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# Consent for Solid Organ Transplantation in Adults

Compiled by a Working Party of
The British Transplantation Society
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British Transplantation Society Guidelines

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# Summary of Recommendations

### Information and consent

All Transplant Units should produce written information about the risks and benefits of transplantation. Such information should follow national standards.

It is good practice for the information to be given both orally and in writing and to be documented clearly in the patient's medical records.

The information presented to patients should be reviewed annually and revised as necessary.

The information provided should be dated.

Where a patient does not wish to have details about risks and benefits, this should be recorded (and witnessed). In such cases, the clinicians must ensure that this does not reflect non-engagement with the transplant process.

Where appropriate, and according to local Unit policy (such as transplantation for patients who are at high risk of non-compliance or of a return to alcohol or substance abuse), written confirmation should be signed by the patient to show that they understand their obligations to ensure graft survival and the consequences of not following the medical advice.

Families, carers and other close supporters should also be made aware of the risks, benefits and implications of transplantation, provided the patient gives consent to this.

The patient (and their family/carers if appropriate) should be seen by relevant members of the multi-disciplinary team on several occasions if time allows.

The patient and their family/friends should have the opportunity to meet someone who has undergone the procedure.

The information, date and type of information (oral, written or other) and the name and role of the person giving that information to patients, family, carers and other close supporters should be recorded in the patient's records and done in accordance with the guidelines of the appropriate hospital Trust or Board.

### Information to be given prior to joining the transplant waiting list

Before the patient is placed on the National Transplant Waiting List, the potential recipient should be given information about the process of donation and be told specifically about:

i) The screening process, including the information requested and investigations done by the Specialist Nurses in Organ Donation (SNODs), prior to offering organs;

ii) the information about the donor that may be shared with the recipient before or after transplantation;

iii) the categories and types of donors and organs (as relevant to the individual);

iv) the risks associated with all organs and those that may derive from the varying characteristics of the donor (such as lifestyle, cause of death), from the organ itself and from the logistics of the transplant;

v) the benefits of transplantation;

vi) the risks of transplantation;

vii) the importance of long-term follow-up, compliance with medical advice and need for immunosuppression;

viii) the consequences of non-transplantation;

ix) the possibility and reasons for possible suspension or removal from the list;

x) they may be contacted whilst on the waiting list on matters related more generally to transplantation, including being invited to take part in approved research projects. Patients should be invited to participate in trials only after consent for transplantation has been given.

**Maintaining consent while on the waiting list**

Consent to transplantation should be obtained at the time the patient is accepted for inclusion on the National Transplant List.

It is the responsibility of the treating clinician to obtain consent (although this may be delegated to an appropriately experienced and trained health care professional).

Whilst awaiting transplantation, patients should be formally reminded every 12 months where possible, or whenever a change in their condition warrants, of the risks and benefits of the transplant and this should be recorded in the patient records.

Consent should be re-affirmed at least every 12 months where possible and immediately prior to the transplant; this should be done by an appropriately experienced and trained health care professional.

**Informing patients about risks**

The risks related to transplantation should be explained clearly to the potential recipient. These should include risks

i) associated with the transplant procedure;

ii) associated with the donor organ affecting its function in the short and long term;

iii) of donor transmissible infection (including cytomegalovirus);

iv) of immunosuppression, including drug side effects, increased incidence of infection and cancer;

v) associated with transplantation in general.

Risks should be explained in a manner that is best understood by the recipient, and may include a mixture of diagrams and numeric illustrations.

The degree of risk associated with a particular transplant procedure or donor/organ type should be explained.

Quoted risks should be current and appropriate to the experience of the Unit; national figures may be used where they are in line with local data.

**Patient choice and the donor organ**

The patient should be fully counselled about the consequences of restricting the characteristics of the organs they are offered and this should be fully recorded.

Where possible, the potential recipient should indicate to the transplant team at the time of listing, the characteristics of the organ that would be unacceptable and this should be noted in the patient's records and on the unit's waiting list.

The potential recipient's wishes should be recorded by the Transplant centre and must be readily available to those who must decide whether to accept or decline an offered organ.

Where a patient has expressed a wish not to receive an organ with defined characteristics (such as from a donor after circulatory death), the potential recipient should not be offered such an organ.

