

Issued by JPAC: 18 July 2017

Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 17 - 2017

Malaria

These changes apply to the individual Tissue and Cells Donor Selection Guidelines as stated below.

1. Tissue Donor Selection Guidelines – Live Donors

Please modify “Obligatory”, “Discretionary”, “Additional Information” and “Reason for Change” as follows:

Obligatory

Must not donate if:

- a) The donor has ever had malaria.
- b) The donor has had an undiagnosed fever (that could have been malaria) while abroad or within **four** months of leaving a malaria endemic area.
- c) The donor has lived in any malaria endemic area for a continuous period of six months or more at any time of life.
- d) Less than 12 months after last leaving a malaria endemic area.

Discretionary

1a) Donors who have had malaria diagnosed in the past:

If more than three years have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved and a validated test for malaria antibody is negative, accept.

If the donor (with a history of malaria) has revisited a malaria endemic area and at least four months have passed since return and a validated test for malaria antibody is negative, accept.

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1b) Donors who have EVER had an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area:

If at least four months have passed since the donor returned from the malaria endemic area, or from the date of recovery from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept.

NB. this may have to be increased to six months if the area is also identified as a risk area for *T. cruzi* or a tropical virus; the longest stipulated deferral period must be applied

1c) Donors who have EVER been resident in a malaria endemic area for six months or more:

If at least four months have passed since the date of the last potential exposure to malaria, and a validated test for malaria antibody is negative, accept.

1d) For all other donors:

If at least four months and less than 12 months have passed since return from a malaria endemic area, and a validated test for malaria antibody is negative, accept.

If travel to a malaria endemic area was more than 12 months prior to donation, and the donor has never been diagnosed with malaria, has never had an undiagnosed fever while abroad, or within four months of leaving a malaria endemic area and has not lived in a malaria endemic area for a continuous period of six months or more at any time of life, the donor can be accepted without the need for malaria antibody testing.

2. If tissue will be sterilized by irradiation post-donation:
Accept.

Additional Information

The SaBTO Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation (2011) confirms that irradiation of the tissue can be allowed as an alternative to malaria antibody testing for donors with a travel history.

Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the donor had symptoms after travel or stay.

Reason for Change

The 'Discretionary' entry has been expanded for clarity.

The interval since last leaving a malaria endemic area for malaria antibody testing has been reduced from 6 to 4 months.

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2. Tissue Donor Selection Guidelines – Deceased Donors

Please modify “Obligatory”, “Discretionary”, “Additional Information” and “Reason for Change” as follows:

Obligatory

Must not donate if:

- a) The donor has ever had malaria.
- b) The donor has had an undiagnosed fever (that could have been malaria) while abroad or within **four** months of leaving a malaria endemic area.
- c) The donor has lived in any malaria endemic area for a continuous period of six months or more at any time of life.
- d) Less than 12 months after last leaving a malaria endemic area.

Discretionary

1a) Donors who have had malaria diagnosed in the past:

If more than three years have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved and a validated test for malaria antibody is negative, accept.

If the donor (with a history of malaria) has revisited a malaria endemic area and at least four months have passed since return and a validated test for malaria antibody is negative, accept.

1b) Donors who have EVER had an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area:

If at least four months have passed since the donor returned from the malaria endemic area, or from the date of recovery from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept.

NB. this may have to be increased to six months if the area is also identified as a risk area for *T. cruzi* or a tropical virus; the longest stipulated deferral period must be applied

1c) Donors who have EVER been resident in a malaria endemic area for six months or more:

If at least four months have passed since the date of the last potential exposure to malaria, and a validated test for malaria antibody is negative, accept.

1d) For all other donors:

If at least **four** months and **less than 12** months have passed since return from a malaria endemic area, and a validated test for malaria antibody is negative, accept.

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If travel to a malaria endemic area is more than 12 months prior to donation and the donor has never been diagnosed with malaria, has never had an undiagnosed fever while abroad or within four months of leaving a malaria endemic area and has not lived in a malaria endemic area for a continuous period of six months or more at any time of life, the donor can be accepted without the need for malaria antibody testing.

2. If tissue will be sterilized by irradiation post-donation:

Accept.

3. Eyes

Accept for corneas only.

If the donor does not comply with any of the above, discuss with the **Designated Medical Officer** who will decide if the donor may be accepted following a documented risk assessment.

Additional Information

The SaBTO Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation (2011) confirms that irradiation of the tissue can be allowed as an alternative to malaria antibody testing for donors with a travel history.

Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the donor had symptoms after travel or stay.

As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Reason for Change

The 'Discretionary' entry has been expanded for clarity.

The interval since last leaving a malaria endemic area for malaria antibody testing has been reduced from 6 to 4 months. The 'additional information' section has also been amended.

