HTA
Human Tissue Authority

Guidance for Transplant Teams and Clinicians

Published: March 2015
(updated April 2024)

Contents

Introduction

1. This document provides guidance to clinicians and transplant teams about the regulatory requirements for the assessment of living organ donations by the Human Tissue Authority (HTA).

2. Where the word organ is used, unless specified, this refers to kidney, liver lobe, small bowel and uterus.

3. This guidance, along with 'The Quality and Safety of Organs Intended for Transplantation: a Documentary Framework', supplements the HTA's code of practice F, part one: Living organ donation.

Legislative Framework

4. The Human Tissue Act 2004 (the HT Act) sets out the licensing and legal framework for the storage and use of human organs and tissue from the living, and also for the removal, storage, and use of human organs and tissue from the deceased.

5. The HT Act makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue, and the removal of material from the bodies of deceased people. The HT Act requires consent for the storage and use of organs or part-organs taken from a living or deceased person, for the purpose of transplantation.

6. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) is the secondary legislation that sets out the requirements that must be met in order for the legal restriction on living organ donation to be lifted. Please read Code of Practice F Part one: Living organ donation for information about the legal requirements under the Regulations that must be met in order for the HTA to give approval for living organ donations.

7. On 1 July 2022, an amendment was made to Section 32 of the Human Tissue Act 2004 and Section 20 of the Human Tissue (Scotland) Act 2006. This amendment extends the offences set out in Section 32 and Section 20 so that they have extraterritorial jurisdiction. These offences relate to financial or commercial dealings in human material for transplant, such as buying or selling human organs.

8. In practice, this means that any person will be committing an offence if they are involved in seeking, offering, or receiving payment or reward for donating organs

for transplantation or initiating, negotiating, advertising or being involved in buying or selling human organs for transplantation, anywhere in the world.

9. Where a patient has travelled and received an organ transplant outside the UK, this must be reported to the HTA. Please see section on 'Supply of Information about Transplants Regulations 2024'

10. Section 33 of the HT Act sets out the restrictions on transplants involving a living donor.

Overview of the regulatory framework for living organ donation

11. The purpose of regulating living donation in the UK is to make sure that donors are not made to act against their wishes, and to safeguard against people trafficking for the purpose of organ donation.

12. The HTA's role is to approve living organ donations, where it is satisfied that the conditions set out in the Regulations have been met. In short, the criminal offence that exists is only lifted when the requirements outlined below are met.

13. Specifically, the Regulations require that:

- A registered medical practitioner with clinical responsibility for the donor must arrange the referral of each case to the Authority [Regulations 11(2)]. Under the requirements of the Quality and Safety (Organs) Regulations, certain specified information from the donor's clinician, as part of this referral, is mandatory .

- The HTA is satisfied that no reward has been given or is to be given; and that where transplantable material is removed, consent for its removal for the purpose of transplantation has been given - or its removal for that purpose is otherwise lawful [Regulations 11(3)].

- The HTA must consider a report from a qualified person (the HTA uses the term Independent Assessor (IA) to designate a qualified person) [Regulations 11(4)]. The IA must interview the donor (or person giving consent on their behalf) and the recipient [Regulations 11(6)]. The report must contain information set out in the Regulations [Regulations 11(8) and 11(9)].

- The HTA must notify the donor, the recipient and the referring medical clinicians of its decision [Regulations 11(5)].

- The HTA must be satisfied that all living organ donors have given valid consent for the removal of their organ for transplantation [Regulations 11(3)(b)(i)]. For consent to be valid, it must be given voluntarily (free from duress or coercion), by an appropriately informed person who has the capacity to agree to the activity in question.

14. While the HTA must take the IA's report into account when making its decision the HTA is free to seek appropriate additional information from the donor and / or the recipient, as well as from the referring clinician before reaching a decision. In all cases, the HTA will discharge its duties in line with the principles of best regulatory practice (transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

15. In reaching a decision about whether the HTA is "satisfied" in relation to the tests described in paragraph 13 the HTA interprets the term "satisfied" to mean satisfied on the balance of probabilities when considering the tests in their entirety. For each individual test, the HTA will consider whether it has sufficient evidence to be satisfied. In situations where it is not satisfied, the HTA will provide its reasoning as part of its notice of decision, set out in the Regulations 11(5).

16. The HTA interprets "duress or coercion" to mean that the will of the person required to act has been compromised, and they can no longer make an independent decision.

