

COVID-19 RT-PCR Ct Values & J&J Vaccine

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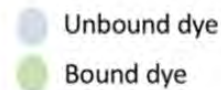
VA Northeast Ohio Healthcare System

April 8th 2021

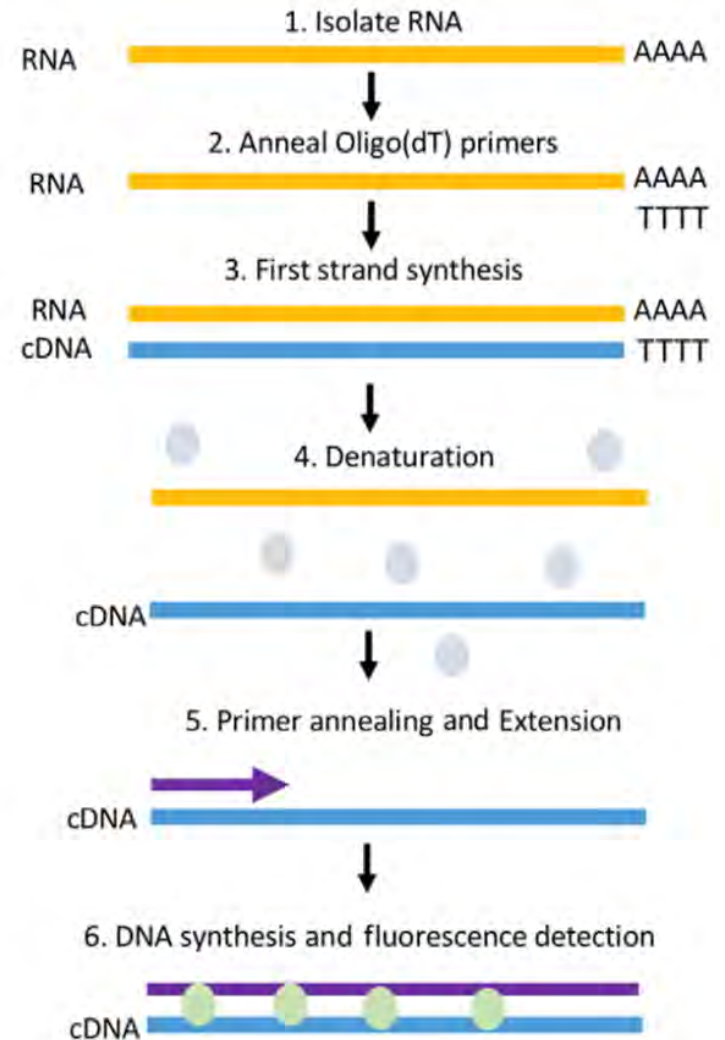
Real Time quantitative PCR

RT-qPCR

RT-PCR



Reverse transcription quantitative real-time PCR (RT-qPCR)



<https://portlandpress.com/biochemist/article/42/3/48/225280/A-beginner-s-guide-to-RT-PCR-qPCR-and-RT-qPCR>

Real Time PCR Cycle Threshold Values



The higher the Ct value, the less the template (starting material) was there.

For SARS-CoV-2, this means less virus to start.

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjz2KrChe3vAhUHUt8KHZFRANEQFjAPegQIGhAD&url=https%3A%2F%2Fwww.wvdl.wisc.edu%2Fwp-content%2Fuploads%2F2013%2F01%2FWVDL.Info_.PCR_Ct_Values1.pdf&usg=AOvVaw00HbJECppH0XLSqMrg4TZW

When is this useful for clinical care?

For infection control and prevention;

- *Documented* COVID-19 infection >90 days ago
- Currently asymptomatic
- Positive PCR test for screening

If keep someone in quarantine who should not be, sad/frustrated/lonely person.



Please, do not rush this decision.

