COVID-19 vaccines: Thromboembolic events with thrombocytopenia

EWG 31st March2021 (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	[redacted]	[redacted]	[redacted]	[redacted]
30-39 yrs	[redacted]	[redacted]	[redacted]	[redacted]
40-49 yrs	[redacted]	[redacted]	[redacted]	[redacted]
50-64 yrs	[redacted]	[redacted]	[redacted]	[redacted]
65+ yrs	[redacted]	[redacted]	[redacted]	[redacted]
Total	19.7	100	10.9	100

(data lock 29th March)

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	[redacted]	10	[redacted]	9	[redacted]	5	[redacted]
30-39 yrs	[redacted]	7	[redacted]	7	[redacted]	3	[redacted]
40-49 yrs	[redacted]	4	[redacted]	4	[redacted]	0	-
50-64 yrs	[redacted]	10	[redacted]	7	[redacted]	4	[redacted]
65+ yrs	[redacted]	3	[redacted]	3	[redacted]	2	[redacted]
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)

(data lock 29th March)

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	[redacted]	8	[redacted]	7	[redacted]
Males 50+	[redacted]	2	[redacted]	1	[redacted]
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	[redacted]	13	[redacted]	13	[redacted]
Females 50+	[redacted]	11	[redacted]	9	[redacted]
Total**	10.3	26	2.5 (1.7,3.7)	24	2.3 (1.5,3.5)

** Includes 2 females with unknown age

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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	[redacted]	12	[redacted]	11	[redacted]	5	[redacted]
30-39 yrs	[redacted]	13	[redacted]	13	[redacted]	5	[redacted]
40-49 yrs	[redacted]	6	[redacted]	6	[redacted]	0	-
50-64 yrs	[redacted]	17	[redacted]	13	[redacted]	5	[redacted]
65+ yrs	[redacted]	10	[redacted]	10	[redacted]	3	[redacted]
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)

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Benefit risk assessment

Estimates of vaccine effectiveness have been calculated by PHE.

Using these estimates have been made of the number of cases, long COVID cases (persistence of cluster of symptoms beyond 5 week), hospitalisations, and deaths (within 28 days of positive test) prevented per 1,000,000 vaccinations over an assumed third wave.

The vaccine effectiveness estimates used are:

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

Benefit risk assessment

- Cases and long COVID – based on PCR or LFD positives from pillar 1 and 2

Age group	Number of cases prevented per 1m vaccinations	Number of long COVID cases prevented per 1m vaccinations*
20-29	33,333	983
30-39	33,333	1,894
40-49	30,303	3,378
50-59	27,027	3,356
60-69	18,182	3,030
70-79	11,765	2,695
80+	22,727	1,825

* Assumes 10% of cases experience long COVID

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 inc. unlikely (95% CI)	No. of cases of CVST exc. unlikely (95% CI)	No. of fatal cases of CVST inc. unlikely (95% CI)
20-24	677	10	10.1 (4.8,18.6)	9.1 (4.2,17.2)	5.1 (1.7,11.9)
25-29					
30-34		40	4.9 (2.0,10.0)	4.9 (2.0,10.0)	2.1 (0.4,6.2)
35-39					
40-44		116	1.9 (0.5,4.8)	1.9 (0.5,4.8)	-
45-49	2,237				
50-54		338	1.2 (0.6,2.1)	0.8 (0.3,1.7)	0.5 (0.1,1.2)
55-60					
60-64		979			
65-70	4,000		0.5 (0.1,1.4)	0.5 (0.1,1.4)	0.3 (0.04,1.1)

* Assuming 2 doses given

(data lock 29th March)

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)
20-24	677	10	12.1 (6.3,21.2)	11.1 (5.6,19.9)	5.1 (1.6,11.8)
25-29					
30-34		40	9.1 (4.9,15.6)	9.1 (4.9,15.6)	2.1 (0.4,6.2)
35-39					
40-44		116	2.8 (1.0,6.2)	2.8 (1.0,6.2)	-
45-49	2,237				
50-54		338	2.0 (1.2,3.2)	1.5 (0.8,2.6)	0.6 (0.2,1.4)
55-60					
60-64		979			
65-70	4,000		1.5 (0.7,2.8)	1.5 (0.7,2.8)	0.5 (0.1,1.4)

* Assuming 2 doses given

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