Food & Drug Administration (FDA) Leaked 10/22/20 Committee Documents

Leaked FDA committee document from 10/22/20. Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation.

Here is the FDA meeting info. It acknowledges that Vaccine Adverse Event Reporting System (VAERS) will be used as a respected source of passive data for follow-up of adverse events from the Covid shots. FDA will also regularly watch the active data from the CMS (Medicare/ Medicaid) database on about 15% of Americans.

Slide 6 – FDA and CDC will co-manage VAERS

Slide 7 – FDA and CDC will have biweekly pharmaco-vigilance meetings to coordinate

Slide 14 – We see here partnership between FDA and CMS, with access to claims and medical charts. 55 million seniors – 92% of U.S. elderly.

Slide 16 – FDA plans on monitoring 10 -20 safety outcomes of interest to be determined based on – among other things – pre-market review of manufacturer safety data submitted to FDA. FDA plans to use CMS data in near real time.

Slide 17 shows adverse events FDA would be alert to! Death, pregnancy and birth outcomes, auto-immune disease, stroke, blood clots, seizures and much more.

Slides 24 & 25 – show the FDA would coordinate its COVID-19 vaccine safety and effectiveness monitoring efforts with other government agencies including near real time surveillance of DOD data, working with CDC and CMS.

https://files.elfsightcdn.com/5266f37f-1e60-4e3b-9202-0f9e41473266/cb5fffe1-e41e-4915-8655-8cd3426b982a.pdf

U.S. FOOD & DRUG ADMINISTRATION

CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness

Steve Anderson, PhD, MPP
Director, Office of Biostatistics & Epidemiology, CBER

VRBPAC Meeting
October 22, 2020

FDA Vaccine Surveillance: Pre-licensure Pharmacovigilance Planning

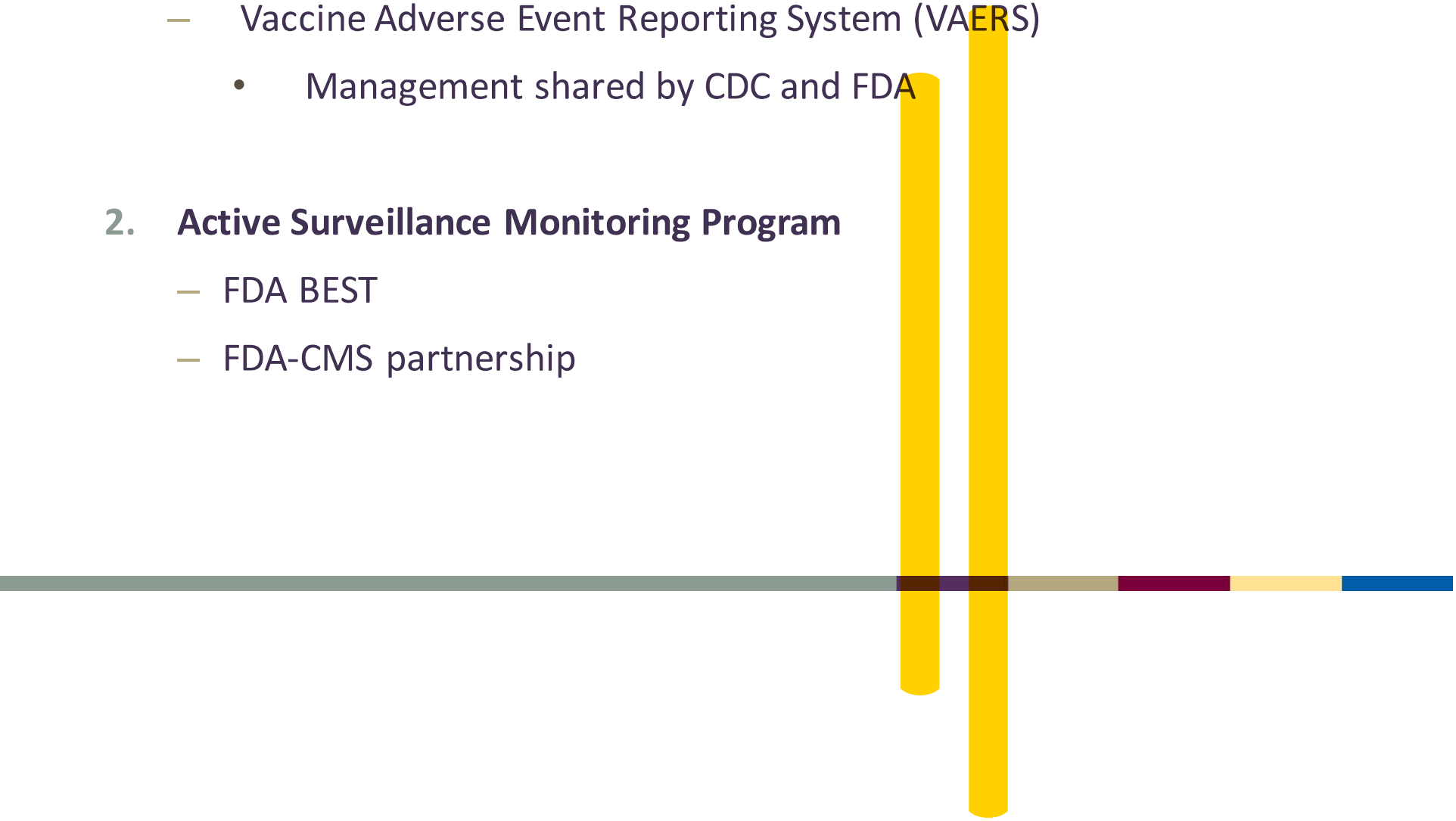
"Safety throughout the lifecycle" approach for vaccines (pre- and post-licensure):

- Manufacturer submits pharmacovigilance plans (PVP) of proposed post-licensure surveillance activities
  - Submitted for BLA and for EUA
  - Post-licensure commitment (PMC) – studies, registries for general safety concern
  - Post-licensure requirement (PMR) – clinical study, epidemiological study, registries, etc. to verify a specific safety signal
  - Routine pharmacovigilance – Passive surveillance (VAERS), review of safety literature, available studies, etc.

FDA Vaccine Surveillance Programs: Post-Licensure

1. **Passive Surveillance of Vaccines**
   - Vaccine Adverse Event Reporting System (VAERS)
     - Management shared by CDC and FDA

2. **Active Surveillance Monitoring Program**
   - FDA BEST
   - FDA-CMS partnership



VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

CDC + FDA

http://vaers.hhs.gov

VAERS – FDA CBER Efforts

- CDC presentation covered VAERS so will provide summary of FDA efforts
- **FDA and CDC have weekly and bi-weekly coordination meetings** on VAERS and Pharmacovigilance activities between CBER OBE and OBE Division of Epidemiology (DE) and CDC Immunization Safety Office
- **CBER DE Physicians will be reviewing the serious adverse event reports** from VAERS for COVID-19 vaccines – review of individual reports, death reports, conduct aggregate analyses, case-series, etc.
- **FDA will utilize statistical data-mining methods** to detect disproportional reporting of specific vaccine-adverse event combinations to identify AEs that are more frequently reported

2. CMS (Center for Medicare & Medicaid Services)

- **Federal Partners**
  - Ongoing FDA-CMS partnership on vaccine safety since 2002
  - Data cover very large population of approximately 55 million elderly US beneficiaries ≥65yrs of age
  - >92% of US elderly use Medicare so database represents the elderly population and not a sample
  - Represents variety of healthcare settings – inpatient, outpatient, etc.
  - Consists of claims data with access to medical charts

FDA COVID-19 vaccine safety surveillance planning

"Near real-time surveillance" or rapid-cycle analyses (RCA)

- FDA plans on monitoring 10 -20 safety outcomes of interest to be determined based on:
  - Pre-market review of sponsor safety data submitted to FDA
  - In coordination with federal partners, international regulatory partners and organizations, academic experts, others
  - Literature and regulatory experience with similar vaccines, novel vaccine platforms, and using other relevant data
  - FDA plans on using CMS data for COVID-19 vaccine RCA – near real time with efforts

FDA Safety Surveillance of COVID-19 Vaccines :

DRAFT Working list of possible adverse event outcomes

Subject to change

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

US Government-wide Efforts
COVID-19 Vaccine Monitoring

Large US Government Effort

FDA Coordinating its COVID-19 vaccine safety and effectiveness monitoring efforts with other government agencies:

- Centers for Disease Control (CDC)
- Centers for Medicare& Medicaid Services (CMS)
- Veterans Administration (VA)
- National Institutes of Health
- Department of Defense
- Indian Health Services

US Government-wide Efforts
COVID-19 Vaccine Monitoring (2)

Large US Government Effort

- Weekly meetings between FDA and CDC, regular meetings with VA and CMS
- Planned sharing of protocols, discussion safety and effectiveness outcomes of interest
- Coordinated planning and conduct of surveillance activities such as near real time surveillance/ RCA between FDA, CDC, CMS, VA, and DOD

Documents Finally Released March 2022 due to Freedom of Information Act Suit

Various requests were refused to make public all of the FDA safety data from Pfizer's COVID-19 vaccine biological product file from December 2020 to February 28, 2021

https://news.bloomberglaw.com/health-law-and-business/why-a-judge-ordered-fda-to-release-covid-19-vaccine-data-pronto

Then in September, a large group of doctors and scientists calling themselves Public Health and Medical Professionals for Transparency submitted a Freedom of Information Act (FOIA) Request. They said this data should be made publicly available to allow independent experts to conduct their own review and analyses. They had to sue the FDA to release the data. The court ordered the FDA to release the data, allowing for a gradual release. So FDA released a little in December 2021, then went back to court along with Pfizer, to request that FDA be given 75 years to spread out the release of the data.