- Take time to gather the history and learn the in/outs of the PCR test used.
- This is best done as a conversation with the laboratory

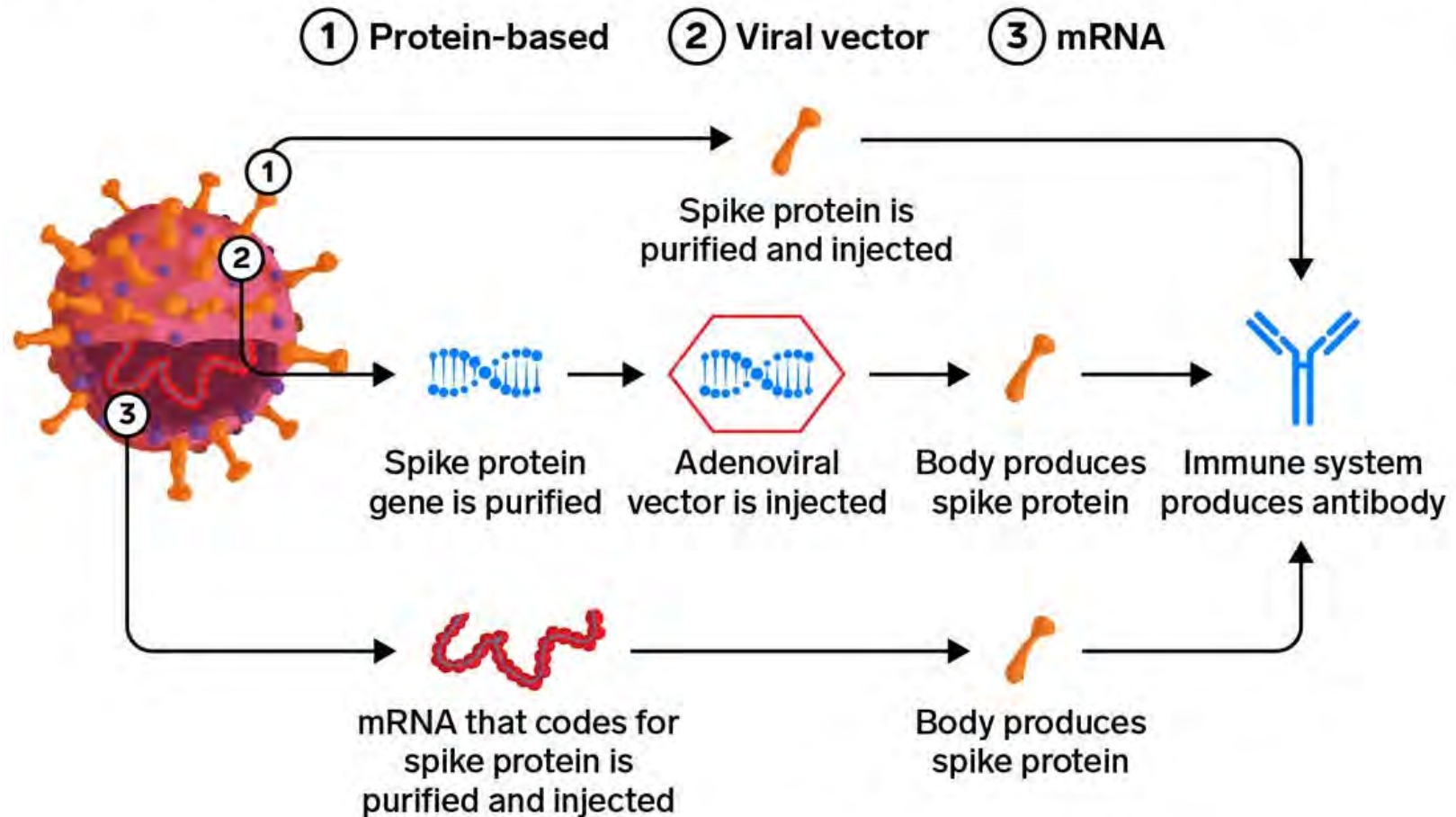
If remove someone who should be in quarantine → risk of outbreak with potential for illness, death and many other sad/frustrated/lonely people



Charleigh
(pandemic puppy)



