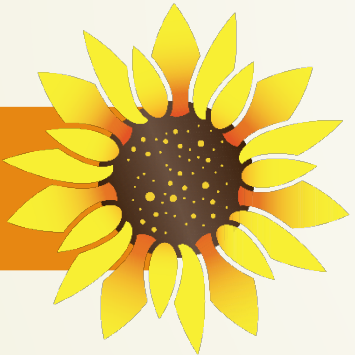
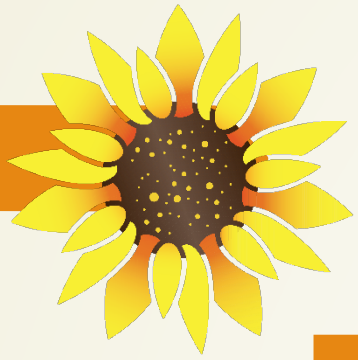


COVID-19 Vaccine Adverse Events

Josh Guetzkow, PhD

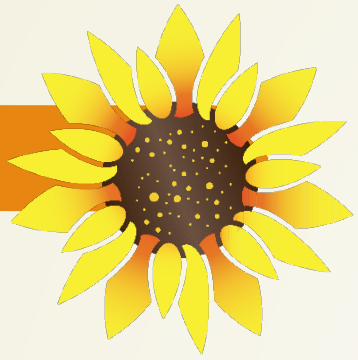
joshg99@gmail.com





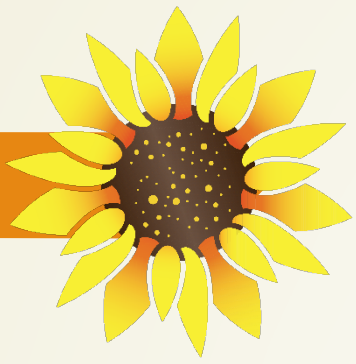
VAERS

- CDC & FDA: Vaccine Adverse Events Reporting System
- Adverse Event: Any medical problem associated with use of drug or treatment
- Adverse *Events* vs. Adverse *Reactions*
- Serious vs. Non-serious



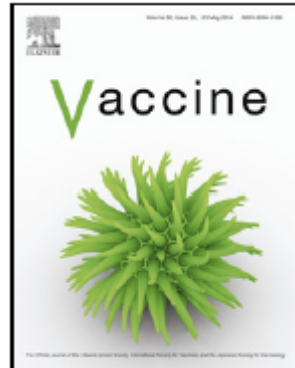
Serious AE's

- Hospitalization
- Life-threatening illness
- Permanent disability
 - Persistent/significant incapacity or substantial disruption of ability to function normally
- Congenital anomaly/birth defect
- Death



What is VAERS for?

- ▶ Goal is “signal detection”
 - ▶ Not designed to detect if vaccine *caused* adverse event
 - ▶ Identify “unusual or unexpected patterns of reporting”
- ▶ Once signal detected, follow-up study needed
- ▶ Passive – relies on people to voluntarily report



Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS)

Tom T. Shimabukuro^{a,*}, Michael Nguyen^b, David Martin^b, Frank DeStefano^a

^a Immunization Safety Office, Division of Health care Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, United States

^b Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, Food and Drug Administration, Silver Spring, MD, United States

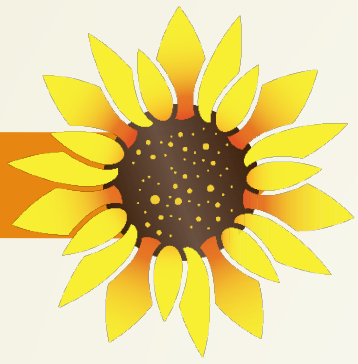
6. How do CDC and FDA analyze VAERS data?

The basic analyses of VAERS data are intended to detect concerning patterns or unusual and unexpected changes in adverse event reporting that might indicate a safety problem in a specific vaccine or vaccine type. CDC and FDA physicians, epidemiologists and statisticians assess numbers of reports, types of reports based on serious and non-serious status, the most common adverse events, current versus historical data, and reporting trends over time, such as comparisons of influenza vaccine reports across multiple consecutive influenza seasons. Analysis also includes evaluation of reporting rates of adverse events in the context of vaccine doses distributed for use in the U.S. marketplace. Vaccine doses

6.2. Disproportionality analysis

	Adverse event of interest	All other adverse events
Vaccine of interest	V_iAE_i	V_iAE_x
Comparator vaccine(s)	V_xAE_i	V_xAE_x

$$\text{Proportional reporting ratio} = \frac{V_iAE_i / (V_iAE_i + V_iAE_x)}{V_xAE_i / (V_xAE_i + V_xAE_x)}$$



Stimulated Reporting?

Comparing COVID to Flu Vaccine AE's

- What if people report more due to increased attention and fear of vaccine?
- Even so, the pattern of reports for different events should be the same as for other vaccines
 - Example: compare percentage of serious AE's
 - H1N1 in 2009 vs. regular flu vaccines
 - Compare: Flu vaccine reports (2016-2019) to COVID

Adverse events following influenza A (H1N1) 2009 monovalent vaccines reported to the Vaccine Adverse Event Reporting System, United States, October 1, 2009–January 31, 2010[☆]

Claudia Vellozzi^{a,*}, Karen R. Broder^a, Penina Haber^a, Alice Guh^a, Michael Nguyen^b, Maria Cano^a, Paige Lewis^a, Michael M. McNeil^a, Marthe Bryant^b, James Singleton^c, David Martin^b, Frank DeStefano^a

^a *Immunization Safety Office, Division of Health Care Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, United States*

^b *Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, MD, United States*

^c *Immunization Services Division, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, United States*