Here is what raised a red flag for us: they are acting scared of our knowing the safety data, and want no one to know until we are all dead.
Glad to say the judge ordered release this year, starting this month.

Health Law & Business

Why a Judge Ordered FDA to Release Covid-19 Vaccine Data Pronto

By Aaron Siri

Jan. 18, 2022, 1:00 AM

A group of scientists and medical researchers sued the FDA under FOIA to force release of hundreds of thousands of documents related to licensing of the Pfizer-BioNTech Covid-19 vaccine. Plaintiff's attorney Aaron Siri, who is representing the group, explains the fight that led a federal court to order expedited release of documents the agency claimed it would take decades to process.

In response to a Freedom of Information Act request, the Food and Drug Administration asked a federal judge for permission to make the public wait until the year 2096 to disclose all of the data it relied upon to license Pfizer's Covid-19 vaccine.

That is not a typo. The FDA wanted court approval to have up to 75 years to publicly disclose this information.

In its attempts to build public support for Covid-19 vaccinations, the FDA repeatedly promised "full transparency," and reaffirmed its "commitment to transparency" when licensing Pfizer's Covid-19 vaccine.

With that promise in mind, after the vaccine's licensure in August 2020, Public Health and Medical Professionals for Transparency, a group of highly credentialed scientists submitted a FOIA request to the FDA for the data submitted by Pfizer. The scientists explained that, until all the data is produced, a proper review cannot be conducted because missing even a single data set could throw off any analysis.

In response, the FDA produced nothing. Therefore, in September 2021, the scientists, represented by their attorneys at Siri & Glimstad, sued the FDA demanding it produce this data by March 2022.

The agency originally estimated it would need to produce 329,000 pages, and asked the court for permission to produce just 500 pages per month, which would have taken 55 years. In its final brief to the Court, the FDA admitted that the total page count was at least 451,000, but still sought permission to produce just 500 pages per month. Meaning that it could have taken 75 years, when most Americans alive today would be dead, to fully publicly disclose this information.

On Jan. 6, a federal court in the Northern District of Texas ordered the expedited release. As of Jan. 12, the FDA hasn't indicated it intends to appeal.

Scientists Requested Data After FDA Licensing

The FDA licensed the Pfizer vaccine on Aug. 23, 2021, just 108 days after Pfizer started producing the records to the agency. During that period, the FDA asserts it conducted an intense, robust, and thorough analysis of those documents to assure the public that the Pfizer vaccine was safe and effective.

Yet, when asked to share those documents with the public, the FDA claimed it needed over 20,000 days. The FDA's production schedule clashed with its promise of transparency.

The purpose of FOIA is government transparency. When it comes to the Pfizer vaccine, the need for transparency is unprecedented. A majority of Americans are now mandated to receive a Covid-19 vaccine under penalty of losing a job, or worse.

This has never been done before. Typically adult vaccine mandates have been limited; even the seminal U.S. Supreme Court vaccine mandate decision, *Jacobson v. Massachusetts,* only involved a state-imposed $5 penalty, and school vaccine mandates have historically had liberal religious or personal belief exemption policies.

Even more problematic is that Americans, if injured, cannot sue Pfizer. There is virtually no other product where a consumer is prohibited from suing the company that manufactures, markets, and profits from the product.

Decoupling a company's profit interest from its interest in safety creates a moral hazard and departs from centuries of product liability doctrine. Thus, it is extraordinary that Americans must take this product under penalty of expulsion from work, school, the military and civil life, but they cannot sue Pfizer for any resulting injuries.

The federal government created this unprecedented situation. It granted the immunity, licensed the product, and aggressively sought mandates. This situation therefore warrants unprecedented transparency.

As then-presidential candidate Joe Biden told the American people, "You've got to make all of it [the vaccine data] available to other experts across the nation so they can look and see." He repeated that need to share the data numerous times. So did senators and representatives on both sides of the aisle.

FDA Claimed It Can't Comply, Judge Orders Compliance

The FDA apparently disagreed. During a hearing on Dec. 14, 2021, its counsel steadfastly maintained that the court should not require the agency to produce more than 500 pages per month, harping on the FDA's purported limited resources, its need to redact personal information, and duty to protect Pfizer's trade secret interests, all the while ignoring the interests of the American people.

The FDA's excuses were incredible. The FDA has more than 18,000 employees and a budget of over $6.5 billion. It would be laughable if any multibillion-dollar company came before a court and claimed poverty to escape making a document production, but that was the FDA's position.

U.S. District Judge Mark T. Pittman, Northern District of Texas, expressed dismay at the FDA's proposed rate of production. He found the duration requested by the FDA unreasonable, comparing it to the actions of totalitarian nations. As such, the judge on Jan. 6 ordered the FDA to produce at least 55,000 pages per month.

In his ruling, the judge recognized that the release of this data is of paramount public importance and should be one of the FDA's highest priorities. He quoted James Madison as saying a "popular Government, without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy" and John F. Kennedy as explaining that a "nation that is afraid to let its people judge the truth and falsehood in an open market is a nation that is afraid of its people."

America has some of the greatest institutions of learning the world has ever known. We need the scientific community, both inside and outside the government, to address the serious ongoing issues with the vaccine program, including waning immunity, variants evading vaccines, and that vaccinated individuals can still transmit the virus.

The FDA's attempt to close the door and lock out independent scientists from the data necessary to address these issues was irresponsible.

Transparent, Independent Review Is Needed

The failure of the government's closed-door approach is exemplified by the fact that the FDA did not send a representative to the court hearing because, as the government attorney explained, the FDA's Covid-19 protocols would not permit it.

Meaning, despite a reported vaccination rate of over 96% across federal health agencies back in November 2021, and the FDA's claim that the vaccines are "effective," Covid-19 is still disrupting everyday life. This brings into stark focus the need to open the door and involve independent scientists.

As Pittman recognized, America needs transparency and independent scientists to review this data—not in 75 years, but now.

This article does not necessarily reflect the opinion of The Bureau of National Affairs, Inc., the publisher of Bloomberg Law and Bloomberg Tax, or its owners.

Write for Us: Author Guidelines

Author Information

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Topics

freedom of information
vaccines
biologics research
coronavirus

Companies

Pfizer Inc

1st document shows that you and I have been lied to when we have been told that the shot stays in the injection site area.

https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf

https://jessicar.substack.com/p/the-pfizer-document-dump-pertaining?s=r

Where do lipid nano-particles go after shot? They used radioactive markers to study biodistribution of the messenger RNA (mRNA) over the first 2 days in rats.

Screen 1: show heading of the document
Screens 25 and 26: the concentration progressively leaves the injection site and spreads to organs throughout the body. Here are the 4 places with particularly high concentrations after 48 hours:

- adrenal glands - make hormones related to sex, sugar and salt balance, and fight-or-flight response.
- liver – filters blood, and detoxifies the body.
- ovaries – hold a girl or woman's total supply of eggs, key to reproduction.
- spleen – helps create blood cells, filter blood, and fight infection.

This in just 2 days. Whether or not the accumulation continued following this time period is unknown. What would be the effect on humans? We don't know.

(b) (4)

FINAL REPORT

Test Facility Study No. 185350
Sponsor Reference No. ALC-NC-0552

A Tissue Distribution Study of a [^{3}H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats

TEST FACILITY:
(b) (4)

SPONSOR:
Acuitas Therapeutics Inc.
6190 Agronomy Road, Suite 402
Vancouver, British Columbia
V6T 1Z3 Canada

Table 2 **Mean Concentration of Total Radioactivity in Whole Blood, Plasma and Tissues Following Single Intramuscular Administration of [^{3}H]-08-A01-C01 to Wistar Han Rats**

Target Dose Level: 50 µg mRNA/Animal; 1.29 mg Total Lipid/Animal

Results expressed as µg lipid equiv/g (mL)

