Covid-19 Vaccine Pharmacovigilance Report

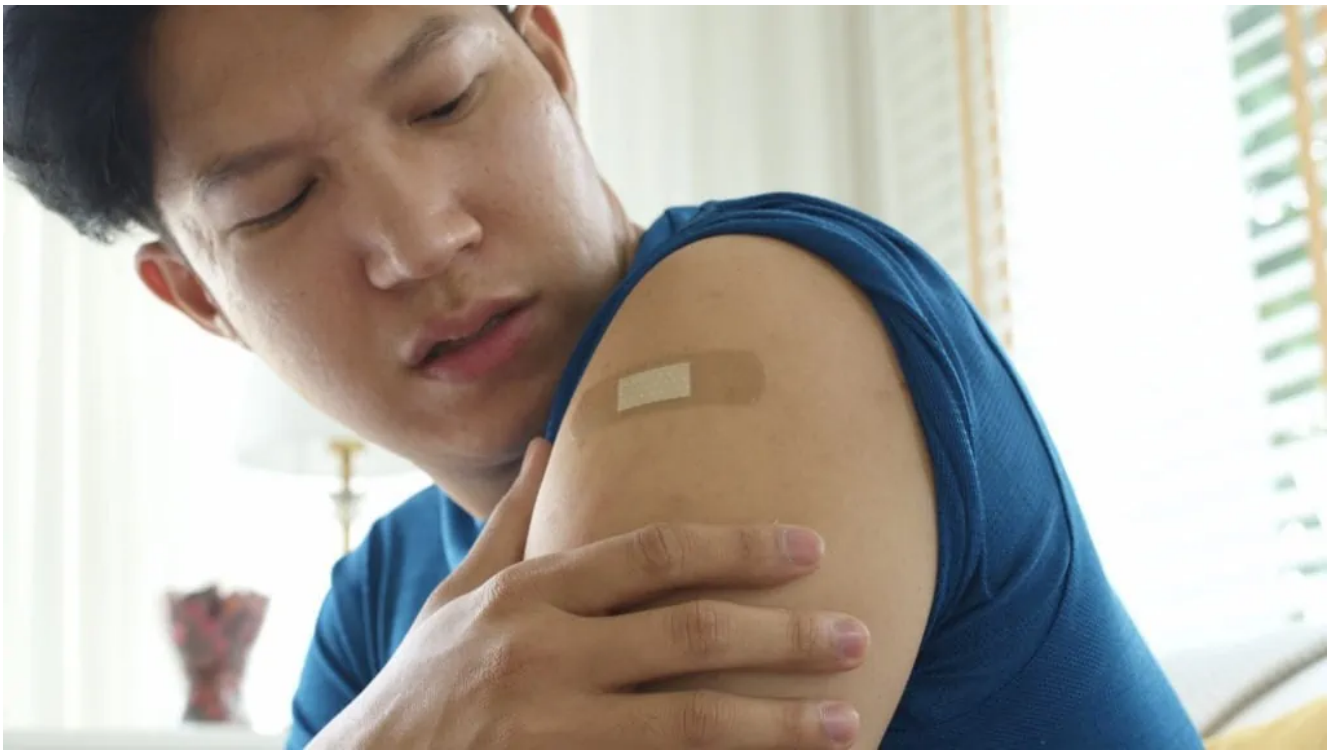
worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report/

Introduction

This report was prepared by the World Council for Health (WCH). The report was prepared to determine whether sufficient pharmacovigilance data exists on WHO VigiAccess, CDC VAERS, EudraVigilance, and UK Yellow Card Scheme to establish a safety signal on Covid-19 vaccines.

These databases are not normally used to establish the safety of an intervention. However, Covid-19 vaccines are in Phase 3 trials, and their safety and efficacy have not yet been established. The majority of those who have received the intervention (several billion people) are not being monitored by the trials. In this report, the WCH aims to use these established pharmacovigilance databases to detect if there is a concerning safety signal in those not being monitored by the clinical trials.

This report collates pharmacovigilance data about Covid-19 vaccines and other commonly administered interventions from these databases. It collates data about the types of adverse event reports linked to Covid-19 vaccines on these databases. Using data from VAERS, FAERS, and historical records, the report collates data about the rate of adverse events that have been sufficient for product recall in the past.



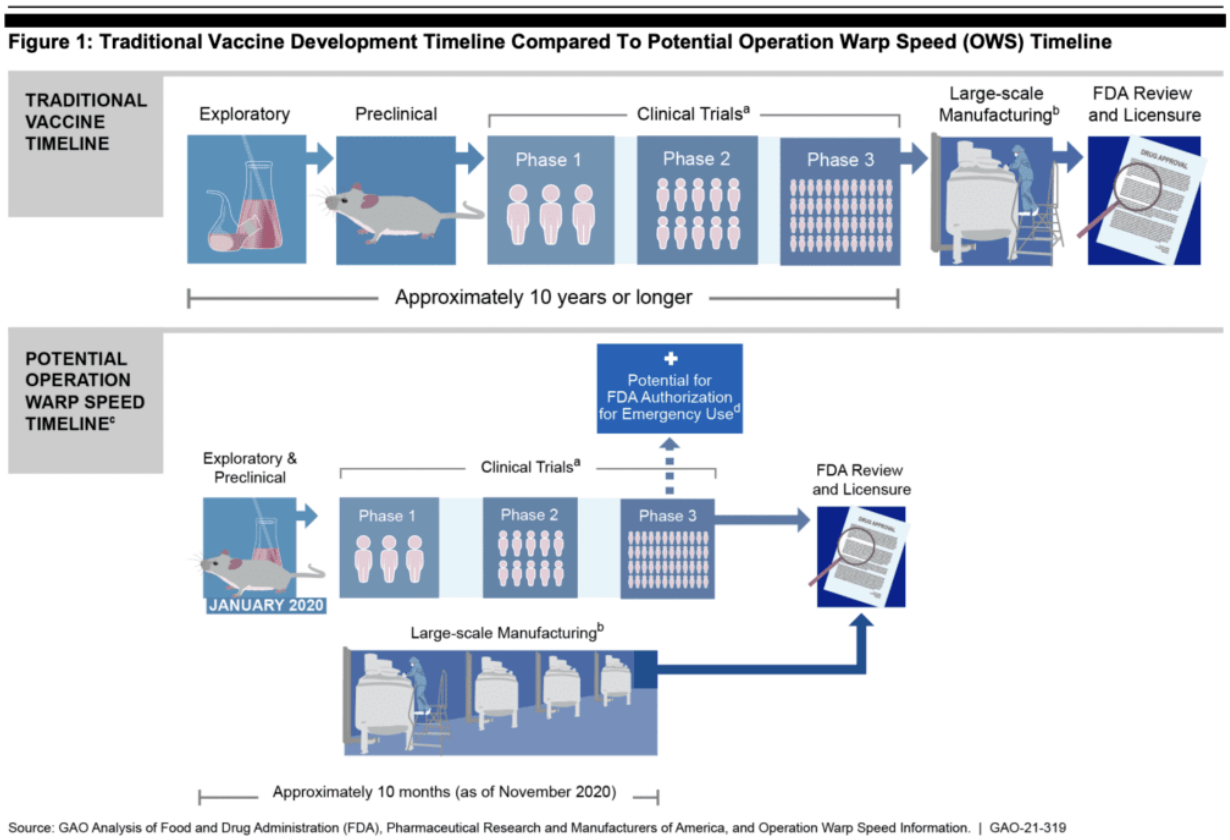
Purpose of Report

This report was prepared **to determine if there is sufficient data on well-established, existing pharmacovigilance databases to establish a safety signal regarding Covid-19 vaccines.**

Covid-19 Vaccine Development was Rushed

Covid-19 vaccine development under Operation Warp Speed was rushed. Traditionally, vaccine development takes 10 years or more before large-scale production and distribution to a wide population. With Covid-19 vaccines, the product moved from exploratory, pre-clinical trials to large-scale manufacturing in just 10 months.

Traditional Vaccine Development Timeline Compared to Potential Operation Warp Speed (OWS) Timeline



Source: GAO Analysis of Food and Drug Adminsitration (FDA), Pharmaceutical Research and Manufacturers of America, and Operation Warp Speed Information

Because the development of these products was rushed, data about their safety are incomplete. In the interest of making a more complete picture of the safety of these novel products, this report collates:

1

Data from Pharmacovigilance Databases about Covid-19 Vaccines and Other Commonly Administered Vaccines and Interventions

This report collates adverse event data on COVID-19 vaccines from the following pharmacovigilance databases:

The Covid-19 vaccine adverse event data gathered on each pharmacovigilance database is compared with the adverse event data of similar pharmacological products (other common vaccines) on the same databases when possible.

2

Data about the Types of Adverse Reactions Linked to Covid-19 Vaccines

In addition, this report examines the types of adverse reaction reports linked to Covid-19 vaccines on the above databases.

3

Data about the Rate of Adverse Events that is Sufficient for Product Recall

This report examines the parameters by which other vaccines and drugs have been recalled in the past.

This is an informational report created by World Council for Health to aid healthcare practitioners, scientists, and individual citizens in making informed decisions about Covid-19 vaccines.

The report seeks to answer the question: Are the pharmacovigilance data contained on these databases sufficient to establish a safety 'signal' for Covid-19 vaccines that indicates product recall?

About World Council for Health

Our Mission

The World Council for Health is a non-profit organization for the people, that is informed and funded by the people. Our global coalition of health-focused organizations and civil society groups seeks to broaden public health knowledge and sense-making through science and shared wisdom. We are dedicated to safeguarding human rights and free will while empowering people to take control of their health and wellbeing.

What we do

The World Council for Health (WCH) is a gathering of the world's best health advocates, doctors, scientists, and innovators committed to an ongoing, transparent conversation on global health issues. This conversation is made accessible to all–governments, organiztions, and individuals looking to advocate for better health. The WCH works collaboratively with 130+ organizations in 40 countries to advance public health knowledge and sensemaking. Together, we take action to defend health freedom and promote healthy lifestyles.