Living donation concepts and definitions

17. The HT Act and the Regulations place an obligation on the HTA to assess all applications for living organ donation that are submitted. For either legislative or policy purposes, the HTA distinguishes several different concepts:

Directed donation - Where a person donates an organ to a specific identified recipient, with whom they have a genetic or pre-existing emotional relationship. These are usually assessed by the Living Donation Assessment Team (LDAT).

Directed altruistic donation - The HTA defines these as cases which fulfil two conditions:

(a) the donation is being directed to a specific individual and;

(b) there is no evidence of a genetic or pre-existing emotional relationship between the donor and recipient.

These cases tend to be characterised by a third party - either a person or other mechanism, such as a social networking website, which brings the donor and recipient together for the purpose of transplantation. Examples of directed altruistic donations include donors coming forward following a social media campaign, or donors donating to a friend of a friend.

Non-directed altruistic donation (NDAD) - Where a person donates an organ to an unknown recipient, that is, someone they have never met and is not known to them. NDAD donors usually donate their organ into the UK Living Kidney Sharing Scheme. By matching two or more donors and recipients, a chain of transplants can be carried out. The remaining organ at the end of the chain is then donated to the best matched recipient on the UK waiting list.

The Regulations state that a panel of three Board Members must make the decision on all NDAD cases.

Paired or pooled donation - This applies to kidneys only. Where a donor is unable to (or chooses not to) donate to their intended recipient because they are either incompatible by blood group or HLA (tissue) type or would prefer a closer age or HLA match. They may be matched with another donor and recipient in the same situation in the

UK Living Kidney Sharing Scheme. The donor organs are then swapped. When two pairs are involved, it is a paired donation and where more than two pairs are involved, it is a pooled donation. The Regulations state that a panel of three Board Members must make the decision on all paired/pooled cases.

Domino donation - The HTA does not regulate domino donations. This is where an organ is removed for the primary purpose of a person's medical treatment. The removed organ may prove suitable to transplant into another person. NHSBT policies and further detail can be found at www.odt.nhs.uk

Non-UK resident donor – Where a donor is resident outside the UK. These cases are usually assessed by the LDAT. Please see the section on non-UK resident donors for more information.

Relationships

18. The following is a list of relationships the HTA considers when determining the category of donation:
    - Spouse or partner
    - Parent or child
    - Brother or sister
    - Grandparent or grandchild
    - Niece or nephew
    - Uncle or aunt
    - Stepfather or stepmother
    - Cousin
    - Half-brother or half-sister
    - Stepbrother or stepsister
    - Mother-in law or father-in-law
    - Brother-in-law or sister-in-law
    - Friend of long standing
    - Work colleague

19. If a donor and recipient relationship (existing/or pre-existing) is defined on this list, then the donation will be considered by the LDAT. The HTA presumes that a case involving a donor and recipient with such a relationship will constitute a directed donation, subject to sufficient evidence of the claimed relationship being provided. This is because in most instances, the donor and recipient will have had an emotional relationship prior to the need for a transplant arising.

20. If the donor and recipient have a genetic relationship which is not included on the list, the presumption that they know each other does not exist. However, if

evidence is provided that they do have a pre-existing emotional relationship, then the case will be considered by the LDAT. If such evidence cannot be provided, the case will be designated as a directed altruistic donation. The case will be assessed either by the LDAT or by a panel of three HTA Board Members.

Independent Assessors (IA)

21. The purpose of the role is to provide an independent check to help protect the interests of living organ donors. Each individual donor has an opportunity to speak freely to someone not connected with the transplant unit to confirm that their wish to donate is free from any pressure. IAs undertake interviews on behalf of the HTA to allow it to fulfil its role. IAs therefore play an essential role.

22. IAs must be totally independent of the living organ donation process, the clinical team and the donor and recipient. This applies to both NHS and private settings. IAs are usually, but not exclusively, based in hospitals with transplant units or referring units.

23. Once trained and accredited by the HTA, IAs interview potential living donors and recipients to explore whether the requirements of the HT Act and the Regulations have been met. The findings from the interviews are strictly confidential between the IA and the HTA and are not shared with the clinical team.

24. It is the responsibility of the clinical team to inform the HTA if there is a need for additional IAs.

25. It is not the role of the IA to determine medical suitability of the donor or recipient. This is the responsibility of treating clinicians and transplant teams.

