2022年2月7日 (月)
17:00- web開催

令和３年度 第11回 採血事業
濵口班 班会議

これまでの班会議のまとめ

- COVID-19 ワクチン接種後の献血制限に関し，mRNAワクチンに関しては，発熱などの主要な副反応の殆どが48時間以内に発生していたことから，献血者の安全性確保の観点から，48時間の献血制限を設定してきた。

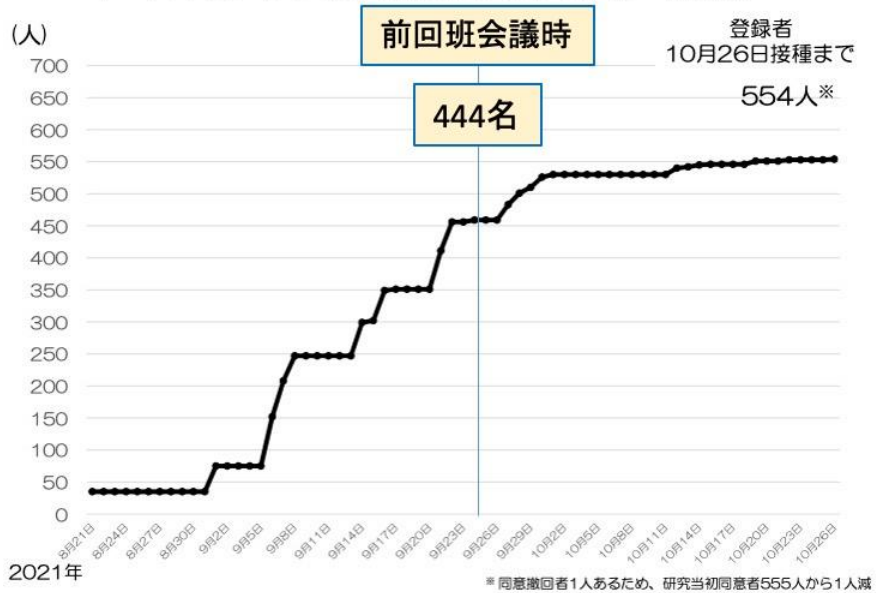
- 2021年12月にアストラゼネカ社(AZ)のウイルスベクターワクチン (バキスゼブリア筋注)(AZワクチン)に関してコホート中間報告がなされ，発熱などの主要な副反応は48時間以内に殆どが発生し，副反応は2回目より初回接種に多いことから，接種後48時間の献血制限により，献血者の安全は確保できると想定された。

- 一方，AZワクチンで非常に稀に発生しているTTS/VITT (ワクチン誘発性免疫血栓性血小板減少症)に関しては，英国では若年層で頻度が高いことから，2021年4月以降，30歳以上の年齢制限を導入し，現在は40歳以上を対象として引き続き接種が継続されている。一方，2回目接種に関しては，mRNAワクチンを推奨しているが，AZワクチンも接種可能である。

- TTS/VITTの原因の一つとして抗PF4抗体産生の関与が疑われているが，ほとんどのケースが3～4週以内に発生している。現時点でAZワクチン接種者の血液に抗PF4抗体が混入するリスクは低いが，4週間の献血制限により献血血の安全性は確保できると考えられる。またVITTを発生した症例において，発生前に重度の頭痛等が発生していることから，問診時に頭痛等の副反応の有無を確認することで，リスク軽減，献血制限の短縮化が可能とも考えられる。

- 一方，抗PF4抗体の血小板活性は微量でも存在し，12週まで続くという報告もあり，献血制限を42日 (6週)にすればリスクが少ないという意見もある。しかし本邦での症例も少なく，抗PF4抗体の産生機序等も不明であり，今後の研究が待たれている。

バキスゼブリア筋注被接種者数の推移（累計）

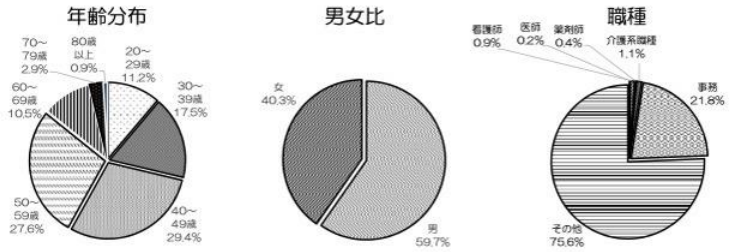


※同意撤回者1人あるため、研究当初同意者555人から1人減

バキスゼブリア筋注被接種者の人口統

R3第9回班会議資料

被接種者数　554人　10月26日



（参考）65歳以上　35（6.3%）

治療中疾患		(割合%)
高血圧	38	6.9%
脂質異常症	16	2.9%
糖尿病	22	4.0%
気管支喘息	6	1.1%
アトピー性皮膚炎	12	2.2%
その他	86	15.5%
なし	408	73.7%

n=554

既往歴		(割合%)
気管支喘息	56	10.1%
悪性腫瘍	17	3.1%
COVID-19	9	1.6%
いずれもなし	472	85.2%

n=554

複数疾患をお持ちの方もあるため合計は100%ではありません

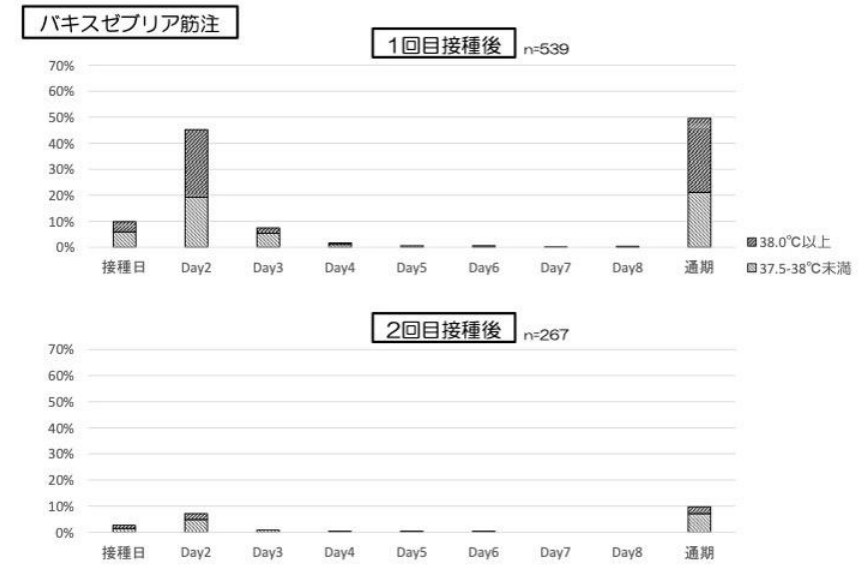
順天堂大学　コロナワクチン研究事務局　30

2回目 被接種者数　507人　11月30日15時現在

新型コロナワクチンの投与開始初期の重点的調査（コホート調査）

発熱（37.5℃以上）

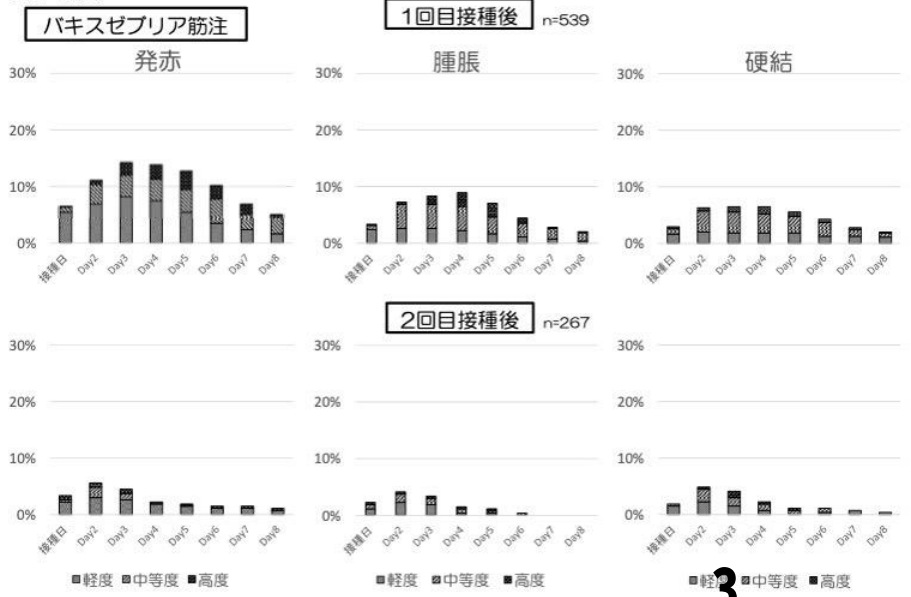
Data Cutoff Date 2021/11/29 7:00



新型コロナワクチンの投与開始初期の重点的調査（コホート調査）

接種部位反応　①

Data Cutoff Date 2021/11/29 7:00



前回，班会議での予想通り，2回目接種の副反応発生率は低い

日本におけるCOVID-19ワクチン接種者数の推移

R3第9回班会議資料

１．医療機関からの副反応疑い報告について

○コロナウイルス修飾ウリジンRNAワクチン（SARS-CoV-2）
販売名：コミナティ筋注
製造販売業者：ファイザー株式会社
販売開始年月：2021年２月
効能・効果：SARS-CoV-2による感染症の予防