Potential recipients will be able to decline offered grafts where there is evidence suggesting a possibility that the donor organ may be compromised in terms of graft function or have a significant impact on the health of the recipient.

It should be noted that some lung recipients have expressed a wish that they should be informed that over one third of deceased donor lungs are from donors who have smoked and may decide not to accept such lungs.

It should be made clear to the patient that they may change their decision at any time without prejudice. Thus, where the allocation process includes waiting time, the patient will continue to accrue waiting time points. Refusal of one offer should not adversely affect the chance of that patient being offered another graft.

The reason for refusal of an offered organ should be based on criteria that have been shown to affect significantly the function of the organ or the health of the recipient. Should a patient wish to impose unacceptable conditions, then the patient would not be accepted for transplantation.

The patient's unacceptable criteria should be reviewed on a regular basis (such as an out-patient visit or change in the patient's clinical condition) and amended as appropriate.

**Discussions at the time of an organ offer**

Consent should be reaffirmed when the potential recipient is admitted for a transplant.

In those cases where the risks exceed those that are accepted within current guidelines (for example where the donor has a primary intra-cranial cancer or a recent history of malignancy such that there is a possibility of tumour transmission), this should be discussed with the potential recipient when the organ is offered and the discussion and outcome documented in the patient records.

Where the potential recipient has indicated they would wish to discuss all offers with the surgeon, this should be discussed ahead of listing and may be accommodated provided

a) there is enough logistic resource available to comply with this request

   *and*

b) the discussion (and possible decline of the organ) do not adversely impact on the quality of the organ if subsequently offered to other recipients.

Because of different maximum cold ischemic times, different approaches are indicated for different organs. The rights of the individual to decide whether to accept an offered organ must not adversely impact on the rights of other potential recipients to have equal access to donated organs.

If the patient wishes to discuss each suitable offer immediately prior to transplantation and refusal of the graft would significantly affect the viability of the graft for the next

potential recipient, then the patient and clinician should agree in advance a satisfactory management plan before the patient is accepted for transplantation.

**Information which the recipient is entitled to know about the donor**

The following information is acceptable for communicating to the recipient:

i) age range;
ii) gender;
iii) type of death (such as trauma or cerebrovascular event) unless this is likely to compromise donor confidentiality;
iv) whether the donor poses a greater risk of transmission of infection or malignancy.

The following information should ***not*** be transmitted to the recipient

i) name (or initials);
ii) occupation or social class;
iii) date of birth;
iv) place of donation;
v) ethnicity;
vi) sexual, alcohol or drug history.

Where specific information is required by the recipient (such as smoking history), that information may be given so long as donor confidentiality is maintained and is relevant to the outcome of the procedure.

The recipient should be informed that the donor family will be given basic information about them.

**Information which the donor family is entitled to know about the recipient**

The following information may be given to the donor family about the recipient

i) age range (by decade);
ii) gender;
iii) outcome of the transplant.

# GUIDELINES FOR CONSENT FOR SOLID ORGAN TRANSPLANTATION

## 1 Background

These Guidelines were drawn up by a group convened by NHS Blood and Transplant and the British Transplantation Society. The membership is shown in Appendix A.

## 2 Purpose

The purpose of these guidelines is to provide standards for consent for adults undergoing solid organ transplantation from deceased donors. This should ensure that there are common practices across the UK and that the needs of all interested parties are met.

## 3 Consent

### 3.1 The principles of obtaining consent

The principles of obtaining and recording consent are published by several organisations including the General Medical Council, the Departments of Health, the Human Tissue Authority and the British Medical Association.

- Consent is a decision making process involving
  - Capacity;
  - Voluntariness;
  - Provision of adequate information.
- Obtaining consent is part of the management of the patient.
- Signing the consent form marks just one stage of the process.
- The patient weighs up the potential benefits, risks and burdens of the various options as well as any relevant non-clinical issues.
- It is the responsibility of the treating clinician to obtain consent (although this may be delegated to an appropriately experienced health care professional).
- Information should be provided to the patient regarding:
  - Options for treatment (including the option not to undergo treatment);
  - Potential benefits, risks, and likelihood of success;
  - The risks and benefits of non-intervention.
- Patients should have time to reflect before reaching a decision.
- Patients should have the right to obtain a second opinion.
- Patients should be told if a treatment might result in
  - a serious adverse event, even if the likelihood is very small;
  - less serious complications which occur more commonly.