Vaccine 28 (2010) 7248–7255



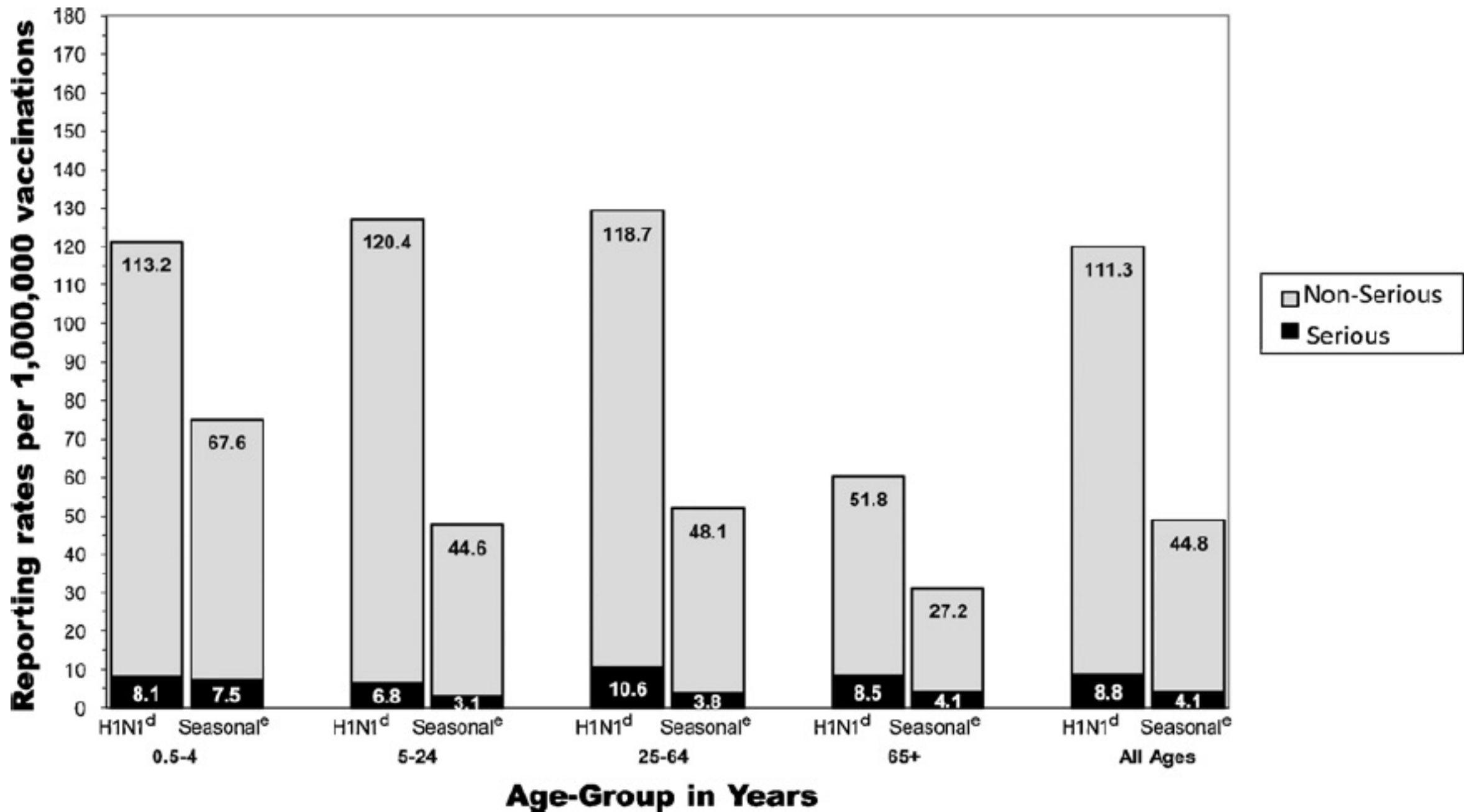


Table 2

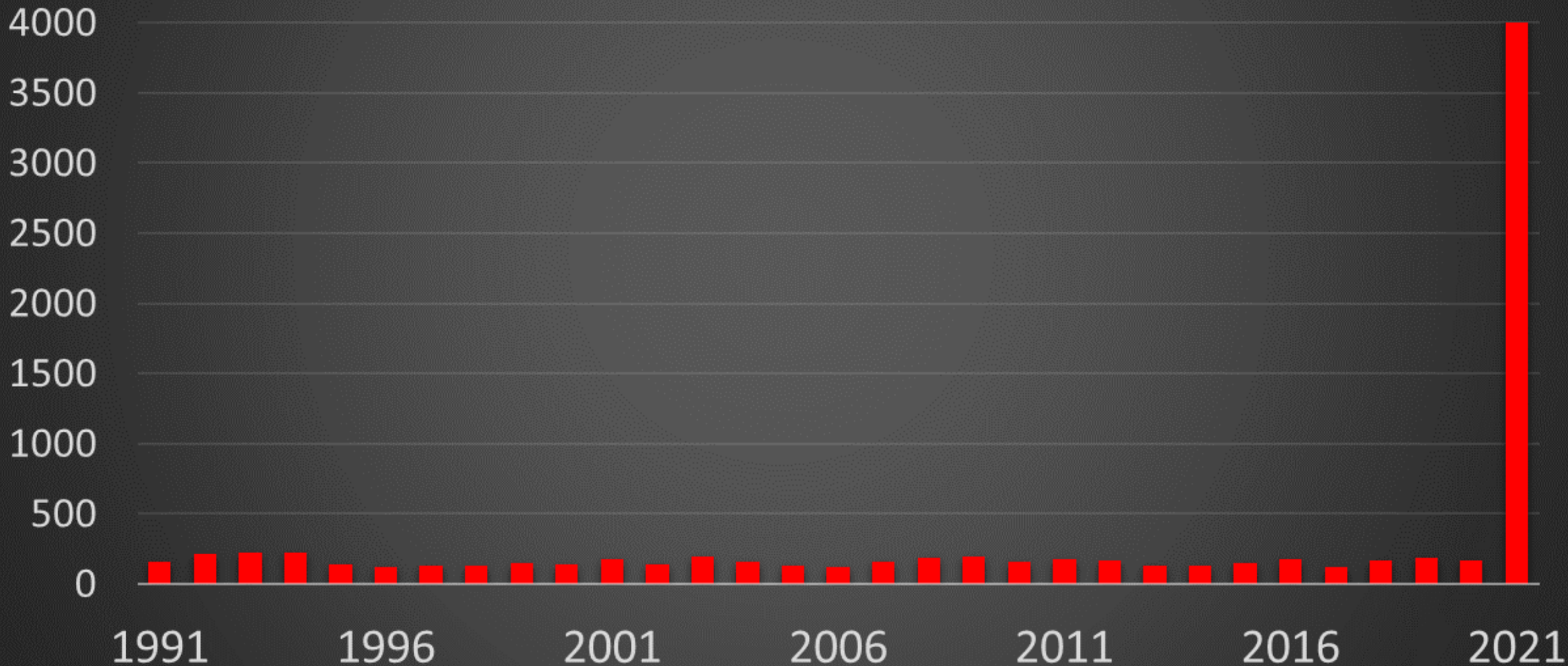
Proportion of serious and Guillain-Barré Syndrome reports received by the Vaccine Adverse Event Reporting System (VAERS) following receipt of 2009-H1N1 and seasonal influenza vaccines, by age group, July 1–March 15 for each season^a.

