

VAERS DATA ANALYSIS

AERS DATA EXTRACT 2021-07-23
Christine COTTON

1

To my niece Tea, 19 yo on the 8/8/21
To my nephew Milan 16 yo
To Charlie, 15 yo
To my parents
To my friends
For all of you

Who am I

2

Biostatistician

- 23 years for pharmaceutical industries
- Run, during 22 years , my own company : a CRO - Clinical Research Organization

Experience

- in **all study phases and various therapeutic domains**: Allergy, Cardiology, Dermatology, Endocrinology, Gastric domain, Gynecology, Metabolism, Odontology / Dentistry, Oncology, ENT, Pneumology, Central Nervous System, Osteo-Muscular system, Rheumatology, Urology, Virology ..
- **Protocol statistical part, number of subjects necessary to conclude to efficacy**

Statistician Expert in IDMC (Independent Data Monitoring Committee)

What is the CDC VAERS database ?

3

General information

- **Administrators** : VAERS is **co-administered** by : 1) the **Food and Drug Administration (FDA)** and 2) the **Centers for Disease Control (CDC)**
- **Database goals**: reports data collection of suspected adverse events, including all Vaccine adverse reactions for the United States of America (USA)
- **Database Access & update frequency** : free access on <https://vaers.hhs.gov/> and updated on a weekly basis each Friday

Data extraction

- **VAERS database extract** → on the 23rd July of 2021
 - **Files downloaded** :
 - 1)** 1 zipped file for 2021
 - 2)** 1 zipped file for 2020Note : each includes 3 CSV file : VAERSDATA, VAERSVAX and VAERSSYMPTOM, the content of each file is clearly documented into a CDC document, VAERS DATA USE GUIDE : https://vaers.hhs.gov/docs/VAERSDataUseGuide_November2020.pdf)
- **VAX file volume of data** : Out of 434 899 lines reported → 429 009, 98.9 % are reported to COVID vaccine in 2021
- **Fast Database size increase** : as an example : 11 Mo for the entire 2020, 16 Mo end of April 2021, 67 Mo first week of June 2021, 90 Mo on the 23rd of July

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the downloadable PDF. *New!*

Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.

¿Ha tenido una reacción después de recibir una vacuna?

1. Contacte a su proveedor de salud.
2. Reporte un evento adverso utilizando el formulario de VAERS en línea *¡Nuevo!*



COVID-19 vaccine EUA reporting requ



REPORT AN ADVERSE EVENT

Review reporting requirements and submit reports.



SEARCH VAERS DATA

Download VAERS Data and search the CDC WONDER database.



REVIEW RESOURCES

Find materials, publications, learning tools, and other resources.

VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

VAERS data available to the public include only the initial report done by VAERS. Updated data which contain data from medical records and corrections reported during follow up are used by the government for analysis. However, for numerous reasons including data coverage, these available data are not available to the public.

Options for Accessing VAERS Data

VAERS data is available in two ways.



Search data with an easy-to-use, main screen tool. Produce tables, maps, charts, and data extracts of vaccine adverse events.

I have read and understand the disclaimer

Search CDC Wonders



Download raw data for import into a database, spreadsheet, or text editing program.

I have read and understand the disclaimer

Download VAERS Data

Clean-up process

5

- Existence of false Adverse Drug Reaction (ADR), many missing data or inconsistencies
- Concatenation of 2020 Database and 2021 Database
- Use of the SAS© software

Methods to manage false ADr

- Delete **useless reports** « No adverse event », « COVID vaccination »
- Delete **false reports** « AAAAA » « DHFOIDHFOIHDASOIH »...
- Delete administration product issues, wrong vaccine (**mixed** vaccines, Pfizer then Moderna, Moderna then Pfizer), **wrong techniques** (dilution problems, **wrong solution and/or dosage**, **needle problems**, **sprynge** issues ..), **expired** products, bad **storage** conditions (temperature), wrong **site of administration** (other muscle than deltoid, buttocks ...), short or long time between doses
- Delete reported **deviations to Emergency use** such as age of patient <18
- When ADr were entered for patients with mixed vaccines, keep patients with several vaccines only if real ADr reported

Out of more than 430 000 lines, only 398 277 are kept for analysis

Methods to deal with inconsistencies or missing data

- Errors on **age** of patient, wrong calculated CAGE_YRS variable, cancel suspicious ages or use of the symptom text to correct the age
- Erroneous or missing sex (patient pregnant but unknown sex ...)
- Erroneous date of vaccination, wrong year, 2000 instead of 2020

Adverse Drug Reaction (ADR) of interest

6

Computation

Deaths

- Compute **Deaths** using the ADR text (« Death », « Patient died », « Pronounced dead », « Found dead », « Patient expired »..), and not only using the entered variable or **the coded symptom**
- Complete missing **date of death** when they are **reported into symptom text**

Serious event

- **Visible** on CDC detailed report **does not exist** into the data file exported, need to **be computed**
- ADR was considered as serious in case of death, life threatening, hospitalization, prolonged hospitalization, pregnancy disorders

Pregnancy

- **Pregnancy status** not available, **need to be computed** using the description of symptom (when pregnancy or pregnant is mentionned) but cancel former pregnancies noted
- **Aborption** not available, need to be computed using the description of symptom **and coded symptom**

Various coded symptoms addition

- **Bleeding, Clotting and Ischaemic** ADRs using coded symptom
- Myocarditis / Pericarditis ADRs using coded symptom
- ADR involving **loss of sight, hearing, speech or smell**

Day lapse between dates

- Time between vaccination and ADR
- Time between vaccination and death

Population with ADR

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Christine COTTON

7

Population with ADR

8

		MODERNA N=175 832	PFIZER-BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
Calculated age	Mean (s.d.)	51.4 (17.3)	47.9 (18.2)	45.1 (16.1)	50.9 (17.7)	49.2 (17.8)
	Median	51.0	47.0	45.0	52.0	49.0
	Q1 - Q3	37.0 - 65.0	34.0 - 61.0	32.0 - 57.0	37.0 - 64.0	35.0 - 63.0
	Min - Max	0.1 - 120.0	0.1 - 119.0	0.1 - 105.0	0.6 - 98.0	0.1 - 120.0
Class	Age<=6 ans	17 (0.0%)	37 (0.0%)	6 (0.0%)	1 (0.1%)	61 (0.0%)
]6-12 ans]	9 (0.0%)	849 (0.5%)	5 (0.0%)	1 (0.1%)	864 (0.2%)
]12-18 ans]	1049 (0.6%)	7822 (4.7%)	622 (1.8%)	12 (1.6%)	9505 (2.5%)
]18-30 ans]	22155 (12.7%)	23101 (13.9%)	7067 (20.3%)	97 (12.6%)	52420 (14.0%)
]30-50 ans]	61687 (35.4%)	60941 (36.7%)	13486 (38.8%)	258 (33.5%)	136372 (36.3%)
]50-70 ans]	62675 (36.0%)	53432 (32.2%)	11533 (33.2%)	294 (38.1%)	127934 (34.1%)
]70-90 ans]	25283 (14.5%)	18616 (11.2%)	1913 (5.5%)	98 (12.7%)	45910 (12.2%)
	> 90 ans	1233 (0.7%)	1161 (0.7%)	97 (0.3%)	10 (1.3%)	2501 (0.7%)

17 % of reports concern patients younger than 30 yo
 More than 50 % concern patients younger than 50 yo
 More than 70 % are woman

Note : as some patients have duplicate lines due to unknown vaccine, results are expressed into reports or ADRs and not into patients even if the concerned number does not exceed 100

Population with ADR

9

		MODERNA N=175 832	PFIZER-BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
Sex	N	175832	179874	41580	941	398227
	Missing	0	0	0	0	0
	Female	131902 (75.0%)	127280 (70.8%)	25729 (61.9%)	594 (63.1%)	285505 (71.7%)
	Male	42712 (24.3%)	49266 (27.4%)	13437 (32.3%)	293 (31.1%)	105708 (26.5%)
	Unknown	1218 (0.7%)	3328 (1.9%)	2414 (5.8%)	54 (5.7%)	7014 (1.8%)

More than 70 % of ADRs concern women

Outcomes

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10

Hospitalization and recovery

11

	MODERNA N=175 832	PFIZER- BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
N	175832	179874	41580	941	398227
Hospitalization	10063 (5.7%)	11888 (6.6%)	2555 (6.1%)	105 (11.2%)	24611 (6.2%)

	MODERNA N=175 832	PFIZER- BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
N	175832	179874	41580	941	398227
Missing	0	0	0	0	0
No Recovery	85281 (48.5%)	82416 (45.8%)	19403 (46.7%)	477 (50.7%)	187577 (47.1%)
Recovery	66938 (38.1%)	62814 (34.9%)	14070 (33.8%)	260 (27.6%)	144082 (36.2%)
Unknown	23613 (13.4%)	34644 (19.3%)	8107 (19.5%)	204 (21.7%)	66568 (16.7%)

6 % of ADRs lead to an hospitalization
 For 47,1 % of the ADRs, there were no recovery when the ADRs was entered into the CDC databse

Note : Hospitalization, CDC variable, need to be validate with text written by reporter

COVID infection

12

	MODERNA N=175 832	PFIZER-BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
COVID	2 580 (3,3%)	8 036 (4,5%)	876 (2,1%)	15 (1,6%)	11 507 (2,9%)

2,9 % of ADRs were declared COVID+ despite the vaccination

COVID item does not exist into the CDC database, It was calculated using the following coded Symptoms
Further checks are necessary to include COVID from text written by the reporter