Sample	0.25 min		1 h		2 h		4 h		8 h		24 h		48 h	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Adipose tissue	0.040	°0.073	0.050	0.149	0.070	0.182	0.093	0.163	0.116	0.069	0.126	0.042	0.129	0.232
Adrenal glands	0.302	°0.240	0.580	2.388	1.206	4.232	2.569	3.206	6.387	7.218	19.948	7.595	21.476	14.942
Bladder	0.049	°0.033	0.095	0.165	0.137	0.155	0.227	0.106	0.211	0.085	0.323	0.171	0.340	0.389
Bone (femur)	0.126	0.056	0.148	0.241	0.235	0.296	0.335	0.217	0.502	0.177	0.504	0.180	0.520	0.854
Bone marrow (femur)	0.761	°0.196	0.910	1.010	1.136	1.337	1.557	0.915	2.397	1.274	3.579	1.405	3.690	3.851
Brain	0.073	°0.016	0.083	0.117	0.143	0.133	0.155	0.075	0.101	0.045	0.090	0.047	0.083	0.052
Eyes	0.014	°0.006	0.027	0.043	0.046	0.058	0.095	0.038	0.088	0.030	0.129	0.052	0.127	0.097
Heart	0.419	°0.144	0.631	1.426	1.122	1.682	1.049	0.925	1.189	0.391	0.583	0.318	0.672	0.420
Injection site	219.940	36.566	587.670	199.950	529.210	93.144	619.850	56.227	299.590	125.930	267.170	122.540	268.770	61.088
Kidneys	0.511	0.271	0.630	1.692	1.124	2.967	1.033	0.814	0.837	0.342	0.504	0.348	0.482	0.368
Large intestine	0.017	°0.008	0.031	0.065	0.080	0.106	0.350	0.224	0.690	0.608	1.741	0.466	1.426	1.249
Liver	1.151	0.323	4.006	5.244	9.574	12.370	18.525	14.569	27.916	25.172	23.360	15.119	18.164	30.411
Lung	0.737	0.247	0.845	1.574	1.594	2.074	1.772	1.222	1.674	0.628	1.316	0.762	1.288	0.898
Lymph node (man)	0.090	°0.038	0.154	0.223	0.217	0.362	0.424	0.391	0.695	0.372	0.744	0.363	0.820	0.633
Lymph node (mes)	0.052	°0.048	0.095	0.196	0.229	0.831	0.441	0.536	0.649	0.729	1.106	0.863	1.057	1.675
Muscle	°0.029	0.012	0.039	0.082	0.067	0.100	0.075	0.130	0.101	0.091	0.098	0.092	0.280	0.104
Ovaries (females)	-	°0.104	-	1.339	-	1.638	-	2.341	-	3.088	-	5.240	-	12.261
Pancreas	0.125	0.037	0.153	0.261	0.423	0.404	0.361	0.398	0.349	0.239	0.396	0.320	0.587	0.611
Pituitary gland	0.537	°0.141	0.446	0.844	0.781	0.955	1.249	0.458	0.669	0.141	0.656	0.300	0.543	0.845
Prostate (males)	0.061	-	0.091	-	0.128	-	0.157	-	0.150	-	0.183	-	0.170	-
Salivary glands	0.114	°0.054	0.148	0.237	0.214	0.295	0.270	0.169	0.176	0.094	0.243	0.096	0.297	0.231
Skin	°0.016	0.010	0.028	0.387	0.054	0.263	0.085	0.204	0.122	0.116	0.195	0.118	0.209	0.297

°=Mean includes results calculated from data less than 30 cpm above background

Table 2 (Continued) **Mean Concentration of Total Radioactivity in Whole Blood, Plasma and Tissues Following Single Intramuscular Administration of [^{3}H]-08-A01-C01 to Wistar Han Rats**

Target Dose Level: 50 µg mRNA/Animal; 1.29 mg Total Lipid/Animal

Results expressed as µg lipid equiv/g (mL)

Sample	0.25 min		1 h		2 h		4 h		8 h		24 h		48 h	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Small intestine	0.038	°0.021	0.194	0.247	0.471	0.481	0.919	0.838	1.525	1.033	1.878	0.726	1.630	1.314
Spinal cord	0.061	°0.024	0.072	0.122	0.166	0.172	0.375	0.124	0.168	0.044	0.121	0.048	0.162	0.062
Spleen	0.354	°0.313	2.140	2.801	5.255	10.213	8.945	11.646	24.434	19.747	22.819	17.341	19.550	27.155
Stomach	0.018	°0.015	0.039	0.091	0.104	0.126	0.186	0.101	0.410	0.126	0.222	0.081	0.235	0.195
Testes (males)	0.031	-	0.042	-	0.079	-	0.129	-	0.146	-	0.304	-	0.320	-
Thymus	0.106	°0.069	0.187	0.298	0.220	0.459	0.461	0.209	0.292	0.100	0.255	0.159	0.296	0.366
Thyroid	0.217	°0.093	0.391	0.680	0.575	1.109	1.097	0.604	0.781	0.307	0.820	0.335	1.344	0.655
Uterus (females)	-	°0.043	-	0.203	-	0.305	-	0.140	-	0.287	-	0.289	-	0.456
Whole Blood	3.003	0.936	2.809	5.928	4.028	6.773	3.400	2.698	2.000	0.628	1.274	0.544	0.535	0.305
Plasma	6.035	1.894	5.379	10.884	8.714	9.091	8.755	4.251	3.573	1.147	2.621	0.945	1.085	0.524
Blood:plasma ratio	0.48	1.15	0.49	0.54	0.46	0.64	0.42	0.60	0.56	0.55	0.49	0.57	0.50	0.58

°=Mean includes results calculated from data less than 30 cpm above background

2nd document of interest: What are the adverse events found from December 2020 through February 28, 2021?

https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

Screen 6: 42,086 cases had adverse effects.
We don't know the percentage of people with adverse effects because the total number who took the shot was REDACTED. We have been barred from calculating the safety rate.
Screen 7: Of these, 1223 were deaths as of February 28, 2021. That is 2.9% of the cases of adverse effects. That is already enough that they should have stopped the roll-out of the shots as being unsafe. (Below this is a paragraph of types of adverse events.)
Screen 8 chart shows: adverse events include nervous system, musculoskeletal, gastrointestinal, skin, respiratory, chest, infections, poisoning, miscarriage, liver, blood, facial paralysis.
Screen 18, top box, for example: In nearly every case, the conclusion related to the adverse event area of the body says: "This cumulative case review does not raise new safety issues. Surveillance will continue."
Whose job is that? The CDC, right?

Also included is an appendix listing 1200 adverse events of significant interest.

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

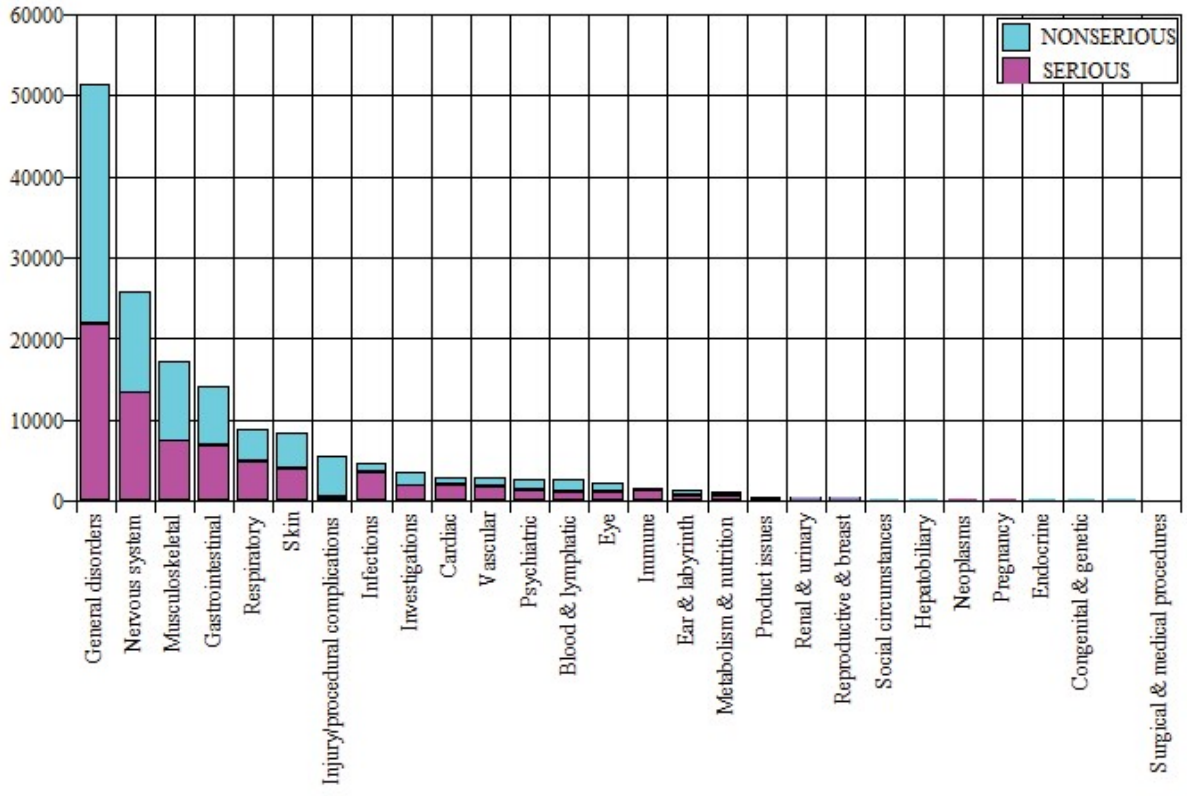


Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

Both CDC & FDA have had roles and responsibility for "pharmaco-vigilance" - have they done their jobs?

https://worldcouncilforhealth.org/multimedia/uvc-jessica-rose/

Dr. Jessica Rose, Ph.D. independent doctor of computational biology, 2/5/22, World Council for Health Law and Activism Committee conference on Understanding Vaccine Causation.

Minute 4:22 screen shot has a screen on pharmaco-vigilance and malfeasance (read it)

Pharmaco-vigilance is science and activities relating to the detection, assessment, understanding and prevention of adverse events. This applies equally throughout the life cycle of a med – EQUALLY to the pre-approval stage, as to the post-approval.