Influenza Season	Age 6 mo–4 y			Age 5–24 y					
	All reports	Serious ^b	GBS ^c	All reports	Serious ^b	GBS ^c			
	<i>N</i>	<i>n</i> (%)	<i>n</i> (%)	<i>N</i>	<i>n</i> (%)	<i>n</i> (%)			
2009-H1N1	1358	91 (6.7)	4 (0.3)	3415	181 (5.3)	21 (0.6)			
2009–2010	658	67 (10.2) [*]	4 (0.6)	1061	59 (5.6)	11 (1.0)			
2008–2009	661	57 (8.6)	0	848	63 (7.4) [*]	8 (0.9)			
2007–2008	623	60 (9.6) [*]	0	569	36 (6.3)	3 (0.5)			
2006–2007	444	44 (9.9) [*]	3 (0.7)	439	38 (8.7) [*]	4 (0.9)			
2005–2006	392	38 (9.7) [*]	1 (0.3)	317	28 (8.8) [*]	1 (0.3)			

	Age 25–64 y			Age ≥65 y			All Ages		
	All reports	Serious ^b	GBS ^c	All reports	Serious ^b	GBS ^c	All reports	Serious ^b	GBS ^c
	<i>N</i>	<i>n</i> (%)	<i>n</i> (%)	<i>N</i>	<i>n</i> (%)	<i>n</i> (%)	<i>N</i>	<i>n</i> (%)	<i>n</i> (%)
2009-H1N1	4599	375 (8.2)	70 (1.5)	538	76 (14.1)	27 (5.0)	9910	723 (7.30)	122 (1.23)
2009–2010	2947	208 (7.1)	62 (2.1)	829	107 (12.9)	36 (4.3)	5495	441 (8.03)	113 (2.06) [*]
2008–2009	2125	133 (6.3) [*]	20 (0.9)	652	67 (10.3) [*]	7 (1.1) [*]	4286	320 (7.47)	35 (0.82) [*]
2007–2008	1513	116 (7.7)	23 (1.5)	589	84 (14.3)	15 (2.6) [*]	3294	296 (8.99) [*]	41 (1.24)
2006–2007	1191	92 (7.7)	22 (1.9)	435	68 (15.6)	12 (2.8)	2509	242 (9.65) [*]	41 (1.63)
2005–2006	1265	106 (8.4)	19 (1.5)	518	54 (10.4)	9 (1.7) [*]	2492	226 (9.07) [*]	30 (1.20)

