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Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 01 - 2022

Coronavirus Infection and Convalescent Plasma

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

Please amend the following entries as shown.

01.1 Coronavirus Infection

2. Person who has been in contact with Coronavirus infection	
<i>Includes:</i>	Donors who have been in contact with a confirmed or suspected case of Coronavirus infection.
<i>Excludes:</i>	Donors with symptoms of Coronavirus infection (see above). Donors who have been in contact with individuals who are contacts of confirmed or suspected Coronavirus infections.
<i>Obligatory:</i>	Must not donate if: Less than 14 10 days from the first day of isolation.
<i>Discretionary</i> :	<p>a) If it is at least 14 10 days since the first day of isolation and the donor remains well, accept.</p> <p>b) If the donor has been advised: that isolation is no longer required and the donor remains well, accept.</p> <ul style="list-style-type: none"> • That isolation is not required, or that the isolation period is complete, and • Any post-contact testing for Coronavirus is negative and that no further testing is required, and • The donor remains well, <p>accept</p> <p>c) If the donor: has not been required to isolate and they remain well and they agree to report any post-donation illness, accept.</p> <ul style="list-style-type: none"> • Has not been required to isolate, and • Did not require any form of Coronavirus testing, and • The donor remains well, <p>accept.</p>

3. Person requiring, isolation, or quarantine or testing after travel	
<i>Includes:</i>	Donors required to isolate, or quarantine or undertake Coronavirus testing after travel . Donors who have returned from a quarantine country but are exempt from quarantine due to their job.
<i>Excludes:</i>	Donors with symptoms of Coronavirus infection (see above).
<i>Obligatory:</i>	Must not donate if: a) Less than 10 days from the first day of isolation or quarantine. b) Less than 10 days from the date of return to the UK for a donor who is exempt from quarantine for job purposes. Coronavirus testing after travel has not been completed, and the results of testing are not negative or the results are unknown.
<i>Discretionary</i> :	If it is at least 10 days since the first day of isolation or quarantine and the donor remains well, accept. a) If it is at least 10 days since the first day of isolation or quarantine and the donor remains well, accept. b) If the donor has been advised: <ul style="list-style-type: none"> • That a period of isolation or quarantine is not required, or that the quarantine or isolation period is complete, and • Any testing for Coronavirus following travel is negative and no further testing is required, and • The donor remains well, accept.
4. Donors of COVID-19 convalescent plasma 4. Person having routine surveillance Coronavirus Testing	
<i>Excludes</i>	Donors requiring testing for Coronavirus due to symptoms, contact or travel (see sections 1, 2 and 3 above).
<i>Obligatory</i>	Must not donate if less than 28 days since resolution of symptoms
<i>Discretionary</i>	If at least 28 days since resolution of symptoms, accept. Donors who have regular screening for the presence of Coronavirus can be accepted to donate provided they have not had a positive test for the virus or symptoms of Coronavirus in the last 28 days. This includes donors who work in a Health, Social Care or Educational setting.

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Reason for change:	<p>The obligatory deferral for donors required to quarantine after travel has been reduced from 14 days to 10 days, in line with current UK government quarantine requirements.</p> <p>The deferral after contact with Coronavirus Infection has been reduced to 10 days. Clarifications that testing after contact and travel must be completed have been added. Reference to convalescent plasma donation has been removed.</p>
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01.2 Transfusion

Obligatory:	<p>1. Must not donate if: At any time the donor has:</p> <p>a) Received, or thinks they may have received, a transfusion of blood or blood components, in a country endemic for malaria or South American trypanosomiasis.</p> <p>b) Received treatment with blood derived coagulation factor concentrates. This includes prothrombin complex to reverse over-anticoagulation.</p> <p>2. Must not donate if: Since January 1st 1980:</p> <p>a) Anywhere in the world the donor has received, or thinks they may have received, a transfusion with red cells, platelets, fresh frozen plasma (FFP), cryoprecipitate, cryodepleted plasma, convalescent plasma, granulocytes, buffy coat preparations, intravenous or subcutaneous human normal immunoglobulin. This includes mothers whose babies have required intra-uterine transfusion.</p> <p>b) Has had a plasma exchange performed.</p>
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Discretionary:	<p>1. a) If on medical inquiry it is unlikely that the donor has been transfused accept.</p> <p>b) If treatment with human immunoglobulin has been limited to specific immunoglobulin given as prophylaxis (e.g. anti D, anti tetanus or hepatitis immunoglobulin etc.), accept.</p> <p>2. Autologous Transfusion in:</p> <ul style="list-style-type: none"> the United Kingdom North America Australasia Western Europe (at any time) EU member states (from February 2005) <p>If only the donor's own blood has been used, accept.</p> <p>3. Donor transfused before 1st January 1980:</p> <p>a) If before 1st January 1980 the donor received, or thinks they may have received, a transfusion in a country endemic for malaria or South American trypanosomiasis, check the 'Geographical Disease Risk Index'. If transfused in an at risk country and a validated malarial antibody test and/or (as appropriate) a validated test for T.cruzi antibody is negative, accept.</p>
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	<p>b) If the transfusion was not within a risk area for either malaria or South American trypanosomiasis, accept.</p> <p>4. Donor transfused with COVID-19 convalescent plasma:</p> <p>a) If the donor was only transfused with COVID-19 convalescent plasma and,</p> <ul style="list-style-type: none"> • the transfusion took place in the UK, • no other blood components were administered, and • it is two or more months since the transfusion took place, <p>accept for COVID-19 convalescent plasma donation only.</p> <p>-</p> <p>b) If the donor was only transfused with COVID-19 convalescent plasma outside UK, and they meet all other criteria listed in 4a:</p> <p>Refer to a DCSO for review of transfusion history and consideration of other risks, including malaria and T. cruzi.</p>
See if Relevant:	<p>Bleeding Disorder</p> <p>Coronavirus Infection</p> <p>Immunoglobulin Therapy</p> <p>Immunosuppression</p> <p>Malaria</p> <p>Prion Associated Diseases</p> <p>South American Trypanosomiasis</p> <p>Geographical Disease Risk Index</p>
Additional Information:	<p>Transfused donors have previously contributed to the spread of some diseases. This happened with hepatitis C.</p> <p>Transfusions in some countries may have put the donor at risk of malaria or South American trypanosomiasis. It is necessary to exclude these infections before accepting the donor.</p>

