

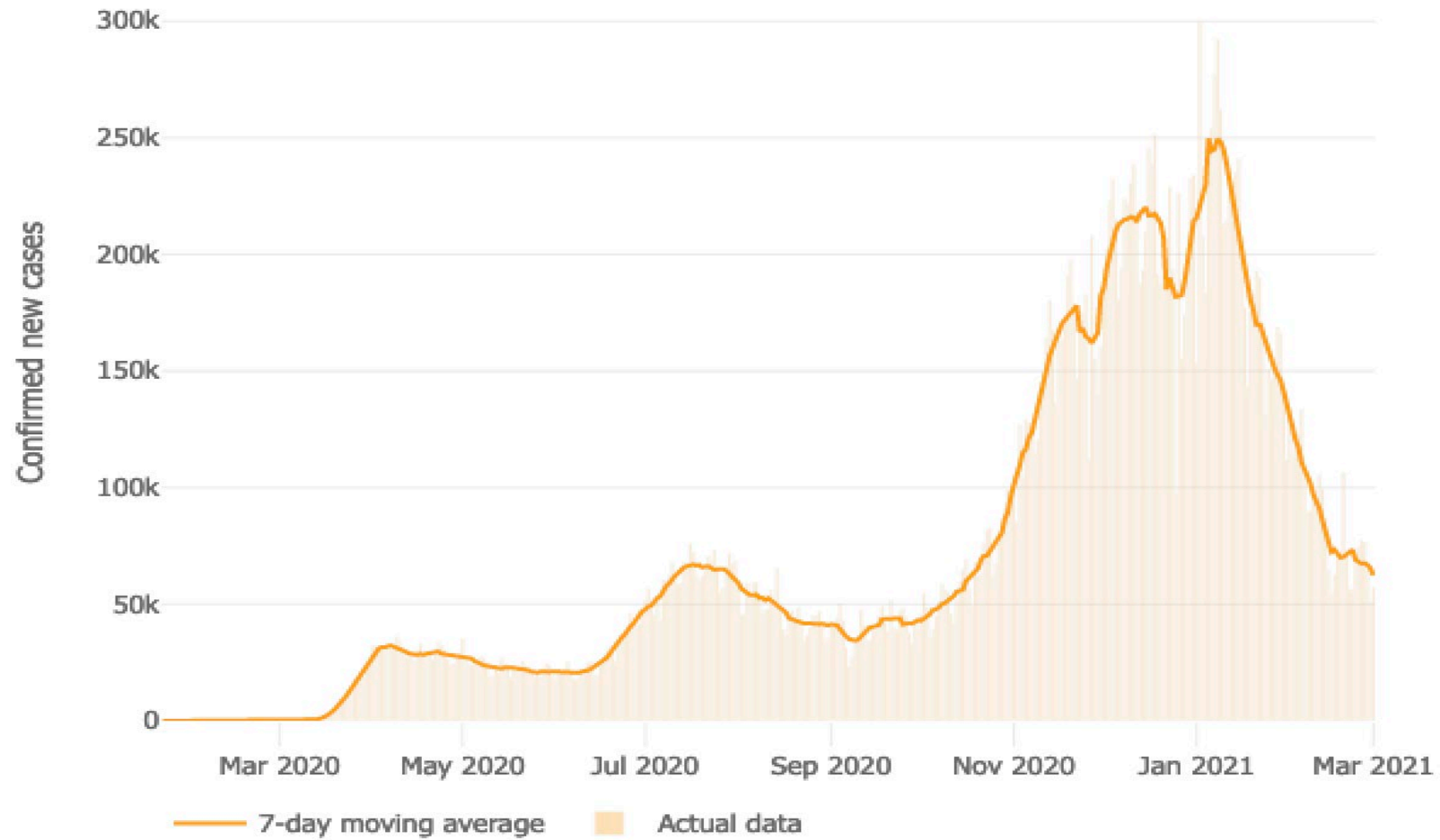
COVID-19 Vaccines

State of the Science:

Where are we???

CAMP 2021

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Where are we?

