

An Overview of the CDC's Safety Signal Analysis for COVID-19 Vaccines

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09/29/21 • COVID > VIEWS

Safety Signals for COVID Vaccines Are Loud and Clear. Why Is Nobody Listening?

By Josh Guetzkow, Ph.D.

Age	SERIOUS	DEATHS	GBS	COAG.	M.I.
Age 10-17	1.35*	1.24	0.28*	2.89*	n.e.
Age 18-49	0.99	2.52*	0.10*	8.82*	15.78*
Age 50-64	1.45*	4.74*	0.14*	13.22*	6.71*
Age 65+	2.76*	9.16*	0.26*	36.97*	8.27*
Age 10+	1.52*	4.93*	0.15*	14.84*	6.78*

Results of My Safety Signal Analysis

Dec. 14, 2020 - Aug. 6, 2021

- Compared all COVID vs. Flu Vaccines 2015-2020
- Safety Signals for 242 Adverse Events
- *Not* due to large number of doses given
- *Not* due to stimulated/exaggerated reporting
- *Not* due to COVID-19
- *Not* due to vaccination targeting older populations



frontiers

| Frontiers in Public Health

Frequency and Associations of Adverse Reactions of COVID-19 Vaccines Reported to Pharmacovigilance Systems in the European Union and the United States



Diego Montano*

Front. Public Health, 03 February 2022

Department of Population-Based Medicine, Institute of Health Sciences, University of Tübingen, Tübingen, Germany

**Vaccine Adverse Event Reporting System
(VAERS)
Standard Operating Procedures for COVID-19
(as of 29 January 2021)**

VAERS Team

**Immunization Safety Office, Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention**



New FOIA Release Shows CDC Lied About Its VAERS Safety Monitoring Efforts

They never found any safety signals, because they didn't look for them

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The CDC Gave Me Whiplash

They said they weren't monitoring for VAERS, then they said they did, then they said they didn't but recently did. Confused yet?

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FDA Refuses to Make Its VAERS Safety Monitoring Analyses Public

In other news: FDA changes the definition of "transparency."

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1,476,227 Reports Through December 02, 2022



FOIA'd Contracts Show CDC Expected up to 1,000 VAERS Reports per Day for COVID Vaccines

"With up to 40% of the reports serious in nature"

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THE EPOCH TIMES

TRUTH AND TRADITION

EXCLUSIVE: CDC Says It Performed Vaccine Safety Data Mining After Saying It Didn't

EXCLUSIVE: CDC Admits It Gave False Information About COVID-19 Vaccine Surveillance

CDC Director Admits Agency Gave False Information on COVID-19 Vaccine Safety Monitoring

EXCLUSIVE: FDA Refuses to Provide Key COVID-19 Vaccine Safety Analyses

CDC Spokesperson in August, 2022:

Results of CDC safety signal analysis “were generally consistent with [the FDA’s] data mining, *revealing no additional unexpected safety signals.*”

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following [ALL 12/14/2020-07/29/2022 COVID19 mRNA Vaccines \(AGES 18+ YEARS\)](#)

Compared to [ALL 01/01/2009-07/29/2022 NON-COVID19 Vaccines \(AGES 18+ YEARS\)](#)

AGES 18+ YEARS Excludes missing ages, Initial domestic reports only, VAERS reports as of 07/29/2022

Vaccination, Received, and Completed Date: 12/14 - 07/29 (Current Week) and 12/14 - 07/22 (Past Week)

N>=3 (Current Week), PRR>=2.00 (Ratio of Proportions), Chi-Square>=4.00

MedDRA PTs sorting based on lower confidence limit and COVID19 mRNA adverse event count from 12/14/2020-07/29/2022

MedDRA Codes ALL Reports (18+)	12/14/2020-07/29/2022 COVID19 mRNA N=660643	01/01/2009-07/29/2022 NON-COVID19 N=242091	12/14-07/29 Chi-Square	12/14-07/29 PRR	12/14-07/29 LCL	12/14-07/29 UCL
EXPOSURE TO SARS-COV-2	2430	4	882.06	222.62	83.49	593.61
COVID-19 PNEUMONIA	5084	11	1846.17	169.37	93.74	306.01
PRODUCT TEMPERATURE EXCURSION ISSUE	3066	7	1109.47	160.50	76.45	336.95
POOR QUALITY PRODUCT ADMINISTERED	3247	8	1173.90	148.73	74.32	297.65
ASYMPTOMATIC COVID-19	1179	3	424.18	144.01	46.38	447.16
SARS-COV-2 TEST POSITIVE	945	3	338.25	115.43	37.16	358.54
COVID-19	47637	157	18041.38	111.19	95.07	130.04
VACCINE BREAKTHROUGH INFECTION	4852	17	1746.15	104.59	64.97	168.38
CEREBRAL THROMBOSIS	201	1	70.00	73.66	10.33	525.44
INTERMENSTRUAL BLEEDING	1339	7	473.66	70.10	33.35	147.32
LUNG OPACITY	1890	11	666.95	62.96	34.81	113.88
HEAVY MENSTRUAL BLEEDING	4312	29	1518.45	54.49	37.82	78.50
INTENTIONAL PRODUCT USE ISSUE	144	1	49.12	52.77	7.38	377.16
RED BLOOD CELL TRANSFUSION	134	1	45.46	49.10	6.87	351.14
PULMONARY THROMBOSIS	648	5	224.66	47.49	19.70	114.48
SUSPECTED COVID-19	878	7	304.43	45.96	21.85	96.70
DISEASE RECURRENCE	245	2	83.83	44.89	11.16	180.50
POST-ACUTE COVID-19 SYNDROME	345	3	118.18	42.14	13.53	131.30
VACCINATION SITE PRURITUS	3991	35	1386.08	41.79	29.96	58.28

Proportional Reporting Ratio (PRR)

$$\text{PRR} = \frac{\text{Reports for An Adverse Event As \% of All Reports for COVID Vaccines}}{\text{Reports for An Adverse Event As \% of All Reports for Other Vaccines}}$$

Proportional Reporting Ratio (PRR)

$$1 = \frac{10\% \text{ of COVID Vaccine Reports are Myocarditis}}{10\% \text{ of Other Vaccine Reports are Myocarditis}}$$