26. IAs should not have access to the donor or recipient's medical notes. This is not necessary to fulfil the statutory requirements of the IA interview.

Person specification

27. IAs must meet the following essential criteria:

- excellent oral and written communication skills;
- IT literate with an ability to grasp new systems;
- excellent interpersonal skills;

- confidence in interviewing patients and exploring and addressing distressing health issues and health risks;
- confidence to probe and challenge where necessary;
- familiar with requirements to maintain patient confidentiality;
- the ability to work confidently in a hospital environment;
- experience of report writing to a high standard;
- familiar with equality and diversity legislation.

28. IAs come from varied backgrounds and do not need to be medically qualified.

29. Once candidates have been identified, the HTA should be contacted for an application form.

30. The HTA will only accept applications from people where there is a clear need for additional IAs to be trained. The form must be completed and submitted to transplants@hta.gov.uk

31. Once the application and reference are approved, the HTA will contact the individual with details of the next training session.

32. Once IA training has been completed, an enhanced Disclosure and Barring Service (DBS) check will be conducted by the HTA. This certificate is considered valid for a period of three years. After this, it is the responsibility of the hospital to keep enhanced DBS checks up-to-date and send a confirmation to the HTA. IA training for delegates that have an existing enhanced DBS check dated within the last six months will be accepted by the HTA.

33. Following the receipt of an enhanced DBS check, a certificate confirming accreditation will be issued, and a letter of confirmation sent to the individual. A letter will also be sent to the Living Donor Coordinator (LDC), Clinical Director of the transplant unit, and Chief Executive of the Trust.

34. Once accredited, the HTA advises that newly accredited IAs observe an IA interview with an experienced IA. The HTA must be informed of changes to an IA's contact details and when an IA leaves their post.

Resources required for the IA role

35. The resources required by IAs to carry out their roles are provided by the hospital.

36. These resources include:

- Hospital email address (it is not appropriate to use personal email addresses);
- Time built into job plan / timetable where the IA is an employee of the hospital;
- A room in which to see the donor and recipient;
- Translation and interpreting services, if required;
- Access to networked IT equipment;
- Access to document scanning equipment.

IA remuneration and liability

37. The HTA is not remunerated to pay IAs. However the HTA recognises that many hospitals have chosen to provide remuneration to IAs in recognition of it being a statutory role.

38. It is recommended that any travel expenses that an IA incurs as part of this role should be paid for by the hospital.

39. The nomination of IAs must be compliant with local hospital governance arrangements.

40. All liabilities in regard to IAs and independent assessment interviews fall to the HTA. The HTA has a duty of care to act in a reasonable manner towards IAs when they are acting on behalf of the HTA; the same duty of care also extends to donors and recipients. The HTA does not have responsibility for any liabilities which an IA may incur in the course of any other work they carry out, which falls outside the role of IA.

The Living Organ Donation Assessment Process

Responsibilities of Clinicians and Transplant Teams

41. While the HTA provides advice on how our regulatory requirements will apply to individual cases, the decision on whether to work-up or refer a case rests

with the clinical team.

42. It is important for Clinical teams to remember that they can decide not to refer a case to the HTA for decision where doubt or concerns exist. It is not appropriate to refer to the IA to seek their views. Where appropriate, report to the HTA. See section on 'Supply of Information about Transplants'

43. The Regulations require the clinician with responsibility for the donor to refer the matter to the HTA for decision. The HTA has created a model referral letter template.

44. Further information can be found in the British Transplantation Society (BTS) document, UK Guidelines for Living Donor Kidney Transplantation and UK Guidelines for Living Donor Liver Transplantation

Cases which do not reach the stage of referral to an IA

45. Occasionally, there are cases that are halted during the work-up process when units take the decision not to proceed, for clinical reasons or other reasons.

46. Specifically, the HTA must be informed about cases where there has been an indication of:

- Reward (being sought by a donor)
- Reward (being offered by a recipient or third party)
- Duress (the donor being placed under pressure to donate)
- Coercion (the donor being forced to donate)
- Verbal or physical threats towards the donor.

47. It is important to note that criminal offences may have been committed even in cases that do not reach the point of being submitted to the HTA.

Prevention of trafficking - both of human beings and of organs

48. Organ and people trafficking and modern-day slavery are a concern for all healthcare professionals. IAs must remain aware of the risks and be vigilant at all times, using their professional curiosity to explore if something does not feel right.