○コロナウイルス修飾ウリジンRNAワクチン（SARS-CoV-2）
販売名：COVID-19ワクチンモデルナ筋注
製造販売業者：武田薬品工業株式会社
販売開始年月：2021年５月
効能・効果：SARS-CoV-2による感染症の予防

○コロナウイルス（SARS-CoV-2）ワクチン（遺伝子組換えサルアデノウイルスベクター）
販売名：バキスゼブリア筋注
製造販売業者：アストラゼネカ株式会社
販売開始年月：2021年５月
効能・効果：SARS-CoV-2による感染症の予防

①週別報告件数

接種日	コミナティ筋注							COVID-19ワクチンモデルナ筋注							バキスゼブリア筋注						
	推定接種者数	副反応疑い報告数		重篤報告数（内数）		死亡報告数（内数）		推定接種者数	副反応疑い報告数		重篤報告数（内数）		死亡報告数（内数）		推定接種者数	副反応疑い報告数		重篤報告数（内数）		死亡報告数（内数）	
	（回分）	報告数	報告頻度	報告数	報告頻度	報告数	報告頻度	（回分）	報告数	報告頻度	報告数	報告頻度	報告数	報告頻度	（回分）	報告数	報告頻度	報告数	報告頻度	報告数	報告頻度
2/17－3/14	230,542	687	0.30%	126	0.05%	2	0.00%														
3/15－4/11	1,361,975	3,745	0.27%	394	0.03%	8	0.00%														
4/12－5/9	3,068,570	4,452	0.15%	514	0.02%	53	0.00%														
5/10－6/6	12,363,954	7,133	0.06%	1,223	0.01%	279	0.00%	229,639	71	0.03%	8	0.00%	0	0.00%							
6/7－7/4	30,792,152	3,669	0.01%	1,285	0.00%	358	0.00%	1,076,115	504	0.05%	79	0.01%	6	0.00%							
7/5－8/1	34,656,408	2,236	0.01%	734	0.00%	174	0.00%	3,602,307	1,634	0.05%	185	0.01%	14	0.00%							
8/2－8/29	26,176,377	1,354	0.01%	403	0.00%	56	0.00%	13,856,369	945	0.01%	162	0.00%	14	0.00%	6,166	0	0.00%	0	0.00%	0	0.00%
8/30－9/26	26,321,054	1,249	0.00%	344	0.00%	34	0.00%	7,536,194	455	0.01%	92	0.00%	5	0.00%	41,615	5	0.01%	2	0.00%	0	0.00%
9/27－10/24	20,483,641	743	0.00%	193	0.00%	21	0.00%	4,331,917	258	0.01%	79	0.00%	5	0.00%	16,932	4	0.02%	3	0.02%	0	0.00%
10/25－10/31	3,433,313	115	0.00%	33	0.00%	4	0.00%	525,569	28	0.01%	12	0.00%	3	0.00%	13,069	1	0.01%	0	0.00%	0	0.00%
11/1－11/7	2,293,677	48	0.00%	16	0.00%	1	0.00%	380,999	19	0.00%	4	0.00%	0	0.00%	10,319	1	0.01%	1	0.01%	0	0.00%
11/8－11/14	1,877,839	13	0.00%	3	0.00%	0	0.00%	229,243	0	0.00%	0	0.00%	0	0.00%	13,401	1	0.01%	1	0.01%	0	0.00%
不明	－	78	－	51	－	23	－	－	5	－	2	－	0	－	－	0	－	0	－	0	－
合計（2021年11月14日現在）	163,059,502	25,522	0.02%	5,319	0.00%	1,013	0.00%	31,768,352	3,919	0.01%	623	0.00%	47	0.00%	101,502	12	0.01%	7	0.01%	0	0.00%

３．報告症例一覧（医療機関からの報告） 報告日 2021年８月３日～2021年11月14日

注：「No」は、全新型コロナワクチンに係る副反応疑い報告（医療機関からの報告）の通番。

2021年11月14日現在

報告数(n=12)

No	年齢	性別	接種日	発生日	接種から発生までの日数	ワクチン名	製造販売業者	ロット番号	症状名（PT名）	因果関係（報告医評価）	重篤度（報告医評価）	転帰日	転帰内容
29442	48歳	男性	2021/09/03	2021/09/10 2021/09/10	7	バキスゼブリア筋注	アストラゼネカ	K004C	TTS（血小板減少症を伴う血栓症） 頭痛（頭痛）	関連あり	重い	未記入 未記入	不明 不明
29443	47歳	女性	2021/09/12	2021/09/12	0	バキスゼブリア筋注	アストラゼネカ	K004C	蕁麻疹（蕁麻疹）	評価不能	重くない	未記入	軽快
29444	51歳	女性	2021/09/24	2021/09/24	0	バキスゼブリア筋注	アストラゼネカ	D016A	アナフィラキシー（アナフィラキシー反応）	関連あり	重い	未記入	軽快
29445	57歳	男性	2021/09/23	2021/09/24 2021/09/24 2021/09/24	1	バキスゼブリア筋注	アストラゼネカ	不明	頭痛（頭痛） 四肢痛（四肢痛） 運動障害（運動機能障害）	評価不能	重くない	未記入 未記入 未記入	不明 不明 不明
29446	58歳	男性	2021/10/09	2021/10/09	0	バキスゼブリア筋注	アストラゼネカ	D016A	アナフィラキシー（アナフィラキシー反応）	関連あり	重い	未記入	軽快
29447	61歳	男性	2021/10/02	2021/10/02 2021/10/02 2021/10/02 2021/10/02 2021/10/02	0	バキスゼブリア筋注	アストラゼネカ	D017A	頭痛（頭痛） 腹痛（腹痛） 呼吸障害・呼吸不全（呼吸困難） 皮疹・発疹・紅斑（発疹） 異常感（異常感）	関連あり	重い	2021/10/03 2021/10/03 2021/10/03 2021/10/03 2021/10/03	回復 回復 回復 回復 回復
29448	48歳	男性	2021/09/03	2021/09 2021/09 2021/09 2021/09	不明	バキスゼブリア筋注	アストラゼネカ	不明	深部静脈血栓症（深部静脈血栓症|深部静脈血栓症） 肺塞栓症（肺塞栓症|肺塞栓症） 熱感（熱感） 末梢腫脹（末梢腫脹）		重くない	未記入 未記入 未記入 未記入	軽快 軽快 軽快 軽快
29449	47歳	男性	2021/10/20	2021/10/20	0	バキスゼブリア筋注	アストラゼネカ	D017A	アナフィラキシー（アナフィラキシー反応）	関連あり	重くない	未記入	不明
29450	43歳	男性	2021/10/26	2021/10/26	0	バキスゼブリア筋注	アストラゼネカ	D016A	蕁麻疹（蕁麻疹）	関連あり	重くない	未記入	軽快
29451	47歳	男性	2021/10/20	2021/10/20 2021/10/20	0	バキスゼブリア筋注	アストラゼネカ	不明	アナフィラキシー（アナフィラキシー反応） 呼吸障害・呼吸不全（呼吸困難）	関連あり	重い	未記入 未記入	軽快 軽快
29452	57歳	男性	2021/11/04	2021/11/04	0	バキスゼブリア筋注	アストラゼネカ	D017A	心肺停止（心停止）	評価不能	重い	未記入	不明
29453	49歳	女性	2021/11/08	2021/11/08	0	バキスゼブリア筋注	アストラゼネカ	D017A	アナフィラキシー（アナフィラキシー反応）	関連あり	重い	未記入	軽快

※１　医療機関から重篤度が「重くない」事例として報告があった場合であっても、症状の転帰が死亡の場合は、「重い」事例として扱っている。

R4第11回班会議資料

新型コロナワクチン接種後の血小板減少症を伴う血栓症疑いとして医療機関から報告された事例の概要
（バキスゼブリア筋注、アストラゼネカ株式会社）

1．報告状況

○前回の集計対象期間（12 月 12 日）以降、バキスゼブリア筋注の副反応疑い報告において、医療機関から血栓症（血栓塞栓症を含む。）（血小板減少症を伴うものに限る。）（TTS）疑いとして報告された事例はなく、令和３年８月３日から令和４年１月９日までに報告された TTS 疑い事例は計２件※となった。

