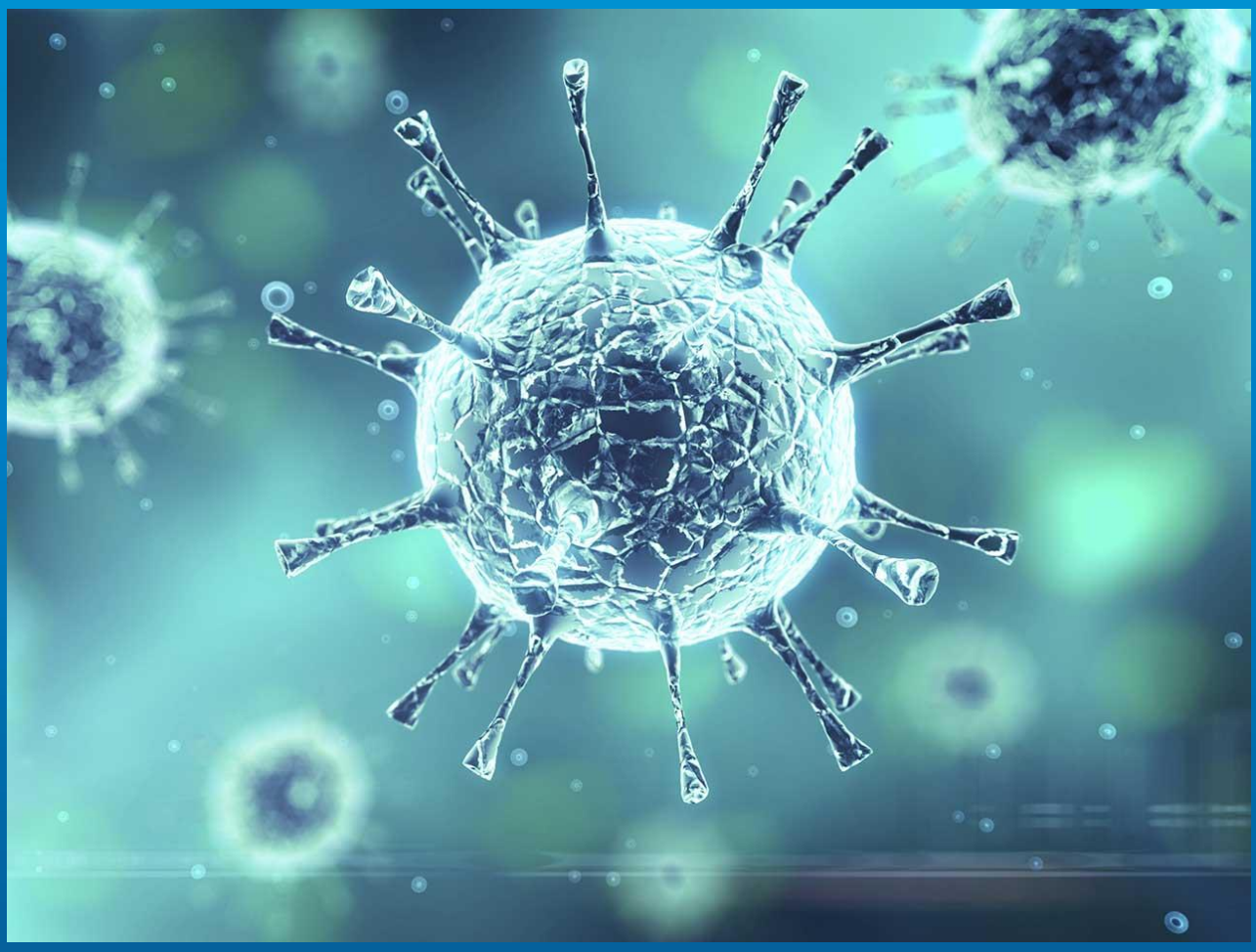
NHS
Blood and Transplant



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

April 2022 - March 2023

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 2022 and 31 March 2023. 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 period.

Acknowledgement

The Clinical Governance Team 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

Organ Donation and Transplantation remains a critical part of the NHS. The whole NHS remains under intense pressure but thanks to the 1,429 people who donated their organs after death and the 958 living donors last year (2022/23), 4,533 people received the transplant they needed.

We are continuing to achieve a steady return to pre-pandemic organ donation and transplantation activity levels. Whilst we observed a 4% increase in patients receiving a transplant last year compared to the previous year, we remain 5% off pre-pandemic levels.

However, this increase is not enough to meet the need of those needing an organ transplant; transplant waiting lists have returned to levels last seen in 2014. Last year (2022/23), 439 patients died while active on transplant lists compared with 429 in the previous year. A further 732 were removed from the transplant list, mostly because of deteriorating health and ineligibility for transplant.