Proportional Reporting Ratio (PRR)

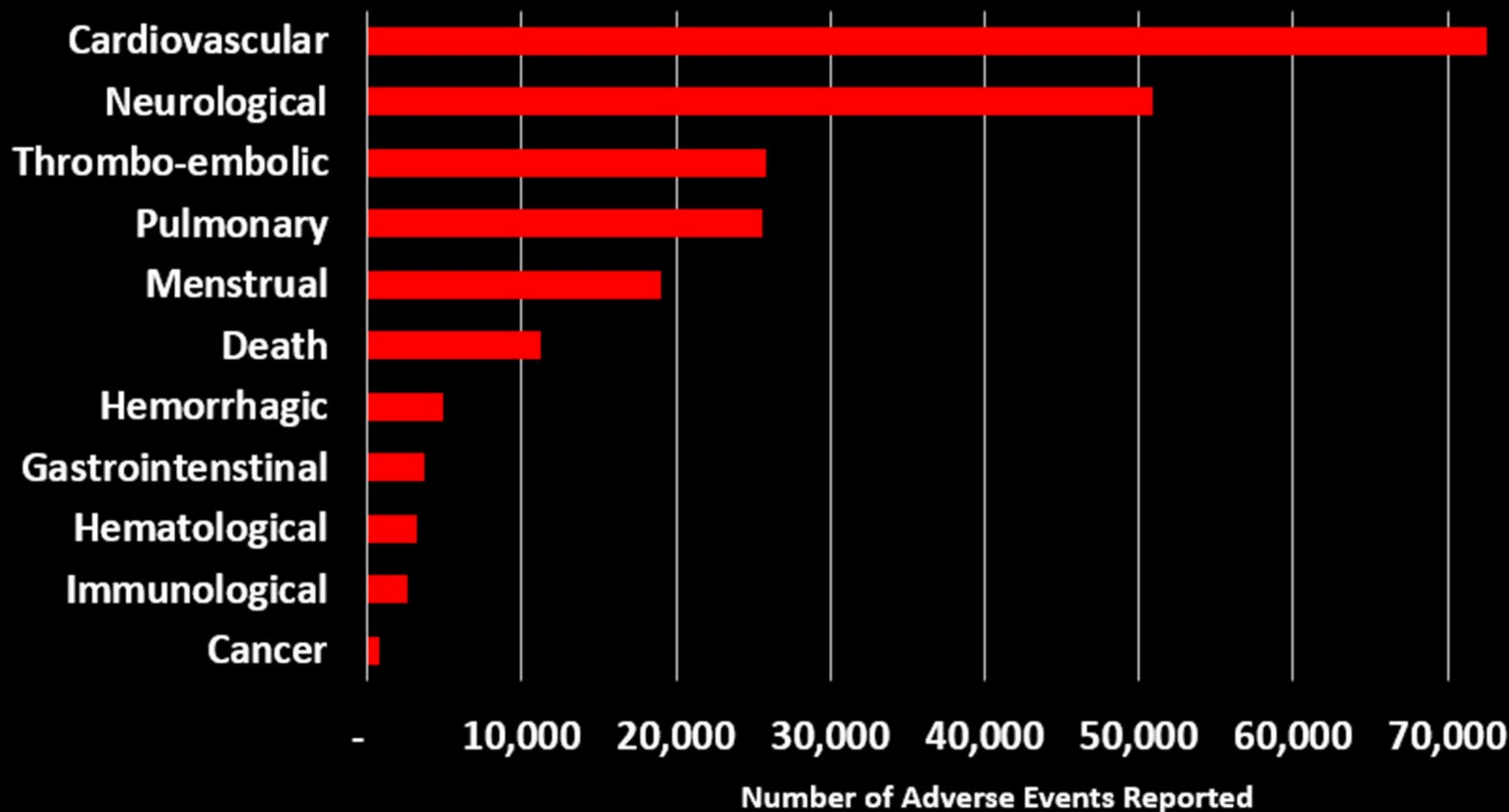
$$2 = \frac{20\% \text{ of COVID Vaccine Reports are Myocarditis}}{10\% \text{ of Other Vaccine Reports are Myocarditis}}$$

