



Update on COVID-19 vaccines and risk of thromboembolic events with concurrent thrombocytopenia

EWG 12th April 2021(data lock: 5 April 2021)



Medicines & Healthcare products Regulatory Agency

OFFICIAL-SENSITIVE

Background

Ongoing, detailed review of reports of very rare events of thromboembolic events (including CVST and non-CVST events) with concurrent thrombocytopenia associated with Covid-19 vaccines.

Assessment of Yellow Card Scheme reports against a case definition developed with independent expert advice. Foreign cases were considered for the Pfizer and Moderna vaccines.

Latest consideration at CHM and Vaccine Benefit Risk Expert Working Group (VBR EWG) meetings:

- VBR EWG meetings: 27th & 31st March, 6th April 2021
- CHM meetings: 1st, 4th, 6th & 8th April 2021

Summary of MHRA Regulatory & JCVI Actions

MHRA:

- [Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca - GOV.UK \(www.gov.uk\)](#)
- HCP letter via Central Alerting System
- [UK regulator confirms that people should continue to receive the COVID-19 vaccine AstraZeneca - GOV.UK \(www.gov.uk\)](#)
- Q&A article

JCVI statement on use of the AstraZeneca COVID-19 vaccine: 7 April 2021 - GOV.UK (www.gov.uk) 7 April 2021

- Benefits far outweigh the risk of adverse events for individuals ≥ 30 years of age and those at higher risk of severe COVID-19 disease;
- Preferable for healthy adults aged < 30 years to be offered an alternative COVID-19 vaccine, if available. People may make an informed choice to receive the AstraZeneca COVID-19 vaccine to receive earlier protection.

AZ Vaccine: summary of EMA regulatory actions

- PRAC recommended EU SmPC updates with no statements on causality:
- 7 April 2021: News: [AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets | European Medicines Agency \(europa.eu\)](#)

Interim statement of the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety

- Based on current information, a causal relationship between the vaccine and the very rare occurrence of blood clots with low platelets is considered plausible but is not confirmed. Specialised studies are needed to fully understand the potential relationship between vaccination and possible risk factors.
- Individuals who experience any severe symptoms – such as shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms, such as severe and persistent headaches or blurred vision, tiny blood spots under the skin beyond the site of the injection - from around four to 20 days following vaccination, should seek urgent medical attention.
- Clinicians should be aware of relevant case definitions and clinical guidance for patients presenting thrombosis and thrombocytopenia following COVID-19 vaccination. A committee of clinical experts including haematologists and other specialists is convened, for advice on as relevant

AZ Covid-19 Vaccine: summary of case reports

100 UK cases of thromboembolic events with thrombocytopenia including confirmed, probable or possible cases (61 female, 39 male):

- 50 CVST (mean age 46 years; range 18-70 years [n=44]), 15 fatal (30%)
- 50 non-CVST (mean age 52 years; range 21-85 years [n=44]), 7 fatal (14%)

Case definition		Number of cases	Number of fatalities
Confirmed	Probable + PF4 antibodies	19*	4
Probable	Possible + D-dimer >4000 mcg/L	34\$	5
Possible	Venous/arterial thrombosis + TCP	47	13
Totals		100	22
Overall case fatality rate		22%	

*includes [REDACTED]

\$ includes one case occurring 3 days after the 2nd dose

AZ Covid-19 vaccine: Confirmed CVST cases (fatal)

[illegible]

AZ Covid-19 vaccine: Confirmed non-CVST cases (fatal)

Case No.	Age, Sex	Co-morbidities	Medication
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	None
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	None	None
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	None	None reported
[REDACTED]	[REDACTED]	[REDACTED]	None reported
Caucasian except [REDACTED]; BMI= body mass index			

Pfizer Vaccine: summary of case reports

2 UK “unlikely” cases of thromboembolic events with thrombocytopenia
- confounding factors and not meeting case definition criteria

5 non-UK cases including confirmed, probable or possible cases:

- 1 CVST [REDACTED] (20%)
- 5 non-CVST (mean age 60 years; range 39-84 years [n=3]), none fatal