### 3.2 The peculiarities of consent to transplantation

Obtaining and giving consent for organ transplantation raises issues not usually seen with other interventions: potential transplant candidates must decide whether they wish to be listed for transplantation and, since the waiting time may be long (in some cases several years), the validity of the consent will need review. When a suitable organ is available for them they must decide whether they wish to undergo the transplant operation and whether they agree to have the offered organ. Because of the need to keep the organ's ischemic time to a minimum, the time between the notification of a donor offer and the time by which a decision must be made will be limited.

Written consent for transplantation is currently obtained either at listing (when the potential candidate has been accepted as an appropriate candidate and after been fully informed as to the benefits, risks and alternative treatment options) or when a donor organ is available, depending upon centre practice and differing with different organ types. We suggest that patients should be asked to consent before they are added to the waiting list and, as indicated below, that consent is re-affirmed when a graft is available. We also suggest that the potential candidate should indicate at listing any restrictions on the type of donor or graft that are not acceptable to them (such as a graft from a DCD donor or one with higher risk of disease transmission).

### 3.3 Refusal to participate in discussing risk

A small proportion of patients do not wish to be informed of the risks associated with the procedure. While the clinician has an obligation to ensure the patient is given the opportunity to discuss benefits and risks of transplantation (as well as of non-transplantation), the patient has a right to decline to be given such information. In such a case, the refusal should be recorded in the records and witnessed by an independent observer. If this refusal is considered as non-engagement with the process of transplantation, the transplant team will need to ensure that the patient will comply with the necessary follow-up after transplantation. The right not to know must be distinguished from the right not to comply.

### 3.4 Refusal to be placed on the waiting list

A patient has the right to refuse to be placed on the waiting list for a transplant. Provided they have the capacity to make such a decision, and have been fully informed of the consequences of such a decision, their wish should be respected. Wishes of the patient to change their mind should be reflected and this decision should not adversely affect their chances of receiving a graft.

## 4 Background to obtaining consent for solid organ transplantation

### 4.1 The peculiarities of risk in transplantation

Solid organ transplantation is usually indicated as a life-saving or life-enhancing treatment for patients with organ failure. As with all forms of medical intervention, there are risks and benefits of transplantation and these have to be compared with the risks and benefits of either no intervention or of alternative treatment modalities. Unlike most forms of surgical intervention, transplantation commits the person to life-long treatment and follow-up. Risks are not inconsiderable and they are varied, the time of greatest risk being in the early months after surgery. Transplantation is associated with an increased risk of death in the short-term but a significantly increased chance of survival in the longer term. Transplantation also differs from conventional surgery in three other important aspects:

- the graft itself is associated with risk, such as transmission of infection or malignancy;
- some grafts are associated with a worse long term outcome than others (as discussed below, and these are often termed higher risk or expanded criteria donor organs);
- the shortage of organs means that there are usually several patients who are eligible to receive the offered organ, so the decision to allocate a donated organ to one individual will deny another the opportunity of receiving it.

Because of the shortage of organs, not all those who would benefit from transplantation can be offered this life-saving or life-enhancing procedure: exclusion of organs because

of a higher perceived risk may deny a life-saving opportunity to an individual with an even greater risk of death without transplantation.

There are many validated models that predict survival with and without a transplant. However, simple extrapolation to the individual may give misleading information as the confidence interval is wide and the models, which are based on historical data, may not take into account new developments. In addition the interaction between donor organ, recipient and logistical characteristics will affect the outcome, hence prediction of the outcome in an individual is often very difficult.

### 4.2 Understanding risk

Organ transplantation, as with any clinical intervention, is associated with risk; conversely, in people with organ failure, no intervention is also associated with risk so when considering transplantation, the patient has to balance the risks and benefits of transplantation against the risks and benefits of either refusing to be listed for transplantation or declining the offered organ in order to wait for the possibility of another offer that is perceived to be "better". Where the proposed intervention is potentially life saving and is the best life-saving therapeutic option available, many will not fully evaluate the risks of the procedure.