- Asymptomatic COVID-19
 - COVID-19
 - COVID-19 pneumonia
 - COVID-19 treatment
 - Coronavirus infection
 - Post-acute COVID-19 syndrome
 - Suspected COVID-19
 - SARS-CoV-2 sepsis
- SARS-CoV-2 antibody test positive
 - SARS-CoV-2 test positive
 - Coronavirus test positive
 - Antibody test positive
 - SARS-CoV-2 RNA increased
 - SARS-CoV-2 test false negative

Note : Pending tests results or negative results were not considered as COVID infection

Deaths and Serious events

13

	MODERNA N=175 832	PFIZER- BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
Death (CDC variable)	2584 (1.5%)	2351 (1.3%)	511 (1.2%)	25 (2.7%)	5 471 (1.4%)
Death (Corrected)	2629 (1.5%)	2376 (1.3%)	516 (1.2%)	25 (2.7%)	5 546 (1.4%)
SAE	14 500 (8.2%)	16 572 (9.2%)	3 416 (8.2%)	144 (15.3%)	34 632 (8.7%)

5 471 deaths according to CDC variable
5 546 after calculation

Fetal deaths are not taken into account into the new calculation
More than 34 000 ADR can be considered as Serious (almost 9 %)

Table 1 for MCHES T3: 1914450-1

Field Name	Value	Field Name	Value
Age	23	Sex	Male
Address	1234 Main St	City	New York, NY
State	NY	Zip	10001
Phone	212-555-1234	Occupation	Student
Education	High School	Marital Status	Single
Religion	Catholic	Smoking	Never
Drugs	None	Alcohol	Occasional
Medical History	None	Current Medications	None
Insurance	Medicaid	Insurance Provider	NY State
Emergency Contact	Parent	Contact Info	212-555-5678

Field Name	Value
Death	No
Death Date	
Death Cause	
Death Location	
Death Cert	No
Death Cert No	
Death Cert Date	
Death Cert State	
Death Cert City	
Death Cert Zip	
Death Cert County	
Death Cert Hospital	
Death Cert Physician	
Death Cert ICD-10	
Death Cert ICD-9	
Death Cert ICD-8	
Death Cert ICD-7	
Death Cert ICD-6	
Death Cert ICD-5	
Death Cert ICD-4	
Death Cert ICD-3	
Death Cert ICD-2	
Death Cert ICD-1	
Death Cert ICD-0	

* If you are reporting a death, you must report the date of death, the cause of death, and the location of death. The cause of death should be reported using the ICD-10 code.

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Field Name	Value	Field Name	Value	Field Name	Value	Field Name	Value
Age	23	Sex	Male	Death	No	Death Date	

Report on the death of a person who died in New York State. The death must be reported to the local health department within 15 days of the death. The death must be reported to the state health department within 30 days of the death. The death must be reported to the federal health department within 60 days of the death.

Report on the death of a person who died in New York State. The death must be reported to the local health department within 15 days of the death. The death must be reported to the state health department within 30 days of the death. The death must be reported to the federal health department within 60 days of the death.

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Report on the death of a person who died in New York State. The death must be reported to the local health department within 15 days of the death. The death must be reported to the state health department within 30 days of the death. The death must be reported to the federal health department within 60 days of the death.

EXAMPLE

Death= No into CDC variable and death reported into symptoms description

23 yo male
« Sudden death from myocardial injury » after Moderna vaccine

Details for VAERS ID: 1138788-1

Event Information				Event Categories			
Patient Age	58.00	Sex	Female	Death	No		
State / Territory	Illinois	Date Report Completed	2021 03 26	Life Threatening	No		
Date Vaccinated	2021 03 24	Date Report Received	2021 03 26	Permanent Disability	No		
Date of Onset	2021 03 24	Date Died		Congenital Anomaly / Birth Defect **	No		
Days to onset	0			Hospitalized	No		
Vaccine Administered By	Other	Vaccine Purchased By	Not Applicable ***	Days In Hospital	None		
Mhr/Imm Project Number	NONE	Report Form Version	2	Existing Hospitalization Prolonged	No		
Recovered	No	Serious	No	Emergency Room / Office Visit ***	N/A		
* VAERS 2.0 Report Form Only				Emergency Room **	Yes		
*** VAERS 1 Report Form Only				Office Visit **	No		
Not Applicable will appear when information is not available on this report form version.				* VAERS 2.0 Report Form Only			
				*** VAERS 1 Report Form Only			
				N/A will appear when information is not available on this report form version.			

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID-19 VACCINE	COVID-19 (COVID-19 (MODERNA))	MODERNA	071B21A	1	IN	RA

Symptom
MALaise
NASOPHARYNGITIS
VOMITING

Adverse Event Description
At 4pm post vaccine the patient was cold, had tremors and later that evening around midnight vomiting and overall not feeling well. Patient went to Hospital ER. Patient expired in the ER.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time Of Vaccination	History/Allergies
	Anemia, DM2, SHPT, Cold/flu/ids, hyperphosphatemia, NKDA

EXAMPLE

Death= No into CDC variable and death reported into symptoms description

58 yo female
« Patient expired into the ER» after Moderna vaccine

Details for VAERS ID: U915282_1

Event Information			
Patient Age	12:00	Sex	Female
State / Territory	California	Date Report Completed	2021-01-14
Date Vaccinated	2020-12-21	Date Report Received	2021-01-14
Date of Onset	2020-12-28	Date Died	
Days to onset	7		
Vaccine Administered By	Private	Vaccine Purchased By	Not Applicable **
Mfr/Loan Project Number	8008	Report Form Version	2
Recovered	No	Serious	No

* VAERS 2.0 Report Form Only

*** VAERS 1 Report Form Only

** "Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only

*** VAERS 1 Report Form Only

** "N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER, BIONTECH))	PFIZER/BIONTECH	NONE	UNK		

Symptom

AUTOPSY

DEATH

MATERNAL EXPOSURE DURING BREAST FEEDING

Adverse Event Description

One week after I was vaccinated, my partially breast fed infant daughter (DOB 11/02/2020) died in her sleep on 11/28/2020. The cause of death is not known. I am reporting her death here because of the relative proximity to my vaccination and her death.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
An autopsy of my daughter has been completed and additional genetic testing is pending.	None	

Medications At Time Of Vaccination History/Allergies

Spinov, Dulera, Escopol, Miquibir Asthma Anxiety Prosefeeding, None

EXAMPLE

Death= No into CDC variable and death reported into symptoms description

32 yo woman reports for her baby
« My partially breast fed infant daughter died in her sleep »

ADR analysed as a baby

Profile of dead people

17

		MODERNA N=2 629	PFIZER- BIONTECH N=2 376	JANSSEN N=516	UNKNOWN N=25	Total N=5 546
Calculated age	Missing	78	126	91	2	297
	Mean (s.d.)	73.9 (15.2)	73.9 (16.4)	65.0 (16.7)	66.7 (19.5)	73.1 (16.0)
	Median	76.0	76.0	65.0	71.0	75.0
	Q1 - Q3	66.0 - 85.0	66.0 - 86.0	55.0 - 77.0	53.0 - 80.0	65.0 - 85.0
	Min - Max	1.0 - 106.0	0.4 - 105.0	19.0 - 103.0	24.0 - 97.0	0.4 - 106.0
Age in class	Age<=6 ans	1 (0.0%)	1 (0.0%)	0	0	2 (0.0%)
]12-18 ans]	5 (0.2%)	17 (0.8%)	0	0	22 (0.4%)
]18-30 ans]	31 (1.2%)	34 (1.5%)	14 (3.3%)	2 (8.7%)	81 (1.5%)
]30-50 ans]	158 (6.2%)	159 (7.1%)	66 (15.5%)	2 (8.7%)	385 (7.3%)
]50-70 ans]	709 (27.8%)	591 (26.3%)	183 (43.1%)	7 (30.4%)	1490 (28.4%)
]70-90 ans]	1355 (53.1%)	1167 (51.9%)	136 (32.0%)	9 (39.1%)	2667 (50.8%)
	> 90 ans	292 (11.4%)	281 (12.5%)	26 (6.1%)	3 (13.0%)	602 (11.5%)
Sex	N	2629	2383	516	25	5553
	Missing	0	0	0	0	0
	F	1100 (41.8%)	1040 (43.8%)	228 (44.2%)	8 (32.0%)	2376 (42.8%)
	M	1493 (56.8%)	1264 (53.2%)	256 (49.6%)	17 (68.0%)	3030 (54.6%)
	U	36 (1.4%)	72 (3.0%)	32 (6.2%)	0	140 (2.5%)

- Mean age of dead people : 73 yo / 55 % of men
 - 24 patients are younger than 18 yo
 - Almost 10 % are younger than 50 yo

<https://wonder.cdc.gov/controller/saved/D8/D197F156>

<https://wonder.cdc.gov/controller/saved/D8/D197F155>

Details for VADRS ID: J000094 L

Event Description	Date	Event Category	Result
Public Health Case	2020	Case Report	Completed
Date Reported	2020-01-11	Date Received	2020-01-19
Date Entered	2020-01-11	Date Received	2020-01-19
Case Status	21	Case Status	21
Case Category	21	Case Category	21
MSIS Case Report Number	00000000000000000000	Case Report Number	0
Case Status	21	Case Status	21

View Case Details

Case Information

Field	Value
Case ID	J000094 L
Case Category	21
Case Status	21
Case Report Number	00000000000000000000
Case Report Date	2020-01-11
Case Report Received Date	2020-01-19
Case Report Entered Date	2020-01-11
Case Report Received Date	2020-01-19
Case Report Entered Date	2020-01-11
Case Report Received Date	2020-01-19

