

## Rationale Document for Patient Assessment Form (PA1)

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### Introduction

The purpose of a patient assessment is to determine if a potential donor is suitable to donate **any** organ or tissue and then to determine **which** organs and tissues can be donated. Whilst the potential donor may 'in general' be acceptable for donation, not all organs or tissues may be suitable due to 'system specific' medical problems.

This document aims to provide a rationale for specific information that is required to assess a potential donor's suitability for organ/tissue donation and should be used in conjunction with the NHS Blood and Transplant [FRM4211](#) Patient Assessment Form (PA1).

The purpose of patient assessment is to collate relevant information for donor characterisation; this can help determine risk factors for the transmission of disease from donor to recipient. It is the responsibility of the Specialist Nurse Organ Donation, Nurse Practitioner/Assistant Nurse Practitioner (Tissue Services) and Tissue Transplant Co-ordinator to collect comprehensive information on medical, behavioural and travel history and relay all of the information obtained to the organ recipient and tissue procurement centres. In addition, for organs, it is the responsibility of the implanting surgeon to assess the risk-benefit of transplant for their individual patients. For tissues, it is the responsibility of the tissue establishment to make the final decision on donor suitability.

Risk of disease transmission is relative to the risks of not receiving a transplant, so the principle of a balanced approach applies. Assessment is only as good as the information which it is based on, hence thorough donor characterisation is essential.

The Specialist Nurse - Organ Donation, Nurse Practitioner/Assistant Nurse Practitioner (Tissue Services) and Tissue Transplant Co-ordinator must be familiar with the purpose of each question and must recognise when to expand the question in order to obtain more details and what additional information might be required; recognising when to seek advice is also important.

For all paediatric donors under the age of 18 months, and for any baby or child who has been breast-fed in the past 12 months, the mother is required to answer the questions in the patient assessment document with regard to both her own, and her child's health.

The conditions which will cause the deferral of a potential donation vary significantly between organs, ocular tissue and other tissues. For many of the questions asked, the principle will be to gain as much relevant information as possible, **clearly document on EOS/inform recipient centres** and assess responses on a case by case basis, seeking expert advice where necessary. For tissue donation this is also relevant, however suitability can also be confirmed by reference to the current version of the UKBTS Tissue Donor Selection Guidelines for Deceased Donors (TDSG-DD) (<http://www.transfusionguidelines.org.uk/dsg/ctd/guidelines>). Contraindications are not frequently specified within this document due to the changing nature of the guidance.

This rationale is a guide and should not replace discussions with Transplant Centres, Tissue Establishments, Microbiologist and other experts where necessary. SaBTO guidance on the microbiological safety of human organs, tissue and cells used in transplantation ([www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/215959/dh\\_130515.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215959/dh_130515.pdf)) will also provide more information on many of the questions below.

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<p><b>FOR PAEDIATRIC DONATION:</b> has your child been breast-fed in the last 12 months?</p>	<p>There is a risk of vertical transmission of some blood borne viral infections from the mother to her child via breast milk</p>	<p>The mother's medical, social and behavioural history should be assessed and both a maternal and infant blood sample must be taken for full microbiological screening</p>	<p>As organ donation</p>
<p>NOTE: for all patients under the age of 18 months and any baby or child who has been breast-fed in the last 12 months, a blood sample is required from the mother of the patient</p>	<p>Some infections can be transmitted from the mother <i>in utero</i>, at birth and perinatally. Examples of some of those viruses, which are also transmissible by transplantation, are CMV, HIV, HBV, HTLV and HCV</p>	<p>If the death of the neonate falls within 48 hours of birth, a full microbiological screening of the mother is required as the mother will be the only possible source of infection in the neonate</p> <p>For death between 48 hours and 28 days of birth, if there has been no identifiable intervention risk, the same microbiological screening on the mother applies. If, however, there are identifiable risks (e.g. transfusion) then a full microbiological testing of the mother <b>and</b> nucleic acid testing (NAT) of the neonate is currently advised by SaBTO, where possible. NAT may not be possible at the time of donation and this should not delay or be a contra-indication for donation. Risk assessment can still be carried out, inform transplant centres. From 28 days of age up to 18 months full microbiological screening of the infant and the mother are both required</p> <p>Refer to SaBTO guidelines for further information</p>	<p>As organ donation</p>
<p><b>For ALL female patients aged between 13 and 53 years of age</b> Is there a possibility that you relative could be pregnant?</p>	<p>If there is a possibility that the patient could be pregnant then a pregnancy test should be performed to determine whether the foetus is viable</p>	<p>If a pregnancy test is confirmed as positive, the donation process should be paused and expert advice should be sought to enable individual case assessment</p>	<p>As organ donation</p>
<p><b>GENERAL HEALTH INFORMATION</b> <b>Was/did your relative or you (if completing as mother of paediatric donor):</b></p>			
<p>1. Visit a general practitioner in the last two years?  2. Currently seeing or waiting to see a general practitioner or any other healthcare professional?</p>	<p>These are broad questions to ascertain if there are any long term/current health problems. If the answer to either is yes, it is important to obtain as much information as possible including symptoms, diagnosis, investigations and medications prescribed</p> <p><b>Note:</b> It is important to obtain accurate information on past/current medical history. Therefore it is a requirement</p>	<p>Attempts should always be made to contact the</p>	<p>As organ donation</p>