Risk is generally poorly understood and poorly evaluated: for example, common risks (such as death from road accidents) are often accepted while less common risks (such as death from airline disasters) are perceived to be greater. To help the patient understand the risks associated with all options, a variety of formats can be used: this may be one or a combination of the written word or a chart or a picture. There are many factors that will affect any individual's response to understanding: in general, such factors include the familiarity with the risk (tends to under-estimate the risk), individual control (greater perceived control over the risk is associated with greater risk taking), trust in those putting the individual at risk but it must be clear that different people understand and respond to risk differently.

The probability of an event can be stated in several ways, including as a percentage (0.1%) or a ratio (1:1000), or it can be compared to known risks (see Appendix B) or by comparison with understandable proportions (such as 1:1000 being one person in a village and 1 in 10000 being one person in a small town). Evidence suggests that understanding is improved when the risk is given in numeric form and a common denominator is used, although this may not always be practicable when some risks are common (such as acute rejection which may occur in 1 in 5 and others (such as inadvertent transmission of HIV very rare (less than 1 in 20000). However, it must be recognised that many people assume that if a risk is given as, say, 1 in 1000 that this will not happen rather than it will happen in 1 case out of 1000. People also tend to misinterpret randomness: if it is difficult for statisticians to determine whether two or three rare events occur randomly or are linked, it is not surprising that other people also find this a challenge!

Survival rates, whether patient or graft, can be expressed in one of several ways: transplant clinicians tend to quote 1 or 5 year survival probabilities while the patient might be more interested in the probability of living 5 or 10 years. It is often assumed that younger people are less aware of their own mortality yet research suggests that this is not the case.

Clinical experience also suggests that how and when risks are explained may affect the patient's decision: for example, if risk is expressed positively (chance of survival as 99 in 100) rather than negatively (risk of death is 1 in 100), the patient is more likely to be

accept that risk. It is also the case that most people who advise on risk over-estimate their skill in communicating the risk and also the understanding of those given the explanation.

It is difficult to determine how much information should be given to an individual and their family: the usual intended benefits of transplantation are primarily two and both are major (increase in quality and length of life) whereas there are many risks, although usually rare and many will focus on the greater number of risks, In assessing how much information to give a patient, a useful yard-stick is whether more information, after the decision would have been made, would have altered their decision.

## 5 Information to be given prior to joining the transplant waiting list

### 5.1 The different types of risk associated with solid organ transplantation

In solid organ transplantation, risks related to transplantation are shown in Appendix C and include:

- risks of surgery (such as haemorrhage);
- donor derived risks (such as the risk of transmission of infection or malignancy);
- organ derived risks (such as non-function);
- risks of immunosuppression:
    - class specific (such as increased risk of some *de novo* malignancies and infections);
    - drug specific (such as calcineurin inhibitor associated renal impairment and diabetes);
- risks of acute rejection (but with the high likelihood of response to treatment in most cases);
- risks associated with transplantation (such as increased risk of cardiovascular disease).

### 5.2 Organ-associated Risk

As is evident from the risks outlined in Appendix C and section 5.2, all transplanted organs are associated with some degree of risk. Those organs that have greater risk are often referred to as marginal, non-standard, extended or expanded criteria grafts. These terms are **unsatisfactory** because they

- do not remind the recipient that no organ is free of risk;
- assume that the criteria for defining higher risks organs are robust and are both sensitive and specific;
- do not differentiate between those features that predict early-onset problems (such as primary non-function) from those associated with late-onset problems (such as transmission of malignancy);
- do not differentiate those risks that are associated with the donor, the organ or the technical and logistic variables;
- assume that the risks are similar for all recipients (for example, an organ from an donor with Hepatitis C virus (HCV) will carry an excess mortality and morbidity for an HCV negative recipient but not for an HCV positive recipient);
- may interrelate with other factors (for example, a steatotic liver is more likely to fail if the cold ischemic time is prolonged);
- ignore that some risks can be reduced by treatment of the recipient (such as a donor with past infection with the Hepatitis B virus).

