Issued by JPAC: 4 May 2021	**Implementation:** To be determined by each Service

Change Notification UK National Blood Services No. 11 - 2021

Coronavirus Vaccination

These changes apply to the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines

Please amend the following sections of this entry:

Obligatory:	**a) Recipients of a COVID-19 vaccine in the UK vaccination programme** **Must not donate if:** i) Less than 14 ~~seven~~ days after the last immunization ~~was given~~ if the vaccine given was nucleic acid (mRNA) vaccine. ~~ii) If donor felt unwell after vaccination, must not donate for 7 days after resolution of symptoms.~~ ii) Less than 28 days after the last immunization if the vaccine given was virus-vector-based (non-replicating virus) vaccine. See additional information for further information on different types of vaccine. iii) If donor felt unwell due to unexpected complications (other than common side effects) after any vaccination, ~~must not donate for 7 days after resolution of symptoms~~. refer to Designated Clinical Support Officer for individual risk assessment. Timings above refer to interval between vaccination and start of G-CSF or general anaesthetic for BM donation. **b) Recipients of a COVID-19 vaccine outside the UK vaccination program, including participants in clinical trials or donors vaccinated outside the UK** Refer to Designated Clinical Support Officer for individual risk assessment. See additional information.
Discretionary:	If the transplant cannot be delayed, Donors may be accepted less than 14 ~~7~~ days (nucleic acid vaccines) or 28 days (viral vector vaccines) after the date of the most recent vaccination, if vaccinated as part of the UK vaccination programme, subject to individual risk assessment. See additional information.

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Joint UKBTS Professional Advisory Committee (JPAC)
JPAC Office
Email: caroline.smith@nhsbt.nhs.uk **Mobile:** +44 (0) 771 144 7302

Additional Information:	~~Individuals vaccinated with inactivated viruses or vaccines that do not contain live agents (i.e. mRNA and protein subunit vaccines) may be accepted as tissue and cell donors if they feel well after vaccination. After vaccination with attenuated viruses (e.g. virus vector-based other than non-replicating or live-attenuated virus vaccines) tissue and cell donors must by default be deferred for four weeks.~~ 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 ~~7 day~~ 14 to 28 day post vaccine deferral period, depending on the type of vaccine ~~from the date of vaccination, or deferral of donors who developed symptoms directly related to the vaccine for at least 7 days after the resolution of symptoms,~~ is recommended. 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. 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 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. 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). 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.

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Joint UKBTS Professional Advisory Committee (JPAC)
JPAC Office
Email: caroline.smith@nhsbt.nhs.uk Mobile: +44 (0) 771 144 7302

	~~Living tissue and cell donors, within 7 days after non-live vaccine, may be considered subject to individual risk assessment, if the benefit of the transplant outweighs the risks of donation.~~ 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. 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. 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 ~~The ECDC recommends that if HSC donors have been vaccinated with attenuated vaccines in the four weeks before donation, a risk assessment should be carried out and taken into account when deciding on transplantation and, if transplanted, the recipient should be monitored post-transplant.~~
Reason for Change:	~~Remove reference to specific brands of vaccine.~~ 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.

Dr Sheila MacLennan
Professional Director - Joint UKBTS Professional Advisory Committee
☎ Direct Dial : (0113) 820 8638 ✉ sheila.maclennan@nhsbt.nhs.uk