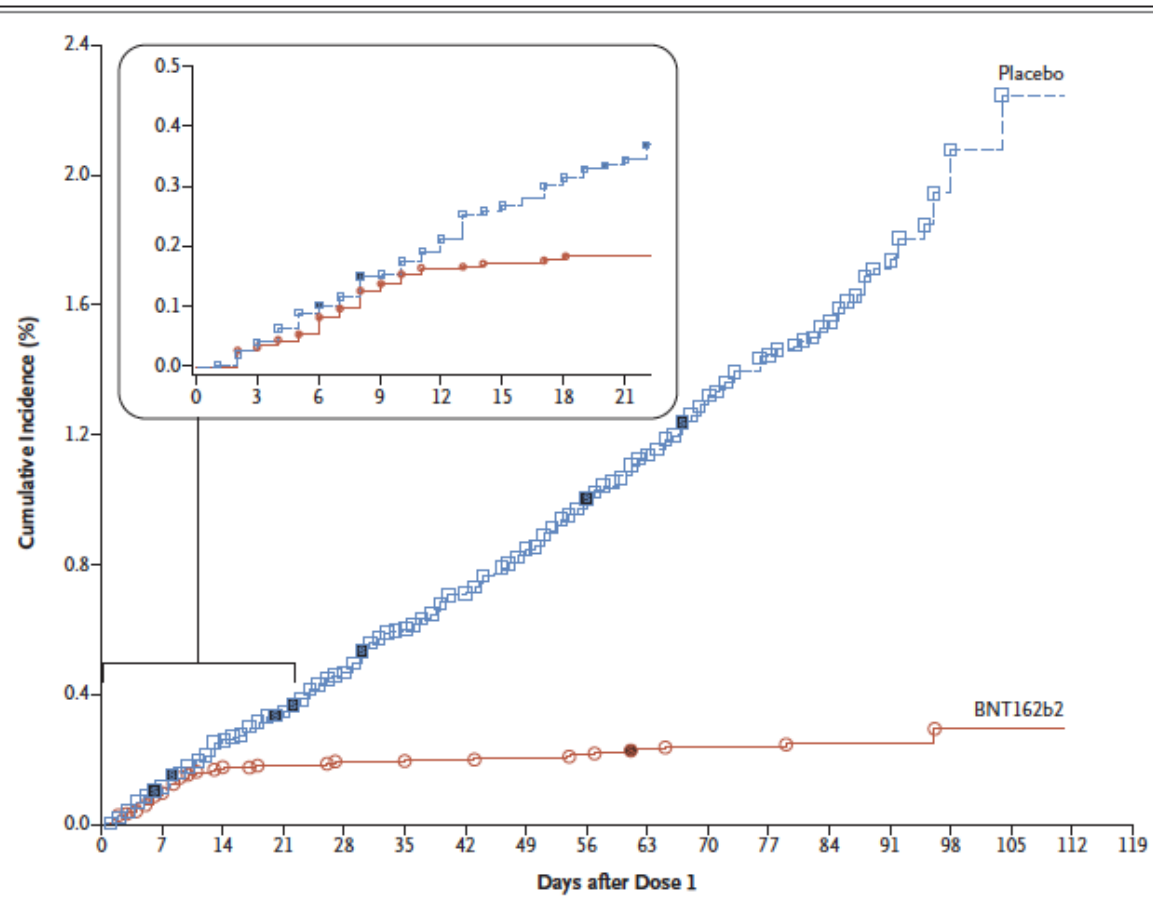
- **Moderna and Pfizer BioNTech mRNA vaccines both shown >90% effective***
- **Janssen now EUA newly approved, ACIP/CDC recommended 85% protective***
- **Novavax, Astra-Zeneca in trials with preliminary evidence of effectiveness from 62-90%**
- **Additional vaccine candidates in varying stages of development**