Three types of coronavirus vaccines in development

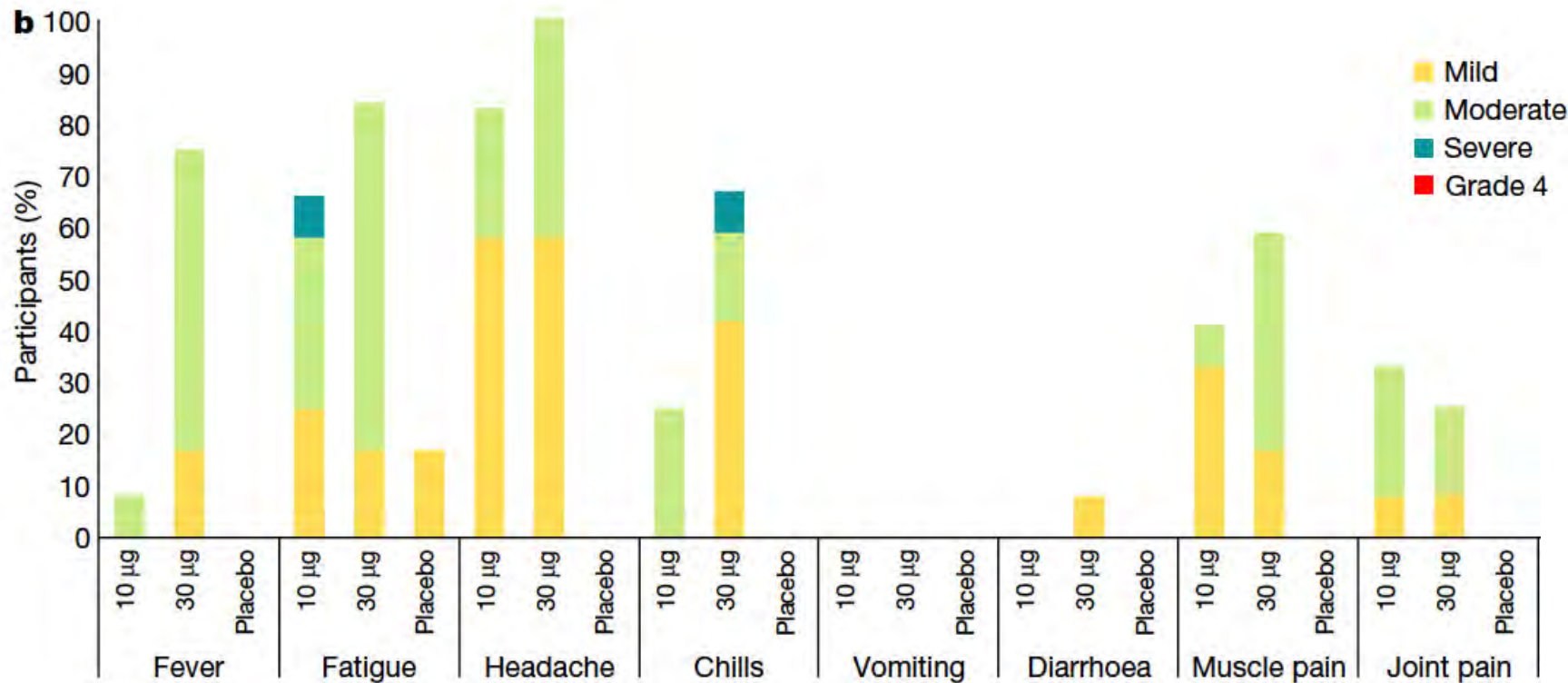


Source: National Institutes of Health presentation at Senate hearing on September 9, 2020

