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Change Notification for the UK Blood Transfusion Services

No. 40 - 2024

West Nile Virus

This notification includes the following changes:

	BM-DSG	CB-DSG	GDRI	TD-DSG	TL-DSG	WB-DSG	Red Book
	Bone Marrow & Peripheral Blood Stem Cell	Cord Blood	Geographical Disease Risk Index	Tissue - Deceased Donors	Tissue - Live Donors	Whole Blood & Components	Guidelines for the BTS in the UK
1. West Nile Virus							

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Changes are indicated using the key below. This formatting will not appear in the final entry.

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I. Changes apply to the Bone Marrow and Peripheral Blood Stem Cell DSG

West Nile Virus (revised entry)

Definition	, ,		
	These are shown in the 'Geographical Disease Risk Index' (GDRI).		
Obligatory	Must not donate if: a) It is less than six months from a donor's return from a WNV endemic area and the donor has been diagnosed with WNV while there or following their return.		
	b) It is less than six months from a donor's return from a WNV endemic area and the donor has either had a history of symptoms suggestive of WNV while there or within 28 days of their return.		
	c) In other cases, it is less than four weeks from a donor's return from a WNV endemic area.		
Discretionary	a) All donors may be accepted six months after their return from an affected area. This may be reduced to four weeks if they have had neither symptoms nor evidence of infection.		
	b) For donors who have been back in the UK for less than four weeks «before clearance or donation», who have not been diagnosed with WNV infection and who have not had symptoms suggestive of WNV infection, if a validated NAT for WNV is to be undertaken see Additional Information.		
	c) Donors who have been back in the UK for less than six months, and more than 28 days, who have had symptoms suggestive of WNV infection while abroad or within 28 days of return (but no firm diagnosis of WNV infection), if a validated NAT for WNV is to be undertaken, accept.		
See if Relevant	The 'Geographical Disease Risk Index'		
Additional Information	West Nile Virus is a flavivirus, similar to Dengue, which causes a wide spectrum of infection. This may range from no or minimal symptoms to death. It is geographically widespread, including areas in Europe and other parts of the world not affected by malaria, and it has reached epidemic proportions in North America in recent years. There it has caused illness and death post transfusion and post transplantation of tissues and organs. It is spread by mosquitoes and so is more prevalent at times of the year when mosquitoes are active.		
	As the problem can vary both in relation to geography and time of the year it is not possible to state areas from which donors need to be deferred and dates of disease activity. These are provided in the 'Geographical Disease Risk Index'.		
	At least one case was reported in the literature that WNV has caused illness and death after transplantation of stem cells from inadequately screened donors, but the spectrum of this illness in recipients is unknown as patients who develop a		

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pyrexia post-transplant and pre-engraftment will not routinely undergo screening for WNV infection.

Testing a donor early in the incubation period and then collecting haematopoietic stem cells some days later may not assure component safety. Therefore, the time of testing of donors within 28 days of return from an affected area becomes important to ensure testing is not carried out too early in the incubation period. This must be balanced against the patient's clinical need, and the likelihood of detecting infection in an asymptomatic donor.

When an allogeneic stem cell donor who has been asymptomatic has returned from a WNV endemic area, the preferred option is to wait for 28 days from return "before clearing the donor" if the stem cell collection can be delayed. In exceptional circumstances and if there is a pressing clinical need to proceed to "clearing the donor or" collection within 28 days of return, a risk assessment should be undertaken in conjunction with the transplant centre clinicians as to how they will manage their patient. This should include awareness of the timing of the return of the donor from the WNV endemic area, the likelihood of receiving a WNV positive donation (with its associated risks) from an asymptomatic donor, and the options of:

- a) Delay the «clearance of the donor and» stem cell collection «plus» and conditioning of the patient as far as possible towards the day 28 of the return of the donor (with possible individual WNV NAT testing).
- b) Product cryopreservation with delayed conditioning until the WNV individual NAT result from the day of donation sample is known.

Data on the risk of a WNV positive donation entering the UK blood supply is available and is considered to be very low. The UK Blood Services have carried out 288,533 WNV NAT tests on asymptomatic whole blood donors within 28 days of returning from WNV affected areas from June 2013 to 2020, and there have been no positives identified (available data: Standing Advisory Committee on Transfusion Transmitted Infections). Further data available in the literature suggests RNA detection is possible within two days and up to 13 days of exposure using individual donor NAT testing. If this is the case, individual NAT testing in asymptomatic donors within 13 days of return from a WNV endemic area would permit donation to proceed if there is a pressing clinical need.

All these considerations support a screening stratification approach to allow the transplant centre to make a judgement based on the perceived clinical need versus risk of transplanting a positive donation to the recipient if the donor is within 28 days of return from a WNV endemic area and there is a pressing clinical need to proceed with transplantation, and so therefore donation.

A 'Position Statement on West Nile Virus (WNV)' is available in the <u>Document Library</u>.

Reason for Change

«To include donor clearance as a timepoint for consideration in risk assessment.»

To update the Additional Information section.