Case definition		Number of cases	Number of fatalities
Confirmed	Probable + PF4 antibodies	0	0
Probable	Possible + D-dimer >4000 mcg/L	1	1
Possible	Venous/arterial thrombosis + TCP	5	0
Totals		6	1
Overall case fatality rate		17%	

Moderna: summary of case reports

- No UK cases of thromboembolic events with thrombocytopenia – initial use has only started this week
- One non-UK case borderline for meeting the possible case definition



[REDACTED]

[REDACTED]

[REDACTED]

Janssen Vaccine: summary of case reports

Janssen vaccine in use in US with nearly 5m doses administered; conditional approval in EU with no doses administered yet

5 non-UK cases including confirmed, probable and possible cases from both clinical trial and post-authorisation use:

- 4 CVST (1 male, 3 female, mean age 34 years; range 18-48 years), 1 fatal
- 2 non-CVST (1 male, 1 female, mean age 60 years; range 59-72 years), none fatal

One possible CVST case from clinical trials potentially confounded by

Case definition		Number of cases	Number of fatalities
Confirmed	Probable + PF4 antibodies	0	0
Probable	Possible + D-dimer >4000 mcg/L	0	0
Possible	Venous/arterial thrombosis + TCP	6	1
Totals		6	1
Overall case fatality rate		17%	

Estimated exposure data – AZ 1st doses

20.6 million first doses given

Age group	Estimated number of first AZ doses in UK (1,000,000s)	%
18-29 years	■	■
30-39 years	■	■
40-49 years	■	■
50-59 years	■	■
60-69 years	■	■
70-79 years	■	■
80+ years	■	■

Incidence rate – CVST by age

Age group	Estimated number of first doses in UK (1,000,000s)	Total number of cases	Case incidence rate (per 1 million doses)	Exc. unlikely cases	Case incidence rate (per 1 million doses)	Number of fatal cases (inc. unlikely)	Fatal incidence rate (per 1 million doses)
18-29 yrs	■	10	■)	9	■	4	■
30-39 yrs	■	10	■	8	■)	6	■)
40-49 yrs	■	4	■)	4	■)	1	■)
50-59 yrs	■	16	■)	14	■	3	■,)
60-69 yrs	■	7	■)	7	■)	3	■)
70-79 yrs	■	2	■)	2	■)	0	■
80+ yrs	■	0	■	0	■)	0	■
Total	20.6	55*	2.3 (2.0,3.5)	50*	2.4 (1.9,3.2)	18**	0.9 (0.5,1.4)

Incidence rate – CVST + other TE by age

Age group	Estimated number of first doses in UK (1,000,000s)	Total number of cases	Case incidence rate (per 1 million doses)	Exc. unlikely cases	Case incidence rate (per 1 million doses)	Number of fatal cases (inc. unlikely)	Fatal incidence rate (per 1 million doses)
18-29 yrs	■	13	■	12	■)	4	■)
30-39 yrs	■	20	■)	15	■)	8	■)
40-49 yrs	■	12	■	12	■)	2	■)
50-59 yrs	■	29	■	26	■)	4	■
60-69 yrs	■	18	■	16	■)	3	■)
70-79 yrs	■	8	■	6	■)	2	■)
80+ yrs	■	1	■	1	■)	0	■
Total	20.6	114*	5.5 (4.6,6.6)	100**	4.9 (4.0,5.9)	25**	1.2 (0.8,.8)

Benefit calculations: approach

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Vaccine effectiveness estimates:

- Against being a **case** (any case, and a long COVID case) = 60% (single dose)
- Against **hospitalisation** = 80% (single dose)
- Against **ICU/HDU admission** = 80% (single dose)
- Against **death** = 80% at first dose, 96% at second dose i.e. an additional 16% at second dose

Number needed to vaccinate calculated for England is based on infection, hospitalisation and death rates from the second wave only – (week 50 2020-end of week 12 2021). For currently unvaccinated groups this therefore assumes a future wave of a similar size and severity in these groups.

