VACCINE ADVERSE EVENTS REPORTING IN VAERS

SEPTEMBER 2021 UPDATE BY

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Safety and Efficacy*

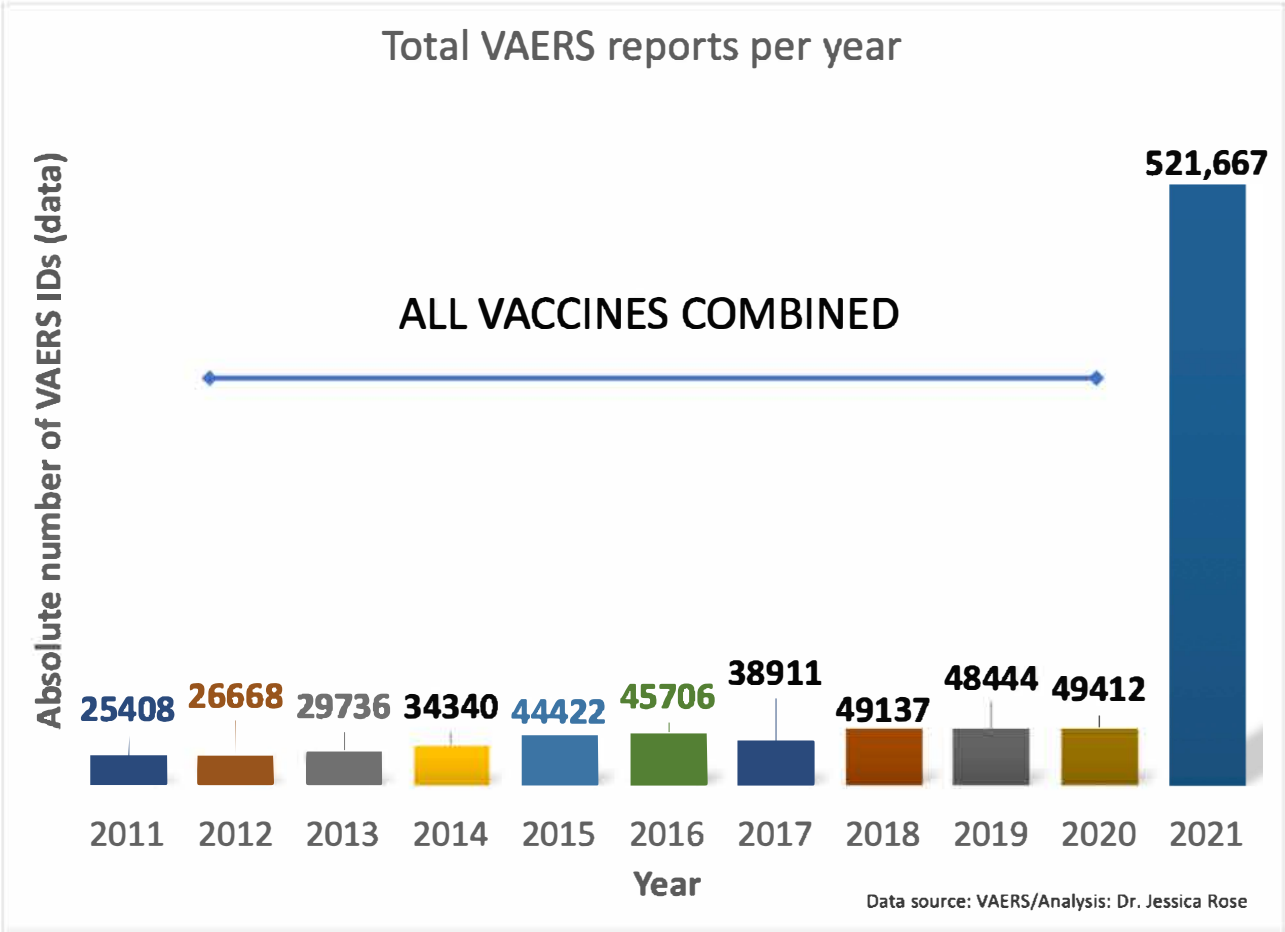
Risk: A measure of the probability of an adverse event or untoward outcome occurring and the severity of the resultant harm to health of individuals in a defined population associated with use of a medical technology applied for a given medical problem under specified conditions of use.

