

Issued by JPAC: 25 January 22

Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 42 - 2021

Recipients of Donated Eggs

These changes apply to the Whole Blood and Component Donor Selection Guidelines.

42.1 Trying to Conceive

Please amend the following sections of this entry:

<i>Obligatory:</i>	<p>Take care to exclude pregnancy.</p> <p>Must not donate if:</p> <ul style="list-style-type: none"> a) Under investigation for infertility. b) Less than 12 weeks after completion of treatment with clomiphene (Clomid®). c) Less than 12 weeks after completion of treatment with tamoxifen. d) Has ever been given human gonadotrophin of pituitary origin. e) Has received donated eggs or embryos since 1980. f) e) If donor knows that they have ever been treated with Metrodin HP®.
<i>Additional Information:</i>	<p>The 12 week period is an additional safeguard to avoid taking a donation early in a pregnancy.</p> <p>The use of human gonadotrophin of pituitary origin (follicle-stimulating hormone (FSH) and luteinizing hormone (LH)) had stopped in the UK by 1986. The situation in other countries varied so specific dates cannot be given.</p> <p>There is a concern that transfer of tissues between individuals might lead to the spread of vCJD.</p> <p>Metrodin HP® was withdrawn by the Committee on Safety of Medicines in 2003 and following advice from the Medicines and Healthcare products Regulatory Agency the precautionary principle has been applied to withdraw donors who have been treated with this product. Donors treated for infertility after 2003 in the UK will not have been treated with this product.</p> <p>Donors trying to conceive naturally can donate provided that they have not missed a period. Taking folic acid or other vitamin and mineral preparations is not a problem.</p>
<i>Reason for Change:</i>	<p>Withdrawal of donors who have ever been treated with Metrodin HP®, donated eggs or embryos has been added.</p> <p>The deferral for recipients of donated eggs or embryos has been removed in line with the most recent update of the SaBTO Microbiological Safety Guidelines.</p>

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42.2 Tissue and Organ Recipients

Please amend the following sections of this entry:

<i>Excludes:</i>	Recipients of donated human eggs, sperm and embryos.
<i>Obligatory:</i>	<p>Must not donate if:</p> <p>1. At any time has:</p> <ul style="list-style-type: none"> a) Needed immunosuppression. b) Had dura mater transplanted. c) Had a stored autologous tissue, matrix implant or organ transplanted (stored autologous fresh or stored autologous frozen egg/embryo transfers as part of IVF treatment are not included in this category and can be accepted) d) Had ocular tissue transplanted. e) Had a Xenotransplant performed. <p>2. Since January 1st 1980:</p> <p>Has had an allogeneic human tissue or organ transplant.</p>
<i>Discretionary:</i>	<ul style="list-style-type: none"> a) If before January 1st 1980 an allogeneic tissue or organ transplant, other than those listed above, was performed and there is no other reason to exclude the donor, accept. b) If at anytime any time a non-stored autologous tissue or organ has been transplanted, accept. c) If has received an acellular non-human non-human matrix graft, accept. d) If has received donated human eggs, sperm or embryos. <p>See <u>Trying to conceive</u></p>
<i>See if Relevant:</i>	<p><u>Dental Treatment</u></p> <p><u>Eye Disease</u></p> <p><u>Immunosuppression</u></p> <p><u>Prion Associated Diseases</u></p> <p><u>Transfusion</u></p> <p><u>Trying to Conceive</u></p> <p><u>Xenotransplantation</u></p>
<i>Additional Information:</i>	<p>The transfer of tissues or organs between individuals and species has led to the spread of infection. The above guidelines are intended to minimize these risks.</p> <p>There is now a concern that this could also happen with vCJD. This is because in the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then, there have been several cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD.</p> <p>In view of this, people who have received a tissue or organ transplant since 1980, will be excluded from donation in the same way as recipients of transfusion are. This date is before BSE, which is believed to have caused vCJD, was prevalent.</p> <p>Following an update to the SaBTO Microbiological Safety Guidelines, recipients of donated human eggs, sperm or embryos can be accepted to donate. Care should be taken to ensure they also meet the other criteria included in the 'Trying to Conceive' entry.</p>

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	Stored autologous tissue has been replaced in the wrong individual. Because of the associated infection risk these donors are not allowed to donate. It is important to check that any tissue transplanted has not be stored (e.g. chondrocytes).
<i>Information:</i>	This entry reflects guidance from the former Committee on the Microbiological Safety of Blood Tissues and Organs of the Department of Health.
<i>Reason for change:</i>	The issue around the acceptance of donors who have had IVF treatment with fresh or frozen autologous eggs or embryos has been clarified and added. The deferral for recipients of donated eggs or embryos has been removed in line with the most recent update of the SaBTO Microbiological Safety Guidelines.

44.3 Prion Associated Disease

Please amend the following sections of this entry:

<i>Obligatory:</i>	<p>Must not donate if:</p> <ol style="list-style-type: none"> 1. Diagnosed with any form of CJD, or other human prion disease. 2. Identified at increased risk of developing a prion associated disorder. <p>This includes:</p> <ol style="list-style-type: none"> a) Individuals at familial risk of prion-associated diseases (have had two or more blood relatives develop a prion-associated disease or have been informed following genetic counselling they are at risk). b) Individuals who have been told that they have been put at increased risk from surgery, transfusion or transplant of tissues or organs. c) Individuals who have been told that they may be at increased risk because a recipient of their blood or tissues has developed a prion related disorder. d) Recipients of dura mater grafts. e) Recipients of corneal, scleral or other ocular tissue grafts. f) Recipients of human pituitary derived extracts. g) Since January 1st 1980: Recipients of a transfusion or allogeneic human tissue (except recipients of donated human eggs, sperm or embryos).
<i>See if Relevant:</i>	<p><u>Tissue and Organ Recipients</u></p> <p><u>Transfusion</u></p> <p><u>Trying to Conceive</u></p>
<i>Additional Information:</i>	<p>A 'Position Statement on Creutzfeldt-Jakob Disease' is available in the 'Document Library' of 'www.transfusionguidelines.org'.</p> <p>The use of human gonadotrophin and growth hormone of pituitary origin had stopped in the UK by 1986. Dura mater use stopped in the UK by 1993. The situation in other countries varied so specific dates cannot be given.</p> <p>Recipients of donated human eggs, sperm or embryos can be accepted to donate, provided they meet the other criteria outlined in the 'Trying to Conceive' entry.</p>

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Reason for Change:

~~Relevant links have been added.~~

~~'Additional Information' on the use of dura mater and human hormones of pituitary origin has been added.~~

The deferral for recipients of donated eggs or embryos has been removed in line with the most recent update of the SaBTO Microbiological Safety Guidelines.

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