

Minutes of Transplantation Advisory Group

Date 3 October 2018
Venue Human Tissue Authority
 151 Buckingham Palace Rd
 London
 SW1W 9SZ

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Present

Members

Anthony Warrens (AW), Chair
 Amanda Gibbon (AG), Authority Member
 Lisa Burnapp (LB), Lead Nurse for Living Donation, NHS Blood and Transplant
 Lorna Williamson (LW), Authority Member
 Michael Heneghan (MH), Consultant Hepatologist, Kings College Hospital
 Penney Lewis (PL), Authority Member
 Sam Abdalla (SA), Authority Member
 Alun Williams (AWi), Consultant Paediatric Urologist, Nottingham
 Jessica Porter (JP), Head of Regulation
 Chitvan Amin (CA), Transplant Manager
 Nicolette Harrison (ANH), Director of Regulatory Delivery
 Jennifer Cole (JC), Transplant Officer
 Adam Wells (ACW) (minutes), Transplant Officer

Apologies

Welcome and apologies

1. AW welcomed all to the meeting.
2. AW welcomed Richard Smith (RS), Consultant Gynaecologist.

Uterine donation and transplantation

3. RS presented proposed plans for living and deceased uterine donation and transplantation in the UK. Uterine living donation is currently well established as a procedure in USA and Sweden.
4. RS assured the group that the donors will be provided with full information on short and long-term risks. Other protocols associated with donor work up and transplantation are in line with current SOPs in the living donation sector. The project is a collaboration between the University of Oxford and Imperial College. All uterine transplants will be funded by a charity.
5. The programme will currently only apply to directed donations in the living donation sector. In the future, there is a possibility to extend the programme to paired, pooled or NDAD donations.
6. Deceased donations are also planned, but that this is less well established. Working with the Oxford retrieval team, uterus retrieval will be the last procedure, so will not impact on the availability of other organs.

Action 1: CA to circulate donor information provided to the donors for uterine transplantation.

Update on actions from previous TAG meeting minutes

7. CA informed the group that all actions from the previous TAG meeting are completed.

Sustainability of IA framework and IA accreditation: Update on project

8. CA provided an update on the project. The work packages on IA recruitment and reaccreditation are now complete; work packages on IA governance arrangements and training are ongoing and set to finish by the end of 2018-19 business year.
9. The group agreed the IA is a key role in the living donation pathway. There is a variability in practice across all transplant units with respect to the formal governance arrangement of the role and payment.

10. JP informed the group that IAs in Northern Ireland and Wales are paid. The group agreed that payment for the IA role is not within the HTA's remit. However, the HTA may wish to increase the awareness of the issue by writing to all transplant units in the UK.
11. Group discussed draft SOP-110 Independent Assessor Reaccreditation Process and draft GD-025 IA Reaccreditation and Performance Assessment Process. CA explained that the new SOP would implement a continuous performance assessment of IAs on a monthly basis.
12. A concern was raised that IAs could get penalised for cases that are more complicated. CA ensured the members that a red or amber rating is only provided if IA reports do not contain mandatory information based on requirements set out in the law. Additional support provided by Living Donation Team (LDT) in complex cases does not result in a red or amber rating. LDT also ensure that both positive and negative feedback is communicated to IAs.
13. The group discussed draft SOP-109 Independent Assessor Application and Accreditation Process. CA informed the group that the IA applications are accepted for the training based on the criteria set out in the job specification of the role. The candidates undertake a written assessment at the end of training and are accredited if they pass this assessment. The group suggested adding this criterion to the SOP.
14. The group discussed conflict of interest in the assessment of living organ donation cases. CA informed the group of the current process of addressing this issue, which includes written confirmation from the IA and from the LDC that family members, friends and partners who also work in the transplant sector would not 'work up' the same donor assessed by the IA.
15. The group advised the team to formulate and implement a policy on potential conflict of interest to mitigate associated risks.
16. Recruitment – the group reviewed the proposed leaflet that will be provided to people interested in the IA role and suggested minor amendments.
17. The group highlighted the need to change the way the role is currently advertised and recruit outside the hospital to attract people from diverse backgrounds. CA informed the group that the recruitment for IA role is the responsibility of the transplant units and the HTA does not have any input in how the role is advertised.

Action 2: CA to liaise with units to collect latest information on the payment for IA role in the UK and write a SMT paper to discuss the best way to disseminate this information to all stakeholders.

Action 3: TAG members to send any suggested changes to the documents in appendix to LDT.

Action 4: CA to add the acceptance criteria for IA applicants in the draft SOP 109.

Action 5: LDT to formulate and implement a policy on potential conflict of interest within the living donation sector.

Oral updates on transplantation in the private sector

18. JP and CA met with the Medical Director of a private hospital in London to discuss best practice in the private sector and were assured that an appropriate framework is in place to meet the requirements set out in the law.
19. In addition, JP inspected a NHS establishment with a private transplant unit and was reassured that suitable practices and appropriate framework were in place.
20. JP informed the group that the private sector can benefit from guidance on an appropriate framework in private units and by being aware of best practice in the private sector. Due to other ongoing projects in the Organ Donation and Transplantation sector the project will be moved to 2019/20 business plan.

Action 6: LDT will develop guidance for living organ donation in the private sector in the next business year.

Update on proposed opt out system for deceased organ donation in England

21. CA updated group on the Deemed Consent bill (England), which is currently in the review stage at the House of Commons.
22. The HTA will work closely with professionals working in the transplantation sector for drafting of the Codes of Practice and stakeholder consultation.

Horizon Scanning / AOB

23. The HTA is anticipating the first independent assessment for a uterine transplant in December. The case will be assigned to a panel of authority members, as this is a new organ type in the UK.
24. The transplant unit will inform the HTA before a referral is made to the HTA. LDT will ensure the IA and panel members are provided with all information about the nature of the procedure, long and short-term risks before a case is assigned to them.

Charity that matches donors and recipients

25. JP updated the group that it is unclear how the donors and recipients are matched by the charity.

Action 7: HTA to arrange a meeting with the charity to understand their processes.

Organisation providing a matching service

26. JP informed the group about an organisation offering payment of funeral costs for donors in return of registration for organ donation with them. The organisation is advertising their services worldwide, including in the UK and their web pages had until recently incorporated the HTA and NHSBT logos, although these have since been removed. The organisation has also recently started raising awareness that it is seeking to raise funds for its activities by seeking investments from the public through cryptocurrency.
27. It is unclear how many people have registered with the organisation. Payment for funeral services is considered as reward for organ donation under the Human Tissue Act 2004. JP, ANH and Matthew Silk (HTA Head of Communications) are in correspondence with the organisation to highlight the HTA's regulatory concerns.

National Kidney Disease Education Program (NKEP)

28. LB is working on the ethical and legal framework of a European Union (EU) living kidney exchange project, National Kidney Disease Education Program (NKEP).
29. NKEP is one of the largest and most diverse trans-national kidney exchange programme. The project is currently in its second year and will be running for a total of four to five years. LB will bring any relevant updates to TAG.

Closing remarks

30. No other business, AW closed. Next TAG meeting will be held on 8 May 2019.