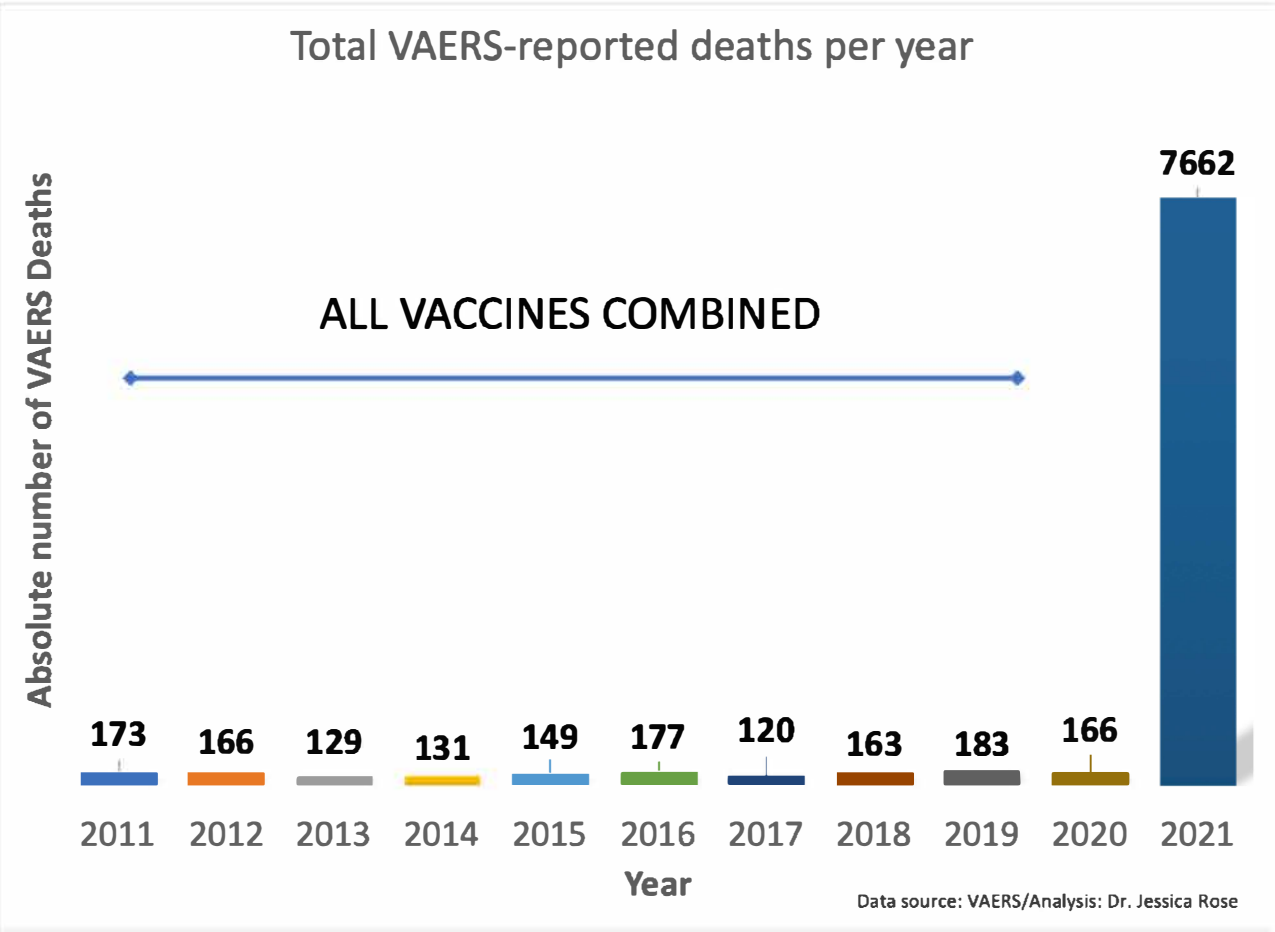
- Safety: A judgement of the acceptability of risk in a specified situation.
- Efficacy: The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use.

Data source: VAERS/Analysis: Dr. Jessica Rose

*Book: Assessing the Efficacy and Safety of Medical Technologies: The Concepts of Efficacy and Safety