As with any health intervention, solid organ transplantation is associated with risk of an adverse outcome and this risk must be balanced against the anticipated benefit. The risk includes that associated with the organ itself, such as transmission of disease, infection, malignancy, metabolic and immune diseases, as well as poor or non-function of the organ following transplantation.

This report is intended to provide a resumé of cases where infection and cancers of possible donor origin have been investigated and confirmed as a donor transmission. There are several cases that have been reported and investigated but it is *only* the cases confirmed as donor transmitted that are included.

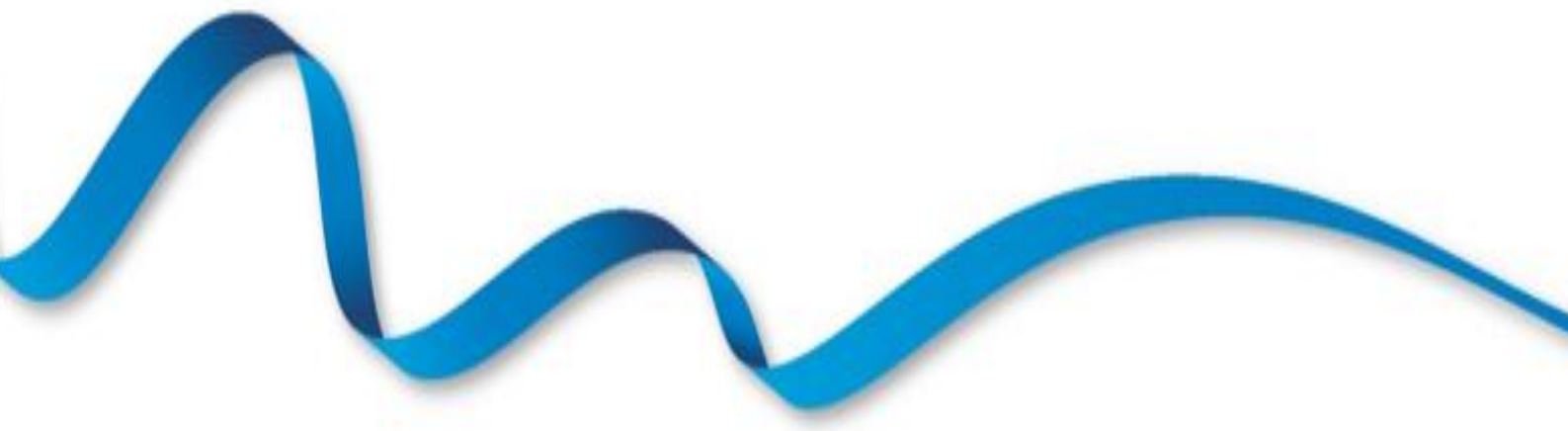
During 1 April 2022 to 31 March 2023, 728 incidents were reported to OTDT. When incidents are reported to OTDT, they are classified under six main categories for investigation purposes as outlined below:

- Donation (238)
- Organ Retrieval (154)
- Transplantation (100)
- Organ offering and allocation (53)
- Living Donation (40)
- Quality Assurance (87)

During the same period, 1 April 2021 to 31 March 2022, 792 incidents were reported to OTDT.

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

The learning from all cases reported is disseminated via a number of channels; Cautionary Tales, Governance report to each Organ Advisory Group, Clinical Governance Leads across the Organ Donation Teams, and various internal and external meetings.



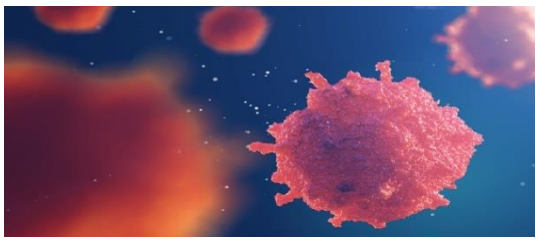
Infection

ODT INC- Strongyloides

A liver transplant recipient was reported to have been re-admitted to hospital 6 months post-transplantation, with a severe illness. Extensive investigation led to a biopsy which confirmed diagnosis of Strongyloidiasis. The patient developed Hyperinfection Syndrome and specific treatment was given, but they died of associated complications. Retrospective pre-transplant serology was negative for Strongyloides.

Two kidneys had been transplanted into two recipients and the transplant centres were informed; both recipients were from countries with high incidence of Strongyloides infection. One of the kidney recipients was already known to be infected with Strongyloides as part of the centre screening policy. The other kidney recipient had missed screening and following the notification of the liver case, investigations indicated an asymptomatic infection acquired sometime around the transplant/post-transplant period; they were both treated and remained well. Testing of donor serum was positive for Strongyloides antibodies. These findings were indicative of a donor-derived transmission of infection to two recipients.

