mRNA RSV Vaccine: 81 Adverse Reactions per Each Prevented Case of RSV (a cold)

Also a marked increase in immune deficiency

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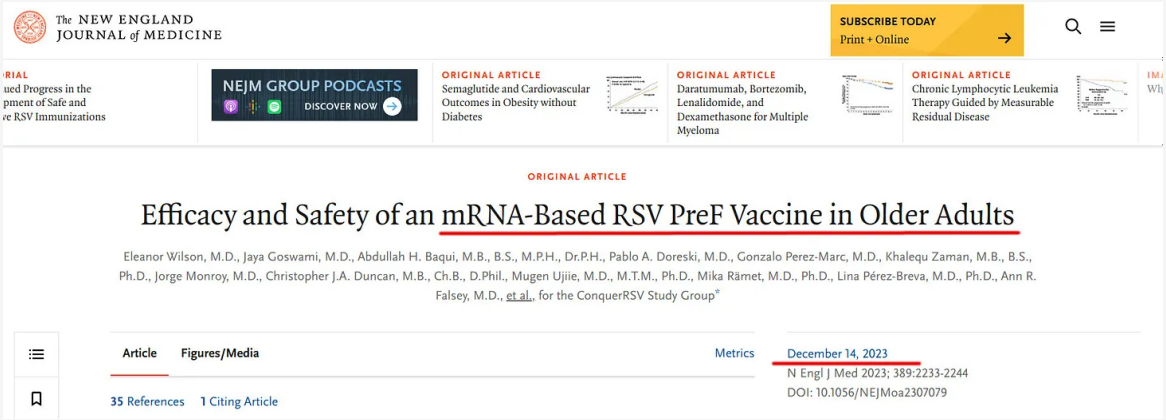
A new mRNA vaccine is being developed: Moderna's mRNA-1345 is a proposed immunization against RSV, one of the viruses causing colds in adults. Clinical trial results were published in the New England Journal of Medicine today.



https://www.nejm.org/doi/full/10.1056/NEJMoa2307079?query=TOC

The clinical trial's 35,541 *participants were assigned to receive the* mRNA-1345 *vaccine* (17,793 *participants*) *or placebo* (17,748). (The placebo was saline.)

Moderna proudly reported that its **RSV vaccine prevented 66 cases of RSV** in 17 thousand vaccinated people. Per the appendix:

Table S8. Vaccine Efficacy against RSV-LRTD with ≥2 or ≥3 Symptoms and RSV-ARD (Randomization Set)*.

End Point	mRNA-1345		Placebo		Vaccine Efficacy % (95% CI)[§]
	Number of Participants	Number of Events[†,‡]	Number of Participants	Number of Events[†,‡]	
RSV-LRTD with ≥2 symptoms	17,793	10	17,748	62	83.9 (68.7, 91.8)
RSV-LRTD with ≥3 symptoms	17,793	3	17,748	20	85.0 (49.7, 95.6)
RSV-ARD	17,793	29	17,748	95	69.6 (53.9, 79.9)

ARD, acute respiratory disease; CI, confidence interval; LRTD, lower respiratory; RSV, respiratory syncytial virus; RT-PCR, reverse transcription polymerase chain reaction; VE, vaccine efficacy

*Data are from the randomization set analysis population. 95-29=66 cases of RSV prevented

[†]RSV-LRTD with ≥2 symptoms or ≥3 symptoms and RSV-ARD were based on eligible symptoms onset within a timeframe of ±14 days from positive RSV RT-PCR collection date.

[‡]The time to first episode of RSV-LRTD with ≥2 symptoms or ≥3 symptoms and RSV-ARD were calculated as date of case –date of randomization + 1.

[§]Vaccine efficacy is defined as 100% × (1 – hazard ratio [mRNA-1345 vs. placebo]). The CI for VE is based on a stratified Cox proportional hazard model with Efron's method of tie handling and with the study vaccination group as a fixed effect, adjusting for stratification factors at randomization.

https://www.nejm.org/doi/suppl/10.1056/NEJMoa2307079/suppl_file/nejmoa2307079_appendix.pdf

The Moderna study explains:

> **Vaccine efficacy was 68.4% (95% CI, 50.9 to 79.7) against RSV-associated acute respiratory disease.** Protection was observed against both RSV subtypes (A and B) and was generally consistent across subgroups defined according to age and coexisting conditions.

mRNA RSV vaccine efficacy of just 68% was relatively meager, far worse than the much-ballyhooed "95% efficacy" of COVID vaccines.

The interesting part follows:

> **Participants in the mRNA-1345 group had a higher incidence than those in the placebo group of solicited local adverse reactions (58.7% vs. 16.2%) and of systemic adverse reactions (47.7% vs. 32.9%)**; most reactions were mild to moderate in severity and were transient.