18yo female with no past medical history died from Thrombosis 23 days after Moderna injection

29yo male with no past medical history died from Pulmonary Haemorrhage 5 days after first Moderna injection

Details for VADRS ID: L450JG L

Event Description	Date	Event Category	Result
Public Health Case	2020	Case Report	Completed
Date Reported	2020-08-13	Date Received	2020-07-28
Date Entered	2020-08-13	Date Received	2020-07-28
Case Status	21	Case Status	21
Case Category	21	Case Category	21
MSIS Case Report Number	00000000000000000000	Case Report Number	0
Case Status	21	Case Status	21

View Case Details

Case Information

Field	Value
Case ID	L450JG L
Case Category	21
Case Status	21
Case Report Number	00000000000000000000
Case Report Date	2020-08-13
Case Report Received Date	2020-07-28
Case Report Entered Date	2020-08-13
Case Report Received Date	2020-07-28
Case Report Entered Date	2020-08-13
Case Report Received Date	2020-07-28

Details for VADRS ID: J000094 L

Event Description	Date	Event Category	Result
Public Health Case	2020	Case Report	Completed
Date Reported	2020-01-11	Date Received	2020-01-19
Date Entered	2020-01-11	Date Received	2020-01-19
Case Status	21	Case Status	21
Case Category	21	Case Category	21
MSIS Case Report Number	00000000000000000000	Case Report Number	0
Case Status	21	Case Status	21

View Case Details

Case Information

Field	Value
Case ID	J000094 L
Case Category	21
Case Status	21
Case Report Number	00000000000000000000
Case Report Date	2020-01-11
Case Report Received Date	2020-01-19
Case Report Entered Date	2020-01-11
Case Report Received Date	2020-01-19
Case Report Entered Date	2020-01-11
Case Report Received Date	2020-01-19

EXAMPLE

16yo boy with no past medical history died from Unknown reason 27 days after Pfizer injection

<https://wonder.cdc.gov/controller/saved/D8/D197F283>

Details for VAERS ID: 1371338-1

EXAMPLE

Details for VAERS ID: 1450297-1

Patient Information			
Patient Age	32:00	Sex	Female
State / Territory	Massachusetts	Date Report Completed	2021-08-24
Date Vaccinated	2021-04-09	Date Report Received	2021-08-03
Date of onset	2021-05-21	Date died	2021-05-24
Days to onset	52		
Vaccine Administered by	Unknown	Vaccine Purchased by	Not Applicable *
MH/Team Project Member	None	Report Form Version	2
Recovered	Unknown	Series	Yes

* VAERS 2.0 Report Form Only
 ** VAERS 1.0 Report Form Only
 TBC Applicable: will appear when information is not available on the report form version.

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
congenital anomaly / with defect *	No
Hospitalized	No
Days in Hospital	None
Exiting Hospitalization Reopened	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only
 ** VAERS 1.0 Report Form Only
 N/A will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID-19 VACCINE	COVID-19 (COVID-19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	EW0162	1		IA
COVID-19 VACCINE	COVID-19 (COVID-19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	EW0164	2		IA

Symptom
DEATH
DELIVERY
EXPOSURE DURING PREGNANCY

Adverse Event Description
 32 year old female received vaccines while pregnant with her 3rd child. She has asymptomatic Factor V Leiden. She delivered on 5/27/2021 and passed away on 5/27/2021.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Autopsy pending	NA	

Medications At Time Of Vaccination	Histories/Allergies
vertical tetracycline	asymptomatic factor v leiden, anxiety, intertrigo, sinusitis, diabetes

Event Category	Date	Time	Location
Death	2021-05-24	12:00:00	Home
Life Threatening	2021-05-24	12:00:00	Home
Permanent Disability	2021-05-24	12:00:00	Home
congenital anomaly / with defect *	2021-05-24	12:00:00	Home
Hospitalized	2021-05-24	12:00:00	Home
Days in Hospital	2021-05-24	12:00:00	Home
Exiting Hospitalization Reopened	2021-05-24	12:00:00	Home
Emergency Room / Office Visit **	2021-05-24	12:00:00	Home
Emergency Room *	2021-05-24	12:00:00	Home
Office Visit *	2021-05-24	12:00:00	Home

* VAERS 2.0 Report Form Only
 ** VAERS 1.0 Report Form Only
 N/A will appear when information is not available on this report form version.

Event Category	Date	Time	Location
Death	2021-05-24	12:00:00	Home
Life Threatening	2021-05-24	12:00:00	Home
Permanent Disability	2021-05-24	12:00:00	Home
congenital anomaly / with defect *	2021-05-24	12:00:00	Home
Hospitalized	2021-05-24	12:00:00	Home
Days in Hospital	2021-05-24	12:00:00	Home
Exiting Hospitalization Reopened	2021-05-24	12:00:00	Home
Emergency Room / Office Visit **	2021-05-24	12:00:00	Home
Emergency Room *	2021-05-24	12:00:00	Home
Office Visit *	2021-05-24	12:00:00	Home

* VAERS 2.0 Report Form Only
 ** VAERS 1.0 Report Form Only
 N/A will appear when information is not available on this report form version.

Event Category	Date	Time	Location
Death	2021-05-24	12:00:00	Home

Symptom
DEATH
DELIVERY
EXPOSURE DURING PREGNANCY

Adverse Event Description
 30 year old female received vaccine while pregnant with her 1st child. She delivered on 5/27/2021 and passed away on 5/27/2021.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Autopsy pending	NA	

Medications At Time Of Vaccination	Histories/Allergies
vertical tetracycline	asymptomatic factor v leiden, anxiety, intertrigo, sinusitis, diabetes

➔ <https://wonder.cdc.gov/controller/saved/D8/D197F296>

32yo female with blood genetic factor died during her 3rd child delivery after Pfizer injections

➔ <https://wonder.cdc.gov/controller/saved/D8/D197F287>

30yo female with no past medical history died from Myocardial infarction after first Pfizer injection

Details for VAERS ID: 1084899-1

Section/Category	Value	Status	Date
Reported by	VAERS	Final Report Completed	11/27/2020
Reported by (Organization)	VAERS	Final Report Completed	11/27/2020
Reported by (Name)	VAERS	Final Report	11/27/2020
Reported by (Address)	VAERS	Final Report	11/27/2020
Reported by (City)	VAERS	Final Report	11/27/2020
Reported by (State)	VAERS	Final Report	11/27/2020
Reported by (Zip)	VAERS	Final Report	11/27/2020
Reported by (Phone)	VAERS	Final Report	11/27/2020
Reported by (Email)	VAERS	Final Report	11/27/2020
Reported by (Fax)	VAERS	Final Report	11/27/2020

Section/Category	Value
Product	VAERS
Manufacturer	VAERS
Lot Number	VAERS
Expiration Date	VAERS
Batch Number	VAERS
Site	VAERS
Site Address	VAERS
Site City	VAERS
Site State	VAERS
Site Zip	VAERS
Site Phone	VAERS
Site Email	VAERS
Site Fax	VAERS

VAERS ID: 1084899-1
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 VAERS ID: 1084899-1
 VAERS ID: 1084899-1

Section/Category	Value	Status	Date	Time	Site
Reported by	VAERS	Final Report Completed	11/27/2020	11:27	VAERS

VAERS ID	1084899-1
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VAERS ID	1084899-1
VAERS ID	1084899-1

<https://wonder.cdc.gov/controller/saved/D8/D200F050>

VAERS ID: 1084899-1
 VAERS ID: 1084899-1
 VAERS ID: 1084899-1

Section/Category	Value
VAERS ID	1084899-1

VAERS ID	1084899-1
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EXAMPLE

78yo male with no past medical history died from a myocardial infarction within 3 hours after Pfizer vaccine

Details for VAERS ID: 0968195-1

Event Information			
Reported Age	82Y00	Sex	Male
State / Territory	Florida	Date Report Completed	2021-01-20
Date Submitted	2021-01-20	Date Report Received	2021-01-20
Date of Onset	2021-01-12	Date Died	2021-01-12
Days Reported	8		
Vaccine Administered By	Other	Vaccine Purchased By	Not Applicable **
NPI/Inoc Provider Number	5839-	Report Form Version	2
Recovered	No	Serious	Yes

Event Categories	
Death	Yes
Life-Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect **	No
Hospitalized	No
Days In Hospital	None
Pending Hospitalization (Preliminary)	No
Emergency Room / Office Visit ***	N/A
Emergency Room †	Yes
Office Visit **	No

† VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 *** "Not Applicable" will appear when information is not available on this report form version.

† VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 *** "N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID-19 VACCINE	COVID-19 (COVID-19 (MODERNA))	MODERNA	5839-	1	IM	LA
COVID-19 VACCINE	COVID-19 (COVID-19 (MODERNA))	MODERNA	NONE	1	IM	LA

- Symptom
- DEATH**
- FEVER
- HEADACHE
- HYPEREMESIS
- PAIN IN EXTREMITY
- PHLEBITIS
- RESUSCITATION
- RINDING
- VOMITING

<https://wonder.cdc.gov/controller/saved/D8/D200F046>

Adverse Event Description

My dad got the Moderna vaccine on Tuesday, January 12, 2021 at 4:45 pm at the Wellington site for the South Department. He was told that the side effects could occur for some feeling, headache, fever, and even a low grade fever. Fortunately, the site administered both (1st dose, with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 24 hours. That evening my dad was experiencing all of these symptoms, and went to bed at 9pm. A little after 10pm on Wednesday, January 13, 2021, when he woke up at 6am in the bathroom sweating, this was when he noticed and went into cardiac arrest. My Mom was alerted about this situation by my mom called 911. Family Mom, Keane PM, and I arrived to confirmed CPR and other attempts of resuscitation all the way to Hospital Emergency Department. We were pronounced dead at 12:45pm on Wednesday, January 13, 2021. He never regained consciousness following the resuscitation of the injection. Looking through his eyes, and experiencing the side effects of the vaccine. My dad had been told the injection he had in the 80880 area, perhaps he could have recognized the symptoms as being that of an myocardial infarction. He really loved his country with devotion for over 60 years, and he loved his country with his heart.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	None known	

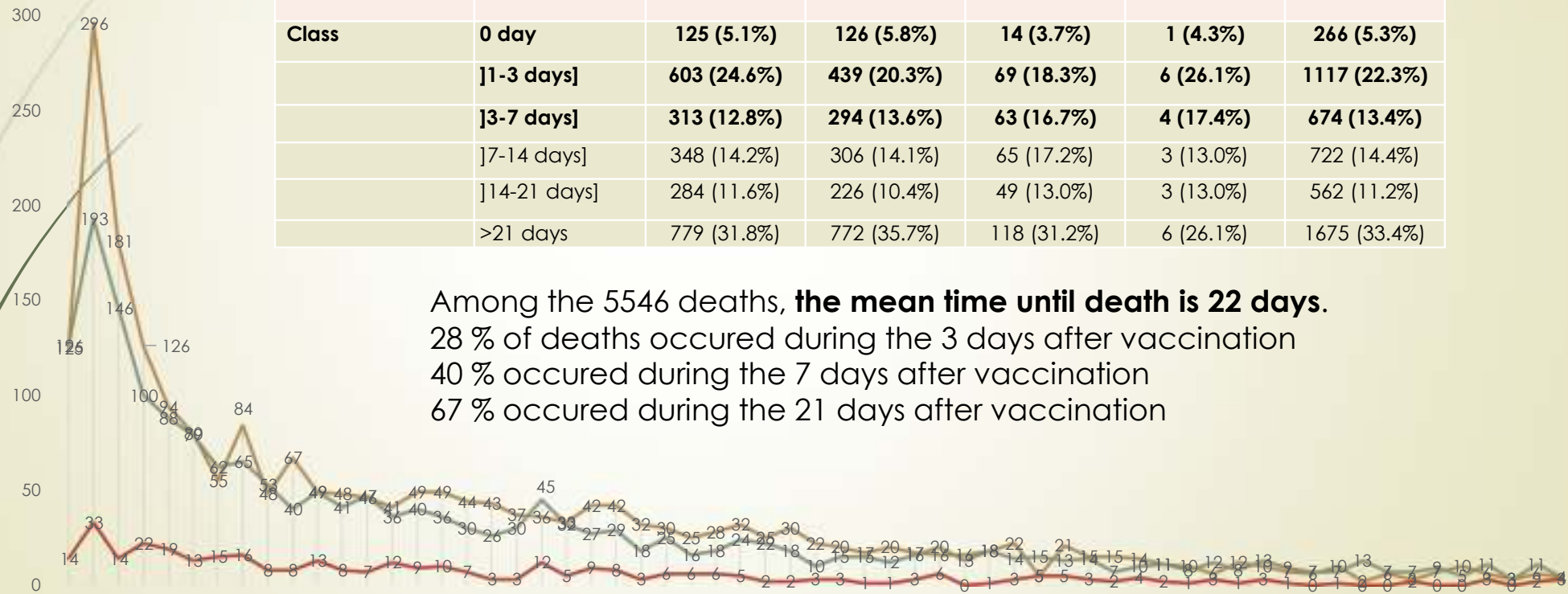
VAERS analysis – Christine Cotton

EXAMPLE

82yo male with no past medical history died from a cardiac arrest within 24 hours after Moderna vaccine

Time to death

		MODERNA N=2 629	PFIZER- BIONTECH N=2 376	JANSSEN N=516	UNKNOWN N=25	Total N=5 546
Time to death (c)	N	2452	2163	378	23	5016
	Missing	177	213	138	2	530
	Mean (s.d.)	19.8 (25.0)	24.6 (30.8)	19.0 (21.0)	14.6 (14.2)	21.8 (27.5)
	Median	11.0	12.0	12.0	8.0	12.0
	Q1 - Q3	3.0 - 27.0	3.0 - 34.0	4.0 - 26.0	3.0 - 25.0	3.0 - 29.0
	Min - Max	0.0 - 159.0	0.0 - 197.0	0.0 - 127.0	0.0 - 48.0	0.0 - 197.0
Class	0 day	125 (5.1%)	126 (5.8%)	14 (3.7%)	1 (4.3%)	266 (5.3%)
]1-3 days]	603 (24.6%)	439 (20.3%)	69 (18.3%)	6 (26.1%)	1117 (22.3%)
]3-7 days]	313 (12.8%)	294 (13.6%)	63 (16.7%)	4 (17.4%)	674 (13.4%)
]7-14 days]	348 (14.2%)	306 (14.1%)	65 (17.2%)	3 (13.0%)	722 (14.4%)
]14-21 days]	284 (11.6%)	226 (10.4%)	49 (13.0%)	3 (13.0%)	562 (11.2%)
	>21 days	779 (31.8%)	772 (35.7%)	118 (31.2%)	6 (26.1%)	1675 (33.4%)



Among the 5546 deaths, **the mean time until death is 22 days.**
 28 % of deaths occurred during the 3 days after vaccination
 40 % occurred during the 7 days after vaccination
 67 % occurred during the 21 days after vaccination

Listing of death <= 18 yo - Moderna

24

VAERS Identification	Age	Corrected Vacc. Date	ADR Onset Date	Nb days onset date-vacc	Reported symptom text	Date of death(c)	Time to death
1261766	1	08/04/2021	10/04/2021	2	INCREASED BODY TEMPERATURE, SEIZURE, DEATH	10/04/2021	2
1463061	13	.	.	.	DIED THREE DAYS AFTER VACCINE; 13 YEAR OLD BOY DIES THREE DAYS AFTER THE MODERNA VACCINE ; THIS SPONTANEOUS CASE WAS REPORTED BY A CONSUMER AND DESCRIBES THE OCCURRENCE OF DEATH (DIED THREE DAYS AFTER VACCINE) IN A 13-YEAR-OLD MALE PATIENT WHO RECEIVED MRNA-1273 (MODERNA COVID-19 VACCINE) FOR COVID-19 VACCINATION. THE OCCURRENCE OF ADDITIONAL NON-SERIOUS EVENTS IS DETAILED BELOW. NO MEDICAL HISTORY INFORMATION WAS REPORTED. ON AN UNKNOWN DATE, THE PATIENT RECEIVED DOSE OF MRNA-1273 (MODERNA COVID-19 VACCINE) (UNKNOWN ROUTE) 1 DOSAGE FORM. ON AN UNKNOWN DATE, THE PATIENT EXPERIENCED PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (13 YEAR OLD BOY DIES THREE DAYS AFTER THE MODERNA VACCINE). THE PATIENT DIED ON AN UNKNOWN DATE. THE CAUSE OF DEATH WAS NOT REPORTED. IT IS UNKNOWN IF AN AUTOPSY WAS PERFORMED. AT THE TIME OF DEATH, PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (13 YEAR OLD BOY DIES THREE DAYS AFTER THE MODERNA VACCINE) HAD RESOLVED. THE ACTION TAKEN WITH MRNA-1273 (MODERNA COVID-19 VACCINE) (UNKNOWN) WAS UNKNOWN. CONCOMITANT PRODUCT WAS NOT PROVIDED BY THE REPORTER. TREATMENT INFORMATION WAS UNKNOWN. COMPANY COMMENT: THIS IS A CASE OF DEATH IN A 13-YEAR-OLD MALE SUBJECT WITH UNKNOWN MEDICAL HISTORY, WHO DIED ONE DAY AFTER RECEIVING THE VACCINE. VERY LIMITED INFORMATION HAS BEEN PROVIDED AT THIS TIME. FURTHER INFORMATION HAS BEEN REQUESTED.; SENDER'S COMMENTS: THIS IS A CASE OF DEATH IN A 13-YEAR-OLD MALE SUBJECT WITH UNKNOWN MEDICAL HISTORY, WHO DIED ONE DAY AFTER RECEIVING THE VACCINE. VERY LIMITED INFORMATION HAS BEEN PROVIDED AT THIS TIME. FURTHER INFORMATION HAS BEEN REQUESTED.; REPORTED CAUSE(S) OF DEATH: UNKNOWN CAUSE OF DEATH	.	.
1187918	15	.	05/04/2021	.	I DO NOT KNOW THE EXACT DATE OF THE FIRST OR SECOND MODERNA VACCINE. I AM THE PICU ATTENDING WHO CARED FOR THE PATIENT AFTER HER CARDIAC ARREST WHICH WE BELIEVE WAS ABOUT 3-4 DAYS AFTER HER SECOND MODERNA VACCINE	06/04/2021	4
1078352	18	02/03/2021	05/03/2021	3	DEVELOPED FATIGUE, BODY ACHES, HEADACHE 1 DAY AFTER VACCINATION ON 3/3. THE MORNING OF 3/5 COMPLAINED OF CHEST PAIN. TOOK TYLENOL AT 8:30 AM. AT 10:30 AM HIS FAMILY FOUND HIM UNRESPONSIVE. EMS WAS CALLED AND HE WAS PRONOUNCED DEAD IN THE HOME.	05/03/2021	3
1105115	18	14/02/2021	18/02/2021	4	RESIDENT DID NOT EXPRESS HAVING ANY SYMPTOMS, THE ONLY THING THAT THE POC OBSERVED ABSCESSSES IN THE ARM, GROIN, THIGH AND KNEES AFTER THE FIRST VACCINATION. AFTER THE SECOND DOSE, HE WAS HYPOACTIVE. ON 2/27 AT ABOUT 3:30 AM HE ASKED HIM TO TURN ON HIS SIDE, BETWEEN 4 AM AND 5 AM POC WENT TO THE ROOM I NOTICE IT STRANGE, BECAUSE HIS HEAD WAS WRAPPED IN THE SHEET. WHEN THE POC REMOVED THE SHEET, SHE OBSERVED THAT HER MOUTH AND NOSE WERE FULL OF SECRETIONS. SO HE TURNED IT AND HE HIMSELF DID NOT REACT. HE CALLED THE EMERGENCY WHO CERTIFIES THAT HE HAD NO VITAL SIGNS. (EMERGENCY ARRIVES WITHIN 5:45 AM TO 6:00 AM)	28/02/2021	14
1386054	18	14/05/2021	06/06/2021	23	DEATH FROM BLOOD CLOT	06/06/2021	23

