National Institute for Health and Care Excellence

IP253/2– Living-donor liver transplantation
Consultation Comments table

IPAC date: Thursday 16th April 2015

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Human Tissue Authority	**1.2**	Clear written information should include the HTA leaflet 'Our role in living donation' which is available in several languages. We would also recommend a reference is added to this paragraph to reflect the requirement for independent assessment interviews and statutory approval from the HTA.	Thank you for your comment. The Committee amended 1.2 as follows: – Clinicians and centres doing this procedure must follow the relevant regulatory and legal requirements of the Human Tissue Authority . This includes carrying out independent assessment interviews and getting statutory approval by the Human Tissue Authority before donation can proceed. During the consent process donors and recipients should have thorough physical and psychological screening and monitoring, and have counselling about the morbidity and risks associated with this procedure. They should also be provided with clear written information including relevant information provided by the Human Tissue Authority. In addition, the use of NICE's information for the public is recommended.

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2	Consultee 1 Human Tissue Authority	**1.3**	It is difficult to understand the relevance of the British Transplantation Society (BTS) guidelines referred to in the context of the paragraph, as it appears to be predominantly focussed on the clinical criteria each living liver donor must meet, whereas these particular BTS guidelines are non-clinical. Perhaps it would be useful in this context to explain that there are decisions to be made beyond the clinical when considering whether an individual may be an appropriate living donor. It might also be helpful to mention the statutory approval procedures at the HTA. The link referring to the liver selection policy appears to link to more general information on the liver advisory group. The specific link to the selection policy is available on the NHS Blood and Transplant website	Thank you for your comment. The Committee amended 1.3 as follows: 1.3 Living-donor liver transplantation should only be performed in accordance with the NHS Blood and Transplant (NHSBT) Organ Donation and Transplantation Liver Advisory Group's Liver Selection Policy and the British Transplantation Society's Guidelines for Directed Altruistic Organ Donation, taking into account the legal framework for living donation from the Human Tissue Authority (HTA). Non-altruistic donation is a possibility and should be discussed with a transplant centre or team. The precise link to the liver selection policy (POLICY POL 195/4) cannot be provided in the guidance because it is a PDF file. Therefore, a link to the webpage that has the PDF file has been provided.
3	Consultee 2 Association of Upper Gastrointestinal Surgeons of GB and Ireland (AUGIS)	**1.3**	Overall congratulations. Comprehensive review and solid recommendations Currently the same indications are applied to cadaveric and LDLT through the Selection Policy of LAG. This is appropriate but might require review in the future.	Thank you for your comment. The Consultee agrees with the recommendations.

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4	Consultee 2 Association of Upper Gastrointestinal Surgeons of GB and Ireland (AUGIS)	**1.4**	There have been 6 centres comissioned in Engalnd to perform LDLT since its implementation. It is my opinion, that given the relationship volume/results and the development achieved since 2006 from each individual centre, LDLT should concentrated in those institutions with greater expertise. I would support consolidation of LDLT within the three adult/paediatric existing units.	Thank you for your comment. Section1.4 in the guidance states that '*Living-donor liver transplantation should be carried out in specialist centres by a multidisciplinary team'*. The Committee does not have a remit to determine the number of units needed for undertaking LDLT. In the UK, the Human Tissue Authority licences organisations, and ensures the quality and safety of organs used in 'Living donor liver transplantation'. HTA do not regulate clinicians or healthcare professionals.
5	Consultee 1 Human Tissue Authority	**2.2**	There appears to be an error on line four which I think should read 'which increase the number of recipients who can benefit' it currently reads 'which increase the number of donors who can benefit'.	Thank you for your comments. The Consultee highlighted an error in 2.2. This has been amended as suggested by the Consultee.
6	Consultee 2 Association of Upper Gastrointestinal Surgeons of GB and Ireland (AUGIS)	**2.4**	LDLT may be an ideal option for those recipients likely to be disadvantatged on the waiting list with predicted long waiting times. I believe that an elective and scheduled LDLT from a high quality graft will be beneficial for these subset of patients.	Thank you for your comment.