Total VAERS counts and death counts for the past decade

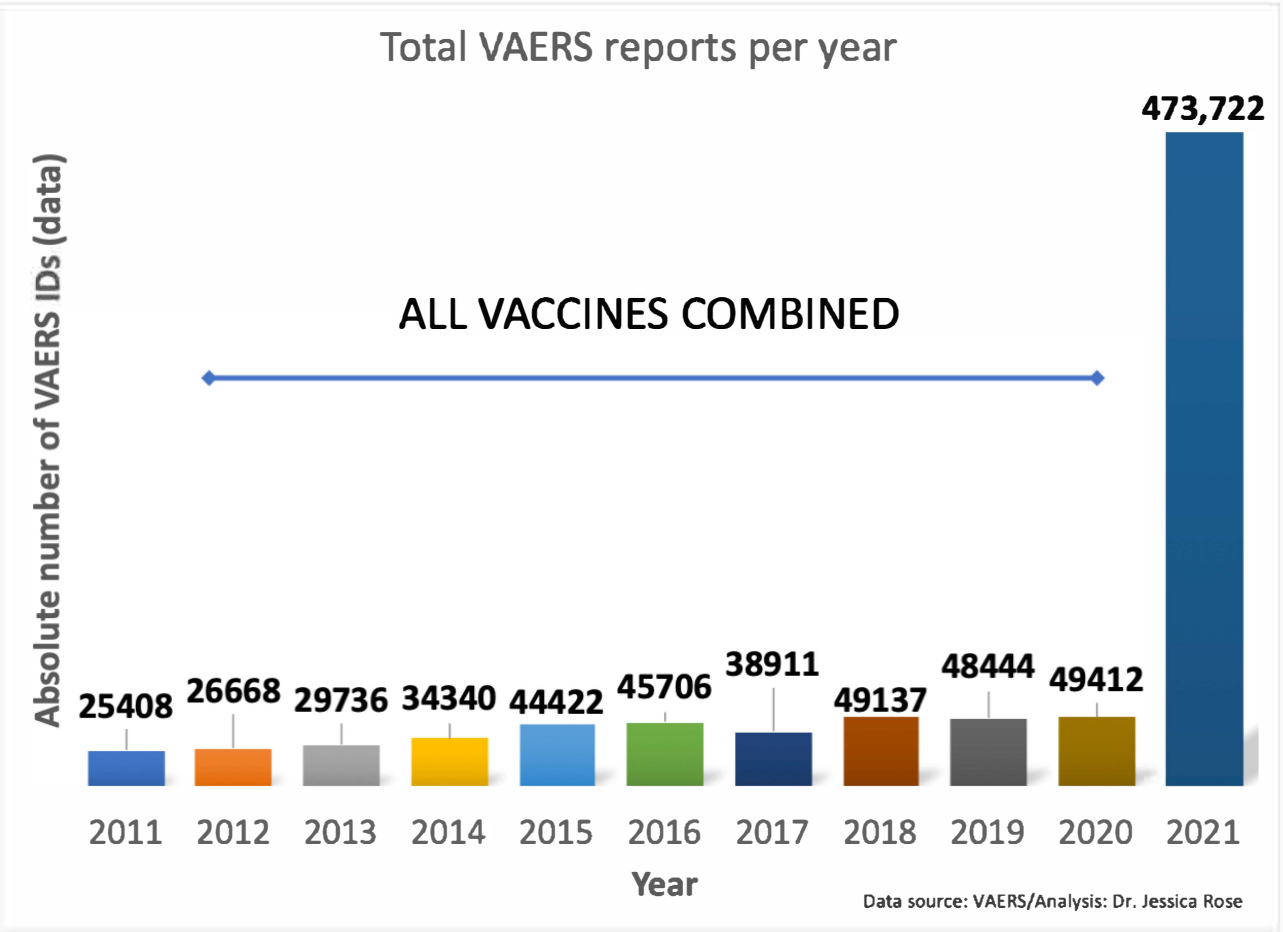




Atypical (Update as of September 3rd, 2021)

Data source: VAERS Domestic data/Analysis: Dr. Jessica Rose

Total VAERS counts for the past decade



This is a 1,108% increase. Since the excess in AEs are NOT due to excess in doses administered*, what explains this?

mean for the past decade = 39,218

Data source: VAERS/Analysis: Dr. Jessica Rose

*Josh Guetzkow. Adverse Events Reported Following COVID-19 Vaccinations (unpublished data). https://tinyurl.com/CovidvFluReport

Cardiovascular, neurological and immunological AEs are all being reported at rates not seen before…

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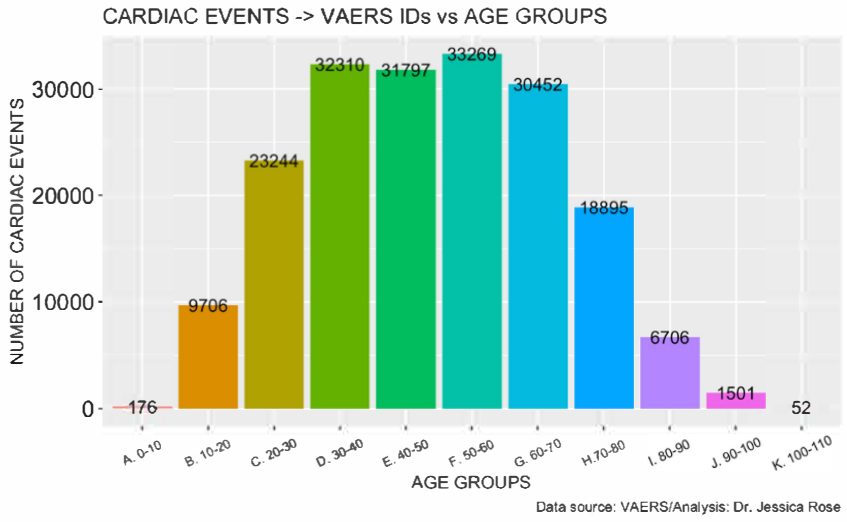

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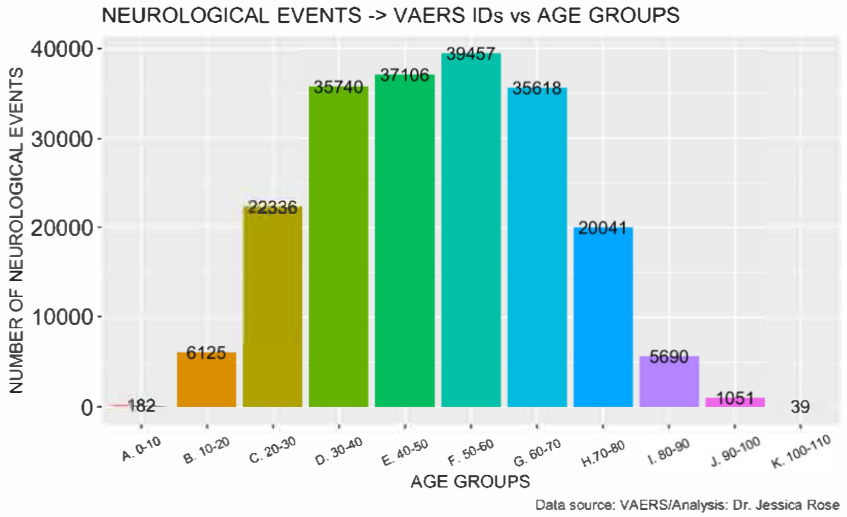