There are many factors that have been identified as characterising higher risks grafts. A non-exhaustive list includes donor, graft and logistic factors. Broadly, risks may be

divided into those risks which are related to the graft function and those which are related to the recipient's health.

Donor factors potentially affecting graft function include

- Age of donor;
- Cause of death of donor;
- Type of donor: donation after circulatory death (DCD) compared with donation after brain death (DBD), the nature of the risk varying between organs;
- Higher body mass index of donor;
- Length of stay in an intensive care unit prior to donation;
- Split or reduced liver;
- Longer warm and cold ischemia times.

Donor factors signifying a risk of transmissible disease which may affect the health of the recipient include:

- Previous use of intravenous drugs;
- High risk sexual behaviour;
- Previous history of malignancy;
- Residence in areas of some epidemic infections.

Although the recipient may wish to know all the relevant details of the donor (see Appendix D for the information collected on all donors), this may not be allowable as, in some cases, it will be possible for the recipient or a family member to identify the donor and we are aware of several cases where this has happened (because the donor's death has been reported in the press or investigated by the HM Coroner/Procurator Fiscal). The rights of privacy for the donor and consideration for the donor's family must be respected, and balanced against the wishes of the potential recipient. For example, we recommend that where a donor may be a greater risk of transmitting infection by reason of multiple sexual partners or use of intravenous illicit drugs, the potential recipient may be informed the donor is higher risk for transmission of some infections but that the reason is not given. Discretion will therefore need to be exercised. The recipient must also understand that not all pertinent information may be available at the time of the offer.

Some diseases, such as cytomegalovirus (CMV), are so commonly transferred from donor to recipient that specific mention needs to be made where the recipient is at risk (CMV naïve), with details of the consequences of such infection and steps taken to minimise its effect (for example CMV prophylaxis with valganciclovir).

Provision of information prior to listing will enable the patient to decide whether to consent for transplantation and to decide whether there are characteristics of a donor or an organ that would be unacceptable to them. Thus patients expressing a preference will not be called in for an organ from such a donor.

### 5.3 Optimising the presentation of information

It is usually helpful to involve other members of the patient's family or friends in the education regarding transplantation and risk, particularly where comorbidity in the recipient may impair comprehension.

It is also helpful for all transplant candidates and their family and friends to meet those who have undergone the transplant. While this will give an incomplete picture of the procedure, it will help understanding and so lead to more informed consent.

5.4 Special considerations

Additional considerations apply to solid organ transplant recipients:

- some patients may be intermittently or long-term confused (for example, because of the effects of medication, hypoxia or encephalopathy) or may lack capacity for other reasons. In these situations, the appropriate law (such as the Mental Capacity Act 2005 or the Adults with Incapacity (Scotland) Act 2000) will provide guidance as to how to proceed. Further advice may be given by the Trust, Department of Health, General Medical Council or British Medical Association.
- the interval between giving information and obtaining consent, and the transplant may be several years. Therefore the patient should be reviewed at least annually and the information about the procedure discussed and consent reaffirmed (see section 6). Consent should be reassessed whenever there is a significant change in the condition of the patient or the profile of the donor pool.

5.4.1 Accepting lungs from donors who have smoked: Lung donors with a history of smoking: in recent years, there has been concern expressed by some patients and their families about the donor's smoking history. The principles remain similar: potential donors and their families should be specifically informed that the donor may have smoked and that available data show that, while the outcomes of the selected lungs from smokers are inferior to those from non-smokers, the risk of death in accepting those lungs is less than awaiting another offer. However, the potential recipient has the right to refuse such donated lungs and that decision should be made at listing rather than when the lungs are offered. Again, the patient has the right to change their mind and without prejudice to their treatment.

## 6 Maintaining Consent while on the waiting list

Waiting times for transplants vary considerably and, during this time, the patient's clinical condition may alter and the patient's wishes may change. The patient's condition may improve such that transplantation is no longer indicated at that time or the balance of risks of transplantation compared with other options (no transplantation or other therapies) may have changed. Alternatively, the patient's condition may have deteriorated, again requiring a review as to whether the patient still meets the eligibility criteria for transplantation or whether the balance of risks favouring transplantation compared with other interventions has significantly changed. Thus, patients should be given the opportunity regularly to review and revise their decisions for transplantation and, where appropriate, the characteristics of the organ they would not wish to receive. The timing of such a review will depend on the condition of the patient and the type of transplant, such that annual review may suffice for someone awaiting a kidney but more frequent review may be appropriate for someone awaiting a liver or lung.