Listing of death <= 18 yo - Moderna

25

VAERS Identification	Age	Corrected Vacc. Date	ADR Onset Date	Nb days onset date-vacc	Reported symptom text	Date of death(c)	Time to death
1166062	0.4	17/03/2021	18/03/2021	1	PATIENT RECEIVED SECOND DOSE OF PFIZER VACCINE ON MARCH 17, 2020 WHILE AT WORK. MARCH 18, 2020 HER 5 MONTH OLD BREASTFED INFANT DEVELOPED A RASH AND WITHIN 24 HOURS WAS INCONSOLABLE, REFUSING TO EAT, AND DEVELOPED A FEVER. PATIENT BROUGHT BABY TO LOCAL ER WHERE ASSESSMENTS WERE PERFORMED, BLOOD ANALYSIS REVEALED ELEVATED LIVER ENZYMES. INFANT WAS HOSPITALIZED BUT CONTINUED TO DECLINE AND PASSED AWAY. DIAGNOSIS OF TTP. NO KNOWN ALLERGIES. NO NEW EXPOSURES ASIDE FROM THE MOTHER'S VACCINATION THE PREVIOUS DAY.	20/03/2021	3
1406840	13	13/06/2021	14/06/2021	1	FLU LIKE SYMPTOMS FOR 2 DAYS THEN WAS FOUND DECEASED	.	.
1429457	13	13/06/2021	01/06/2021	.	A 13-YEARS-OLD MALE PATIENT RECEIVED BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, FORMULATION: SOLUTION FOR INJECTION, LOT NUMBER: EW0217 AND EXPIRY DATE NOT REPORTED), DOSE 2 VIA AN UNSPECIFIED ROUTE OF ADMINISTRATION ON 13JUN2021 (AT THE AGE OF 13 YEARS) AS DOSE 2, SINGLE FOR COVID-19 IMMUNISATION. THE PATIENT RECEIVED THE FIRST DOSE, BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, FORMULATION: SOLUTION FOR INJECTION, LOT NUMBER: EW0168 AND EXPIRY DATE NOT REPORTED) ON 03MAY2021 (AT THE AGE OF 13 YEARS) AS DOSE 1, SINGLE FOR COVID-19 IMMUNISATION. THE PATIENT MEDICAL HISTORY WAS NOT REPORTED. PATIENT HAD NO KNOWN HEALTH PROBLEMS, WAS HEALTHY AND WAS ON NO MEDICATIONS. REPORTEDLY, PATIENT DIED LESS THAN 3 DAYS LATER OF 2ND COVID SHOT. THE INITIAL AUTOPSY RESULTS (DONE FRIDAY) WERE THAT HIS HEART WAS ENLARGED AND THERE WAS SOME FLUID SURROUNDING IT. THE TEAM SPECULATED THE PATIENT SAID HE HAD A CARDIAC EVENT.
1431289	13	02/06/2021	19/06/2021	17	DATE OF ADMISSION: 6/19/2021 DATE OF DEATH: 6/20/2021 PRIMARY CARE PHYSICIAN: NO PRIMARY CARE PROVIDER ON FILE. REASON FOR ADMISSION: PATIENT IS A 13-YEAR-OLD PREVIOUSLY HEALTHY MALE WHO WAS ADMITTED AFTER OUT-OF-HOSPITAL CARDIAC ARREST WITH ROSC AFTER CPR FOR 15 MINUTES IN THE FIELD, FOUND TO BE IN THE CONTEXT OF LARGE CEREBELLAR HEMORRHAGE SECONDARY TO BRAIN LESION (AVM VS TUMOR) ...	20/06/2021	18
1242573	15	18/04/2021	19/04/2021	1	HEART FAILURE	20/04/2021	2
1382906	15	15/05/2021	07/06/2021	23	UNEXPLAINED DEATH WITHIN 48 HOURS	07/06/2021	23
1225942	16	19/03/2021	28/03/2021	9	PATIENT WAS A 16YR FEMALE WHO RECEIVED PFIZER VACCINE 3/19/21 AT VACCINE CLINIC AND PRESENTED WITH ONGOING CPR TO THE ED 3/28/21 AFTER CARDIAC ARREST AT HOME. PATIENT PLACED ON ECMO AND IMAGING REVEALED BILATERAL LARGE PULMONARY EMBOLISM AS LIKELY ETIOLOGY OF ARREST. RISK FACTORS INCLUDED ORAL CONTRACEPTIVE USE. LABS HAVE SINCE CONFIRMED ABSENCE OF FACTOR V LEIDEN OR PROTHROMBIN GENE MUTATION. PATIENT DECLARED DEAD BY NEUROLOGIC CRITERIA 3/30/21.	30/03/2021	11
1386841	16	03/06/2021	07/06/2021	4	PRODROME OF HEADACHE AND GASTRIC UPSET OVER 2 DAYS FOLLOWING SECOND DOSE. THEN FELT FINE. FOUND THE FOLLOWING DAY DEAD IN BED. AUTOPSY PENDING	07/06/2021	4
1420630	16	13/03/2021	03/04/2021	21	~4 WEEKS AFTER THE 2ND DOSE OF PFIZER, PATIENT PRESENTED TO THE HOSPITAL WITH CHEST PAIN; HAD PERICARDIAL EFFUSION. INITIALLY IMPROVED BUT THEN HAD DECOMPENSATION, PROLONGED HOSPITALIZATION. DIAGNOSED WITH HEMOPHAGOCYtic LYMPHOHISTOCYTOSIS (HLH) AND ULTIMATELY DIED.	15/06/2021	94
1466009	16	03/04/2021	30/04/2021	27	MY SON DIED, WHILE TAKING HIS MATH CLASS ON ZOOM. WE ARE WAITING FOR THE AUTOPSY BECAUSE THE DOCTORS DID NOT FIND ANYTHING. HE WAS A HEALTHY BOY, HE HAD A GOOD ACADEMIC INDEX, HE WANTED TO BE A CIVIL ENGINEER. HE WAS THE BEST THING IN MY LIFE.	30/04/2021	27
1475434	16	07/07/2021	13/07/2021	6	THE PATIENT DIED 6 DAYS AFTER RECEIVING DOSE #2	13/07/2021	6
1199455	17	02/04/2021	10/04/2021	8	PATIENT REPORTED DIFFICULTY BREATHING AND CHEST PAIN; SUFFERED CARDIAC ARREST AND DEATH	10/04/2021	8
1243487	17	13/04/2021	21/04/2021	8	PATIENT COMMITTED SUICIDE WITH A FIREARM.	21/04/2021	8

Listing of death \leq 18 yo - Moderna

26

VAERS Identification	Age	Corrected Vacc. Date	ADR Onset Date	Nb days onset date-vacc	Reported symptom text	Date of death(c)	Time to death
1307657	17	19/04/2021	23/04/2021	4	DEATH BY SUICIDE .	23/04/2021	4
1388042	17	23/05/2021	07/06/2021	15	PATIENT HAD MASSIVE ACUTE INTRACRANIAL HEMORRHAGE . WAS FOUND DOWN IN BATHROOM. IN ED CT SCAN SHOWED LARGE INTRAVENTRICULAR HEMORRHAGE, EVD PLACED, PATIENT PROGRESSED TO MASSIVE BRAIN SWELLING AND INFARCTIONS, DECOMPRESSIVE CRANIECTOMY, UNABLE TO CONTROL INTRACRANIAL PRESSURE, PARENTS AGREED TO DNR STATUS AND PATIENT IS NOT EXPECTED TO SURVIVE.	.	.
1420762	17	17/06/2021	23/06/2021	6	CARDIAC ARREST WITHOUT RESUSCITATION. UNKNOWN CAUSE OF CARDIAC ARREST. AWAITING AUTOPSY REPORT.	23/06/2021	6
1095634	18	12/03/2021	12/03/2021	0	2ND INJECTION GIVEN ON 2/19/2021 DEATH 2/27/21	.	.
1446849	18	02/07/2021	04/07/2021	2	DEATH	04/07/2021	2

Note : 2 suicides on 24

Pregnancy Issues

AERS DATA EXTRACT 2021-07-23
Christine COTTON

27

Pregnancy issues

28

2 436 women were found to be pregnant when searching for pregnant, pregnancy or foetal disorders, abortion, premature delivery into coded symptom
According to CDC variable, only 4,1 % ADRs lead to birth defect or congenital anomaly.