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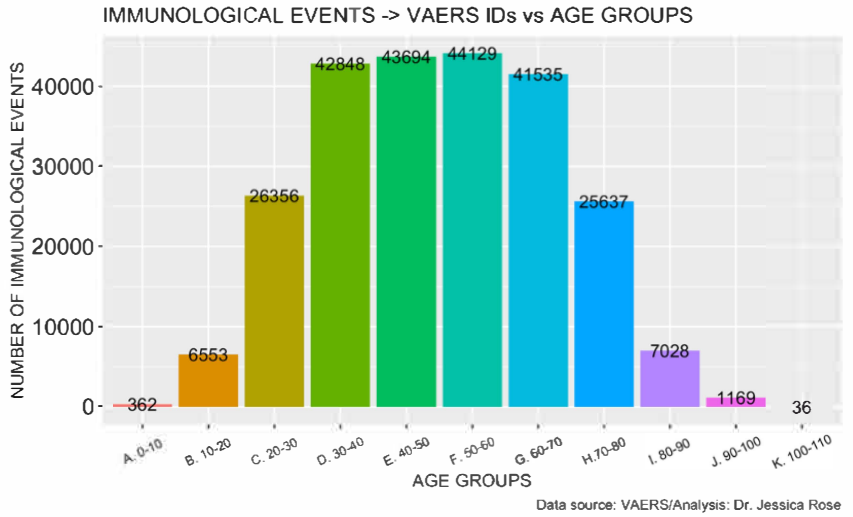
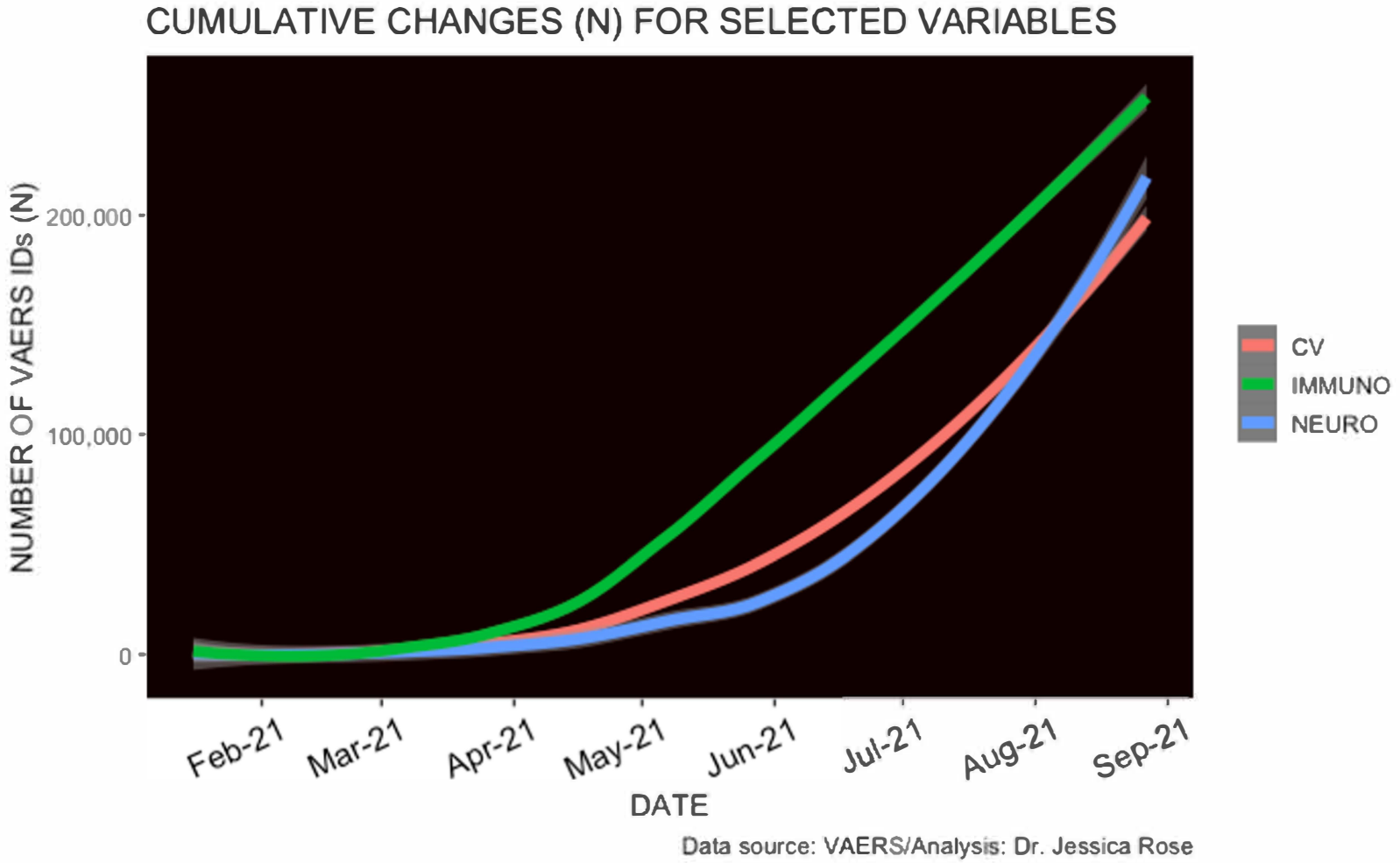


Data source: VAERS/Analysis: Dr. Jessica Rose

Cardiovascular, Neurological and Immunological AE reports are exploding*

The rates of AEs are also increasing for Cardiovascular, Neurological and Immunological Categories



Data source: VAERS/Analysis: Dr. Jessica Rose

*As of August 27th, 2021

The Potential Under-Reporting Factor (URF)

Table 14. Study C4591001 Safety Overview- Ages 16 years and older

Participants Experiencing at Least One:	BNT162b2 n/N (%)	Placebo n/N (%)
Immediate unsolicited AE Within 30 minutes after vaccination[a]		
Dose #1	78/18801 (0.4)	66/18785 (0.4)
Dose #2	52/18494 (0.3)	39/18470 (0.2)
Solicited injection site reaction within 7 days[b]		
Dose #1	3216/4093 (78.6)	525/4090 (12.8)
Dose #2	2748/3758 (73.1)	396/3749 (10.6)
Solicited systemic AE within 7 days[b]		
Dose #1	2421/4093 (59.1)	1922/4090 (47.0)
Dose #2	2627/3758 (69.9)	1267/3749 (33.8)
From Dose 1 through 1 month after Dose 2[a]		
Unsolicited non-serious AE	5071/18801 (27.0)	2356/18785 (12.5)
SAE	103/18801 (0.5)	81/18785 (0.4)
From Dose 1 through cutoff date (safety population)		
SAE	124/18801 (0.7)	101/18785 (0.5)
From Dose 1 through cutoff date (all-enrolled)[c]		
Withdrawal due AEs	37/21621 (0.6)	30/21631 (0.5)
SAE	126/21621 (0.6)	111/21631 (0.5)
Deaths	2/21621 (0.0)	4/21631 (0.0)

Source: c4591001-safety-tables-ae3.pdf pages 216,446,459,463; c4591001-safety-tables-cos-reacto.pdf, pages 113-114.
n= number of participants with the specified reaction or AE.
[a] N: number of participants in the phase 2/3 safety population.
[b] N: number of participants in the reactogenicity subset of the phase 2/3 safety population.
[b] N: number of participants in the all-enrolled population.
Data analysis cutoff date: November 14, 2020.

