

HTA response to the NICE living-donor liver transplantation consultation

Introduction

1. 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.
2. 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.
3. The HTA welcomes the opportunity to respond to the National Institute for Health and Care Excellence (NICE) consultation on living donor liver transplantation.

Comments on specific paragraphs

4. **Paragraph 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.
5. **Paragraph 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.
6. It might also be helpful to mention the statutory approval procedures at the HTA.

7. 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](#).
8. **Paragraph 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'.
9. **Paragraphs 4.13, 4.14, 4.17:** 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.
10. **Paragraph 5.1:** 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 \(Regulation 15\)](#).
11. **Paragraph 5.2:** The same comments as for 1.3 apply here in terms of the reference to BTS guidelines and link to the selection policy.
12. **Paragraph 6.3:** 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](#).

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