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	<p>Coagulation concentrates:</p> <p>People who have received blood derived coagulation concentrates (these are made from the blood of many donors) may have been put at risk of infections that can be passed through blood.</p> <p>Donors transfused since 1980:</p> <p>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 transfused, or possibly transfused, since 1980 are now excluded from donation. This date is before BSE, which is believed to have caused vCJD, was prevalent.</p> <p>Plasma exchange results in a patient being exposed to multiple donors. In view of the increased vCJD risk, donations may not be taken from individuals who have had a plasma exchange performed since 1980.</p> <p>COVID-19 convalescent plasma</p> <p>As part of the response to the COVID-19 pandemic, UK transfusion services have collected convalescent plasma (CP) from individuals who have recovered from this infection. In line with a recommendation from SaBTO, recipients of COVID-19 CP can be accepted two months after transfusion and do not need to wait for four months as</p>
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	<p>detailed in the Blood Safety and Quality Regulations (BSQR). This change has been implemented to ensure the ongoing supply of CP should its use become more widespread.</p> <p>Individuals who receive CP outside the UK must be referred to a DCSO for detailed assessment of their transfusion and travel history. For donors with potential exposure to malaria or T. cruzi, expert advice may be required regarding discretionary testing to optimise the timing of donation for COVID-19 antibodies.</p>
Reason for change:	<p>A discretion has been added to allow recipients of COVID-19 convalescent plasma to donate convalescent plasma on their recovery. The guidance for autologous transfusion in Europe has been clarified.</p> <p>Blue discretion which allowed recipients of COVID-19 convalescent plasma to donate convalescent plasma on their recovery has been removed.</p>

01.3 Clinical Trials

2. Covid-19 Clinical Trials

Discretionary:	<p>For donors who have been enrolled in Covid-19 treatment trials, if:</p> <ul style="list-style-type: none"> the donor is fully recovered from Covid-19 for 28 days or more, and the treatment which the donor received (or was randomised to) in the trial does not prevent donation, and the donor meets all other criteria in the Donor Selection Guidelines, accept.
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<p>The table shows individual treatments used in Covid-19 clinical trials and their consequences for whole blood or component donation. Donors must be assessed on the basis of their recovery from Covid-19 as well as the information below. If in doubt, refer to a DCSO.</p>	
Treatment Received	Consequence for donation
Short course of steroids e.g. dexamethasone	Can donate, provided at least 7 days from last date of treatment
Antivirals e.g. lopinavir, remdesivir, ritonavir	Can donate, provided at least 7 days from last date of treatment
Convalescent plasma	Can donate convalescent plasma only, provided at least 2 months from date of convalescent plasma transfusion
Anti-SARS-CoV-2 monoclonal antibodies e.g. AZD7442, bamlanivimab, Regeneron	Defer for 12 months from last day of treatment
Monoclonal antibodies that affect the immune system e.g. infliximab, MEDI3506, ravulizumab, sarilumab, tocilizumab	Defer for 12 months from last day of treatment

	Immunosuppressive or immunomodulatory therapy e.g. acalabrutinib, anakinra, baricitinib, bemcentinib, interferon- β 1a, interferon β 1b, recombinant IL-7 (CYT107), zilucoplan	Defer for 12 months from last day of treatment
	Convalescent plasma	Permanent Deferral (see Transfusion entry)
Reason for change:	<p>Addition of specific information for Covid-19 clinical trials Removal of the discretion allowing recipients of Covid-19 convalescent plasma to donate convalescent plasma after recovery.</p>	

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