124/18801 = 0.7% = Pfizer rate of SAE incidence

Calculation of expected number of SAEs based on Pfizer SAE rate

0.7% * # of Pfizer doses administered (as of August 10th, 2021) =
0.7% * 351,400,000 = 2,459,800

Observed number of as of August 10th, 2021 = 80011

∴ URF = Expected/Observed = 2,459,800/80011 = 31

∴ 31 is the Under-Reporting Factor (URF)

Since under-reporting of Mild Adverse Events is likely higher than for SAEs, this factor is not inappropriate for any AE.

Data source: VAERS/Analysis: Dr. Jessica Rose

Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020. FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine

Some examples of the URF conversion

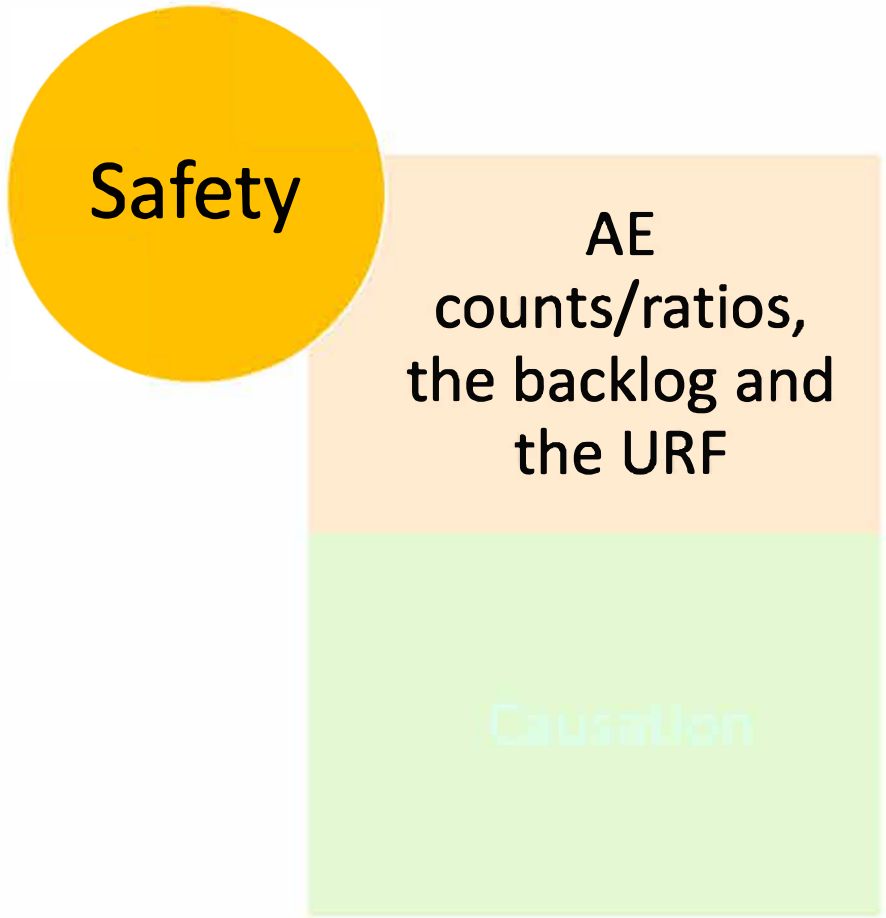
Adverse Event	Absolute number	URF applied
Bell's Palsy	2,637	81,747
Herpes zoster	4,807	149,017
Tinnitus	6,523	202,213
Female Reproductive Issues	6,549	203,019
Death	6,639	205,809
Cough	9,637	298,747
Paraesthesia	9,860	305,660
Lymphadenopathy	10,420	323,020
Chest pain	11,492	356,252
Breakthrough COVID-19	11,805	365,955
Diarrhoea	13,495	418,345
Injection site pruritis	15,549	482,019
Myalgia	17,047	528,457
Pruritus	18,103	561,193
Dyspnoea (difficulty breathing)	20,674	640,894
Pain	40,084	1,242,604
Fatigue	61,900	1,918,900
Chills	61,972	1,921,132
Headache	73,565	2,280,515
Hospital	26,402	818,462
ER	59,061	1,830,891
Life-threatening events	7,423	230,113
Disabled	6,861	212,691
Birth defects	258	7.998