Results of CDC's Safety Signal Analysis 18+

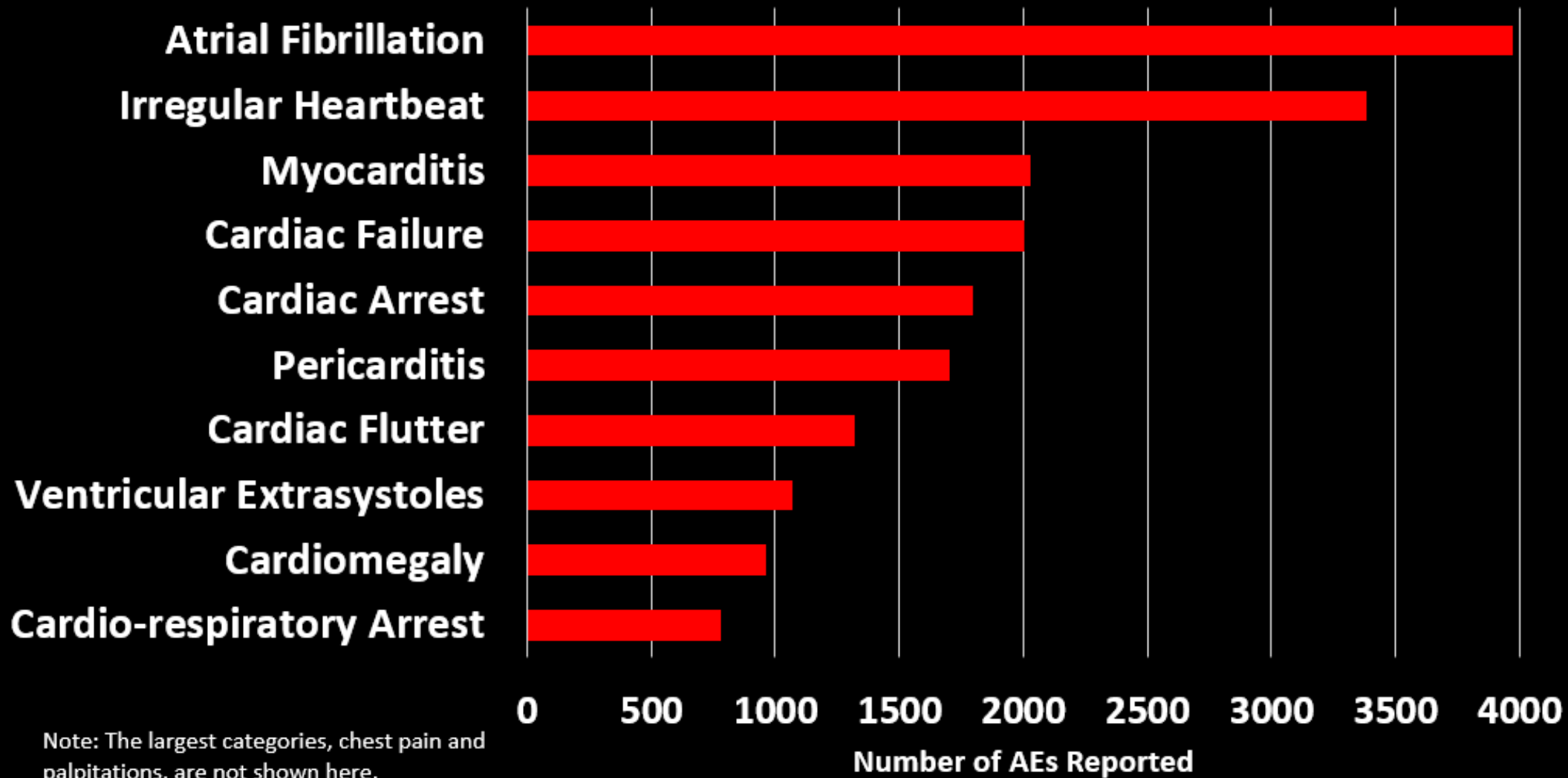
Dec. 14, 2020 – July 29, 2022

- **Compares mRNA COVID vs. all non-COVID vaccines since 2009**
- **Safety signals for 770 Adverse Events in 18+**
- **2/3 have a safety signal larger than myocarditis**
- **% of serious reports double all other vaccines (11% vs. 5.5%)**
- **73K serious reports for mRNA vs. 13K all other since 2009**
- **Signals not due to stimulated/exaggerated reporting**

Major Categories of Adverse Event Safety Signals from CDC's Analysis of VAERS Reports for mRNA COVID Vaccines



Major Cardiovascular Adverse Event Safety Signals from the CDC's Analysis of VAERS Reports for mRNA COVID Vaccines

