

Minutes of Transplantation Advisory Group

Date 18 October 2017

Venue Boardrooms 1 & 2, Human Tissue Authority
151 Buckingham Palace Road
London
SW1W 9SZ

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Present

Members

Sarah Bedwell (SB), (Chair) Director of Regulation

Sam Abdalla (SA), Authority Member

Lisa Burnapp (LB), Lead Nurse for Living Donation, NHS Blood and Transplant

Amanda Gibbon (AG), Authority Member

Keith Rigg (KR), Consultant Transplant Surgeon, Nottingham

Lorna Williamson (LW), Authority Member

Anthony Warrens (AW), Authority Member

Penney Lewis (PL), Authority Member

Jessica Porter (JP), Head of Regulation (Organ Donation and Transplantation Sector)

Chitvan Amin (CA), Transplant Manager

Niamh Marren (NM) (Secretary), Living Donation Officer

Jennifer Cole (JC), Living Donation Officer

Nima Sharma (NS), Regulation Manager

Apologies

Sharmila Nebhrajani (SN), Authority Member

Michael Heneghan (MH), Consultant Hepatologist, Kings College Hospital

Item 1 – Welcome, apologies and minutes from 14 October 2016 meeting

1. Apologies were received from SN and MH.
2. The minutes from the 14 October 2016 meeting were agreed.

Item 2 – Update on outstanding actions from previous TAG meeting minutes

3. CA updated the Group on the outstanding actions from the previous TAG meeting.
4. The ‘Guidance to transplant teams and independent assessors’ (IA guidance) has been updated. The IA guidance will be published once the new LDAT policies have been implemented. These policy changes are included in the updated IA guidance document.
5. LDAT to send the updated IA guidance to LB and KR to review and provide feedback.
6. Action 16 is outstanding due to other projects in the living donation team having taken priority. The action ‘To discuss with the full Authority a piece of work or research on the presence of duress, coercion, reward and how that might fit with the priorities for the next business year’ is not on the business plan for 2018/19.
7. All other actions were completed.

Action

1. **To send an update on the actions to TAG members by correspondence if there is no TAG meeting going ahead.**
2. **To pre-plan IA training dates for the next calendar year and send out a communication to the living donation sector.**
3. **LDAT to send the updated IA guidance to LB and KR to review and provide feedback.**

Item 3 – Update on policy changes

Removal of requirement for enhanced IA

8. NM updated the group on the policy change to remove the requirement for Enhanced IAs to complete assessments of Directed Altruistic Donation (DAD) cases and Directed Donation cases with an element of Economic Dependence (DED).

9. The Group considered the need for additional training for all IAs as part of removal of the enhanced IA requirement. NM informed the group that a small group of enhanced IAs had expressed their reluctance to complete additional training as part of their role.
10. The Group noted that mandating the training could lead to some IAs leaving the role. The HTA will work with the individual centres to understand the impact of losing IAs who do not wish to do the mandatory training. This work will be further considered as part of the IA sustainability project (paper presented by JP).

Changes to timing for paired/pooled cases

13. JC updated the Group on the policy to change the timing for paired/pooled cases.
14. Some Transplant units have adopted the policy change and are referring paired/pooled cases before they have been matched in the matching run.
15. It was clarified that if a pair have not been matched within one year of receiving HTA approval a second IA assessment will only be required if there has been a change in circumstances.
16. LB opened a discussion to the Group suggesting that the NHSBT are considering the possibility of changing the waiting time for surgery within the kidney sharing scheme. The waiting time could be reduced from current eight weeks to reduce the clinical risk of transplants not proceeding. The transplants will happen sooner and therefore reduce the risk of chain breaking down. Such a policy change may encourage Living Donor Coordinators (LDC) to seek earlier assessment but it may cause an increase in urgent requests for assessments of such cases.

Revised statutory referral letter template and guidance

17. NS provided an update on the progress of the policy to revise the statutory referral letter template and the associated guidance document.
18. This policy has received legal review, comments from SN and TAG. It has also been reviewed by the policy team at the Scottish government.
19. The new template referral letter will be available on the HTA website from 10 November 2017. The units are expected to use the new template from 15 January 2018. The Group suggested the LDAT consider gradually fading out the use of old referral letter and implement complete policy change by early January.

20. LB highlighted the problem of inserting the surgeon's name into section five. The surgeon will have spoken to the donor but may not be available when the LDC is completing the referral letter. In addition, it was suggested to refine the letter to support its use for Non-directed altruistic donors (NDAD).
21. The Group discussed the type of information that should be included in Section one describing risks specific to the donor. It was suggested since Section one of the letter will contain the long term risks specific to that donor, the letter could include suggestions regarding the type of information requested, for example in the context of age, lifetime risks, long standing illness etc.
22. The Group agreed the communication of this policy change needs be completed using a number of methods to ensure it is received by all those who need to know.

