

Events investigated for possible donor-derived transmission of infections, malignancies, and other cases of interest

April 2021 - March 2022



Preface

This report has been produced by Clinical Governance, Organ Donation and Tissue and Transplantation Directorate (OTDT), NHS Blood and Transplant.

All figures quoted in this report are events as reported to NHSBT between 1 April 2021 and 31 March 2022. The purpose of this report is to share information with clinical teams working in organ donation, organ retrieval and transplantation about cases reported and investigated for this timeframe.

Acknowledgement

The Clinical Governance in OTDT at NHS Blood and Transplant would like to thank all colleagues in the organ donation, organ retrieval and transplant community responsible for reporting clinical incidents and events to us. We are grateful to all clinical colleagues for providing the information required to investigate each case. Without the in-depth investigations and help from colleagues this report would not be possible. Thanks also to pathology and microbiology colleagues UK wide and all who have provided their expertise during the investigations

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Executive Summary

The whole NHS has been and is under intense pressure but thanks to the 1,397 donors who gave their organs after death last year and the 909 living donors, 4,324 transplants operations took place last year. This equates to an increase of 18% in organ donors and 27% more transplants than the previous financial year.

The NHS has been through the toughest of times due to the Covid-19 global pandemic with undoubtedly many challenges to come including workforce and financial challenges

Despite the pandemic, we saw incredible family support for organ donation with record numbers of families agreeing to donation, testament to the strong foundation of altruism and support for donation, across the UK during the previous year. However, one of our biggest challenges at present is consent/authorisation. The consent rate fell slightly last year from 69% of families supporting donation at the point of asking, to 66% of families last year. Despite this fall in consent/authorisation, deceased organ donation and transplant activity is now almost back to pre-covid levels of activity.

In the financial year to 31 March 2022, compared with the previous year

- There was an 18% increase in the number of deceased donors to 1,397
- The number of donors after brain death increased by 2% to 785
- The number of donors after circulatory death increased by 48% to 612 (after usual criteria for DCD donation were reinstated following the first wave of the pandemic)
- The number of living donors increased by 102% to 909, accounting for 39% of the total number of organ donors • the total number of patients whose lives were potentially saved or improved by an organ transplant increased by 27% to 4,324 (as services started to increase to normal levels)

This report is intended to provide a resumé of cases where infection and cancers of possible donor origin have been investigated. It is a representation of what was reported to OTDT. Some additional cases of interest are also described.

During the same timeframe, 1 April 2021 to 31 March 2022, 792 incidents were reported to OTDT. When incidents are reported to OTDT, they are classified under 6 main categories for investigation purposes and are outlined below:

- Donation (244)
- Organ Retrieval (160)
- Transplantation (155)
- Transplant Support Services (Organ offering and allocation) (81)
- Living Donation (22)
- Quality Assurance (136)

The number in brackets represents the number of reported incidents for that category.

It is important to view the number of reported and confirmed donor transmissions in relation to the number of organs transplanted. The Activity Report for the same period can be found here:

[Annual Activity Report - ODT Clinical - NHS Blood and Transplant](#)

Infection

The underlying principle remains that the risk of an infection being passed on through transplanted organs and tissues must be kept to an acceptable minimum. What constitutes an acceptable minimum is dependent on the balance of risk and benefit for the potential intended recipient in terms of either receiving that transplant or waiting until the next suitable organ offer. In some super-urgent and urgent situations, a higher risk of infection may be acceptable. The reports below reflect clinical incidents that have been reported investigated and confirmed as a probable/confirmed donor transmission case. Any learning is also shared.

Bacterial and fungal infections

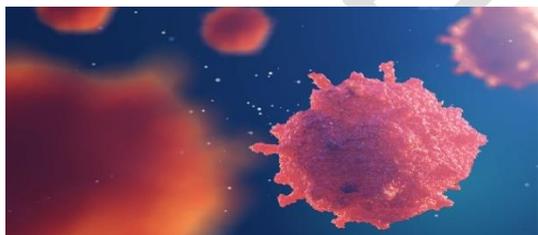
ODT INC – Mycobacterium tuberculosis (MTB)

Following the detection of an abnormality in the donor chest X-Ray, a lung wedge biopsy was taken pre-implantation in the recipient centre, with no evidence of malignancy. Seven days after transplantation NHSBT was notified of the histological result which revealed multiple granulomas with necrosis and mycobacteria on staining in donor bronchus tissue. PCR confirmed *M. tuberculosis*. All recipient centres were informed.