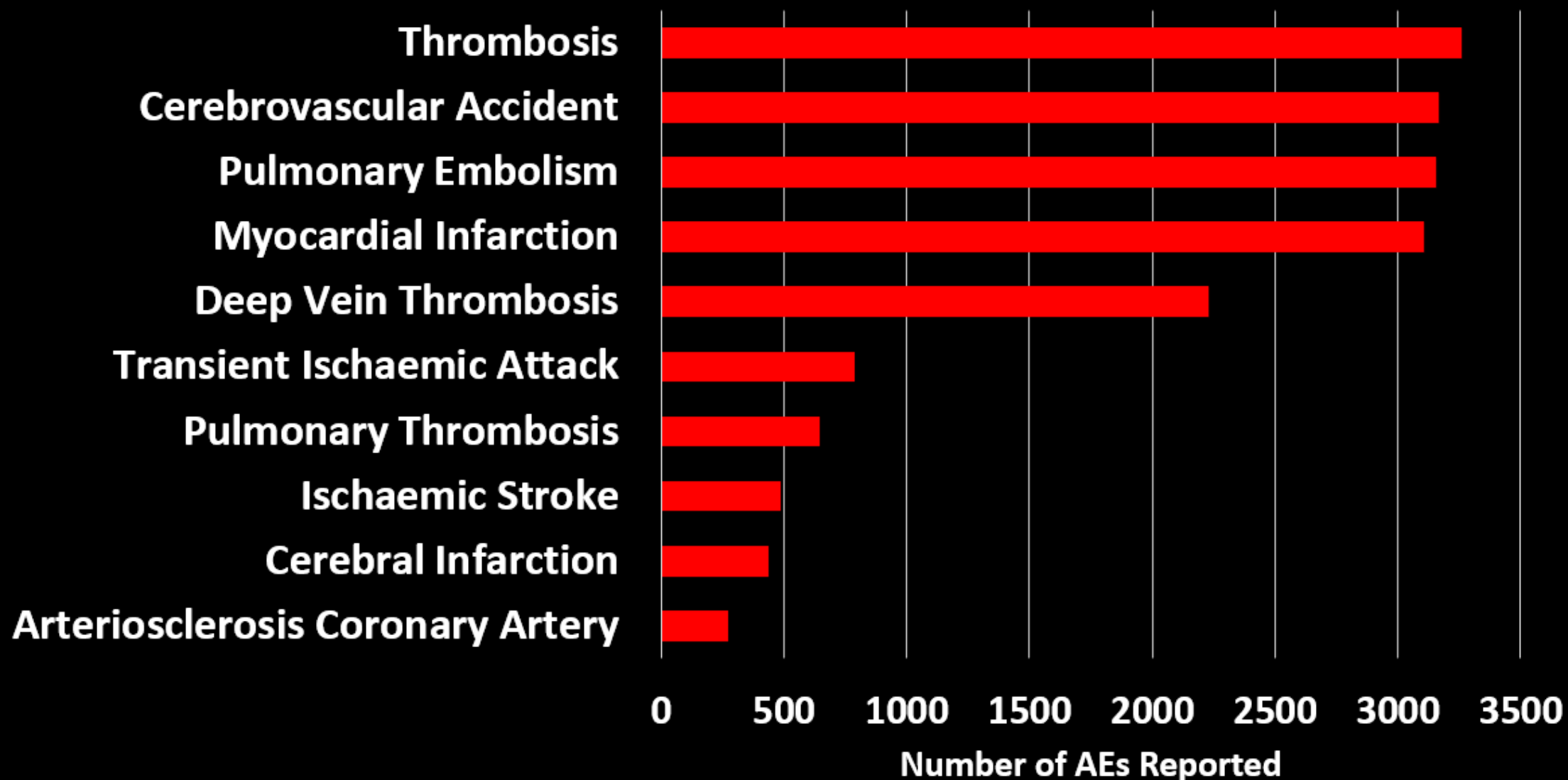


ARTERIOSCLEROSIS
BLOOD PRESSURE ABNORMAL
SUPRAVENTRICULAR TACHYCARDIA
HEART RATE ABNORMAL
BLOOD PRESSURE FLUCTUATION
VENTRICULAR TACHYCARDIA
TROPONIN INCREASED
ATRIAL FLUTTER
CARDIAC DISCOMFORT
CARDIAC FAILURE ACUTE
SUPRAVENTRICULAR EXTRASYSTOLES
BLOOD PRESSURE DIASTOLIC INCREASED
CARDIOGENIC SHOCK
VENTRICULAR FIBRILLATION
LEFT VENTRICULAR FAILURE
HYPERTENSIVE HEART DISEASE
EJECTION FRACTION DECREASED
LEFT VENTRICULAR DYSFUNCTION
AORTIC ARTERIOSCLEROSIS
CHRONIC LEFT VENTRICULAR FAILURE
VENTRICULAR HYPOKINESIA
HEART SOUNDS ABNORMAL
ATRIOVENTRICULAR BLOCK
ACUTE LEFT VENTRICULAR FAILURE
AORTIC STENOSIS

POOR PERIPHERAL CIRCULATION
CARDIOVASCULAR DISORDER
CORONARY ARTERY BYPASS
RIGHT VENTRICULAR DYSFUNCTION
PERICARDIAL DRAINAGE
ACUTE CORONARY SYNDROME
LEFT ATRIAL ENLARGEMENT
ISCHAEMIC CARDIOMYOPATHY
HYPERTENSIVE EMERGENCY
CONGESTIVE CARDIOMYOPATHY
STRESS CARDIOMYOPATHY
IMPLANTABLE DEFIBRILLATOR INSERTION
CARDITIS
CARDIAC TAMPONADE
CORONARY ARTERY STENOSIS
RIGHT VENTRICULAR DILATATION
ATRIAL SEPTAL DEFECT
HEART VALVE INCOMPETENCE
SUDDEN CARDIAC DEATH
AORTIC DILATATION
ANGIOPATHY
ANGIOPLASTY
IMPLANTABLE CARDIAC MONITOR INSERTION
VENTRICULAR HYPERTROPHY
SYSTOLIC DYSFUNCTION

ANGINA UNSTABLE
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION
ENDOCARDITIS
CARDIAC FAILURE CHRONIC
CARDIAC OPERATION
CARDIAC VALVE DISEASE
LEFT VENTRICULAR DILATATION
MYOCARDIAL FIBROSIS
ATRIAL ENLARGEMENT
COR PULMONALE ACUTE
AORTIC VALVE REPLACEMENT
RIGHT VENTRICULAR FAILURE
MYOCARDIAL OEDEMA
CARDIOPULMONARY FAILURE
ACUTE CARDIAC EVENT
MITRAL VALVE CALCIFICATION
VENTRICULAR ARRHYTHMIA
RIGHT ATRIAL DILATATION
RIGHT ATRIAL ENLARGEMENT
COR PULMONALE
LEFT VENTRICULAR ENLARGEMENT
AORTIC DISORDER
VENTRICULAR ASSIST DEVICE INSERTION

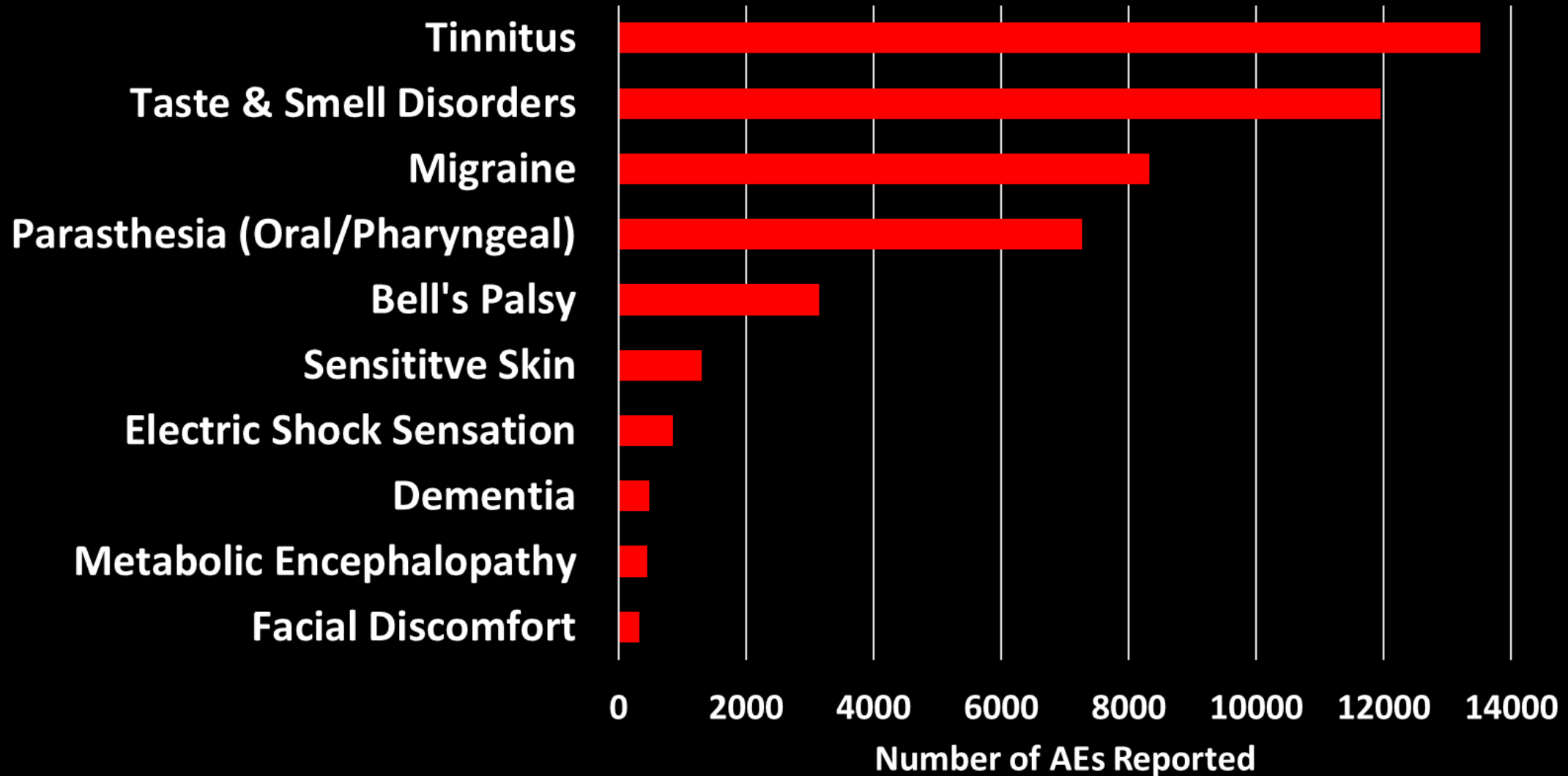
Major Thrombo-Embolic Adverse Event Safety Signals from CDC's Analysis of VAERS Reports for mRNA COVID Vaccines



