium publicity was given to the high percentage of non-residents on national transplant waiting lists.

Rumours about organ trafficking (mainly false) have achieved the status of a “modern myth” probably because they embody some of the most potent fears about “science” in modern day life. Such rumours have caused significant damage to altruistic attitudes to organ donation all over the world.

In contrast, the so-called "Nicholas Green effect" is claimed to have had a positive effect on Italian public opinion with regards to organ donation. Nicholas was a 7-year-old American child, shot dead by a bandit near Reggio Calabria in September 1994. His parents agreed to donate his organs after being asked to do so by Italian doctors. The Italian media reporting of the story - that the parents could still be generous to the Italian people in the face of the violence inflicted on their son - added to the positive impact of the parents' decision on organ donation rates.

The media can have either a positive or negative influence on willingness to consent to donation. Journalists do not appear to deliberately promote or sensational stories about organ transplantation. Often they ask real questions about a complex and sensitive area but may report mistaken or imprecise answers. Such problems could be reduced by either better self control on the part of the media or better education of the media about transplantation issues (see below).

4.6.5 Communication strategies

There is no evidence that media stories, particularly the positive ones, have any long term effect on public attitudes to donation or on overall organ donation rates. This raises the question as to whether formal public education programmes can influence public attitudes to transplantation. In general, there is little evidence to suggest that direct publicity campaigns would influence the public unless resources comparable to the publicity budgets of major international companies are used. A television campaign conducted by the Department of Health in the UK showed a drop in the refusal rates from 30% to 22% during a period of intense publicity but it soon returned to pre-campaign levels.⁽²¹⁾ In 1987 an Australian national survey was undertaken to determine the population's knowledge about organ donation and transplantation. Two years later TV advertisements highlighting the need for organ donation were screened over a period of 6-12 months. A national follow-up survey in 1990 showed that knowledge about the next of kin's decision increased from 30% to 60%, but the percentage expressing a willingness to donate remained unchanged.⁽³⁷⁾ There are no convincing reports from the medical literature, which support the idea that this type of approach can predispose people to organ donation.⁽²¹⁾ On the contrary, there is a growing feeling that such campaigns are ineffective or at least have a very high cost-effectiveness ratio.

During the last few years, attention has turned to trying to provide the media with accurate and positive information about organ donation and transplantation. In Spain, the Organisation National de Transplant (ONT) is responsible not only for co-ordination transplant services and providing guidance for the health care professions, but also for provision of information for the public and the media. Several strategies have been followed

in an attempt to harness the power of the mass media and to improve the general level of information about these topics. The aims of these strategies are clearly defined:

- i. to manage all potentially adverse publicity by trying to turn the media attitude to donation from negative to at least a receptive and, if possible, a positive attitude towards organ donation and transplantation;
- ii. creating a more positive atmosphere towards organ donation through the periodic dissemination of positive news.

The central messages to get over to the public have also been made very clear:

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

In contrast there are negative messages which need to be countered. Organ transplantation should not be seen as:

- i. an experimental procedure;
- ii. a procedure whose main objective could be to benefit an individual surgeon, institution or any other form of self interest;
- iii. a procedure only available for the wealthy or influential.

News or many kinds of programme, although not negative in themselves, can still pass on implicitly negative messages of this sort and need to be guarded against.

4.6.6 Target audiences

Given that the impact of public education is likely to be limited and also that the greatest potential for increasing the donor pool is detecting currently undetected donors, other types of education and/or communication might be more effective in increasing the supply of donors. The most important group which needs to receive adequate and appropriate information is health professionals, particularly those responsible for identifying potential donors and/or approaching the grieving relatives. Most such health care professionals are not themselves involved directly in the transplant process and their knowledge of the success rates etc. can be sparse. This group is also prone to being influenced by negative stories about transplantation.

It takes a special type of courage to discuss organ donation with shocked and distraught relatives and is not surprising, therefore, that health care staff put in such a position, are easily discouraged. Equally, the more such staff feel that what they are doing is beneficial and necessary, the more likely they are to be willing to try. The support of this group of health professionals is essential so that they should not just be the focus of communication strategies but should be directly involved in the development of such strategies to ensure that they have full confidence in the messages and are willing themselves to pass them on to other health care workers and the general public.