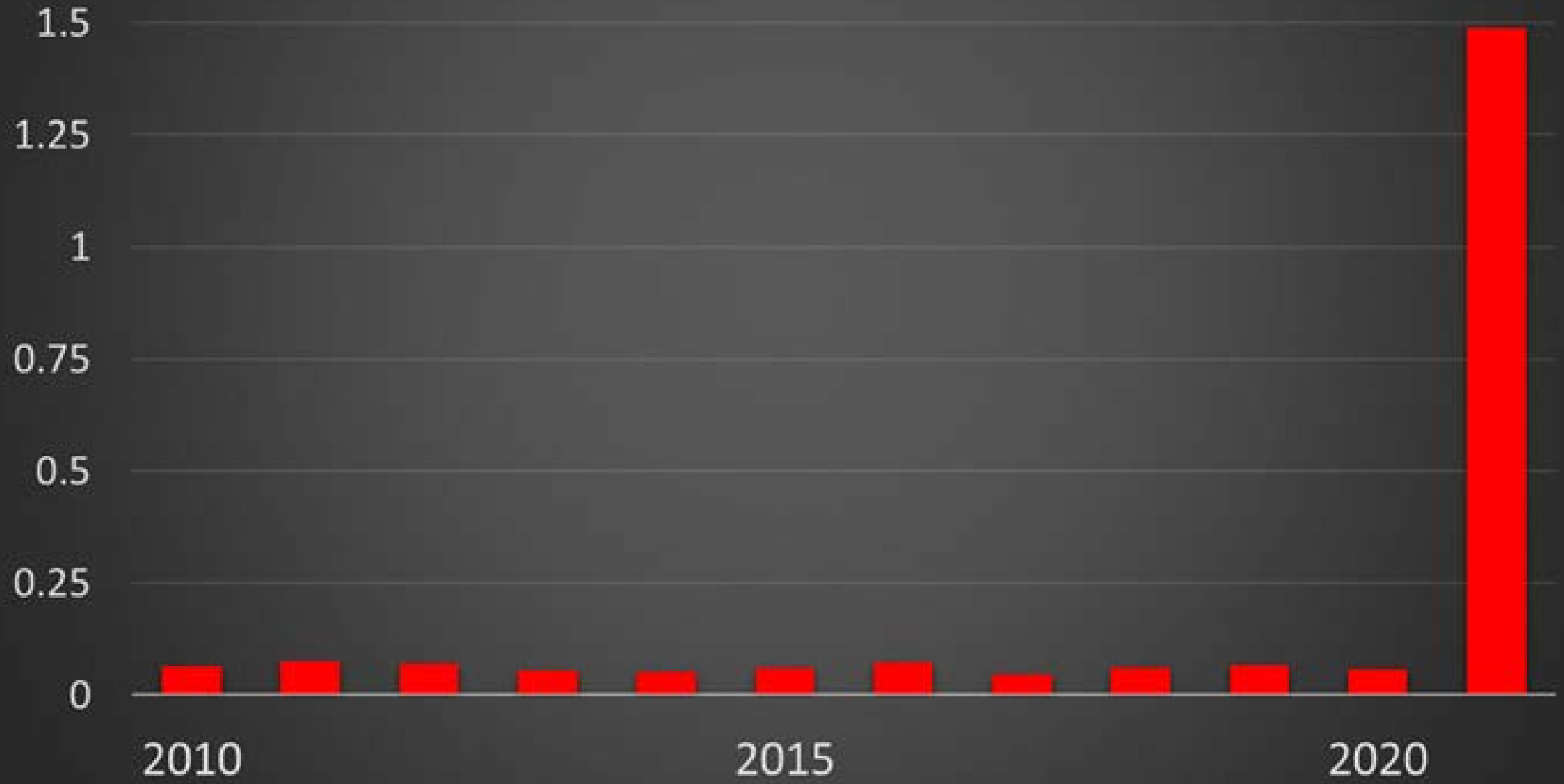
Deaths Reported to VAERS, 1991-2021

COVID Vaccine Deaths So Far in 2021 Are 50% of All Deaths & 30x Annual Average



Deaths Reported to VAERS per 100,000 Vaccine Doses

Annual Average 2010-2020: 0.06 Covid Vaccines: 1.5 =24x Annual Average



Adverse Events Reported to VAERS per Vaccine Dose: COVID-19 vs. Flu Vaccines

	Per 100,000 Doses		Relative
	COVID-19	Flu	Difference
Serious	9.1	0.3	30x
Not Serious	109	5.8	19x
Death	1.5	0.02	82x
Disability	1.5	0.08	19x
Emergency Room	16	1.1	14x
Hospitalized	6.6	0.22	30x
Life Threatening	1.9	0.06	31x
Blood Clot Related Events	0.3	0.04	7x
Myocardial Infarction	0.7	0.06	12x

Note: Adverse events and doses for flu vaccines based on 2016, 2017 & 2018 flu seasons.

COVID-19 vs. Flu Vaccines: Adverse Events Reported per 100,000 Vaccine Doses

Ages	ALL EVENTS			SERIOUS EVENTS			DEATHS		
	COVID-19	Flu	Relative Difference	COVID-19	Flu	Relative Difference	COVID-19	Flu	Relative Difference
Age 10-17	92.77	3.10	30x	5.01	0.11	47x	0.09	0.001	84x
Age 18-49	140.69	4.93	29x	6.05	0.23	27x	0.27	0.004	62x
Age 50-64	122.14	4.36	28x	8.66	0.20	43x	0.93	0.005	197x
Age 65+	99.43	8.62	12x	16.25	0.41	40x	4.17	0.028	149x
All Ages	122.37	5.43	23x	9.48	0.25	38x	1.51	0.010	154x

Note: Flu reporting rates represent the average reporting rate to VAERS across the 2015-2019 flu seasons for each age group. Covid-19 reporting rates include all reports to VAERS for COVID-19 vaccines for each age group. Annual vaccine doses estimated using data from the CDC and the US Census Bureau. Relative difference is the ratio of COVID-19 reporting rates to the average flu reporting rate across the 2015-2019 flu seasons.

COVID-19 vs. Flu Vaccines: Proportion of Serious Adverse Events and Deaths

Ages	Reports (N)		SERIOUS EVENTS			DEATHS		
	COVID-19	Flu	Proportion		Relative Difference	Proportion		Relative Difference
			COVID-19	Flu		COVID-19	Flu	
Age 10-17	12,868	519	0.054	0.035	1.5x	0.0010	0.0004	2.8x
Age 18-49	18,2533	2,219	0.043	0.046	0.9x	0.0019	0.0009	2.1x
Age 50-64	98,759	1,789	0.071	0.046	1.6x	0.0076	0.0011	6.8x
Age 65+	84,384	2,816	0.163	0.046	3.4x	0.0419	0.0034	12.5x
All Ages	36,5676	7,342	0.077	0.048	1.6X	0.0123	0.0033	3.71x

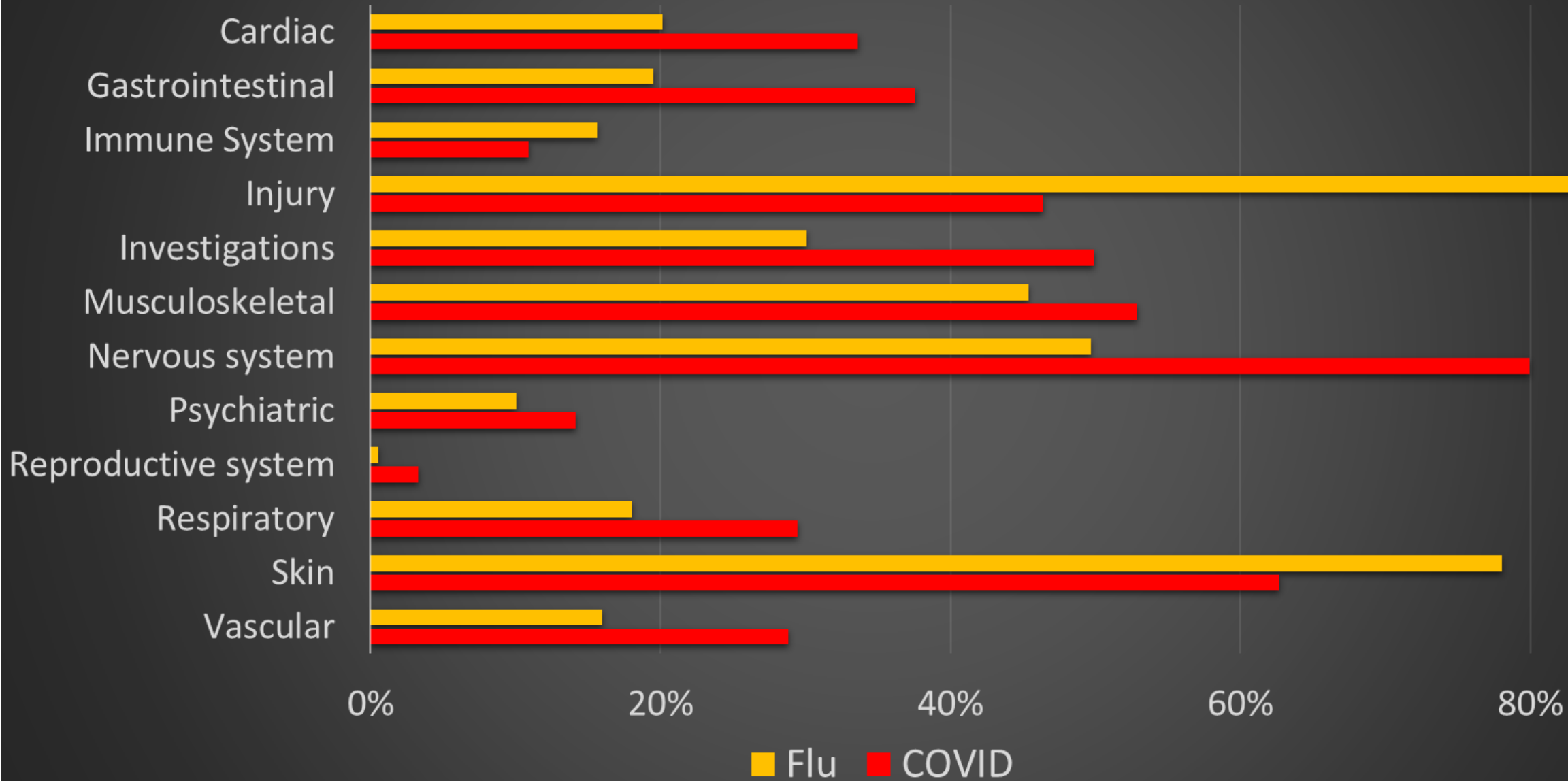
Note: Flu estimates represent the average reporting rate to VAERS across the 2015-2019 flu seasons for each age group. Covid-19 reporting rates include all reports to VAERS for COVID-19 vaccines for each age group. Vaccine doses estimated using CDC and the US Census data.

