

Online Resource 5

Electronic Supplementary material

Article Title: Implementation and results of active vaccine safety monitoring during the COVID-19 pandemic in the UK: a regulatory perspective

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MedDRA® Reaction Seriousness

Supplementary Table 8. Number of Individuals reporting and not reporting a MedDRA serious ADR following vaccination, stratified by demographics and vaccination dose reporting

	Individuals reporting a MedDRA serious ADR (% of the cohort reporting any vaccine dose)		Individuals reporting a MedDRA serious ADR after the 1 st dose (% of the cohort reporting a 1 st vaccine dose)		Individuals reporting a MedDRA serious ADR after the 2 nd dose (% of the cohort reporting 1 st and 2 nd vaccine doses)		Individuals reporting a MedDRA serious ADR after the 3 rd dose (% of the cohort reporting 1 st , 2 nd , and 3 rd vaccine doses)	
Sex								
Male	1,387	(11.2)	978	(8.8)	182	(3.5)	118	(3.4)
Female	2,696	(15.4)	1,890	(11.9)	342	(4.8)	208	(4.8)
Unknown	51	(12.9)	31	(9.0)	7	(5.2)	3	(4.2)
Age bands (years)								
Under 12	3	(2.5)	3	(2.8)	0	(0.0)	0	(0.0)
12-17	111	(9.0)	86	(7.0)	15	(5.7)	5	(6.5)
18-29	250	(17.9)	178	(13.6)	33	(7.2)	13	(6.0)
30-39	498	(13.8)	357	(10.8)	69	(5.4)	16	(2.5)
40-49	581	(21.4)	462	(18.4)	52	(5.1)	37	(6.0)
50-59	731	(18.6)	539	(15.4)	68	(4.1)	72	(6.2)
60-69	893	(14.8)	600	(11.2)	126	(4.3)	98	(4.7)

	Individuals reporting a MedDRA serious ADR (% of the cohort reporting any vaccine dose)		Individuals reporting a MedDRA serious ADR after the 1 st dose (% of the cohort reporting a 1 st vaccine dose)		Individuals reporting a MedDRA serious ADR after the 2 nd dose (% of the cohort reporting 1 st and 2 nd vaccine doses)		Individuals reporting a MedDRA serious ADR after the 3 rd dose (% of the cohort reporting 1 st , 2 nd , and 3 rd vaccine doses)	
70-79	910	(10.2)	576	(7.2)	141	(3.5)	83	(3.1)
80+	153	(6.6)	97	(4.6)	26	(3.2)	5	(1.2)
Unknown	4	(16.0)	1	(4.5)	1	(4.2)	0	(0.0)
Ethnicity								
White British, White Irish, or any other white background	3,592	(13.7)	2,522	(10.6)	477	(4.3)	298	(4.1)
Other	254	(14.4)	187	(11.5)	32	(5.7)	15	(4.8)
Unknown	288	(12.9)	190	(9.7)	22	(3.0)	16	(4.5)
BMI Category								
Underweight	107	(16.0)	70	(11.4)	19	(6.9)	14	(8.7)
Normal	1,304	(14.6)	907	(11.2)	193	(4.8)	101	(3.8)
Overweight	1,088	(13.3)	773	(10.4)	138	(3.8)	94	(4.0)
Obese	637	(14.4)	453	(11.3)	77	(4.3)	52	(4.5)
Unknown	998	(12.4)	696	(9.6)	104	(3.7)	68	(4.2)
Immunocompromised								
Yes	514	(14.8)	346	(11.0)	75	(5.2)	43	(4.6)
No/Unknown	3,620	(13.5)	2,553	(10.5)	456	(4.1)	286	(4.1)

Abbreviations: *ADR* Adverse Drug Reaction, *BMI* Body Mass Index, *MedDRA* Medical Dictionary for Regulatory Activities. Table Percentages: Proportion of Individuals who reported a MedDRA serious ADR in association with a dose of a COVID-19 vaccine, stratified by demographics and by the cohort definition. Example: Amongst the male individuals who had reported a 1st dose and a 2nd dose vaccination, 3.5% (n=182) had reported a MedDRA serious ADR occurring after the 2nd dose vaccination.