Hospitalisation/ICU estimates based on aggregate data from the SARI Watch surveillance system from 135 acute trusts

Benefits and risks (CVST only, <50 years)

Age group	Hospitalisations prevented (per 1 million doses)	ICU/HDU prevented (per 1 million doses)	Case incidence rate (exc. unlikely per 1 million doses)	Mortality prevented (per 1 million courses)	Fatal incidence rate (inc. unlikely per 1 million doses)	
15-19 years	325	19	7.7 (3.5,14.6)	4	3.4 (0.9,8.7)	
20-24 years				8		
25-29 years	857	85		5.2 (2.2,10.2)		13
30-34 years			29			
35-39 years			53	1.7 (0.5,4.2)	80	0.4 (0.01,2.3)
40-44 years			158			
45-49 years	1,464	193				

Benefits and risks (CVST only, 50+ years)

Age group	Hospitalisations prevented (per 1 million doses)	ICU/HDU prevented (per 1 million doses)	Case incidence rate (per 1 million doses)	Mortality prevented (per 1 million courses)	Fatal incidence rate (per 1 million doses)
50-54 years	1,893	237	2.2 (1.2,3.7)	261	0.5 (0.1,1.4,)
55-59 years	2,920	402		441	
60-64 years			3,997	378	624
65-69 years	1,415				
70-74 years	8,548	231	0.6 (0.1,2.2)	1,890	0 (0,1.1)
75-79 years				3,667	
80+ years*			0 (0,3.3)	6,506	0 (0,3.3)

* To note benefit estimates are for the 80-84 age cohort only

Benefits and risks (CVST + other TE, <50 years)

Age group	Hospitalisations prevented (per 1 million doses)	ICU/HDU prevented (per 1 million doses)	Case incidence rate (exc. unlikely per 1 million doses)	Mortality prevented (per 1 million courses)	Fatal incidence rate (inc. unlikely per 1 million doses)
15-19 years	325	19	10.2 (5.3,17.9)	4	3.4 (0.9,8.7)
20-24 years				8	
25-29 years	857	85		9.7 (5.4,16.0)	
30-34 years			29		
35-39 years			53	0.8 (0.1,3.0)	
40-44 years			80		
45-49 years	1,464	193	5.0 (2.6,8.7)	158	

Benefits and risks (CVST + other TE, 50+ years)

Age group 80+	Hospitalisations prevented (per 1 million doses)	ICU/HDU prevented (per 1 million doses)	Case incidence rate (per 1 million doses)	Mortality prevented (per 1 million courses)	Fatal incidence rate (per 1 million doses)
50-54 years	1,893	237	4.1 (2.7,6.0)	261	0.6 (0.2,1.6)
55-59 years	2,920	402		441	
60-64 years			3.4 (1.9,5.5)	624	0.6 (0.1,1.9)
65-69 years	3,997	378		1,415	
70-74 years			1.8 (0.7,4.0)	1,890	0.6 (0.1,2.2)
75-79 years	8,548	231		3,667	
80+ years			0.1 (0.02,5.0)	6,506	0 (0,3.3)

* To note benefit estimates are for the 80-84 age cohort only



Public Health
England

Protecting and improving the nation's health

Rapid evaluation of event of interest after COVID-19 vaccines

Official Sensitive

8th April 2021

Methods

- England only
- Initially extracting all events back to 1/12/2019
- Only first episodes in the SUS database are used
- Episodes analysed from Nov 30th 2020 to Feb 28th 2021
- Linked to National Immunisation Management System (NIMS) using NHS number.
- Obtained vaccination dates and manufacturer as well as flag for CEV.
- CEV = clinically extremely vulnerable
- NIMS data were used to construct the cumulative vaccination status of the population according to unvaccinated, 1 dose AZ, 2 dose AZ, 1 dose PF, 2 dose PF by day from December 8th to February 28th
- Cumulative counts were stratified by age (5 year bands), sex and cev
- Poisson regression was used to model the data with an offset for population and adjusting for age, sex and cev
- age stratification of 15-39,40-64,65+.
- $P < 0.01$ regarded as signal. $P < 0.001$ regarded as strong evidence as long as N-events also ≥ 3 .

