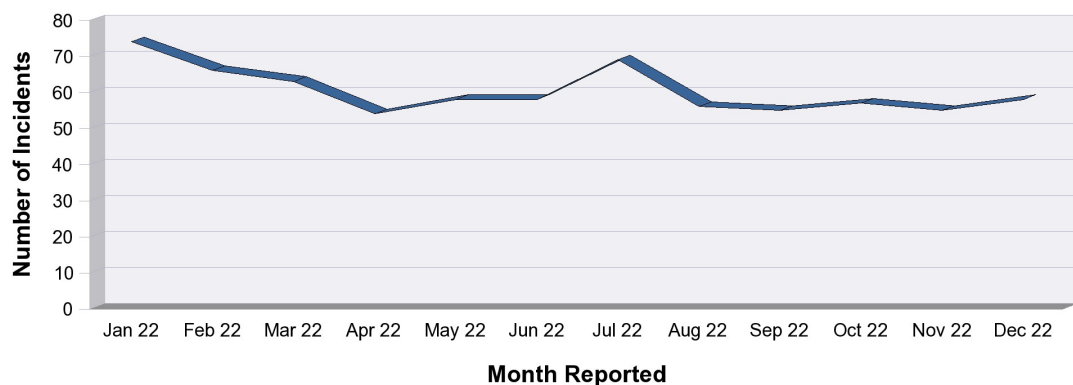


**Pancreas Advisory Group
ODT Clinical Governance Report March 2023**

1. Status – Confidential**2. Action Requested**

PAG are requested to note the findings within this report.

3. Data**4. Learning from reports**

Date reported: 25/10/22

Reference INC 6619

| What was reported |
|---|
| <p>Reported that on assessment of the pancreas in at the recipient centre the bile duct was found to be left open at retrieval rendering the organ contaminated and unsuitable for transplantation. No loose ties were found to suggest the tie had come off in transit.</p> <p>The pancreas was accepted into a research study with the accompanying kidney re-offered, accepted and transplanted.</p> |
| <p>Investigation findings:</p> <p>Details of the report and supplied images shared with the NORS Clinical lead</p> |

who subsequently discussed the case at their monthly review meeting.

The Lead Retrieval Surgeon reported that they were certain that the duct was tied at retrieval as it is ingrained into their standard retrieval practice. Their conclusion was that the tie must have come off at some stage in the process.

A review of collated findings was done by the NHSBT Clinical Governance Surgical Lead who reported that the finding of the open bile duct by the recipient centre when they inspected the pancreas led to the loss of organ for transplant and was therefore reported to the HTA as a Serious Adverse Event

Learning

The loss of surgical tie leading to bile duct contamination is not a specific absolute contraindication to transplantation however there are differences in approach amongst surgeons and recipient centres.

Reference INC 6510

What was reported

That there was prolonged offering of a DCD pancreas due to difficulties in recipient centres contacting isolation laboratories and confirming provision of isolation of islets.

As the Pancreas had not been placed by the time of retrieval it was fast tracked and placed into research.

Investigation findings:

There were multiple different factors as why the offering was prolonged:

- The donor had a history of drug use and Islet labs deemed the pancreas unsuitable for isolation however the history did not preclude transplantation of the pancreas.
- The anticipated isolation of the pancreas occurred at the time of handover on the islet isolation rota.
- There were some unavoidable delays with a transplant centre responding to the offer.

A timeline of the case was shared with the PAG Chair and Islet Steering Group Chair who agreed to discuss at the Islet Steering Group Meeting.

Questions asked for the Islet Steering Group Meeting

- The Islet labs did not accept for isolation due to the fact that the donor history did not meet tissue guidelines. This raises the question of whether a pancreas for islets should be accepted based on tissue guidelines or organ guidelines?
- Who decides acceptance of a pancreas for islets; the isolated lab or the transplant centre?

Awaiting the outcome of this meeting.

5.Trends noted

NHSBT were notified by Bridge to Life (supplier of UW® Cold Storage Solution) that several NORS teams had contacted them regarding discolouration of the solution and/or leaking within the solution bag overwrap. An investigation is ongoing and the ODT Commissioning Team and key stakeholders are working closely with Bridge to Life. The NHSBT Quality Team are also linked with relevant regulators. All NORS teams have been advised that for the interim period to switch to HTK as an alternative perfusion fluid and amend volumes as required (Perfusion protocol has been updated, circulated and available on the ODT website).

6.Requirement from PAG

Note findings in this report

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