



COVID-19 vaccines: Thromboembolic events with thrombocytopenia

EWG 31st March 2021 (data lock 29th March)



Medicines & Healthcare products Regulatory Agency

Comparative exposure data – 1st doses

Age group	Estimated number of first AZ doses in UK (1,000,000s)	%	Estimated number of first Pfizer doses in UK (1,000,000s)	%
18-29 yrs				
30-39 yrs				
40-49 yrs				
50-64 yrs				
65+ yrs				
Total	19.7	100	10.9	100

Incidence rate – further analysis of CVST (all cases assumed to be after 1st dose)

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	█	5	█
30-39 yrs	█	7	█	7	█	3	█
40-49 yrs	█	4	█)	4	█	0	-
50-64 yrs	█	10	█	7	█	4	█
65+ yrs	█	3	█	3	█	2	█
Total*	19.7	39	2.0 (1.4,2.7)	35	1.8 (1.2,2.5)	15	0.8 (0.4,1.3)

* Includes 5 patients with unknown age (none unlikely, 1 fatal)

Incidence rate – further analysis of CVST (all cases assumed to be after 1st dose)

Age/sex group	Estimated number of first doses in UK (1,000,000s)	Total number of cases	Case incidence rate (per 1 million doses)	Total number of cases (exc. unlikely)	Case incidence rate (per 1 million doses)
Males <50	█	8	█	7	█
Males 50+	█	2	█	1	█
Total*	9.4	13	1.4 (0.7,2.4)	11	1.2 (0.6,2.1)

* Includes 3 males with unknown age

Age/sex group	Estimated number of first doses in UK (1,000,000s)	Total number of cases	Case incidence rate (per 1 million doses)	Total number of cases (exc. unlikely)	Case incidence rate (per 1 million doses)
Females <50	█	13	█	13	█
Females 50+	█	11	█	9	█
Total**	10.3	26	2.5 (1.7,3.7)	24	2.3 (1.5,3.5)

** Includes 2 females with unknown age

Incidence rate – further analysis (CVST + other TE, all cases assumed to be after 1st dose)

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	█	12	█	11	█)	5	█
30-39 yrs	█	13	█	13	█	5	█
40-49 yrs	█	6	█	6	█	0	-
50-64 yrs	█	17	█	13	█	5	█
65+ yrs	█	10	█	10	█	3	█
Total*	19.7	67	3.4 (2.6,4.3)	62	3.2 (2.4,4.0)	19	1.0 (0.6,1.5)

* Includes 9 patients with unknown age (non unlikely, 1 fatal)

Benefit risk assessment

Estimates of vaccine effectiveness have been calculated by PHE.



Benefit risk assessment

- Cases and long COVID – [REDACTED]

Age group	Number of cases prevented per 1m vaccinations	Number of long COVID cases prevented per 1m vaccinations*
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

* Assumes 10% of cases experience long COVID

Benefit risk assessment

- Hospitalisation and mortality (per 1 million doses)

	No. of hospitalisations prevented	No. of deaths (within 28 days) prevented*	No. of cases of CVST inc. unlikely (95% CI)	No. of cases of CVST exc. unlikely (95% CI)	No. of fatal cases of CVST inc. unlikely (95% CI)
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]		[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]		[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]		[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	1
[Redacted]		[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]		[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]		[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

Benefit risk assessment

- Hospitalisation and mortality (per 1 million doses)

Age group	No. of hospitalisations prevented	No. of deaths (within 28 days) prevented*	No. of cases of CVST+TE inc. unlikely (95% CI)	No. of cases of CVST+TE exc. unlikely (95% CI)	No. of fatal cases of CVST+TE inc. unlikely (95% CI)
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	1
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]