We also include foetal death, heart abnormality, growth abnormality, cardiac arrest, cerebral haemorrhage), abortion, premature baby death, premature delivery, rupture of membranes, separation of placenta, vaginal haemorrhage in pregnancy ...

	MODERNA N=924	PFIZER- BIONTECH N=1 308	JANSSEN N=201	UNKNOWN N=3	Total N=2 436
Congenital anomaly or birth defect (CDC variable) - A	43 (4.7%)	55 (4.2%)	3 (1.5%)	0	101 (4.1%)
Premature delivery or Abortion or foetal disorders - B	337 (36.5%)	462 (35.3%)	55 (27.4%)	0	854 (35.1%)
Abortion or Foetal death	276 (29.9%)	356 (27.2%)	43 (21.4%)	0	675 (27.7%)
A and / or B	348 (37.7%)	476 (36.4%)	55 (27.4%)	0	879 (36.1%)

Abortion or foetal death was documented for 28 % of women.

When mixing CDC variable and calculated variable, **36 % of women suffers from pregnancy disorders**

Note: 778 ADRs not counted into the CDC variable Congenital anomaly of Birth defect

Pregnancy issues

29

	MODERNA N=348	PFIZER- BIONTECH N=476	JANSSEN N=55	Total N=879
Abortion or foetal death or stillbirth	43	276	356	675
Other reasons	1	17	37	55
Premature labour or delivery	4	17	33	54
Haemorrhage	3	14	14	31
Foetal Heart Rate Abnormal	2	6	8	16
Premature Rupture of membranes	1	5	8	14
Foetal Growth restriction		2	6	8
Foetal hypokinesia	1	4	2	7
Preterm or Premature Rupture of membranes		4	2	6
Premature labour or delivery / Haemorrhage			3	3
Foetal cystic hygroma			2	2
Premature Rupture of membranes / Premature labour or delivery			2	2
Premature labour or delivery / Foetal hypokinesia		2		2
Cardiac arrest neonatal			1	1
Foetal Growth restriction / Foetal hypokinesia		1		1
Haemorrhage/ Foetal Growth restriction			1	1
Premature labour or delivery / Preterm or Premature Rupture of membranes / Haemorrhage			1	1
Total	55	348	476	879

At least 675 baby deaths / $5\,546 + 675 = 6\,221$ deaths

Profile of women with pregnancy issues

30

		MODERNA N=348	PFIZER- BIONTECH N=476	JANSSEN N=55	Total N=879
Calculated age	N	338	460	52	850
	Missing	10	16	3	29
	Mean (s.d.)	33.3 (4.8)	33.7 (4.6)	33.6 (4.3)	33.5 (4.7)
	Median	33.0	33.0	33.0	33.0
	Q1 - Q3	30.0 - 37.0	31.0 - 37.0	30.0 - 37.0	31.0 - 37.0
	Min - Max	19.0 - 53.0	21.0 - 50.0	24.0 - 44.0	19.0 - 53.0
Age in class]10-20 ans]	3 (0.9%)	0	0	3 (0.4%)
]20-30 ans]	82 (24.3%)	111 (24.1%)	14 (26.9%)	207 (24.4%)
]30-40 ans]	237 (70.1%)	316 (68.7%)	36 (69.2%)	589 (69.3%)
]40-50 ans]	14 (4.1%)	33 (7.2%)	2 (3.8%)	49 (5.8%)
]50-60 ans]	2 (0.6%)	0	0	2 (0.2%)

The mean age of pregnant women with pregnancy disorders was 34 yo
25 % are younger than 30 yo

Time to pregnancy issues

31

		MODERNA N=348	PFIZER- BIONTECH N=476	JANSSEN N=55	Total N=879
Nb days ADR- vaccination (c)	N	337	453	52	842
	Missing	11	23	3	37
	Mean (s.d.)	23.6 (27.9)	22.2 (28.5)	16.7 (19.8)	22.4 (27.8)
	Median	15.0	12.0	11.0	13.0
	Q1 - Q3	3.0 - 34.0	2.0 - 30.0	1.0 - 23.0	2.0 - 30.0
	Min - Max	0.0 - 179.0	0.0 - 186.0	0.0 - 87.0	0.0 - 186.0
Class	0 day	35 (10.4%)	55 (12.1%)	9 (17.3%)	99 (11.8%)
]1-3 days]	59 (17.5%)	74 (16.3%)	7 (13.5%)	140 (16.6%)
]3-7 days]	38 (11.3%)	54 (11.9%)	6 (11.5%)	98 (11.6%)
]7-14 days]	33 (9.8%)	69 (15.2%)	7 (13.5%)	109 (12.9%)
]14-21 days]	38 (11.3%)	54 (11.9%)	8 (15.4%)	100 (11.9%)
	>21 days	134 (39.8%)	147 (32.5%)	15 (28.8%)	296 (35.2%)

- 28 % (11,8+16,6) of pregnant women have a disorder during 3 days after vaccination
- 40 % during the 7 days after vaccination
- 65 % during the 21 days after vaccination

Details for VAERS ID: 1059615-1

Event Information				Event Categories	
Patient Age	33.000	Sex	Female	Death	No
State / Territory	Tennessee	Date Report Completed	2021-02-27	Life-Threatening	No
Date Vaccinated	2021-01-15	Date Report Received	2021-02-27	Permanent Disability	No
Date of Onset	2021-02-15	Date Died		Congenital Anomaly / Birth Defect *	No
Days to onset	32			Hospitalized	No
Vaccine Administered By	Unknown	Vaccine Purchased By	Not Applicable *	Days in Hospital	None
Mfr/Imm Project Number	0000	Report Form Version	2	Existing Hospitalization Prolonged	No
Recovered	Yes	Serious	No	Emergency Room / Office Visit **	N/A
<small>* VAERS 2.0 Report Form Only ** VAERS-1 Report Form Only "Not Applicable" will appear when information is not available on this report form version.</small>				Emergency Room *	No
				Office Visit *	Yes
				<small>* VAERS 2.0 Report Form Only ** VAERS-1 Report Form Only "N/A" will appear when information is not available on this report form version.</small>	

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID-19 VACCINE	COVID-19 (COVID-19 (MODERNA))	MODERNA	None	1	IM	

Symptom
MISCARRIAGE (MISCARRIAGE)

<https://wonder.cdc.gov/controller/saved/D8/D198F357>

Adverse Event Description
Miscarriage after receiving first Moderna vaccine dose

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Confirmed miscarriage at OB appt 2/24/2021	None	

Medications At Time Of Vaccination	History/Allergies
Prenatal Vitamin	None, N/A

EXAMPLE

CDC variable =No
33 yo female with no previous medical history miscarried 33 days after Moderna first dose

Myocarditis / Pericarditis

AERS DATA EXTRACT 2021-07-23
Christine COTTON

33

Myocarditis/Pericarditis ADRs

34

We used the following search terms: Pericarditis / Myocarditis into coded symptom Cancellation of viral diseases

	MODERNA N=175 832	PFIZER- BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
Myocarditis / Pericarditis (c)	612 (0.3%)	1 182 (0.7%)	63 (0.2%)	4 (0.4%)	1 861 (0.5%)
Death due to Myocarditis ...	9	7	2	1	19