※令和３年８月３日以降に第一報の報告がなされたもの。

○なお、上記に加え、令和４年１月 10 日から令和４年１月 14 日までに、医療機関から TTS 疑いとして報告された事例はなかった。

（１）接種回数別報告頻度

接種回数	レベル１～３の報告件数／推定接種回数[注1]	100 万回あたりの報告件数
１回目	2 件／58,159 回接種	34.4 件
２回目	0 件／57,494 回接種	0 件
合計[注2]	2 件／115,653 回接種	17.3 件

注：「No」は、全新型コロナワクチンに係る副反応疑い報告（医療機関からの報告）の通番。新型コロナワクチン全体の集計対象期間後に報告があった事例については、その時点では「-」と表記。

2022年1月2日現在

No	年齢	性別	接種日	発生日	接種から発生までの日数	ワクチン名	製造販売業者	ロット番号	接種回数	基礎疾患等	症状名（PT名）	因果関係（報告医評価）	重篤度（報告医評価）	転帰日	転帰内容	専門家の因果関係評価 注：TTSの場合は、ワクチンとTTS症例としての評価。TTS以外の場合は、ワクチンと症状との評価。	専門家のブライトン分類レベル 注：TTSの場合は、ワクチンとTTS症例としての評価。TTS以外の場合は、ワクチンと症状との評価。	専門家の意見	備考
30699	48歳	男性	2021/09/03	2021/09/10 2021/09/10	7	バキスゼブリア筋注	アストラゼネカ	K004C	1回目	報告なし	TTS（血小板減少症を伴う血栓症） 頭痛（頭痛）	関連あり	重い	未記入 未記入	不明 不明	α	1	血小板減少症を伴う血栓症について：血小板減少を認めます。血液疾患の既往を判断するために接種前の血小板の値が欲しいところですが、 最終的に回復した値を参考に接種後に新たに発生した血小板減少であることが推測可能であると考えます。 造影CTによる画像所見において血栓症（静脈洞、門脈内）が確認されています。 検査値異常（Dダイマーの著増）を認めます。 上記に加え、抗PF4抗体（ELISA法）が陽性であることが確認され、 TMA（TTP, HUS）、DICを除外するための検査所見が得られてはいないものの、 臨床上バキスゼブリア投与による既知の副反応であるTTSを発症したと判断することが可能です。 以上より、本症例の因果関係を「因果関係は否定できない」と評価します。	
30714	70歳	男性	2021/09/18	2021/10/27	39	バキスゼブリア筋注	アストラゼネカ	不明	1回目	当院で接種は行っていないため、「予診票での留意点」は正確には「不明」。但し当院での問診より、既往歴、アレルギー歴、常用薬、は特記事項がなかったため、留意点は「無」として報告。	TTS（血小板減少症を伴う血栓症）	関連あり	重い	2021/12/07	後遺症あり	α	1	39日後に腹痛、嘔吐、下痢、血便。40日後に心肺停止。造影CTで上腸間膜動脈閉塞症、小腸～右側結腸壊死、腎梗塞、脾梗塞、左心室内血栓。緊急手術を行い自発呼吸再開得られたが、意識障害遷延。 抗PF4抗体ELISA法で陽性、経過中、D-dimer最高60.0μg/mL、Plt最低5.1万。 TTSを発症した蓋然性が高いと考える。 HITや抗リン脂質抗体症候群は除外できている。ワクチン接種後に発症したTMA等の鑑別疾患を除外できているわけではなく、接種後30日以上を経過してからの発症であるが、リスク因子は喫煙のみ、抗PF4抗体（ELISA法）陽性もふまえると因果関係はありと考える。	

※予防接種後副反応疑い報告書の別紙様式１の報告基準に記載のある症状（「その他の反応」は除く。）について、報告状況をもとに集計を行った。アナフィラキシーは、接種開始日（コミナティ筋注：令和3年2月17日、スパイクバックス筋注：令和3年5月22日、バキスゼブリア筋注：令和3年8月3日）以降の累計報告件数。TTSは、いずれのワクチンも令和3年8月3日以降に第一報の報告がなされたものの累計件数。心筋炎及び心膜炎は、いずれのワクチンも令和3年12月6日以降に第一報の報告がなされたものの累計件数。

※集計対象のMedDRA PT（ver.24.0）は以下のとおり。
アナフィラキシー：アナフィラキシーショック、アナフィラキシー様ショック、アナフィラキシー反応、アナフィラキシー様反応
心筋炎：免疫性心筋炎、好酸球性心筋炎、巨細胞性心筋炎、心筋炎、自己免疫性心筋炎
心膜炎：心膜炎、胸膜心膜炎、自己免疫性心膜炎
TTSは、MedDRA（ver.24.1）にて、TTS関連事象を集計。

バキスゼブリア筋注 まとめ

R3第9回班会議資料

2021/12/1現在

- 2021年5月21日に特例承認となり、2021年8月3日に臨時接種の対象となった新型コロナワクチン「バキスゼブリア筋注」を、2021年8月21日からコホート調査対象者に接種開始した。
- 2021年11月30日15時現在、554人が1回目接種し、コホート調査に登録された。2回目接種は507人が接種した。
- 被接種者は20歳代が11.2%、30歳代が17.5%、40歳代が29.4%、50歳代が27.6%、60歳代が10.5%、70歳代が2.9%、80歳以上が0.9%、男性59.7%、女性40.3%、医師0.2%、看護師0.9%、薬剤師0.4%、介護系職員1.1%、事務21.8%、その他の職種75.6%であった。
- 1回目接種後1週間（Day8）までの日誌が回収できた539人では、発熱が49.5%にみられ、局所反応は疼痛が73.4%みられた。局所発赤は接種後2日後（Day3）をピークに14.3%にみられたが、接種後1週間（Day8）でも5%程度は残存していた。発熱、倦怠感、頭痛等は若い人に頻度が高かった。また、女性にAEの頻度が高かった。
- 1回目接種後、接種翌日を中心として23.4%の被接種者が病休を取得していた。病休日数は、病休を取得した人のうち93.7%が2日以内であった。
- 2回目接種後1週間（Day8）までの日誌が回収できた267人では1回目接種後よりもAEの頻度が低いように見受けられた。
- コホート調査に登録された方において、SAEの報告が2例あった。このうち1例については、副反応疑いとしてPMDAに報告された。

TECHNICAL REPORT

Suspected adverse reactions to COVID-19 vaccination and the safety of substances of human origin

3 June 2021

Table 1. Number of administered doses of COVID-19 vaccines and selected suspected adverse reactions* by reaction type in EU/EEA, as of 28 April 2021 [15,16]

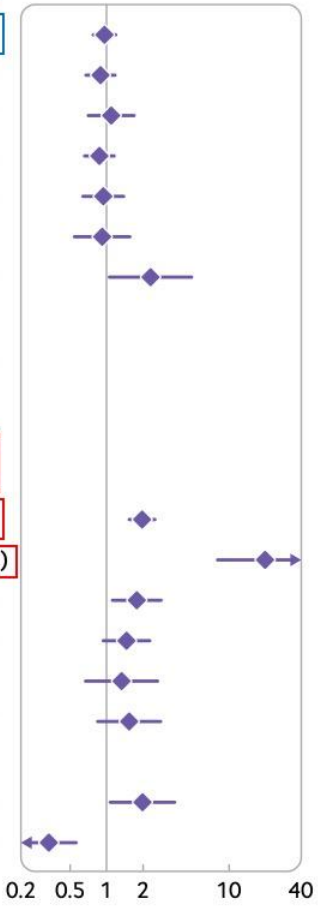
Vaccine	ADM (doses)	Adverse events (% of ADM)	Coagulopathy (% of ADM)		DIC (% of ADM)		ITP (% of ADM)		TP (% of ADM)	
			Total	Deaths	Total	Deaths	Total	Deaths	Total	Deaths
COVID-19 Vaccine Moderna	9691295	17625 (0.181864)	5 (0.000052)	1 (0.000010)	5 (0.000052)	1 (0.000010)	39 (0.000402)	2 (0.000021)	55 (0.000568)	6 (0.000062)
Comirnaty	96519666	151306 (0.156762)	44 (0.000046)	7 (0.000007)	7 (0.000007)	4 (0.000004)	85 (0.000088)	0 (0)	178 (0.000184)	15 (0.000016)
Vaxzevria	27430533	184833 (0.673822)	79 (0.000288)	2 (0.000007)	33 (0.000120)	11 (0.000040)	167 (0.000609)	6 (0.000022)	605 (0.002206)	45 (0.000164)
COVID-19 Vaccine Jansen	98139	413 (0.420832)	0 (0)	0 (0)	2 (0.002038)	0 (0)	0 (0)	0 (0)	7 (0.007133)	0 (0)
Total	133739633	354177 (0.264826)	128 (0.000096)	10 (0.000007)	47 (0.000035)	16 (0.000012)	291 (0.000218)	8 (0.000006)	845 (0.000632)	66 (0.000049)