As noted above, another important target audience for any communication strategy is the media. Their influence on public opinion has already been discussed and it would be helpful to have the media generally better informed. One strategy being tried in Spain and Portugal is periodic meetings between journalists, experts in communications and leaders in the field of transplantation which are aimed at educating the media, addressing their misconceptions and emphasising the positive life-saving aspects of donation/transplantation.

4.6.7 Transplant "Hot line"

Another information tool that has proved popular in some countries is a transplant hotline. Most comprise a single telephone number for a country or region, which is manned 24 hours/day, seven days/week, by trained staff who can provide relevant and accurate information rapidly. Originally intended for the public, such hotlines are popular with health care professionals, especially GPs, and the media. The fact that anyone, including the media, can, at any time, obtain medical, legal or statistical information about organ donation, has helped reduce the incidence of adverse stories about transplantation, increased public confidence and helped generate a climate of trust and transparency about organ transplantation.

4.6.8 The need of professional support

Developing and managing an effective communications strategy is in itself a complex task. There are a number of elements for which either specialised training or the support of communications professionals are advisable. Training in communication and media skills is essential for those members of the transplant community who are highly visible and so likely to be approached by the media, and those who can and should act as spokespersons. Credibility is a major factor in good communications and it is helpful to be able to field representatives who can unhesitatingly produce positive messages.

Many transplant issues are either very delicate or complex. Some of the topics, e.g. brain death, organ trafficking, access to transplants, are controversial. If not handled correctly, they can have a catastrophic effect, at least in the short term, on organ donation rates. Professional advice should be sought on the best way to get over difficult messages. Again, help with the preparation of material, press releases, briefing packs, leaflets, etc., intended to explain such matters to the public and media. It may be helpful to issue to health professionals involved in transplantation with specific guidelines, which explain clearly and accurately such difficult topics to help them get effective messages to other health professionals, the public and the media.

Recommendations: Because both positive and negative messages can affect the public's willingness to donate organs, there is a need for a professional attitude towards, and support from experts in, the field of communications. They should help to minimise the impact of "bad news" on, and to maximise the communication of "good news" about, transplantation to health professionals, the media and the public. Special attention should be paid to both the content of the message and the best means of dealing with the most controversial topics. The preparation of specific briefing materials should be considered.

The most cost effective means of increasing the public's willingness to donate seems to be improving the knowledge of health professionals (not directly involved in transplantation) and the media about transplantation issues. Continuing education should form an essential element of any communication strategy. A transplant hot line manned by appropriately trained professionals should be considered.

4.6.9 Approaching the relatives

The other major factor in reducing refusals when the wishes of the donor are not known is the manner in which the approach is made to the relatives at the time consent is sought. The high percentage of relatives refusing to agree to donation when the request is made has been noted. It is known that, when the wishes of the deceased are not known, only 50% of people will agree to organ retrieval from their relatives.^(35,36) One answer is to encourage people to speak about organ donation and transplantation and make their wishes known to their relatives. This could completely change the picture^(31,34) resulting in 93-94% of people allowing donation. But, as it is unlikely that the wishes of most people will be known, it is important to ascertain whether the attitude and skills of the staff in a position to seek agreement from relatives can influence their decision.

In the USA the Uniform Anatomical Gift Act 1987 contains a provision that requires staff to make routine enquiries of all potential donor's relatives about organ donation. It provides that failure on the part of hospitals to adopt routine enquiry will lead to the denial of Medicare and Medicaid reimbursements. In spite of the requirements, it has been reported⁽³⁸⁾ that up to 20% of potential donor families are not approached by the hospital staff. The reasons given include views of staff that donation can compound the family's grief; there is a perceived conflict of interest, they are uneasy with the idea of donation itself or presenting the option to the relatives, or simply that staff lack of awareness of the process. The USA experience illustrates that simply to enact required request legislation is not enough. If you simply cite the law when asking relatives about organ donation the consent will be zero.⁽³⁹⁾

Analysis of the reasons for relatives refusing retrieval (Table III) do not vary very much from one country to another.^(19,40,41) In at least a proportion of the cases, the relatives' decision could have been influenced by the way, in which the family was approached and informed. A large Spanish multicentre trial showed that an initial negative response can be changed into consent if the approach is right and the relatives' doubts relate to brain death, the integrity of the corpse or religious causes. It is not so easy if the relatives have a negative attitude to transplantation or there have been problems with the hospital staff.⁽⁴⁰⁾

A study by the Partnership for Organ Donation⁽⁴²⁾ and another Spanish study⁽⁴³⁾ have demonstrated that bereaved families can also benefit from organ donation. The feelings of donor and non-donor families were studied one year after the death. Among donor families, 85% in one study and 86% in the other believe that donation provided a positive outcome of the death. Some 80% said that donation helps the bereaved families, and 89% or 100% would donate again. Of the families that refused consent, 30% in both studies would have changed their mind one-year later.