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	that the GP is contacted to complete the NHSBT GP questionnaire (FRM1602)	GP prior to the retrieval of organs. If following these attempts, the GP cannot be contacted; this <b>MUST</b> be completed within three working days. Any new relevant information must be shared appropriately.	
3. a Did you relative have diabetes? If yes, were they on insulin?  3.b Is there a family history of diabetes	Due to the effect diabetes can have on a number of organs particularly the kidneys, this information helps inform transplant centres when considering organs for transplantation	If yes, absolute contraindication for pancreas and islet donation Refer to POL188 (Contraindications to Organ Donation)	
4. Take regular medication?	This is a broad question to ascertain if there are any long term/current health problems. Include type of medication, length of therapy and reason for treatment		
5. Ever undergo any investigations for cancer or were they ever diagnosed with cancer?	The presence, or previous history, of malignancy poses a risk of transmission of malignant cells to a recipient. If yes, obtain further information regarding dates, diagnosis and treatments	It is important to assess the type, grade and time scales of any malignancy, as certain types are contraindicated in organ donation. Refer to POL188 (Contraindications to Organ Donation)	If organ and tissue donation is contraindicated, corneal donation may be possible. Refer to current version of TDSG-DD
6. Recently suffer from significant weight loss?	Recent weight loss may be an indication of illness, including malignancy. It is important therefore to obtain the reason for the weight loss, if it was investigated, or accompanied by other problems, or if it was planned	If unplanned weight loss, inform recipient centres	As organ donation
7. Ever suffer from any bone, joint, skin or heart disease	Responses will inform transplant centres and tissue establishments when assessing the patient's suitability to donate. Specific diseases may preclude donation		If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated
8. Have a history of eye disease or undergo eye surgery or laser treatment?	This question is specifically designed to assess the suitability of ocular tissue		
9. Ever have any operations?	If the answer is yes, it is important to obtain as much information as possible, such as reasons for surgery, as this may provide important past medical history		
10. Ever have any surgery on the brain or spine?  If yes, was this before 1993?	Before 1993 dura mater from cadaveric donors, which has been known to transmit CJD, was used in brain and spinal surgery. Therefore where this answer is yes, the patient is at increased risk. Clarity should be sought on type of procedure, dates and location/hospital where procedure occurred		If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated
11. Ever have an organ or tissue transplant	This will provide information regarding any previous requirement of immunosuppression, risk of CJD transmission if within specific time frames, and inform decision making		If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated
12. Ever told not to donate blood?	If answered yes, reason for this must be clarified. Some deferrals are due to reasons such as a patient's age or weight, however there may be other reasons such as infection risk		