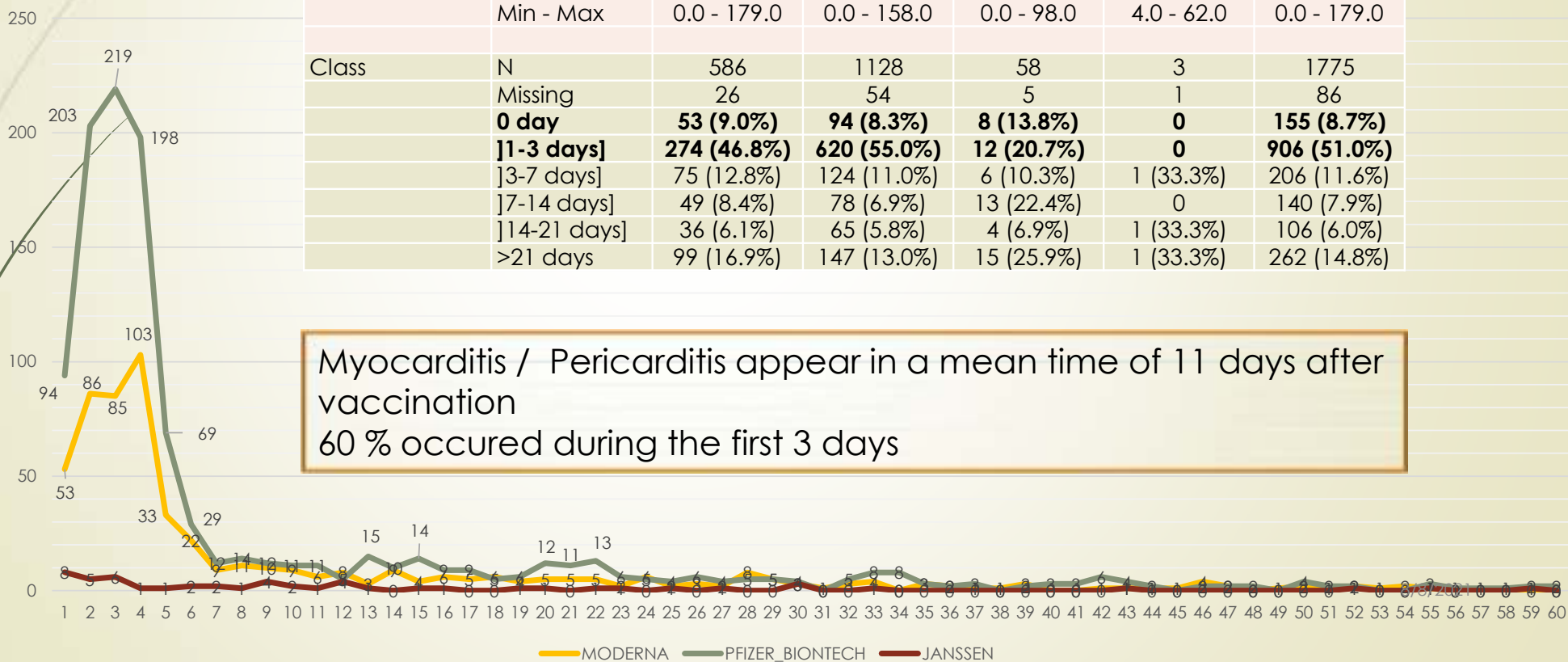
		MODERNA N=612	PFIZER- BIONTECH N=1 182	JANSSEN N=63	UNKNOWN N=4	Total N=1 861
Calculated age	N	595	1 159	63	4	1 821
	Missing	17	23	0	0	40
	Mean (s.d.)	38.5 (18.2)	30.2 (17.8)	40.8 (16.7)	40.8 (23.8)	33.3 (18.4)
	Median	33.0	23.0	37.0	39.0	27.0
	Q1 - Q3	23.0 - 54.0	16.0 - 40.0	27.0 - 53.0	21.0 - 60.5	18.0 - 46.0
	Min - Max	14.0 - 94.0	11.0 - 86.0	18.0 - 76.0	17.0 - 68.0	11.0 - 94.0
Class	[6-12 ans]	0	26 (2.2%)	0	0	26 (1.4%)
	[12-18 ans]	30 (5.0%)	415 (35.8%)	2 (3.2%)	1 (25.0%)	448 (24.6%)
	[18-30 ans]	243 (40.8%)	299 (25.8%)	23 (36.5%)	1 (25.0%)	566 (31.1%)
	[30-50 ans]	157 (26.4%)	226 (19.5%)	19 (30.2%)	0	402 (22.1%)
	[50-70 ans]	126 (21.2%)	151 (13.0%)	17 (27.0%)	2 (50.0%)	296 (16.3%)
	[70-90 ans]	38 (6.4%)	42 (3.6%)	2 (3.2%)	0	82 (4.5%)
	> 90 ans	1 (0.2%)	0	0	0	1 (0.1%)
Sex	N	612	1 182	63	4	1 861
	Missing	0	0	0	0	0
	F	176 (28.8%)	294 (24.9%)	21 (33.3%)	0	491 (26.4%)
	M	428 (69.9%)	878 (74.3%)	42 (66.7%)	4 (100.0%)	1352 (72.6%)
	U	8 (1.3%)	10 (0.8%)	0	0	18 (1.0%)

1994 symptoms for
1861 ADRs
57 % of patients with
Myocarditis /
Pericarditis
are less than 30 yo

73 % are men
19 patients died

Time to Myocarditis/Pericarditis ADRs

		MODERNA N=612	PFIZER- BIONTECH N=1182	JANSSEN N=63	UNKNOWN N=4	Total N=1861
Nb days ADR- vaccination	N	586	1128	58	3	1775
	Missing	26	54	5	1	86
	Mean (s.d.)	12.3 (22.5)	10.1 (20.1)	16.6 (21.9)	29.0 (29.8)	11.1 (21.1)
	Median	3.0	3.0	8.0	21.0	3.0
	Q1 - Q3	2.0 - 13.0	1.0 - 8.0	2.0 - 22.0	4.0 - 62.0	1.0 - 10.0
	Min - Max	0.0 - 179.0	0.0 - 158.0	0.0 - 98.0	4.0 - 62.0	0.0 - 179.0
Class	N	586	1128	58	3	1775
	Missing	26	54	5	1	86
	0 day	53 (9.0%)	94 (8.3%)	8 (13.8%)	0	155 (8.7%)
]1-3 days]	274 (46.8%)	620 (55.0%)	12 (20.7%)	0	906 (51.0%)
]3-7 days]	75 (12.8%)	124 (11.0%)	6 (10.3%)	1 (33.3%)	206 (11.6%)
]7-14 days]	49 (8.4%)	78 (6.9%)	13 (22.4%)	0	140 (7.9%)
]14-21 days]	36 (6.1%)	65 (5.8%)	4 (6.9%)	1 (33.3%)	106 (6.0%)
	>21 days	99 (16.9%)	147 (13.0%)	15 (25.9%)	1 (33.3%)	262 (14.8%)



Listing of deaths by Myocarditis/Pericarditis

36

Vaccination Name	Calculated age	VAERS Identification Number	Adverse Event MedDRA Term	Calculated Nb days AE-vaccination (c)	Died	Date of death(c)	Time to death (c)
JANSSEN	30	1413736	MYOCARDITIS	-	Death	-	-
JANSSEN	55	1459756	PERICARDITIS	11	Death	02/05/2021	22
MODERNA	19	1336767	MYOCARDITIS	27	Death	-	-
MODERNA	19	1435941	MYOCARDITIS	8	Death	11/06/2021	41
MODERNA	23	1314450	MYOCARDITIS	1	Death	-	-
MODERNA	38	1408027	MYOCARDITIS	7	Death	-	-
MODERNA	44	1463962	MYOCARDITIS	8	Death	31/03/2021	8
MODERNA	55	1343266	MYOCARDITIS	17	Death	19/04/2021	18
MODERNA	69	1022440	PERICARDITIS	9	Death	09/02/2021	17
MODERNA	76	1396353	MYOCARDITIS	0	Death	11/03/2021	9
MODERNA	80	1415239	MYOCARDITIS	2	Death	19/06/2021	37
PFIZER-BIONTECH	13	1429457	MYOCARDITIS	-	Death	-	-
PFIZER-BIONTECH	32	1465112	MYOCARDITIS	2	Death	28/03/2021	3
PFIZER-BIONTECH	36	1044420	MYOCARDITIS	22	Death	08/02/2021	30
PFIZER-BIONTECH	54	1474379	MYOCARDITIS	37	Death	10/07/2021	66
PFIZER-BIONTECH	60	1340821	MYOCARDITIS	20	Death	26/04/2021	20
PFIZER-BIONTECH	78	1371818	MYOCARDITIS	1	Death	14/05/2021	1
PFIZER-BIONTECH	78	1394140	MYOCARDITIS	1	Death	14/05/2021	1
LNKNOWN	53	1285361	MYOCARDITIS	21	Death	27/04/2021	26

Note : in yellow patients younger than 35 yo

Blood events, coagulation, bleeding issues, ischemia ADR

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37

Blood events, coagulation, bleeding issues, ischemia ADRs

38

The following search terms were used to identify bleeding, clotting and ischaemic ADRs using coded symptom: **bleed, haemo*, thrombo*, emboli*, coag*, death, ischaem*, infarct*, angina, stroke, cerebrovascular, CVA.**

22 568 symptoms were found for 17 398 ADRs, 4,4 % of the total of ADRs reported

	MODERNA N=175 832	PFIZER- BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
Bleeding, clotting and ischaemic ADRs (c)	6 537 (3.7%)	7 984 (4.4%)	2 796 (6.7%)	81 (8.6%)	17 398 (4.4%)
Death among blood ADRs	421	417	157	9	1004

When looking at detailed symptoms, they mainly concern women's bleeding
Cerebral disorders
Thrombosis, Haemorrhage ...

- Heavy menstrual bleeding 1903
- Vaginal haemorrhage 540
- Intermenstrual bleeding 451
- Postmenopausal Haemorrhage 186
- Haemorrhage in pregnancy 33
- Uterine Haemorrhage 32

Female reproductive system bleeding

- Cerebrovascular accident 1642
- Cerebral haemorrhage 251
- Cerebral infarction 141
- Cerebral Thrombosis 88
- Cerebral venous sinus thrombosis 85
- Cerebral artery occlusion 43
- Cerebellar stroke stroke 37

Cerebrovascular Disorders

- Thrombosis 1430
- Deep vein Thrombosis 1248
- Pulmonary Thrombosis 211
- Portal vein Thrombosis 28
- Coronary artery Thrombosis 15
- Arterial Thrombosis 14
- Axillary vein Thrombosis 14
- Aortic Thrombosis 13

Thrombosis

- Pulmonary embolism 1186
- Myocardial infarction 677
- Acute Myocardial infarction 502
- Haemorrhage 495
- Injection site Haemorrhage 357
- Eye Haemorrhage 230
- Gastrointestinal Haemorrhage 145
- Rectal Haemorrhage 131
- VACCINATION SITE Haemorrhage 108
- Mouth Haemorrhage 58