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7	Consultee 2 Association of Upper Gastrointestinal Surgeons of GB and Ireland (AUGIS)	**3.2**	Including the middle hepatic vein is likely to affect the donor's liver regeneration and therefore the potential morbidity. Although not essential, is highly desireable to obtain donor 3D volumetry prior to graft selection and liver partition.	Thank you for your comment. Section 3 is intended to be brief a summary of the way the procedure is typically done. Therefore this level of detail is not needed in the guidance.
8	Consultee 2 Association of Upper Gastrointestinal Surgeons of GB and Ireland (AUGIS)	**3.4**	The required size of graft (...) is determined by the recipient's size in conjunction with his/her condition. Traditionally its size has been expressed as a ratio between graft's weight and recipient's weight (GRWR), although the percentage of the recipient's Liver standard volume (SLV) is also referenced.	Thank you for your comment. The Committee amended 3.4 as follows: The size of graft (that is, right or left hepatic lobe, or liver segment) is determined by the body size ratio or by estimating the standard liver volume of both the donor and recipient.
9	Consultee 1 Human Tissue Authority	**5.13** **5.14** **5.17**	There appears to be inconsistency in the way data is presented. In some cases as a % with the figures X/Y given, in others just a number of cases. It is clear enough but it may be helpful to have overall figure presented as a % and X/Y, with the split of types of case then presented as N=, as is done in 4.19.	Thank you for your comments. The Consultee highlighted some inconsistencies in the way the data is presented. For consistency, these have been amended.
10	Consultee 1 Human Tissue Authority	**6.1**	The requirements in relation to the follow up of living donors is set out in law in the Quality and Safety of Organs Intended for Transplantations Regulations 2012 (Regulation 15).	Thank you for your comment. Section 6.1 has been amended as follows: The Committee was advised that clinical follow-up of donors is mandatory and that this should include attention to their psychological wellbeing.

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11	Consultee 1 Human Tissue Authority	**6.2**	The same comments as for 1.3 apply here in terms of the reference to BTS guidelines and link to the selection policy.	Thank you for your comment. See response to comment 2.
12	Consultee 1 Human Tissue Authority	**7.2**	This statement may need amending as it is not strictly factually correct. The HTA has responsibility for giving approval for living donor transplantation based on criteria set out in legislation (valid consent and no evidence of duress, coercion or reward). In summary some aspects are regulated by us, but most of the clinical side and much of the donor selection are not. Information on our statutory responsibilities can be found on our website.	Thank you for your comment. The Committee amended 7.2 as follows: – The Human Tissue Authority has responsibility for approving living-donor transplantation based on criteria set out in the legislation. It also regulates organisations in the UK, ensuring they meet the quality and safety standards set out in legislation for the use of human tissue, including organs for living-donor liver transplantation.

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13	Consultee 1 Human Tissue Authority	**General**	The Human Tissue Authority (HTA) is an expert regulator that licenses more than 850 organisations that remove, store and use human tissue and organs for research, medical treatment, post-mortem examination, education and training, and display in public. We also give approval for organ and bone marrow donations from living people. The interests of the public and those we regulate are central to our work. We work with stakeholders to build on the confidence people have in our regulation by ensuring that human tissue and organs are used safely and ethically, and with proper consent. The HTA welcomes the opportunity to respond to the National Institute for Health and Care Excellence (NICE) consultation on living donor liver transplantation.	Thank you for your comment. Section 7.2 in the guidance provides reference to the role of HTA in Living donor liver transplantation.
14	Consultee 4 Clinical Service lead, Liver unit, Queen Elizabeth Hospital , University Hospital Birmingham NHS Professional	**General**	Live donor liver transplantation (LDLT) has been slow to take off in the UK compared to other European centres and the US and especially the far east. Of the seven transplant units in the UK , 6 have done LDLT but the numbers in most have been very small and the progress has been very inconsistent and slow. No doubt this is because we have active and improving cadaveric donor programmes in the UK but we feel there is scope to develop LDLT in the UK as there is a definite waiting list mortality and LDLT will add to the organ pool and there are circumstances and patients where this is the ideal approach to actualising a liver transplant.	Thank you for your comments.