Who we are

Founded in 2021, World Council for Health is a non-profit initiative supported by EbMCsquared CiC, a community interest organization. World Council for Health is guided by its international Coalition Partners, Steering Committee, Volunteers, and Support Staff.

Our vision

We believe in a healthy world, where everyone enjoys information transparency, access to proven medicines, and real action in the face of disease – while respecting each individual's personal health decisions, without fear of discrimination or persecution. We believe in a world where we keep our water and air clean, food uncontaminated, and families together.

Our partners

Our coalition partners bring expertise in science, medical care, legal protection, and community organizing skills to help us achieve our goals.

Our Values

Freedom

Freedom is the right to say, think and do whatever you want to do without being limited. Everyone has this innate human right. It is our responsibility to use it wisely.

Community

The strength of the World Council for Health is in its approach to collaboration. We are powered almost entirely by volunteers in our growing number of committees made up of scientists, medical practitioners, lawyers, activists, and patients. We work across borders dissolving barriers through international coalition partnerships united for the protection of humanity.

Integrity

We value honesty, self-awareness, and a strong moral compass. These together make up integrity and it is important that we hold these in our hearts in order to create the foundations for change.

Transparency

World Council for Health is committed to clear and open communication. Many of the issues we see in the world today are a result of a lack of transparency and accountability, as well as censorship of important truths. We live stream out weekly General Assembly meetings and other events to the public so that anyone can tune in, listen and learn or rewatch later.

Empowerment

Through education and ethos, we empower people to step away from fear and engage more fully in living life. We do this by providing them with the resources to optimize their health and wellbeing so we might be able to step into our collective power.

Methodology

This report was designed to see whether or not there is sufficient evidence on the WHO VigiAccess, CDC VAERS, EudraVigilance, and UK Yellowcard databases to establish a safety signal about Covid-19 vaccines. In ordinary circumstances, Phase 3 and 4 trials would establish the safety and efficacy of a pharmaceutical product. However, these trials are not complete for Covid-19 products. The products have been administered to a wide population that is not being monitored by the clinical

trials. The need exists, therefore, to look at all available evidence to establish the safety of these products and how they might be impacting those who have taken the product but are not being monitored by the clinical trials.

The Need to Examine All Evidence

Traditionally, pharmacovigilance data from passive reporting systems (such as those highlighted in this report) are only used to detect safety signals for rare adverse events that may have been missed in clinical trials. However, several key factors arising from the unique acceleration of Covid-19 products for use in the general public highlight the need to examine all available evidence to establish the suitability of these products for use in humans. These include:

- The safety of Covid-19 products has not been established through the completion of Phase 3 and Phase 4 clinical trials
- The dubious, waning, and decreasing efficacy of Covid-19 products
- Covid-19 products do not function like other similar vaccine products. (i.e. they do not prevent someone from contracting, spreading, or becoming ill with the virus)
- Covid-19 products are being employed on billions of people, including children, during the clinical trial phase. The vast majority of these people are not being monitored
- A greater understanding of the risks associated with Covid-19 illness
- The availability of other safer products to mitigate harm from the disease

Method

This report was completed as follows:

1. We looked at each database–WHO VigiAccess, CDC VAERS, EudraVigilance, and UK Yellow Card Scheme–and documented how many adverse events were related to Covid-19 vaccines.
2. We looked at other similar products (other commonly administered vaccines, where possible, and other commonly administered pharmaceutical products) and documented how many adverse events were related to those products.
3. We normalized these, where possible, to the number of adverse events per individual who had received each intervention, and contrasted the number of adverse events related to Covid-19 vaccines with the number of adverse events related to similar products.
4. In addition, where possible, we examined the trends in reports of adverse events and deaths over the past two years.
5. We note adverse event reports in age groups for which the Covid-19 products have not been authorized.
6. We examine the most commonly reported adverse events on each database by type.
7. We examine whether pharmacovigilance reports are over-reported or under-reported.
8. We note historical cases where adverse event reports have led to recalls of pharmaceutical products.

Pharmacovigilance at a Glance

pharmacovigilance **noun**

phar·ma·co·vig·i·lance |

Medical Definition of *pharmacovigilance*

: the monitoring, evaluation, and prevention of adverse effects associated with the administration of medicines

What is Pharmacovigilance?

Pharmacovigilance is a pharmaceutical science, also known as drug safety. The goal of pharmacovigilance is to collect, assess, and monitor data and, ultimately, to prevent adverse events related to pharmaceutical products. Most data in pharmacovigilance is gathered through adverse event (AE) reporting, but it is also collected in other ways.

Pharmacovigilance databases containing adverse events are an inexpensive and accessible way to detect safety concerns around pharmaceutical products.

How Pharmacovigilance Data is Gathered

Adverse Events Reports

Pharmacovigilance data is commonly gathered through adverse event reporting. Generally, adverse events reports are made by:

- An individual who has experienced an adverse event
- A healthcare practitioner who suspects an adverse event in a patient
- Organizations who create reports from patient support programs
- Pharmaceutical companies in the form of clinical or post-marketing studies
- Literature reviews
- Media reports

Studies

Pharmacovigilance data may also be gathered through other studies including:

- Retrospective studies
- Cohort studies
- Clinical studies
- Post-marketing studies
- Literature reviews

Reports

Some pharmacovigilance data is sourced from reports from:

- Patient support organizations
- Media
- Pharmaceutical companies
- Drug regulatory bodies
- Government agencies

Population Data

Pharmacovigilance data may also be from sourced population data such as:

Statistics

adverse event noun

ad·verse e·vent \

Medical Definition of *adverse event*

: a harmful effect associated with the use of a medical product including but not limited to: death, life-threatening injury, hospitalization, disability, congenital defects, and other serious medical events

severe adverse event noun

se·vere ad·verse e·vent \

Medical Definition of *severe adverse event*

: a harmful effect associated with the use of a medical product that significantly limits daily function including but not limited to: death, life-threatening injury, hospitalization, disability, congenital defects, and other serious medical events

Pharmacovigilance Databases Around the World

Many countries around the world have their own reporting systems for adverse events. Some databases gather reports from around the world, and some databases gather reports solely from their country of origin. All of them have **different methods of reporting**. Reports may be:

- Made by healthcare practitioners on behalf of patients
- Made by individuals experiencing an adverse event
- Vetted by public health authorities
- Vetted by regulatory officials

For this report, we will focus on pharmacovigilance data sourced from Adverse Event Reports on some of the largest and most well-established databases in the world: WHO VigiAccess, VAERS, EudraVigilance, and UK Yellowcard Reporting System.

Pharmacovigilance Data Establishes Signals

Reports made on pharmacovigilance databases do not establish causation. One important part of the science of drug safety is a process known as **'Signal Detection'** in which a variety of techniques are employed to determine if reports point to a **possible causal relationship** between the product and the adverse events being reported. A possible causal relationship established through this process is known as a 'signal.' If a signal is detected, further in-depth investigation is required.

List of Pharmacovigilance Databases

Table 0: Vaccine adverse event or reaction reporting databases

Covid-19 vaccines are a new type of therapy, and their safety is still being understood; therefore, it is especially important to report serious side effects. Depending on where you are in the world, there are various databases set up to record adverse drug reactions:

Country	Database	Website
UK	Medicines and Healthcare Regulatory Advisory (MHRA)	In the UK, the Medicines and Healthcare Regulatory Advisory (MHRA) uses the Yellow Card System to monitor reports, and any individual who suspects an adverse reaction can report it directly onto their website: https://coronavirus-yellowcard.mhra.gov.uk

Country	Database	Website
USA	Vaccine Adverse Event Reporting System (VAERS)	In the USA, the Centres for Disease Control (CDC) and the Food and Drug Administration (FDA) manage the Vaccine Adverse Event Reporting System (VAERS) database, which allows individuals to send in reports through the website: https://vaers.hhs.gov/reportevent.html
Canada	Government of Canada	In Canada, you can report an adverse event at the Government of Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html. There is also the Canada Vigilance Adverse Reaction Online Database: https://cvp-pcv.hc-sc.gc.ca/arq-rei/index-eng.jsp
Australia	Therapeutic Goods Administration	In Australia, the Therapeutic Goods Administration (TGA) monitors adverse events and a report can be filed here: https://aems.tga.gov.au
France	Signalement-sante.gouv.fr	In France, https://solidarites-sante.gouv.fr/soins-et-maladies/signalement-sante-gouv-fr/
South Africa	South African VAERS	In South Africa, https://thj-africa.org.za/ has a link to the South African VAERS.
New Zealand	Government of New Zealand official reporting system	In New Zealand Health Professionals, public and 'others' can report adverse reactions here - https://report.vaccine.covid19.govt.nz/s/
Central America	Noti-FACEDRA reporting system	http://www.notificacentroamerica.net/n/Pages/mapa.aspx#no-back-button
The Phillipines	VARR-PH	https://docs.google.com/forms/d/e/1FAIpQLSezImFX8-euM35Oc_UsSuhv6nql0J0iWRT0NM9Syyf4FAZrlA/viewform?fbclid=IwAR2zQ-CPYb4bnnvd713w1ICwECHm_UA8cRB8z8rmFApkpHmtqlPSzcWGKEQ

Learn more about vaccine adverse event reporting databases

WHO VigiAccess

At a Glance

Launched in 2015 by the WHO, VigiAccess is an international database of reported potential adverse events related to medicinal products**. Some of their stated goals are to "enable individual countries to be alerted to patterns of harm emerging across the world" and "to analyse reports of suspected harm caused by medicines, to find what are known as "signals" of potential adverse drug reactions."**