Data source: VAERS/Analysis: Dr. Jessica Rose

***updated August 27th, 2021**

Data analysis: Steve Kirsch/Dr. Jessica Rose

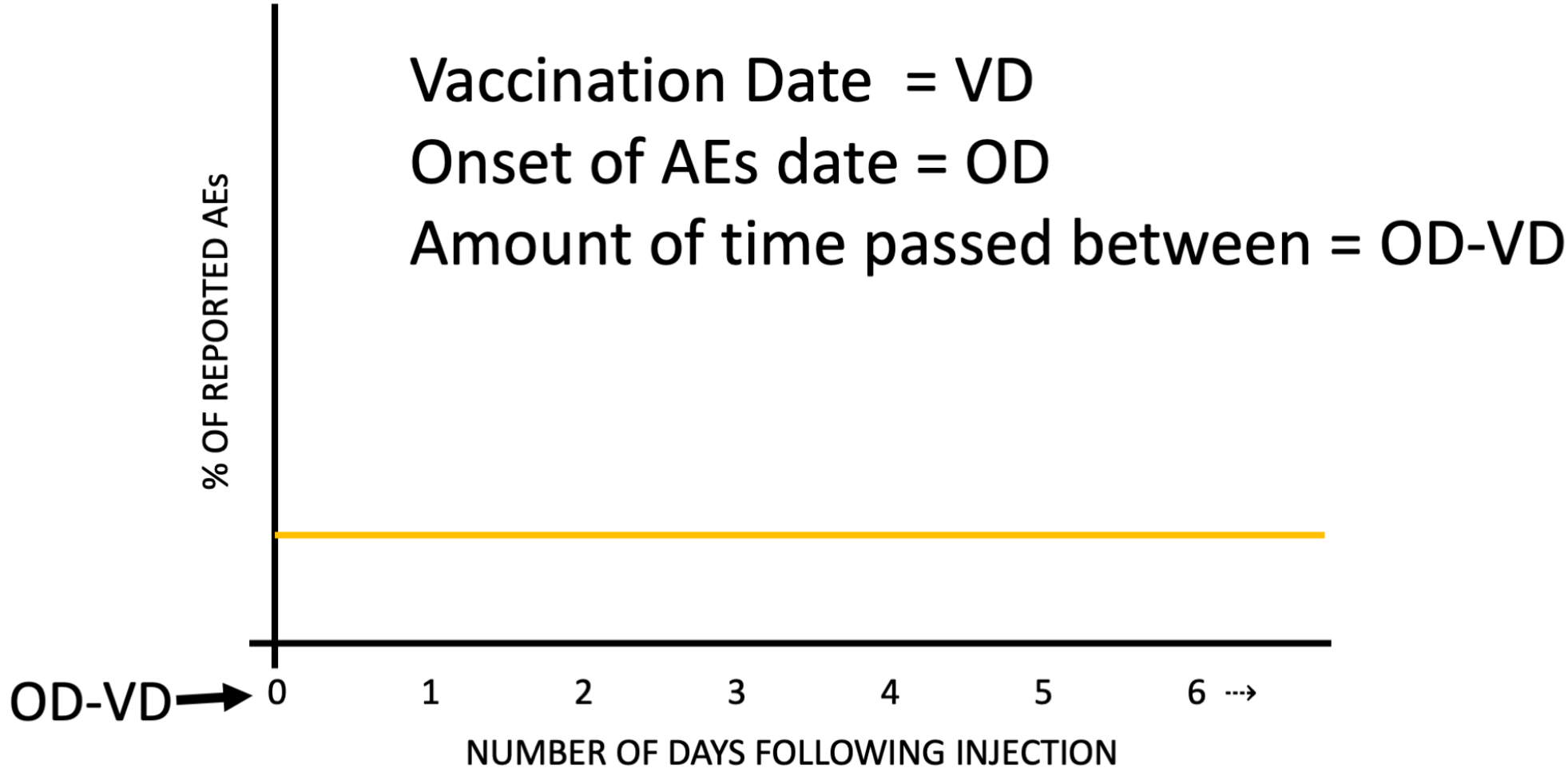
Summary



- AEs atypically high and number continue to grow
- Injection-induced injury rates increasing anew in spite of waning injections
- This is not just happening in the elderly
- The backlog of data is resulting in lost safety signals
- The URF is telling

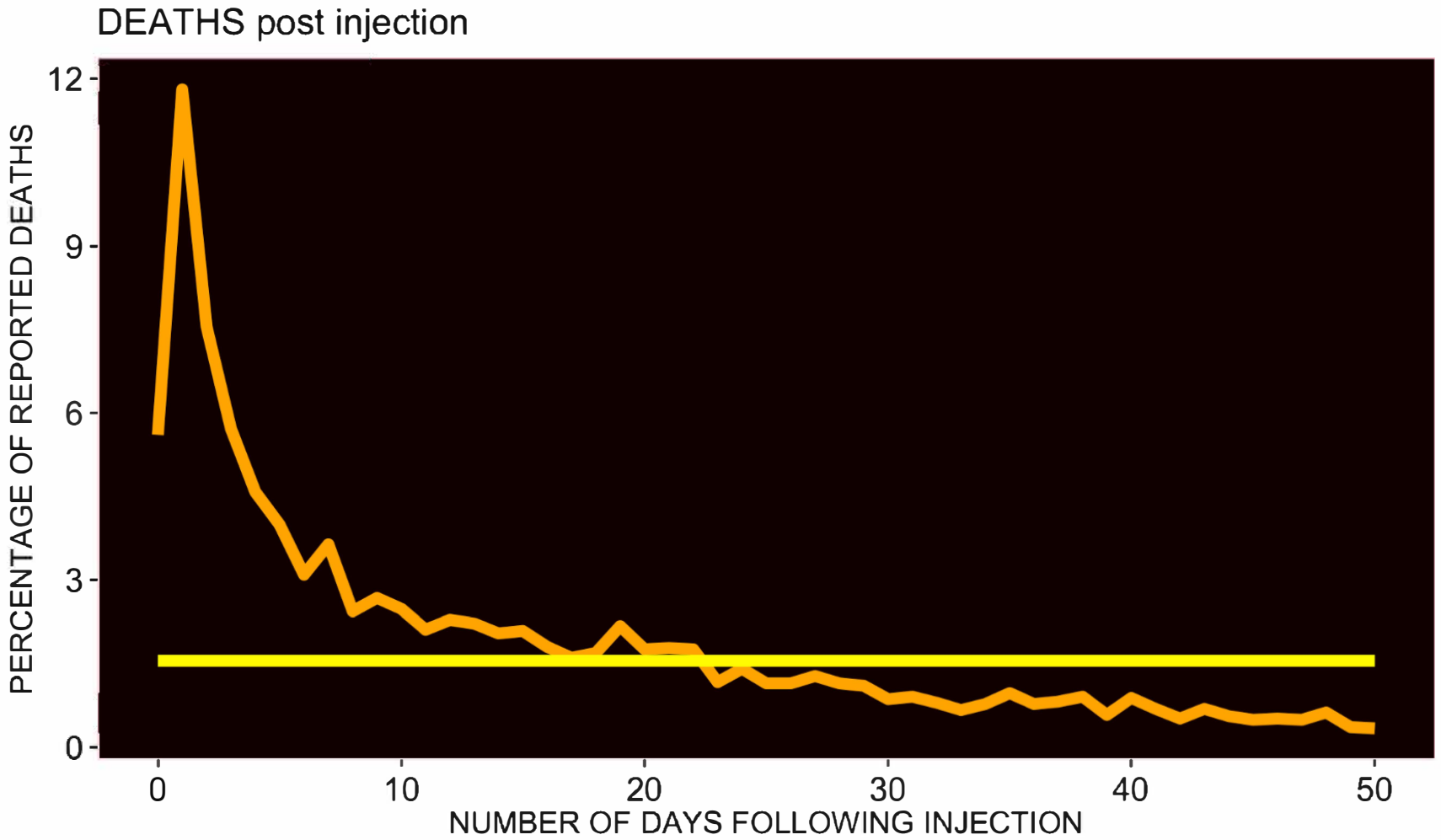
Data source: VAERS/Analysis: Dr. Jessica Rose