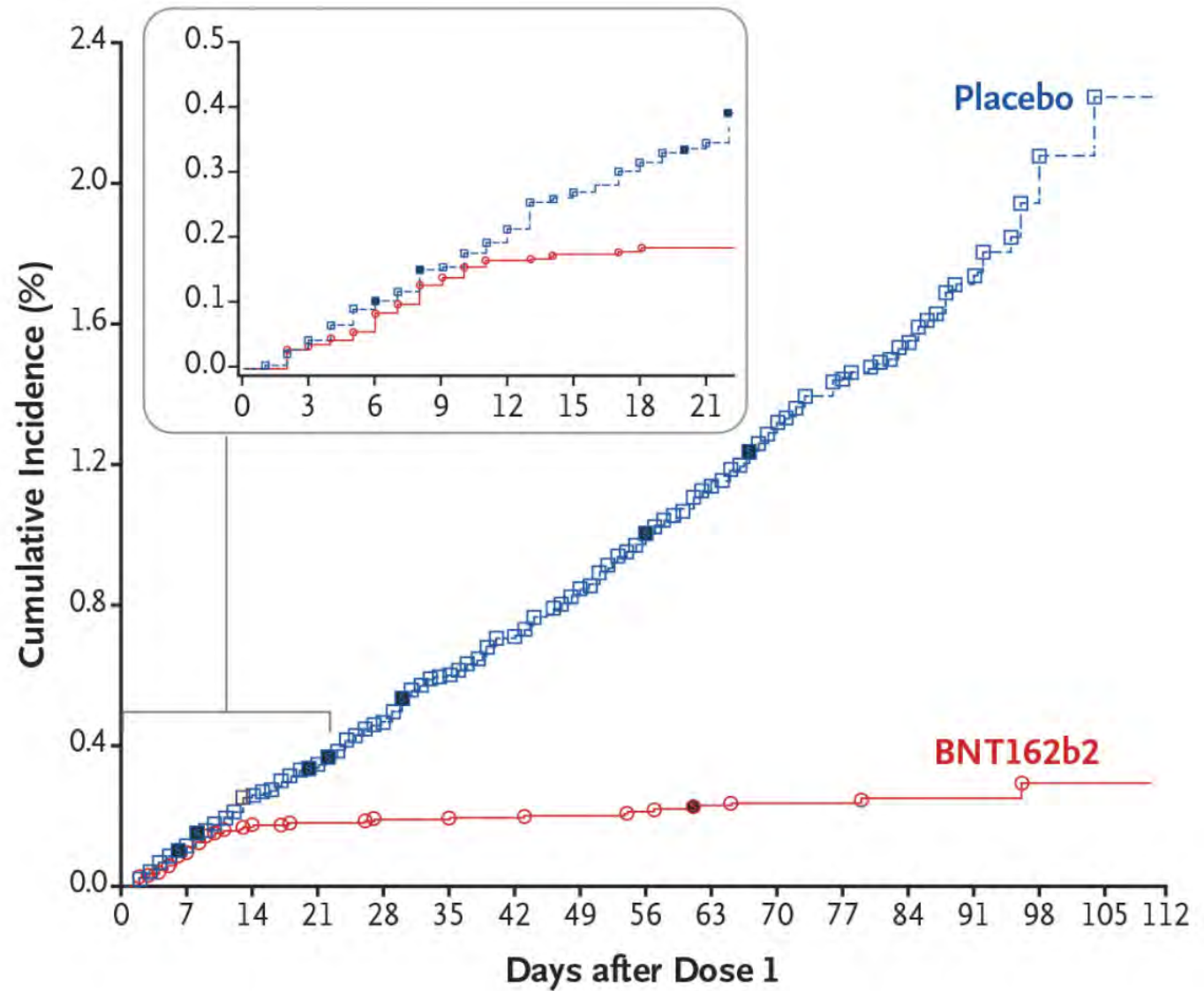
INSIDER

Side Effects, Pfizer Vaccine

- Local reactions
 - Pain (mild to moderate; 100%)
 - Redness (15%), swelling (20%)