In many cases, the willingness or otherwise of relatives to agree to donation is not fixed but can be influenced by the attitude and skills of the health care staff who have to tell relatives

bad news. It is essential that such staff are fully trained and experienced, not just in breaking the bad news of the donor's death, but also in communicating the request for organ donation sensitively and being able to answer any doubts the relatives may have. Formal training should be mandatory for all such staff to give them the confidence to approach the relatives in the first place and to give them the best chance of obtaining a positive response. Contrary to the opinion of some authors, it seems that, if skilfully requested, agreement rates by relatives can be improved,^(44,45,46) or, at least, such training is not detrimental to organ donation.⁽⁴⁷⁾ Some of the key attitudes include:

- i. we must realise that we are there to help and be useful and never to upset anyone;
- ii. it is essential to make a comprehensive offer of help by trained staff who will continue to support the relatives independent of their decision;
- iii. the first approach must be carefully prepared including learning about the family members/relatives; the time and place carefully considered and the request for organ donation separated from the communication of the death to allow the family the time necessary to accept the news;
- iv. the relatives must not feel they are being hurried, for them there is no longer any need for speed;
- v. it is advisable to continue to provide support and information to the family after donation;

Staff approaching grieving families should have been on specifically designed training programmes. Interviews should be carefully analysed in a follow up process by the responsible donation team to identify avoidable errors, e.g. not having provided adequate information; not following the rate of assimilation of concepts by the relatives; having lost control following some reactions; etc. Such routine evaluation helps determine and maintain best practice.

Recommendation: People should be encouraged to speak about organ donation and transplantation and to communicate their wishes to their relatives. As a donor's wishes will not always be known, staff in a position to make requests for agreement to organ donation to relatives should be properly trained for the purpose. If such requests are well handled, the rate of donation refusals can be reduced.

4.7 Organ retrieval

4.7.1 Introduction

Once brain death has been established and the necessary consent or authorisation obtained, organ retrieval can take place. The age, condition and management of the donor will determine the number of organs and tissue that can be retrieved. The retrieval procedure should be efficient and dignified so as to minimise the disruption to the donor hospital and staff. The key donation person or a transplant co-ordinator should be made responsible for making the arrangements including alerting the transplant centres to a possible donation early; providing donor data to a transplant centre or organ allocation organisation (see below) for identification of the most appropriate recipient; preparing for the

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retrieval team(s) and ensuring packing and transport is available for organs to be used in other centres. Procedures should be carefully planned, well rehearsed and regularly audited to ensure delays are kept to a minimum and that procedures are amended as necessary.

4.7.2 Multi organ retrieval

A single donor can provide multiple organ and tissue donations (2 kidneys, heart, 2 lungs, liver, pancreas, small bowel, 2 corneas, heart valves, etc.). It is now recognised that as many organs as possible should be retrieved from each donor. Reported multi organ donation rates vary from 30-80% but are improving. The latest report from the UKTSSA⁽⁴⁸⁾ shows an average of 3.5 organs retrieved per donor. However, organ transplant centres tend to be based on a single organ (kidney, liver and heart and lung). This has meant that specific organs have been retrieved by teams from different centres. Sometimes two or even three teams have arrived at the donor hospital each wanting to retrieve particular organs. This creates problems of timing as others may have to wait for the slowest team, prolongs retrieval times and risks one team damaging or affecting the viability of other organs. Such complex procedures can be distressing for the staff of the donor hospital making them less willing to participate in future organ donation.

Increasing use is being made of area or zonal retrieval teams with the skills and experience to retrieve several organs, preserve them and prepare them for transport to other centres. Appropriately trained teams can greatly improve the efficiency and dignity of the retrieval process. They arrive quickly and will often take a complete team including anaesthetist and nursing staff so that staff of the donor hospital do not have to be involved in the retrieval. Countries should examine their retrieval methods and, where necessary, establish a retrieval system, which maximises multi organ (and tissue) retrieval and minimises the length of the retrieval process and the disruption to the donor hospital.