ADM – Administered; DIC-Disseminated Intravascular Coagulation; ITP – Immune Thrombocytopenia; TP – Thrombocytopenia
** The causality between the suspected adverse reactions/adverse events and vaccines has not been assessed.*

Arterial events, venous thromboembolism, thrombocytopenia, and bleeding after vaccination with Oxford-AstraZeneca ChAdOx1-S in Denmark and Norway: population based cohort study

R3第8回班会議資料

Outcome	Incidence rate* (Denmark /Norway)	Observed† 実数	Expected 予想数 (発生率)	Standardised morbidity difference‡ /100 000 (95% CI)	Standardised morbidity ratio (95% CI) 標準化罹患率
動脈性(心筋梗塞・脳梗塞))					X0.97 変化なし
Arterial events	4.52/4.71	83	86	-1.0 (-7.2 to 6.4)	0.97 (0.77 to 1.20)
Cardiac events	2.93/3.56	52	57	-1.9 (-6.8 to 4.1)	0.91 (0.68 to 1.19)
Acute myocardial infarction (AMI)	1.04/1.21	20	18	0.6 (-2.3 to 4.6)	1.09 (0.66 to 1.68)
Ischaemic heart disease without AMI	2.58/3.35	46	52	-2.2 (-6.8 to 3.5)	0.89 (0.65 to 1.18)
Cerebrovascular events	1.62/1.21	27	28	-0.5 (-3.9 to 4.0)	0.95 (0.63 to 1.38)
Cerebral infarction	1.03/0.75	16	17	-0.5 (-3.0 to 3.2)	0.92 (0.53 to 1.50)
Intracerebral haemorrhage	0.20/0.14	8	3	1.7 (0.0 to 4.6)	2.33 (1.01 to 4.59)
Occlusion and stenosis§	0.07/0.21	n<5	3	NR	NR
Stroke, unspecified	0.40/0.06	0	5	-1.8 (-1.8 to -0.4)	0.00 (0.00 to 0.78)
Subarachnoid haemorrhage	0.14/0.09	n<5	3	NR	NR
Transient ischaemic attack	0.07/0.09	0	2	-0.6 (-0.6 to 0.8)	
Other arterial events¶ 静脈血栓塞栓症	0.11/0.10	n<5	3	NR	X1.97 に増加
Venous thromboembolism	1.58/1.26	59	30	10.8 (5.6 to 17.1)	1.97 (1.50 to 2.54)
Cerebral venous thrombosis 脳静脈血栓症	0.02/0.01	7	0.3	2.5 (0.9 to 5.2)	20.25 (8.14 to 41.73)
Pulmonary embolism	0.57/0.57	21	12	3.4 (0.5 to 7.5)	1.79 (1.11 to 2.74)
Lower limb venous thrombosis	0.94/0.48	22	15	2.6 (-0.4 to 6.8)	1.47 (0.92 to 2.23)
Deep thrombophlebitis of veins in legs	0.35/0.38	10	7	0.9 (-1.0 to 4.0)	1.34 (0.64 to 2.46)
Unspecified deep thrombophlebitis in lower limbs	0.66/0.05	12	8	1.6 (-0.6 to 4.9)	1.54 (0.79 to 2.69)
Splanchnic thrombosis	0.04/0.06	n<5	1	NR	NR
Other venous thrombosis**	0.22/0.36	12	6	2.2 (0.1 to 5.5)	1.99 (1.03 to 3.48)
All cause mortality	2.54/1.84	15	44	-10.6 (-13.0 to -7.0)	0.34 (0.19 to 0.57)

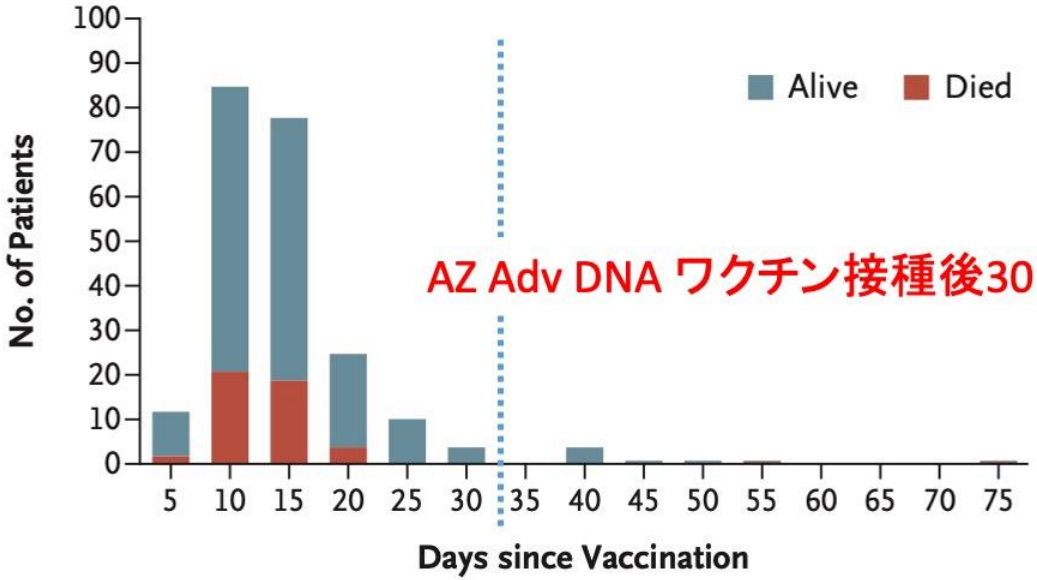


X20.25 に増加

BMJ. May 5, 2021 (doi.org/10.1136/bmj.n1114)

Baseline Distribution of Variables in Patients with Vaccine-Induced Immune Thrombocytopenia and Thrombosis (VITT).

R3第9回班会議資料



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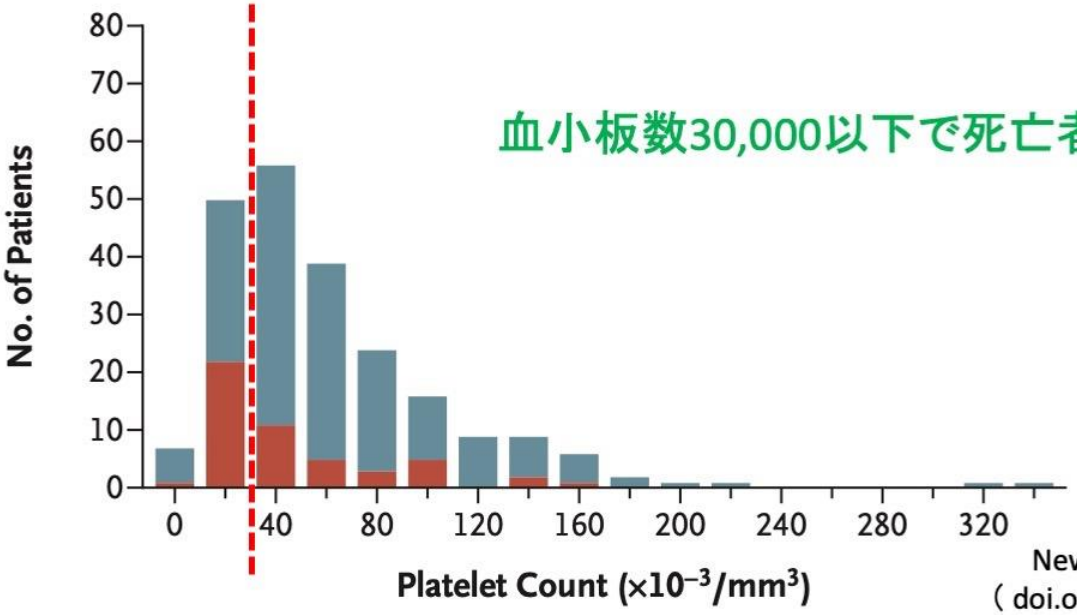
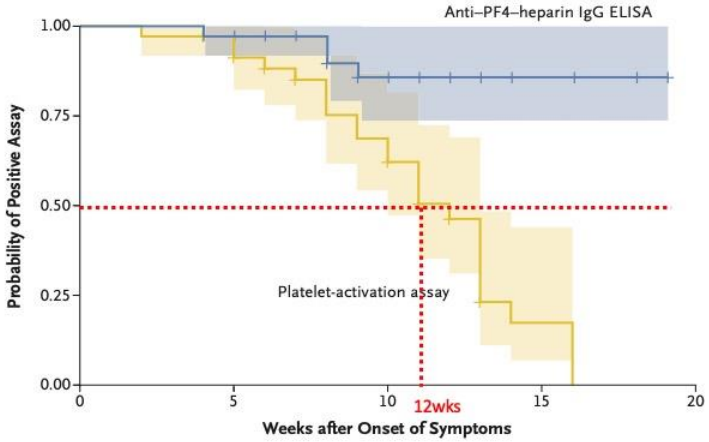