Efficacy, Pfizer Vaccine

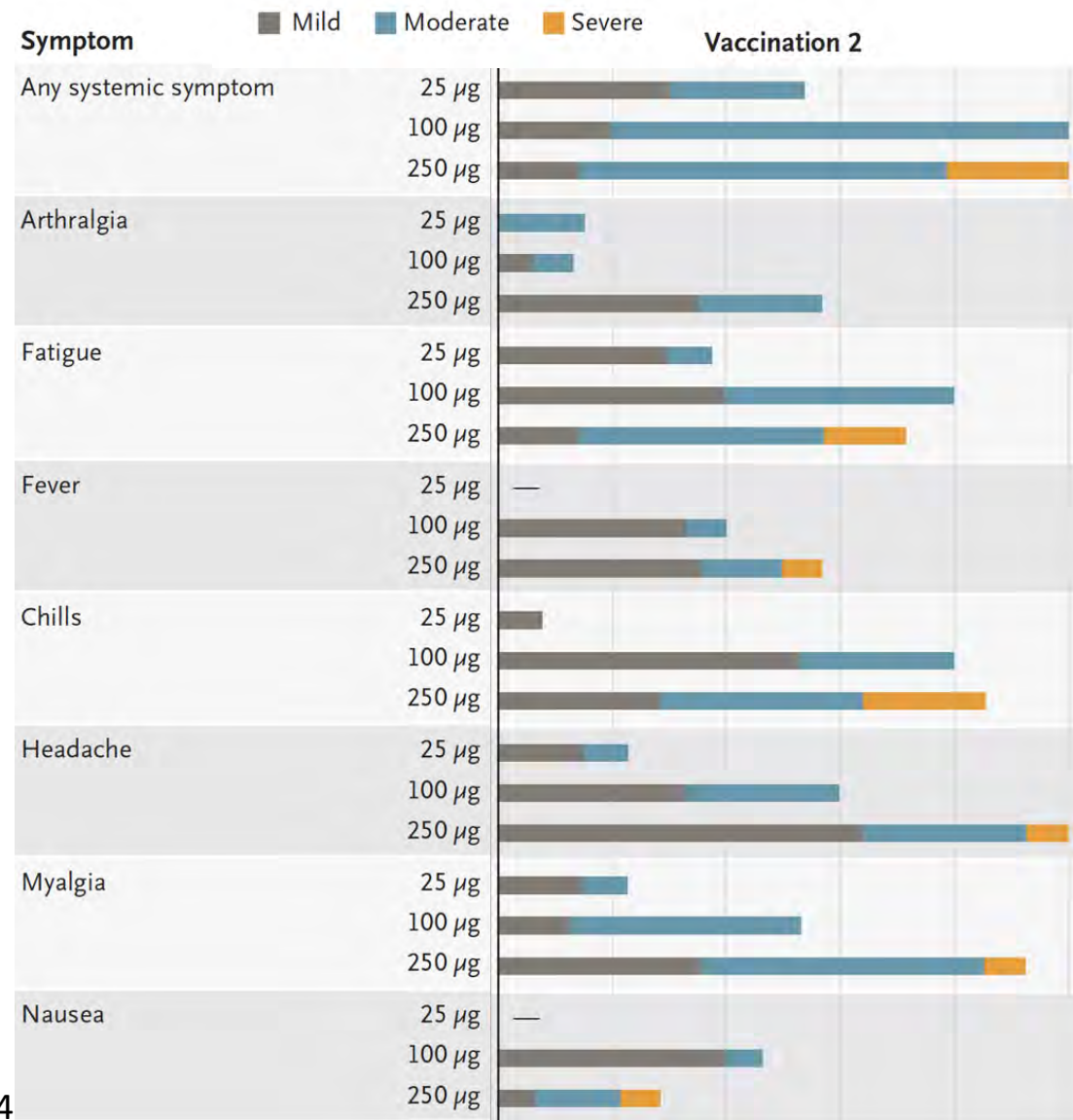


Efficacy, Pfizer Vaccine

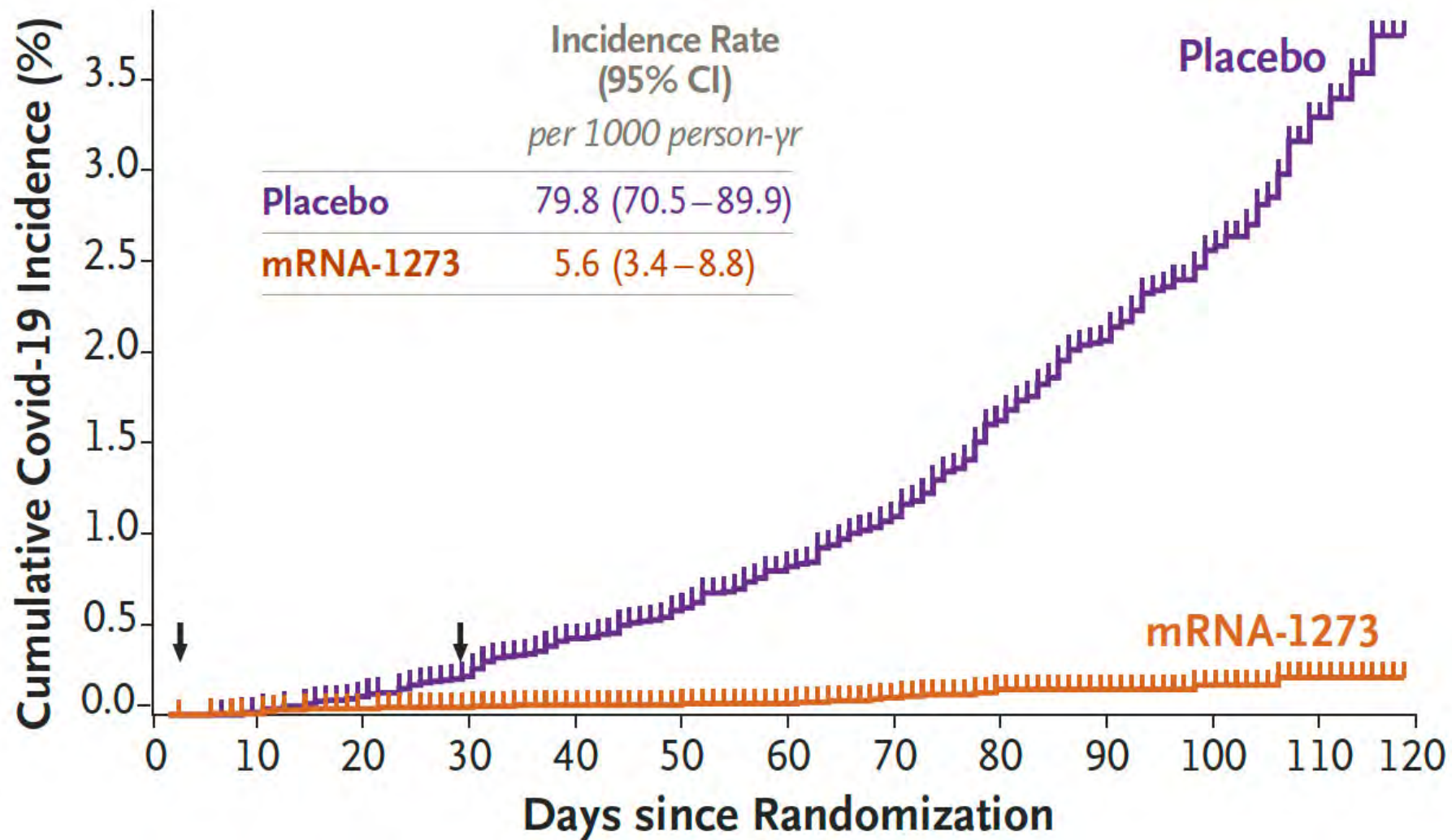
	BNT162b2 Vaccine	Placebo
Symptomatic Covid-19	8 N=18198	162 N=18325
Severe Covid-19	1 N=21669	9 N=21686
Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)		

Side Effects, Moderna Vaccine

- Local reactions
 - Pain (mild to moderate; 100%)
 - Redness (20%), swelling (10%)



Efficacy, Moderna Vaccine



Efficacy, Moderna Vaccine

	mRNA-1273 Vaccine N=14,550	Placebo N=14,598
Symptomatic Covid-19	11	185
Severe Covid-19	0	30

Vaccine efficacy of 94.1% (95% CI, 89.3–96.8%; P<0.001)

Johnson & Johnson Vaccine

Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19

Table 26. Frequency of Solicited Systemic Adverse Reactions Within 7 Days Following Vaccination, Safety Subset^a, Study 3001