## 7 Consent and Acceptance of an organ

7.1 Information available about the donor

When a potential deceased donor is notified to the specialist nurse in organ donation (SNOD) a full history is taken from the family and, where possible, the medical attendants, and various investigations are done. This information is made available on the Electronic Offering System (EOS); the Duty Office at NHSBT will ensure that the organ is offered either to one of the designated transplant centres for local allocation or to a named recipient, according to national allocation protocols (available on the NHSBT website (www.odt.nhs.uk)).

NHSBT is responsible for ensuring that all the relevant data and information are collected and transmitted to the recipient team. Occasionally, more relevant information becomes available after the organ has been offered or accepted. In such cases, NHSBT is responsible for ensuring the recipient team are informed.

### 7.2 The decision to accept the organ that has been offered

The recipient team will decide whether the offered graft is appropriate for the potential recipient (where there is a national allocation scheme) or which recipient is most appropriate (where there is a local allocation scheme). Accepting a donor organ for a recipient is complex and the decision is based on many factors, donor, graft and patient specific. This decision is best made by an experienced surgeon, after discussion with the transplant physician and other members of the transplant team. The reasons for the decision to use or decline the offer should be recorded. It is desirable for the decisions to be reviewed by the unit's Multi-Disciplinary Team.

### 7.3 Recipient choice

The potential recipient has the right to specify the characteristics of the organ they would wish to receive and their treatment should not be prejudiced by the exercise of that right. The surgeon must abide by the strongly expressed desire of a patient not to receive an organ with specified characteristics, even if the surgeon considers this desire illogical. The criteria for exclusion may be donor or graft specific. It should be noted that some grounds for refusing an organ (such as skin colour) are unacceptable where they are irrelevant to the outcome of the transplant or contrary to the law.

Potential recipients should be counselled and given written information about the implications of making such decisions at the time of listing. Patients will need to understand that

- Specifying factors that are unacceptable in a donor organ will avoid the risks associated with a transplant using that organ, but may put the patient at increased risk of dying before an "acceptable" graft becomes available.
- Patients will have the right to decline offered organs where there is evidence of significant increased risk of either graft dysfunction or risk to the recipient's health (such as transmission of infection).
- The patient may not be given all the information about the donor they request but would be informed if the donor is associated with a greater risk of transmission of infection or malignancy, or risk of non-function or greater technical complications. The potential recipient would not be informed of the reasons for the increased risk.
- It is not often possible to quantify the degree of increased risk.
- § Not all the information requested may be available before a decision to accept or reject the offer is made.
- § No organ is free of risk.

The potential recipient's wishes should be recorded not only in the patient's records but also on the Unit's list of transplant candidates.

### 7.4 Discussing the donor details with the recipient

For the transplant surgeon to discuss each offered organ with the selected recipient gives autonomy to the recipient but may adversely impact on the viability of the organ and so the rights of other potential recipients, since every organ suffers progressive damage with increasing cold ischaemia. It is particularly relevant for those organs where the maximal ideal cold ischemic time is short (such as for heart, lungs and in

some instances liver and pancreas). The optimal cold ischemia times for a heart is less than 4 hours, for intestine 6 hours, for a lung 8 hours, for a liver 12 hours and for a kidney 18 hours (although tolerance to cold ischaemia is significantly less with DCD organs). It should be noted that for every organ every additional hour of ischaemia adds to the risk of non- or poor function. This time pressure emphasises the importance of establishing the potential recipient's preferences before they are listed.

Notwithstanding any prior discussions and agreement at the time of listing, the recipient has the right to refuse the offer of an organ at any time before surgery for any reason. Although the pressures of cold ischaemia are important they do not supersede this right. Exercise of these rights to decline an offered organ must not disadvantage the patient.