Dr. Rose concludes: "Thus, if causation is suspected, then it is of UTMOST RELEVANCE AND IMPORTANCE to inform the public. If you willingly withhold safety data from the public and continue to administer unsafe products, then you are guilty of malfeasance."

PHARMACO /VIGILANCE

- Science and activities relating to the detection, assessment, understanding and **prevention** **of adverse events**

- This applies **throughout the life cycle** of a med - EQUALLY to the pre-approval stage as to the post approval

Thus, is causation if suspected, then it is of UTMOST RELEVANCE AND IMPORTANCE to inform the public. If you willingly withhold safety data from the public and continue to administer unsafe products, then you are guilty of malfeasance.

Data source: VAERS/Analysis: Dr. Jessica Rose

VAERS Data: Vaccine Adverse Events Reporting System

1. Deaths and adverse events to date

Adverse events & deaths from last Friday, March 18, 2022, the CDC released the following data for Dec. 14, 2020 to March 11, 2022:

https://www.medalerts.org/vaersdb/findfield.php?
TABLE=ON&GROUP1=CAT&EVENTS=ON&VAX=COVID19

1,183,495 reports of adverse events from all age groups following COVID shots,
including 25,641 deaths (including 76 deaths - age 16 and younger)
and 208,209 serious injuries
Includes 141,112 hospitalizations.

2. VAERS site itself states that adverse events are underreported on their site

VAERS website explains clearly that they are aware that there is underreporting of adverse events:

https://vaers.hhs.gov/data/dataguide.html

" 'Underreporting' is one of the main limitations of passive surveillance systems, including VAERS. The term, underreporting refers to the fact that VAERS receives reports for only a small fraction of actual adverse events."

3. Bar Graphs for past 11 years

https://www.jessicasuniverse.com/news - see January 2022 slide presentation: Is there another side? Presentation of VAERS data

(slide 11) Adverse events on VAERS – 2011 through 2021 (greater than 1700% increase in 2021)
(slides 12 & 13) Deaths on VAERS – 2011 through 2021 (greater than 7000% increase in 2021)

National Vaccine
Information Center
Your Health. Your Family. Your Choice.

MedAlerts.org

Search Results

From the 3/11/2022 release of VAERS data:

Found 1,183,495 cases where Vaccine is COVID19

Government Disclaimer on use of this data

Table

Event Outcome	Count	Percent
Death	25,641	2.17%
Permanent Disability	47,676	4.03%
Office Visit	181,686	15.35%
Emergency Room	103	0.01%
Emergency Doctor/Room	123,732	10.45%
Hospitalized	140,759	11.89%
Hospitalized, Prolonged	353	0.03%
Recovered	328,324	27.74%
Birth Defect	992	0.08%
Life Threatening	29,135	2.46%
Not Serious	526,937	44.52%
TOTAL	† 1,405,338	† 118.74%

† Because some cases have multiple vaccinations and symptoms, a single case can account for multiple entries in this table. This is the reason why the Total Count is greater than 1183495 (the number of cases found), and the Total Percentage is greater than 100.

Guide to Interpreting VAERS Data

Evaluating VAERS Data

When evaluating data from VAERS, it is important to note that for any reported event, no cause-and-effect relationship has been established. Reports of all possible associations between vaccines and adverse events (possible side effects) are filed in VAERS. Therefore, VAERS collects data on any adverse event following vaccination, be it coincidental or truly caused by a vaccine. The report of an adverse event to VAERS is not documentation that a vaccine caused the event.

VAERS Data Limitations

Millions of vaccines are given each year to children less than 1 year old in the United States, usually between 2 and 6 months of age. At this age, infants are at greatest risk for certain medical adverse events, including high fevers, seizures, and sudden infant death syndrome (SIDS). Some infants will experience these medical events shortly after a vaccination by coincidence.

These coincidences make it difficult to know whether a particular adverse event resulted from a medical condition or from a vaccination. Therefore, vaccine providers are encouraged to report all adverse events following vaccination, whether or not they believe the vaccination was the cause.

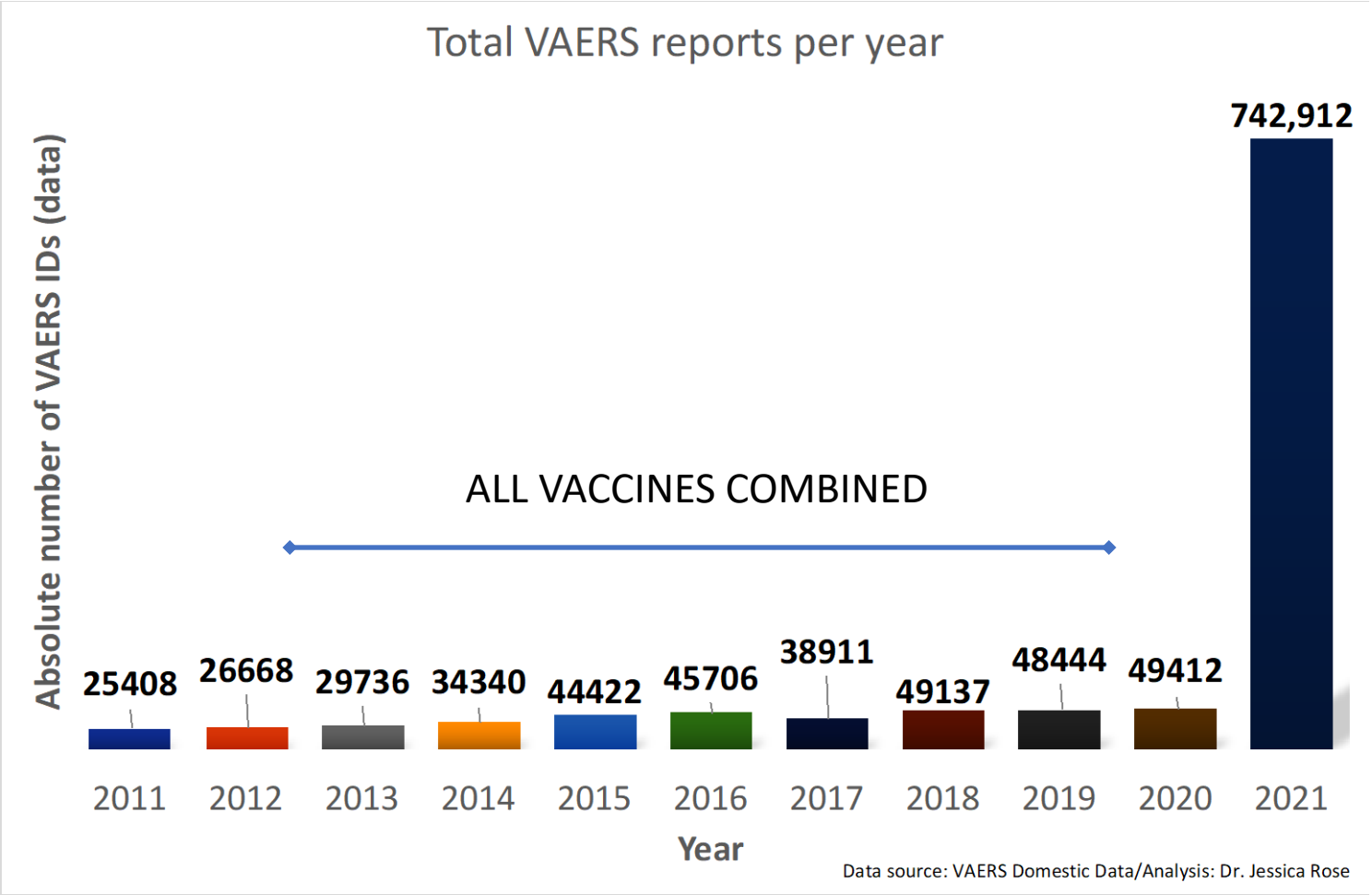
When reviewing data from VAERS, please keep in mind the following limitations:

VAERS is a passive reporting system, meaning that reports about adverse events are not automatically collected, but require a report to be filed to VAERS. VAERS reports can be submitted voluntarily by anyone, including healthcare providers, patients, or family members. Reports vary in quality and completeness. They often lack details and sometimes can have information that contains errors.

"Underreporting" is one of the main limitations of passive surveillance systems, including VAERS. The term, underreporting refers to the fact that VAERS receives reports for only a small fraction of actual adverse events. The degree of underreporting varies widely. As an example, a great many of the millions of vaccinations administered each year by injection cause soreness, but relatively few of these episodes lead to a VAERS report. Physicians and patients understand that minor side effects of vaccinations often include this kind of discomfort, as well as low fevers. On the other hand, more serious and unexpected medical events are probably more likely to be reported than minor ones, especially when they occur soon after vaccination, even if they may be coincidental and related to other causes.

A report to VAERS generally does not prove that the identified vaccine(s) caused the adverse event described. It only confirms that the reported event occurred sometime after vaccine was given. No proof that the event was caused by the vaccine is required in order for VAERS to accept the report. VAERS accepts all reports without judging whether the event was caused by the vaccine.