4.7.3 Organ damage

There are very few reports of rates of organ damage during retrieval. However, recently there was sufficient concern about damaged kidneys in Finland to organise courses in retrieval training.⁽⁴⁹⁾ Similarly a report to the UKTSSA Kidney Advisory Group in 1997⁽⁵⁰⁾ showed that some 20% of kidneys were being damaged. Most were repaired and used but a further analysis of data for 1995-6 showed that approximately 1% of all organs (kidneys, hearts, lungs and livers) were not used because of damage during retrieval.⁽⁵¹⁾ In view of the organ shortage even the loss of one organ as a result of poor retrieval procedures is a matter for concern. All organ retrieval teams should be lead by a senior surgeon experienced in organ retrieval. Consideration should be given to ensuring that, as far as possible, all organs are retrieved by appropriately trained multi organ retrieval teams. Organ damage should be reported and audited and, if necessary, further training provided. Regular training courses in organ retrieval should be provided for transplant surgeons in training. Finally, procedures for organ preservation, packaging and transport need to be well established and regularly reviewed. There is anecdotal evidence of organs being damaged e.g. by ice due to faulty packaging.

Recommendation: Organ retrieval procedures should be well planned to minimise delay and disruption to donor hospital. Retrieval teams should be lead by experienced surgeons trained, where appropriate in multi organ retrieval. Organ damage during retrieval should be reported and monitored and further training provided as necessary to minimise damage during retrieval or transportation.

4.8 Organ Allocation and organisational issues

4.8.1 Introduction

Given the short time (a few hours) that some organs (heart, lungs and liver) can be maintained in good condition prior to implantation, and the necessity to ensure that the organ is matched to a suitable recipient (size, blood group, HLA match etc.), it is essential that effective systems are in place to ensure that the organs (and/or tissues) retrieved are allocated to the most appropriate patient(s). There should be at least a national patient waiting list with some form of co-ordinating office, covering a defined area which could be a region, country or even group of countries, in charge of all the organisational and administrative tasks necessary to ensure rapid and fair organ allocation. Every country should ensure there is in place a system which has transparent and justifiable organ allocation rules.

4.8.2 Organ allocation/exchange organisations

There is general agreement about the need for some sort of organisation to support transplant activity in a specific area, country or group of countries. Many such organisations already exist. Many are primarily organ sharing offices (OSOs) or Organ Exchange Organisations (OEOs) which were originally closely related to the tissue typing laboratories. The first and largest European organisations (EUROTRANSPLANT and France Transplant) had their origin and philosophy on HLA based kidney sharing during the sixties. They were created and developed as a result of professional agreements, which evolved further during the eighties to cover non-renal organs. However, such existing transplant organisations vary significantly from country to country in terms of:

- i. scope - regional, national, supranational;
- ii. size of population served - small <10m; medium 10-60m; large >60m;
- iii. management - professional; health administration; mixed;
- iv. structure - non-for-profit foundation; state agency; private agency;
- v. organisation - centralised/decentralised;
- vi. objectives and responsibilities - organ sharing/ exchange/ procurement;
- vii. activities - organs +/- tissues +/- bone marrow.

Such differences result from the origin and development of the organisation, the national health system of the country, the resources available and even the personal profiles of the founders and directors. Most such organisations world-wide are, however, dedicated at least to maintaining common patient waiting lists, agreeing and effecting organ sharing and allocation methods, registering donors and/or transplants, producing statistics and, in some cases, organising organ retrieval team arrangements.

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Recommendation: An organ sharing/allocation organisation is essential but its roles and responsibilities must be clearly defined, particularly if it is to have a role in organ donation and procurement (see below).

4.9 Organisational support for transplantation

4.9.1 Introduction

The preceding sections have covered the essential steps in transplantation and considered how the effectiveness of each step can be improved to maximise the procurement of high quality organs and their distribution to the most appropriate recipients. However, some sort of organisational framework is required to support, monitor and regulate not just organ allocation and exchange, but the whole process. This final section considers what support is required and how best it might be delivered.