New Engl J Med. August 11, 2021.
（doi.org/10.1056/NEJMoa2109908）

Decline in Pathogenic Antibodies over Time in VITT

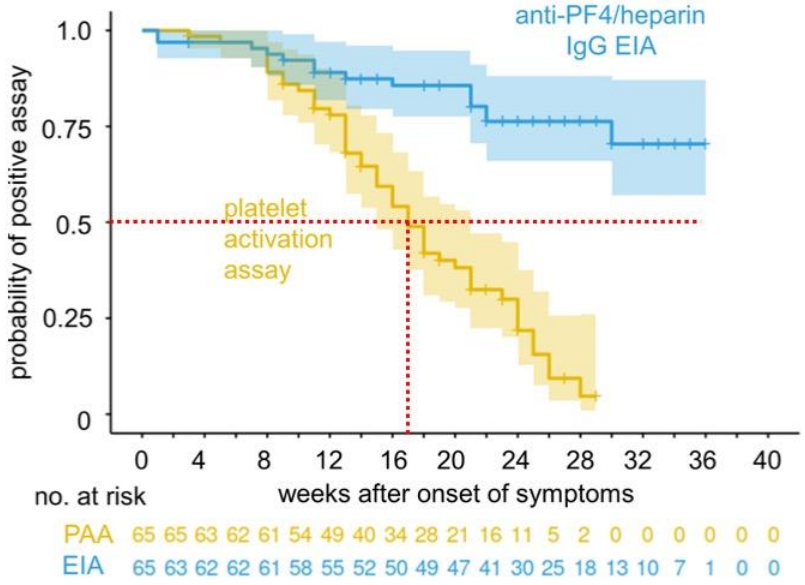
R4第11回班会議資料



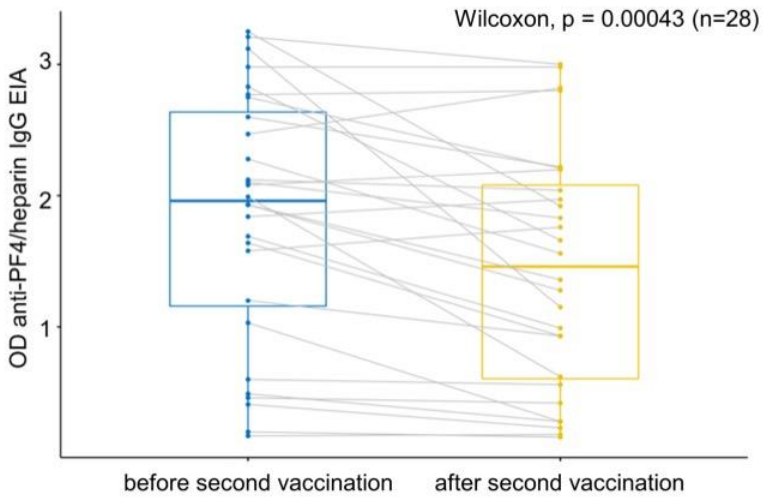
No. at Risk					
Anti–PF4–heparin IgG ELISA	35	33	21	4	0
Platelet-activation assay	35	33	21	3	0

N Engl J Med 2021; 385:1815-1816
DOI: 10.1056/NEJMc2112760

Most Anti-PF4 Antibodies in Vaccine-induced Immune Thrombotic Thrombocytopenia are transient



2nd vaccination (Pfizer mRNA)

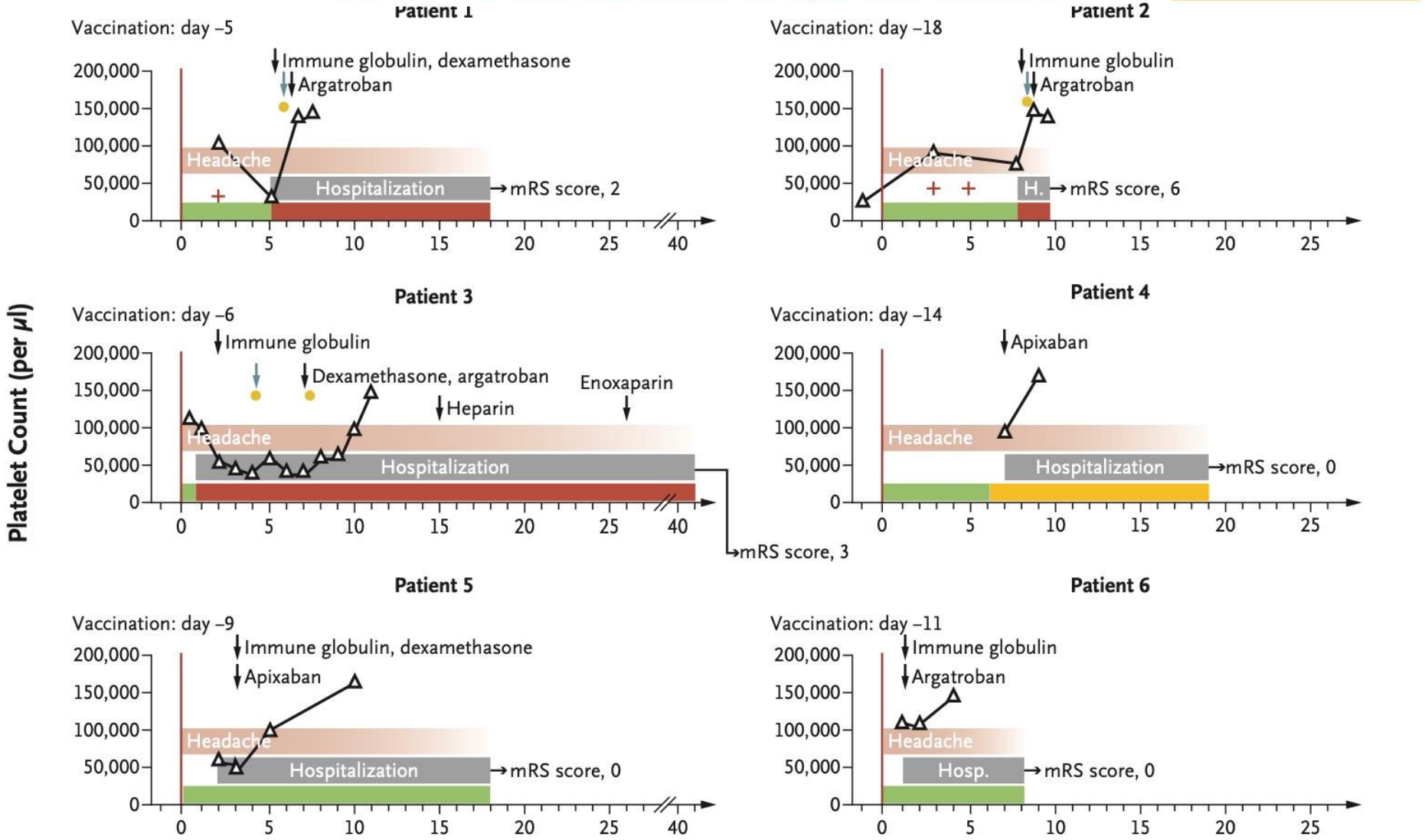


Blood. 2022 Feb 3
https://doi.org/10.1182/blood.2021014214

Clinical and Laboratory Data for Patients with VIT and Severe Headache (Pre-VITT Syndrome).