Total VAERS counts for the past decade



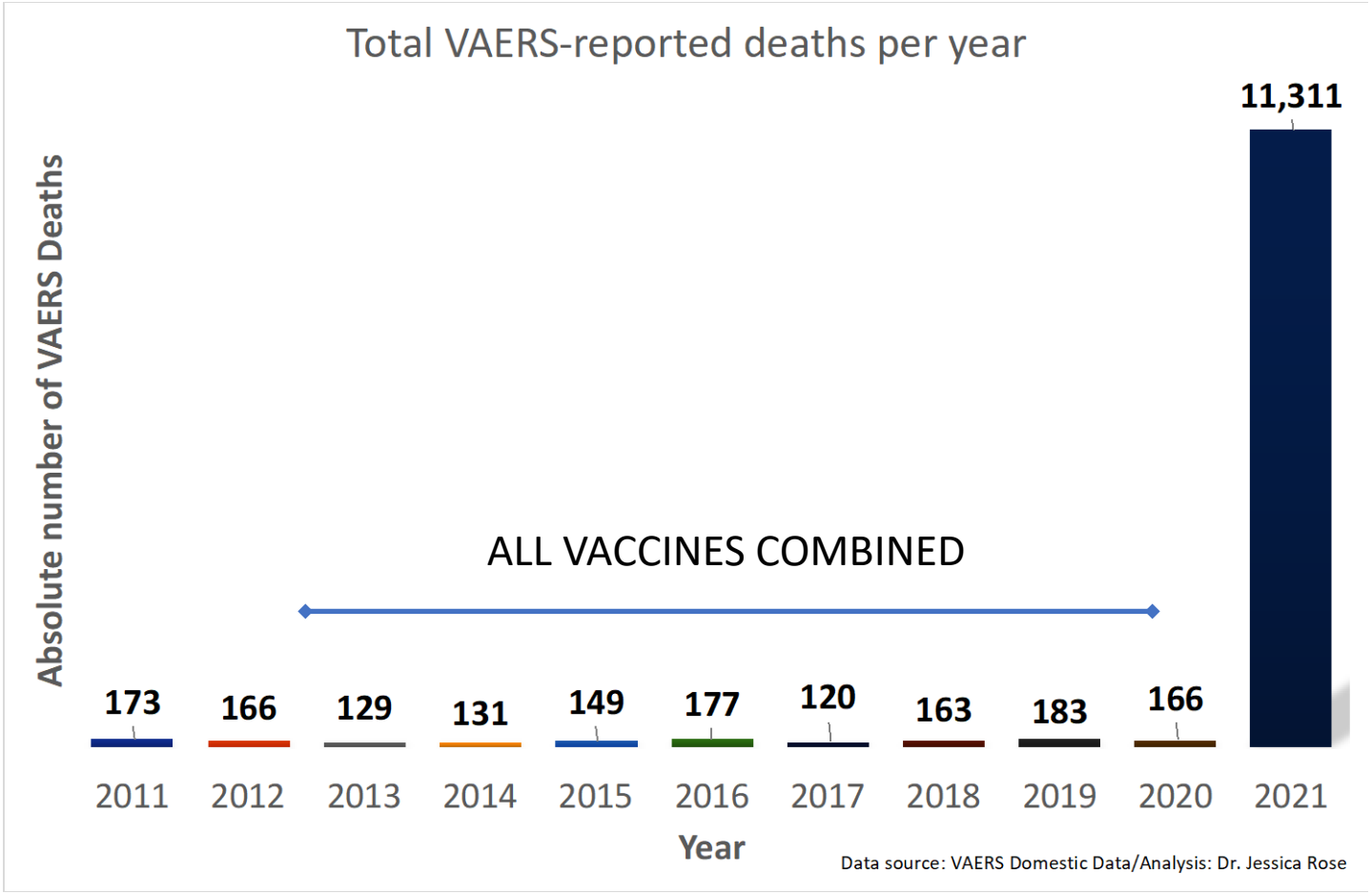
This is a >1,700% increase. Since the excess in AEs are NOT due to excess in doses administered*, what explains this?

mean for the past decade = 39,218

Total VAERS counts for the past decade

This is a 7,197% increase. Since the excess in AEs are NOT due to excess in doses administered*, what explains this?

