Joint UKBTS Professional Advisory Committee ([1])

Position Statement

COVID-19 Vaccines and Blood Transfusion

July 2021

***Approved by:* JPAC**

***July 2021* - The contents of this document are believed to be current. Please continue to refer to the website for in-date versions.**

There are three COVID-19 vaccines currently deployed in the UK. The Pfizer/BioNTech COVID-19 vaccine was authorised for use by the independent Medicines and Healthcare products Regulatory Agency (MHRA) on the 2nd December 2020 and it is estimated that over 30 million doses have been administered in the UK to date. The AstraZeneca COVID-19 vaccine was authorised for use by the MHRA on 30th December 2020 and over 46 million doses have been administered in the UK to date. The Moderna COVID-19 vaccine was authorised for use by the MHRA on the 8th January 2021 and over 1 million doses have been administered in the UK to date.

Overall, at the time of writing, over 39 million people (59% of the population) in the UK are fully vaccinated and 47 million people (71%) have received at least one dose. Post-vaccination pharmacovigilance is the responsibility of the MHRA and the manufacturers.

The vaccines approved for use in the UK have met strict standards of safety, quality and effectiveness set out by the MHRA. Any COVID-19 vaccine that is approved must go through all the clinical trials and safety checks all other licensed medicines go through. The COVID-19 vaccines contain either mRNA or modified adenoviral DNA which does not replicate and is not copied on cell division. This has the consequence that these components remain close to where they are injected into the muscle. While a small amount may get into the blood, this is not critical to how the vaccines work and any blood penetration that does occur is likely to be short-lived.

Some non-active ingredients (lipids) contained in mRNA vaccines do distribute through the body and are cleared slowly but no safety issue is recognised with this profile; these non-active ingredients include cholesterol and phosphatidylcholine which are present in the body naturally.

Biodistribution of the spike protein to various organs around the body was investigated in the animal studies that are described in the Public Assessment Reports. The public assessment reports describe the experiments on biodistribution using both a luciferase surrogate reporter and also radiolabelled lipid nanoparticles for the Pfizer vaccine. In addition, the two repeat-dose toxicity rat studies and one development and reproductive toxicology study, concluded that non-clinical data reveal no special hazard for humans based on studies of repeat dose toxicity and reproductive and developmental toxicity.

Advice from the MHRA and from the European Centre for Disease Prevention and Control (https://www.ecdc.europa.eu/en/publications-data/suspected-adverse-reactions-covid-19-vaccination-and-safety-substances-human) is that no additional blood and plasma safety measures are recommended in relation to the occurrence of suspected adverse reactions to COVID-19 vaccines and that individuals vaccinated with inactivated / killed viruses or vaccines that do not contain live agents (such as mRNA vaccines and replication-deficient virus vector based vaccines) may be accepted as donors provided they feel well. UK Blood Services, in common with other blood services internationally, cannot provide information about the vaccine status of donors to recipients, nor is this necessary from a safety or efficacy perspective.

In light of the frequency of mild to moderate symptoms following COVID-19 vaccination UK Blood Services have chosen to introduce a 7-day deferral post-vaccination in order to ensure donor health and avoid unnecessary withdrawal of blood components post-donation. A review of European national guidelines for post-vaccination blood donation showed that most countries (69%) have opted for no waiting period or a shorter waiting period than 7 days.

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