Statutory Reporting to the UK Health Security Agency (HSA) was undertaken by the lung recipient centre. UK HSA then co-ordinated a national incident group to work with all involved parties. Recommendation for chemoprophylaxis of all other organ recipients was made by the group. No patients developed microbiological evidence of MTB including the bilateral lung recipient. There was no evidence of transmission of infection or disease.

Viruses

ODT INC – Hepatitis B Post Liver Transplantation



A liver recipient was diagnosed with hepatitis B infection eight months post liver transplantation.

Donor blood microbiology testing was carried out as per usual processes before organ offering. A low-level inconclusive Hepatitis B Core antibody result was obtained and as past Hepatitis B infection could not be excluded, donor anti-HB core status was considered positive. The liver recipient was commenced on HBV

prophylaxis but this was stopped after post-transplant repeat testing resulted in a negative anti-HB core antibody result. Complete donor HBV serology was performed in another laboratory, with results compatible with a previous HBV infection.

There was no impact on two kidney recipients who received no prophylaxis and did not develop any evidence of HBV infection. The liver recipient did not have serological evidence of exposure to HBV pre-transplantation and was said not to have apparent alternative risk factors for HBV; therefore, HBV reactivation from the donor liver is deemed possible or probable.

2.0 Malignancy

ODT INC - High-Grade Epithelioid Tumour

Eight months post-transplantation NHSBT were notified by a renal centre that the right renal recipient had developed a rapidly growing tumour in the transplanted kidney and had metastatic disease. Immediate contact was made with the renal transplant centres, at the time both patients were thought to be well.

After reviewing the patients, NHSBT were informed by the liver transplant centre that lesions had been identified in the transplanted liver. A liver biopsy confirmed the lesions as malignant with similar pathology to the right kidney recipient.

A mass was also identified in the recipient of the left kidney, confirmed as malignant on biopsy with similar pathology to the right kidney recipient.

Transplant centres confirmed the pathology of the malignancy unusual and difficult to characterise. Histological findings concluded a donor derived malignancy, ultimately classified as a high-grade epithelioid tumour. Genetic testing also confirmed this. All three recipients have died.

There was no known history of cancer in the donor, and all previous imaging and clinical information was reviewed with no possible indication of possible malignancy, a finding that was subsequently confirmed by the coroner.

Cases for Interest

ODT INC – Ornithine Transcarbamylase Deficiency

Five months following transplantation, NHSBT received a report from a liver transplant centre suggesting the recipient's clinical presentation was highly suggestive of Ornithine Transcarbamylase Deficiency (OTC). Further genetic testing carried out which confirmed a diagnosis of OTC Deficiency donor derived disease.

OTC was not known at the time of donation and there was no family history. Genetic testing and counselling were offered.

ODT-INC - Unexpected finding in gall bladder and bile ducts

A finding of a 4 mm grade 1 well-differentiated neuroendocrine tumour was found as part of a routine histopathology review of a gall bladder and bile duct, a month following liver and other organ transplantation. Once the histopathology report was completed it was reported to NHSBT and the transplant centres all made aware.

Donor characterisation confirmed no findings of concern or suggestion that there was a suspicion of a tumour or malignancy in the donor. There was no impact to the transplanted recipients.

Update on HHV-8 Testing

HHV8 testing: Following previous reports of HHV-8 infection, OTDT formally contacted the Advisory Committee on the Safety of Blood, Tissues, and Organs (SaBTO) to request HHV8 impact on deceased organ donation and transplantation to be reviewed. A working group was established and SABTO accepted the

recommendation for universal screening of deceased organ donors. In the first instance, it is proposed testing is done centrally and post-donation, subject to post-implementation review.

We are currently awaiting ministerial approval to commence HHV-8 testing.

Conclusion

The benefit of reporting concerns post-transplant cannot be over-estimated. Timely reporting of incidents is important as it may affect the health of another transplant recipient and may inform clinical management of patients.

We would like to acknowledge all centres that continue to report to us but also encourage everyone to report rare, unusual and/or unsuspected findings post-transplantation.

We would advise that any cancer diagnosed post-transplant is reported to OTDT.

In relation to infection, we would again advise that any unusual infection, unexpected occurrence, or something that may impact the health of another recipient is reported.

Please continue to do so via the link below:

<https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/>

Thank you to everyone involved in the organ donation, organ retrieval and transplant pathway for their continued help and support, and above all for reporting to us and assisting OTDT with our investigations.