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13. Receive a transfusion of blood or product(s) at any time?	<p>Try to obtain information on the type of product, such as Fresh Frozen Plasma (FFP), Platelet, Cryoprecipitate or Immunoglobulin and specific dates and country where transfusion took place. The reason for the transfusion should also be obtained as this may provide significant medical history</p> <p>Transfusions have been known to transmit bacterial, viral, protozoal and prion infections, such as CJD. Testing of blood donors for markers of infection varies by country and also by date, so level of risk will also vary.</p>	Any transfusions should be noted within EOS and the laboratory completing the microbiology testing should be informed if the potential donor received any transfusions within the last 3 weeks. Antibodies can be acquired passively through transfusions so a positive antibody test in a post transfusion sample may need to be interpreted accordingly. The laboratory interpretation must take this into account and the information should be passed on to the transplant centres	As Organ Donation
14. Suffer from recent memory loss, confusion or unsteady gait?	CNS conditions may be of infectious or non-infectious origin such as a neurodegenerative condition of unknown aetiology e.g. Parkinson disease or Alzheimer disease	Any condition should be noted, and any CNS symptoms of recent onset must be explored and highlighted to the transplant centres.	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated
15. Suffer from any type of brain disease such as Parkinson or Alzheimer's disease?	Neurological disease may be of infectious or non-infectious origin or a neurodegenerative condition of unknown aetiology e.g. Parkinson disease or Alzheimer disease		If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated
16. Have a family history of prion disease such as CJD, or were told that they were at risk of prion disease?	Individuals at familial risk of prion-associated disease are those who have two or more blood relatives with a prion-associated disease or where the family has been informed they are at risk following genetic testing and counselling. These patients are at increased risk of prion disease transmission	<p>Assessment must be made on a case by case basis and expert advice sought where necessary. 'At risk' and familial history is not an absolute contraindication to organ donation</p> <p>Refer to POL188 (Contraindications to Organ Donation)</p>	If answer yes, patient is contraindication for tissue donation
17. Ever receive human pituitary extracts e.g. growth hormones, fertility treatment or test injections for hormone imbalance?	Human Pituitary extracts have been known to have been contaminated and have led to the transmission of CJD. They have not been used in the UK since 1985, however it is uncertain as to when their use was stopped in other countries		If answer yes, patient is contraindication for tissue donation
18. Suffer from any chronic or autoimmune illnesses or disease of unknown cause?	Some diseases of unknown aetiology, such as multiple sclerosis, inflammatory bowel and chrons disease, may have a yet unrecognised infectious origin. More importantly, if there is a current process that is suspected to be of infectious origin but a cause has not been identified, there is a risk of transmission		If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated
19. Ever have hepatitis, jaundice or liver disease?	Jaundice can have infectious causes, such as viral hepatitis, and non-infectious causes, such as gallstones. Enquire regarding dates, causes, diagnosis, investigations and treatments		

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20. Ever have any other significant infection?	Significant infections can be regarded as any infection where an individual has required investigations, hospitalisation or a specialist referral. Infections identified in this section, such as meningitis, and tuberculosis, may be transmittable during transplantation depending on the detail. Therefore it is important to ascertain diagnosis, treatments, and dates	Refer to POL188 (Contraindications to Organ Donation)	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated
21. Have any signs of recent infection e.g. colds, flu, fevers, night sweats, swollen glands, diarrhoea, vomiting and skin rash?	Answers to this question will add to the clinical picture. It is important to enquire as to any treatment given, investigations and duration of illness.		
22. Come into contact with an individual with an infectious disease recently or have any immunisations within the last 8 weeks?	Potential donors who have been in recent contact with an infectious disease may be in the asymptomatic stage of an infection at the time of donation  Immunisations with live vaccine may cause severe illness in people who are immunosuppressed. By eight weeks any infection caused by the immunisation should have been controlled and so should not be passed on through donated organs or tissues. Very recent vaccination with HBV vaccine for instance (7 days) can give positive result for HBsAg during screening, which does not mean infection.	Enquire regarding dates, type and nature of exposure, who was ill and what the diagnosis was.  Laboratory completing the donor microbiological screen must be informed	If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated
23. Have any acupuncture, tattooing, body piercing, botox, injections or cosmetic treatments that involve piercing the skin in the last 4 months?	Any piercing of the skin for these reasons may carry a risk of viral disease transmission depending on the standards of practice. It is helpful to ascertain where and when the treatment was carried out, as if carried out in certain establishments, i.e. NHS, tissue donation may be possible. During this period, if infection has occurred, it may not be detected by serological tests (window period).		If answer yes to this question refer to current TDSG-DD as tissue donation may be contraindicated
24. In the last 12 months has your relative been bitten by or been in close contact with a bat anywhere in the world, or been bitten by any other animal whilst abroad.	Exposure to animal secretions (e.g. bites or exposure to saliva through broken skin) may result in infections, for example rabies. In the UK the only risk of rabies comes from contact with infected bats. Outside the UK, bites and scratches from infected mammals, (more commonly dogs and cats), can be a source of rabies in endemic countries.  A potential exposure to rabies is significant at any time, so if the NoK volunteers a significant exposure, obtain information regardless of time elapsed.	If the answer to this question is yes, as much information as possible must be ascertained. Important questions to ask include:  Place of incident (country, region, area)  When did it happen? Time of the day?  Circumstances of incident - e.g. Was the bat dead or alive? What the dog bite provoked or unprovoked? Was it directly on bare, broken or unbroken skin?  Was any medical advice sought afterwards? Any treatment?  Would any one else have further information?	Tissue donation is contraindication if the patient has ever been bitten by a non-human primate, has any animal bite where the wound is infection or not healed, or if it is less than 12 months since being bitten anywhere in the world by a bat or any mammal outside the British Isles.  refer to current TDSG-DD