49. There are some key signs and indicators to be aware of during contact with

living donors and recipients:

- is the donor withdrawn and submissive, or afraid to speak to anyone in authority?
- does the donor provide vague and inconsistent explanations of where they live, or their employment?
- does the donor's appearance suggest general physical neglect?
- does the donor have official means of identification?
- Is the donor in possession of their own passport, identification or travel documents? Are these documents in the possession of someone else? Do the documents look suspicious?
- Does the donor act, or do you suspect, they have been instructed or coached by someone else?
- Does the donor allow others to speak for them when spoken to directly?
- Is the donor under the impression that they are bonded by debt, or in a situation of dependence?
- is the donor accompanied by someone who appears controlling, who insists on giving information and speaking for them?
- is there an apparent significant disparity between the donor and recipient (for example, age, wealth or education)?

50. All three of the following components must be present for an adult to be considered trafficked: Action, Means and a Purpose (however, in relation to children, the 'means' component is not required as they are not able to give consent*).*

    - **Action** - Recruitment, transportation, transfer, harboring or receipt, of persons.
    - **Means** - Threat or use of force or other forms of: coercion, abduction, fraud, deception, the abuse of power, taking advantage of someone in a vulnerable position, giving or receiving payments or benefits to achieve the consent of a person having control over another person**.**
    - **Purpose** - Removal of organ(s).

51. Please refer to the Royal College of Nursing Guidance on Modern Slavery and Trafficking: Modern Slavery and Trafficking | Royal College of Nursing (rcn.org.uk)

52. If you have concerns on any of these aspects, you must involve your hospital safeguarding team. Where you have concerns about a person being in

immediate danger of harm, please call 999.

Supply of Information about Transplants Regulations 2024

53. On 1 April 2024, the Supply of Information about Transplants Regulations 2024 ('Regulations') came into force under section 34 of the HT Act. It places a statutory duty on 'relevant clinicians' in England, Wales and Northern Ireland who work closely with patients that need or have received an organ transplant to report information to the HTA if:

    a. they have a reasonable suspicion that an organ transplant-related offence has been committed under sections 32, 32A or 33 of the HT Act, section 2 of the Modern Slavery Act 2015, or section 2 of the Human Trafficking and Exploitation (Criminal Justice and Support for Victims) Act (Northern Ireland) 2015, or

    b. in the course of their profession, the clinician becomes aware that a patient has received an organ transplant outside the UK.

How to report to the HTA

54. Clinicians must report any concerns as outlined above to the HTA via our website: www.hta.gov.uk/supply-transplant-information

55. Following this, a separate form will be sent to the relevant clinician to complete. Clinicians should provide as much detail as possible. Guidance on how to complete the form is available at

56. Following submission of the form, the HTA will review the information provided and consider whether a police referral should be made. Clinicians will be updated as to whether a referral has been made or not.

    Please email report@hta.gov.uk if you have any questions.

Valid consent of the donor

57. A member of the clinical team must discuss the following areas with the donor.

- The nature of the surgical / medical procedure and the short- and long-term

risks involved, including the risk of death (this should be explained by a medical practitioner with appropriate qualifications).

- The nature of any risks specific to the donor's clinical history which may predispose them to a higher-than-average risk of developing a certain condition.

- The chances of the transplant being successful and any possible side-effects or complications, for both donor and recipient.

- The right to withdraw consent at any time before the removal of the transplantable material.

- The decision to donate must be free of duress or coercion.

- That it is an offence to give or receive a reward for the supply of, or for an offer to supply, any organ. It is also an offence to seek to find a person willing to supply any organ for reward. If found guilty of this offence, a person may face up to three years in prison, a fine, or both.

58. For potential NDAD and paired / pooled donors, a member of the clinical team must inform the donor of how the process works, and how recipients are identified.

59. A member of the clinical team must inform the donor about the nature of the interview with the IA, and that a report will be submitted for decision by the HTA. Information should be provided to the donor and recipient on the areas which will be covered in the interview.

60. Potential donors should be referred to the *"Guidance for living organ donors on the HTA independent assessment process* and Independent Assessment process HTA webpage in advance of the IA interview.