How Reports are Made

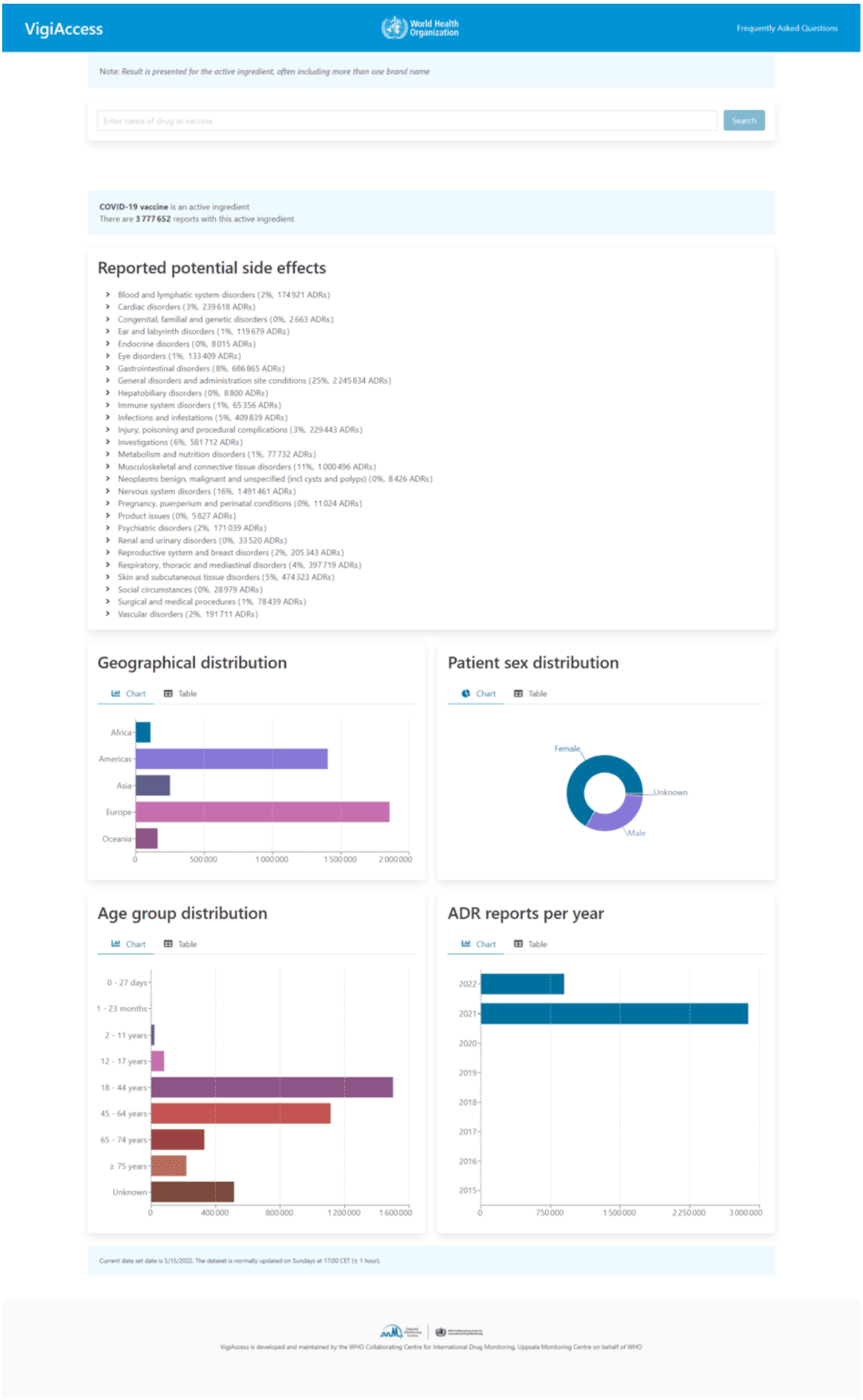
Reports to VigiAccess are made by members of the WHO Programme of International Drug Monitoring (PIDM). Created in 1968, the WHO PIDM members include national pharmacovigilance centres and drug regulatory bodies from 170 countries who collaborate to monitor and identify harms caused by medicines. This collaboration covers about 99% of the world's population.

Important Notes

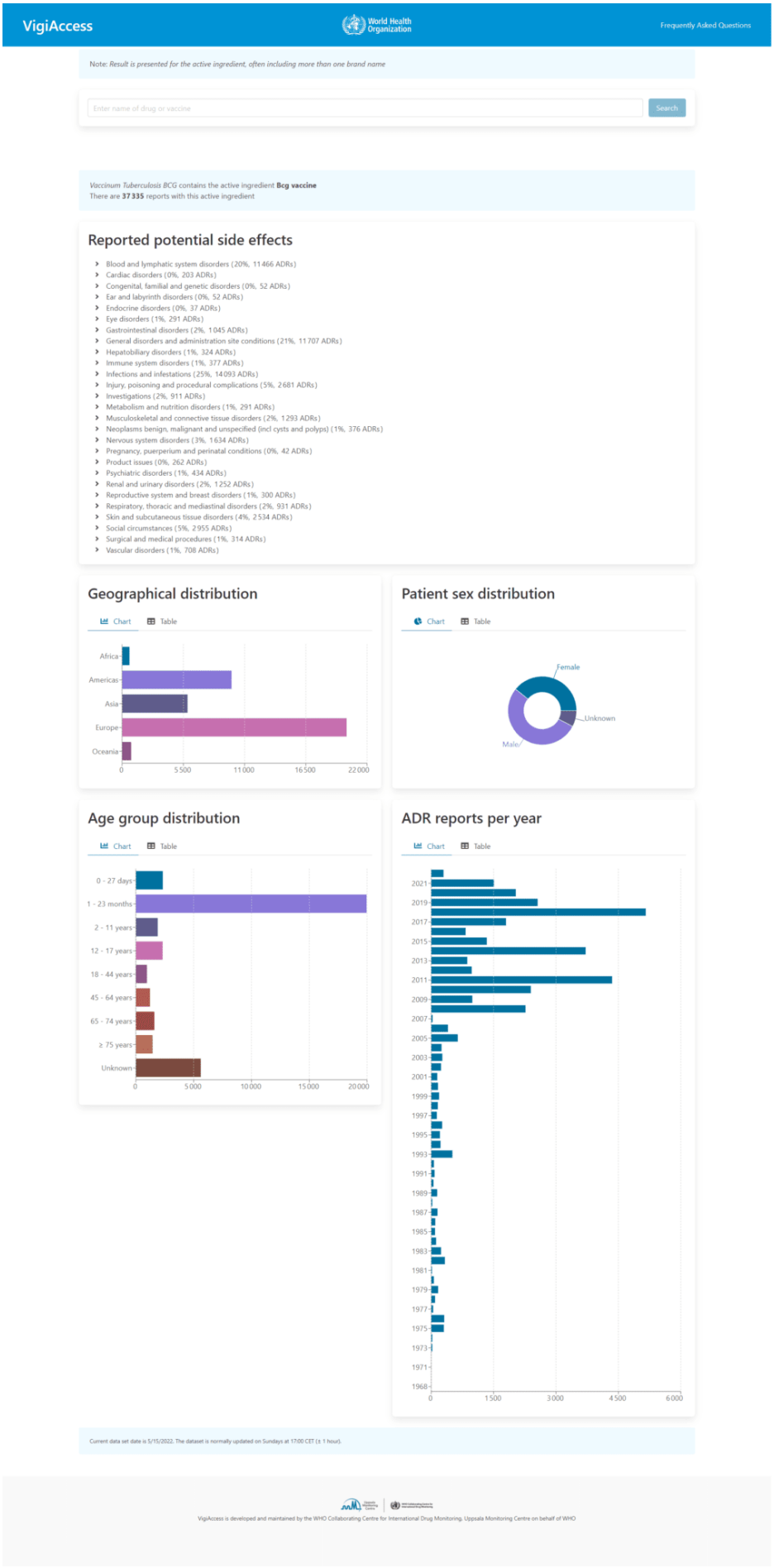
- Covid-19 vaccine adverse event reports on VigiAccess encompass all Covid-19 vaccines
- Other vaccine adverse event reports are for the active ingredient and often include multiple brand names
- VigiAccess does not contain contextual data such as how many people have taken a product, how long it has been on the market, or disparities in reporting. Some of this data is sourced elsewhere for this report
- Reports are collected from 1968 or later

The Data

VigiAcess Data for Covid-19 Vaccines and Tuberculosis Vaccines

- 
VigiAccess
World Health Organization
Frequently Asked Questions
Note: Result is presented for the active ingredient, often including more than one brand name
Enter name of drug or vaccine
Search
COVID-19 vaccine is an active ingredient
There are 3 777 652 reports with this active ingredient
Reported potential side effects
Blood and lymphatic system disorders (2%, 174 921 ADRs)
Cardiac disorders (3%, 239 618 ADRs)
Congenital, familial and genetic disorders (0%, 2 663 ADRs)
Ear and labyrinth disorders (1%, 119 679 ADRs)
Endocrine disorders (0%, 8 015 ADRs)
Eye disorders (1%, 133 409 ADRs)
Gastrointestinal disorders (8%, 686 865 ADRs)
General disorders and administration site conditions (25%, 2 245 834 ADRs)
Hepatobiliary disorders (0%, 8 800 ADRs)
Immune system disorders (1%, 65 356 ADRs)
Infections and infestations (5%, 409 839 ADRs)
Injury, poisoning and procedural complications (3%, 229 443 ADRs)
Investigations (6%, 581 712 ADRs)
Metabolism and nutrition disorders (1%, 77 732 ADRs)
Musculoskeletal and connective tissue disorders (11%, 1 000 496 ADRs)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (0%, 8 426 ADRs)
Nervous system disorders (16%, 1 491 461 ADRs)
Pregnancy, puerperium and perinatal conditions (0%, 11 024 ADRs)
Product issues (0%, 5 827 ADRs)
Psychiatric disorders (2%, 171 039 ADRs)
Renal and urinary disorders (0%, 33 520 ADRs)
Reproductive system and breast disorders (2%, 205 343 ADRs)
Respiratory, thoracic and mediastinal disorders (4%, 397 719 ADRs)
Skin and subcutaneous tissue disorders (5%, 474 323 ADRs)
Social circumstances (0%, 28 979 ADRs)
Surgical and medical procedures (1%, 78 439 ADRs)
Vascular disorders (2%, 191 711 ADRs)
Geographical distribution
Chart
Table
Africa
Americas
Asia
Europe
Oceania
0
500 000
1 000 000
1 500 000
2 000 000
Patient sex distribution
Chart
Table
Female
Unknown
Male
Age group distribution
Chart
Table
0 - 27 days
1 - 23 months
2 - 11 years
12 - 17 years
18 - 44 years
45 - 64 years
65 - 74 years
≥ 75 years
Unknown
0
400 000
800 000
1 200 000
1 600 000
ADR reports per year
Chart
Table
2022
2021
2020
2019
2018
2017
2016
2015
0
750 000
1 500 000
2 250 000
3 000 000
Current data set date is 5/15/2022. The dataset is normally updated on Sundays at 17:00 CET (± 1 hour).
VigiAccess is developed and maintained by the WHO Collaborating Centre for International Drug Monitoring, Uppsala Monitoring Centre on behalf of WHO

