In official relations with the World Health Organization

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POSITION STATEMENT

25 May 2021

ADDRESSING BLOOD SUPPLY ISSUES LINKED TO COVID-19 VACCINATION DEFERRAL TIMES

SUMMARY

HEADQUARTERS

The Thalassaemia International Federation (TIF) wishes to address and clarify to the extent possible, the below basic questions:

- How many days after vaccination may blood donors donate?
- Is the duration of the deferral time based on the technology on which the vaccine provided is developed? If so, what is the duration of the deferral time suggested by international expert bodies?
- Does each vaccination dose have a deferral time?

As a general rule, **people receiving SARS-CoV-2 vaccines which do not contain live (replicationcompetent) viruses may donate blood, seven (7) days after their vaccination**. This is a precautionary deferral period, provided that vaccinated individuals feel well, to minimise the impact of call back from donors who develop symptoms soon after vaccination and subsequent to donation.

BACKGROUND

Purpose

The Thalassaemia International Federation¹ (TIF), voicing the patients' perspective and unmet needs, wishes to reiterate its grave concerns as to the challenges involved in maintaining and sustaining

¹ The **Thalassaemia International Federation (TIF)** is a patient-oriented non-profit, non-governmental umbrella federation, established in 1986 with Headquarters in Nicosia, Cyprus. TIF's mission is to help ensure equal access to quality health and other care for every patient with thalassemia and other haemoglobin disorders around the world. To-date membership boasts 232 members from 64 countries across the globe. TIF works in official relations with the World Health Organization (WHO) since 1996 and enjoys active consultative status with the United Nations Economic and Social Council (ECOSOC) since 2017. Moreover, it is a strategic partner of the European Commission under the Third Health Programme since 2018 and a member of the Patients and Consumers Working Party (PCWP) of the European Medicines Agency (EMA) since 2010. In 2019, TIF obtained a participatory status at the Council of Europe, as a Member of the Conference of International NGOs. Moreover,



adequate supplies of blood and its components during the COVID-19 period. This is undoubtedly recognised as a major challenge for Transfusion Dependent Thalassaemia (TDT) and other patients with haemoglobin disorders who are lifelong dependent on regular blood transfusion therapy with Red Blood Cells (RBCs).

Uncertain of their access to such therapy, which constitutes the cornerstone of their treatment, people affected with thalassaemia and their treating physicians have been reporting a constant feeling of fear, tension and worry about access to blood products since the SARS-CoV-2 outbreak. Indeed, the maintenance of adequate blood supply in most countries across the world has been hindered by challenges pertaining to movement and travel restrictions, the safe access of donors to blood collection centres, the existence of mobile blood collection units, the fear of donors to donate, the infection of donors with SARS-CoV-2 and national conditions in relation to blood transfusion services (e.g. decentralised, with limited capacity and resources).

Existing Policies

Blood donor safety is of utmost importance for every new or updated deferral policy put forward by competent blood transfusion authorities, as any disease or syndrome may put a donor at risk of an adverse event. More specifically, some individuals may have COVID-19 symptoms for a protracted length of time after the systemic and respiratory symptoms of the acute infection have resolved. Such symptoms vary and donors must report them to their blood collection establishments, especially if these include chest pain, palpitations, shortness of breath, fatigue, even if seemingly mild or infrequent, suggesting that a donor may not have fully recovered to their pre-COVID-19 state of health.

According to the Interim Guidelines of the World Health Organization² on **blood donation deferral times**, donors who are known to have antibodies to SARS-CoV-2 are eligible to donate, provided they have not had symptoms of COVID-19 infection in the last 28 days. Donors who have had screening for the detection of SARS-CoV-2 for reasons other than suspected infection or contact (e.g. occupational) may be accepted to donate provided they have not had a positive test for the virus or related symptoms in the last 28 days. Donors who have travelled may be required to self-isolate (also termed "quarantine") on their return, depending on the country of departure, and when their return occurred. Some donors may be exempt from self-isolation for professional reasons but such an exemption does not apply to donating blood.

Challenges for national blood supplies

Other factors that have inevitably contributed to the negative impact of the pandemic on the **sustainability of national blood supplies** are the low blood donation rates, the absence or the inappropriate or ineffective functioning of haemovigilance systems, demographic, geophysical and climatic conditions, including floods and the presence of mountains or islands, and large populations. Revisiting of the donors' questionnaire so as to comply with the recommendations of international relevant bodies in safeguarding the safety of blood has undoubtedly added to more exclusions of donors and/or delayed procedures, altogether these contributing to the reduction of the numbers of blood donors and blood supplies.