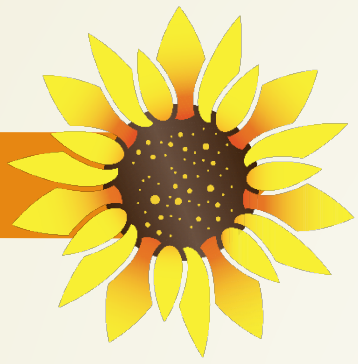
Proportion of Serious AEs and Deaths Reported for COVID-19 and Flu Vaccines

	Age 10-17 Years					Age 18-49 Years				
	All Report Serious			Deaths		All Report Serious			Deaths	
	N	N	%	N	%	N	N	%	N	%
COVID-19	12868	695	5.4	13	0.1	182533	7846	4.3	355	0.19
Flu 2015-16	439	25	5.7	0	0.0	2368	105	4.4	0	0.00*
Flu 2016-17	477	25	5.2	0	0.0	2302	110	4.8	2	0.09
Flu 2017-18	533	19	3.6	0	0.0	2238	103	4.6	3	0.13
Flu 2018-19	585	1	0.2*	0	0.0	2284	109	4.8	2	0.09
Flu 2019-20	560	17	3.0*	1	0.2	1903	82	4.3	3	0.16

	Age 50-64 Years					Age 65+ Years					All Ages (10+)				
	All Report Serious			Deaths		All Report Serious			Deaths		All Report Serious			Deaths	
	N	N	%	N	%	N	N	%	N	%	N	N	%	N	%
COVID-19	98759	7001	7.1	754	0.8	84384	13788	16.3	3539	4.2	378544	29330	7.7	4661	1.2
Flu 2015-16	1813	78	4.3*	0	0.0*	2483	143	5.8*	12	0.5*	7103	351	4.9*	12	0.2*
Flu 2016-17	1851	84	4.5*	6	0.3*	2826	128	4.5*	10	0.4*	7456	347	4.7*	18	0.2*
Flu 2017-18	1840	79	4.3*	0	0.0*	3201	139	4.3*	7	0.2*	7812	340	4.4*	10	0.1*
Flu 2018-19	1905	98	5.1*	2	0.1*	3053	138	4.5*	8	0.3*	7827	346	4.4*	12	0.2*
Flu 2019-20	1530	71	4.6*	2	0.1*	2633	127	4.8*	9	0.3*	6626	297	4.5*	15	0.2*

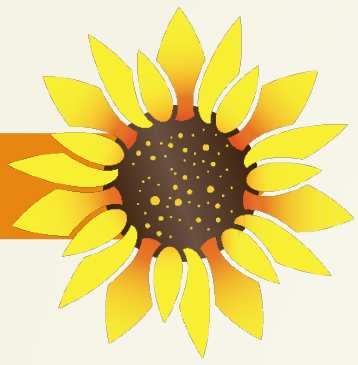
COVID vs. Flu Vaccine Reporting Comparison for Selected Reaction Groups





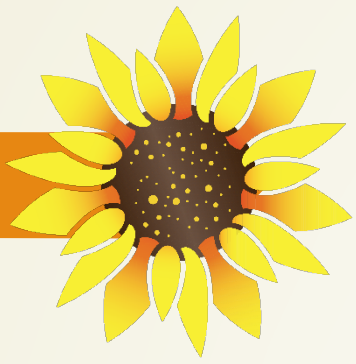
Adverse Event Underreporting: *Pharmaceutical Drugs*

- Meta-analysis: average underreporting rate 94% (80% for serious AE's)
- Former FDA commissioner cites study showing 1% of serious AE's reported



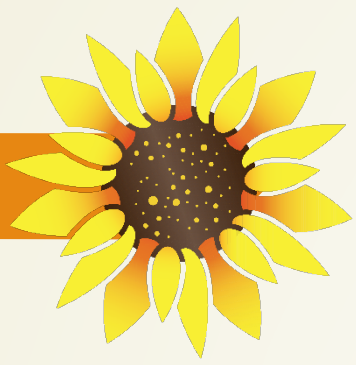
Adverse Event Underreporting: *Vaccines*

- HMO grant report: less than 1% of vaccine adverse events reported
- Study: Vaccine AE reporting 30x higher after partially automated system
- CDC: Underreporting for anaphylaxis and Guillain-Barré Syndrome (GBS)
 - Anaphylaxis: 13-25% of events reported (76% for H1N1)
 - GBS: 12-64% of events reported



COVID-19 Vaccine Underreporting

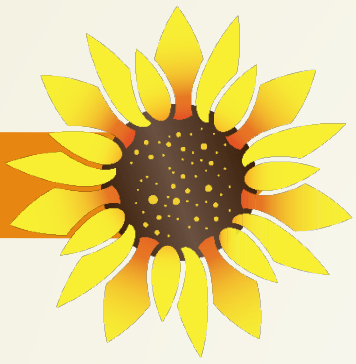
- ▶ Anaphylaxis: Life-threatening allergic reaction
- ▶ JAMA Mass General Employees: 2.5 per 10,000
- ▶ CDC estimate based on VAERS: .02 - .05 per 10,000
- ▶ Underreporting Rate for Anaphylaxis: 2% to 0.8%
- ▶ True Number of Cases of Anaphylaxis: 50x to 125x



Adverse Events Reported to VAERS

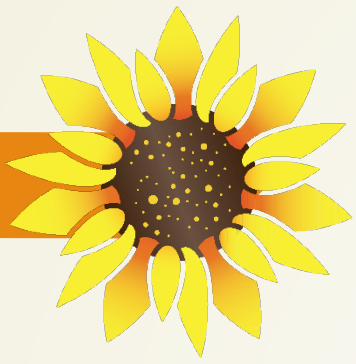
	<u>Total</u>	<u>x50</u>	<u>x125</u>
➤ Total Cases	384,270	19,213,500	48,033,750
➤ Total Events	1,667,140	83,357,000	208,392,500
➤ Serious AE's	29,583	1,479,150	3,697,875
➤ Hospitalization	21,440	1,072,000	2,680,000
➤ Life Threatening	6,299	314,950	787,375
➤ Permanent Disability	4,996	249,800	624,500
➤ Deaths	4,812	240,600	601,500

Note: Includes reports from U.S. state & territories and unknown locations only.