Adverse Reaction	Ad26.COV2.S 18-59 Years N=2036 n/N (%)	Placebo 18-59 Years N=2049 n/N (%)	Ad26.COV2.S ≥60 Years N=1320 n/N (%)	Placebo ≥60 Years N=1331 n/N (%)
Any Systemic	1252 (61.5%)	745 (36.4%)	598 (45.3%)	440 (33.1%)
Grade 3	47 (2.3%)	12 (0.6%)	14 (1.1%)	9 (0.7%)
Fatigue ^b	891 (43.8%)	451 (22.0%)	392 (29.7%)	277 (20.8%)
Grade 3	25 (1.2%)	4 (0.2%)	10 (0.8%)	5 (0.4%)
Headache ^b	905 (44.4%)	508 (24.8%)	401 (30.4%)	294 (22.1%)
Grade 3	18 (0.9%)	5 (0.2%)	5 (0.4%)	4 (0.3%)
Myalgia ^b	796 (39.1%)	248 (12.1%)	317 (24.0%)	182 (13.7%)
Grade 3	29 (1.4%)	1 (<0.1%)	3 (0.2%)	5 (0.4%)
Nausea ^c	315 (15.5%)	183 (8.9%)	162 (12.3%)	144 (10.8%)
Grade 3	3 (0.1%)	3 (0.1%)	3 (0.2%)	3 (0.2%)
Fever ^d	261 (12.8%)	14 (0.7%)	41 (3.1%)	6 (0.5%)
Grade 3	7 (0.3%)	0	1 (0.1%)	0
Antipyretic/Analgesic Use	538 (26.4%)	123 (6.0%)	130 (9.8%)	68 (5.1%)

