**Guidelines for the Blood Transfusion Services**

**Chapter 20: Tissue banking: selection of donors**

http://transfusionguidelines.org/red-book/chapter-20-tissue-banking-selection-of-donors

# Chapter 20:

# Tissue banking: selection of donors

## 20.1: General considerations

The overall responsibility for applying the policies for the selection and care of tissue donors lies with the Tissue Establishment authorised clinician, who must have relevant clinical experience and will be familiar with the various legal statutes and relevant documents which apply to tissue banking (see Chapter 19). The Tissue Establishment authorised clinician must consult with relevant specialist advisors as appropriate.

The authorised clinician will rely on procedures and documentation that enable the appropriate medical and behavioural history to be acquired, to prevent microbial infection and transmission of disease (for example neurodegenerative disease) to the recipient[1,2]. Decisions on donor assessment should be consistent with JPAC *Donor Selection Guidelines*.[3]

Tissues must be procured, transported, processed, stored, and distributed according to the regulatory requirements specified in Chapter 19 of these guidelines.

Procedures must be in place to document a complete audit trail from donor to recipient. Tissue Establishments must ensure that tissues can be traced from the donor to the point of issue. It is the responsibility of the hospital to ensure procedures are in place to document the fate of the tissue from its receipt to its use or discard. Tissue Establishments should have end user agreements in place with all hospitals to whom they provide tissue to ensure hospitals are aware of these requirements and have agreed to comply with them, and systems in place, such as periodic audit, to ensure this is being done. Evidence of such checks should be retained by Tissue Establishments. This will ensure that the audit trail can be followed in both directions. Clinicians caring for the recipients of tissues associated with risks identified following the issue of tissue must be informed where pertinent. Mechanisms should be in place to ensure that confidentiality is maximised.

UK Blood Transfusion Services Tissue Establishments may collect tissues from donors referred to them by Specialist Nurse Practitioners for Organ or Tissue Donation or another Tissue Establishment and may also refer donors to other Tissue Establishments. Whenever information regarding donor medical and behavioural history and/or consent for donation is obtained by, or on behalf of, a third party this must be subject to a written agreement between the parties involved. The agreement must specify what information is required regarding the medical and behavioural history of the donor and consent for donation, the standards for obtaining this information and the responsibilities of both parties in ensuring that the information is accurate and properly documented. The information should, as a minimum, be provided in accordance with the guidance in this document, regulatory requirements and the current JPAC *Donor Selection Guidelines*.[3] It is the responsibility of the designated clinician to determine the Tissue Establishment's policy for the referral of donors. Donors must be excluded from donation if any of the

criteria defined in Annex A of the HTA's Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment[4] apply, unless the donation is justified on the basis of a documented risk assessment process approved by the establishment's Designated Individual.

## 20.2: Consent

Consent must be obtained and documented by appropriately trained professionals competent in the issues and processes of tissue donation. No coercion or inducement to donate can be applied during the consent procedure. The statutory requirements for consent are detailed in the relevant national legislation. Further detailed guidance is laid out in the Human Tissue Authority Codes of Practice: Code A Guiding Principles and the Fundamental Principle of Consent[5], Codes F part one and two[6], the Code of Practice on the Human Transplantation (Wales) Act 2013[7], and in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.[4]

Living donors must be competent to give consent before donations can be accepted, and be provided with the opportunity to consider and receive responses to any questions they may have. Where donors are not competent to provide consent, national legislation and the guidance of the Human Tissue Authority (HTA) must be followed. When a deceased person (while alive and competent) has explicitly consented/given authorisation to donation of organs and tissues then that consent/authorisation is sufficient for the activity to be lawful. Where the decision or wishes of the deceased person are unknown, the Human Tissue Authority Codes of Practice should be followed which reflect the legal requirements in each UK nation.

Consent/authorisation where donated tissue is to be used for transplantation must cover retrieval, testing, storage, discard and access to medical records. If the tissue may be used for non-clinical purposes, as specified in the HTA Code of Practice A, specific consent/authorisation must be obtained for this as well. Living donors and families of deceased donors must be informed that information relating to the donation will be stored in accordance with the Data Protection Act (2018)[8] and may be shared with relevant healthcare professionals.

For deceased donors, information to be supplied to the next of kin regarding various aspects of tissue donation which forms the basis of consent should include the following:

- that reconstruction will be performed following retrieval
- generic information on which tissue is to be retrieved and the clinical purpose to which it is likely to be used
- if tissue is found to be unsuitable for clinical transplantation it will be discarded via local discard policies or, if permission is granted, it may be used for research or educational purposes
- that the donor will be tested for markers of microbial infection including HIV, hepatitis, HTLV and other infections and after individual case assessment, those relevant contacts will be informed in the event of a relevant confirmed positive result
- that details of medical and behavioural history will be sought from additional professional sources and recorded.