mean for the past decade = 155

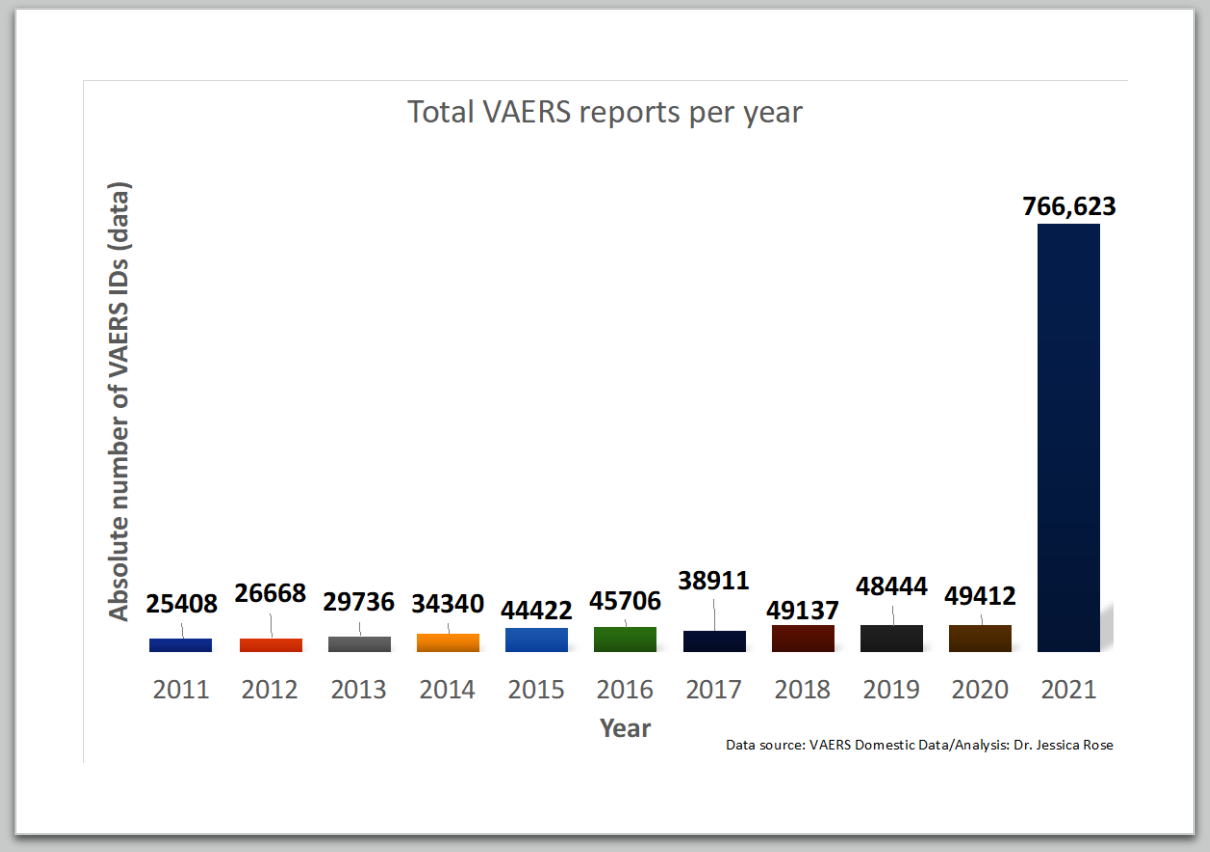


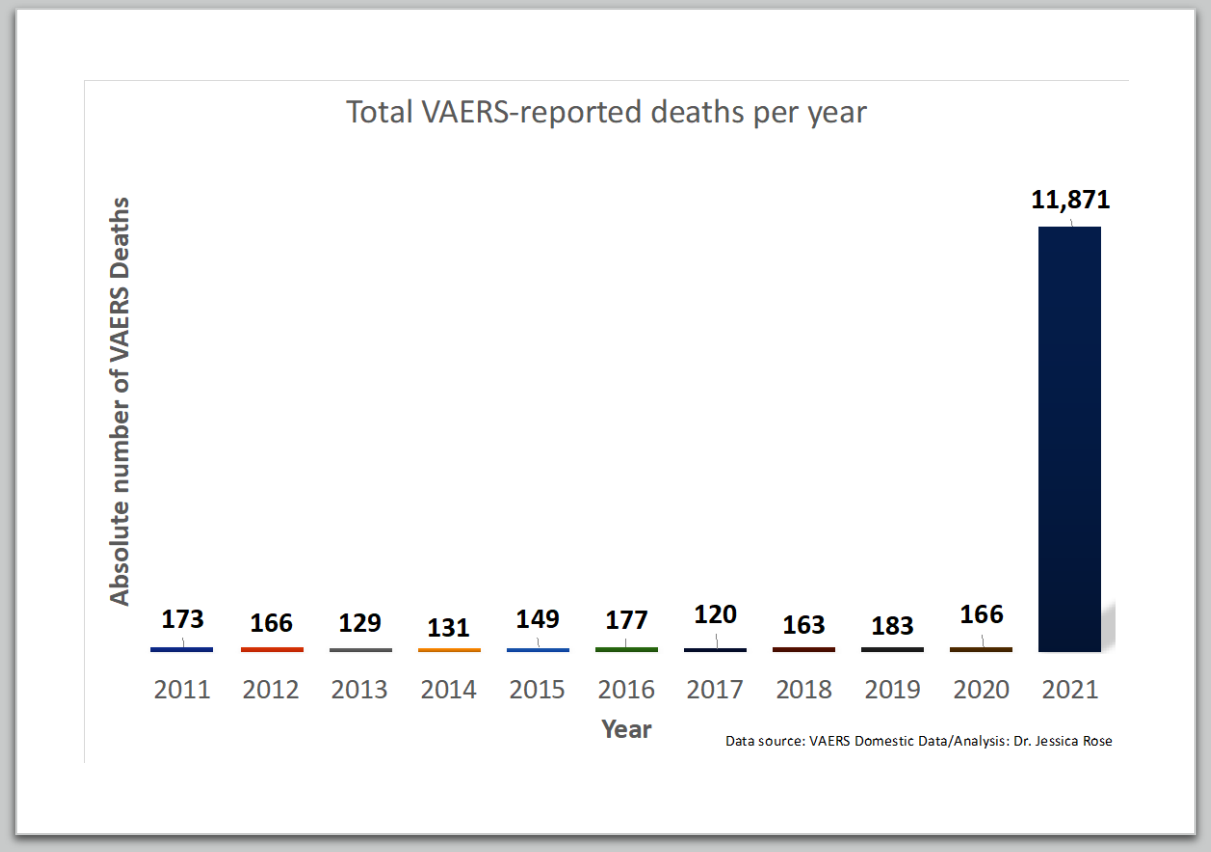
Update as of 12/24/21

Data source: VAERS/Analysis: Dr. Jessica Rose

ATYPICAL – REQUIRES INVESTIGATION

- Greater than 1700% increase in AE reports
- Greater than 7000% increase in deaths in 2021





Update as of 01/21/22

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

FDA and CDC review the Dept. of Defense's DMED (Defense Medical Epidemiology Database), which shows huge number of adverse events of these shots - whistleblowers provided

We have explored just some of the evidence of these shots not being safe. There is also evidence exposed by whistleblowers who have shared data from 2 large databases which the FDA said at the October 2020 meeting that they'd be watching. First, we will look at the DOD's Defense Medical Epidemiology Database.

https://renz-law.com/attorney-tom-renz-whistleblowers-dmed-defense-medical-epidemiology-database-reveals-incredibly-disturbing-spikes-in-diseases-infertility-injuries-across-the-board-after-the-military-was-forced-to/

As you will recall, back in October 2020, the FDA said they would watch the DOD data. The DOD data became public when 3 military doctors who were concerned about their unheeded concerns for their troops' health and our national security, became whistleblowers to alert the government to the enormous health impacts of the shots. They downloaded data from 2016 to 2021 to show the huge difference in 2021. This information was shared at a Senate Covid Roundtable meeting on January 24. It included 10x spike in neurological illness – critical in pilots – 21x spike in hypertension, plus enormous spikes in serious ailments including cancer, heart disease, M.S., infertility, miscarriage, birth defects, and more.

https://renz-law.com/special-notice-regarding-evidentiary-findings-related-to-the-official-renz-law-covid-19-investigation/

Screens 179 and 180 show the charts comparing the prior 5 years, the 5-year average and 2021 for various diseases.

Disconcertingly, once the leak was discovered, the DOD modified the prior 5 years of data to make it look like 2021 was a more normal year. They claimed they were correcting a glitch that just happened to not affect 2021, not be caught before, and only affect ailments known to be linked to the shots. Even so, the ailment data was much higher than baseline.

Defense Medical Surveillance System (DMSS) Defense Medical Epidemiology Database (DMED) DoD Data - January 2022

Diagnosis or Injury	Query Date	2016	2017	2018	2019	2020	Total 2016-2020	Avg Injuries Per Year 2016-2020	2021 (Partial Year)	Percent Increase in 2021
All Diseases & Injuries										
All Disease & Injuries (Amb)	1/19/2022	2,059,630	2,058,379	2,022,663	2,110,383	1,976,724	10,227,779	2,045,555.80	**21,512,583**	**1052%**
All Disease & Injuries (Hosp)	1/19/2022	43,786	43,338	42,024	43,493	40,052	212,693	42,538.60	**54,776**	**129%**
Cancer										
Neoplasms (ALL CANCERS)	1/19/2022	41,557	39,139	37,756	38,889	36,050	193,391	38,678.20	**114,645**	**296%**
Malignant Neoplasms of Digestive Organs	1/19/2022	660	654	633	602	704	3,253	650.60	**4,060**	**624%**
Malignant Neoplasms of Thyroid & Other Endocrine Glands	1/19/2022	550	394	369	374	372	2,059	411.80	**1,950**	**474%**
Malignant Neuroendocrine tumors	1/19/2022	167	135	98	113	117	630	126.00	**440**	**349%**
Testicular Cancer (Amb)	1/10/2022	1,156	1,008	866	880	889	4,799	959.80	**3,537**	**369%**
Ovarian Cancer (Amb)	1/10/2022	121	88	73	82	69	433	86.60	**181**	**209%**
Breast Cancer (Amb)	1/10/2022	934	810	766	792	766	4,068	813.60	**4,357**	**536%**
Malignant Neoplasm of Esophagus	1/19/2022	29	36	35	20	26	146	29.20	**261**	**894%**
Mental Health & Metabolic Function										
Anxiety (Amb)	1/10/2022	37,011	36,667	36,145	37,762	37,870	185,455	37,091.00	**931,791**	**2512%**
Anxiety (Hosp)	1/10/2022	2,478	2,577	2,534	2,666	2,642	12,897	2,579.40	**6,496**	**252%**
Suicide	1/10/2022	359	496	530	570	550	2,505	501.00	**1,798**	**359%**
Endocrine Nutritional & Metabolic Diseases (Amb)	1/19/2022	33,140	31,825	30,814	31,504	30,506	157,789	31,557.80	**134,053**	**425%**
Disorders of Thyroid Gland	1/19/2022	8,078	7,694	7,357	7,289	6,893	37,311	7,462.20	**24,769**	**332%**
Malasie & Fatigue (Amb)	1/10/2022	3,851	3,842	3,832	3,885	3,735	19,145	3,829.00	**26,416**	**690%**
Thyroid Dysfunction (Amb)	1/10/2022	8,074	7,696	7,357	7,289	6,891	37,307	7,461.40	**22,620**	**303%**
Diabetes Type 1 (Amb)	1/10/2022	1,319	1,167	1,072	1,036	960	5,554	1,110.80	**5,269**	**474%**
Disease of Liver (Amb)	1/10/2022	1,994	2,053	2,063	2,234	2,322	10,666	2,133.20	**6,187**	**290%**
Narcolepsy & Cataplexy										
Narcolepsy & Cataplexy	1/19/2022	995	898	864	830	766	4,353	870.60	**2,097**	**241%**
Neuromuscular & Skeletal Systems										
Diseases of the Nervous System	1/19/2022	82,435	81,998	81,382	85,012	80,786	411,613	82,322.60	**863,013**	**1048%**
Diseases of the Eye & Adnexa	1/19/2022	88,091	87,712	86,417	91,503	79,529	433,252	86,650.40	**280,206**	**323%**
Migraine	1/19/2022	15,734	15,714	16,462	17,116	16,331	81,357	16,271.40	**73,490**	**452%**
Seizures (Amb)	1/10/2022	196	148	130	150	123	747	149.40	**489**	**327%**
Guillian-Barre Syndrome (Amb)	1/10/2022	66	79	71	85	65	366	73.20	**403**	**551%**

Defense Medical Surveillance System (DMSS) Defense Medical Epidemiology Database (DMED) DoD Data - January 2022