Hospital inpatient admissions (patient classification 1/2/9) in all ages from the Secondary Uses Service (SUS) were identified using the following grouped ICD10 codes:

Set 1:

ICD10 code in *first 5 diagnosis fields*:

G08 Intracranial and intraspinal phlebitis and thrombophlebitis
I676 Nonpyogenic thrombosis of intracranial venous system
I636 Cerebral infarction due to cerebral venous thrombosis, nonpyogenic

Set 3:

ICD10 code in *first 5 diagnosis field with D69 (thrombocytopenia) in any of the concomitant 5 diagnosis fields*:

G08 Intracranial and intraspinal phlebitis and thrombophlebitis
I676 Nonpyogenic thrombosis of intracranial venous system
I636 Cerebral infarction due to cerebral venous thrombosis, nonpyogenic
I80 Phlebitis and thrombophlebitis
I81 Portal vein thrombosis
I82 other venous embolism and thrombosis
I26 Pulmonary embolism
I74 Arterial embolism and thrombosis

Or

ICD10 code in *first diagnosis field*:

M311 Thrombotic microangiopathy

Set 2:

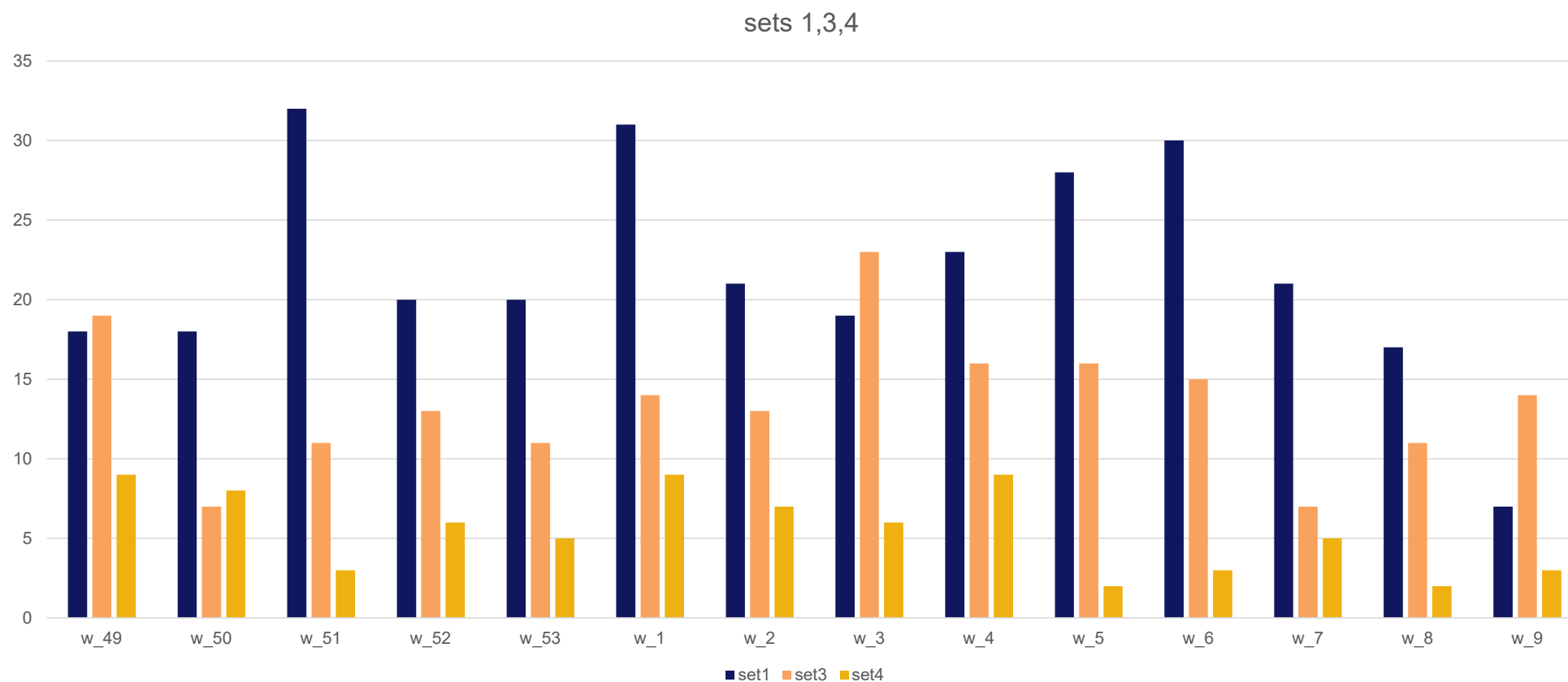
ICD10 code in *first diagnosis field*:

I80 Phlebitis and thrombophlebitis
I81 Portal vein thrombosis
I82 her venous embolism and thrombosis
I26 Pulmonary embolism

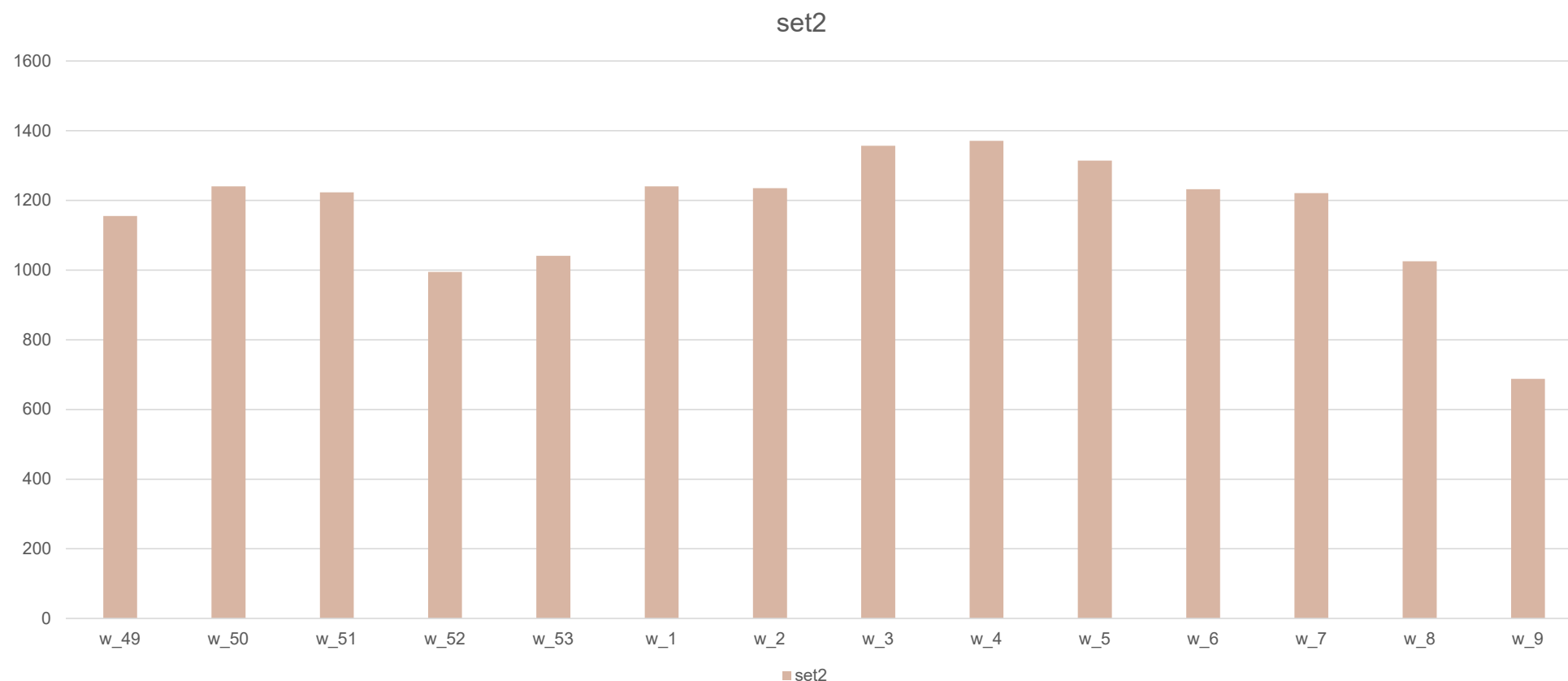
Set 4: ICD10 code in *first 5 diagnosis field*

D65 – Disseminated intravascular coagulopathy

Distribution of event over time- set 1,3,4



Distribution of events over time- set 2



Set 1: ICD10 code in *first 5 diagnosis fields*:

G08 Intracranial and intraspinal phlebitis and thrombophlebitis

I676 Nonpyogenic thrombosis of intracranial venous system

I636 Cerebral infarction due to cerebral venous thrombosis, nonpyogenic

			cases	per 100,000	ADJUSTED
age	level	p_yrs	set1	risk1	aRI1
15_39	unvaccinated	5303152	103	1.94	baseline
	AZ1	61342	7	11.41	6.7 (2.9-15.3)
	AZ2	108	0	0.00	N <2
	PF1	132615	2	1.51	0.8 (0.2-3.4)
	PF2	6850	0	0.00	N <2
40_64	unvaccinated	4834343	113	2.34	baseline
	AZ1	166784	5	3.00	1.4 (0.5-3.7)
	AZ2	266	0	0.00	N <2
	PF1	271247	5	1.84	0.9 (0.3-2.3)
	PF2	15703	0	0.00	N <2
15_64	unvaccinated	10137495	216	2.13	baseline
	AZ1	228126	12	5.26	2.6 (1.4-4.9)
	AZ2	374	0	0.00	N <2
	PF1	403862	7	1.73	0.8 (0.4-1.8)
	PF2	22553	0	0.00	N <2
65+	unvaccinated	1855352	42	2.26	baseline
	AZ1	449495	14	3.11	1.5 (0.7-3.4)
	AZ2	444	0	0.00	N <2
	PF1	538899	14	2.60	1.3 (0.6-2.6)
	PF2	60737	0	0.00	N <2
All	unvaccinated	11992847	258	2.15	baseline
	AZ1	677621	26	3.84	1.9 (1.2-3)
	AZ2	818	0	0.00	N <2
	PF1	942761	21	2.23	1.1 (0.7-1.8)
	PF2	83290	0	0.00	N <2

Set 1: ICD10 code in *first 5 diagnosis fields*:

G08 Intracranial and intraspinal phlebitis and thrombophlebitis

I676 Nonpyogenic thrombosis of intracranial venous system

I636 Cerebral infarction due to cerebral venous thrombosis, nonpyogenic

vaccine	period	length	p-time	doses	RI	AF	Events	AE	AR per million doses
AZ	4 to 13	10	20465	746960	13.6	93%	5	4.6	6.2

age	level	p_yrs	cases set1	per 100,00 risk1	ADJUSTED aRI1
15_39	unvaccinated	5303152	103	1.94	baseline
	AZ1_0_3	11386	0	0.00	N <2
	AZ1_4_13	20465	5	24.43	13.6 (5.3-35.3)
	AZ1_14_27	17556	2	11.39	6.5 (1.5-27.8)
	AZ1_28+	11936	0	0.00	N <2
	AZ2_0+	108	0	0.00	N <2
	PF1_0_3	14059	0	0.00	N <2
	PF1_4_13	32940	0	0.00	N <2
	PF1_14_27	36072	1	2.77	N <2
	PF1_28+	49544	1	2.02	N <2
	PF2_0+	6850	0	0.00	N <2
40_64	unvaccinated	4834343	113	2.34	baseline
	AZ1_0_3	36447	1	2.74	N <2
	AZ1_4_13	59746	2	3.35	1.5 (0.4-6.3)
	AZ1_14_27	45921	1	2.18	N <2
	AZ1_28+	24671	1	4.05	N <2
	AZ2_0+	266	0	0.00	N <2
	PF1_0_3	34487	0	0.00	N <2
	PF1_4_13	78704	2	2.54	1.2 (0.3-5.1)
	PF1_14_27	70700	1	1.41	N <2
	PF1_28+	87356	2	2.29	1.2 (0.3-5.5)
	PF2_0+	15703	0	0.00	N <2
15_64	unvaccinated	10137495	216	2.13	baseline
	AZ1_0_3	47832	1	2.09	N <2
	AZ1_4_13	80211	7	8.73	4.1 (1.9-9.1)
	AZ1_14_27	63477	3	4.73	2.2 (0.7-7.2)
	AZ1_28+	36606	1	2.73	N <2
	AZ2_0+	374	0	0.00	N <2
	PF1_0_3	48546	0	0.00	N <2
	PF1_4_13	111644	2	1.79	0.8 (0.2-3.4)
	PF1_14_27	106772	2	1.87	0.8 (0.2-3.4)
	PF1_28+	136900	3	2.19	1.1 (0.3-3.7)