OVS Vaccine Candidates

- **mRNA**
 - **Pfizer/BioNTech and Moderna**
- **Replication-defective live-vector**
 - **Astra-Zeneca and Janssen**
- **Recombinant-subunit-adjuvanted protein**
 - **Novavax and Sanofi-GSK**
- **Attenuated replicating live-vector**
 - **TBA**

mRNA Vaccines

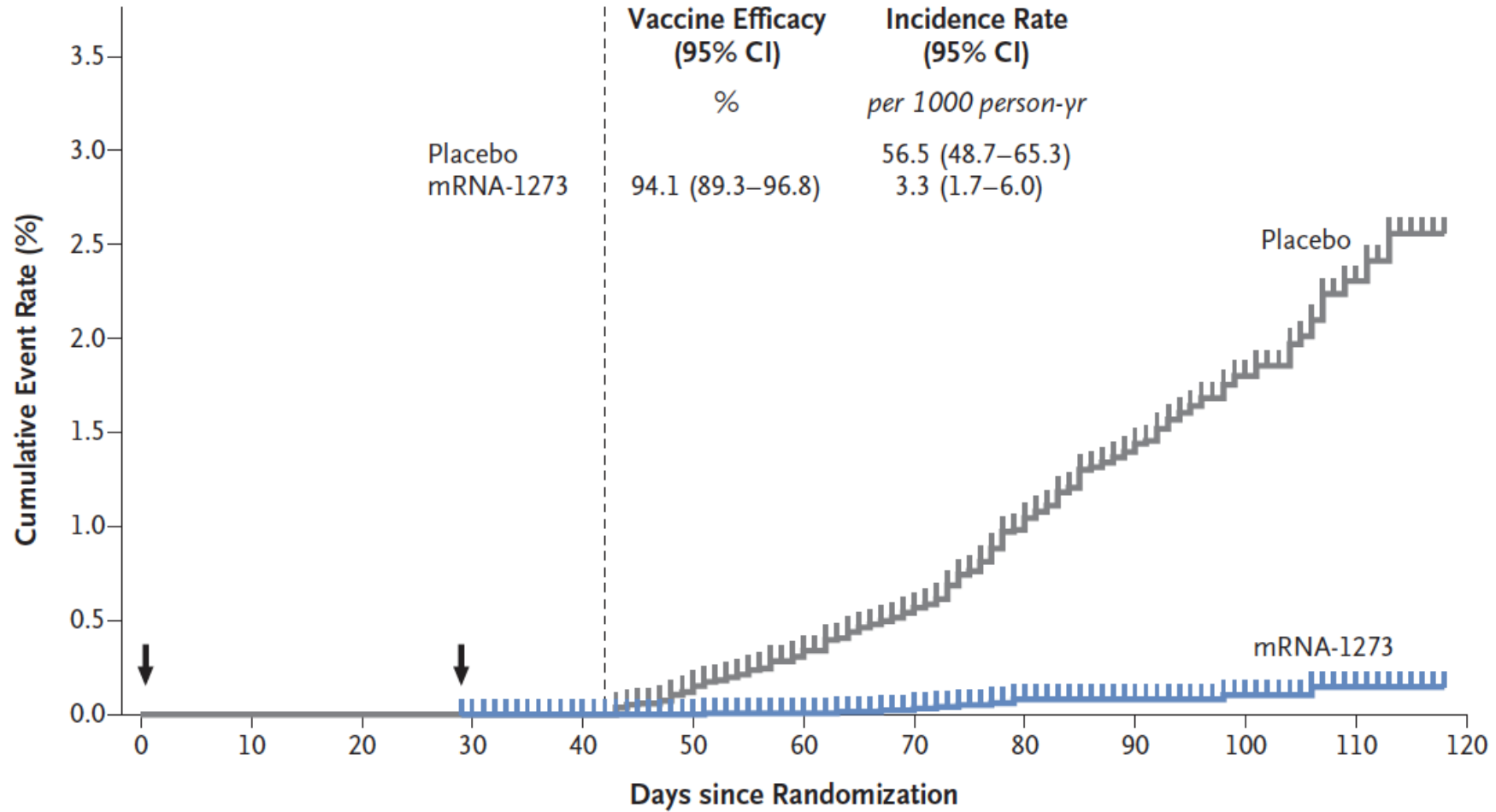
Pfizer and Moderna



Efficacy End-Point Subgroup	BNT162b2, 30 µg (N=21,669)		Placebo (N=21,686)		VE (95% CI) percent
	No. of participants	Surveillance time person-yr (no. at risk)	No. of participants	Surveillance time person-yr (no. at risk)	
Covid-19 occurrence					
After dose 1	50	4.015 (21,314)	275	3.982 (21,258)	82.0 (75.6–86.9)
After dose 1 to before dose 2	39		82		52.4 (29.5–68.4)
Dose 2 to 7 days after dose 2	2		21		90.5 (61.0–98.9)
≥7 Days after dose 2	9		172		94.8 (89.8–97.6)