Virus



ODT INC - Herpes Simplex Virus type 2 (HSV-2)
A liver recipient became unwell and was diagnosed with primary HSV-2 infection, 6 days post-transplant. The other recipient centres were informed and the recipients (Simultaneous Pancreas-Kidney), SPK and kidney only) were commenced on anti-viral treatment. The renal recipient developed severe, systemic primary HSV-1 disease and responded to prolonged treatment. The SPK recipient also developed symptomatic HSV-1 infection and responded to treatment. Donor serum was negative for HSV antibodies and positive for HSV-2 DNA. There was no known donor history indicative of herpes infection. This was graded as a proven donor-derived HSV-1 transmission.

ODT INC- Herpes Simplex Virus type 1 (HSV-1)
A liver transplant recipient showed significant deterioration of liver function tests requiring a transfer back to ICU in the first week following transplantation. Liver biopsy confirmed Herpes Simplex Virus type 1 (HSV-1) infection. The two other recipient centres (heart and left kidney) were informed. No tissues were retrieved from the donor.

The liver recipient had a difficult post-operative period but responded to treatment and eventually recovered. The renal and heart recipients had detectable HSV antibodies in pre-transplant sera and did not develop symptoms. Donor serum was tested retrospectively and found to be positive for HSV-1 and HSV-2 antibodies, with no detectable viral DNA in plasma. This was therefore graded as “possible/probable donor derived infection.”

2.0 Malignancy

ODT INC- Papillary Transitional Cell Carcinoma Grade 2
An unexpected lesion was discovered on the back bench at the transplant centre receiving the right kidney. The transplant centre declined the organ. The left kidney centre was informed of this finding; transplant surgery was almost completed at the time. Biopsy of the lesion confirmed a non-invasive, low grade papillary urothelial carcinoma (papillary transitional cell carcinoma grade 2) of the ureter.
There was no relevant clinical history nor any urological symptoms in the donor’s history and no unusual findings at organ retrieval were documented. The renal recipient has recovered well and will be monitored closely with a CT Urogram every 2 years.

ODT INC- Low Grade B Cell Lymphoma

Two kidneys were retrieved and transplanted along with corneas for tissue donation. Prior to the left kidney being transplanted the implanting surgeon took a routine biopsy, a “quality biopsy” which was sent for routine histopathology. Two weeks later the biopsy was reviewed, and it was found that the kidney had a “low grade B cell lymphoma.” The right kidney centre and Tissue Services were informed of the finding.

The right kidney recipient died shortly after transplantation from unrelated causes. The left kidney recipient is doing well post operatively and has opted to keep the kidney with regular clinical monitoring. The corneal recipients have been informed and are being monitored. The donor was known to have Monoclonal Gammopathy of Undetermined Significance (MGUS), which carries a small risk of cancer developing. This is not a contraindication to donation of organs and tissues and there was no history of cancer in the donor. The donor history of MGUS was known at the time of organ offering and allocation. Factors that made MGUS more suspicious:

- Serum M-protein level ≥1.5 g/dL (≥15 g/L)
- Non-IgG MGUS (i.e., IgA, IgM, IgD MGUS)
- Abnormal serum free light chain (FLC) ratio (i.e., ratio of kappa to lambda free light chains <0.26 or >1.65)

Case for Interest

ODT INC - Hepatitis B Infection

A donor testing positive for HBV core antibody proceeded to donation and both kidneys were transplanted. Twenty months post-transplant, a probable Hepatitis B infection occurred in the right kidney transplant recipient, and possible donor origin was reported. The recipient was anti-Hepatitis B core antibody (HBcAb) and Hepatitis B surface antigen (HBsAg) negative pre-transplant. The renal recipient received Hepatitis B prophylaxis for 6 months.

The left kidney recipient showed no evidence of HBV infection with HB surface antigen and HBV DNA remaining negative throughout. Having been anti-HB core negative before transplantation, a low level of HB core antibody became detectable 7 months’ post-transplant and then tested negative. The reason for that has not been found and significance is uncertain. It is possibly a false-positive reaction as there is no history of transfusion. Both recipients received treatment at their local centre.

It was concluded that this was a possible donor-derived infection.

Conclusion

Timely reporting of incidents is important as it may affect the health of another transplant recipient and may inform clinical management of patients. Sharing of the learning continues via the usual channels.

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 support and assisting with our investigations, ensuring the continued safety of transplant recipients