AZ ワクチン接種後18日までにpre-VITT syndrome

R3第8回班会議資料



・ 11名の患者がCVST(脳静脈洞血栓症)を伴わない重度の頭痛を伴うVIT(ワクチン誘発性血小板減少症)を呈する

・ VITTに先行して血小板減少，Dダイマー高値，抗PF4-ヘパリンIgG抗体高値

New Engl J Med. Sep 15, 2021.（doi.org/10.1056/NEJMc2112974）

R3第9回班会議資料

Table 2. Waiting period for blood donation following COVID-19 vaccination and deferral p suspected adverse reaction in EU by country (30 April 2021)

Country	Waiting period following COVID-19 vaccination	Deferral period after suspected adverse reaction
Austria	48 hours	7 days
Belgium	48 hours	7 days
Bulgaria	28 days	-
Croatia	48 hours (Co,Mo,Cv) or 28 days (Va)	7 days
Czechia	48 hours (Co,Mo,) or 28 days (Va)	-
Cyprus	48 hours (Co,Mo,) or 28 days (Va,JJ)	-
Denmark	No waiting period	14 days after fever
Estonia	No waiting period (Co,Mo) or 28 days (Va)	-
Finland	No waiting period	2 days
France	No waiting period	-
Germany	No waiting period	-
Greece	No waiting period	7 days
Hungary	No waiting period	A few days
Ireland	7 days	-
Italy	48 hours	7 days
Latvia	7days	-
Lithuania	No waiting period	Symptom-free
Luxembourg*	7 days	7 to 14 days after fever
Malta	7 days	7 days
Netherland	7 days	-
Portugal	48 hours	7 days
Poland	48 hours (Co,Mo) or 14 days (Va,JJ)	7 days
Romania	7 days (Co,Mo) or 28 days (Va,JJ)	-
Slovakia	14 days (Co,Mo) or 28 days (Va,JJ)	-
Slovenia	24 hours	7 days
Spain	48 hours	7 days or 14 days after fever
Sweden	7 days	14 days

*Co – Comirnaty vaccine; Mo – COVID-19 Moderna vaccine; Cv – CuraVax vaccine; Va – Vaxzevria vaccine; JJ – COVID-19 Janssen vaccine, * personal communication.*

IPFA position on acceptance criteria for Covid-19 vaccinated donors

2 October 2021

Dr Françoise Rossi,

Director of Scientific and Regulatory Affairs

First published Jan 2021, Rev. July 2021

IPFA position on acceptance criteria for Covid-19 vaccinated donors

In anticipation of the regulatory approval for use of a number of Covid-19 vaccines and the commencement of national mass vaccination programmes the European Centre for Disease Prevention and Control (ECDC) has published its updated technical guidance – Coronavirus disease 2019 (COVID-19) and supply of substances of human origin in the EU/EEA – second update.

The guidance in respect of donor deferral following vaccination recommends:

- A minimum deferral of 4 weeks for investigational vaccines (clinical trials) of any type
- No deferral period for mRNA or protein vaccines
- A minimum of 4 weeks for viral vector-type vaccines when considered "attenuated virus" (as per Directive 2004/33).

https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-supply-substances-human-origin-second-update.pdf

On Dec 12th, 2020, the PEI published its recommendation concerning post vaccination donor deferral in line with the above stating that:

"*On the basis of the current state of knowledge, no donor deferral is required after vaccination with the SARS-CoV-2 vaccines under approval, which contain inactivated viruses or non-infectious virus components such as mRNA. All other default criteria set out in the Hemotherapy Directive remain fully applicable.*" (in German: https://www.pei.de/EN/medicine-safety/haemovigilance/guidelines/guidelines-node.html;jsessionid=12DF32D0B1D6547F1004A53F0749348D.intranet211)

On January 19, 2021, FDA published an Updated Inform
Establishments Regarding the COVID-19 Pandemic and Blood Donation
recommending

- individuals who received a nonreplicating, inactivated, or mRNA-based COVID-19 vaccine can donate blood without a waiting period,
- individuals who received a live-attenuated viral COVID-19 vaccine, refrain from donating blood for a short waiting period (e.g., 14 days) after receipt of the vaccine

On 3 Jun 2021, the ECDC published a report on Suspected adverse reactions to COVID-19 vaccination and the safety of substances of human origin, stating that "*Currently available data and evidence suggest a low probability of whole blood and plasma donation by asymptomatic individuals in the early phase of TTS, posing a very low risk of venepuncture bleeding or post-transfusion thrombocytopenia by passive transfer of anti-platelet antibodies. Therefore, no additional blood and plasma safety measures related to the occurrence of suspected adverse reactions to COVID-19 vaccines are recommended.*"

Whilst IPFA strongly supports the above current recommendations it is also important to recognise the impact on the global blood and plasma supply of the Covid pandemic and accordingly advocates caution in the development of any future regulatory actions, based on the precautionary principle, concerning donor deferral which may further worsen plasma collection and consequently Plasma derived medicinal products supply.

COVID-19 update - please wait 48 hours from your vaccine before donating.
Read our latest coronavirus update

Coronavirus: latest advice

Last reviewed: 31 January 2022 **2022年1月up date**

We need you to keep donating blood, plasma and platelets during the pandemic. Donor centres are still open despite coronavirus restrictions.

To make donating as safe as possible for everyone, we've made a few changes at our centres. We are regularly reviewing government advice to ensure we have measures in place to keep you and our staff safe.

Before coming to donate:

- **Check you are ok to attend** – read coronavirus health rules for donors
- COVID-19 vaccine – please wait 48 hours from your vaccine before donating (you can attend on the 3rd day from the date of your vaccine). **接種後48日後**

  If you had side effects from the vaccine such as headache, temperature, aches and chills, please wait until these symptoms have passed before donating. Find out more about donating after a vaccine.
- **Travelling to donate –** donation is allowed despite coronavirus restrictions
- **Keep your appointment and arrive on time** – please reschedule it if you can't come by calling us on 0300 123 23 23
- **Wear a fabric face covering** – unless you're medically exempt, this must cover your mouth and nose - get more information about face masks
- **Attend alone –** as part of latest safety changes it is vitally important that you come on your own, to help minimise social contact.

Health Sciences Authority Singapore

R3第9回班会議資料

Type of COVID-19 Vaccine	Deferral Period	
1. mRNA vaccine · Pfizer-BioNTech / Comirnaty COVID-19 vaccine · Moderna COVID-19 vaccine	No side effects	1 week after vaccination
	Muscle ache or pain at injection site(localized)	1 week after side effect has resolved
	Any of the following: Fever or chills Generalized muscle or joint aches/pains Rashes Lymph node swelling	4 weeks After side effects have resolved
2. Inactivated virus vaccine · Sinovac-Coronavac COVID-19 vaccine		
Virus vector based or live attenuated (e.g. those manufactured by Astra Zeneca, Janssen /J&J) or Unknown type of Covid-19 Vaccine	No side effects	4 weeks after vaccination
	Any of the following: Fever or chills Any muscle or joint aches /pains Rashes Lymph node swelling	4 weeks after vaccination or 4 weeks from the time the side effects have resolved (which ever is longer)

U.S. FOOD & DRUG ADMINISTRATION

Home / Vaccines, Blood & Biologics / Safety & Availability (Biologics) / Updated Information for Blood Establishments Regarding the COVID-19 Pandemic and Blood Donation

2022年1月up date

Updated Information for Blood Establishments Regarding the COVID-19 Pandemic and Blood Donation

Share Tweet Linkedin Email Print

Safety & Availability (Biologics)
Biologic Product Security
Blood Safety & Availability
CBER-Regulated Products: Shortages and Discontinuations
Pandemics & Emerging Diseases
Tissue Safety & Availability
Vaccine Safety & Availability
HIV Home Test Kits
Recalls (Biologics)
Report a Problem to the Center for Biologics Evaluation & Research

January 11, 2022

FDA continues to work closely with CDC and other federal and international agencies to monitor the coronavirus disease 2019 (COVID-19) pandemic caused by the virus, SARS-CoV-2. Respiratory viruses, in general, are not known to be transmitted by blood transfusion. There have been no reported cases of transfusion-transmitted coronavirus, including SARS-CoV-2, worldwide.

Routine measures used to determine blood donor eligibility prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10).

It is imperative that healthy individuals continue to donate blood and blood components, including Source Plasma.

Considerations

- FDA does not recommend using COVID-19 laboratory tests to screen routine blood donors.
- The blood establishment's responsible physician must evaluate prospective donors and determine eligibility (21 CFR 630.5). The donor must be in good health and meet all donor eligibility criteria on the day of donation (21 CFR 630.10). The responsible physician may wish to consider the following:
  - individuals diagnosed with COVID-19 or who are suspected of having COVID-19, and who had symptomatic disease, refrain from donating blood for at least 10 days after complete resolution of symptoms,
  - individuals who had a positive diagnostic test for SARS-CoV-2 (e.g., nasopharyngeal swab), but never developed symptoms, refrain from donating at least 10 days after the date of the positive test result,
  - individuals who are tested and found positive for SARS-CoV-2 antibodies, but who did not have prior diagnostic testing and never developed symptoms, can donate without a waiting period and without performing a diagnostic test (e.g., nasopharyngeal swab),
  - individuals who received a nonreplicating, inactivated, or mRNA-based COVID-19 vaccine can donate blood without a waiting period,
  - individuals who received a live-attenuated viral COVID-19 vaccine, refrain from donating blood for a short waiting period (e.g., 14 days) after receipt of the vaccine,
  - individuals who are uncertain about which COVID-19 vaccine was administered, refrain from donating for a short waiting period (e.g., 14 days) if it is possible that the individual received a live-attenuated viral vaccine.

FDA will continue to monitor the situation and issue updated information as it becomes available.