Figure 3. Efficacy of BNT162b2 against Covid-19 after the First Dose.
 Shown is the cumulative incidence of Covid-19 after the first dose (modified intention-to-treat population). Each symbol represents Covid-19 cases starting on a given day; filled symbols represent severe Covid-19 cases. Some symbols represent more than one case, owing to overlapping dates. The inset shows the same data on an enlarged y axis, through 21 days. Surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from the first dose to the end of the surveillance period. The confidence interval (CI) for vaccine efficacy (VE) is derived according to the Clopper–Pearson method.

A Per-Protocol Analysis



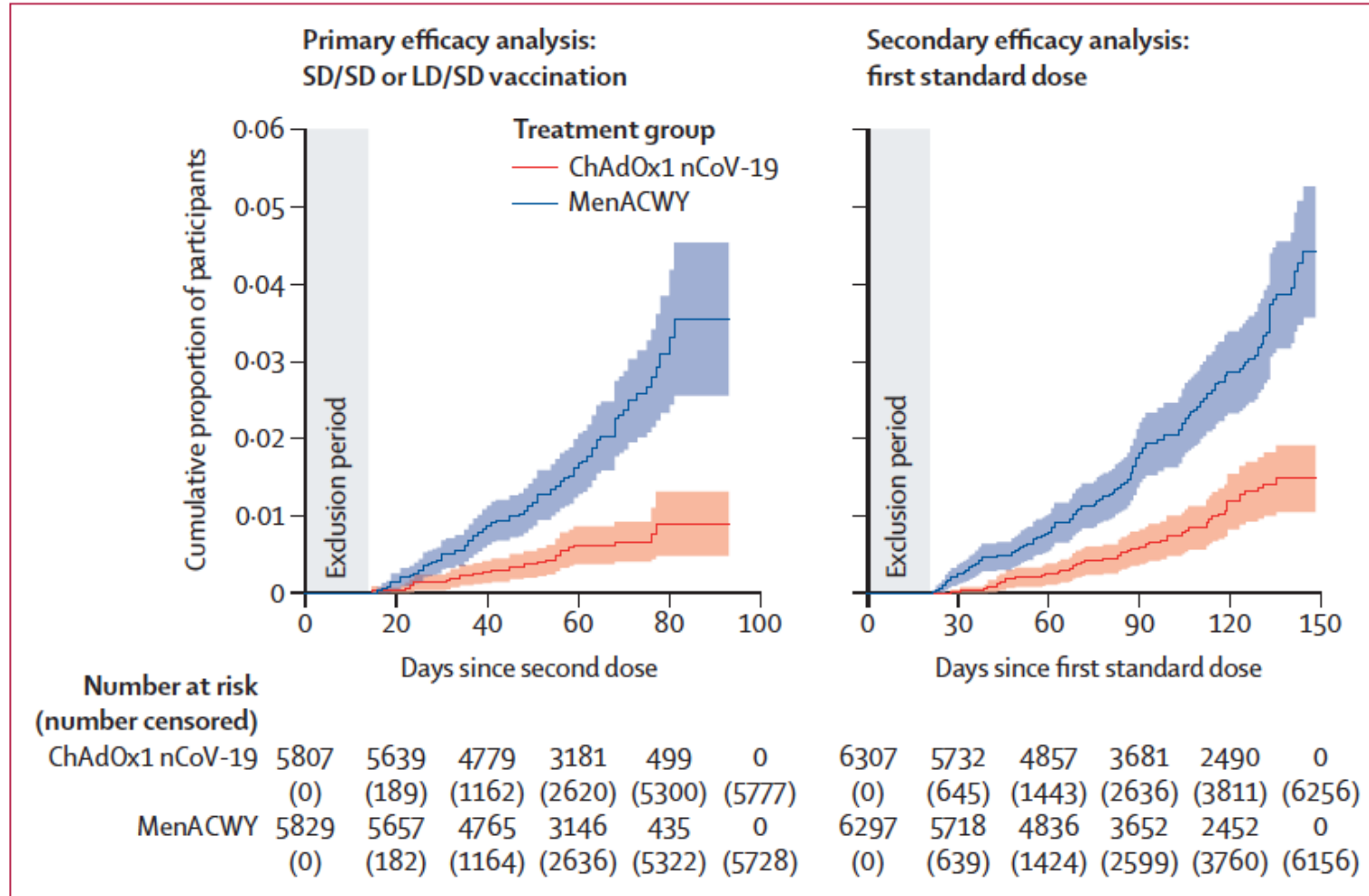
No. at Risk

Placebo	14,073	14,073	14,073	14,072	13,416	12,992	12,361	11,147	9474	6563	3971	1172	0
mRNA-1273	14,134	14,134	14,134	14,133	13,483	13,073	12,508	11,315	9684	6721	4094	1209	0