It is reasonable for the surgeon to discuss the following donor information with the potential recipient:

i) age range (by decade);
ii) gender;
iii) type of death (such as trauma or cerebrovascular event);
iv) the type of donor (DCD or DBD);
v) whether the donor poses a greater risk of transmission of infection or malignancy;
vi) whether the donor organ has a particular risk of poor function (such as acute tubular necrosis in a kidney; severe steatosis in a liver).

Issues of equity of access may also arise since those who are sickest are least able to wait for a low risk organ and so may be disadvantaged as the less sick recipient may be able to wait for another and less high risk graft to become available.

### 7.5 Research

The potential recipient may be asked to participate in research: this may include giving consent for removed organs not required for clinical purposes to be used for research and/or participation in clinical studies, before, during or after transplantation. While it is important to support and facilitate all approved research studies, it is recommended that giving information about possible research projects and asking for consent for participation in approved studies is done only after consent for transplantation has been given so there is no potential for the patient to feel any degree of coercion to consent to participation in research.

## 8 Confidentiality

Information that the donor family may reasonably know about the recipients of the donor's organs, and which the recipient may reasonably know about the donor is detailed in the summary. Care should be taken to avoid including data identifying a donor in the recipient's hospital record from where it may be inadvertently disclosed to the recipient.

The following information should ***not*** be transmitted to the recipient

i) name (or initials);
ii) occupation or social class;
iii) date of birth;
iv) place of donation;
v) ethnicity;

vi) sexual, alcohol or drug history.

Just as potential recipients will wish to have some personal details about the donor, so the donor family will wish to have some information about the recipients. Information that may be given about the recipient will include some details but should be limited to retain confidentiality of the donor and the donor family.

The following information about the recipient may be given to the donor family:

i) age range (by decade);

ii) gender;

iii) outcome of the transplant.

It is common for a recipient to want to write a letter of thanks to the donor family following transplantation. This should be anonymised, and should be sent to a third party (such as the specialist nurse in organ donation) for forwarding to the donor family.

The specialist nurses in organ donation also write to the donor's next of kin and detail the following:

- which organs/tissues were donated.
- which organs/tissues were subsequently transplanted, sent for research or not used.
- why organs/tissues were not donated / transplanted.
- The age range and gender of the recipient
- the length of time the recipient/s have been on the transplant list/dialysis and their post operative condition.

The following information will not be provided:

- Name of the recipient
- Specific geographical location of the recipient

## 9 Appendix A: Membership of Original Guideline Group

*Co-chairs*

Professor James Neuberger, Associate Medical Director, Directorate for Organ Donation and Transplantation NHS Blood and Transplant and Consultant Physician

Professor Chris Watson, President British Transplantation Society and Consultant Transplant Surgeon

Dr Kosh Agarwal, Consultant Hepatologist and Transplant Physician

Miss Lisa Burnapp, Nurse Consultant (representing the Human Tissue Authority)

Dr Tony Calland, Family Doctor (representing the British Medical Association)

Mr John Dark, Consultant Transplant Surgeon

Professor Heather Draper, Professor of Biomedical Ethics

Dr Chris Dudley, Consultant Nephrologist and Transplant Physician

Professor Bobbie Farsides, Professor of Clinical and Biomedical Ethics

Professor John Forsythe, Chair of the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and Consultant Transplant Surgeon

Professor Peter Friend, Consultant Transplant Surgeon

Dr Alex Gimson, Consultant Hepatologist and Transplant Physician

Professor David Price, Professor of Medical Law

Ms Alison Rogers, Chief Executive, British Liver Trust

Miss Tracey Sinclair, National Kidney Federation

## 10 Appendix B: Communicating Risk

10.1 Communicating risk:

Nothing is safe

Transplanted organs are not “new” organs; they all carry a risk

Balance adverse risks with potential benefits

Avoid emotive terms for grafts (such as suboptimal, marginal, high risk)

Avoid descriptive terms (such as common, rare, possible, unlikely)

Use standardised terminology

For numeric estimates:

- Give actual frequencies
- Use a consistent denominator
- Consider choice of denominator (i.e. 1:10 is considered greater than 10:100)
- Use whole numbers rather than decimals
- Avoid logarithmic scales

Consider pictorial presentation of risk

Balance relative risk with absolute risk and benefit; don’t quote relative risk in isolation

Personalise risk: data are derived for population but need application to the individual