We would expect AEs to happen at any given point on the x-axis if no causal relationship



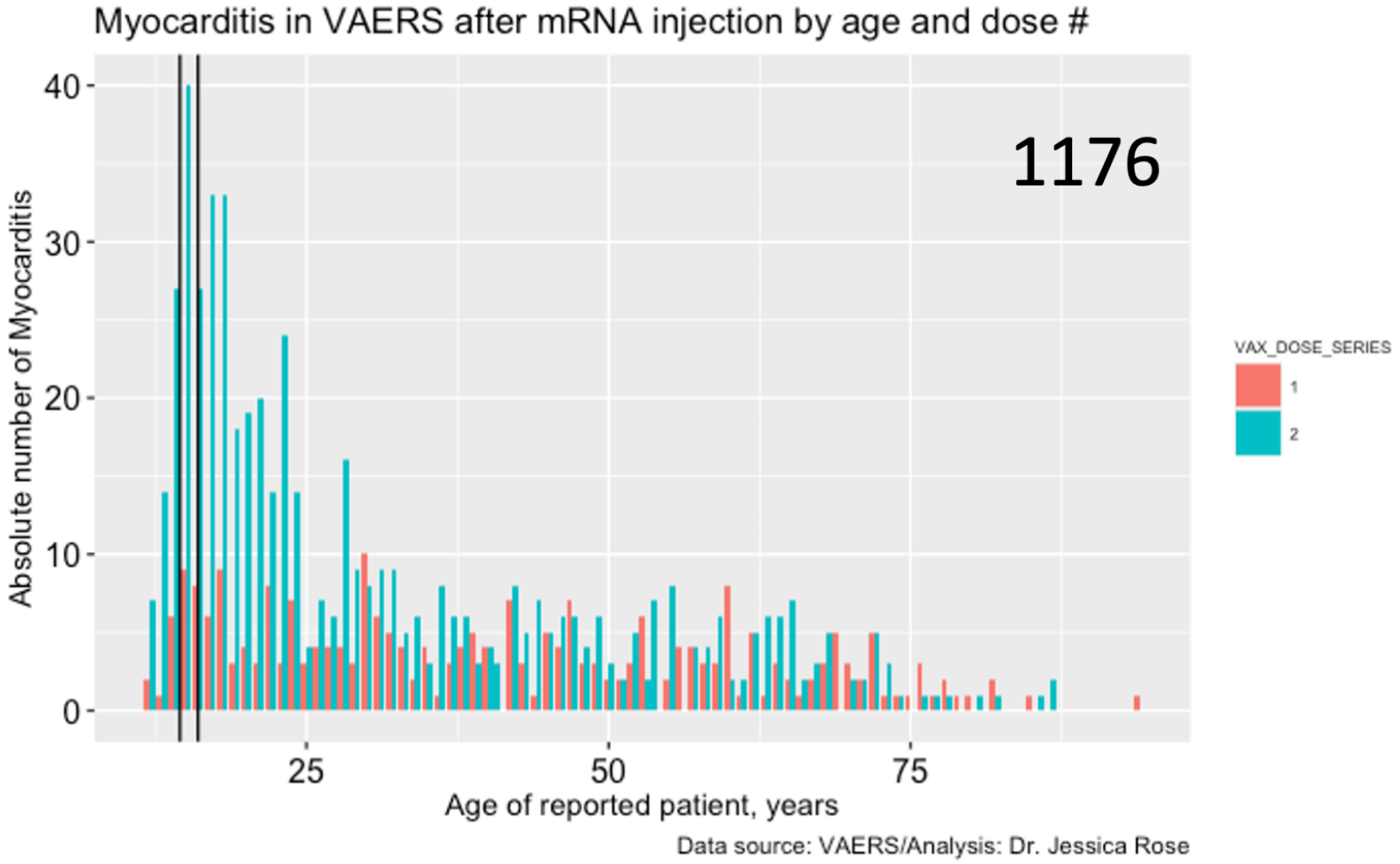
Data source: VAERS/Analysis: Dr. Jessica Rose

Evidence of causation remains from previous update…



Data source: VAERS/Analysis: Dr. Jessica Rose

Second dose frequency reporting strong evidence to support causation of Myocarditis



- 24% of reports were made within 24 hours
- 43% of reports were made within 48 hours

