

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

April 2020 - March 2021

Preface

This report has been produced by Clinical Governance and the Lead Clinical Microbiologist, 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 2020 and 31 March 2021. 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

NHS Blood and Transplant Clinical Governance 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 in the United Kingdom (UK) is an NHS success story. However, the last 12 months have been the most challenging in our history due to the Covid-19 pandemic. The whole NHS was put under intense pressure and remains so, the impact also seen in Organ Donation and Transplantation.

In April 2020, during the peak of the first wave of the pandemic, we saw a sharp reduction in the number of deceased donors and transplants – the lowest number ever recorded on a monthly with just 100 transplants taking place. However, with a great team effort across clinical teams, deceased organ donation and transplant activity continued for the most urgent patients during the first wave of Covid-19 and returned to pre- Covid levels quite rapidly.

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. In the financial year to 31 March 2021, compared with the previous year:

- There was a 25% fall in the number of deceased donors to 1,180
- The number of donors after brain death fell by 19% to 766
- The number of donors after circulatory death fell by 35% to 414

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 2020 to 31 March 2021, 657 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 (209)
- Organ Retrieval (132)
- Transplantation (130)
- Transplant Support Services (Organ offering and allocation) (85)
- Living Donation (9)
- Quality Assurance (92)

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



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 or have come to the attention of ODT, investigated and lessons shared.

Bacterial and fungal infections

No reported bacterial or fungal infections for the timeframe.

Viruses

ODT-INC – Herpes Simplex Virus (HSV)-2

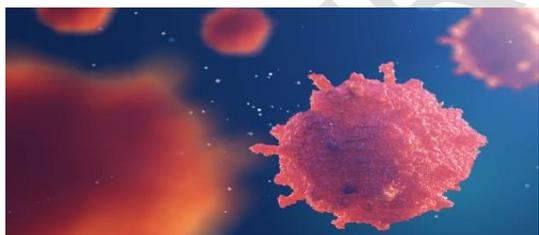
A transplant centre reported a case of histologically proven diagnosis of Herpes Simplex Virus (HSV) -2 in a liver recipient, 15 days post-transplant. On retrospective testing, recipient was seronegative for HSV on a pre-transplant sample. Patient was treated with intravenous Acyclovir but died of complication of the HSV-2 infection.

Two kidneys from the same donor had been transplanted into two recipients. Renal transplant centres promptly informed. Retrieved tissues were discarded.

Donor testing was performed with HSV-1 and HSV-2 antibodies detected; HSV-2 DNA was detected in plasma at the limit of assay detection (very weak positive).

Left kidney recipient was seronegative pre-transplant and remained seronegative at 5- and 7-weeks post-transplant. HSV DNA negative in blood at 5 weeks' post-transplant. Received 14 days of oral Acyclovir prophylaxis. Remained well.

Right kidney: patient had pre-existing (pre-transplant) HSV-1 and HSV-2 antibodies. No antiviral treatment given, patient well 5 weeks' post-transplant, with undetectable HSV-2 DNA in blood.



ODT-INC – HHV-8, liver transplantation

Liver recipient died of histologically proven Kaposi sarcoma, 5 months' post-transplantation.

Renal transplant centres informed and recipient HHV-8 testing undertaken. Stored blood samples from the solid organ donor tested. Liver transplant centre: accompanying liver vessels destroyed

Retrospective serological and molecular testing of donor sample demonstrated HHV-8infection.

Left kidney recipient: Seronegative pre-transplant, with no demonstrable seroconversion 7 months' post-transplant. Being followed up.

Right kidney recipient: HHV-8 seroconversion demonstrated. Remained well and is being followed up.

With a new infection being detected in in the same time frame in two recipients, these transmissions were of donor origin.

ODT-INC – HHV-8, liver transplantation

Nodular Kaposi sarcoma diagnosed histologically 3 months' post-transplantation. Successful excision of the axillar mass. No other organs or tissues donated from donor.

The recipient was not known to have any risk factors associated with HHV8, and was seronegative for HHV-8 antibodies, seroconverting post-transplantation.