CORONARY ARTERY OCCLUSION
COAGULOPATHY
CEREBRAL THROMBOSIS
MYOCARDIAL ISCHAEMIA
THROMBOPHLEBITIS SUPERFICIAL
PULMONARY INFARCTION
LACUNAR INFARCTION
RETINAL ARTERY OCCLUSION
CEREBRAL ARTERY OCCLUSION
ISCHAEMIA
EMBOLIC STROKE
INTRACARDIAC THROMBUS
RETINAL VEIN OCCLUSION
ATRIOVENTRICULAR BLOCK COMPLETE
CEREBELLAR STROKE
PERIPHERAL ARTERY THROMBOSIS
PORTAL VEIN THROMBOSIS
ARTERIAL OCCLUSIVE DISEASE
EMBOLISM
HYPERCOAGULATION
THALAMIC INFARCTION
TRANSVERSE SINUS THROMBOSIS
CORONARY ARTERY THROMBOSIS
CAROTID ARTERY OCCLUSION
THROMBOTIC THROMBOCYTOPENIC PURPURA

INTESTINAL ISCHAEMIA
ISCHAEMIC HEPATITIS
PERIPHERAL ARTERIAL OCCLUSIVE DISEASE
PERIPHERAL ISCHAEMIA
MESENTERIC VEIN THROMBOSIS
JUGULAR VEIN THROMBOSIS
RENAL INFARCT
SPLENIC INFARCTION
EMBOLISM VENOUS
THROMBOEMBOLECTOMY
INFARCTION
ISCHAEMIC CEREBRAL INFARCTION
PERIPHERAL ARTERY OCCLUSION
VENOUS THROMBOSIS LIMB
CEREBRAL VENOUS THROMBOSIS
BASAL GANGLIA INFARCTION
SUBCLAVIAN VEIN THROMBOSIS
LACUNAR STROKE
ARTERIAL THROMBOSIS
AORTIC THROMBOSIS
VERTEBRAL ARTERY OCCLUSION
HAEMORRHAGIC TRANSFORMATION STROKE
CEREBRAL ARTERY EMBOLISM
CEREBRAL ARTERY THROMBOSIS
SPLENIC VEIN THROMBOSIS

Major Neurological Adverse Event Safety Signals from the CDC's Analysis of VAERS Reports for mRNA COVID Vaccines