The potential for discretionary acceptance after risk assessment has been explained

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3. Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines for Unrelated Donors

Please modify “Obligatory”, “Discretionary”, “Additional Information” and “Reason for Change” as follows:

Obligatory

Must not donate if:

- a) The donor has ever had malaria.
- b) The donor has had an undiagnosed fever (that could have been malaria) while abroad or within **four** months of leaving a malaria endemic area.
- c) The donor has lived in any malaria endemic area for a continuous period of six months or more at any time of life.
- d) Less than 12 months after last leaving a malaria endemic area.

Discretionary

1a) Donors who have had malaria diagnosed in the past:

If more than three years have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved and a validated test for malaria antibody is negative, accept.

If the donor (with a history of malaria) has revisited a malaria endemic area and at least four months have passed since return and a validated test for malaria antibody is negative, accept.

1b) Donors who have EVER had an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area:

If at least four months have passed since the donor returned from the malaria endemic area, or from the date of recovery from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept.

NB. this may have to be increased to six months if the area is also identified as a risk area for *T. cruzi* or a tropical virus; the longest stipulated deferral period must be applied

1c) Donors who have EVER been resident in a malaria endemic area for six months or more:

If at least four months have passed since the date of the last potential exposure to malaria, and a validated test for malaria antibody is negative, accept.

1d) For all other donors:

If at least **four** months and **less than 12** months have passed since return from a malaria endemic area, and a validated test for malaria antibody is negative, accept.

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If travel to a malaria endemic area is more than 12 months prior to donation and the donor has never been diagnosed with malaria, has never had an undiagnosed fever while abroad or within four months of leaving a malaria endemic area and has not lived in a malaria endemic area for a continuous period of six months or more at any time of life, the donor can be accepted without the need for malaria antibody testing.

If the donor does not comply with any of the above, discuss with the **Designated Medical Officer** who will decide if the donor may be accepted following a documented risk assessment and discussion with the Transplant Centre.

Additional Information

Cases of malaria transmission have occurred many years after the donor was last at risk of becoming infected with malaria. This is mainly a problem in people who have had repeated episodes of infection with malaria. This is uncommon, but before allowing someone who has had, or may have had malaria to donate, it is safer to test for malaria antibodies rather than to wait a specific length of time. Malaria may be fatal.

Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the donor had symptoms after travel or stay.

Reason for Change

The 'Discretionary' entry has been expanded for clarity

The interval since last leaving a malaria endemic area for malaria antibody testing has been reduced from 6 to 4 months.

4. Cord Blood Donor Selection Guidelines

Please modify "Obligatory", "Discretionary", "Additional Information" and "Reason for Change" as follows:

Obligatory

Must not donate if:

- a) The mother has ever had malaria.
- b) The mother has had an undiagnosed fever (that could have been malaria) while abroad or within **four** months of leaving a malaria endemic area.
- c) The mother has lived in any malaria endemic area for a continuous period of six months or more at any time of life.
- d) Less than 12 months after last leaving a malaria endemic area.

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Discretionary

1a) Mothers who have had malaria diagnosed in the past:

If more than three years have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved and a validated test for malaria antibody is negative, accept.

If the donor (with a history of malaria) has revisited a malaria endemic area and at least four months have passed since return and a validated test for malaria antibody is negative, accept.

1b) Mothers who have EVER had an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area:

If at least four months have passed since the donor returned from the malaria endemic area, or from the date of recovery from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept.

NB. this may have to be increased to six months if the area is also identified as a risk area for *T. cruzi* or a tropical virus; the longest stipulated deferral period must be applied

1c) Mothers who have EVER been resident in a malaria endemic area for six months or more:

If at least four months have passed since the date of the last potential exposure to malaria, and a validated test for malaria antibody is negative, accept.

1d) For all other mothers:

If at least four months and less than 12 months have passed since return from a malaria endemic area, and a validated test for malaria antibody is negative, accept.

If travel to a malaria endemic area is more than 12 months prior to donation and the mother has never been diagnosed with malaria, has never had an undiagnosed fever while abroad or within four months of leaving a malaria endemic area and has not lived in a malaria endemic area for a continuous period of six months or more at any time of life, the mother can be accepted without the need for malaria antibody testing.

If the malaria antibody is positive obtain details of exposure and treatment and discuss with the **Designated Medical Officer**. A risk assessment must be documented and, if accepted, the details must be discussed at selection with the transplant centre.

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Additional Information

Cases of malaria transmission have occurred many years after the mother was last at risk of becoming infected with malaria. This is mainly a problem in people who have had repeated episodes of infection with malaria. This is uncommon, but before allowing someone who has had, or may have had malaria to give a donation, it is safer to test for malaria antibodies rather than to wait a specific length of time. Malaria may be fatal.

Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the mother had symptoms after travel or stay.

Reason for Change

The 'Discretionary' entry has been expanded for clarity.

The interval since last leaving a malaria endemic area for malaria antibody testing has been reduced from 6 to 4 months.

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