

Change Notification for the UK Blood Transfusion Services

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Implementation: to be determined by each Service

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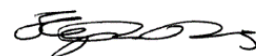
Coronavirus Vaccination

This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG Cord Blood	GDRI Geographical Disease Risk Index	TD-DSG Tissue - Deceased Donors	TL-DSG Tissue - Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1. Coronavirus Vaccination	●	○	○	○	○	○	○
2. Coronavirus Vaccination	○	●	○	●	●	○	○
3. Immunisation – Non-Live	○	●	○	○	○	○	○
4. Immunisation – Non-Live	○	○	○	●	●	○	○
5. Table of Immunisations	○	●	○	●	●	○	○



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Chair of Standing Advisory Committee on Tissues & Cellular Therapy Products (SACTCTP)



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Professional Director of JPAC

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

original text	«inserted text»	deleted text
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1. Changes apply to the **Bone Marrow DSG**

Coronavirus Vaccination

(revised entry)

<p><i>Obligatory</i></p>	<p>a) Recipients of a COVID-19 vaccine in the UK vaccination programme</p> <p>Must not donate if:</p> <p>i) Less than 14 days after the last immunisation if the vaccine given was nucleic acid (mRNA) vaccine.</p> <p>ii) Less than 28 days after the last immunisation if the vaccine given was virus-vector-based (non-replicating virus) vaccine.</p> <p>See additional information for further information on different types of vaccine.</p> <p>iii) If donor felt unwell due to unexpected complications (other than common side effects) after any vaccination, refer to Designated Clinical Support Officer for individual risk assessment.</p> <p>Timings above refer to interval between vaccination and start of G-CSF or general anaesthetic for BM donation.</p> <p>b) Recipients of a COVID-19 vaccine outside the UK vaccination program, including participants in clinical trials or donors vaccinated outside the UK</p> <p><i>Refer to Designated Clinical Support Officer for individual risk assessment. See additional information.</i></p>
<p><i>Discretionary</i></p>	<p>If the transplant cannot be delayed, Donors may be accepted less than 14 days (nucleic acid vaccines) or 28 days (viral vector vaccines) after the date of the most recent vaccination, <i>if vaccinated as part of the UK vaccination programme</i>, subject to individual risk assessment. See additional information.</p>
<p><i>See if Relevant</i></p>	<p><u>Coronavirus Infection</u></p>
<p><i>Additional Information</i></p>	<p>All COVID-19 vaccines currently licensed in the UK are non-live. Normally, no deferral period is applied after immunisation with non-live vaccines. However as the effects of the newly developed coronavirus vaccines on donor health and donation safety are not fully established yet, as a precautionary principle, a 14 to 28 day post vaccine deferral period, depending on the type of vaccine is recommended.</p> <p>Immune thrombocytopenia (ITP) can occur after all types of Covid 19 vaccines. There have been a small number of reports of vaccine induced thrombosis and thrombocytopenia syndrome (VITTS), in people receiving virus vector based (non-replicating) coronavirus vaccine. VITTS patients have severe clinical symptoms whilst ITP may be sub-clinical and go unnoticed on symptoms alone. The incidence is unclear but may be similar to other vaccine induced ITP. Therefore a 14 day deferral period has been recommended after vaccination with mRNA vaccines.</p> <p>GCSF administration carries a small risk of inflammation associated thrombosis and thrombocytopenia. There is a theoretical concern that GCSF could exacerbate the immune response related to VITTS. Headaches and abdominal pain are side effects of</p>

	<p>GCSF which are primary symptoms associated with cerebral venous thrombosis and splanchnic vein thrombosis respectively, due to VITTS. As a precautionary measure the post vaccination deferral period for bone marrow and PBSC donors receiving virus-vector-based (non-replicating virus) vaccines has been extended to 28 days, for donor protection. As the reported events are extremely rare, donors may be accepted less than 28 days after vaccination subject to a careful individualised risk assessment.</p> <p>Consideration of checking a platelet count after vaccination to rule out thrombocytopenia is recommended. This could be included as a part of medical assessment if undertaken 14 days or more after vaccination. If less than 14 days between vaccination and medical assessment, or vaccination was given after medical assessment, additional Full Blood Count should be done before commencing GCSF/ general anaesthetic (frozen cells) and before commencing patient conditioning (for fresh cells).</p> <p>For donors who have commenced GCSF, the vaccination (first or second dose) must be delayed at least until 72 hours after stem cell collection (both PBSC & Bone Marrow Donation). This is a precautionary advice to avoid vaccination when receiving GCSF and allow for post donation recovery period.</p> <p>For donors vaccinated as part of a clinical trial or outside of the UK, the type of vaccine used should be established to determine the appropriate deferral period.</p> <p>There may be new types of vaccine that become available, and it may not be known which type of vaccine was used for immunisation. In situations where information about vaccine type is missing or the vaccination is experimental, a four-week deferral period should be applied.</p> <p>The British Society for Immunology has published an infographic to explain to the general public the different types of COVID-19 vaccines, including brand names, available in the UK, in other countries, and in clinical trials. See the following link: https://www.immunology.org/coronavirus/connect-coronavirus-public-engagement-resources/types-vaccines-for-covid-19</p>
<p><i>Reason for Change</i></p>	<p>«To update the obligatory and discretionary sections.»</p> <p>To increase the post-vaccination deferral period for nucleic acid (mRNA) vaccines to 14 days and virus-vector based vaccines (non-replicating) to 28 days for donor protection. Additional Information section has been updated.</p>