Live-Vector Vaccines

Astra-Zeneca and Janssen

Efficacy Outcomes 1 (Astra-Zeneca Phase III)



Efficacy Outcomes 2 (Astra-Zeneca Phase III)

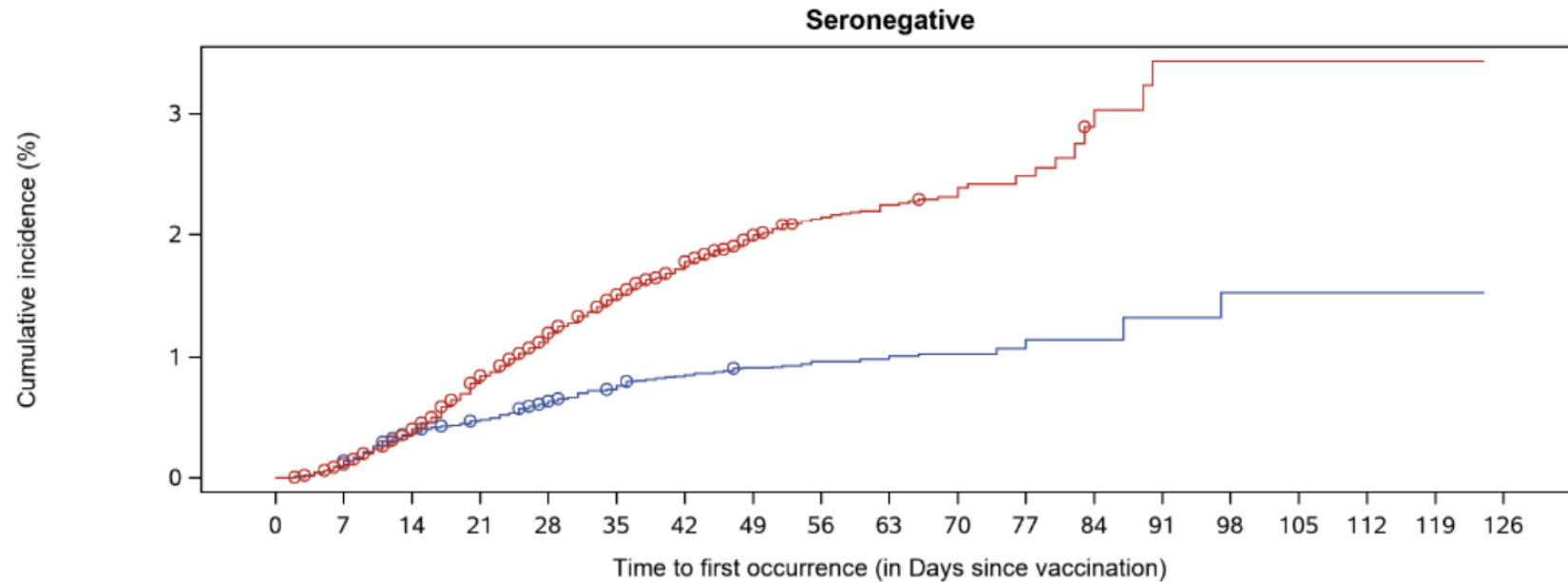
	Total number of cases	ChAdOx1 nCoV-19	Control	Vaccine efficacy (95% CI)	p value for interaction
COV002 (UK), age 18–55 years*	0.019
LD/SD recipients	33	3/1367 (0.2%)	30/1374 (2.2%)	90.0% (67.3 to 97.0)	..
SD/SD recipients	49	14/1879 (0.7%)	35/1922 (1.8%)	59.3% (25.1 to 77.9)	..
COV002 (UK), age 18–55 years with >8 weeks' interval between vaccine doses*	0.082
LD/SD recipients	33	3/1357 (0.2%)	30/1362 (2.2%)	90.0% (67.3 to 97.0)	..
SD/SD recipients	34	8/1407 (0.6%)	26/1512 (1.7%)	65.6% (24.5 to 84.4)	..
All SD/SD (UK and Brazil)†	0.557
<6 weeks' interval between vaccine doses	28	9/1702 (0.5%)	19/1698 (1.1%)	53.4% (–2.5 to 78.8)	..
≥6 weeks' interval between vaccine doses	70	18/2738 (0.7%)	52/2757 (1.9%)	65.4% (41.1 to 79.6)	..