Others

Profile of patients with blood ADRs

39

		MODERNA N=6 537	PFIZER- BIONTECH N=7 984	JANSSEN N=2 796	UNKNOWN N=81	Total N=17 398
Calculated age	N	6330	7511	2503	76	16420
	Missing	207	473	293	5	978
	Mean (s.d.)	57.4 (18.4)	53.3 (19.3)	53.2 (16.5)	56.8 (14.2)	54.9 (18.6)
	Median	59.0	53.0	53.0	60.5	55.0
	Q1 - Q3	43.0 - 72.0	38.0 - 69.0	41.0 - 64.0	46.0 - 65.0	40.0 - 69.0
	Min - Max	17.0 - 102.0	0.4 - 105.0	0.2 - 105.0	24.0 - 94.0	0.2 - 105.0
Class	Age<=6 ans	0	1 (0.0%)	1 (0.0%)	0	2 (0.0%)
]6-12 ans]	0	15 (0.2%)	0	0	15 (0.1%)
]12-18 ans]	18 (0.3%)	211 (2.8%)	15 (0.6%)	0	244 (1.5%)
]18-30 ans]	515 (8.1%)	738 (9.8%)	213 (8.5%)	1 (1.3%)	1467 (8.9%)
]30-50 ans]	1791 (28.3%)	2495 (33.2%)	884 (35.3%)	26 (34.2%)	5196 (31.6%)
]50-70 ans]	2250 (35.5%)	2387 (31.8%)	1018 (40.7%)	34 (44.7%)	5689 (34.6%)
]70-90 ans]	1634 (25.8%)	1547 (20.6%)	345 (13.8%)	14 (18.4%)	3540 (21.6%)
	> 90 ans	122 (1.9%)	117 (1.6%)	27 (1.1%)	1 (1.3%)	267 (1.6%)
Sex	N	6537	7984	2796	81	17398
	Missing	0	0	0	0	0
	F	4155 (63.6%)	5248 (65.7%)	1725 (61.7%)	39 (48.1%)	11167 (64.2%)
	M	2307 (35.3%)	2616 (32.8%)	993 (35.5%)	40 (49.4%)	5956 (34.2%)
	U	75 (1.1%)	120 (1.5%)	78 (2.8%)	2 (2.5%)	275 (1.6%)

The mean age of patients is 55 yo.
 10 % of blood ADRs occurred in patients younger than 30 yo
 Women are mainly concerned

Time to blood ADRs

40

		MODERNA N=6 537	PFIZER- BIONTECH N=7 984	JANSSEN N=2 796	UNKNOWN N=81	Total N=17 398
Nb days ADR- vaccination	N	6215	7295	2257	74	15841
	Missing	322	689	539	7	1557
	Mean (s.d.)	13.5 (21.4)	12.7 (21.3)	14.1 (16.9)	21.2 (26.8)	13.2 (20.8)
	Median	5.0	4.0	9.0	11.5	5.0
	Q1 - Q3	1.0 - 17.0	1.0 - 15.0	2.0 - 19.0	2.0 - 31.0	1.0 - 16.0
	Min - Max	0.0 - 290.0	0.0 - 241.0	0.0 - 115.0	0.0 - 121.0	0.0 - 290.0
Class	0 day	998 (16.1%)	1220 (16.7%)	290 (12.8%)	8 (10.8%)	2516 (15.9%)
]1-3 days]	1747 (28.1%)	2228 (30.5%)	437 (19.4%)	14 (18.9%)	4426 (27.9%)
]3-7 days]	850 (13.7%)	987 (13.5%)	321 (14.2%)	8 (10.8%)	2166 (13.7%)
]7-14 days]	865 (13.9%)	990 (13.6%)	458 (20.3%)	12 (16.2%)	2325 (14.7%)
]14-21 days]	482 (7.8%)	631 (8.6%)	256 (11.3%)	6 (8.1%)	1375 (8.7%)
	>21 days	1273 (20.5%)	1239 (17.0%)	495 (21.9%)	26 (35.1%)	3033 (19.1%)

The mean time for a blood ADR to occur is **13 days**.
 16 % of Blood ADRs appear the day of vaccination
 44 % appear during the 3 days after vaccination
 57 % appear during the 7 days after vaccination
80 % appear during the 21 days after vaccination

Other ADRs

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41

Other ADR of interest

42

The following search terms were used to identify each ADR of interest into the coded symptom

Immune System ADRs Infection, Inflammation, Autoimmune, Allergic

- Immun*,
- multiple sclerosis,
- lupus, myasthenia,
- pernicious, diabetes,
- Addison,
- Crohn's, Coeliac, Graves,
- alopecia,
- amyloidosis,
- antiphospholipid,
- angioedema,
- Behcet's, pemphigoid,
- psoriasis, aplasia,
- sarcoidosis, scleroderma,
- thrombocytopenia,
- vitiligo, Miller Fisher, Guillain-Barre; allerg*, urticaria, rash, eczema,
- asthma

Neurological ADRs paralysis, neurological degeneration, and convulsive ADRs

- **Paralysis:** palsy, paresis, neuropathy, incontinence, Guillain-Barre, Miller Fisher, multiple sclerosis;
- **Neurodegeneration :** encephalopathy, dementia, ataxia, spinal muscular atrophy, delirium, Parkinson;
- seizure,
- Convuls,

ADRs involving loss of sight, hearing, speech or smell

- speech,
- taste,
- smell,
- olfactory,
- blind,
- sight,
- visual,
- vision,
- deaf,
- hearing

Other ADR of interest

43

	MODERNA N=175 832	PFIZER-BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
ADR involving loss of vision, hearing, smell, taste 13 124 symptoms	4481 (2.5%)	5774 (3.2%)	1609 (3.9%)	29 (3.1%)	11 893 (3.0%)
Neurological ADR s 13 009 symptoms	4561 (2.6%)	5431 (3.0%)	1336 (3.2%)	42 (4.5%)	11 370 (2.9%)
Auto-immune ADRs 75 153 symptoms	32 907 (18.7%)	19 901 (11.1%)	3 411 (8.2%)	108 (11.5%)	56 327 (14.1%)

Vision blurred	4062
Visual impairment	1926
Taste disorder	1302
Speech disorder	930
Deafness	906
Blindness	666

Seizure	2895
Bell's palsy	2427
Facial paralysis	1222
Neuropathy peripheral	588
Hemiparesis	421
Guillain-Barre Syndrom	363

Rash	21915
Urticaria	9706
Asthma	880
Angiooedema	619
Alopecia	426
Guillain-Barre Syndrom	421
Thrombocytopenia	390

3 % of ADRs involve loss of a sense or several
 2,9 % of ADR involve neurological issues
 14,1 % of ADR involve auto-ommune ADRs

Time to Other ADR of interest

44

		MODERNA N=175 832	PFIZER- BIONTECH N=179 874	JANSSEN N=41 580	UNKNOWN N=941	Total N=398 227
ADR involving loss of vision, hearing, smell, taste	N	4366	5432	1348	27	11173
	Missing	115	342	261	2	720
	0 day	2092 (47.9%)	2907 (53.5%)	705 (52.3%)	9 (33.3%)	5713 (51.1%)
	[1-3 days]	1287 (29.5%)	1372 (25.3%)	302 (22.4%)	4 (14.8%)	2965 (26.5%)
	[3-7 days]	315 (7.2%)	423 (7.8%)	105 (7.8%)	4 (14.8%)	847 (7.6%)
	[7-14 days]	240 (5.5%)	285 (5.2%)	114 (8.5%)	4 (14.8%)	643 (5.8%)
	[14-21 days]	131 (3.0%)	184 (3.4%)	39 (2.9%)	1 (3.7%)	355 (3.2%)
>21 days	301 (6.9%)	261 (4.8%)	83 (6.2%)	5 (18.5%)	650 (5.8%)	
Neurological ADRs	N	4376	5047	1210	38	10671
	Missing	185	384	126	4	699
	0 day	1509 (34.5%)	1968 (39.0%)	547 (45.2%)	18 (47.4%)	4042 (37.9%)
	[1-3 days]	1236 (28.2%)	1304 (25.8%)	204 (16.9%)	8 (21.1%)	2752 (25.8%)
	[3-7 days]	421 (9.6%)	521 (10.3%)	101 (8.3%)	4 (10.5%)	1047 (9.8%)
	[7-14 days]	400 (9.1%)	506 (10.0%)	127 (10.5%)	5 (13.2%)	1038 (9.7%)
	[14-21 days]	260 (5.9%)	295 (5.8%)	94 (7.8%)	1 (2.6%)	650 (6.1%)
>21 days	550 (12.6%)	453 (9.0%)	137 (11.3%)	2 (5.3%)	1142 (10.7%)	
Auto-immune ADRs	N	32396	18487	2686	87	53656
	Missing	511	1414	725	21	2671
	0 day	7146 (22.1%)	7242 (39.2%)	785 (29.2%)	24 (27.6%)	15197 (28.3%)
	[1-3 days]	8859 (27.3%)	6485 (35.1%)	851 (31.7%)	38 (43.7%)	16233 (30.3%)
	[3-7 days]	6670 (20.6%)	2091 (11.3%)	480 (17.9%)	6 (6.9%)	9247 (17.2%)
	[7-14 days]	8038 (24.8%)	1415 (7.7%)	288 (10.7%)	12 (13.8%)	9753 (18.2%)
	[14-21 days]	653 (2.0%)	518 (2.8%)	131 (4.9%)	0	1302 (2.4%)
>21 days	1030 (3.2%)	736 (4.0%)	151 (5.6%)	7 (8.0%)	1924 (3.6%)	

More than 75 % of ADR occurred in the first 3 days after vaccination.

Only 6 % after 21 days.

64 % of ADR occurred in the first 3 days after vaccination.

Only 11 % after 21 days

Almost 60 % of ADR occurred in the first 3 days after vaccination.

Only 3,6 % after 21 days