61. LDCs should also provide donors with a copy of the donor declaration form ahead of the IA interview, along with referring them to the HTAs Guidance for living organ donors on the HTA's Independent Assessment process on www.hta.gov.uk

62. The donor will be required to bring the donor declaration form to the IA interview. This can be signed either in advance of the interview, or at the interview. Where the form has been signed prior to being given to the IA, confirmation must be

sought that the signature is the donors.

Non-UK resident donors

63. Cases involving non-UK resident donors can be complex and require additional scrutiny.

64. It is important that the HTA is given sufficient time to review these cases and seek clarification where appropriate. These cases need to be submitted to the HTA prior to a transplant date being agreed where possible.

65. Where a visa is needed to enter the UK for the purposes of organ donation, the clinical team must assure themselves that the donor and recipient can provide sufficient evidence of the claimed relationship. Only then should a letter in support of the visa be written.

66. The clinical team, usually the LDC, should ask for and review all identification and evidence of relationship documents prior to considering providing a letter of support for a visa. Visas should not be supported where clear evidence of a genetic or close personal relationship with the intended recipient in the UK cannot be provided.

67. UK Visas and Immigration guidelines make clear that a genetic relationship is where the donor is a blood relative of the identified recipient in the UK. Close personal relationships would typically include spouse, partner, or close friend. It does not extend to relationships established through media or social media campaigns or remote relationships through family connections where the donor does not and/or has never had a relationship with the recipient.

68. The visa requirements are set out on page 56: www.gov.uk/government/publications/visit-guidance

Preparing donors and recipients ahead of the interview

69. LDCs must ensure that donors and recipients understand the HTA assessment process, the purpose of the IA interview and also what documentation they will need to bring to the interview.

Provision and review of ID and evidence of relationship documents

70. LDCs should ensure the ID and evidence of relationship documents are available and should review these themselves in advance of the IA interviews. This mitigates the risk of delays in the HTA's decision making due to incomplete or inadequate information being presented at a late stage. This applies to every

living organ donation case.

71. IAs should ideally be provided with the ID and evidence of relationship documents before any virtual interviews. Your local (hospital) data protection policies should be adhered to at all times.

Understanding the HTAs role and the IA process

72. LDCs should ensure they refer donors and recipients to the relevant information about the IA process and the HTA's role on the HTA website www.hta.gov.uk.

Photographic evidence of identity

73. LDCs must ensure that donors and recipients can provide sufficient satisfactory evidence of identity and relationship for the IA assessment. This applies in all cases.

74. The HTA considers the following documents to be suitable forms of photographic identification:
    - Passport
    - Photographic driving licence (including provisional license)
    - Photographic identity cards
    - Blue Badge
    - Certain concessionary travel cards e.g. bus pass
    - Identity card with PASS mark (Proof of Age Standards Scheme)
    - Biometric Immigration Document
    - Defense identity card
    - Certain national identity cards

75. If LDCs are unsure of acceptable photographic ID, please contact the HTA by email at transplants@hta.gov.uk

76. For donors and recipients who are unable to provide the of identification listed above, LDCs must state the reasons for this in the referral letter.

77. For child recipients who have no photographic ID, photographs of the child with person/s with parental responsibility where all concerned are identifiable will also be accepted.

Evidence of relationship

78. The donor and recipient must provide evidence of their claimed relationship.

79. This must be brought to the IA interview and the donor and recipient should be prepared to expect to discuss their evidence and the nature of their relationship with the IA.

Directed cases – evidence

80. For genetically related individuals (such as siblings), birth certificates of donor and recipient are required. Where there is a more remote relationship, for example a nephew donating to a maternal aunt, the birth certificate of the donor's mother will also be required and must be brought to the IA interview to support the genetic connection.

81. Where birth certificates are not available, alternative supporting information could include the following:

- Family photographs clearly spanning the duration of the relationship (recent photographs in isolation will not be accepted) and where the donor and recipient can be clearly identified.
- Text/WhatsApp/email/social media messages spanning the duration of the relationship (these are unlikely to be accepted alone as evidence of a claimed relationship, given the obvious issues in verifying the origin and source of any such material).

82. The following supporting evidence will only be considered in addition to the evidence listed above; these items cannot be the sole piece of evidence of a claimed relationship:

- Certified family tree;
- A statement / testimonial, ideally from an individual in a position of authority (e.g., Lawyer, Teacher, GP, Pilot, Accountant, Police Officer) who is able to attest to the claimed relationship.