Content current as of:
01/11/2022

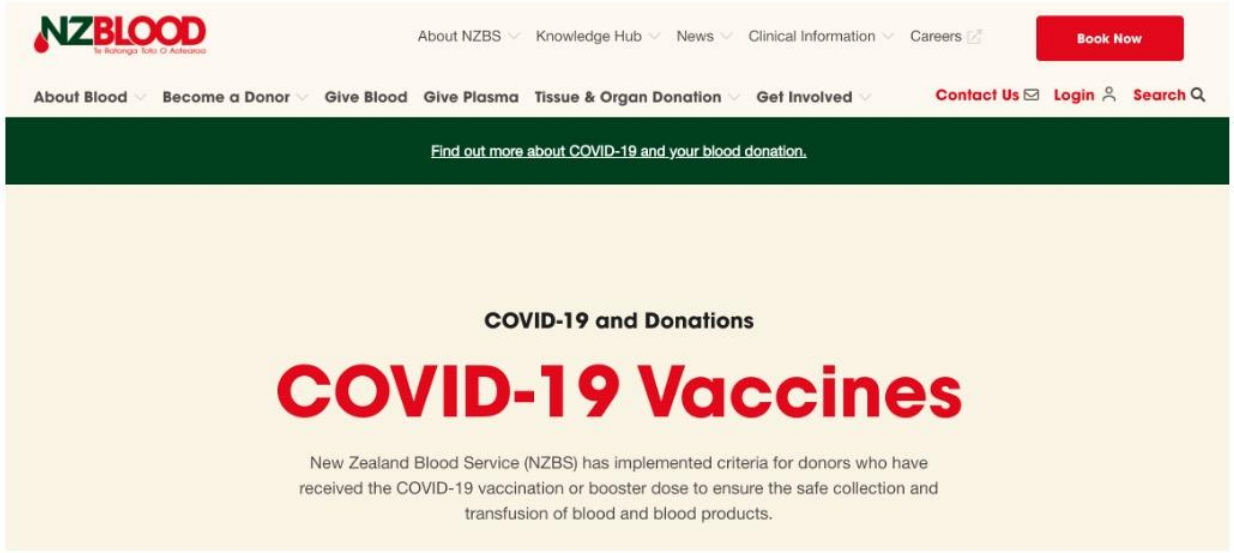
Health Topic(s)
Coronavirus

回復してから10日

無症候なら・・・
検査してから10日

非増殖型・不活化
mRNAワクチン
制限なし

生ワクチン
不明な場合
接種後14日



NO STAND DOWN REQUIRED	28-DAY STAND DOWN REQUIRED
Pfizer BioNTech (BNT-162b2)	Bharat Biotech (COVAXINTM)
Janssen/Johnson & Johnson (Ad26.COV2.S)	CanSino Biologics (Convidecia or Ad5-nCoV)
AstraZeneca (Oxford - AstraZeneca)	Gamaleya Research Institute (Sputnik V)
	Inovio (INO-4800)
	Moderna (mRNA-1273)
	Novavax (NVX-CoV2373)
	Sinopharm (Two vaccines)
	Sinovac (CoronaVac)

https://www.nzblood.co.nz/knowledge-hub/covid-19/covid-19-vaccines/

Vaccine-induced immune thrombotic thrombocytopenia

Frederikus A Klok, Menaka Pai, Menno V Huisman, Michael Makris

Lancet Haematol 2021; 9: 73–80

Published Online
Niovember 11, 2021
https://doi.org/10.1016/
S2352-3026(21)00306-9

R4第11回班会議資料

Epidemiology

In **Norway**, Schultz and colleagues 4 reported five cases of VITT among 130 000 individuals who received the AstraZeneca– Oxford vaccine giving an incidence of one in 26,000

In the **UK**, the MHRA reported 367 VITT cases after 24·7 million of the first vaccination and 44 cases after the second AstraZeneca–Oxford vaccination, giving rates of one case per 67,302 vaccinations and one case per 518,181 vaccinations, respectively.

From the USA, reported 12 cases of VITT after the Johnson & Johnson vaccine after 7 million doses, suggesting a rate of one case per 583,000 vaccinations.

The MHRA gives the risk of VITT after the first dose of AstraZeneca–Oxford vaccination as one in 100,000 for people older than 50 years and one in 50,000 for those aged 49 years or younger.

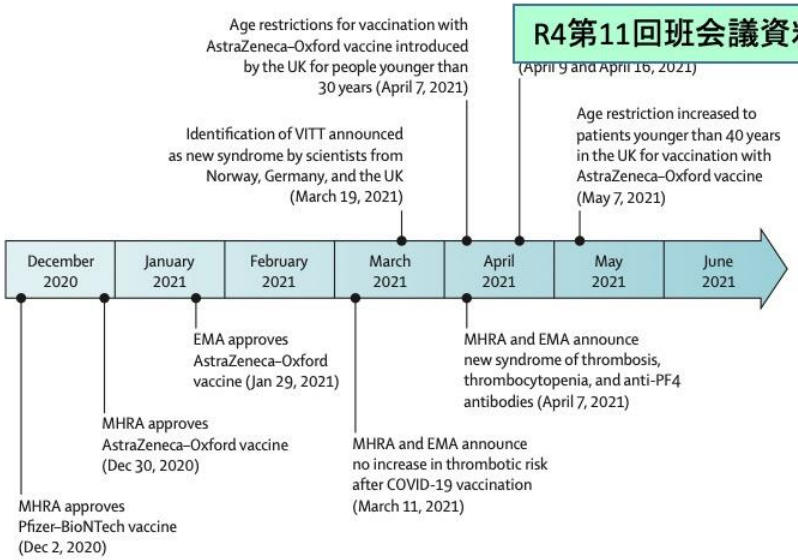


Figure 1: **Timeline of the development of adenovirus-based coronavirus vaccines and first recognition of vaccine-induced immune thrombotic thrombocytopenia**
On August 12, 2021, the full report from the first 294 UK cases was published.[9] EMA=European Medicines Agency. MHRA=Medicines and Healthcare Products Regulatory Agency. VITT=vaccine-induced immune thrombotic thrombocytopenia.

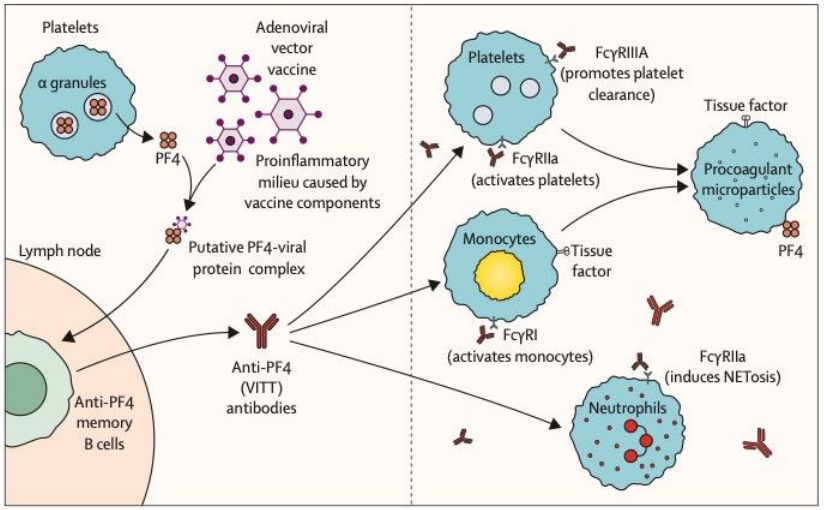


Figure 2: **Proposed pathophysiology of vaccine-induced immune thrombotic thrombocytopenia**
PF4=platelet factor 4.

UK Expert Haematology Panel

Suspected VITT in case of:	Required tests in diagnostic work-up of VITT	VITT diagnostic criteria
AstraZeneca–Oxford or Johnson & Johnson vaccine 5–30 days before onset of symptoms	Full blood count and blood film, liver or renal function	Thrombocytopenia (platelet count <150×10^9 cells per L), D-dimer >4000 FEU (fibrinogen-equivalent units), venous (or arterial) thrombosis, ELISA positive, functional test positive
Signs of venous or arterial thrombosis, such as severe headache or other neurological symptoms (or both)	Activated partial thromboplastin time, prothrombin time, fibrinogen concentrations, D-dimer concentrations	
New bleeding tendency or petechiae	Heparin-induced thrombocytopenia ELISA test for anti-platelet factor 4 antibodies and functional assay	

Figure 3: **Overview of the diagnostic investigation of VITT**
Functional assays might involve a functional heparin-induced platelet activation assay, a serotonin-release assay, or a flow-based platelet activation assay. FEU=fibrinogen-equivalent units. VITT=vaccine-induced immune thrombotic thrombocytopenia.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2022

COVID-19 vaccines safety update

Comirnaty (BioNTech Manufacturing GmbH)
COVID-19 Vaccine Janssen (Janssen-Cilag International NV)
Nuvaxovid (Novavax CZ, a.s.)
Spikevax (Moderna Biotech Spain, S.L.)
Vaxzevria (AstraZeneca AB)

Vaxzevria (AstraZeneca AB)

About 69 million doses of Vaxzevria were administered in the EU/EEA between EU marketing authorisation on 29 January 2021 and 2 January 2022[1].