HYPORESPONSIVE TO STIMULI

BRAIN INJURY

BRADYKINESIA

COMMUNICATION DISORDER

SKIN SENSITISATION

DEMENTIA ALZHEIMER'S TYPE

HYPOGEUSIA

HYPERAESTHESIA TEETH

DISORGANISED SPEECH

PARKINSON'S DISEASE

CLUSTER HEADACHE

OPHTHALMIC MIGRAINE

TOXIC ENCEPHALOPATHY

HYPOSMIA

SPINAL STENOSIS

MENIERE'S DISEASE

CEREBRAL MASS EFFECT

CRANIOTOMY

NEW DAILY PERSISTENT HEADACHE

NEUROLOGIC NEGLECT SYNDROME

VESTIBULAR MIGRAINE

BRAIN OPERATION

VASCULAR DEMENTIA

DEPERSONALISATION/DEREALISATION DISORDER

INTRACRANIAL MASS

ATTENTION DEFICIT HYPERACTIVITY DISORDER

LACK OF SPONTANEOUS SPEECH

SENSITISATION

LANGUAGE DISORDER

IDIOPATHIC INTRACRANIAL HYPERTENSION

REDUCED FACIAL EXPRESSION

HEMIPARAESTHESIA

HEMIPLEGIC MIGRAINE

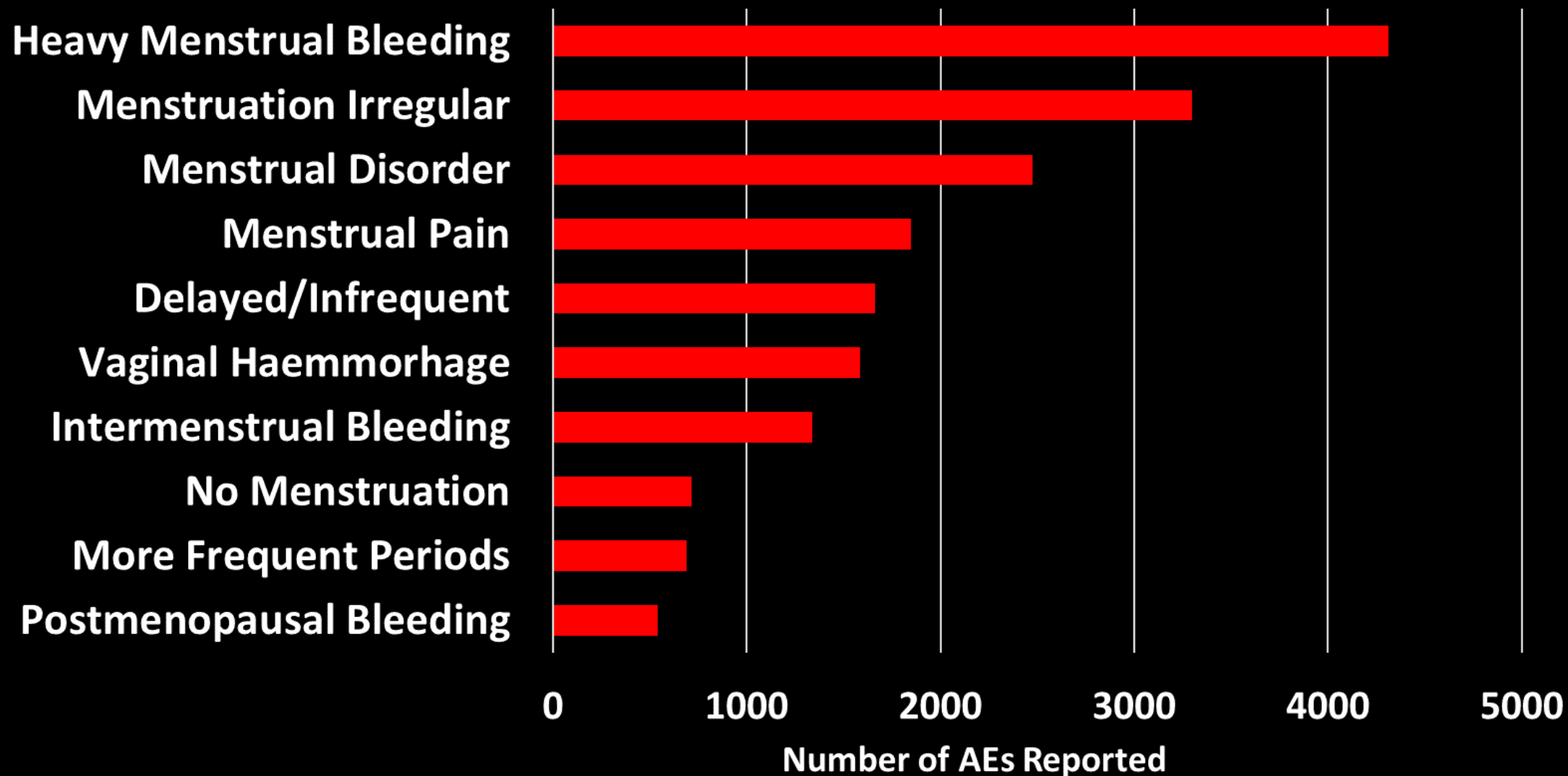
PHANTOM LIMB SYNDROME

PARAESTHESIA EAR