Data source: VAERS/Analysis: Dr. Jessica Rose

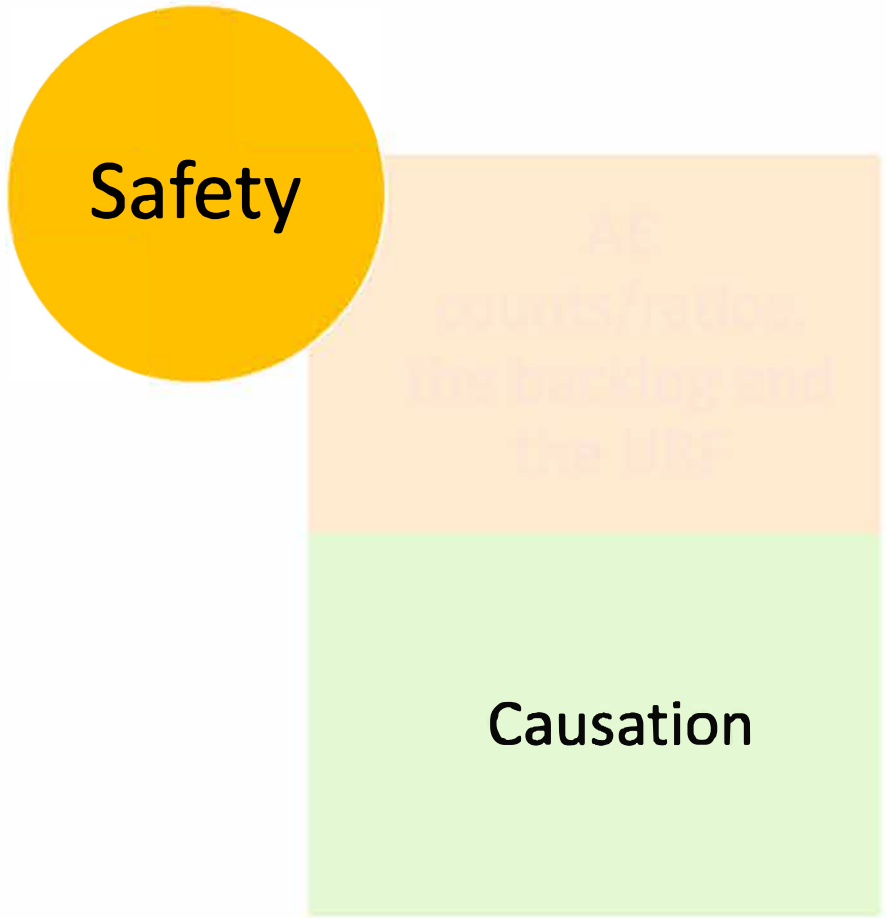
Evidence of causation remains from previous update…

Causation by Bradford Hill Criteria

1. **Strength** (effect size): A small association does not mean that there is not a causal effect, though the larger the association, the more likely that it is causal.
2. **Consistency** (reproducibility): Consistent findings observed by different persons in different places with different samples strengthens the likelihood of an effect.
3. **Specificity**: Causation is likely if there is a very specific population at a specific site and disease with no other likely explanation. The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship.[1]
4. **Temporality**: The effect has to occur after the cause (and if there is an expected delay between the cause and expected effect, then the effect must occur after that delay).
5. **Biological gradient** (dose-response relationship): Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect. In other cases, an inverse proportion is observed: greater exposure leads to lower incidence.[1]
6. **Plausibility**: A plausible mechanism between cause and effect is helpful (but Hill noted that knowledge of the mechanism is limited by current knowledge).
7. **Coherence**: Coherence between epidemiological and laboratory findings increases the likelihood of an effect. However, Hill noted that "... lack of such [laboratory] evidence cannot nullify the epidemiological effect on associations".
8. **Experiment**: "Occasionally it is possible to appeal to experimental evidence".
9. **Analogy**: The use of analogies or similarities between the observed association and any other associations.
10. **Reversibility**: If the cause is deleted then the effect should disappear as well.

Data source: VAERS/Analysis: Dr. Jessica Rose

Summary



- Large percentage of reports made within 48 hours
- Bradford Hill Criteria satisfied
- Dose 2 myocarditis reports provide further evidence of causative effect
- Autoimmune myocarditis AEs reported in the absence of COVID-19*
- 1:1 ratio between deaths and injections

Data source: VAERS/Analysis: Dr. Jessica Rose

*Chamling B, Vehof V, Drakos S, et al. Occurrence of acute infarct-like myocarditis following COVID-19 vaccination: just an accidental co-incidence or rather vaccination-associated autoimmune myocarditis? Clin Res Cardiol. 2021;1-5.

EFFICACY IS NOT THE FOCUS OF THIS PRESENTATION, YET …

Safety and efficacy called into question

Israel Confirmed Cases, July 11 – July 17 , Fully Vaccinated vs. Unvaccinated				
Age Group	Cases, Vaccinated	Cases, Unvaccinated	Percent of Cases Vaccinated	Percent of Population Vaccinated
20-29	441	124	**78%**	**79%**
30-39	481	127	**79%**	**83%**
40-49	554	113	**83%**	**86%**
50-59	366	53	**87%**	**90%**
60-69	363	33	**92%**	**91%**
70-79	236	13	**95%**	**95%**
80-89	68	8	**89%**	**94%**
קבוצת גיל	נדבקים מחוסנים	נדבקים לא מחוסנים	אחוז נדבקים מחוסנים	אחוז מחוסנים באוכלוסיה
ישראל, מקרי קורונה מאומתים, 11 ביולי עד 17 ביולי, מחוסנים לעומת לא מחוסנים				

Source: Israel Ministry of Health Dashboard
https://datadashboard.health.gov.il/COVID-19/general

Data source: Laniado Hospital Israel/MOH Israel/Analysis: Dr. Rafi Zioni