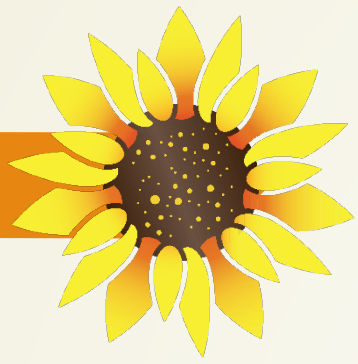
History of Harms Caused by Approved Vaccines

- ▶ 1955 The Cutter Incident
 - ▶ 120,000 polio vaccine doses with live polio
- ▶ 1976 Swine Flu vaccination stopped after 25 *reported* deaths and 362 cases of Guillain-Barré syndrome
- ▶ 1987 Canada withdrew Trivirix MMR vaccine due to association with aseptic meningitis



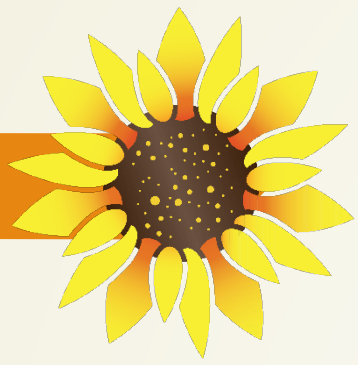
History of Harms Caused by Approved Vaccines

- ▶ 1998 Rotavirus vaccine – suspended after 15 cases of intussusception were reported
- ▶ 2009 “swine flu” vaccine withdrawn due to narcolepsy
 - ▶ At least 800 children; UK payed out \$60 USD
- ▶ 2015 Denguevax – higher risk of severe infection
 - ▶ Philippine DOJ filed charges for “reckless imprudence resulting in homicide” alleging knowledge of risks



Next Steps

- Standardize reporting dates/years across analyses
- Exclude (verified) coronavirus cases
- Conduct 'disproportionality analysis' for all AE's
- Compare AE rates first vs. second dose
- Compare AE rates across COVID-19 vaccines
- Gender & Also menstrual / vaginal bleeding AEs



Blood Clot Related Events after COVID Vaccines

- Reports of “rare” type of blood clot after Astrazeneca and J&J vaccine
- TTS & TTP: blood clots with low platelets
- 3 countries suspended Astrazeneca vaccine
- US: Suspended J&J vaccine after 6 reports

Thrombotic Thrombocytopenic Purpura (TTP) Events Reported Following COVID-19 Vaccinations

US VAERS			EU EUDRAVIGILANCE				UK YELLOW CARD	
Pfizer	Moderna	J&J	Pfizer	Moderna	Astrazeneca	J&J	Pfizer	Astrazeneca
10	5	2	9	0	5	2	5	1

Embolic and Thrombotic Related Adverse Events Reported Following COVID-19 Vaccinations by Vaccine and Reporting System as of May 8, 2021

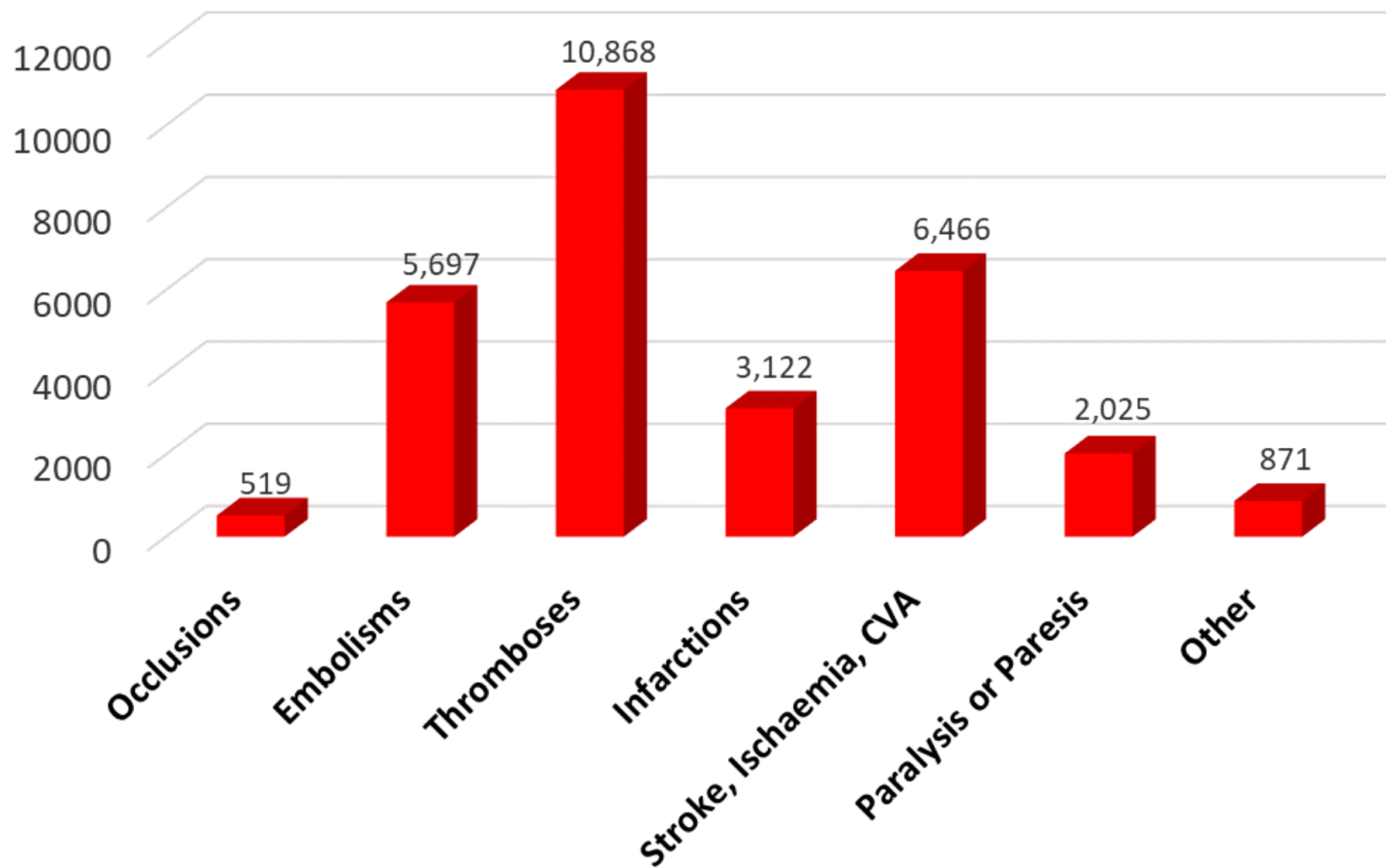
Type	US VAERS			EU EUDRAVIGILANCE				UK YELLOW CARD	
	Pfizer	Moderna	J&J	Pfizer	Moderna	Astrazeneca	J&J	Pfizer	Astrazeneca
Occlusions	71	49	57	104	38	118	19	14	49
Embolisms	325	361	277	1,137	292	1,745	156	234	1,154
Thromboses	759	502	886	1,830	379	3,824	404	301	1,965
Infarctions	351	310	120	785	257	707	78	144	369
Stroke, Ischaemia, CVA	578	613	233	1,519	489	1,451	160	312	1,099
Paralysis or Paresis	182	194	95	503	164	468	54	93	268
Other	155	129	192	85	33	141	67	14	54
TOTAL	2,421	2,158	1,860	5,963	1,652	8,454	938	1,112	4,958