Was taking the RSV vaccine worth it for the trial participants? Consider this: as per the above image, **the vaccine prevented 66 cases of RSV among 17,793 vaccine recipients**. However, it caused 5,337 *more adverse events in the vaccine group than in the placebo group*.

Table S11. Number of Days Reporting Solicited Adverse Reactions within 7 Days after Vaccination (Solicited Safety Set).

Solicited Adverse Reaction Category	mRNA-1345, 50 µg (N=17,665) n (%)	Placebo (N=17,598) n (%)
Solicited adverse reactions – N1*	17,665	17,598
Any	12,119 (68.6)	6782 (38.5)
Day of onset		
Mean (SD)	1.8 (1.07)	2.4 (1.70)
Median	2.0	2.0
Min, Max	1, 7	1, 7
Duration (days)		
Mean (SD)		
Median		
Min, Max	1, 184	1, 117
Persisted beyond 7 days	1200 (6.8)	915 (5.2)

12,119-6782=5,337 additional adverse events in the vaccine group

Adverse events were varied, ranging from trivial, such as minor headaches, to more disturbing ones, such as *underarm lymph node swelling*, fevers, vomiting, etc.

Overall, for *each* prevented case of RSV (remember, the vaccine prevented only 66 cases), the vaccinated subgroup suffered 5337/66 = 81 adverse events.

Let me repeat: there were *81 adverse events* per *each prevented case of* RSV.

Is having **81 adverse events per case of RSV, essentially a mild cold**, a good deal? Not to me!

What about preventing more serious illness? As per the vaccine efficacy picture below, the RSV vaccine prevented 17 cases of RSV-LRTD with >= three symptoms.

Table S8. Vaccine Efficacy against RSV-LRTD with ≥2 or ≥3 Symptoms and RSV-ARD (Randomization Set)*.

End Point	mRNA-1345		Placebo		Vaccine Efficacy % (95% CI)[§]
	Number of Participants	Number of Events[†,‡]	Number of Participants	Number of Events[†,‡]	
RSV-LRTD with ≥2 symptoms	17,793	10	17,748	62	83.9 (68.7, 91.8)
RSV-LRTD with ≥3 symptoms	17,793	3	17,748	20	85.0 (49.7, 95.6)
RSV-ARD	17,793	29	17,748	95	69.6 (53.9, 79.9)

ARD, acute respiratory disease; CI, confidence interval; LRTD, lower respiratory; RSV, respiratory syncytial virus; RT-PCR, reverse transcription polymerase chain reaction; VE, vaccine efficacy

*Data are from the randomization set analysis population.

20-3 = 17 cases of RSV with >= 3 symptoms prevented.

[†]RSV-LRTD with ≥2 symptoms or ≥3 symptoms and RSV-ARD were based on eligible symptoms onset within a timeframe of ±14 days from positive RSV RT-PCR collection date.

[‡]The time to first episode of RSV-LRTD with ≥2 symptoms or ≥3 symptoms and RSV-ARD were calculated as date of case –date of randomization + 1.

[§]Vaccine efficacy is defined as 100% × (1 − hazard ratio [mRNA-1345 vs. placebo]). The CI for VE is based on a stratified Cox proportional hazard model with Efron's method of tie handling and with the study vaccination group as a fixed effect, adjusting for stratification factors at randomization.

Mind you, these were not hospitalizations — merely instances of RSV with more symptoms than usual.

For example, if the patient had a 1) cough, 2) fever over 100F, and 3) sputum production, it would fit the above-underlined definition:

RSV-LRTD with ≥3 symptoms	• RT-PCR–confirmed RSV infection plus new or worsening of at least 3 of the following symptoms: shortness of breath, cough and/or fever (≥37.8°C [100.0°F]), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥20 breaths per minute, or increase of ≥2 breaths per minute from baseline measurement in those who have baseline tachypnea), hypoxemia (new oxygen saturation ≤93% or new or increasing use of supplemental oxygen), pleuritic chest pain for at least 24 hours • In case of inability to fully assess other clinical parameters, radiologic evidence of pneumonia with RT-PCR–confirmed RSV infection can also be used to confirm RSV-LRTD

How many adverse events would the RSV-vaccinated study subjects have to suffer to prevent 17 such instances? The math works out to 5,337 vaccine adverse events, preventing 17 cases of RSV-LRTD with >= 3 symptoms, or

5337/17 = **313 adverse events per prevented RSV illness** with at least three symptoms.

Did all 17 of the above instances involve fevers? Moderna's study is silent on this, but let's give them the benefit of the doubt and assume that *all* the above-mentioned prevented cases had a fever.