Use local centre-specific data regarding outcomes wherever possible

10.2 Examples of Everyday Risk (from Health and Safety Executive)

Annual risk of death averaged over the entire population

| | |
|---|---|
| Cancer | 1 in 387 |
| Injury and poisoning | 1 in 3137 |
| Road Accident | 1 in 16800 |
| Lightning | 1 in 18700000 |

Average annual risk of death as a consequence of an activity

| | |
|---|---|
| Maternal death in pregnancy | 1 in 8,200 pregnancies |
| Scuba diving | 1 in 200,000 dives |
| Rock climbing | 1 in 320,000 climbs |
| Canoeing | 1 in 750,000 outings |
| Rail accidents | 1 in 43,000,000 passenger journeys |
| Aircraft accidents | 1 in 125,000,000 passenger journeys |
| Fairground rides | 1 in 834,000,000 rides |

## 11 Appendix C: Benefits, risks and implications associated with solid organ transplantation

1. General risks
    a. Transmission of donor cancer
        i) known current / past medical history
        ii) unknown
    b. Transmission of donor infection
        i) identified(CMV, EBV, HBV, HCV, HTLV, HIV, syphilis)
        ii) unknown

2. Transplant Related Risks
    a. Increased cardiovascular morbidity and mortality
    b. Immunosuppression
        i) general side-effects
            increased risk of some *de novo* cancers, especially skin and lymphoma
            increased risk of some infections
            increased weight
            increased risk of diabetes mellitus
        ii) drug-specific side-effects
            corticosteroids
            calcineurin-inhibitors
            anti-proliferatives
            mTOR inhibitors
            others

3. Organ Specific Risks
    a. Risk of death on the waiting list
    b. Patient and graft survival probability
    c. Risks of specific organ complications
    d. Risks associated with types of
        i. donor (such as DCD and DBD)
        ii. graft (such as split or damaged organ)
    e. Re-graft and access to re-graft
    f. Risk of non-function
    g. Risk of delayed function
    h. Need for renal support
    i. Recurrent disease

4. Life-style issues
    a. need for compliance with
        i) immunosuppression
        ii) outpatient attendances and monitoring
    b. life-style
        i) alcohol and illicit drug use
        ii) pregnancy and sexual health
        iii) travel and immunisations

5. Benefits
    a. Improved survival
    b. Improved quality of life

## 12 Appendix D: Donor Data collected by the SNODs on Donor Assessment Form

(note that this is not a complete list of data)

General Health
- Visit to GP within 24 months (details*)
- Diabetes
- Cancer: investigations or treatment (details*)
- Recent infections or contact with infection (details*)[#]
- Ever had hepatitis, jaundice or liver disease (details*)[#]
- Neurosurgical surgery or implantation of dura mater before August 1992[#]
- Blood transfusion before 1980[#]
- Any type of brain disease (details*)
- Ever received pituitary extract (details*)[#]
- History of autoimmune/chronic disease (details*)
- Ever had serious infection (such as TB, West Nile Virus, typhoid, toxoplasmosis, brucellosis, rabies, Lyme disease (details*))[#]
- Acupuncture, body piercing, tattoo, botox or collagen injection (details*)[#]
- Ever had a sexually transmitted disease (such as syphilis, gonorrhoea, genital herpes or warts) (details*)[#]

Travel risk assessment (details*)

Behavioural Risk assessment
- Alcohol
- Smoking
- May be infected with HTLV, HIV, HBV, HCV
- Ever injected with non-prescription drugs[#]
- Ever been given payment for sex with drugs or money[#]
- Ever had oral/anal sex with another man (male donors only)[#]
- Had sex within 12 months with a man who has had sex with another man[#]
- Has been in prison for >3 days within last 12 months[#]
- Had sex in the last 12 months with anyone who is HIV or HTLV positive, HBV or HCV positive, had sexually transmitted disease, given payment for sex, ever injected drugs or ever had sex in any part of the world where HIV/AIDS is very common[#]

* in general, we recommend that specific details are passed to recipient only when this would impact on treatment

[#] we recommend recipients may be informed that there is an increased risk of transmissible disease but specific details not given (except where treatment would be given such as for TB, HCV, HBV)