Where the Coroner (the Procurator Fiscal in Scotland) is in legal possession of the body, permission must be requested to undertake the retrieval. It is good practice if this can be done in writing.

## 20.3: Medical and behavioural history

The information noted in the following two subsections for living and deceased donors should be reviewed by the designated clinician who is familiar with the relevant standards in the field of tissue banking (see Chapter 19).

### 20.3.1: For living donors

Medical and behavioural history must be sought by appropriately trained professionals and in compliance with the following guidance.

- Information may be obtained from the donor by either face-to-face interview or by recorded telephone interview by appropriately trained Tissue Establishment staff. This must allow for the exclusion of lifestyle infectious risks. During interviews, a mechanism should be in place to ensure that confidentiality is maximised.
- The interview must be conducted while the donor is free from the effect of anaesthetic, hypnotic or narcotic medication. The donor must be mentally competent to give an accurate history.
- If the medical interview is not done at the time of admission for surgery, a system must be in place to capture any relevant medical and behavioural history changes that may occur in the interval between interview and donation.
- A standard questionnaire to elicit the medical and behavioural history must be used.
- Donors should be selected according to the regulatory requirements and *JPAC Donor Selection Guidelines*.[3]
- The completed questionnaire must be retained as part of the Tissue Establishment donor record.
- If considered necessary, and they are available, the medical records must be consulted to review the medical and behavioural history and the medical examination.

Further medical history may be sought, where appropriate, from:

- the general practitioner
- any other relevant medical personnel.

### 20.3.2: For deceased donors

The cause of death and the medical and behavioural history should elicit whether the donor meets the selection criteria outlined in the regulations and JPAC *Donor Selection Guidelines*.[3] Modifications for the behavioural and medical history questions may be needed when accepting paediatric donors. Where the deceased donor is less than 18 months of age, or breast fed within the 12-month period prior to donation, the mother’s risk for transmissible disease must also be evaluated. Information must be sought from the following sources by appropriately trained professionals and must be documented using a standard form:

- The donor's next of kin or other person identified as the most likely to be in possession of relevant information. This may not necessarily be the same person(s) as defined in the hierarchy of consent /authorisation.
- The medical notes if the donor was admitted to hospital prior to death.
- The general practitioner.
- The post-mortem (where one is undertaken). If no post-mortem is undertaken, the cause of death of the donor, as ascertained from the medical notes, must be documented in the Tissue Establishment donor record.

A record must be made of how the donor was identified (e.g. toe tag, wristband) and by whom.
The deceased donor's external appearance should be thoroughly examined at the time of retrieval. The appearance must be documented with respect to the donor's medical and behavioural history, including the presence of any obvious medical intervention, scars, tattoos, skin or mucosal lesions, jaundice, infection, trauma or needle tracks.

The date and time of death must be documented, and where applicable the time the body was refrigerated.

## 20.4: Tissue-specific donor considerations

Reference must be made to the JPAC *Donor Selection Guidelines*[3] document for ages and other specific donor requirements for different tissues.

## 20.5: Donor testing

The general principles of microbiological testing and the specific testing requirements for tissue donors are covered in Annex B of the HTA's Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment, and Chapter 9 of this Guide. Testing must be completed in a licensed Tissue Establishment or under a third-party agreement between the testing laboratory and the licensed Tissue Establishment. If a third-party laboratory is used to perform any aspect of donor testing, the specific requirements and responsibilities of both parties in achieving them must be defined in a written agreement. Such testing should, as a minimum, be performed in accordance with regulatory requirements and the guidance in this document. There should be protocols for assuring the veracity and security of the sample, labelling, and supporting documentation. The time from sample acquisition to initial processing, testing or freezing of the sample should be minimised and must be compliant with test kit manufacturers' recommendations. Any deviations from these must be validated for the purpose. Due consideration should be given to dilution of the sample (see section 20.7).

The Tissue Establishment should have a documented policy to follow in the case of donors with reactive screening tests. There should be protocols for alternative or confirmatory testing and acceptance or rejection of donations.