83. For emotionally related individuals (such as spouse, partner and friend of long standing), documentary evidence could include:

- A marriage or civil partnership certificate

- Proof of joint residence, such as utility bills or mortgage/rent statements in joint names
- Photographs clearly spanning the duration of the relationship (recent photographs in isolation will not be accepted), where the donor and recipient are clearly identifiable.
- Text/WhatsApp/email/social media messages spanning the duration of the relationship (these are unlikely to be accepted alone as evidence of a claimed relationship, given the obvious issues in verifying the origin and source of any such material).

84. The following evidence may on occasion be considered in addition to the evidence listed above, this cannot be the sole piece of evidence supporting the claimed relationship:

- A statement / testimonial, ideally from an individual in a position of authority (e.g., Lawyer, Teacher, GP, Pilot, Accountant, Police Officer) who is able to attest to the claimed relationship.

85. The HTA is unable to accept affidavits as evidence of a claimed relationship.

Paired/Pooled cases – evidence

86. Donors and recipients are expected to present the evidence listed for directed cases outlined above.

Directed altruistic cases – evidence

87. The referral letter from the LDC should clearly state how the donor and recipient came to know about each other and explain how the offer of donation arose. Please also see section on 'Joint interview'.

NDAD cases – evidence

88. Donors must present photographic evidence of identity as listed in paragraph 74. As the recipient is not known to the donor, the evidence of claimed relationship is not required.

Organs or part organs that cannot be transplanted into intended recipient

89. The following guidance only applies to directed, directed altruistic and paired or

pooled donors. This guidance does not apply to NDAD donors.

90. During the work up process, LDC's must ask donors what their wishes are in the event that their organ cannot be transplanted into the intended recipient. This is a precaution to avoid the worst-case scenario of an organ being disposed of when the donor's wishes are not known.

91. Donors have the following four potential options:

- Organ can be transplanted into an alternative recipient on the UK waiting list (if the donor's preference is for another family member or friend to receive the organ, and they are a suitable donor; then an additional directed donation IA report must be submitted – please see information below in *Request for re-direction to secondary recipient if organ cannot be transplanted into intended recipient section).*

- Organ can be re-implanted into the donor (not appropriate for liver lobes)

- Organ can be used for research; or

- Organ can be disposed of.

92. Once the donor has made their choice this must be included in the referral letter.

93. HTA provides separate approval in cases where the donor has consented for the organ to be transplanted into an alternative recipient.

94. For donors who decide to have their organ re-implanted, the clinical team must explain the possible risks associated with additional surgery. They should also understand the expected function of the organ after re-implantation. LDCs must confirm in the referral letter that a member of the clinical team has explained the risks, and the donor understands them.

Request for re-direction to secondary recipient if organ cannot be transplanted into intended recipient

95. If a donor requests, in advance, to re-direct their organ to a secondary recipient, the HTA need to be satisfied that there is no duress, coercion and reward involved in the re-direction.

96. For example, a father donating to his child at the same time that his wife also requires a transplant. In the unlikely event that the organ cannot be transplanted into the child, he may wish for the organ to go to his wife instead. Therefore, a separate IA interview and report must be submitted for the secondary recipient.

Joint interviews

97. There may be exceptional cases of directed donation or directed altruistic donation where the donor and recipient do not wish to be interviewed together. For example, the donor may have offered to donate as a result of a social media campaign and wishes to remain anonymous to the recipient.

98. In these cases, the transplant team must contact the HTA to make an application for the requirement of the joint interview being withdrawn. These applications will be considered by the Director of Regulation. To manage expectations, LDCs should explain to donors and recipients that the decision not to require a joint interview can only be made by the HTA and so their wishes may not be able to be accommodated and they may need to have a joint interview.

99. The purpose of the joint interview is to allow the IA to observe the interaction between the donor and recipient, to contribute towards an understanding of whether duress or coercion are likely to be factors in the donor's decision to donate; and to explore the issue of reward jointly with the donor and recipient.

100. While the donor and / or recipient may request that a third party sits in on the interview to provide support, third parties including other family members must not attend interviews unless there is a specific need to do so.

Virtual Interviews

101. Where possible, interviews should be held face to face, however they may take place virtually. Where an interview is carried out virtually, this must be undertaken in line with the hospital's IT policy.

102. IAs should ideally be provided with the ID and evidence of relationship documents before any virtual interviews. Your local (hospital) data protection policies should be adhered to at all times.