4.9.2 Hospital organisation

Starting at the beginning, the potential donors are to be found primarily in the ICU units of hospitals. There is a need to develop policies, which encourage hospitals to engage actively in organ donation. Such policies should address the financial and other resource issues relating to organ donation. For example, the number of ICU beds, the facilities available for retrieval, the cost of maintaining patients on ICU, cumbersome brain death certification or organ retrieval procedures can, unless addressed, all inhibit a hospital from seeking to maximise organ donation.

Recommendation: Attention should be paid to ensuring that hospitals are properly resourced and, if necessary, reimbursed for maximising organ procurement.

4.9.3 Organ procurement organisation

There is no single formula for an appropriate supra hospital organisation that can ensure good results. It is increasingly argued that the ideal situation is an integrated organisation that can support the whole process of organ donation and allocation (see below). There is, however, an apparent contradiction, which must be recognised because it has implications for the optimum size and type of organisation. As far as organ sharing is concerned, and with some limitations (time, cost), it has been accepted that "the larger the pool of patients, the better the match."⁽⁵²⁾ Suitable organs cannot easily be found for urgent patients and "difficult" recipients (children, highly sensitised renal patients, and rare HLA types) within the scope of a small organisation. Such considerations point to a large organisation as the optimum model.

However, when it comes to maximising organ donation, there are data, which indicate the opposite is true, i.e. that smaller organisations are more effective than the bigger ones.⁽⁵³⁾

This is thought to be due to a better knowledge of local factors, knowing and being able to influence the professionals involved and more direct accountability for the whole process. Large centralised organisations whose staff do not fully participate in the decision making process are generally strongly de-motivating and so would not readily promote increased organ donation. Moreover, there are those who would argue strongly that cadaveric organs

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procured within a community should be considered assets of the community and that the community rather than just the medical profession should determine their allocation through agreed criteria.⁽⁵⁴⁾

Recommendation: In order to optimise organ donation there is need for a supra hospital transplant organisation, appropriate in size and structure to the local situation with specific responsibilities for the whole process of organ procurement.

4.9.4 Transplant support: Organisational objectives

Ideally, any transplant-co-ordinating organisation should fulfil two fundamental functions. It should provide overall support for the donation/transplant process and be in direct charge of distributing organs with all that that entails. Such an organisation would not be an OPO or OSO, i.e. concerned only with organ sharing, but have a clear objective of maximising the supply of donor organs. Such an organisation should be able to detect any problem, which could lead to a loss of donors, and offer solutions. This would only be possible if the organisation could develop well established protocols covering the whole process described above, audit the results of hospitals or local organisations through effective data analysis, promote relevant research, provide training programmes and supply accurate and appropriate information.

The organisation would be responsible for ensuring the legal and ethical acceptability of the donation process and be able to guarantee the fairness and transparency of both organ allocation criteria and the equity of access of all recipients. The organisation should also be responsible for organ (and tissue) exchange between it and other recognised national or supranational organ transplant co-ordinating organisations. In summary, the organisation should be able to agree and implement operational policies covering all aspects of the donation/transplant process.

4.9.5 Transplant support organisations

The question then arises as to whether there are any existing examples of organisations which have attempted to combine the benefits of smaller local organisations directed to organ procurement with those of the large, possibly multinational OEO? As has been noted above, there are in Europe (and elsewhere) a number of large transplant organisations, which vary in their roles and responsibilities, Eurotransplant, France Transplant, Scandia Transplant, ONT, and the UKTSSA. The UKTSSA maintains a common waiting list and is responsible for organ allocation, but has also agreed protocols for organ retrieval. Three years ago, it introduced zoning arrangements throughout the UK to improve organ retrieval and distribution. In Spain, ONT is implementing a system of interdependence between district/regional based procurement arrangements which work as part of a national transplant organisation. The type of organisational solution, which seems to be the most appropriate, is one which offers the possibility of ensuring a common approach and standards with sufficient local autonomy to maintain enthusiasm.

Recommendation: The most effective organisational approach balances the requirements for effective organ procurement (small/local) with those for organ allocation (large, national/multinational). The aim should be to optimise organ procurement whilst ensuring the most clinically effective allocation of organs and tissues.

4.9.6 National responsibilities

Whatever organisation is established, the direct, or at least indirect involvement, of national health administrations in the transplant system is essential to provide the necessary legal framework and resources and to guarantee that someone is held accountable for the performance of the transplant service and the safety and traceability of the organs and tissues donated.