A positive result should be notified urgently to the source Tissue Establishment, Specialist Nurse Organ Donation or supplier of the tissue or cells so that clinicians in all centres that have received material from the same donor can be informed and take appropriate action. Where tissue or cells from a donor have been

sent to other Tissue Establishments  or centres, these Tissue Establishments or centres must be told about the positive result. Reports of positive tests should be included in the routine donor surveillance programmes and notified to the relevant public health authority. (See section 21.8).

In addition to mandatory tests done on all donor samples, additional discretionary testing may be required (e.g. for malaria, Chagas disease or West Nile Virus), dependent on the donor's travel history. RhD testing may be required on donors if the retrieved tissues will contain residual red cells or red cell membranes at the time of implantation. Discretionary tests, where undertaken, must be undertaken in accordance with the requirements set out above, to ensure that results can be relied upon.

## 20.6: Living tissue donor samples

All blood samples from living tissue donors must be acquired using positive donor identification by an individual trained to ensure the security of the sample and supporting documentation. Living tissue donors can be tested by either a single sample taken at the time of donation where testing includes a nucleic acid amplification technique (NAT) for, as a minimum, HIV, HBV and HCV, or by two samples including a post 180-day quarantine sample where additional NAT testing is not required. For guidance relating to living stem cell donors, please see Chapter 22.

Where only a single sample is tested the 'donation sample' must be obtained at the time of donation or, if not possible, within 7 days post-donation.

Where two samples are tested the post 180-day sample is required after an interval of at least 180 days from the date of donation. In these circumstances of repeat testing, the donation sample can be taken up to 30 days prior to and 7 days after donation. When the donation blood sample is taken prior to the date of tissue donation a system must be in place to ensure that the pre-quarantine sample reflects the risk status at the time of donation. Tissue must not be released from quarantine until the results from both the donation sample and the post 180-day sample have been reviewed and accepted in accordance with defined procedures.

For amnion donation only a maternal sample is required, i.e. a cord blood smaple is not required.

## 20.7: Deceased donor samples

Appropriate mechanisms must be in place to ensure:

- The secure identification of samples obtained from hospital laboratories. Where there is doubt about the identity of a blood sample from a tissue donor (inadequate labelling), DNA profiling may be accepted as an accurate method for confirming the identity of the blood sample.
- Documentation of the date and time the sample was taken, the name of the individual and laboratory supplying the sample and sample storage conditions.

An ante-mortem blood sample, up to 7 days preceding death, is always preferable to a post-mortem sample for testing. Where no ante-mortem sample is available, then a post-mortem sample can be used. Samples for testing must not be taken more than 24 hours post-mortem and the time from sampling to testing or freezing of the sample should be minimised and must be consistent with the test kit manufacturer's recommendations or validated for the purpose.

The anatomical site from which the post-mortem sample was obtained should be documented. The sample appearance should be documented. If the sample appears dilute or grossly haemolysed, a repeat sample, preferably from an alternative site, should be obtained if possible. Tissue Establishments should have a protocol for post-mortem sampling, clearly defining preferred sites for sampling (e.g., cardiac puncture or femoral vessel puncture and avoiding sites close to intravenous lines).

Where a deceased donor with significant blood loss has received ante-mortem transfusions, a pre-transfusion sample should be used whenever possible for testing. If a pre-transfusion sample is not available, Tissue Establishments must employ an algorithm incorporating the timing, nature and volume of the fluids infused and the donor's own blood volume to assess any resultant plasma dilution (see the JPAC *Donor Selection Guidelines*[3] for an example of a deceased donor intravenous fluid report form). Samples of blood estimated to be more than 50% dilute are not suitable for testing unless the testing procedure is validated.

For post-mortem samples, concluded test results other than negative for current infection will debar tissues from release unless a superior sample can be obtained (e.g., obtained ante-mortem or closer to the time of death), and this sample is tested and negative results are obtained. The acquisition of the 'superior' sample must be subject to the same requirements given above.

There must be a documented process for the resolution of discrepant test results, underpinned by a risk assessment authorised by the Designated Individual

For neonatal sample requirements for testing, see Chapter 9.

## 20.8: Follow-up

There is a duty of care to the donor and/or donor's family. For donors who on confirmatory testing have positive or indeterminate results, there should be protocols in place for contacting, informing, and referring the donor, for further investigation and treatment as appropriate. Similarly, there should be processes in place for informing relevant contacts of deceased donors as appropriate.

Confidentiality must be ensured, and for living donors, the donor's permission sought prior to referral for further medical follow-up and assessment. If the donor is still in hospital, the results may be given through the medical team, provided that this is covered by the consent.