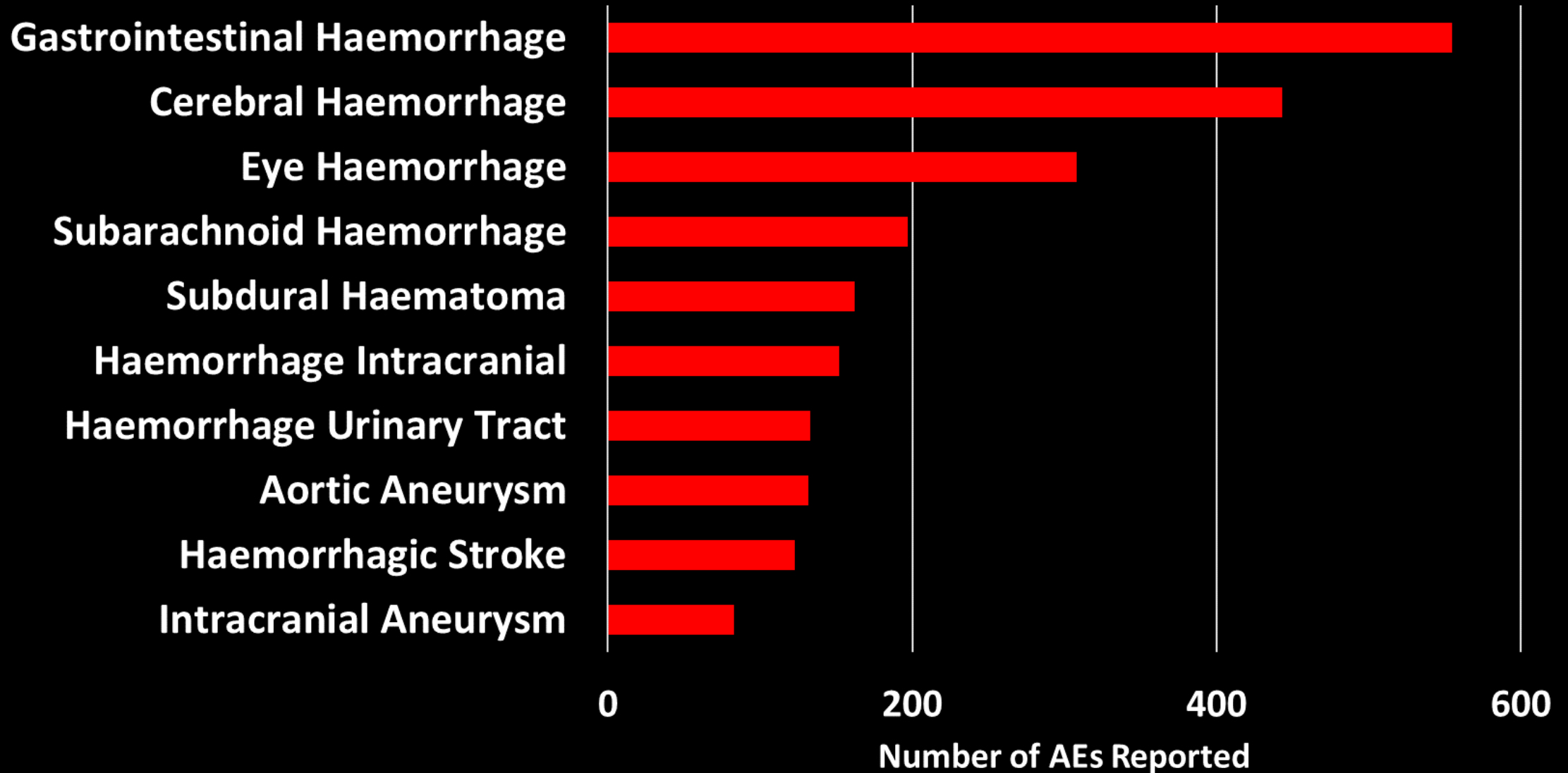
THUNDERCLAP HEADACHE

DENTAL PARAESTHESIA

Major Menstrual Adverse Event Safety Signals from CDC's Analysis of VAERS Reports for mRNA COVID Vaccines



Major Haemorrhagic Adverse Event Safety Signals from CDC's Analysis of VAERS Reports for mRNA COVID Vaccines



UPPER GASTROINTESTINAL HAEMORRHAGE

INTERNAL HAEMORRHAGE

ACUTE PULMONARY OEDEMA

SHOCK HAEMORRHAGIC

INTRAVENTRICULAR HAEMORRHAGE

BRAIN HERNIATION

SUBDURAL HAEMORRHAGE

PULMONARY HAEMORRHAGE

ANAL HAEMORRHAGE

LOWER GASTROINTESTINAL HAEMORRHAGE

VASOGENIC CEREBRAL OEDEMA

BASAL GANGLIA HAEMORRHAGE

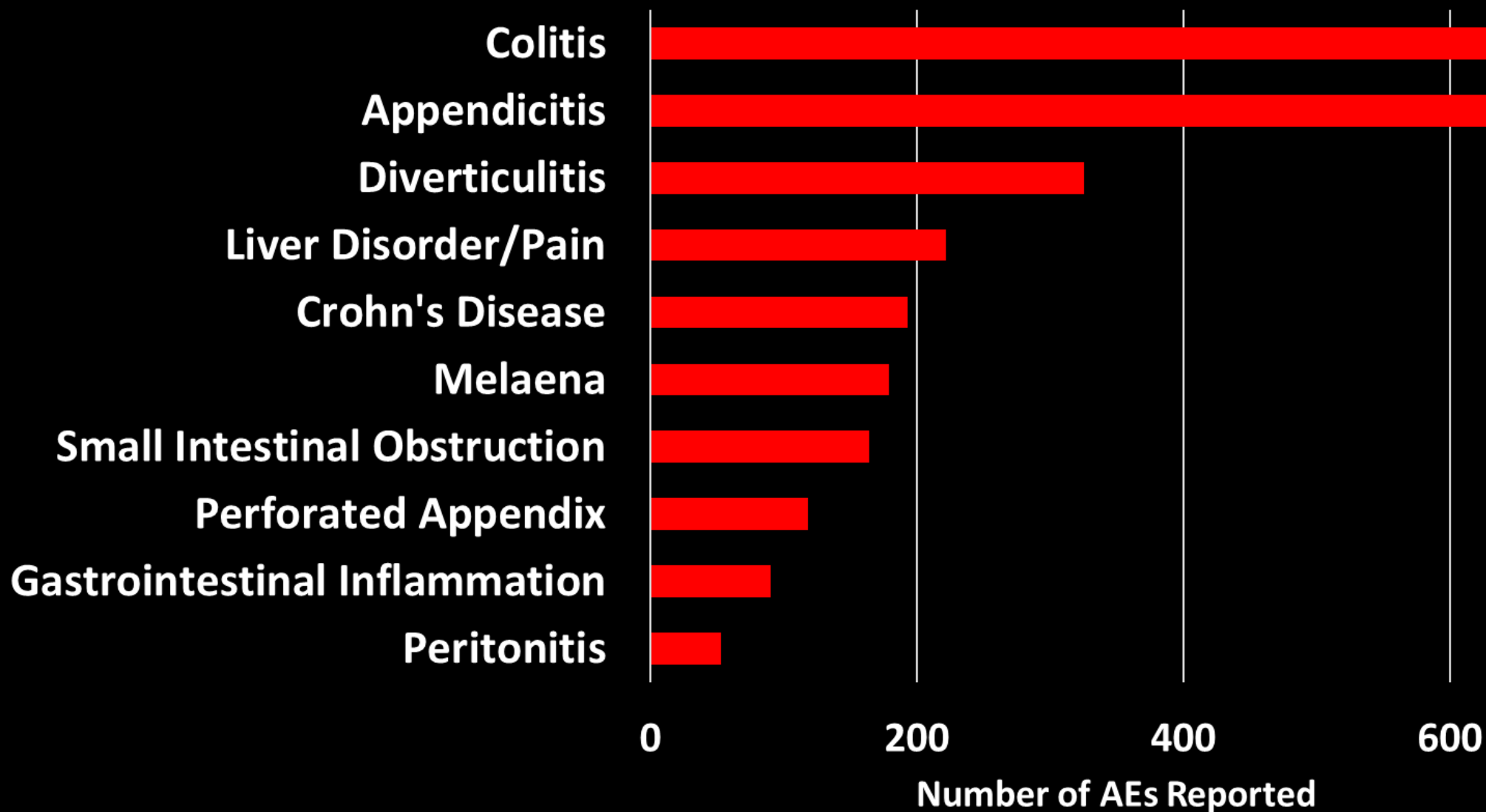
CEREBRAL HAEMATOMA

VEIN RUPTURE

CARDIAC ANEURYSM

VASCULAR PSEUDOANEURYSM

Major Gastrointestinal Adverse Event Safety Signals from CDC's Analysis of VAERS Reports for mRNA COVID Vaccines