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<p><b>TRAVEL RISK ASSESSMENT :</b>                      This group of questions are designed to establish the risks of a potential donor having/being at risk of an infection which is not endemic within the UK. Due to the evolving patterns of infections worldwide, when a detailed travel history has been obtained it is necessary to consult both the TDSG-DD (link above) and the Geographical Disease Risk Index (GDRI) (<a href="http://www.transfusionguidelines.org.uk/dsg/gdri">http://www.transfusionguidelines.org.uk/dsg/gdri</a>) for up to date information on the risk assessment criteria. It is the responsibility of the SNOD to gather appropriate information, <b>including date, length of travel, destination and purpose of trip;</b> document and communicate to transplant centres.</p>			
<p>25. <b>In the last 12 months</b> did your relative go outside the UK (including business trips)? If yes, please give details of date and destination visited</p>	<p>Any travel within 12 months may trigger further investigations for potential diseases such as malaria. Certain infections are distributed geographically and the risk of exposure will depend on the length of time and activities performed in the area. Full details are important including area, dates, duration, nature of visit, type of activities.</p>	<p>Due to continual changing guidance in relation to travel refer to current GDRI</p> <p>Document on EOS if any additional tests are being processed</p>	<p>Due to continual changing guidance in relation to travel refer to current TDSG-DD and GDRI</p>
<p>26. Was your relative born outside the UK or have they ever lived or stayed outside the UK for a continuous period of 6 months or more?</p>	<p>Certain infections are distributed geographically and the risk of exposure will depend on the length of time and activities performed in the area. For some infections, risk is highest for residents of endemic areas, regardless of how long ago they have left the area</p> <p>Individuals who have lived in a malaria affected areas, particularly from early age, may develop a partial immunity to malaria through repeated exposure; they very often have no symptoms, despite infection being present</p>	<p>Due to continual changing guidance in relation to this aspect refer to current GDRI</p> <p>Document on EOS if any additional tests are being processed</p>	<p>Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI</p>
<p>27. Did your relative ever have malaria or an unexplained fever which they could have picked up whilst abroad?</p>	<p>Malaria and other endemic infections such as West Nile Virus and T. cruzi can be transmitted by blood, organs, tissues and cells</p> <p>Full details are required, including date and duration of visit, and any treatments or investigations undertaken</p>	<p>Due to continual changing guidance in relation to this aspect refer to current GDRI</p> <p>Document on EOS if any additional tests are being processed</p>	<p>Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI</p>
<p>28. Did your relative ever go to Central America, Mexico, or South America for a continuous period of 4 weeks or more?</p> <p>Was your relative's mother born in Central America, Mexico or South America?</p>	<p>Individuals who have ever been in certain areas such as impoverished, rural communities (refer to SaBTO guidelines) of Central America, Mexico or South America for a period of 4 weeks or more may be at risk of T. cruzi infection. Full details are important including area, dates ,duration, nature of visit, type of activities</p> <p>T. cruzi infection can be passed vertically from mother to child so that a child born outside this area and who has</p>	<p>Due to continual changing guidance in relation to this aspect refer to current GDRI</p> <p>Document on EOS if any additional tests are being processed</p>	<p>Due to continual changing guidance in relation to this aspect refer to current TDSG-DD and GDRI</p>