Cohorts are all subsets of the primary efficacy population. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. LD/SD=low-dose prime plus standard-dose boost. SD/SD=two standard-dose vaccines given. BMI=body-mass index. *Models adjusted for BMI (<30 vs ≥30 kg/m²), health-care worker status (yes vs no), and ethnicity (white vs non-white). †Model adjusted for BMI (<30 vs ≥30 kg/m²), health-care worker status (yes vs no), ethnicity (white vs non-white), age (<56 years vs ≥56 years), and study (COV002 vs COV003).

Table 3: Subgroup comparisons of efficacy against SARS-CoV-2 more than 14 days after a second dose of ChAdOx1 nCoV-19 vaccine in the primary efficacy population

Janssen Phase 3 Data (FDA VRBPAC review)

Figure 1. Cumulative Incidence Curve of Centrally Confirmed Moderate to Severe/Critical COVID-19 Cases With Onset at Least 1 Day After Vaccination, Full Analysis Set



Participants at risk

Ad26 5c10 vp	19744	19725	19669	19642	19612	19578	18541	14909	10930	7831	3998	1468	713	484	483	482	142	31	0
Placebo	19822	19804	19745	19652	19579	19488	18411	14814	10823	7740	3876	1439	708	485	482	480	133	27	0

Number of cases

Ad26 5e10 vp	0	27	76	96	126	151	168	178	184	188	189	191	191	192	193	193	193	193	193
Placebo	0	22	81	168	237	299	351	387	407	416	423	425	430	432	432	432	432	432	432

— Ad26 5e10 vp — Placebo

Estimated vaccine effectiveness

Vaccine	Efficacy at preventing disease - wildtype / B.1.1.7	Efficacy at preventing infection - wildtype/B.1.1.7	Efficacy at preventing disease - B.1.351 / P.1	Efficacy at preventing infection - B.1.351 / P.1
Pfizer	95%	86%	72%	63%
Moderna	94%	85%	72%	62%
AstraZeneca	74%	52%	10%	9%
Janssen	72%	72%	64%	56%
Sputnik V	92%	80%	70%	61%
Novavax	89%	77%	49%	43%
CoronaVac	50%	43%	38%	33%
Sinopharm	73%	63%	56%	48%
CanSinoBio	66%	57%	50%	44%
Other mRNA vaccines	95%	83%	72%	63%
All other vaccines	75%	65%	57%	50%
	Based on observed value			
	Assumed efficacy			
	Imputed based on average infection:disease ratio	0.87		
	Imputed based on Pfizer infection:disease ratio	0.91		
	Imputed based on B.1.351:Wildtype ratio (excl. AZ)	0.76		
	Imputed based on B.1.351:Wildtype ratio (excl. AZ) and infection:disease ratio			

Kids!

- **Pfizer – began 12-16 yo trial in fall**
- **Moderna began 12-18 yo trial in December**
- **AZ has announced 6-19 yo trial**
- **No information yet from J&J and others**