Cancers / Neoplasms

LUNG NEOPLASM MALIGNANT
NEOPLASM
CHRONIC LYMPHOCYTIC LEUKAEMIA
PLASMA CELL MYELOMA
BREAST CANCER
COLON CANCER
METASTASIS
B-CELL LYMPHOMA
PANCREATIC CARCINOMA
METASTASES TO LIVER
METASTASES TO BONE
METASTASES TO CENTRAL NERVOUS SYSTEM
BREAST CANCER METASTATIC
METASTASES TO LYMPH NODES
LUNG ADENOCARCINOMA
FOLLICULAR LYMPHOMA

Miscellaneous

HYPERPYREXIA

CORONARY ARTERY DISSECTION

AORTIC DISSECTION

DYSHIDROTIC ECZEMA

ACUTE KIDNEY INJURY

CHRONIC KIDNEY DISEASE

RENAL PAIN

RENAL IMPAIRMENT

DIALYSIS

END STAGE RENAL DISEASE

HAEMODIALYSIS

AZOTAEMIA

NEPHROSCLEROSIS

RENAL TRANSPLANT

RENAL ATROPHY

HEPATIC CIRRHOSIS

LIVER INJURY

HEPATIC LESION

CHOLECYSTITIS ACUTE

BILIARY COLIC

HEPATIC MASS

GALLBLADDER ENLARGEMENT

OCULAR DISCOMFORT

DYSCHROMATOPSIA

DIABETIC KETOACIDOSIS

PANCREATITIS ACUTE

BLOOD GLUCOSE ABNORMAL

BLOOD GLUCOSE FLUCTUATION

SEPTIC SHOCK

HYPERTHYROIDISM

THYROID MASS

BASEDOW'S DISEASE

THYROIDITIS

THYROIDITIS SUBACUTE

96 Safety Signals for 12-17 Year-olds

- Myocarditis
- Pericarditis
- Bell's Palsy
- Genital ulcerations
- High blood pressure
- Tachycardia
- Menstrual irregularities
- Cardiac valve incompetencies
- Pulmonary embolism
- Cardiac arrhythmias
- Thromboses
- Pericardial and pleural effusion
- Appendicitis (and perforation)
- Immune thrombocytopenia
- Chest pain
- Intensive care
- Increased troponin levels
- Anticoagulant therapy

66 Safety Signals for 5-11 Year-olds

- Myocarditis
- Pericarditis
- Ventricular dysfunction
- Cardiac valve incompetencies
- Pericardial & pleural effusion
- Chest pain
- Appendicitis & appendectomies
- Kawasaki's disease
- Menstrual irregularities
- Vaccine breakthrough infection
- Vitiligo

Objections to VAERS

- ***Unreliable / Fraudulent***
 - So why does CDC use it to publish in top journals?
 - It's their system! If it's broken, why don't they fix it?
- ***More reports because more doses given***
 - Safety signals not dependent on total #, but on %
 - Twice as many regular vaccines given since 2009
- ***Due to exaggerated/stimulated reporting***
 - If it was, the increase should be similar across AEs
 - Also regular vaccine reports have not increased since 2020
- ***Due to COVID-19*** – My analysis dropped reports w/COVID
- ***Due to age differences*** – Broken down by age



January 25, 2022

Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021

Matthew E. Oster, MD, MPH^{1,2,3}; David K. Shay, MD, MPH¹; John R. Su, MD, PhD, MPH¹; et al

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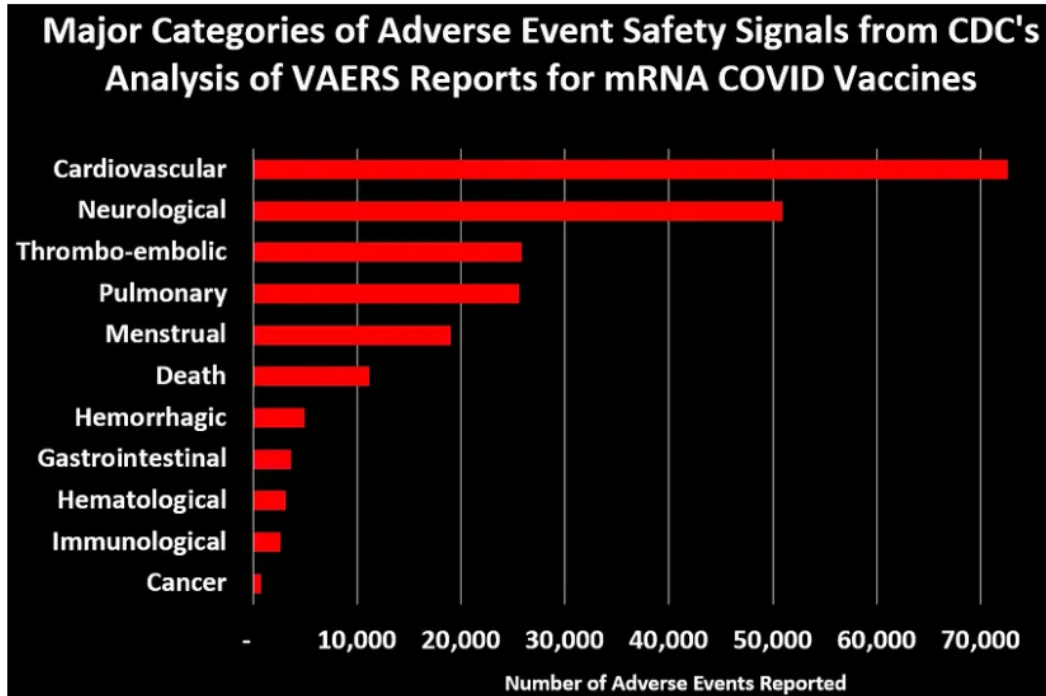
⁶Boston Medical Center, Boston, Massachusetts

⁷Duke University, Durham, North Carolina

Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe

CDC COVID-19 Response Team
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L E Markowitz MD,
T T Shimabukuro MD,
D K Shay MD) and **Epidemic
Intelligence Service**
(H G Rosenblum), **Centers for
Disease Control and
Prevention, Atlanta, GA, USA**

[Click here for full write-up and analysis on my blog](#)



CDC Finally Released Its VAERS Safety Monitoring Analyses for COVID Vaccines via FOIA

And now it's clear why they tried to hide them.

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