How many vaccinations resulted in *vaccine-caused fevers*? Page 53 helpfully provides information:

Solicited Adverse Reaction Category	mRNA-1345, 50 µg (N=17,665) n (%)	Placebo (N=17,598) n (%)
Mean (SD)	2.2 (1.40)	2.6 (1.74)
Median	2.0	2.0
Min, Max	1, 7	1, 7
Duration (days)		
Mean (SD)	3.7 (5.36)	4.0 (5.61)
Median	2.0	2.0
Min, Max	1, 184	1, 117
Persisted beyond 7 days	1034 (5.9)	866 (4.9)
Fever – N1*	17,651	17,593
Any	501 (2.8)	234 (1.3)
Day of onset	Vaccine caused 501-234=267 fevers.	
Mean (SD)	2.7 (1.54)	3.4 (1.96)
Median	2.0	3.0
Min, Max	1, 7	1, 7
Duration (days)		
Mean (SD)	1.5 (1.80)	1.5 (1.82)
Median	1.0	1.0
Min, Max	1, 27	1, 24
Persisted beyond 7 days	17 (<0.1)	6 (<0.1)

So, to prevent about 17 *worse-than-usual cases of RSV involving fevers*, the vaccinated subgroup had to suffer through 267 *vaccine-caused fevers.* Similarly, to prevent all 66 *cases of RSV*, avoided in the vaccinated subgroup, the vaccinees had to suffer through 267 *fevers caused by the RSV vaccine*.

Is that a good risk-benefit tradeoff?

Underarm Swelling

More worryingly, the mRNA RSV vaccine caused a whopping 1,620 cases of "underarm swelling" in axillary lymph nodes:

Axillary (underarm) swelling or tenderness – N1*	17659	17592
Any	2711 (15.4)	1091 (6.2)
Day of onset	mRNA RSV Vax Caused 2711-1091=1,620 underarm lymph node pswellings	
Mean (SD)	2.4 (1.42)	2.7 (1.84)
Median	2.0	2.0
Min, Max	1, 7	1, 7
Duration (days)		
Mean (SD)	2.1 (2.36)	2.2 (3.03)
Median	1.0	1.0
Min, Max	1, 28	1, 48
Persisted beyond 7 days	120 (0.7)	49 (0.3)

Even more disappointingly, the vaccine caused **120 long-term axillary swellings,** compared to only **49 in the unvaccinated subgroup**.

All of this misery and suffering, like 70 *vaccine-caused long-term underarm lymph node swellings* and 1,620 *vaccine-caused total lymph node swellings*, was imposed upon the unlucky vaccinated subgroup to prevent a measly 66 cases of RSV.

EDIT: Why Did Placebo Group have so much Lymph Node Swelling?

An astute reader, "Rustam," asked a good question:

Igor - aside from the vax recipient cohort - how did a massive 1,091 of the "saline placebo" patients end up with underarm swelling?! 1,091 out of 17,679 cohort = 6.17%. Did moderna by chance get unlucky and recruit the world's most unhealthy armpit owners? Or are they lying about the placebo being saline (which sounded a bit too good to be true)?

My answer: Moderna trial participants are mRNA vaccine fanatics and most likely took COVID boosters in addition to the RSV vaccine. That explains why the "placebo" group had so much lymph node swelling, as well as other adverse events.

Another mRNA Vaccine Causing Immune Deficiency?

Of particular note is the fact that far more vaccinated subjects had severe "infections and infestations" up to 28 days after vaccination compared to the unvaccinated ones:

Table S14. Participant Incidence of Serious AEs Regardless of Causality Up to 28 Days after Injection by System Organ Class and Preferred Term (PTs Reported for ≥2 Participants in Either Group [Safety Set]).

System Organ Class Preferred Term	mRNA-1345, 50 µg (N=17734) n (%)	Placebo (N=17679) n (%)
Number of participants reporting serious AEs	102 (0.6)	93 (0.5)
Number of serious AEs	117	120
Infections and infestations	22 (0.1)	7 (<0.1)
Pneumonia	6 (<0.1)	2 (<0.1)
Gastroenteritis	2 (<0.1)	0
Influenza	2 (<0.1)	0
Urinary tract infection	2 (<0.1)	1 (<0.1)
Cellulitis	0	2 (<0.1)
Neoplasms benign, malignant and unspecified (incl		

Vaxed ppl had MORE infections!

Why would mRNA-vaccinated subjects have more pneumonia and other serious illnesses?

Does all that make the proposed mRNA RSV vaccine safe and effective?

Is there a “positive risk-benefit balance”?

Will the corrupt FDA careerists rubber-stamp this ineffective mRNA vaccine, whose only benefit would be enriching Moderna’s shareholders?

Let us know what you think!

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318 Comments