Action

4. **To remove the requirement for Surgeon's name to be inserted into Section five of the letter.**
5. **To change "should" to "will ensure..." in the last sentence of Section five.**
6. **To communicate the policy change in the IA bulletin and by LB via email to all LDCs.**
7. **To update the IA Guidance to reflect the requirement for IAs to question the donor on the long-term risks.**
8. **To send the proposed referral letter for review to one IA and one LDC in England and Scotland. LB to suggest LDC names.**
9. **To send revised policy change to LB for comments.**

Item 4 – Update on project: Sustainability of the IA framework and reaccreditation process

23. JP updated the Group on the plan to review the sustainability of the IA framework and reaccreditation process.
24. The HTA is currently seeing very small numbers of delegates coming forward for the IA training. The HTA trained four new IAs in September 2017. Historically, there would be up to 15 delegates at each IA training.
25. The numbers of cases submitted by IAs demonstrates that IAs are completing between zero and 46 assessments per year.
26. The IA reaccreditation procedure has not been reviewed or updated for almost seven years. There are gaps in the current procedure which could be improved.

27. JP suggested that the LDAT will design a survey to gather thoughts regarding the current IA framework and its sustainability from various stakeholder groups i.e. LDC, IAs and Clinical Directors.
28. The group suggested designing the survey to ensure maximum input by using minimum free text questions and more tick box style responses.
29. The Group questioned whether the amber and red criteria for reaccreditation could be considered as part of the project to ensure the criteria are as clear.

Action

- 10. To seek input from Penney when designing the survey questions.**
- 11. To provide a comprehensive survey via Survey Monkey to IAs, LDCs and Clinical Directors at each unit.**
- 12. To review the reaccreditation criteria to include key performance indicators.**
- 13. To consider whether an Authority Member should attend future IA training.**

Item 5 – AOB

Survey of TAG Members

30. SB informed the Group that this will be rolled out in the next few months as part of a wider piece of work looking at the role of the HTA standing committees TAG members are all asked to respond.

Donor advocate programme at Royal Free

31. CA spoke about the new Donor Advocate pilot project at the Royal Free, London. The project started in March 2017 and is in its initial stages. This programme has been adapted from the Donor Advocate programme currently run in the Johns Hopkins hospital in the USA.
32. The donor advocate, identified by a potential recipient, could speak on behalf of the potential recipient who may not be able to approach his or her family and friends to become a donor. A donor advocate could approach a potential donor in person or via social media, email etc.
33. Two/three pairs have come forward to use this programme.

Action

- 14. To liaise with the Transplant unit at Royal Free London and discuss the possibility of informing the HTA when a donor comes forward using the Donor Advocate Program.**

DBS checks for IAs

34. The HTA currently has a total of 127 IAs, excluding four that were recently trained in the September 2017 training session.

35. All 127 IAs have valid enhanced DBS or equivalent checks in place. We have applied for enhanced DBS checks for the newly trained IAs. Once they have received these checks these IAs will be considered accredited by the HTA and will be allowed to carry out independent assessments.

Publication of Scottish Guidance and Guidance for Transplant Units and IAs

36. Following legal review, the Scottish Guidance was published in August 2017.

37. The LDAT aims to publish the Guidance to transplant units and IAs in beginning of 2018.

Re-direction to family member on national waiting list

38. The LDAT received three cases in quick succession where a donor knew of another person who needed a kidney/liver and wished to redirect their organ/part organ to a second named recipient, if the first recipient was not able to be transplanted.

39. Legal advice was sought. This advice stated that a second IA assessment would be required if the kidney/liver was to be redirected to a second named recipient.

Action

15. The LDAT to work up a policy position that could be shared with transplant units.

Approved Paired/Pooled donation cases proceeding for directed donation

40. The LDAT have received a significant increase in the number of paired/pooled cases where the pair wish to proceed to a directed donation. This could happen when the pair are matched in a matching run for the kidney sharing scheme.

41. The LDAT have agreed that a second, light touch IA assessment is required to ensure there has been no change in circumstances for the donor and recipient. This conversation could be carried out by the IA via telephone and a second report will be submitted to the HTA.

Action

16. To include the requirement for a second IA assessment in the IA Guidance

ODT audits

42. 14 ODT on-site audits have been completed so far, at a rate of one per month.

43. These audits have demonstrated the broad compliance of the ODT sector with 10 establishments meeting all the criteria and four establishments receiving minor shortfalls.

Panel case assessment deadlines

44. There has been an increase in the number of 'urgent' cases being reviewed by a panel, in particular NDAD cases. This is due to timelines that LDCs need to work towards in order to register a NDAD donor in the matching run.

45. The Group discussed whether these cases could be assigned to a panel earlier than the other cases.

46. The Group also discussed the possibility of reducing the panel case review timeline from ten to seven or five working days.

Action

17. To review the procedure for assigning panel cases when the LDAT know a case approval is 'urgent'.

18. To seek opinion of all Authority Members on whether the number of days to review a case should be changed from ten working days to five days at the next authority meeting.

Transplant without HTA Approval

47. Recently, a transplant unit proceeded to complete a living donor transplant before receiving HTA approval. CA is currently liaising with the unit to ensure appropriate mitigating steps have been taken by the establishment.

Matnat chaim

48. There is a police investigation in Israel involving the CEO and other members of this organisation.

49. The HTA is seeking legal advice for review of future cases from this organisation.

Date of next TAG meeting TBC.