2019 Compliance update questions: Organ Donation and Transplantation (ODT) sector

1. **To ensure we are holding the correct information, please provide names and contact details of the staff you would like the HTA to hold as named contacts against your Organ Donation and Transplantation licence.**

2. **Approximately how many transplants take place each year at your establishment?**
    - Living donor transplants
    - Deceased donor transplants

3. **Have you undertaken, or do you intend to undertake, any major changes to your activity e.g. NORS activity, type of organs retrieved or types of organs transplanted?**
    - Yes
    - No

    If yes, please provide further information.

4. **Living donation only: Does your establishment have a sufficient number of Independent Assessors to support the size of your living donor programme?**
    - Yes
    - No

    If no, please provide further information.

5. **Living donation only: Have you encountered any difficulties recruiting Independent Assessors, if yes, what have the barriers been?**
    - Yes
    - No
    - N/A – our centre does not carry out living donations

    If yes, please provide further information.

Retrieval questions

6. **Do you participate in national organ retrieval services (NORS) for organs from the deceased?**
    - Yes
    - No

Implantation questions

7. **Do you have a documented procedure to ensure that the implanting surgeon has access to the required donor and organ characterisation information, prior to implantation surgery?**
    - Yes
    - No

If yes, do you record that the implanting surgeon has reviewed donor and organ characterisation before implantation?

If no, please provide further information.

8. **Where there is any increase risk posed to the recipient by donor or organ factors, how do you document any risk-benefit discussions held with the recipient?**

9. **Is there someone at your establishment who reviews SABTO guidance when reviewing donor and organ characterisation information for each organ offer where donor conditions or risks indicate it necessary?**
    - Yes
    - No

    If no, please provide further information.

Research questions

10. **Is your establishment involved in any research into any novel transplant techniques?**
    - Yes
    - No

    If yes, please provide further information.

11. **Is tissue removed for research during the retrieval and/or transplantation process?**
    - Yes, for QUOD
    - Yes, for QUOD and in house research
    - Yes, for in house research only

- No, tissue is not removed for research

If no, please provide further information.

Transport questions

12. Do you hold a contract covering transport of organs?

- Yes, we hold our own contract
- No, we do not hold our own contract

If no, please provide further information.

Testing questions

13. Do you undertake serological testing of donor samples?

- Yes – living donors only
- Yes – deceased donors only
- Yes – for living donors and deceased donors
- No, we do not undertake serological testing of donor samples

If yes, please provide further information.

14. In the case of living donors, is serological testing undertaken or repeated within 30 days of donation?

- Yes
- No

15. Are the testing laboratories (including histological analysis and H&I) accredited by UKAS?

- Yes
- No

If no, please provide details.

16. Do you test transport fluid for microbiology?

- Yes
- No

17. In which format are serology test results received from the laboratory?

- Electronically (email or through electronic patient record system)
- Verbally over the telephone
- Fax
- Other – If "Other", please provide details.

If "Other", please provide details.

Incidents / SAEARs questions

18. What mechanisms do you have in place to ensure all Serious Adverse Events and Reactions (SAEARs) in relation to organ donation and transplantation are reported to NHSBT?

19. How do you ensure all staff are aware of SAEARs reporting requirements?

20. When you report SAEARs to NHSBT, do you also report via an internal trust incident reporting system?

- Yes, we also report via an internal trust incident reporting system
- No, we only report to NHSBT

If no, please provide further information.

21. Have you encountered any difficulties reporting incidents or SAEARs to NHSBT?

- Yes
- No, no difficulties encountered

If yes, please provide further details of any issues encountered.

Machine preservation/perfusion questions

22. Does your centre use machine preservation / perfusion devices?

- Yes – established process
- Yes – part of a trial
- No

If yes, please provide details, including the type / make of the device(s) used.

23. If yes, is machine preservation / perfusion carried out on every occasion or only in specific circumstances?

- Yes – every occasion
- Yes – in specific circumstances
- N/A – we do use machine preservation / perfusion devices

If yes to specific circumstances, do you have established criteria that you use to decide when to place an organ onto machine preservation / perfusion device?

24. Do you ever transport organs on perfusion devices? Please provide details of the device?

25. Does your hospital perform Normothermic Regional Perfusion (NRP)?

- Yes
- No

If yes, is this process formally documented in a procedural document? Please provide details.

26. Does your centre use machine preservation / perfusion devices for in situ or ex-vivo perfusion (or both)?

- In situ perfusion
- Ex-vivo perfusion
- Both

Please provide details.

27. If your centre is using machine preservation / perfusion devices, how is data for organ characterisation captured during the use of these devices, and how do you ensure that this data is stored for 30 years?

28. **If you use any type of machine preservation / perfusion devices, are these devices part of a maintenance contract?**
    - Yes
    - No
    - N/A – our centre does not use machine preservation / perfusion devices

    If no, please describe how maintenance is arranged and what records of maintenance are kept?

Other

29. **Please provide any other comments or issues that you would like to share with the HTA (optional)?**