Set 2: ICD10 code in *first diagnosis field*:

I80 Phlebitis and thrombophlebitis

I81 Portal vein thrombosis

I82 her venous embolism and thrombosis

I26 Pulmonary embolism

			cases	per 100,000	ADJUSTED
age	level	p_yrs	set2	risk2	aRI2
15_39	unvaccinated	5303152	1554	29.30	baseline
	AZ1	61342	34	55.43	1.1 (0.8-1.5)
	AZ2	108	0	0.00	N<2
	PF1	132615	48	36.20	0.8 (0.6-1)
	PF2	6850	7	102.19	2 (0.9-4.2)
40_64	unvaccinated	4834343	5458	112.90	baseline
	AZ1	166784	275	164.88	1 (0.9-1.2)
	AZ2	266	0	0.00	N<2
	PF1	271247	287	105.81	0.8 (0.7-0.9)
	PF2	15703	13	82.79	0.7 (0.4-1.1)
15_64	unvaccinated	10137495	7012	69.17	baseline
	AZ1	228126	309	135.45	1 (0.9-1.2)
	AZ2	374	0	0.00	N<2
	PF1	403862	335	82.95	0.8 (0.7-0.9)
	PF2	22553	20	88.68	0.8 (0.5-1.3)
65+	unvaccinated	1855352	5783	311.69	baseline
	AZ1	449495	1247	277.42	0.7 (0.7-0.8)
	AZ2	444	0	0.00	N<2
	PF1	538899	1443	267.77	0.6 (0.6-0.7)
	PF2	60737	188	309.53	0.6 (0.5-0.7)
All	unvaccinated	11992847	12795	106.69	baseline
	AZ1	677621	1556	229.63	0.9 (0.8-0.9)
	AZ2	818	0	0.00	N<2
	PF1	942761	1778	188.59	0.7 (0.7-0.8)
	PF2	83290	208	249.73	0.7 (0.6-0.8)

Set 3:
ICD10 code in *first 5 diagnosis field* with D69
(thrombocytopenia) in any of the concomitant 5
diagnosis fields:

G08 Intracranial and intraspinal phlebitis and
thrombophlebitis
I676 Nonpyogenic thrombosis of intracranial venous
system
I636 Cerebral infarction due to cerebral venous thrombosis,
nonpyogenic
I80 Phlebitis and thrombophlebitis
I81 Portal vein thrombosis
I82 other venous embolism and thrombosis
I26 Pulmonary embolism
I74 Arterial embolism and thrombosis
Or
ICD10 code in *first diagnosis field*:
M311 Thrombotic microangiopathy

			CASES	per 100,000	ADJUSTED
age	level	p_yrs	set3	risk3	aRI3
15_39	unvaccinated	5303152	27	0.5	baseline
	AZ1	61342	1	1.6	N<2
	AZ2	108	0	0.0	N<2
	PF1	132615	3	2.3	3.1 (0.8-11.5)
	PF2	6850	0	0.0	N<2
40_64	unvaccinated	4834343	56	1.2	baseline
	AZ1	166784	6	3.6	1.1 (0.4-2.9)
	AZ2	266	0	0.0	N<2
	PF1	271247	4	1.5	0.8 (0.3-2.5)
	PF2	15703	1	6.4	N<2
15_64	unvaccinated	10137495	83	0.8	baseline
	AZ1	228126	7	3.1	1.1 (0.5-2.7)
	AZ2	374	0	0.0	N<2
	PF1	403862	7	1.7	1.2 (0.5-2.7)
	PF2	22553	1	4.4	N<2
65+	unvaccinated	1855352	61	3.3	baseline
	AZ1	449495	13	2.9	1.1 (0.5-2.3)
	AZ2	444	1	225.4	N<2
	PF1	538899	16	3.0	0.9 (0.5-1.8)
	PF2	60737	1	1.6	N<2
All	unvaccinated	11992847	144	1.2	baseline
	AZ1	677621	20	3.0	1.2 (0.7-2)
	AZ2	818	1	122.3	N<2
	PF1	942761	23	2.4	1.1 (0.6-1.8)
	PF2	83290	2	2.4	0.8 (0.2-3.3)