VigiAcess Data for Covid-19 Vaccines

- 
VigiAccess
World Health Organization
Frequently Asked Questions
Note: Result is presented for the active ingredient, often including more than one brand name
Enter name of drug or vaccine
Search
Vaccinum Tuberculosis BCG contains the active ingredient Bcg vaccine
There are 37 335 reports with this active ingredient
Reported potential side effects
Blood and lymphatic system disorders (20%, 11 466 ADRs)
Cardiac disorders (0%, 203 ADRs)
Congenital, familial and genetic disorders (0%, 52 ADRs)
Ear and labyrinth disorders (0%, 52 ADRs)
Endocrine disorders (0%, 37 ADRs)
Eye disorders (1%, 291 ADRs)
Gastrointestinal disorders (2%, 1 045 ADRs)
General disorders and administration site conditions (21%, 11 707 ADRs)
Hepatobiliary disorders (1%, 324 ADRs)
Immune system disorders (1%, 377 ADRs)
Infections and infestations (25%, 14 093 ADRs)
Injury, poisoning and procedural complications (5%, 2 681 ADRs)
Investigations (2%, 911 ADRs)
Metabolism and nutrition disorders (1%, 291 ADRs)
Musculoskeletal and connective tissue disorders (2%, 1 293 ADRs)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (1%, 376 ADRs)
Nervous system disorders (3%, 1 634 ADRs)
Pregnancy, puerperium and perinatal conditions (0%, 42 ADRs)
Product issues (0%, 262 ADRs)
Psychiatric disorders (1%, 434 ADRs)
Renal and urinary disorders (2%, 1 252 ADRs)
Reproductive system and breast disorders (1%, 300 ADRs)
Respiratory, thoracic and mediastinal disorders (2%, 931 ADRs)
Skin and subcutaneous tissue disorders (4%, 2 534 ADRs)
Social circumstances (5%, 2 955 ADRs)
Surgical and medical procedures (1%, 314 ADRs)
Vascular disorders (1%, 708 ADRs)
Geographical distribution
Chart
Table
Africa
Americas
Asia
Europe
Oceania
0
5 500
11 000
16 500
22 000
Patient sex distribution
Chart
Table
Female
Unknown
Male
Age group distribution
Chart
Table
0 - 27 days
1 - 23 months
2 - 11 years
12 - 17 years
18 - 44 years
45 - 64 years
65 - 74 years
≥ 75 years
Unknown
0
5 000
10 000
15 000
20 000
ADR reports per year
Chart
Table
2021
2019
2017
2015
2013
2011
2009
2007
2005
2003
2001
1999
1997
1995
1993
1991
1989
1987
1985
1983
1981
1979
1977
1975
1973
1971
1968
0
1 500
3 000
4 500
6 000
Current data set date is 5/15/2022. The dataset is normally updated on Sundays at 17:00 CET (± 1 hour).
VigiAccess is developed and maintained by the WHO Collaborating Centre for International Drug Monitoring, Uppsala Monitoring Centre on behalf of WHO

VigiAcess Data for Covid-19 Tuberculosis Vaccines

Source: *vigiaccess.org*

Table 1: Contextual Data of Covid-19 and Tuberculosis Vaccines on VigiAccess

As of May 2022	Covid-19 Vaccine	Tuberculosis (Bacille Calmette-Guérin – BCG) Vaccine
As of May 2022	~ 5 100 000 000	~ 4 000 000 000
Data collected since	2020	1968
Total Adverse Event Reports on VigiAccess	~ 3 800 000	~ 37 000

Discussion

The tuberculosis vaccine has been administered to the highest percentage of the world's population, more than any other vaccine. 88% of 1 year olds have been immunized against tuberculosis. Some 4 billion individuals have received the vaccine. VigiAccess reports around 37 thousand adverse event reports relating to the tuberculosis vaccine.

At least one dose of the Covid-19 vaccine has been administered to 65.7% of the world's population or approximately 5.1 billion individuals. VigiAccess reports around 3.8 million adverse events reports relating to the Covid-19 vaccine.

Table 2: Other Vaccine Adverse Event Data on VigiAccess

Vaccine	Total Number of Adverse Event Reports on VigiAccess as of May 2022	Percentage of 1 year olds who have been immunized globally	Data Collected Since
Tuberculosis Vaccine	37335	88%	1968
Polio Vaccine	123732	86%	1968
Diphtheria Vaccine	1914	85%	1979
Tetanus Vaccine	15381	85%	1968
Pertussis Vaccine	2259	85%	1972
Hepatitis B Vaccine	106761	85%	1984

Vaccine	Total Number of Adverse Event Reports on VigiAccess as of May 2022	Percentage of 1 year olds who have been immunized globally	Data Collected Since
H. Influenza B Vaccine	90044	72%	1986
Measles Vaccine	6231	71%	1968
Rubella Vaccine	2640	71%	1971
Covid-19 Vaccine	3777652	65.7%***	2020

*** *Percentage of current world population* ***

Discussion

For common vaccines that have been distributed to the vast majority of the world's population, we see a range of adverse event reports numbering **between 2000 and 100 000** on VigiAccess.

For the Covid-19 vaccines, which have currently been administered to around 65% of the world population, there are over **3.7 million reports** of adverse events on VigiAccess.

Comments

VigiAccess shows a number of adverse events that is unprecedented on the database for any other pharmaceutical product or vaccine. The total reports of adverse event reports cannot be compared directly because of the lack of contextual data discussed earlier. However, given that other similar products have been widely distributed on a global scale in comparable numbers, **the magnitude of disparity is cause for grave concern**. This data is particularly relevant given that Covid-19 vaccines are being widely distributed, are still in clinical trials, and **must be scrutinized using all available evidence**.

In Table 2, we see 37 335 adverse event reports from an estimated 4 billion individuals who have received the tuberculosis immunization and over 3.7 million reports from an estimated 5.1 million individuals who have received the Covid-19 vaccine. Correcting for the difference in the number of individuals who have received the two vaccines, we see an 80-fold increase in the number in adverse events reported to VigiAccess for the Covid-19 vaccine.

Given VigiAccess' stated purpose–to analyse reports of suspected harm caused by medicines, to find "signals" of potential adverse drug reactions–immediate investigation and urgent action are required from the World Health Organization.

CDC VAERS

At a Glance

Vaccine Adverse Event Reporting System (VAERS) was established in 1990 and co-managed by the United States Centers for Disease Control and Prevention (CDC) and the United States Food and Drug Administration (FDA). The system is designed to be an early warning system for safety concerns related to US-licensed vaccines. VAERS inputs and analyzes reports of adverse events that occur after a vaccination.

Some of the stated purposes of VAERS are to **"detect new, unusual, or rare vaccine adverse events," "assess the safety of newly licensed vaccines,"** and **"provide a national safety monitoring system that extends to the entire population for response to public health emergencies, such as large-scale pandemic influenza vaccination programs."**

How Reports are Made

Any individual who has experienced an adverse event following a vaccine may report to VAERS. In addition, healthcare practitioners are required to report prescribed events that occur in their patients after vaccination, and vaccine manufacturers are required to report all adverse events that come to their attention. It is a passive reporting system which relies on individuals to self-report or healthcare providers to report on their behalf.

Important Notes

- VAERS is a passive surveillance system
- VAERS does not contain contextual data such as how many people have taken a vaccine, how long it has been on the market, or disparities in reporting. Some of this data is sourced elsewhere for this report
- VAERS Reports are from 1990 to the present
- Covid-19 vaccine data on VAERS encompasses Moderna, Pfizer, and Janzen vaccines
- It is a federal offence in the United States to submit a false VAERS report
- **VAERS has been used as a pharmacovigilance tool in the past for intussusception of vaccines** (a small number of anamolous reports in VAERS related to the Rotavirus vaccine in children led to intussusception)