Translation and communication issues

103. Where an interpreter has been required for discussions between the transplant team and the donor and / or recipient, this must be mentioned in

the referral letter so that the IA is aware that an interpreter will be required for the interview.

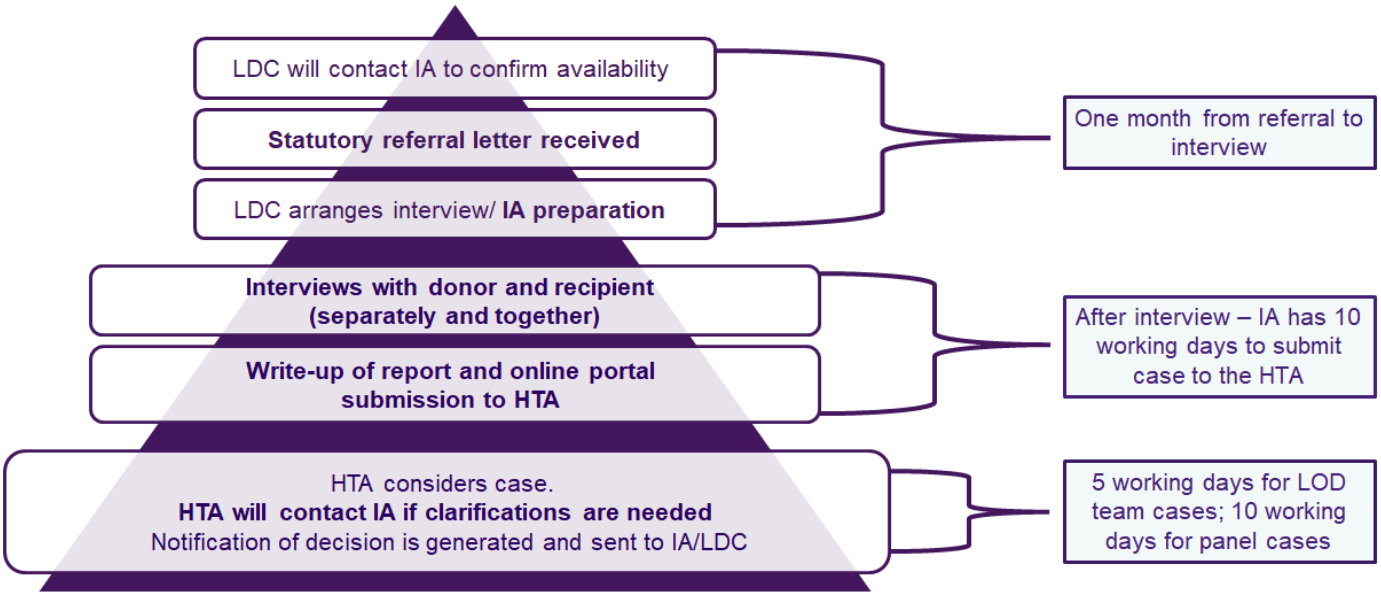
104. In situations where an accredited local independent interpreter is not available, a facility such as 'Language Line' or equivalent can be used. In the case of someone with a speech or hearing disability, an accredited interpreter with experience in signing must be used.

105. The interpreter must not have any personal connection with either the donor, the recipient or the clinical team.

106. An interpreter who is personally known to either the donor, recipient or clinical team must not be used. For example, family members and members of the clinical team must never act as interpreters. IAs may also act as an interpreter, provided that they are fluent in the specified language.

The referral and independent assessment process

107. The diagram below provides an overview of the referral and independent assessment process:



The referral letter

108. The Regulations require that a medical practitioner with clinical responsibility for the donor must have caused the matter to be referred to the HTA. The referral must state that the medical practitioner, or person acting under their supervision:

- is satisfied that the donor's health and medical history are suitable for the purposes of donation;
- has provided the donor with the information the donor requires to understand the consequences of donation; and
- has endeavored to obtain information from the donor that is relevant to transplantation.

109. As a matter of HTA policy, the HTA requests that referring donor clinicians also state that the medical practitioner is satisfied that the donor has capacity to consent to the donation. The recipient's capacity to participate in an interview should also be included, to allow the IA to make any necessary adjustments.