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	never travelled to this area is still at risk of infection if their mother was born within the stated areas		
<b>BEHAVIOURAL RISK ASSESSMENT</b>			
<b>To the best of your knowledge did your relative?</b>			
29. a Consume alcohol	The effect of alcohol can impact on the quality of liver tissue. If yes, it is important to obtain as much information as possible. How much did the potential donor drink per day? What they drank (e.g. beer, spirits, wine etc)?		
29. b Smoke tobacco or any other substances	The effect of smoking can impact on the quality of lung tissue. If yes, it is important to obtain as much information as possible. How much did the potential donor smoke, what did they smoke and if they stopped smoking, when did they stop?		
<p>Based on information obtained from blood donors who tested positive and epidemiological data from larger populations, it is known that certain groups of people may be at increased risk of infection by HIV, HCV, HTLV and HBV. Unfortunately it is not possible to exclude all cases of infection by relying on blood testing alone as infected donors may not be identified in the very early stages of infection, commonly referred to as the 'window period'. This refers to the period between being infected and the appropriate test being able to detect the infection. It takes a number of days/weeks for an infected individual to start forming antibodies, and a number of weeks before the antibody levels are high enough to be detected by using an antibody detection test, however, tests that are based on antigen detection will identify the infection earlier. During all this period the potential "negative" donor is infectious. The focus of this group of questions is to identify behavioural risks that can be associated with increased risk of infection. It is particularly important to note recent risks; whilst established blood borne infections will be detected through screening, very recent ones may not. Information must be passed onto to the labs and transplant centres.</p>			
30. a Is it possible any of the following apply to your relative: Was, or may have been infected with HIV, hepatitis B or C, or HTLV?	These blood borne viruses can all be transmitted via organ/tissue donation	Refer to POL188 (Contraindications to Organ Donation)	If yes to this question tissue donation is contraindicated
30. b Ever, injected or been injected with non-prescribed drugs, including body-building drugs, even if it was a long time ago or only once?	Individuals with a history of intravenous drug use remain the largest group diagnosed with HCV infection in the UK. They also have a higher rate of HIV and HBV infection. Ascertain if there was frequent exposure and dates of any exposure		If yes to this question tissue donation is contraindicated
30. c Been in prison or a juvenile detention centre for more than 3 consecutive days in the last 12 months?  <i><u>NB:</u> This excludes those who have been in a police cell for &lt;96 hours.</i>	Individuals in prison are at a higher risk of being exposed to transmissible viruses through sexual contact and intravenous drug abuse ascertain details of dates and duration		If yes to this question tissue donation is contraindicated

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31. Was your relative ever sexually active? If no, go to question 33. If yes, it is possible that your relative has:			
31. a Ever given payment for sex with money or drugs?	Individuals who receive payment for sex are at a higher risk of contracting HIV/hepatitis B or C and other sexually transmitted diseases. The increased risk could be related to the high number of sexual partners, the potential promiscuity of these partners and possible drug related habits		If yes to this question tissue donation is contraindicated
31. b Ever have a sexually transmitted infection?	If the answer is yes, ascertain type of infection, treatment and dates. Untreated STIs may eventually cause damage to many organs and tissues or could be transmitted to the recipient		Acceptance criteria are specific for each condition, refer to current TDSG-DD.
32. Was your relative sexually active in the last 12 months? If yes, is it possible that in the last 12 months your relative had sex with:			
32. a (for male patients only) another man?	Men who have sex with men have a much higher prevalence of HIV infection and other sexually transmitted diseases		If yes to this question tissue donation is contraindicated
32. b (for female patients only) a man who has ever had sex with another man?	The sexual partners of individuals who fall into the above category (32a) are at higher risk of HIV infection and other sexually transmitted diseases		If yes to this question tissue donation is contraindicated
32. c Anyone who is HIV or HTLV positive? 32. d Anyone who has hepatitis B or C? 32. e Anyone who had a sexually transmitted disease? 32. f Anyone who has ever been given payment for sex with money or drugs? 32. g Anyone who has ever injected drugs? 32. h Anyone who may ever have had sex in a part of the world where AIDS/HIV is very common (this includes most countries in Africa)?	Transmission of blood borne sexually transmitted diseases is higher in individuals who fall into these categories  There is a higher risk of contracting some sexually transmitted infections in some parts of the world where they are more common.		If yes to any of these questions tissue donation is contraindicated
<b>33. Having answered all the previous questions is there anyone else who you think may provide more information? If YES, please specify details.</b>		<b><i>This question provides the opportunity to suggest others who may have alternative knowledge of any aspects of the patient's history. For example parents for past medical history or close friends for behavioural history.</i></b>	