Thrombosis with thrombocytopenia syndrome

Update to the product information

Following the last update to the product information regarding the very rare side effect of thrombosis (formation of blood clots in the blood vessels) with thrombocytopenia (low blood platelets) syndrome (TTS) (see safety update for Vaxzevria of 8 September 2021), in January 2022 PRAC concluded that the product information should be updated further. This update will reflect that the majority of TTS cases were reported after the first, rather than the second, dose. Further information can be found in the PRAC highlights of January 2022.

- ***Thrombosis with thrombocytopenia syndrome:*** Thrombosis w
(TTS), in some cases accompanied by bleeding, has been obser
vaccination with Vaxzevria. This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. Some cases had a fatal outcome. The majority of these cases occurred within the first three weeks following vaccination. The reporting rates after the second dose are lower compared to after the first dose. See also section 4.3. TTS requires specialised clinical management. Healthcare professionals should consult applicable guidance and/or consult specialists (e.g., haematologists, specialists in coagulation) to diagnose and treat this condition.

3週以内

- ***Cerebrovascular venous and sinus thrombosis:*** Events of cerebrovascular venous and sinus thrombosis without thrombocytopenia have been observed very rarely following vaccination with Vaxzevria. Some cases had a fatal outcome. The majority of these cases occurred within the first four weeks following vaccination. This information should be considered for individuals at increased risk for cerebrovascular venous and sinus thrombosis. These events may require different treatment approaches than TTS and healthcare professionals should consult applicable guidance.

4週以内

- ***Thrombocytopenia:*** Cases of thrombocytopenia, including immune thrombocytopenia (ITP), have been reported after receiving Vaxzevria, typically within the first four weeks after vaccination. Very rarely, these presented with very low platelet levels (<20,000 per µL) and/or were associated with bleeding. Some of these cases occurred in individuals with a history of immune thrombocytopenia. Cases with fatal outcome have been reported. If an individual has a history of a thrombocytopenic disorder, such as immune thrombocytopenia, the risk of developing low platelet levels should be considered before administering the vaccine and platelet monitoring is recommended after vaccination.

4週以内

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, leg pain, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches, blurred vision, confusion or seizures after vaccination, or who experiences spontaneous bleeding, skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

Individuals diagnosed with thrombocytopenia within three weeks after vaccination with Vaxzevria, should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within three weeks of vaccination should be evaluated for thrombocytopenia.

Reminders: The administration of Vaxzevria is contraindicated in individuals who have experienced TTS following vaccination with this vaccine.

People should seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain following vaccination, or experience after a few days following vaccination severe or persistent headaches, blurred vision, confusion or seizures (fits), or unexplained bleeding or skin bruising or pinpoint round spots beyond the site of vaccination which appears after a few days (see product information).

R4第11回班会議資料

Organ transplantation from deceased donors with vaccine-induced thrombosis and thrombocytopenia

UKでのTTS発症13人のドナーから26人のレシピエントへの臓器移植結果
・7例/6人で移植後9日以内に血栓症・出血事象発生
・3人の肝移植で抗PF4抗体検出(3-22day after TP)

TABLE 1 Deceased donors with VITT and the recipients of their organs

Characteristic	Value
Consented deceased donors[a]	13[b]
Age (years)	34 (21 to 63)
Female	11 (85%)
Donation after brain death	13 (100%)
Time from vaccine administration to hospital admission (days)	10 (7 to 18)
Clinical features[c]	
Intracranial hemorrhage	12 (92%)
Cerebral venous sinus thrombosis	7 (54%)
Extra-cranial thrombosis[d]	6 (46%)
Platelet count ($\times 10^9$/L)	
On admission to hospital	26 (3 to 61)
Lowest value prior to donation	7 (2 to 50)
Fibrinogen (g/L, NR 2 to 4)[e]	1.0 (<0.3 to 4.5)
D-dimer (ng/ml, NR < 500)[f]	41 000 (6500 to >80 000)
Anti-PF4 antibodies (OD, assay cut-off 0.4)[g]	2.7 (1.4 to 3.2)
Transplant recipients	26
Age (years)	40 (2 to 63)
Female	12 (46%)
Transplant type	
Kidney-only	15
Liver[h]	7
Heart	1
Bilateral lung	1
Simultaneous pancreas and kidney (SPK)	1
Pancreatic islet	1
Major postoperative complications[i]	7
Liver recipients	
Major hemorrhage	0
Thrombosis/thromboembolism	3
Kidney/SPK/islet recipients	
Major hemorrhage	3
Thrombosis/thromboembolism	1
Heart/lung recipients	
Major hemorrhage	0
Thrombosis/thromboembolism	0
Patient and allograft outcomes	
Delayed graft function/early graft dysfunction[j]	4
Graft explant	3
Death	1
Lowest postoperative platelet count ($\times 10^9$/L)[k]	124 (32 to 267)
Anti-PF4 antibodies[g]	
Positive	3
Negative	10
Result pending	2
Not tested	11

Note: Numbers are *n* (%) or median (range).

Abbreviations: VITT, vaccine-induced thrombosis and thrombocytopenia; NR, normal range; PF4, platelet factor 4; OD, optical density units.

[a]Individuals in whom consent for organ donation has been granted.

[b]All organ offers from one donor were declined, so no organs were retrieved. Two donors had organs retrieved that were not eventually transplanted. Ten donors donated at least one organ that was transplanted.

[c]Clinical features are not exclusive; six donors presented with intracranial hemorrhage only.

[d]Portal vein (2), pulmonary embolus (1), splenic vein (1), mesenteric vein (1), aorta (1).

[e]Lowest result reported by donor center.

[f]Highest result reported by donor center.

[g]Donor serum samples from all probable cases were centrally tested by NHSBT for anti-PF4 antibodies, using the Lifecodes PF4 IgG enzyme-linked immunosorbent assay (ELISA, Immucor).

[h]Includes two split liver transplants from one donor.

[i]Numbers represent events; some recipients experienced more than one complication. Excludes death.

[j]Defined as at least one session of hemodialysis/hemofiltration in the first 7 postoperative days in kidney recipients, any need for ongoing extracorporeal membrane oxygenation in heart/lung recipients, or super-urgent listing for re-do transplantation in liver recipients. Excludes graft failure/explant.

[k]In the first 2 weeks after transplantation.

Am J Transplant. 2021 Jul 2. doi: 10.1111/ajt.16735.

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

Change Notification UK National Blood Services No. 11 - 2021

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.
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.

R3第9回班会議資料

GCSF administration carries a small ris… thrombosis and thrombocytopenia. The… GCSF could exacerbate the immune re… 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.

	~~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.

Appendix 3. Table of Immunizations

Please make the following amendment to this table:

Diseases Protected against	Comments and example trade names of adult preparations	
COVID-19 (SARS-CoV-2)	Pfizer/BioNTech COVID-19 vaccine, AstraZeneca COVID-19 vaccine, Moderna COVID-19 vaccine ~~7 days post immunisation~~; see 'Coronavirus vaccination' entry	Non-Live

まとめ

- AZ社のTTS/VITT事例報告後(2021年3月)も，世界各国の献血制限は変わっておらず，無制限 (米国・カナダ)，48時間 (英国)(元々は7日)，14日～28日(欧州各国)，4週 (HSA)となっている。
- ECDC，IPFAもTTS/VITTには関心を持ちつつも，現時点で対応を変更する必要はないという意見
- 一方，臓器移植に関し，UKでのTTS発症13人のドナーから26人のレシピエントへの臓器移植結果が報告され，7例/6人で移植後9日以内に血栓症・出血事象発生し，肝移植後3～22日に3人のレシピエントで抗PF4抗体が検出されている。
- 英国の骨髄移植ガイドラインでは，mRNAワクチン接種後の制限を7日より14日，AZワクチンを14日より28日に変更した。
- 本邦では40歳以上を接種対象に絞っており，VITTの発生頻度はさらに低いことが想定されるが，現時点で約58,120人(初回), 57381人(2回目)に接種され，初回接種後の2例の疑い症例がPMDAに報告されている。UKでは1/67,302(初回), 1/518,181(2回目), 米国では1/583,000 (J&J初回)であり，単純比較すると本邦での発生頻度は高いが，引き続き，発生頻度，抗PF4抗体との関わりを含め，詳細な検討が必要である。
- 現時点で，抗PF4抗体の懸念はあるものの，概ね海外で撮られている対応に準じ，本邦では，AZ社 AZワクチンに関しては，4週間の献血制限を設定しつつ，問診等で，重度の頭痛等がないか，また過去に血栓等が発生していないか等も含め確認し，リスクの軽減を図ることが求められる。