Johnson & Johnson Vaccine

Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19

Table 10. Vaccine Efficacy Against Centrally Confirmed Moderate to Severe/Critical COVID-19 With Onset at Least 14 and at Least 28 Days After Vaccination, Per-Protocol Set, Study 3001

Co-primary Endpoint Subgroup	Onset at Least 14 Days			Onset at Least 28 Days		
	Ad26.COV2.S Cases (N) ^a Person-yrs ^b	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)
All participants	116 (19514) 3116.6	348 (19544) 3096.1	66.9% (59.0, 73.4)	66 (19306) 3102.0	193 (19178) 3070.7	66.1% (55.0, 74.8)
Age 18-59 years	95 (12750) 2106.8	260 (12782) 2095.0	63.7% (53.9, 71.6)	52 (12617) 2097.6	152 (12527) 2077.0	66.1% (53.3, 75.8)
Age ≥60 years	21 (6764) 1009.8	88 (6762) 1001.2	76.3% (61.6, 86.0)	14 (6689) 1004.4	41 (6651) 993.6	66.2% (36.7, 83.0)

Source: Sponsor tables GEFPE02_A and GEFPE02_C

^a N=Total number of participants at risk per category

^b Person-years include time from vaccination to the onset of moderate to severe/critical COVID-19, discontinuation from study, major protocol deviation, unblinding to receive alternative vaccine, or data cutoff, whichever comes first.

<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjDyJjao4rvAhVMTd8KHdbTBAUQFjAAegQIBBAD&url=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F146217%2Fdownload&usg=AOvVaw2PVIWsMshNjOxvNGPx3KvJ>

Johnson & Johnson Vaccine

Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19

Table 13. Vaccine Efficacy of First Occurrence of **Moderate to Severe/Critical COVID-19**, Including Non-centrally Confirmed Cases, With Onset at Least 14 or at Least 28 Days After Vaccination, by Risk Factors for Severe COVID-19, Per-Protocol Set, Study 3001

Subgroup	Onset at Least 14 Days			Onset at Least 28 Days		
	Ad26.COV2.S Cases (N) Person-yr	Placebo Cases (N) Person-yr	VE% ^a (95% CI)	Ad26.COV2.S Cases (N) Person-yr	Placebo Cases (N) Person-yr	VE% ^a (95% CI)
Age group and comorbidity presence						
18-59, no	89 (8346) 1433.5	258 (8411) 1428.2	65.6% (56.1, 73.3)	58 (8267) 1428.2	180 (8254) 1418.3	68.0% (56.8, 76.6)
18-59, yes	48 (4404) 671.5	131 (4371) 661.0	63.9% (49.4, 74.7)	29 (4350) 668.1	79 (4273) 654.8	64.0% (44.3, 77.3)
≥60, no	14 (3391) 541.6	57 (3335) 530.0	76.0% (56.3, 87.6)	11 (3355) 539.0	39 (3298) 527.6	72.4% (45.0, 87.3)
≥60, yes	22 (3373) 467.4	63 (3427) 469.9	64.9% (42.2, 79.4)	15 (3334) 464.9	26 (3353) 465.2	42.3% (-13.1, 71.6)