Total Events: 29,568

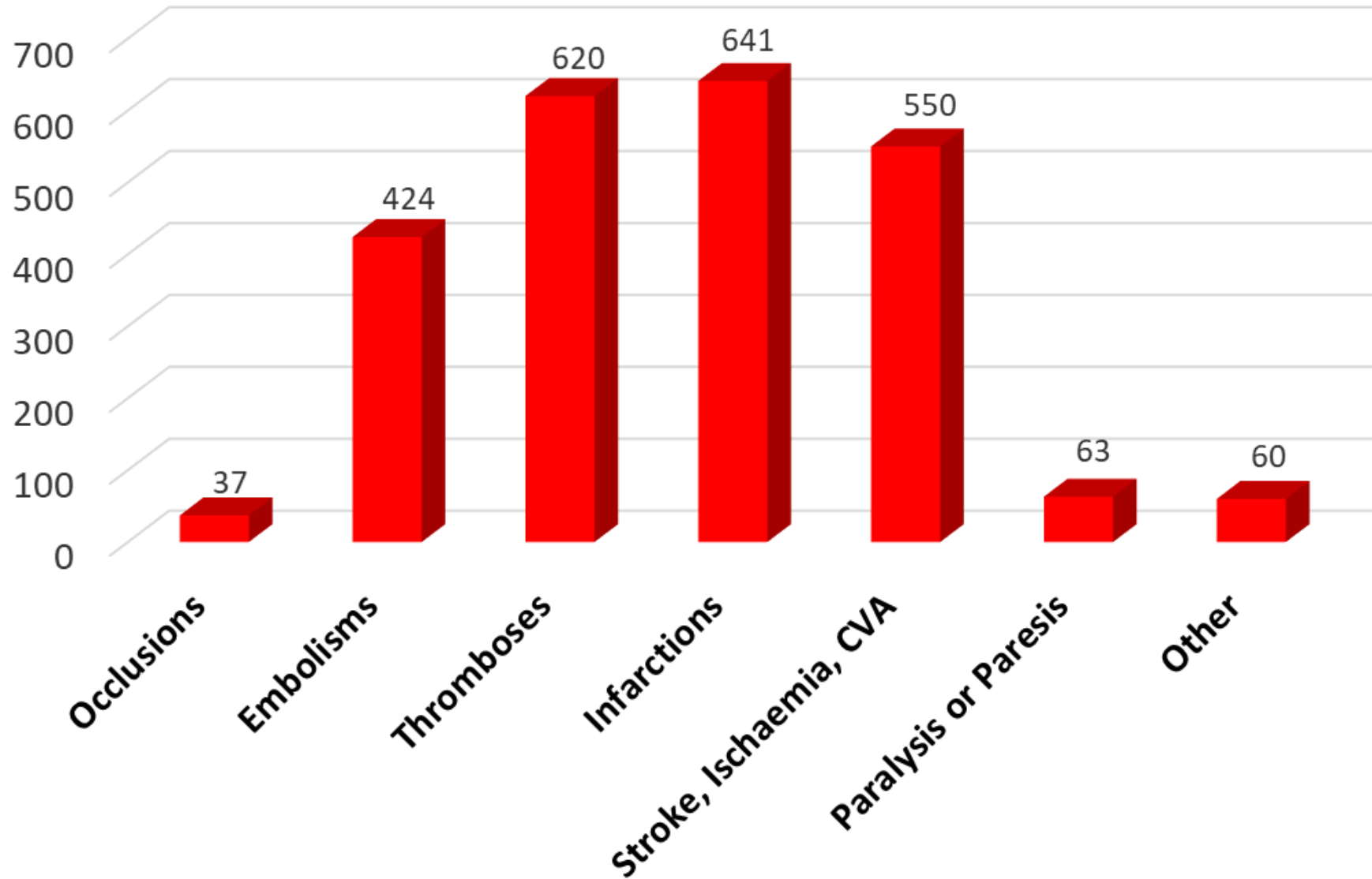
Total Deaths: 2,395

Embotic & Thrombotic Related Adverse Events Reported Following COVID-19 Vaccinations in the US, EU and UK

(Total Events = 29,568)



Deaths Associated with Embolic & Thrombotic Adverse Events Following COVID-19 Vaccinations in the US, EU and UK (Total Deaths = 2,395)

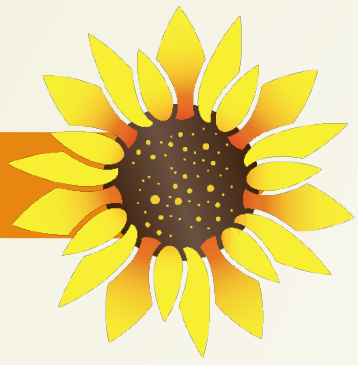




Most Serious Clotting Events Reported

(US, EU and UK Reports Combined)

