Eye Bank Association of Australia and New Zealand

Eye Bank Association of Australia and New Zealand (EBAANZ)
32 Gisborne St, East Melbourne VIC 3002

02/02/2022

EBAANZ Medical Advisory Committee Notification:

HTLV donor testing in eye donors

Executive Summary:

The Therapeutic Goods Administration (TGA) has mandated deceased donors of human cell and tissue materials (HCT) to be serology tested for HTLV-1 and HTLV-2.

The TGA has stated that HTLV testing may not be required if:

1. A risk assessment is submitted which demonstrates that the HCT material is not a viable, leukocyte-rich cell or tissue, AND
2. The donor, the donor's parents, the donor's sexual partners originate from a low risk HTLV area.

The EBAANZ Medical Advisory Committee has assessed the risk of HTLV in eye only donors and makes the below recommendations on when HTLV testing is required for eye only donors.

1. Ocular tissue (cornea and sclera) are not considered to be viable, leukocyte-rich tissues. Donor testing for HTLV for eye only donors is not recommended.

2. For donors born in Australia, whose parents and sexual partners originate from Australia, donor testing for HTLV is not recommended unless the origin of birth for the donor, donor's parents and sexual partners are Indigenous communities in central Australia.

3. If a donor *or* the donor's parents *or* the donor's sexual partners originate from a high risk HTLV area, then HTLV testing is recommended.

The below table provides supporting risk assessments and evidence for the above recommendations.

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Risk Area	TGA Requirement	Supporting Evidence	Risk Assessment	MAC Recommendations
Leukocyte-rich Tissue	• TGA recognise the cornea and sclera are not considered to be viable, leukocyte rich tissues. • TGA provides guidance that sponsors should describe how manufacturing steps reduce leukocyte content from these tissues.	• There has not been a documented transmission of HTLV by cornea transplantation[1,2]. • Australian Eye Banks do aim to reduce leukocytes through processing steps in particular betadine washes and media preservation following removal from the donor. • Typically, tissue washing is seen as being enough for corneas due to the lack of blood vessels and lymphatics. • Preservation of corneas in cold or organ culture storage for more than 5 days results in a loss of leucocytes as the storage media does not support leukocyte viability. • For sclera, preservation in alcohol or glycerol destroys all viable cells and thus prevents HTLV viability. • Complete removal of all risk of transmission in corneal tissue is only possible by methods that completely remove all cellular live materials from the tissue. ○ Corneal tissue cannot be processed in such a manner as it would sterilise the tissue and make it non-viable for transplant.	• Low Risk • Acceptable	• Testing not required.

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Risk Area	TGA Requirement	Supporting Evidence	Risk Assessment	MAC Recommendations

Prevalence	• Provide evidence that the donor, the donor's parents, or the donor's sexual partners originate from a low risk HTLV area.
	• TGA consider 'High prevalence' as a prevalence over 1% in the general population of adults over 18 years old or prevalence of over 1/10,000 among first-time blood donors.
		• All Australian states but TAS have a prevalence less than 1/10,000 in first time blood donors.
		• The prevalence of HTLV in 2019 for first-time blood donors were[2]:
		  ○ NSW/ACT – 0.89/10,000
		  ○ TAS – 3.14/10,000
		  ○ Caution should be taken in interpretation of HTLV prevalence in first-time donors in Tasmania as this rate equates to only one positive donor[2].
		  ○ VIC – 0.34/10,000
		  ○ NT – 0/10,000
		  ○ QLD – 0/10,000
		  ○ SA – 0/10,000
		  ○ WA – 0/10,000
		• The prevalence of HTLV infection in first-time blood donors has remained at zero in the Northern Territory for the past 10 years (2010-2019).
		• There is a significant high rate of HTLV infection in indigenous communities in remote Australia of up to 40%[4]
		• Main risk factors identified in the reporting period 2015-2019 are:
		  ○ Ethnicity/Country of Birth
		• Secondary Risk factors identified in the reporting period 2015-2019 are:
		  ○ Partner with known risk/known to be positive
		  ○ Partner with unspecified risk was only reported in 2019
		• HTLV-1 is highly endemic in certain geographic regions including Japan, the Caribbean and central Africa and to a lesser extent in Iran, Iraq, southern India and China.
			• Low and acceptable risk for donors born in Australia, whose parents and sexual partners originate from Australia. *This does not include indigenous communities in remote Australia.*
			• Variable Risk for donors based on country and certain areas globally.
				• For donors born in Australia, whose parents and sexual partners originate from Australia:
				  ○ Donor testing for HTLV is not recommended unless the origin of birth for the donor, donor's parents and sexual partners are indigenous communities in remote Australia.
				• If a donor, the donor's parents or the donor's sexual partner's originate from a high risk HTLV area, meaning a prevalence of over 1% in the general population of adults over 18 years old, or prevalence of over 1/10,000 among first-time blood donors, then HTLV testing is recommended.
				• To determine if HTLV-1 testing is required outside of Australian born donors, consult the European Centre for Disease Prevention and Control (*https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/geographical-distribution-areas-high-prevalence-HTLV1.pdf)*

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References:

1. ECDC Technical Report. Risk assessment of HTLV-I/II transmission by tissue/cell transplantation. Part 2: Risks by tissue type, impact of processing and effectiveness of prevention measures.
2. Dubord, Paul J. MD; Evans, G. Dewey PhD; Macsai, Marian S. MD; Mannis, Mark J. MD, FACS; Glasser, David B. MD; Strong, Douglas M. PhD; Noël, Luc MD; Fehily, Deirdre PhD. Eye Banking and Corneal Transplantation Communicable Adverse Incidents Current Status and Project NOTIFY Cornea: August 2013 - Volume 32 - Issue 8 - p 1155-1166
3. Transfusion-transmissible infections in Australia: 2020 Surveillance Report. Kirby Institute, UNSW Sydney, and Australian Red Cross Lifeblood; 2020
4. Lloyd Einsiedel, Hai Pham, Mohammad Radwanur R Talukder, Joel Liddle, Kerry Taylor, Kim Wilson, Hubertus Jersmann, Antoine Gessain, Richard Woodman, John Kaldor. Pulmonary Disease Is Associated With Human T-Cell Leukemia Virus Type 1c Infection: A Cross-sectional Survey in Remote Aboriginal Communities Clinical Infectious Diseases, Volume 73, Issue 7, 1 October 2021, Pages e1498–e1506

On behalf of the EBAANZ Medical Advisory Committee.

Regards,

Luke Weinel – EBAANZ Chair

Dr Con Petsoglou – EBAANZ MAC chair