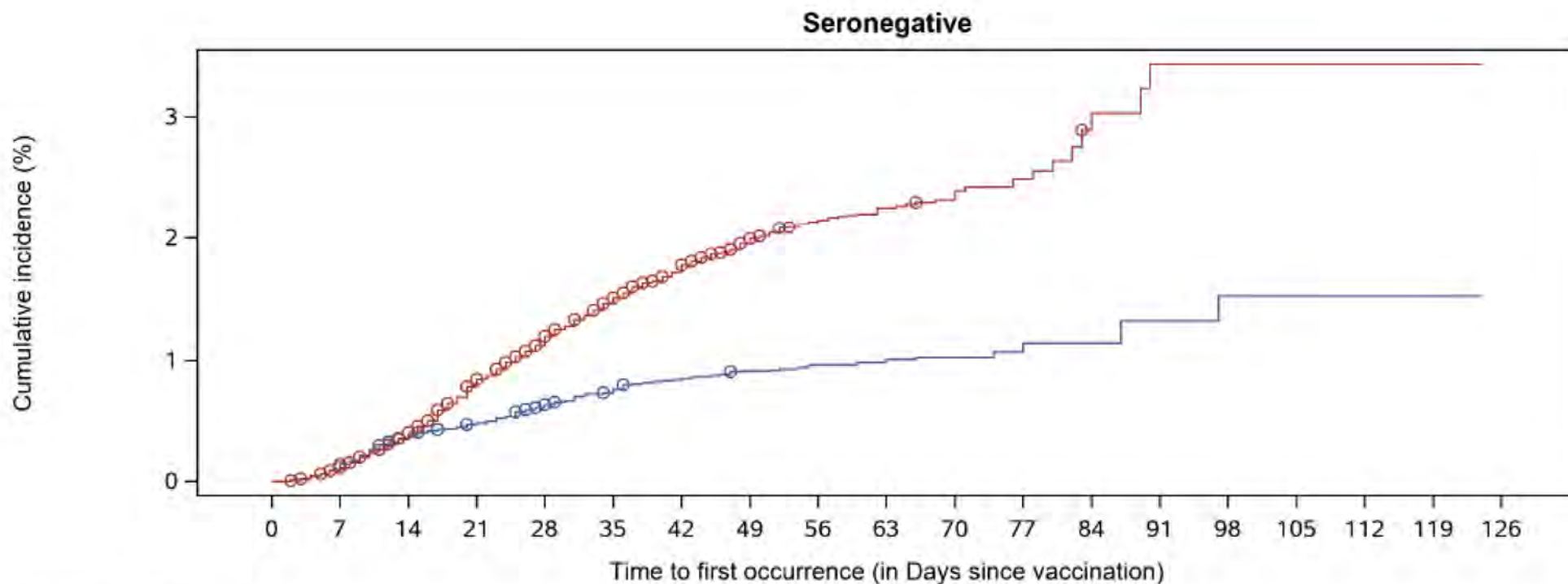
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Subgroup	Onset at Least 14 Days			Onset at Least 28 Days		
	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% ^a (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% ^a (95% CI)
C Type 2 diabetes mellitus	15 (1399) 198.7	32 (1410) 199.5	52.9% (10.5, 76.3)	10 (1380) 197.5	13 (1378) 197.7	23.0% (-90.1, 69.8)
Serious heart conditions	3 (460) 65.3	13 (487) 67.7	76.1% (12.9, 95.6)	1 (455) 64.9	5 (472) 66.8	79.4% (-83.7, 99.6)
HIV infection	5 (467) 69.1	5 (498) 72.4	-4.8% (-355.2, 75.9)	2 (461) 68.7	4 (493) 72.2	47.5% (-266.0, 95.3)
Hypertension	14 (1999) 283.3	38 (2019) 282.8	63.2% (30.6, 81.6)	11 (1978) 281.9	17 (1977) 280.2	35.7% (-45.6, 72.8)
Obesity	51 (5383) 794.1	151 (5352) 780.3	66.8% (54.1, 76.3)	30 (5318) 790.0	86 (5223) 772.0	65.9% (47.8, 78.3)

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		19744	19725	19669	19642	19612	19578	18541	14909	10930	7831	3998	1468	713	494	483	482	142	31	0
Ad26 5c10 vp		19744	19725	19669	19642	19612	19578	18541	14909	10930	7831	3998	1468	713	494	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		0	27	76	96	126	151	168	178	184	188	189	191	191	192	193	193	193	193	193
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