² Dated 17 February 2021 – May be retrieved at: <u>https://apps.who.int/iris/rest/bitstreams/1333552/retrieve</u>



TIF was awarded, in the context of the 68th World Health Assembly in May 2015, the 'Dr Lee Jong-wook Memorial Prize' for its outstanding contribution to public health.

Moreover, the current **COVID-19 vaccination programmes** have added to the above challenges causing further delays, as vaccinated blood donors need to respect a certain deferral time before donating blood or may go through some vaccine-related illness, mild or more severe, which requires a certain amount of time for recovery prior to any blood donation. The duration of such a deferral time has been a topic of controversy as this has been set to 7 days by some countries and 28 days by others, adding further to delays and blood supply concerns.

The deferral time of donors after vaccination

Competent authorities in the United States, the United Kingdom, Australia and other countries, have proposed that individuals vaccinated with inactivated viruses or vaccines that do not contain live agents or based on mRNA technologies may be accepted for blood donation without any deferral period, given that the vaccine recipient does not develop any symptoms. The six (6) COVID-19 vaccines approved by the World Health Organization, manufactured by Moderna, Pfizer/BioNTech, Janssen (Johnson & Johnson), Oxford/AstraZeneca, the Serum Institute of India and Sinopharm (Beijing), do not require long deferral times and do not consequently pose a transfusion safety risk³.

For precautionary purposes and to reduce the risk of discarding a donation if the donor develops symptoms directly related to the vaccine, **a seven-day deferral after immunization is recommended to ensure donor and donation safety**. This policy has been adopted by a number of countries to protect donor health, avoid the theoretical risk of unintentionally transmitting the vaccine agent to transfusion recipients, and prevent or minimize any compromise to blood supply.

As the administration of some vaccines requires more than one doses, each dose should be regarded as an independent event for purposes of blood donor deferral. Where mass vaccinations are anticipated, the blood centre should work closely with local health authorities to minimize any impact this may have on the availability of blood donors.

POSITION

The Thalassaemia International Federation (TIF) strongly encourages national competent authorities to reconsider and revisit their respective policies on the deferral time of donors after each vaccination dose (taking into account the types of vaccines authorised and marketed in their territories).

Considering deferral time as an important pillar to ensure the sustainability of blood reserves, the TIF is working closely with the World Health Organisation (WHO) and other international bodies to further clarify the matter and inform national blood establishments accordingly.

³ Please refer to this document's Annex I and the "Vaccines Roadmap/Infographics" developed by TIF (Annex I) for your easy reference with regard to the current state of affairs in your country.



What Types of Vaccines Are There?																					
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vaccine. Vaccines train our immune system to fight this pathogen.																					
													WHOLE VACCINES								
Virus-like		+		+		Non-replicating Replicating				g		*		tive attenuated							
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Approved by the WHO	 ✓ 	√	√	√	✓	✓															
Approved by the EU	 ✓ 	✓	✓	✓										<u> </u>							
Approved at national level	✓	✓	\checkmark	\checkmark	\checkmark	✓	\checkmark	\checkmark	✓	✓	✓	✓	✓	✓	\checkmark						
Approved by thalassaemia-	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	✓	\checkmark			\checkmark	\checkmark							
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Manufacturer	Moderna	Pfizer/ BioNTech	Oxford/ AstraZeneca	Janssen	(Johnson & Serum	Institute of	Sinopharm (Beiiing)	Gamaleya	Sinovac	Sinopharm	Bharat Biotech	Chimakov	Center	FBRI		Anhui Zhifei	Longcom	CanSino	Kazakhstan RIBSP
Vaccine Name	mRNA-1273	BNT162b2	AZD1222	Ad26.COV2.S	Covishield		BBIBP-CorV	Sputnik V	CoronaVac	Inactivated (Vero Cells)	Covaxin	KoviVac		EpiVacCoron	а	RBD-Dimer		Ad5-nCoV	QazCovid-in
Vaccine Type	RNA	RNA	Non Replicating VV	Non	Replicating VV Non	Replicating VV	Inactivated	Non Boolicating VV	Inactivated	Inactivated	Inactivated	Inactivated		Protein	Subunit	Protein	Subunit	Non Penlicating VV	Inactivated
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