In the case of a deceased organ and tissue donor, the initial contact should be by the medical team who provided clinical care at the time of death, or in the case of a deceased tissue donor where death occurred outside a healthcare facility by the Specialist Nurse Organ Donation or the Tissue Establishment. They should ensure that those close contacts of the deceased donor for whom results may have health implications are appropriately informed.

## 20.9: Autologous tissue donation

The designated clinician should decide the policy in relation to the provision of an autologous service. Autologous donors should be tested for the same microbiological markers as for an allogeneic living donor. Where the tissue is to be stored, microbiological testing must include bacteriological culture, where the

tissue does not undergo a validated terminal antimicrobial treatment (for allogeneic tissues see Chapter 21). The medical history may be less relevant than for allogeneic donation of tissues. The rationale for any exceptions must be documented. Testing requirements for allogeneic tissues are detailed in Chapter 21.

Separate storage must be used to avoid inappropriate issue. Autologous tissue must be securely segregated from allogeneic tissue at all stages from collection to issue. Autologous donations must not be issued for allogeneic use.

A system must be in place to enable the hospital to recognise that the tissue is autologous. The autologous tissue must be labelled with the patient's name, hospital number and date of birth.

## 20.10: Archiving of donor samples

An archive blood sample should be kept for look-back investigations in the event of an adverse reaction. It is recommended that this should be for a minimum of 10 years from the date of donation.

Tissues can be held for a number of years prior to issue. During this period in storage there may be changes to the mandatory microbiology test requirements and improvements in screening assays for mandatory or other markers. Consideration should be given for an additional blood sample archive for tissues with a long expiry for possible future testing that is not currently available.

When new, or significantly improved, mandatory tests are introduced consideration should be given to the re-testing of archive samples from the donors of tissue still in issuable stock. Where there is no archive sample available to test, a risk assessment must be performed. It should include factors such as the seriousness of the infection, any viral inactivation procedures performed on the tissue, the effect on inventory of discarding such tissues and the severity of impact of possible tissue shortages on recipients.

## 20.11: Release criteria

For allogeneic donors the concluded result of all microbiological assays, with the exception of syphilis and anti-HBc, must be negative for a tissue to be released from quarantine for issue. For donors who are found to be 'repeat reactive' in any screening assay but for whom subsequent testing confirms lack of infection, the initial reactivity in the screening assay is due to non-specific reactivity and any tissue products from this donation may be safely released for clinical use (see Chapter 9). In the case of allogeneic donors, the completed donor records must be reviewed and assessed for suitability and signed by a registered healthcare professional.

In the case of a deceased infant donor where a maternal sample is found to be positive for any mandatory marker of infection, the donation must not be used irrespective of the test result for the infant.

Donors with reactive confirmatory tests for the presence of treponemal infection should be fully assessed, taking into account the results of confirmatory (reference) testing and medical history. The presence of current (active) infection will exclude the use of tissues from such donors. Where the assessment leads to the conclusion that the risk of active infection is remote, then non-cardiovascular tissues may be used. The presence of serological marker patterns of treponemal infections (e.g. IgM positivity) should not be used as a sole criterion to determine the presence of active infection (and therefore their eligibility). Any reactive results obtained on confirmatory testing should be discussed with staff experienced in interpreting treponemal test results, before a decision is made to use tissues.

For autologous donors positive test results will not necessarily prevent the tissues or cells or any product derived from them being stored, processed and reimplanted, if appropriate isolated storage facilities are available to ensure no risk of cross-contamination with other grafts and/or no risk of mix-ups at issue.

## 20.12: References


1. SaBTO (2017) Blood, tissue and cell donor selection criteria report: 2017 (updated 2019) https://www.gov.uk/government/publications/blood-tissue-and-cell-donor-selection-criteria-report-2017
2. SaBTO (2020). Microbiological Safety Guidelines. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876161/SaBTO-microbiological-safety-guidelines.pdf
3. Joint UKBTS Professional Advisory Committee's (JPAC) Donor Selection Guidelines. Available at www.transfusionguidelines.org
4. Human Tissue Authority Guide to the Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment. Available at www.hta.gov.uk
5. Human Tissue Authority Code of Practice Code A – Guiding Principles and the Fundamental Principle of Consent. Available at www.hta.gov.uk
6. Human Tissue Authority Code of Practice Code F parts 1 and 2 - Donation of solid organs and tissue for transplantation. Available at www.hta.gov.uk
7. Human Transplantation (Wales) Act 2013. Available at http://www.legislation.gov.uk/anaw/2013/5/contents/enacted
8. Data Protection Act 2018. Available at https://www.gov.uk/data-protection