110. The referral letter must include information about any risks specific to the donor, and confirmation that these have been addressed by the clinical team and are understood by the donor. This may include, for example, the donor having a higher-than-average risk of developing hypertension or diabetes post donation. Where no risks specific to the donor have been identified this must be stated in the referral letter. A model referral letter is available; please refer to www.hta.gov.uk

111. The referral letter must document any risks specific to the donor in a format which can be easily understood by the IA undertaking the assessment of the donor.

The referral process

112. The referral must be made by a registered medical practitioner, or a person acting under their supervision. The HTA considers a LDC to be a suitable person to make the referral.

113. The referral is made to the HTA at the point at which it is received by the IA; however, the HTA cannot assess a case until it receives the IA report, referral letter and donor declaration. The referral letter must be provided to the IA in advance of the IA interview to enable the IA sufficient time to review these.

Emergency Out of Hours service

114. If an emergency assessment is needed out of hours, please call the HTA emergency out of hours' number on 020 7269 1991.

115. There must be a clinical need for an emergency transplant. The HTA representative will ask for confirmation that there is a clinical need for an emergency decision to be made.

116. The HTA representative will request confirmation that an IA has interviewed the donor and recipient. If the donor and/or recipient have not been interviewed by an IA, either face-to-face or on the phone (such assessments often take place over the phone), then this must be arranged. The referral letter or the donor declaration form does not need to be emailed to the HTA representative at this stage.

117. The HTA representative will then request the IAs name and contact number from the clinical representative and will contact the IA to ascertain details of the IA interview.

118. The HTA representative will assess the case, once a decision has been made the LDC will receive:

    a) verbal decision via phone and
    b) written confirmation via email of the decision

119. The usual 'Txxxx' number will not be issued and is not required for emergency case approvals. The IA will submit a retrospective report to the HTA and upload the referral letter and donor declaration form. A 'Txxxx' number will be generated at that point.

120. Out of hours' cases are rare and this process should only be used in urgent living liver lobe donation cases. The HTA recommends that all transplant units, and especially those which have a living liver programme, make arrangements for an IA to conduct interviews at short notice and out of hours.

Cases from the private sector

121. Where a transplant takes place in the private sector, clinicians must endeavor

to ensure that a LDC is involved (or equivalent role). This provides essential continuity and coordination of patient care.

122. Clinicians responsible for the care of the donor must be separate from those responsible for the care of the recipient.

123. As cases taking place in a private setting often involve non-UK resident donors, please see the section on non-UK resident donors.

Reimbursements of living donor expenses

124. Reimbursement guidelines of the hospital must be followed. The HTA advises that the clinicians refer to the relevant reimbursement policies:
    - NHS England commissioning policy for reimbursement of expenses to the living donor.
    - Living donor expenses commissioning policy - Wales
    - The reimbursement policy for Northern Ireland was being refined at the point if publication.

125. The HTA may request to review the evidence of payment of reasonable expenses and the agreement as to the basis on which the recipient (or the family of recipient) is reimbursing expenses whether these are medical, travel, subsistence or accommodation costs.

Timeframes for decision making and points to note

126. Clinical teams must allow sufficient time for referral of all cases, particularly those requiring a decision by an HTA panel of three Board Members. See paragraph 17.

127. The HTA must receive these cases from the IA by 9am on a Monday to refer to a panel that week.

128. Referrals to panel take place every Wednesday and the panel has 10 working days to make a decision. Board Members need appropriate time to make a considered decision for robust decision making, on average they each receive several cases a week for decision.

129. Requests for very short turnaround times are extremely difficult to accommodate. Clinical teams should review their referral timeframes and ensure 3 to 4 weeks are allowed before an HTA decision.

130. Clinical teams may refer donor and recipient pairs that have been registered,

but not necessarily matched, in the National Kidney Sharing scheme, for IA and HTA decision. This does not apply to recipients registered with more than one potential donor.

131. Third parties including other family members must not attend interviews unless there is a specific need to do so. Please contact the HTA in advance for advice and ensure donors and recipients are clear on expectations.

132. LDCs must arrange a follow up phone call for all cases where a transplant does not take place within 12 months. This is to ensure the donor still understands the nature and risks of procedure, there have been no changes in circumstances affecting the donor's decision to consent, and that the donor still consents to proceed with donation. Once this phone call has taken place and the IA has emailed a summary of the conversation to the HTA, the HTA will confirm whether the approval still stands. Donation should not proceed until HTA confirmation has been provided.