Diagnosis or Injury	Query Date	2016	2017	2018	2019	2020	Total 2016-2020	Avg Injuries Per Year 2016-2020	2021 (Partial Year)	Percent increase in 2021
Acute Transverse Myelitis in Demyelinating Disease of CNS	1/19/2022	46	57	48	35	34	220	44.00	202	459%
Demyelinating Diseases of the CNS	1/19/2022	785	737	690	677	648	3,537	707.40	3,444	487%
Multiple Sclerosis	1/19/2022	479	391	367	400	385	2,022	404.40	2,750	680%
Rhabdomyolysis (Hosp)	1/10/2022	216	209	227	222	198	1,072	214.40	440	205%
Rhabdomyolysis (Amb)	1/10/2022	706	696	740	755	669	3,566	713.20	5,162	724%
Eye Disorder (Amb)	1/10/2022	6,044	6,013	5,647	6,312	5,623	29,639	5,927.80	11,892	201%
Extra Pyramidal (Amb)	1/10/2022	1,509	1,474	1,339	1,371	1,338	7,031	1,406.20	3,669	261%
Bell's Palsy (Amb)	1/10/2022	483	462	457	447	450	2,299	459.80	1,338	291%
Cardiovascular System										
Diseases of the Blood & Blood-forming Organs & Certain Disorders Involving the Immune Mechanism	1/19/2022	11,533	11,122	10,851	11,773	11,429	56,708	11,341.60	34,486	304%
Acute Myocardial Infarction (Amb)	1/10/2022	324	370	376	366	372	1,808	361.60	1,650	456%
Hypertension (Amb)	1/10/2022	2,308	2,323	2,363	2,392	2,415	11,801	2,360.20	53,846	2281%
Acute Myocarditis (Amb)	1/21/2022	84	92	116	159	108	559	111.80	307	275%
Acute Pericarditis (Amb)	1/10/2022	535	538	522	531	499	2,625	525.00	850	162%
Nontraumatic subarachnoid hemorrhage	1/19/2022	219	139	134	170	196	858	171.60	640	373%
Pulmonary Embolism (Amb)	1/19/2022	678	701	668	716	968	3,731	746.20	3,489	468%
Tachycardia (Amb)	1/10/2022	845	814	893	903	849	4,304	860.80	2,595	301%
Disease of the Arteries (Amb)	1/10/2022	3,164	2,965	2,938	3,096	2,860	15,023	3,004.60	6,069	202%
Cerebral Infarction (Amb)	1/10/2022	887	848	858	888	887	4,368	873.60	3,136	359%
Reproductive System & Birth										
Spontaneous Abortion (First Occurrence)	1/19/2022	2,668	2,532	2,475	2,608	2,404	12,687	2,537.40	2,164	85%
Spontaneous Abortion (All Occurences)	1/10/2022	1,431	1,518	1,493	1,578	1,477	7,497	1,499.40		0%
Congenital Malformations (Amb)	1/19/2022	11,710	11,131	10,456	11,081	10,153	54,531	10,906.20	18,951	174%
Infertility, Female (Amb)	1/19/2022	2,261	2,262	2,243	2,340	2,262	11,368	2,273.60	11,748	517%
Infertility, Male (Amb)	1/19/2022	2,187	2,287	2,037	2,152	1,990	10,653	2,130.60	8,365	393%
Ovarian Dysfunction (Amb)	1/19/2022	862	936	908	945	1,022	4,673	934.60	4,086	437%
Dysmenorrhea (Amb)	1/10/2022	3,104	3,403	3,481	3,943	3,900	17,831	3,566.20	12,539	352%
Vaccine Adminstration										
T50.B95A Adverse Effect of Other Viral Vaccine, Initial Encounter	Unassigned						914	182.80	1,281	701%

FDA and CDC also review the CMS (Medicare/Medicaid) database which shows many adverse events and deaths of these shots – data is from 9/28/21 – whistleblower provided

https://renz-law.com/special-notice-regarding-evidentiary-findings-related-to-the-official-renz-law-covid-19-investigation/

Screen 146 – Here we can see the CDC and CMS data are being used in conjunction with the DOD.

What is being publicly told to us is that they don't count deaths from the shots until 14 days from the date of injection, thus minimizing the numbers:

CDC site says you are not fully vaccinated until 14 days after your last shot. So if you have a side effect from the shot, or if you only took the 1st of the 2, you are not considered vaccinated. If you suffer immediate side effects of the shot, you will be listed as unvaccinated by the hospital.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated_archived.html

However, internally, CMS is specifically tracking the increasing deaths in the 14 days being related to the shot. As of September 28, more than 50 thousand seniors died within 14 days from diagnoses they did not have before.

Screen 156: here we see the CMS data showing that almost 6 out of 1,000 seniors getting the shots, esp. those over 80, die within 2 weeks after a Covid injection…

Screen 157: …60% after the 1st dose…

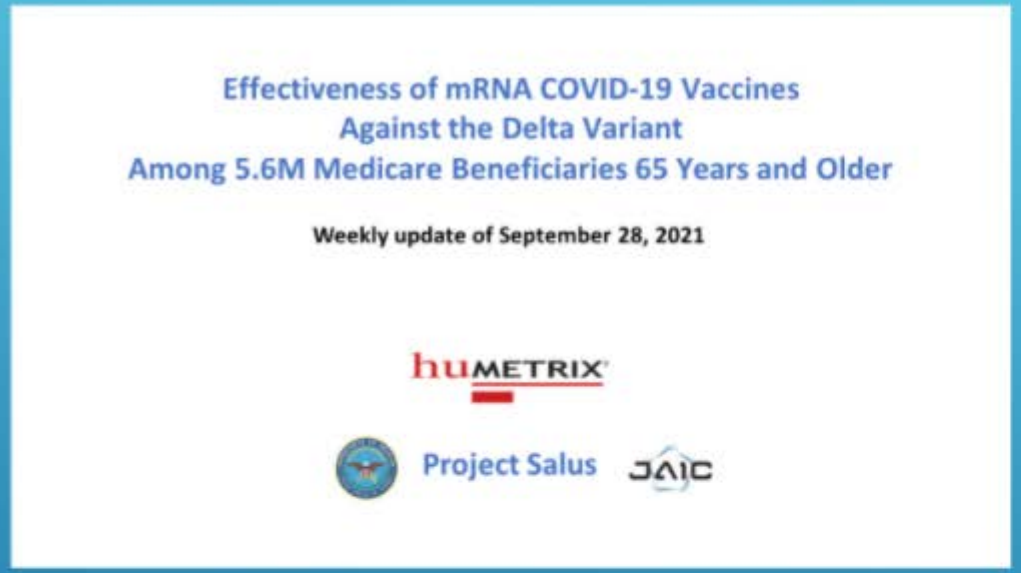
Screen 158: …and 40% after the 2nd dose, with more dying daily.

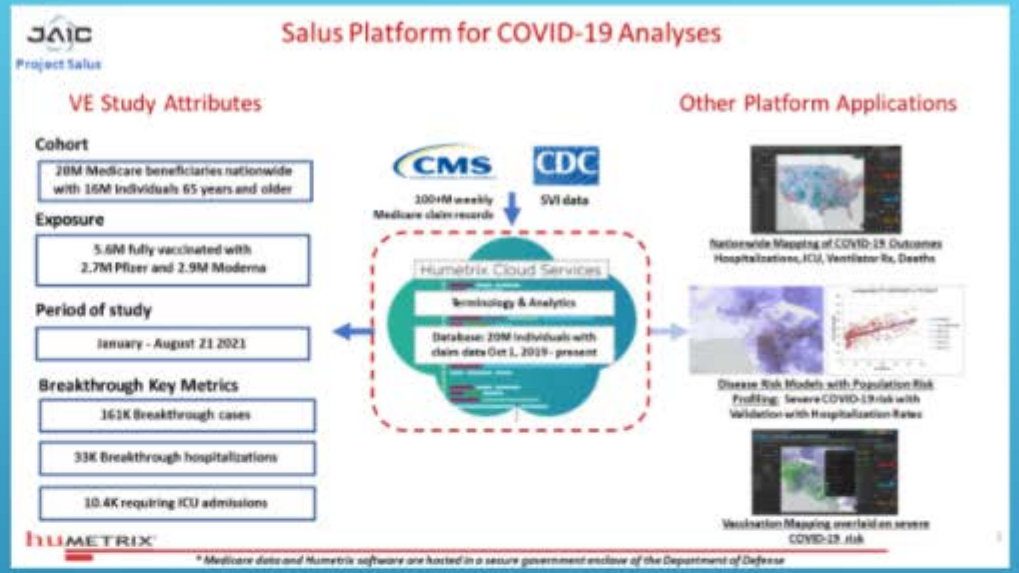
Screen 160: shows the various diagnosed causes of death of these seniors who died of a disease not diagnosed previously. "The closest we can get to showing causation."

Yet our agencies tell us these shots are safe.

Screen 165: In 44% of those on Medicare who died within 28 days of the shot, one of the last 5 diagnosis codes prior to death was the Covid shot.

Screen 167: In people under 30 on Medicaid, there were 10x as many deaths from the Covid shot as from the flu shot, and 24x more heart attacks and cardiac arrests from the Covid shot as from the flu shot.



