

Human Tissue Authority

Board Meeting Conducted in Public

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Living Organ Donation (LOD) update

Purpose of paper

1. To update the Board on important issues and developments in the area of LOD, and the work undertaken so far to refine and strengthen systems and processes.
2. To ask the Board to approve the updated Policy for the assessment of living organ donation cases.

Decision making to date

3. There have been several conversations with SMT during the past 12 months which touch on a number of these issues.

Action required

4. The Board are asked to approve the revised Policy for the assessment of living organ donation cases (HTA-POL-102), available at Annex A.
5. The Board are asked to agree the proposed changes, which have been made in response to lessons learnt from recent experiences and in recognition of the increased risk posed by the growing threat of human trafficking for the purpose of organ removal.

Background on new and emerging risks

UK citizens travelling overseas for transplantation

6. On 1 July 2022, amendments to the Human Tissue Act 2004 (HT Act) and the Human Tissue (Scotland) Act 2006 came into force, inserting a new section 32A and 20A into each Act respectively.
7. These amendments extended the offences set out in Section 32 of the HT Act and Section 20 of the HT (Scotland) Act (HT (S) Act) to acts done by defined classes of persons outside of the United Kingdom.
8. These offences relate to financial or commercial dealings in human material for transplant, such as buying or selling human organs. The amendment only applies to human organs, it does not apply to tissues and cells.
9. In practice, this means that a person habitually resident in England, Wales or Scotland, or a UK national not habitually resident in Northern Ireland, will be committing an offence if they:
 - a) Give, receive, seek or offer payment or reward for donating organs for transplantation;
 - b) Initiate or negotiate an arrangement involving the giving of a reward for the supply of or offer to supply any part of a human body for transplantation, or take part in the management or control of an organisation whose activities include the initiation or negotiation of such arrangements; or
 - c) Publish or distribute an advert inviting people to supply or offer to supply part of a human body for transplantation or reward or indicating that the advertiser is willing to initiate or negotiate such an arrangement.
10. Whilst fewer than ten cases have been referred to the HTA so far since July 2022, the numbers of cases are higher than anticipated.
11. The HTA is actively engaged in further work with the Department of Health and Social Care (DHSC) and NHS Blood and Transplant (NHSBT) to raise awareness of this issue across the transplant community and the public.
12. This change in the statute has led to a notable increase in activity and hence in resource pressures on the LOD team.

Addressing the risk of people trafficking into the UK for the purpose of organ donation

13. During 2022/23, the HTA LOD team undertook a targeted and structured review of LOD cases with certain features that had been submitted for HTA approval over the previous five years.
14. That internal process aimed to identify if there were any indications of systemic weakness in HTA processes, for example, if cases that should have been referred to a panel of Board Members for decision had not been, or to identify if there were indications of any other major concerns with the internal processes. No systemic issues were identified although areas with scope for improvement were identified. All cases that had, by law, to be referred to a panel for decision had been referred.
15. Alongside this piece of work, other immediate actions were also put in place. These included holding Regulatory Decision Meetings (RDM) for all living donation cases where the donor was travelling from overseas, all cases from the private sector and all cases submitted from a particular NHS Trust. RDMs are a standard part of the HTA's regulatory decision making and escalation processes across all sectors we regulate. These meetings are attended by the Director of Regulation and/or Head of Regulation in addition to the LOD team.
16. Later in 2022/23, these criteria were amended, with RDMs continuing to be held for cases with an overseas donor and cases from the private sector.
17. Additionally, the HTA has seen a very significant increase in the number and complexity of enquiries in the LOD sphere, particularly in relation to complex overseas cases. These encompass all stages of the LOD pathway, including dealing with enquiries and issues from before the potential donor arrives in the UK, as well as after their arrival.
18. The Board should also note that the HTA is working closely and actively with other agencies to continue to strengthen LOD-related processes, including UK Visas and Immigration, the National Crime Agency, NHSBT and DHSC.
19. This significant increase in level and complexity of demand-led and proactive activity has further increased the resource pressure on the LOD team.