2. Changes apply to the **Cord Blood, Live Tissues** and **Deceased Tissues** DSGs

Coronavirus Vaccination

(removed entry)

The current entry will be **removed** and replaced with the following redirection in the A-Z index:

Coronavirus Vaccination » Immunisation – Non-Live

3. Changes apply to the **Cord Blood DSG**

Immunisation – Non-Live

(revised entry)

<i>«Excludes</i>	Post-exposure. See: Immunisation - 2. Post Exposure »
<i>Obligatory</i>	<p>1. Hepatitis B</p> <p>Must not donate if: Less than seven days after administration</p> <p>2. Coronavirus: See Coronavirus Vaccination entry</p>
<i>Discretionary</i>	Other non-live immunisations, accept.
<i>See if Relevant</i>	Immunisation – 2. Post Exposure
<i>Additional Information</i>	<p>Sensitive assays for HBsAg may be positive following recent immunisation. Full screening for Hepatitis B may be required.</p> <p>«Note, hepatitis A immunisation may be combined with hepatitis B immunisation.»</p> <p>'Non-Live' immunisations do not use material that can cause infection. This means there is no risk to people receiving «donated material from a recently immunised non-exposed donor.» stem cells.</p>
<i>Reason for Change</i>	<p>«To remove Coronavirus Vaccination from obligatory section, and additional information section updated.»</p> <p>To add Coronavirus Vaccination to obligatory section.</p>

4. Changes apply to the **Live Tissues** and **Deceased Tissues** DSGs

Immunisation – Non-Live

(revised entry)

<i>«Excludes</i>	Post-exposure. See: Immunisation - 2. Post Exposure »
<i>Obligatory</i>	<p>1. Hepatitis B</p> <p>Must not donate if: Less than seven days after administration</p> <p>2. Coronavirus: See Coronavirus Vaccination entry</p>
<i>Discretionary</i>	Other non-live immunisations, accept.
<i>See if Relevant</i>	Immunisation – 2. Post Exposure
<i>Additional Information</i>	<p>Sensitive assays for HBsAg may be positive following recent immunisation. Full screening for Hepatitis B may be required.</p> <p>«Note, hepatitis A immunisation may be combined with hepatitis B immunisation.»</p> <p>'Non-Live' immunisations do not use material that can cause infection. This means there is no risk to people receiving «donated material» blood or tissues from a recently immunised «non-exposed» donor.</p>
<i>Reason for Change</i>	<p>«To remove Coronavirus Vaccination from obligatory section, and additional information section updated.»</p> <p>To add Coronavirus Vaccination to obligatory section.</p>

5. Changes apply to the **Cord Blood, Live Tissues** and **Deceased Tissues** DSGs

Table of Immunisations (in DSG appendices)

Diseases protected against	Comments and example trade names of adult preparations	
<i>(other entries are unchanged)</i>		
COVID-19 (SARS-CoV-2)	<p>All COVID-19 vaccines licenced in the UK are Non-Live. These include:</p> <ul style="list-style-type: none"> • «Pfizer BioNTech (tozinameran/Comirnaty®)» • «AstraZeneca (Vaxzevira®)» • «Moderna (Spikevax®)» • «Janssen Ad26.COV2-S» • «Novavax (Nuvaxovid®)» • «COVID-19 Vaccine Valneva» <p><i>Pfizer/BioNTech COVID-19 vaccine, AstraZeneca COVID-19 vaccine, Moderna COVID-19 vaccine, Janssen Ad26.COV2-S; Novavax (Nuvaxovid®); COVID-19 Vaccine Valneva: See Coronavirus Vaccination entry.</i></p>	<u>Non-Live</u>
<i>(other entries are unchanged)</i>		