Donor had serological evidence of HHV8 infection. As no other recipients, this is a probable donor-derived transmission.

HHV8 testing: OTDT formally contacted the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) to request this is reviewed. A working group was established and SABTO accepted the recommendations presented by this group. Their recommendation included: universal screening in phase one, to be reviewed in year 3 or earlier, if necessary. Post donation testing at the point of implementation as it is currently not possible to deliver the results pre-donation. Given the nature of the testing required and the fact that HHV8 serology is not performed anywhere in the UK , the recommendation is to have it performed in a central laboratory. More information to follow on implementation and roll-out of HHV8 testing.

2.0 Malignancy

ODT-INC – Malignant Melanoma

Eight months' post-transplant a likely donor derived malignancy in a pancreas islet recipient was reported. The recipient had developed a melanotic liver cancer. Molecular genetic analysis report confirmed a donor-derived malignancy.

Immediate contact made with the renal transplant centres, at the time both patients thought to be well.

Right kidney recipient has since died from likely donor derived metastatic malignant melanoma. Left Kidney recipient has developed metastatic disease: confirmed melanoma.

Melanoma excision was known at the time of donation and the report available within guidance for organ acceptance. Due to the complexity of grading and reporting on this type of cancer, malignant melanoma referrals and acceptance were paused within OTDT. SaBTO informed of this case. Guidance from SaBTO has been updated and can be found at:

[Transplantation of organs from donors with a history of cancer \(publishing.service.gov.uk\)](https://publishing.service.gov.uk)



Cases for Interest

ODT-INC – Fabry’s Disease

8 weeks’ post-transplant a renal centre reported a biopsy report highly suggestive of Fabry’s disease. No history of Fabry’s disease noted in the donor history however, there was a history of familial renal disease. The donors (male), mother had end stage renal failure and underwent a transplant in 2016 with a diagnosis of “FSGS.”

All transplant centres informed. Following investigations, the heart transplant recipient underwent an endomyocardial biopsy which was consistent with Fabry’s disease. Advice gained from an expert in this area who confirmed that genetic testing of the family would be in their benefit and beneficial for recipient management. Genetic testing confirmed Fabry’s disease and with family consent the GP was informed and advised to refer to a specialist.

ODT-INC – Parvovirus

A heart recipient was diagnosed with transfusion-dependent anaemia caused by human Parvovirus B19 infection, 90 days post-transplant; patient was seronegative prior to transplantation. The donor blood samples tested negative for Parvovirus B19 antibodies and DNA; The recipient received several units of red blood cells; blood donor archives tested negative for Parvovirus B19 DNA.

No evidence of transmission of infection of donor origin.

ODT-INC – COVID-19, Liver transplantation

Virological diagnosis of COVID19 was confirmed on day +5 post-transplant. All appropriate routes of inquiry were pursued immediately to try and understand the possible origin of infection in the recipient, most likely community acquired. Organ donor tested negative for SARS-CoV-2 RNA (mandatory screening) in upper and lower tract infection. No evidence to suggest donor-derived infection.

ODT INC – COVID-19, Kidney Transplantation

Kidney recipient discharged home on post-transplant day 9, onset of compatible COVID-19 symptoms and positive test 6 days later; admitted to hospital on the following day and died 3 weeks later. Donor had negative SARS-CoV2 RNA results on admission to hospital and at the time of donor characterisation. No positive results reported from the left kidney or the liver recipient. No evidence to suggest infection of donor origin.

ODT INC- COVID-19 Lung transplantation

A recipient of bilateral lungs tested positive for SARS-CoV-2 RNA 5 days’ post-transplantation. The recipient tested negative in a nose and throat swab taken on admission to hospital. Donor had also tested negative in endotracheal aspirate and had a very weak reactive result in the nose and throat swab, interpreted and reported as negative at the time of screening. The donors Bronchoalveolar Lavage (BAL) sample was tested and confirmed as negative. No evidence this was donor derived.

The lung recipient did well post-transplant and did not develop symptoms of COVID-19.

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-transplant.

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

In relation to infection, we would again recommend 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 timely investigations.

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