Review of Policies, procedures and guidance

20. The HTA Board is responsible for the Policy for the assessment of living organ donation cases (policy HTA-POL-102).
21. The Executive has undertaken a comprehensive review of this policy in response to the activities noted above and to implement recent learning. The revised policy has undergone legal review.
22. The Executive believes that the changes proposed make this policy more robust, with the additional detail helping to reduce the risk of approval of cases that may not meet the statutory tests or may involve people trafficking for the purpose of organ donation.
23. Three main changes have been to:
- i) provide additional clarity on which cases should, as a matter of HTA policy, be referred to panel (the so-called 'retained cases') by adding more detail to the section on retained panel cases.
 - ii) provide clarity around what we mean by, and how to interpret, certain terms, such as 'economic dependence'.
 - iii) provide for the Executive to make decisions to refuse a case, undertaken through a RDM process, for cases that would otherwise not need to be referred to panel.
24. We do not anticipate that these changes will of themselves increase the number of cases referred to panel for decision. However, the Board should note that this is an area of significant emerging risk and so we cannot be certain that number or complexity of cases requiring panel consideration will not increase.

Training

25. The LOD Team has planned and is delivering a significant amount of training and awareness-raising sessions across the sector.
26. Further training and awareness-raising for the Board will be covered in separate training organised by the LOD Team.
27. Two Independent Assessor (IA) training days were held in May and June, which has resulted in 19 new IAs being trained. There was a renewed emphasis on the purpose of the role, as well how to look for signs of trafficking through suitable challenge and probing.

28. Targeted, mandatory refresher training will be delivered to all existing IAs during this business year, to remind IAs of their role, namely to explore the risk factors on which the HTA needs to make a decision. This training will reinforce the importance of the role in identifying potential instances of people trafficking for organ donation as well as raising awareness of risk signs and indicators of other potential unlawful acts in connection with living organ donation.
29. The Head of Regulation attended, and presented at, a four-day course in June, organised by the Metropolitan Police, covering the investigation of Modern Slavery Offences.
30. The Head of Regulation has assisted in delivering four training and awareness sessions, in conjunction with the Metropolitan Police, on the risks of offences relating to LOD to NHS staff at one NHS Trust. A session was also delivered to staff at another NHS Trust.
31. In May, the Head of Regulation gave a presentation at the UK Living Kidney Donor Network Meeting, providing a number of current, anonymised scenarios for the clinical audience to engage with. This reinforced the importance of early contact with the HTA in complex overseas donor cases or any other challenging issues clinical teams may be facing that fall within the HTA's remit.

Additional checks

32. Some changes have been made to the HTA's internal processes to allow for the capture of risk factors in our case management (CRM) system and to provide a proportionate amount of additional scrutiny of cases prior to decision.
33. Two changes have been made to the CRM system.
 - i) The first allows the LOD team to flag cases that meet certain criteria as high-risk to help identify and track these applications and increase visibility.
 - ii) This functionality enables such higher risk cases which are also panel cases to be readily identified as such by the referring Officer and the panel themselves. This enables the panel to the importance of reviewing all relevant paperwork pertinent to decision making, including the Independent Assessor report, referral letter and donor declaration, when assessing these cases.

34. We have introduced a weekly quality assurance sample check by the Transplant Manager prior to a formal decision being made by the Living Donation Assessment Team.

Next steps

35. A review of both HTA Guidance documents for transplant teams and Independent Assessors (one for England, Wales and Northern Ireland and the other for Scotland) has begun. This will include a fundamental revision of content and layout. This will be a significant piece of work.

36. Changes will include strengthening the guidance in several areas, for example making clear that affidavits in isolation will not be accepted as proof of a claimed relationship and that translators must be professional translators who are independent of both the donor and recipient and of the clinical team.

37. We will publish these by the end of the calendar year once we have consulted with relevant colleagues in the sector.

38. A communications plan is being developed with the HTA Communications team to provide regular updates throughout the year to the sector.

Recommendation

39. The Board are asked to note the content of this paper and approve the revised Policy at Annex A.