Data

VAERS Data: Percentage of Total Adverse Event Reports by Vaccine Type

- 
Percent By Vaccine Type
ADENOVIRUS TYPE 4 &7 VACCINE, LIVE ORAL
ADENOVIRUS VACCINE LIVE ORAL TYPE 7
ANTHRAX VACCINE
BACILLUS CALMETTE-GUERIN VACCINE
CENTRAL EUROPEAN ENCEPHALITIS
CHOLERA VACCINE
COMVAX
COVID19 VACCINE
DENGUE TETRAVALENT VACCINE (DENGVAXIA)
DIPHTHERIA AND TETANUS TOXOIDS ACELLULAR PERTUSSIS...
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTU...
DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCI...
DIPHTHERIA AND TETANUS TOXOIDS PERTUSSIS AND HAEMO...
DIPHTHERIA AND TETANUS TOXOIDS, PEDIATRIC
DIPHTHERIA TOXOID
DIPHTHERIA/PERTUSSIS/INACTIVATED POLIO VIRUS
DIPHTHERIA/PERTUSSIS/POLIO (ORAL [LIVE] OR INACTIV...
DIPHTHERIA/TETANUS/PERTUSSIS/HEPATITIS B
DIPHTHERIA/TETANUS/WHOLE PERTUSSIS-INACTIVATED POL...
DT-IPV COMBINED DT AND IPV VACCINE
DTP-IPV COMBINED DTP AND IPV VACCINE
EBOLA ZAIRE VACCINE
HAEMOPHILUS B CONJUGATE VACCINE
HAEMOPHILUS B POLYSACCHARIDE VACCINE
HEPATITIS A
HEPATITIS A AND HEPATITIS B VACCINE
HEPATITIS A AND TYPHOID VACCINES
HEPATITIS B VACCINE
HUMAN PAPILLOMAVIRUS (TYPES 6, 11, 16, 18) RECOMBI...
HUMAN PAPILLOMAVIRUS (TYPES 6, 11,16, 18, 31, 33, ...
HUMAN PAPILLOMAVIRUS VACCINE
HUMAN PAPILLOVAVIRUS BIVALENT
INFLUENZA (H1N1) MONOVALENT (INJECTED)
INFLUENZA (H1N1) MONOVALENT, (INTRANASAL SPRAY)
INFLUENZA VIRUS VACCINE, NO BRAND NAME
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED)
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INTRANASAL ...
INFLUENZA VIRUS VACCINE, QUADRIVALENT, ADJUVANT (I...
INFLUENZA VIRUS VACCINE, QUADRIVALENT, CELL-CULTUR...
INFLUENZA VIRUS VACCINE, QUADRIVALENT, RECOMBINANT...
INFLUENZA VIRUS VACCINE, TRIVALENT (INJECTED)
INFLUENZA VIRUS VACCINE, TRIVALENT (INTRANASAL SPR...
INFLUENZA VIRUS VACCINE, TRIVALENT, ADJUVANT (INJE...
INFLUENZA VIRUS VACCINE, TRIVALENT, CELL-CULTURE-D...
INFLUENZA VIRUS VACCINE, TRIVALENT, RECOMBINANT (I...
INFLUENZA(H1N1) MONOVALENT, UNKNOWN MANUFACTURER
JAPANESE ENCEPHALITIS VIRUS VACCINE
JAPANESE ENCEPHALITIS VIRUS VACCINE (NO BRAND NAME...
JAPANESE ENCEPHALITIS VIRUS VACCINE, INACTIVATED, ...
LYME VACCINE (LYMERIX)
MEASLES AND MUMPS VIRUS VACCINE, LIVE
MEASLES AND RUBELLA VACCINE
MEASLES VACCINE
MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE
MEASLES, MUMPS, RUBELLA, AND VARICELLA VACCINE (PR...
MENINGICOCCAL GROUP C & Y + HIB
MENINGOCOCCAL B VACCINE
MENINGOCOCCAL CONJUGATE VACCINE
MENINGOCOCCAL GROUPS C AND Y + HAEMOPHILUS B TETAN...
MENINGOCOCCAL POLYSACCHARIDE VACCINE
MENINGOCOCCAL VACCINE (MENACTRA)
MUMPS AND RUBELLA VIRUS VACCINE, LIVE
MUMPS VIRUS VACCINE, LIVE
PANDEMIC FLU VACCINE
PERTUSSIS, ADSORBED VACCINE
PLAGUE VACCINE
PNEUMOCOCCAL, 15-VALENT VACCINE (VAXNEUVANCE)
PNEUMOCOCCAL, 20-VALENT VACCINE (PREVNAR20)
PNEUMOCOCCAL VACCINE, POLYVALENT
PNEUMOCOCCAL, 10-VALENT VACCINE (SYNFLORIX)
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR13)
PNEUMOCOCCAL, 7-VALENT VACCINE (PREVNAR)
POLIOVIRUS VACCINE INACTIVATED
POLIOVIRUS VACCINE TRIVALENT, LIVE, ORAL
RABIES VIRUS VACCINE
ROTAVIRUS (NO BRAND NAME)
ROTAVIRUS VACCINE (ROTASHIELD)
ROTAVIRUS VACCINE, LIVE, ORAL
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT
RUBELLA VACCINE
SMALLPOX VACCINE
SUMMER/SPRING ENCEPHALITIS VACCINE (SSE)
TETANUS AND DIPHTHERIA TOXOIDS AND ACELLULAR PERTU...
TETANUS AND DIPHTHERIA TOXOIDS, ADULT
TETANUS TOXOID
TETANUS, DIPHTHERIA AND ACELLULAR PERTUSSIS, AND I...
TETRAMUNE
TICK-BORNE ENCEPHALITIS VACCINE (TBE)
TYPHOID VACCINE
VARIVAX-VARICELLA VIRUS LIVE
YELLOW FEVER VACCINE
ZOSTER VACCINE
UNKNOWN VACCINES
Vaccine Type
0
20
40
Percent

VAERS Data: Percentage of Total Adverse Event Reports by Vaccine Type

The Vaccine Adverse Event Reporting System (VAERS) Results

Covid-19 Vaccine

Data current as of 05/06/2022

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Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 1,575,654 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Vaccine Type	Events Reported	Percent (of 1,575,654)
ADENOVIRUS TYPE 4 &7 VACCINE, LIVE ORAL (ADEN_4_7)	185	0.01%
ADENOVIRUS VACCINE LIVE ORAL TYPE 7 (ADEN)	11	0.00%
ANTHRAX VACCINE (ANTH)	9,267	0.59%
BACILLUS CALMETTE-GUERIN VACCINE (BCG)	203	0.01%
CENTRAL EUROPEAN ENCEPHALITIS (CEE)	1	0.00%
CHOLERA VACCINE (CHOL)	200	0.01%
COMVAX (HIBHEPB)	5,414	0.34%
COVID19 VACCINE (COVID19)	856,340	54.35%
DENGUE TETRAVALENT VACCINE (DENGVAXIA) (DF)	40	0.00%
DIPHTHERIA AND TETANUS TOXOIDS ACELLULAR PERTUSSIS POLIOVIRUS INACTIVATED HAEMOPHILUS INFLUENZA B AND HEPATITIS B VACCINE (HEXAVAX) (VAX-F)	199	0.01%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (DTAP)	57,135	3.63%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE (DTAPIPV)	9,627	0.61%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	11,658	0.74%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (DTAPIPVHIB)	9,113	0.58%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE + HEPATITIS B + (VAXXILIS) (DTPPVHBHPB)	76	0.00%
DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE (DTP)	20,794	1.32%
DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE) (DTPPHIB)	51	0.00%
DIPHTHERIA AND TETANUS TOXOIDS PERTUSSIS AND HAEMOPHILUS INFLUENZA B VACCINE (HEXAVAX) (DTPHIB)	6,077	0.39%
DIPHTHERIA AND TETANUS TOXOIDS, PEDIATRIC (DT)	2,409	0.15%
DIPHTHERIA TOXOID (DTOX)	77	0.00%
DIPHTHERIA/PERTUSSIS/POLIO (ORAL [LIVE] OR INACTIVATED NOT NOTED) (DPP)	197	0.01%
DIPHTHERIA/TETANUS/PERTUSSIS/HEPATITIS B (DTPHEP)	41	0.00%
DIPHTHERIA/TETANUS/WHOLE PERTUSSIS INACTIVATED POLIO VIRUS-HAEMOPHILUS INFLUENZA B (PENTACOQR) (DTPHE)	57	0.00%
DT-IPV COMBINED DT AND IPV VACCINE (DTIPV)	28	0.00%
DTP-IPV COMBINED DTP AND IPV VACCINE (DTPIPV)	86	0.01%
EBOLA ZAIRE VACCINE (EBZR)	46	0.00%
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	49,557	3.15%
HAEMOPHILUS B POLYSACCHARIDE VACCINE (HBPV)	258	0.02%
HEPATITIS A (HEPA)	38,242	2.43%
HEPATITIS A AND HEPATITIS B VACCINE (HEPAB)	3,311	0.21%
HEPATITIS A AND TYPHOID VACCINES (HEPATYP)	6	0.00%
HEPATITIS B VACCINE (HEP)	60,228	3.82%
HUMAN PAPILLOMAVIRUS (TYPES 6, 11, 16, 18) RECOMBINANT VACCINE (HPV4)	37,100	2.35%
HUMAN PAPILLOMAVIRUS (TYPES 6, 11,16, 18, 31, 33, 45, 52, 58) RECOMBINANT VACCINE (HPV9)	16,043	1.02%
HUMAN PAPILLOMAVIRUS VACCINE (HPVX)	1,067	0.07%
HUMAN PAPILLOVAVIRUS BIVALENT (HPV2)	261	0.02%
INFLUENZA (H1N1) MONOVALENT (INJECTED) (FLU(H1N1))	8,491	0.54%
INFLUENZA (H1N1) MONOVALENT, (INTRANASAL SPRAY) (FLUN(H1N1))	2,889	0.18%
INFLUENZA VIRUS VACCINE, NO BRAND NAME (FLUX(SEASONAL))	22,039	1.40%
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED) (FLU4(SEASONAL))	36,004	2.29%
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INTRANASAL SPRAY) (FLUN4(SEASONAL))	3,066	0.19%
INFLUENZA VIRUS VACCINE, QUADRIVALENT, ADJUVANT (INJECTED) (FLUAA(SEASONAL))	1,490	0.09%
INFLUENZA VIRUS VACCINE, QUADRIVALENT, CELL-CULTURE-DERIVED (INJECTED) (FLUC4(SEASONAL))	5,201	0.33%
INFLUENZA VIRUS VACCINE, QUADRIVALENT, RECOMBINANT (INJECTED) (FLUR4(SEASONAL))	2,358	0.15%
INFLUENZA VIRUS VACCINE, TRIVALENT (INJECTED) (FLU3(SEASONAL))	93,366	5.93%
INFLUENZA VIRUS VACCINE, TRIVALENT (INTRANASAL SPRAY) (FLUN3(SEASONAL))	5,817	0.37%
INFLUENZA VIRUS VACCINE, TRIVALENT, ADJUVANT (INJECTED) (FLUA3(SEASONAL))	2,450	0.16%
INFLUENZA VIRUS VACCINE, TRIVALENT, CELL-CULTURE-DERIVED (INJECTED) (FLUC3(SEASONAL))	1,076	0.07%
INFLUENZA VIRUS VACCINE, TRIVALENT, RECOMBINANT (INJECTED) (FLUR3(SEASONAL))	203	0.01%
INFLUENZA(H1N1) MONOVALENT, UNKNOWN MANUFACTURER (FLUX(H1N1))	2,020	0.13%
JAPANESE ENCEPHALITIS VIRUS VACCINE (JEV)	486	0.03%
JAPANESE ENCEPHALITIS VIRUS VACCINE (NO BRAND NAME) (JEVX)	40	0.00%
JAPANESE ENCEPHALITIS VIRUS VACCINE, INACTIVATED, ADSORBED (JEV1)	384	0.02%
LYME VACCINE (LYMERIX) (LYME)	2,222	0.14%
MEASLES AND MUMPS VIRUS VACCINE, LIVE (MM)	66	0.00%
MEASLES AND RUBELLA VACCINE (MER)	161	0.01%
MEASLES VACCINE (MEA)	640	0.04%
MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE (MMR)	77,954	4.95%
MEASLES, MUMPS, RUBELLA, AND VARICELLA VACCINE (PROQUAD) (MMRV)	17,545	1.11%
MENINGOCOCCAL GROUP C & Y + HIB (MNQHIB)	22	0.00%
MENINGOCOCCAL B VACCINE (MENB)	6,934	0.44%
MENINGOCOCCAL CONJUGATE VACCINE (MNC)	1	0.00%
MENINGOCOCCAL GROUPS C AND Y + HAEMOPHILUS B TETANUS TOXOID CONJUGATE VACCINE (MENHIB)	19	0.00%
MENINGOCOCCAL POLYSACCHARIDE VACCINE (MEN)	2,760	0.18%
MENINGOCOCCAL VACCINE (MENACTRA) (MNQ)	24,917	1.58%
MUMPS AND RUBELLA VIRUS VACCINE, LIVE (MUR)	28	0.00%
MUMPS VIRUS VACCINE, LIVE (MU)	156	0.01%
PANDEMIC FLU VACCINE (H5N1)	5	0.00%
PERTUSSIS, ADSORBED VACCINE (PER)	142	0.01%
PLAGUE VACCINE (PLAGUE)	28	0.00%
PNEUMOCOCCAL, 15-VALENT VACCINE (VAXNEUVANCE) (PNC15)	5	0.00%
PNEUMOCOCCAL, 20-VALENT VACCINE (PREVNAR20) (PNC20)	150	0.01%
PNEUMOCOCCAL VACCINE, POLYVALENT (PPV)	61,328	3.89%
PNEUMOCOCCAL, 10-VALENT VACCINE (SYNFLORIX) (PNC10)	38	0.00%
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR13) (PNC13)	28,359	1.80%
PNEUMOCOCCAL, 7-VALENT VACCINE (PREVNAR) (PNC)	23,378	1.48%
POLIOVIRUS VACCINE INACTIVATED (IPV)	36,953	2.35%
POLIOVIRUS VACCINE TRIVALENT, LIVE, ORAL (OPV)	23,699	1.50%
RABIES VIRUS VACCINE (RAB)	4,266	0.27%
ROTAVIRUS (NO BRAND NAME) (RVX)	899	0.06%
ROTAVIRUS VACCINE (ROTASHIELD) (RV)	698	0.04%
ROTAVIRUS VACCINE, LIVE, ORAL (RV1)	2,645	0.17%
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	19,720	1.25%
RUBELLA VACCINE (RUB)	884	0.06%
SMALLPOX VACCINE (SMALL)	5,719	0.36%
SUMMER/SPRING ENCEPHALITIS VACCINE (SSE) (SSEV)	3	0.00%
TETANUS AND DIPHTHERIA TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (BOOSTRIX/ADACEL) (TDAP)	39,709	2.52%
TETANUS AND DIPHTHERIA TOXOIDS, ADULT (TD)	17,752	1.13%
TETANUS TOXOID (TTOX)	3,247	0.21%
TETANUS, DIPHTHERIA AND ACELLULAR PERTUSSIS, AND INACTIVATED POLIO VIRUS (TDAPIPV)	9	0.00%
TETRAMUNE (DTAPH)	704	0.04%
TICK-BORNE ENCEPHALITIS VACCINE (TBE) (TBE)	3	0.00%
TYPHOID VACCINE (TYP)	7,973	0.51%
VARIVAX-VARICELLA VIRUS LIVE (VARCEL)	80,655	5.12%
YELLOW FEVER VACCINE (YF)	3,517	0.22%
ZOSTER VACCINE (VARZOS)	101,754	6.46%
UNKNOWN VACCINES (UNK)	18,849	1.20%
Total	**1,999,301**	**126.89%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information.