EVENT CLASSIFICATION	EVENTS	DEATHS
Myocardial infarction (heart attack)	2108	545
Pulmonary embolism	4856	388
Cerebrovascular accident	3792	364
Thrombosis	3813	194
Venous thrombosis (limb and general)	326	105
Ischaemic stroke	764	65
Deep vein thrombosis	3415	50
Cerebral venous sinus thrombosis	439	46
Cerebral infarction	463	39
Cerebral thrombosis	196	36
Disseminated intravascular coagulation	98	29
Pulmonary thrombosis	249	24
Embolism	591	17
Cerebral venous thrombosis	107	15
Ischaemic cerebral infarction	84	9
Embolic stroke	89	6



Why Would COVID Vaccines Cause Blood Clots?

Spike Protein:

- Present in blood up to a month after vaccination
- By itself can activate platelets and promote clotting
- By itself penetrates the blood-brain barrier
- Has been found in cerebral tissue with micro-thromboses
- By itself can damage the lungs

Popular Tamil Actor, Comedian Vivekh, Dies In Chennai At 59

(One day after vaccination.)

On Thursday, Vivekh had taken his first Covid vaccine shot at a public event in the presence of Tamil Nadu's Health Secretary to promote vaccination.

Tamil Nadu | Written by Uma Sudhir | Updated: April 17, 2021 1:25 pm IST

NDTV



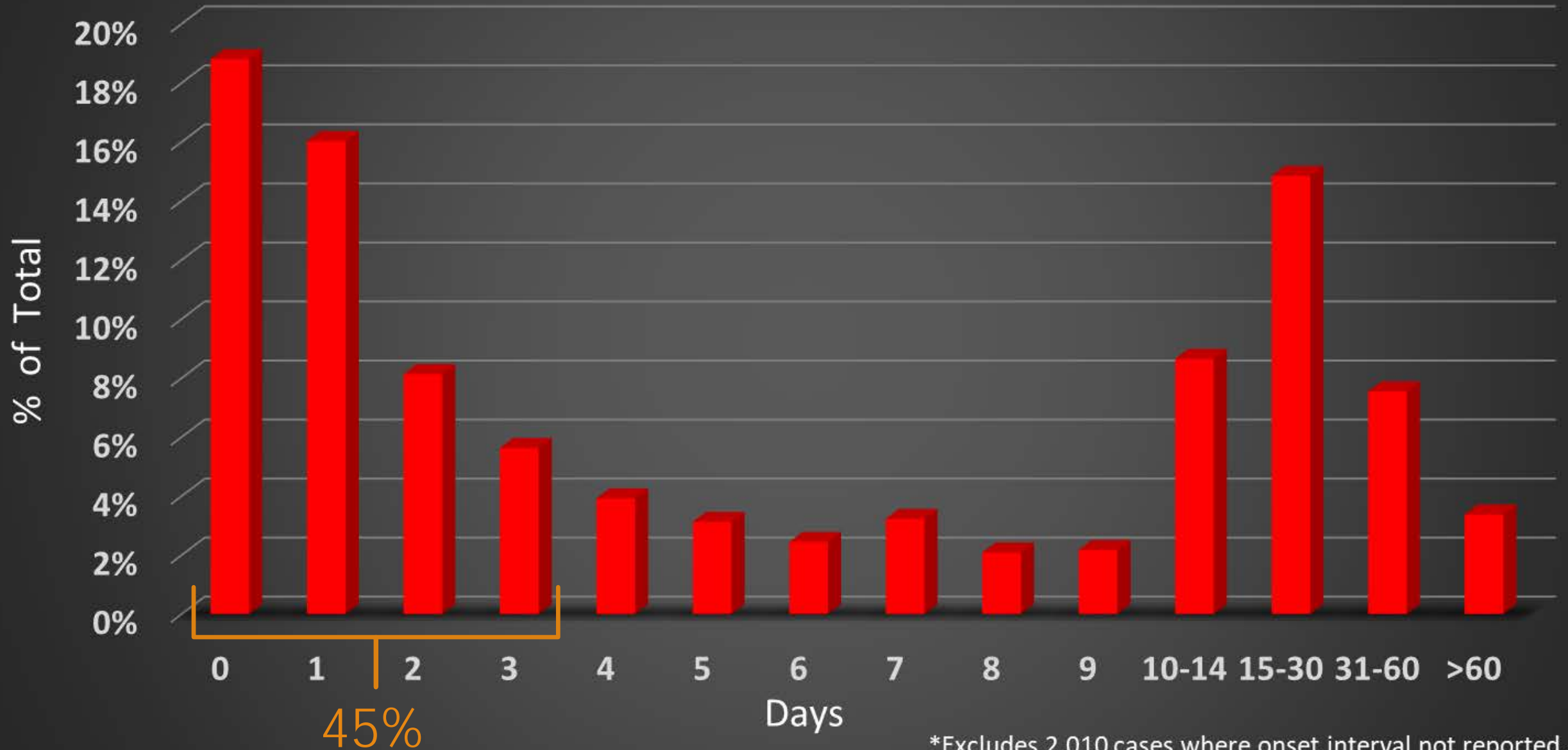
Chennai: Popular Tamil actor and comedian Vivekh died this morning in the hospital, hours after he was admitted after a cardiac arrest.

The 59-year-old was reportedly critical in a Chennai hospital after a cardiac arrest on Thursday morning. He was brought in unconscious at 11 am, was resuscitated, subsequently underwent a coronary angiogram and then angioplasty. A medical bulletin said he was critical on ECMO support, which pumps and oxygenates blood outside the body, but died at 4:35 am today.

On Thursday, Vivekh had taken his first Covid vaccine shot at a public event in the presence of Tamil Nadu's Health Secretary to promote vaccination.

The hospital clarified that he suffered an acute coronary syndrome with cardiogenic shock. There was 100 per cent blockage in a vessel and his cardiac arrest may not be due to the vaccination.

Days Since Vaccination that Serious Event Occurred - VAERS



*Excludes 2,010 cases where onset interval not reported.

Serious Adverse Events Reported to VAERS, 1991-2021

COVID Vaccine Serious AE's So Far in 2021 Are 36% of All Serious AE's & 17x Annual Average

