Safety Notice 010/21

Requirements for post-transplant blood-borne virus surveillance of recipients of organs from increased-risk donors

18 May 2021

Distributed to:

- Chief Executives
- Directors of Clinical Governance

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Heads of Department
- Transplant Unit Directors
- Transplant Physicians
- Transplant Unit staff

Expert Reference Group

Content reviewed by:

- Organ and Tissue Retrieval Quality and Safety Committee
- Agency for Clinical Innovation Renal Network Transplant Working Group
- NSW Organ and Tissue Donation Service
- Office of Chief Health Officer, MoH
- Health Protection NSW

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Review date

May 2022

Situation

A recent investigation following transmission of hepatitis C virus (HCV) from an increased-risk donor to organ recipients identified inconsistent compliance with the Transplantation Society of Australia and New Zealand's (TSANZ) Clinical Guidelines for Organ Transplantation from Deceased Donors. These guidelines are developed nationally by the TSANZ and guide NSW Health's post-transplant surveillance activities.

Background

Organ donors undergo comprehensive testing for blood-borne viruses (BBV), including HCV, hepatitis B virus (HBV), and human immunodeficiency virus (HIV), to avoid transmission from organ donor to recipient. Despite this, there is a small risk of transmission of microbial agents due to a recent infection in a donor, prior to infection being detectable by either nucleic acid testing (NAT) or serological testing. This is called the "eclipse" period for NAT (the point from infection to detectable viraemia) or the "window period" for serology (the point from infection to detectable antibody). The eclipse period is 3 to 5 days for HCV, 7 to 14 days for HBV and 10 to 14 days for HIV.

Unexpected transmission is more likely to occur where there are certain risk factors in the donor such as a history of intravenous drug use, high-risk sexual contact or when a social and medical history cannot be accurately obtained.

In donors where increased-risk features have been identified, donation and transplantation may still occur **with informed consent and post-transplant surveillance for the appearance of infection.** Timely identification of transmission allows earlier treatment for the organ recipient and to initiate coordination of urgent testing in recipients from the same donor.

Clinical Guidance

Each NSW Health transplant unit, or delegate unit where care has been transferred, is responsible for ensuring that the TSANZ Clinical Guidelines are operationalised locally. When certain high-risk features are suggestive of the donor being in the eclipse or window period, the NSW Organ and Tissue Donation Service (OTDS) will inform the recipient transplant teams.

The recipient's transplant team is responsible for:

- Ensuring that post-transplant BBV surveillance is undertaken according to the TSANZ Clinical Guidelines
- Informing the OTDS immediately of new infection with HBV, HCV or HIV in the post-transplant follow-up period
- Notifying clinical teams who may receive transplant patients for ongoing care of the need for post-transplant BBV surveillance activities

When notified of a transplant-related infection, the OTDS will assist in donor organ tracing to facilitate testing of other recipients.

Reference:

1. Organ and Tissue Authority (2021) *Clinical Guidelines for Organ Transplantation from Deceased Donors* - Version 1.6 (Section 2.3: Risk of donor transmitted infectious disease).

Actions required by Local Health Districts/Networks

1. Review local procedures to ensure that transplant units, or units who receive transplant patients for ongoing care, have implemented the TSANZ Clinical Guidelines
2. Review local systems to ensure roles and responsibilities related to post-transplant BBV surveillance are clear and well-understood by relevant parties
3. Ensure local procedures and clinical pathways include immediate notification to OTDS of any new infection with HBV, HCV or HIV detected in the post-transplant period
4. Submit a notification to the incident notification system in the event of any systems issues or new infection with HBV, HCV or HIV detected in the post-transplant period.