Data contains VAERS reports processed as of 05/06/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information.

About COVID19 vaccines:

- For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/.
- One report may state that the patient received more than one brand of COVID-19 vaccine on the same visit. This is a reporting error, but explains why the total number of reports may not equal the total number of COVID-19 vaccine doses.

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation for more information.

Query Date: May 19, 2022 4:55:17 PM

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Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA). Vaccine Adverse Event Reporting System (VAERS) 1990 - 05/06/2022, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on May 19, 2022 4:55:17 PM

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Query Criteria:

Title: Covid-19 Vaccine
State / Territory: The United States/Territories/Unknown
Group By: Vaccine Type
Show Totals: True
Show Zero Values: False

Content source: CDC WONDER

VAERS Data: Percentage of Total Adverse Event Reports by Vaccine Type

Source:
https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=CB19840534D33730BADDAAEB1AE0https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=CB19840534D33730BADDAAEB1AE0

Discussion

Over 50% of total adverse event reports made on VAERS, that is reports made for ALL vaccines since 1990, are attributed to COVID-19 vaccines.

Table 3: Contextual Data of Covid-19 Vaccine and Measles, Mumps, Rubella Vaccine on VAERS

# of	Covid-19 Vaccine	Measles/Mumps/Rubella
Approximate Number of Individuals Vaccinated	255000000	301000000
Total number of Adverse Event Reports on VAERS	856340	77954

Discussion

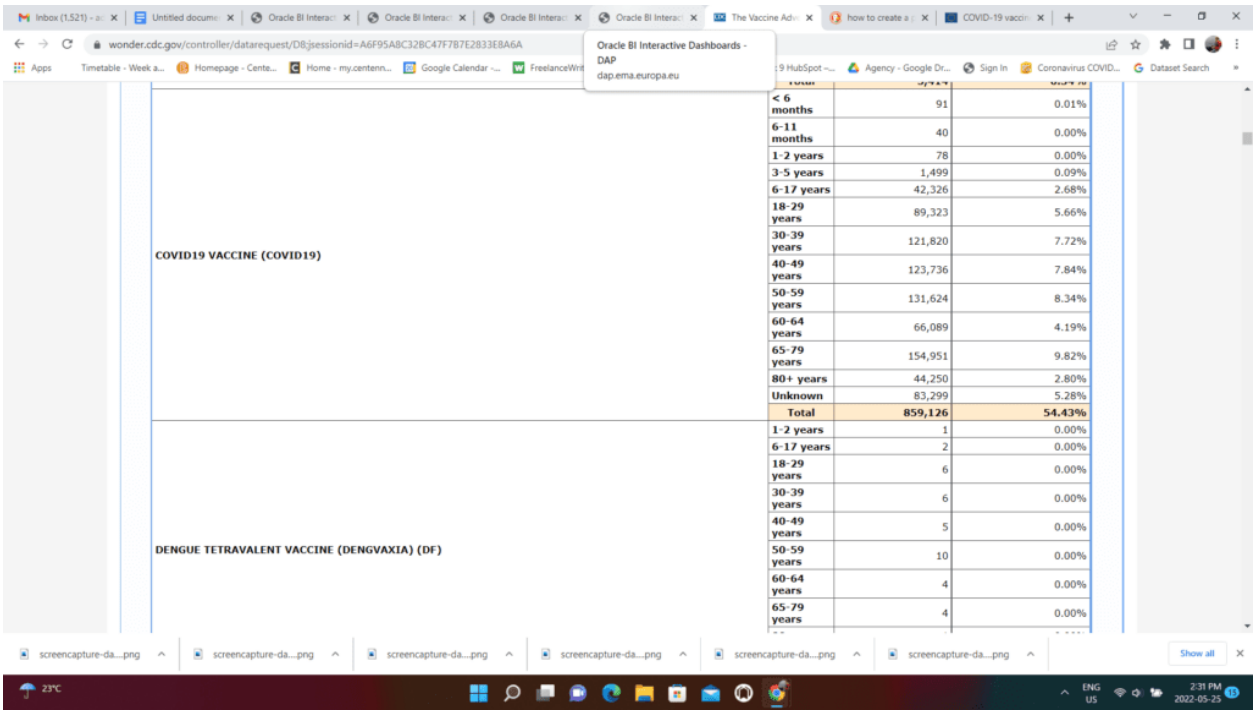
Over 50% of total adverse event reports made on VAERS, that is reports made for ALL vaccines since 1990, are attributed to COVID-19 vaccines.

OpenVAERS is a project that allows browsing and searching of VAERS reports without the need to compose an advanced search. OpenVAERS has generated the above graphs and tables regarding Covid-19 adverse events reports and total death reports which are updated regularly.

The second table above shows the mean number of deaths reported on VAERS from 1990 – 2020 at 122, followed by an alarming and unprecedented spike in death reports for 2021 and 2022.

From these data representations, we can observe an alarming trend in the number of deaths reported to VAERS per year. Starting in 2020 and continuing to 2022, we see a dramatic and unprecedented spike in deaths reported to VAERS. Currently of the over 37 000 deaths reported to VAERS since 1990, 27 968 are related to Covid-19 products. A death in close proximity to a vaccine indicates a more likely causal relationship. As illustrated in the second to last graphic above, a vast majority of reports are made within 3 days of the vaccine being administered.