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15	Consultee 4 Clinical Service lead, Liver unit, Queen Elizabeth Hospital , University Hospital Birmingham NHS Professional	**General**	We feel that the number of centres should be limited to ensure an adequate through put to maintain expertise and focus on donor safety in this very high stakes undertaking. The units undertaking LDLT should have demonstrated a large volume and experience of both complex HPB surgery, and large volume and complex cadaveric liver transplant surgery. This includes all of the following a. An active liver splitting programme b. An active paediatric programme c. Active domino transplant programme Its preferable that the centres undertaking LDLT should be able to demonstrate on going donor safety standards and good results with LDLT.	Thank you for your comments. The Interventional Procedures Programme at NICE assesses the safety and efficacy of interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. Section1.4 in the guidance states that '*Living-donor liver transplantation should be carried out in specialist centres by a multidisciplinary team'*. The Committee does not have a remit to determine the number of units needed for undertaking LDLT. In the UK, the Human Tissue Authority licences organisations, and ensures the quality and safety of organs used in 'Living donor liver transplantation'. HTA do not regulate clinicians or healthcare professionals.
16	Consultee 4 Clinical Service lead, Liver unit, Queen Elizabeth Hospital , University Hospital Birmingham NHS Professional	**General**	We feel that three centres in the UK will be appropriate to achieve the needed number of LDLT. Given the above requirements this should be limited to the three centres with both active paediatric and adult liver transplant programmes, which have shown consistent results in LDLT, excellent donor safety records and are geographically well distributed across the UK.	Thank you for your comment. See response to comment 15.

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17	Consultee 3 LDLT Donor – (Adult to Adult donation)	**General**	I am a living donor having donated my left lobe to my adult son in 2012. Despite being listed due to end stage and complex PSC-AIH crossover his condition deteriorated and required intervention. The procedures you describe to meet the HTA criteria were followed, I do not recall involvement by the NHSBT. I consented right lobe but on the day the left was taken. His recovery was poor, early rejection and severe ascites. Treated with record amounts of ATG in an attempt to preserve the graft. Two months later with little improvement he dramatically developed a portal vein thrombosis and acute Budd-Chiari. Listed super urgent and received a full liver transplant four later. Very little rejection followed. Now almost three years post transplant and well.	Thank you for your comment. The Committee discussed your views and experiences in their deliberations and agreed with your point. Section 2.4 in the guidance states that 'Living-donor liver transplantation may be an option for patients who are deteriorating clinically while waiting for a deceased donor transplant'.
18	Consultee 3 LDLT donor-(Adult to Adult donation)	**General**	LDLT was only considered after his condition became such that he could die. Should LDLT be considered earlier in certain cases before the patients lives are at risk in the UK. Centres such as King's College Hospital have considerable experience. Should the LTA review procedures and policy in favour of early LDLT if appropropriate?	Thank you for your comment. The Committee discussed your views and experiences in their deliberations and agreed with your point. Section 2.4 in the guidance states that 'Living-donor liver transplantation may be an option for patients who are deteriorating clinically while waiting for a deceased donor transplant'.
19	Consultee 5 Children's Liver Disease Foundation	**General**	Children's liver disease Foundation has no comment to add to the document in this draft.	Thank you for your comment.

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20	Consultee 6 NHS Professional	**General**	Despite the paediatric centres showing interest in this, the numbers of NHS adult living donor liver transplants have not gone up. It is important that the transplant units who wish to do this are encouraged and not stopped from delivering this service.	Thank you for your comment.