

NHS BLOOD AND TRANSPLANT

MULTI-VISCERAL AND COMPOSITE TISSUE ADVISORY GROUP

Governance Report for MCTAG - March 2018

In the past, a keyword search relating to “bowel” revealed very few Incidents – there were for instance just 4 of these in the 6 months prior to October 2017.

We now have a method to capture incidents related to other vascularized tissues.

There were 10 such Incidents in the 6 months running up to 1st March 2018. Eight of these were of no relation to bowel or vascularized tissues.

The only two of relevance concern reporting and traceability of abdominal or rectus fascia.

1. Organ Summary form did not state rectus fascia was taken therefore family letter was incorrect, however this was picked up during checking.

This has been reviewed by the Head of Hub Operations and the reason why the fascia was not included on the organ outcome summary form is because this is classified as tissue not a solid organ. This is a known issue.

These grafts currently have no coding, however there is work under way to add in additional codes so these grafts can be captured. A temporary system has been put into place to code these grafts under bowel and free texting fascia.

The IT JIRA numbers for this work are:

ODT-7708

ODT-4953

2. It has been reported that there was a lack of traceability of abdominal fascia that had been retrieved. It was not documented on the organ outcome summary that abdominal fascia had been retrieved following a request received prior to NORS arriving and consent given by the family. Hub Operations and the Transplant Centre were contacted to confirm abdominal fascia retrieved and if transplanted - both unaware that it had been retrieved. Following further investigation by Bowel RCPoC it was discovered it had been retrieved but was not used and was disposed of 48 hours post retrieval as per policy.

A similar Incident was covered at length in the previous report – please refer to the next page. This whole area is being explored with the HTA, but there is a pre-meeting on 27th March to explore the requirements across the transplant community.

John Dark
March 2018

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For background, excerpt from, the report in October 2017:

In addition, there was no HTA form for the abdominal wall transplant. Also whilst NHSBT have a system to provide traceability for this type of transplant, it is not 'coded' within NTxD in the same fashion as other organs and whilst the traceability is present, it is not as clear. This meant that whilst the abdominal wall centre were informed of the result there was a delay (although not significant).

These points raise a number of Governance issue in vascularized tissue transplants. When the abdominal wall is transplanted with a liver, in a multivisceral transplant or with small bowel, it is regarded as a component of that transplant. It is analogous to the iliac artery being implanted, to aid the transplant, with a kidney. Therefore any traceability is linked to the 'main' transplant (liver, MV or small bowel).

But if abdominal wall is to be transplanted separately, as seems to be the case in this Incident, then we need to ensure that the traceability is clear to allow for centres to be contacted as necessary. As such the following actions are required:

- 1. Ensure that the abdominal wall is documented in the 'other' section on an abdominal organ HTA A form to ensure it is clear it has been retrieved.*
- 2. Completion of a HTA B form by the transplant centre that is sent to NHSBT to allow for the recipient details to be captured.*
- 3. NHSBT to ensure that the current traceability system is as robust as possible.*
- 4. NHSBT to amend NTxD so that it allows the same system of traceability as all other organs.*
- 5. MCTAG to consider allocation rules; less important, but due to an increasing need this should be reviewed to prevent future allocation disputes.*

As well as the above, there is also ongoing work with the HTA regarding the regulatory requirements when accessory tissues (e.g. rectus muscle fascia and blood vessels) are used to support organ transplantation in secondary recipients (who have not received an organ from the same donor). According to the regulations, such transplants should be carried out in accordance with tissues and cells regulations. Following discussion between NHSBT, a clinical representative, and the HTA, the HTA have agreed that fascia used in secondary recipients may be treated as an accessory tissue, under ODT Regulations, as an interim solution. Traceability should be captured in the same way as for abdominal wall.

The HTA will develop a framework to cover fascia and other tissues currently procured in theatres by NORS teams (vessels, islets, hepatocytes etc). NHSBT and clinicians will be involved in this process to advise HTA on what is operationally / clinically viable.