Covid-19 VAERS reports by Age



COVID19 VACCINE (COVID19)	< 6 months	91	0.01%
	6-11 months	40	0.00%
	1-2 years	78	0.00%
	3-5 years	1,499	0.09%
	6-17 years	42,326	2.68%
	18-29 years	89,323	5.66%
	30-39 years	121,820	7.72%
	40-49 years	123,736	7.84%
	50-59 years	131,624	8.34%
	60-64 years	66,089	4.19%
	65-79 years	154,951	9.82%
	80+ years	44,250	2.80%
	Unknown	83,299	5.28%
	Total	859,126	54.43%
DENGUE TETRAVALENT VACCINE (DENGVAXIA) (DF)	1-2 years	1	0.00%
	6-17 years	2	0.00%
	18-29 years	6	0.00%
	30-39 years	6	0.00%
	40-49 years	5	0.00%
	50-59 years	10	0.00%
	60-64 years	4	0.00%
	65-79 years	4	0.00%

Covid-19 VAERS reports by Age

Source:
https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=F9E61FE2A2B457AD46D5FC21F667

Discussion

There are 209 reports of adverse events on VAERS for children under 2. These vaccines have not been authorized for these age groups. There are an additional 1499 reports in the 2 – 5 year old group, many of which are likely in children for whom the vaccine has not been authorized. These may be related to exposure to the product in-utero, via breastfeeding, or being administered to children for whom the product is not authorized.

Comments

VAERS data shows an overwhelmingly large proportion of adverse events reports relating to the Covid-19 vaccine with over 50% of total reports since 1990 being attributed to the vaccine. Though, for many reasons, the adverse event reports of individual vaccines cannot be compared directly, **the magnitude of the disparity in adverse events and deaths is indicative of a cause for concern**. As shown in Table 3, we see a 10 fold difference in the number of adverse event reports for the MMR vaccine and the Covid-19 vaccine. In addition there is a 169 fold increase in reported deaths to VAERS after Covid-19 vaccination when compared to the flu vaccine and a 56 fold increase in adverse event reports on VAERS after Covid-19 vaccination when compared to the flu vaccine. Most deaths and adverse events occurred days after vaccination, making a causal relationship more likely. Given that Covid-19 vaccines are novel and still in clinical trials, **VAERS data is sufficient to establish a concerning safety signal.**

The reports on VAERS that occurred in children in age groups that have not been authorized to receive the vaccine are extremely concerning. This indicates the possibility of adverse events obtained in utero, from breastfeeding or administering the vaccine to age groups for

whom it has not been authorized.

Given VAERS stated objectives–to detect new, unusual, or rare vaccine adverse events, to assess the safety of newly licensed vaccines, and to provide a national safety monitoring system that extends to the entire population for response to public health emergencies, such as large-scale pandemic influenza vaccination programs–immediate investigation and urgent action are required from the CDC and the FDA.

EudraVigilance

At a Glance

EudraVigilance – European database of suspected adverse drug reaction reports is a pharmacovigilance database for gathering and analysing suspected adverse reaction data primarily from the European Economic Area (EAA). EudraVigilance is part of the European Medicines Agency which is tasked with evaluating, supervising and monitoring the safety of medicines in the EU.

EudraVigilance seeks to gather information "on suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the EEA" that "enables the early detection of potential safety issues."

How Reports are Made

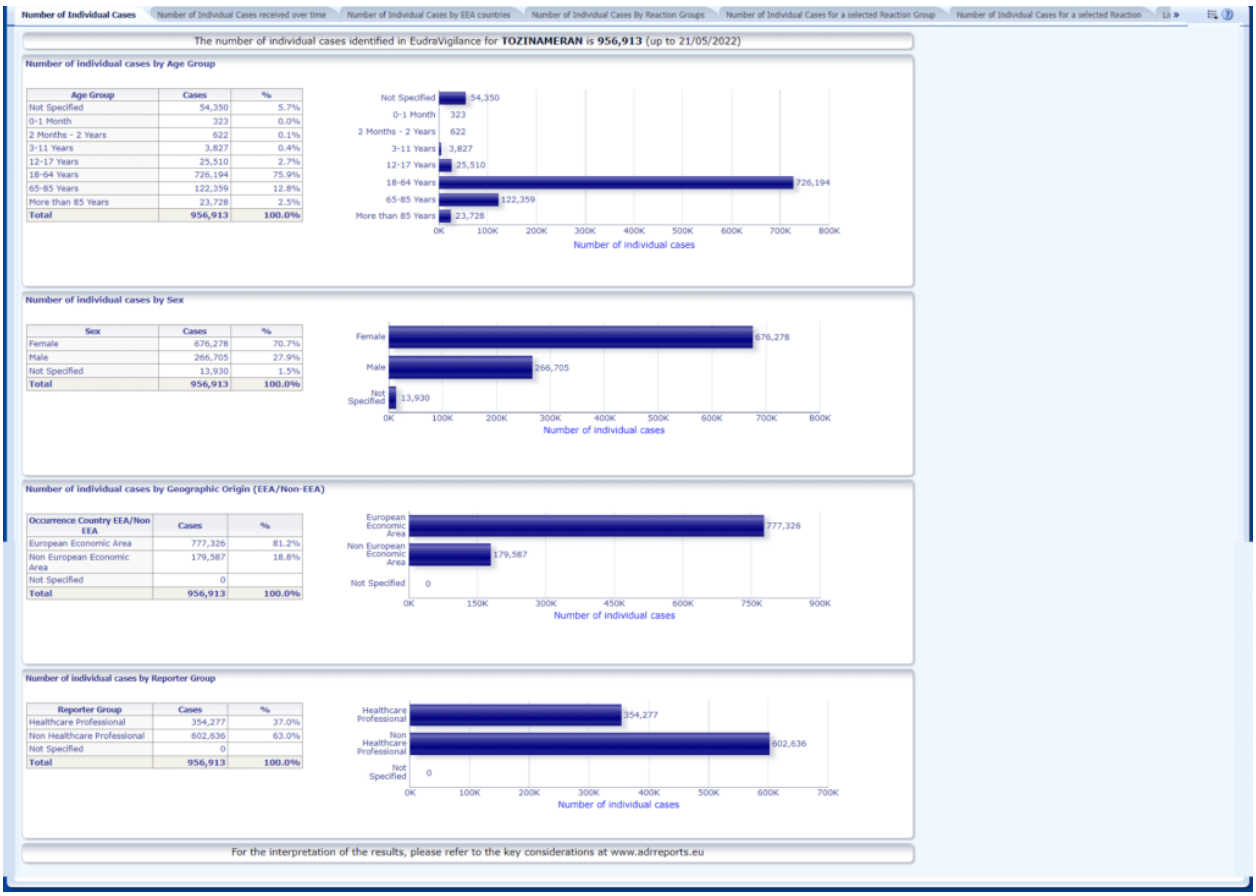
Reports on EudraVigilance are made electronically by sponsors of clinical trials, marketing authorisation holders, and national authorities.

Important Notes

- Adverse events reports are separated by brand, but collated for the purposes of this reports
- Data from EudraVigilance is analysed by regulatory authorities across the EEA, the European Medicines Agency and pharmaceutical companies
- Covid-19 vaccine uptake in individual European countries varies dramatically with Malta having the highest vaccination rate (248 doses per 100 people) and Bulgaria have the lowest vaccination rate (63 doses per 100 people)

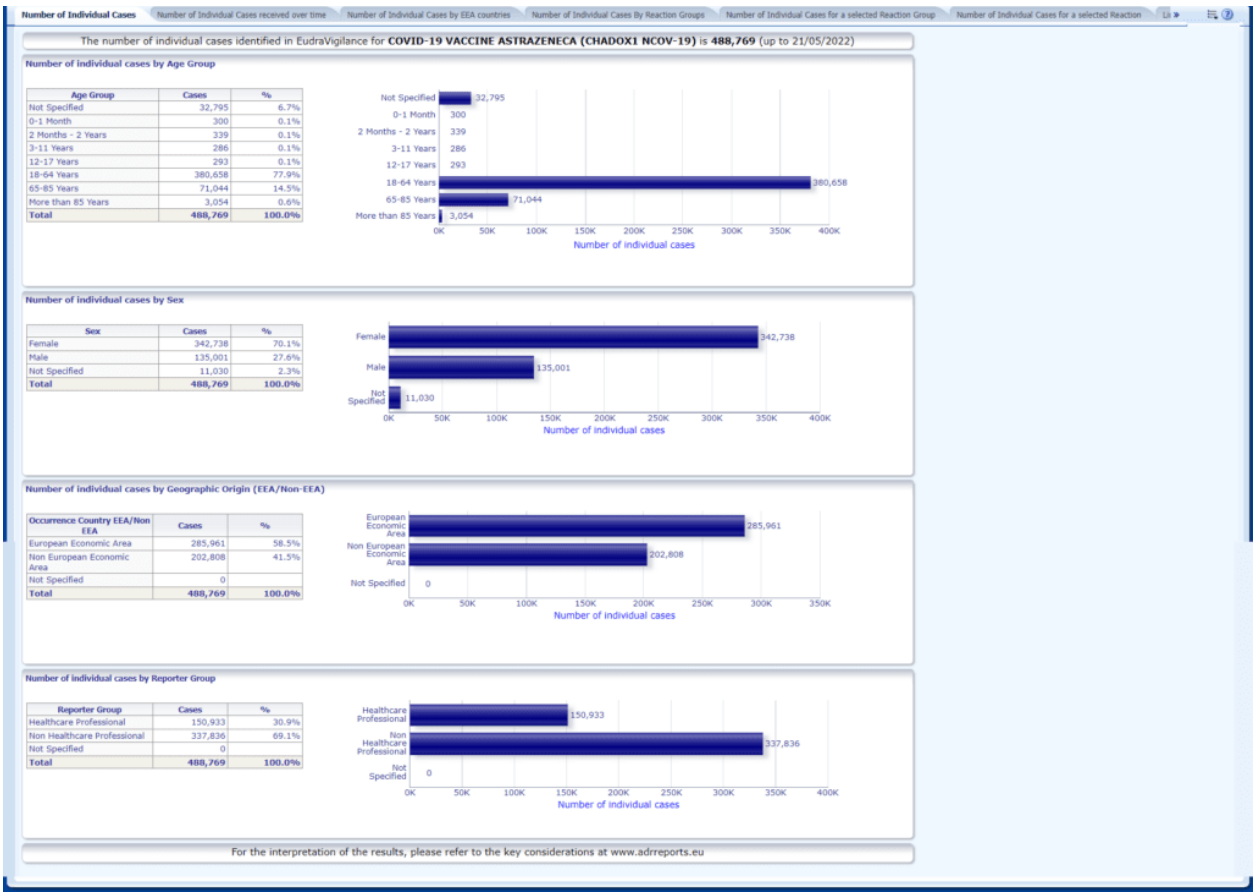
Data

Individual Cases of Adverse Events Identified in EudraVigilance for Covid-19 Vaccines