Recommendation: Health Administrations are responsible for ensuring that there is proper organisational support for organ donation and distribution and should guarantee the fairness, transparency and safety of the whole system.

5. INTERNATIONAL CO-OPERATION

The majority of organs retrieved will be used either in the same region or within a country of organ transplant organisation, but some international exchange of organs is desirable either for urgent cases (livers) or difficult tissue matches (kidneys, bone marrow). It is important that the clinicians using such organs can feel confident in the screening and retrieval systems in the donor country. The organisation of organ retrieval systems will be regional and/or national and be adapted to best meet local health service organisation and legal framework. Again, however, it is desirable that such systems achieve some common standards. Bad publicity about organ transplantation in one country may have an impact on organ donor rates in others. Patients may try to get put on waiting lists in different countries. There is, therefore, a common interest in ensuring that transplant services are, and are seen to be, above reproach. Organisations may have much to learn from each other about solutions to problems and cost effective organisation.

Such co-operation should be established and may be achieved either by international agreement or by some sort of supranational organisation.

The following aspects of the organ donation/transplantation process might be the subject of such international co-operation:

- i. learning, exchange of experience;
- ii. training of people involved in organ donation;
- iii. prevention of commercialisation;
- iv. validation of waiting lists;
- v. finding organs for "problem" recipient;
- vi. tracing of organs from donor to recipient;
- vii. accountability and transparency of transplantation services;
- viii. standardisation and/or accreditation of e.g. hospitals, laboratories and transplantation services;
- ix. educating and informing the population and the media.

Recommendation: International co-operation on the promotion of organ donation is desirable to maximise organ donation and equalise access to transplantation between countries. Governments should actively promote such co-operation.

Recommendation: Priority should be given to international co-operation which improves standards of training, exchange of experience, and which helps guarantee the safety of organs and the ethical standards by which they are retrieved and transplanted.

TABLE I. Potential organ donation rates and effectiveness in donor detection in different countries/areas

| | Year | Potential donor pool (donors pmp/year) | Donor detection effectiveness rate |
|---|---------|--|------------------------------------|
| | 1988 | 50.8 | 75% |
| Siminof et al. Pennsylvania + Minnesota (11) 1995 | 1991-92 | 65.4(*) | 91.5% |
| Nathan et al. Pennsylvania (12) 1991 | 1987 | 38.3-55.2 | 52% |
| Espinel et al. Cataluña (13) 1989 | 1987 | 40 | 92% |
| Aranzabal et al. Euskadi (14) 1995 | 1993 | 53 | 90 |
| Evans et al Usa (15) 1992 | -- | 43.7 | Estimation |
| Multicentre Spanish study (16) 1994 | 1994 | 65 (*) | 90 |

*Brain dead declared people medical contra-indications including () = References

TABLE II. The type of consent required in different countries

| <u>Presumed Consent</u> | <u>Theoretically presumed consent but practically Informed consent</u> |
|--|--|
| Finland Portugal Austria Sweden Czech Republic Slovak Republic Hungary Poland | Spain Italy Greece Belgium Luxembourg France |
| <u>Informed Consent</u> | <u>No legislation. Practically: informed consent</u> |
| USA Latin America United Kingdom Ireland Denmark Netherlands Germany | |

TABLE III. Causes for refusal by relatives

| Cause | Country | | |
|--|-----------|---------|----------------|
| | Spain | France | Spain (Madrid) |
| Study Date | 1993 - 94 | 1992-93 | 1993-94 |
| Centres | 12 | 8 | 11 |
| Interviews | 618 | 213 | 352 |
| Refusal Rate | 16.6 | 26 | 25.2 |
| Reference | (30) | (32) | (17) |
| Lack of/ Inaccurate information provided to the Family | | | |
| - Brain Death | 5.8% | 22% | 9% |
| - Corpse Integrity | 4.8% | | 5% |
| Family opposed | 24.2% | 32.3% | 25% |
| Lack of information about donors wishes | 3.8% | | 3% |
| Social claims | 3.8% | | 2% |
| Negative attitude of the deceased during his/her life | 40% | 36.7% | 38% |
| Religious Causes | 2.9% | | 7% |
| Problems with hospital staff | 7.7% | 9% | 12% |

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