Set 4: ICD10 code in *first 5 diagnosis field*

D65 – Disseminated intravascular coagulopathy

Not strong evidence because number of events is <3.

			cases	per 100,000	ADJUSTED
age	level	p_yrs	set4	risk4	aRI4
15_39	unvaccinated	5303152	8	0.2	baseline
	AZ1	61342	1	1.6	N<2
	AZ2	108	0	0.0	N<2
	PF1	132615	2	1.5	25.1 (4.3-146.9)
	PF2	6850	0	0.0	N<2
40_64	unvaccinated	4834343	22	0.5	baseline
	AZ1	166784	0	0.0	N<2
	AZ2	266	0	0.0	N<2
	PF1	271247	0	0.0	N<2
	PF2	15703	0	0.0	N<2
15_64	unvaccinated	10137495	30	0.3	baseline
	AZ1	228126	1	0.4	N<2
	AZ2	374	0	0.0	N<2
	PF1	403862	2	0.5	2.3 (0.5-10.3)
	PF2	22553	0	0.0	N<2
65+	unvaccinated	1855352	30	1.6	baseline
	AZ1	449495	3	0.7	0.7 (0.2-2.6)
	AZ2	444	0	0.0	N<2
	PF1	538899	10	1.9	1.5 (0.6-3.5)
	PF2	60737	1	1.6	N<2
All	unvaccinated	11992847	60	0.5	baseline
	AZ1	677621	4	0.6	0.9 (0.3-2.8)
	AZ2	818	0	0.0	N<2
	PF1	942761	12	1.3	1.7 (0.9-3.6)
	PF2	83290	1	1.2	N<2

Set 4: ICD10 code in *first 5 diagnosis field*

D65 – Disseminated intravascular coagulopathy

The 2 events post PF were 14-27 days in the <40 age group. Also overall the 14-27 day period signals at the lower sig level.

age	level	p_yrs	set4	risk4	aRI4
15_39	unvaccinat	5303152	8	0.2	baseline
	AZ1_0_3	11386	0	0.0	N<2
	AZ1_4_13	20465	0	0.0	N<2
	AZ1_14_27	17556	1	5.7	N<2
	AZ1_28+	11936	0	0.0	N<2
	AZ2_0+	108	0	0.0	N<2
	PF1_0_3	14059	0	0.0	N<2
	PF1_4_13	32940	1	3.0	N<2
	PF1_14_27	36072	1	2.8	N<2
	PF1_28+	49544	0	0.0	N<2
	PF2_0+	6850	0	0.0	N<2
65+	unvaccinat	1855352	30	1.6	baseline
	AZ1_0_3	56368	0	0.0	N<2
	AZ1_4_13	136540	1	0.7	N<2
	AZ1_14_27	161678	1	0.6	N<2
	AZ1_28+	94908	1	1.1	N<2
	AZ2_0+	444	0	0.0	N<2
	PF1_0_3	51295	0	0.0	N<2
	PF1_4_13	127289	2	1.6	1.1 (0.2-4.6)
	PF1_14_27	159586	6	3.8	3.3 (1.2-9.1)
	PF1_28+	200728	2	1.0	1.2 (0.2-6.3)
	PF2_0+	60737	1	1.6	N<2
All	unvaccinat	11992847	60	0.5	baseline
	AZ1_0_3	104200	0	0.0	N<2
	AZ1_4_13	216751	1	0.5	N<2
	AZ1_14_27	225155	2	0.9	1.6 (0.3-7.5)
	AZ1_28+	131515	1	0.8	N<2
	AZ2_0+	818	0	0.0	N<2
	PF1_0_3	99841	0	0.0	N<2
	PF1_4_13	238934	3	1.3	1.5 (0.4-4.8)
	PF1_14_27	266359	7	2.6	3.7 (1.5-8.8)
	PF1_28+	337628	2	0.6	1.2 (0.2-5.4)
	PF2_0+	83290	1	1.2	N<2

I74 Arterial embolism in primary diagnosis field only with a procedure code for amputation either X09 (leg) or X07 (arm) (in any of the 12 procedure codes) in study period

Age group	count
15 to 39	4
40 to 64	39
15 to 64	43
65 +	69
All	112

** Only first episodes in the SUS database*