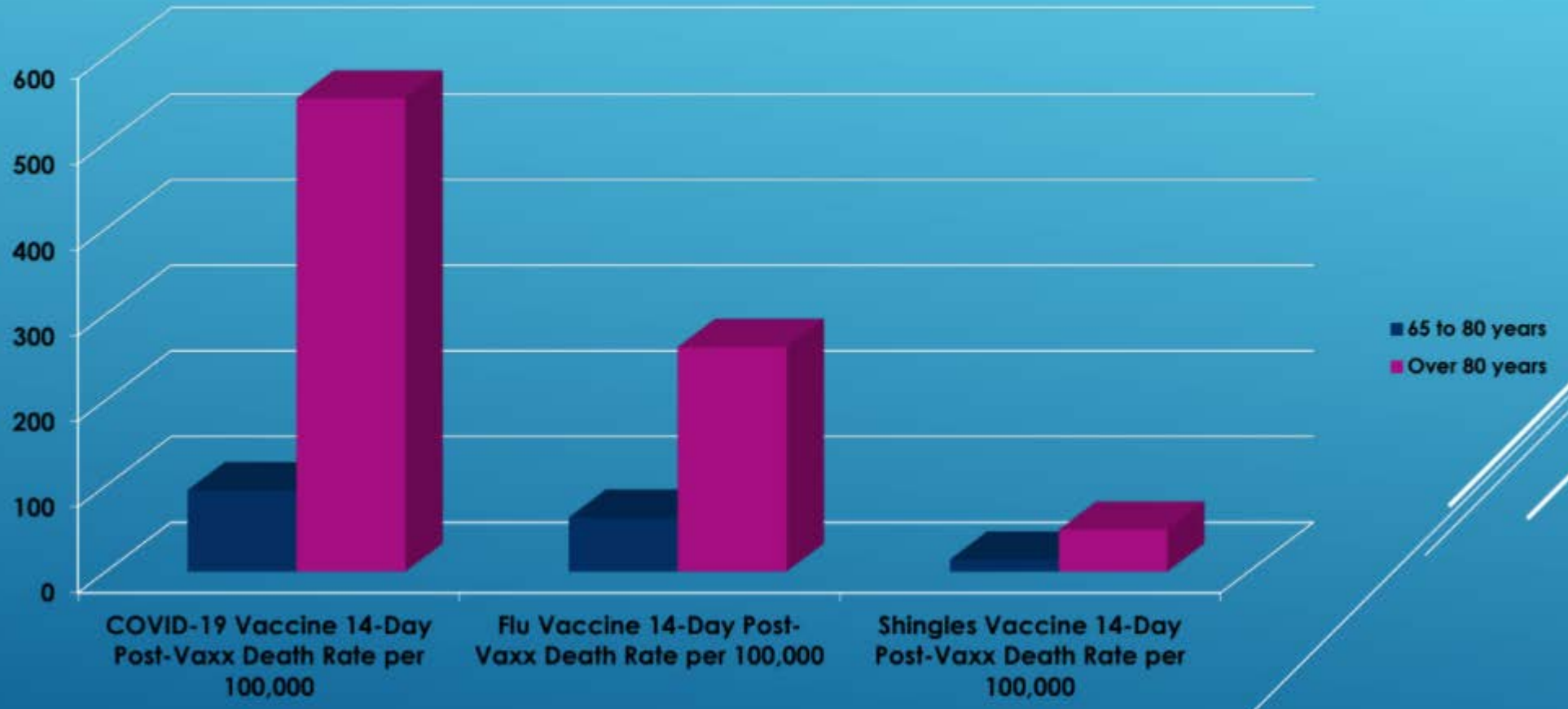


DOD EXCERPTS

- NOTE THE DOD SEAL AND THAT THEY ANALYZE CMS

Comparison of COVID-19 Vaccine with Other Vaccine: Death Rates per 100,000

Death rates per 100,000 where death occurred within *14 days of the vaccine*



MEDICARE DEATHS WITHIN 14 DAYS OF 1ST VACCINE DOSE

n=29,398

Total deaths 14 days after 1st dose: 29,398

Total deaths 14 days after 2nd dose: 21,031

Total: 50,429

Days Died After 1st Dose	# Beneficiaries Died	% Beneficiaries Died	Cumulative Number	Cumulative Percentage
0	555	1.89	555	1.89
1	1,137	3.87	1,692	5.76
2	1,492	5.08	3,184	10.83
3	1,654	5.63	4,838	16.46
4	1,750	5.95	6,588	22.41
5	1,876	6.38	8,464	28.79
6	1,924	6.54	10,388	35.34
7	2,095	7.13	12,483	42.46
8	2,099	7.14	14,582	49.60
9	2,244	7.63	16,826	57.24
10	2,266	7.71	19,092	64.94
11	2,458	8.36	21,550	73.30
12	2,593	8.82	24,143	82.12
13	2,595	8.83	26,738	90.95
14	2,660	9.05	**29,398**	100.00

MEDICARE DEATHS WITHIN 14 DAYS OF 2ND VACCINE DOSE

n=21,031

Total deaths 14 days after 1st dose: 29,398

Total deaths 14 days after 2nd dose: 21,031

Total: 50,429

Days Died After 2nd Dose	# Beneficiaries Died	% Beneficiaries Died	Cumulative Number	Cumulative Percentage
0	362	1.72	362	1.72
1	1023	4.86	1385	6.59
2	1186	5.64	2571	12.22
3	1218	5.79	3789	18.02
4	1326	6.30	5115	24.32
5	1398	6.65	6513	30.97
6	1426	6.78	7939	37.75
7	1508	7.17	9447	44.92
8	1541	7.33	10988	52.25
9	1570	7.47	12558	59.71
10	1602	7.62	14160	67.33
11	1708	8.12	15868	75.45
12	1678	7.98	17546	83.43
13	1740	8.27	19286	91.70
14	1745	8.30	**21031**	100.00

This section analyzes Medicare beneficiaries who did NOT have selected serious adverse events from July 1 2020 to the date of vaccination, then developed the adverse event (AE) within 14 days of the COVID-19 vaccine. This is as close to causality as we can get in the data. The patient did not have any Medicare claims with the select diagnosis codes, then had a sudden onset of the condition within 14 days of the shot. Refer to table 1 for the list of adverse events

14 days later…

VACCINE CAUSALITY?

List Serious Adverse Event (AE)
ACUTE KIDNEY FAILURE
ANAPHYLAXIS
CARDIAC ARREST
CEREBROVASCULAR EVENT
COVID-19
EMBOLISM
ENCEPHALITIS/MYELITIS/ENCHEPHALOMYELITIS /MENINGITIS/ENCEPHOLATPATHY
GUILLAIN-BARRE SYNDROME
INTRAVASCULAR COAGULATION
KAWASKI DISEASE
MYO-ENDO-PERI-CARDITIS
MYOCARDIAL INFARCTION
NARCOLEPSY/CATAPLEXY
PLEGIA/PALSY/PARALYSIS
PNEUMONIA
RESPIRATORY DISTRESS
RESPIRATORY FAILURE
RESPIRATORY INFECTION
RESPIRATORY SYNCYTIAL VIRUS
SEIZURE/CONVULSION
STROKE/CEREBRAL INFARCTION
THROMBOCYTOPENIA
THROMBOSIS

MEDICAID PATIENTS WHO DIED WITHIN 28 DAYS OF COVID-19 VACCINE, CAUSES OF DEATH

Top 10 Causes of Death* for patients who died within 28 days after vaccine, when The patient did NOT have the exact diagnosis from Oct 1 2020 to time of vaccination

Diagnosis Code	Diagnosis Description (1st or 2nd diagnosis code only)	# Recipients
Z23	Encounter for immunization	3122
I469	Cardiac arrest, cause unspecified	755
A419	Sepsis, unspecified organism	429
U071	COVID-19	418
J9601	Acute respiratory failure with hypoxia	408
J189	Pneumonia, unspecified organism	235
N179	Acute kidney failure, unspecified	230
I10	Essential (primary) hypertension	229
R4182	Altered mental status, unspecified	177

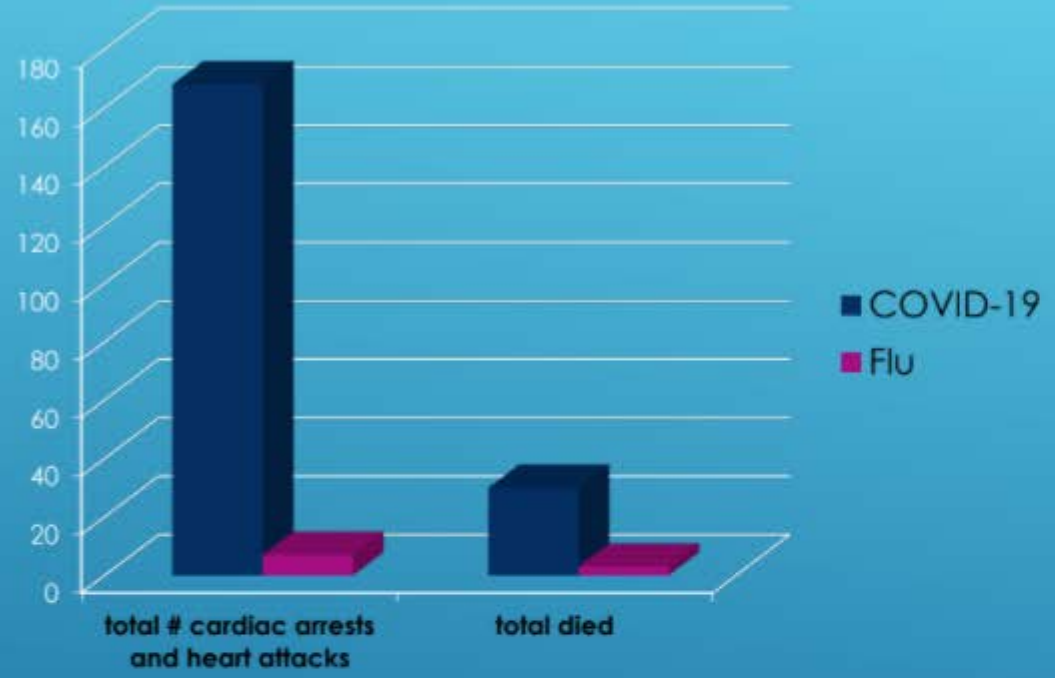
Interpretation:

For *3,122 (44%)* recipients, One of the last 5 diagnosis Codes prior to death Was the COVID-19 vaccine.

For *755* recipients, One of the last 5 diagnosis Codes prior to death was Cardiac Arrest

This is out of 7,036 recipients who Died within 28 post-vaccine

"Cause of death" defined as one of last 5 diagnosis codes prior to death



- COVID Vaccine: 168
- Flu Vaccine: 7

- COVID Vaccine Deaths: 30
- Flu Vaccine Deaths: 3

- 10X AS MANY DEATHS!!

MEDICAID CARDIAC ARRESTS & HEART ATTACKS: UNDER AGE 30