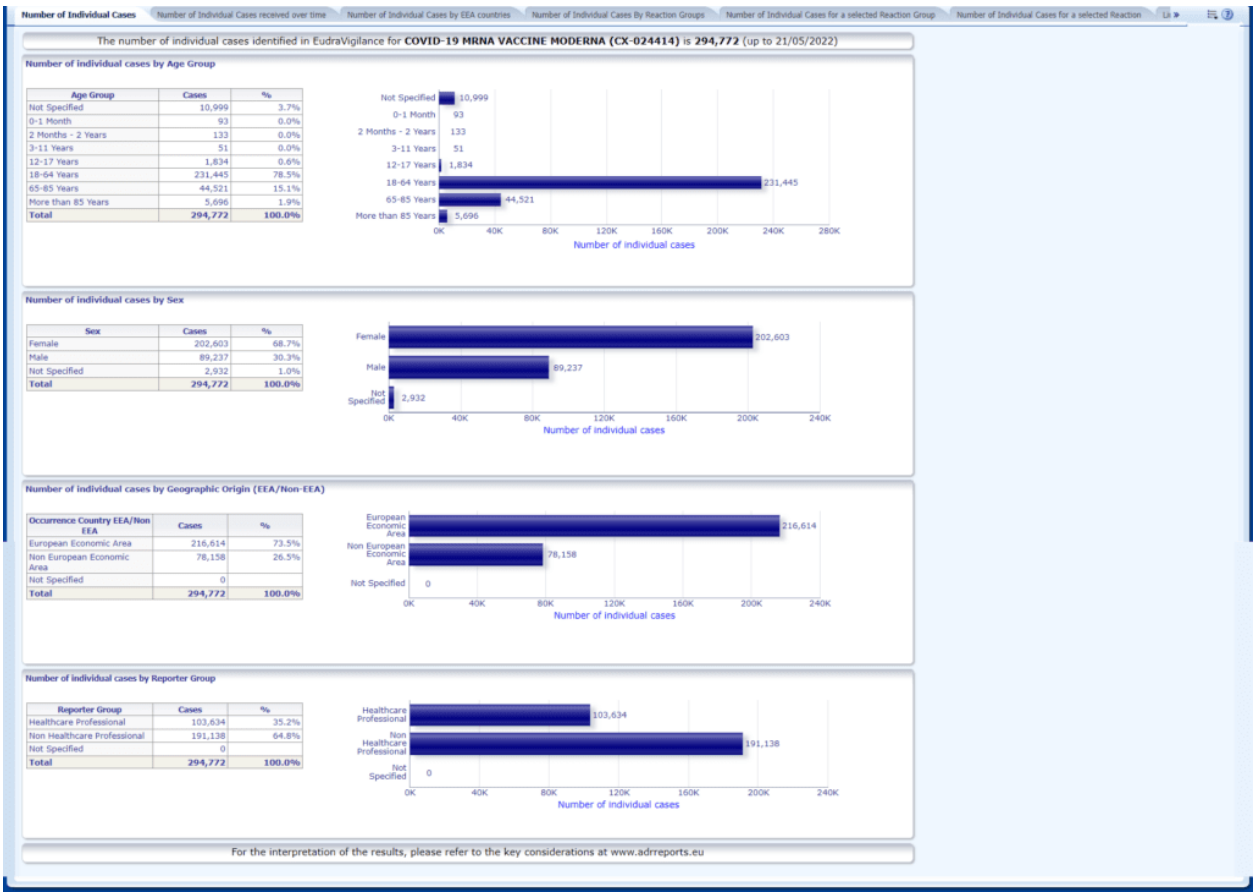
Individual Cases of Adverse Events Identified in EudraVigilance for Covid-19 Vaccine Tozinameran (Pfizer BioNTech)

Source: *https://dap.ema.europa.eu/analytics/saw.dll?PortalPages&PortalPath=%2Fshared%2FPHV%20DAP%2F_portal%2FDAP&Action=Navigate&P0=1&P1=eq&P2=%22Line%20Listing%20Objects%22.%22Substance%20High%20Level%20Code%22&P3=1+42325700*



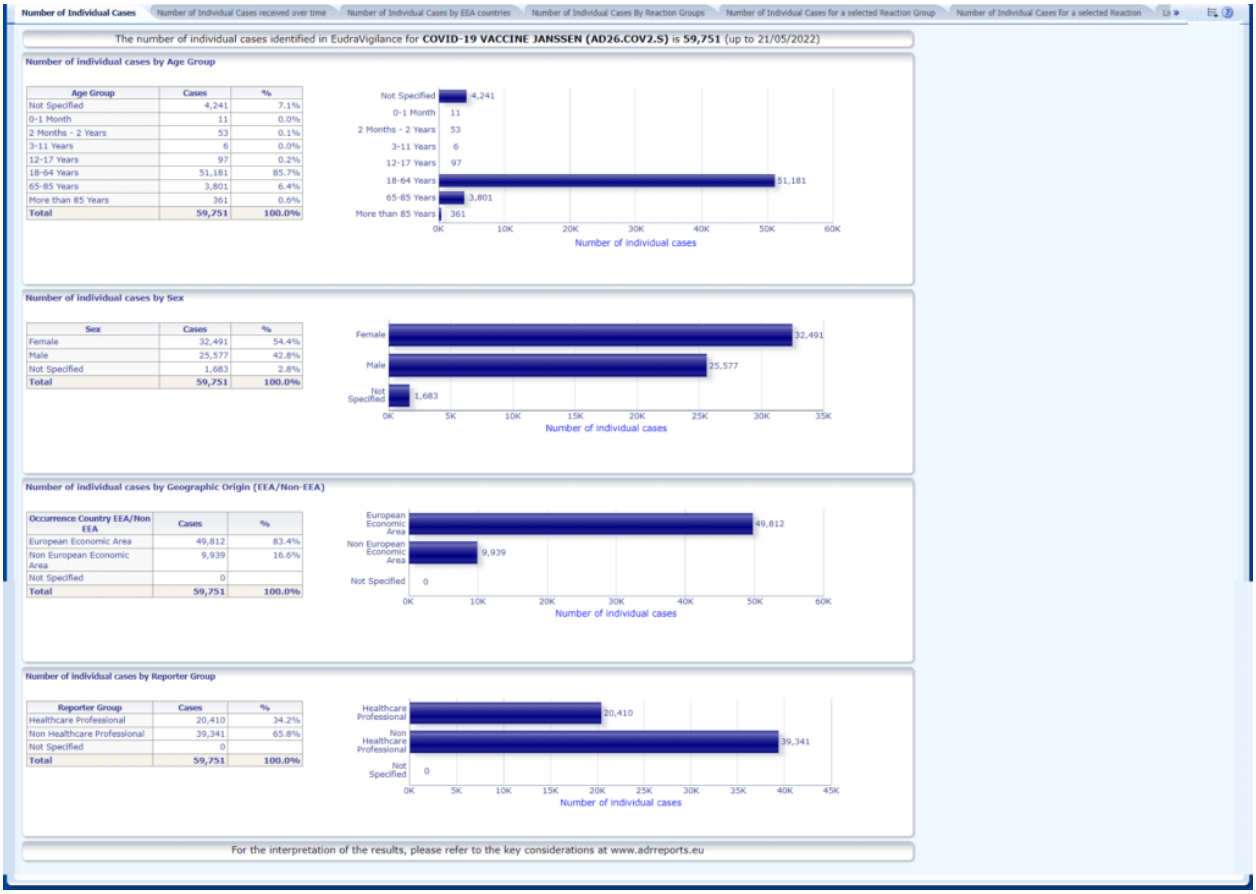
Individual Cases of Adverse Events Identified in EudraVigilance for Covid-19 Vaccine Astrazeneca

Source: *https://dap.ema.europa.eu/analytics/saw.dll?PortalPages&PortalPath=%2Fshared%2FPHV%20DAP%2F_portal%2FDAP&Action=Navigate&P0=1&P1=eq&P2=%22Line%20Listing%20Objects%22.%22Substance%20High%20Level%20Code%22&P3=1+40995439*



Individual Cases of Adverse Events Identified in EudraVigilance for Covid-19 Vaccine Moderna

Source: *https://dap.ema.europa.eu/analytics/saw.dll?PortalPages&PortalPath=%2Fshared%2FPHV%20DAP%2F_portal%2FDAP&Action=Navigate&P0=1&P1=eq&P2=%22Line%20Listing%20Objects%22.%22Substance%20High%20Level%20Code%22&P3=1+40983312*



Individual Cases of Adverse Events Identified in EudraVigilance for Covid-19 Vaccine Janssen

Source: *https://dap.ema.europa.eu/analytics/saw.dll?PortalPages&PortalPath=%2Fshared%2FPHV%20DAP%2F_portal%2FDAP&Action=Navigate&P0=1&P1=eq&P2=%22Line%20Listing%20Objects%22.%22Substance%20High%20Level%20Code%22&P3=1+42287887*

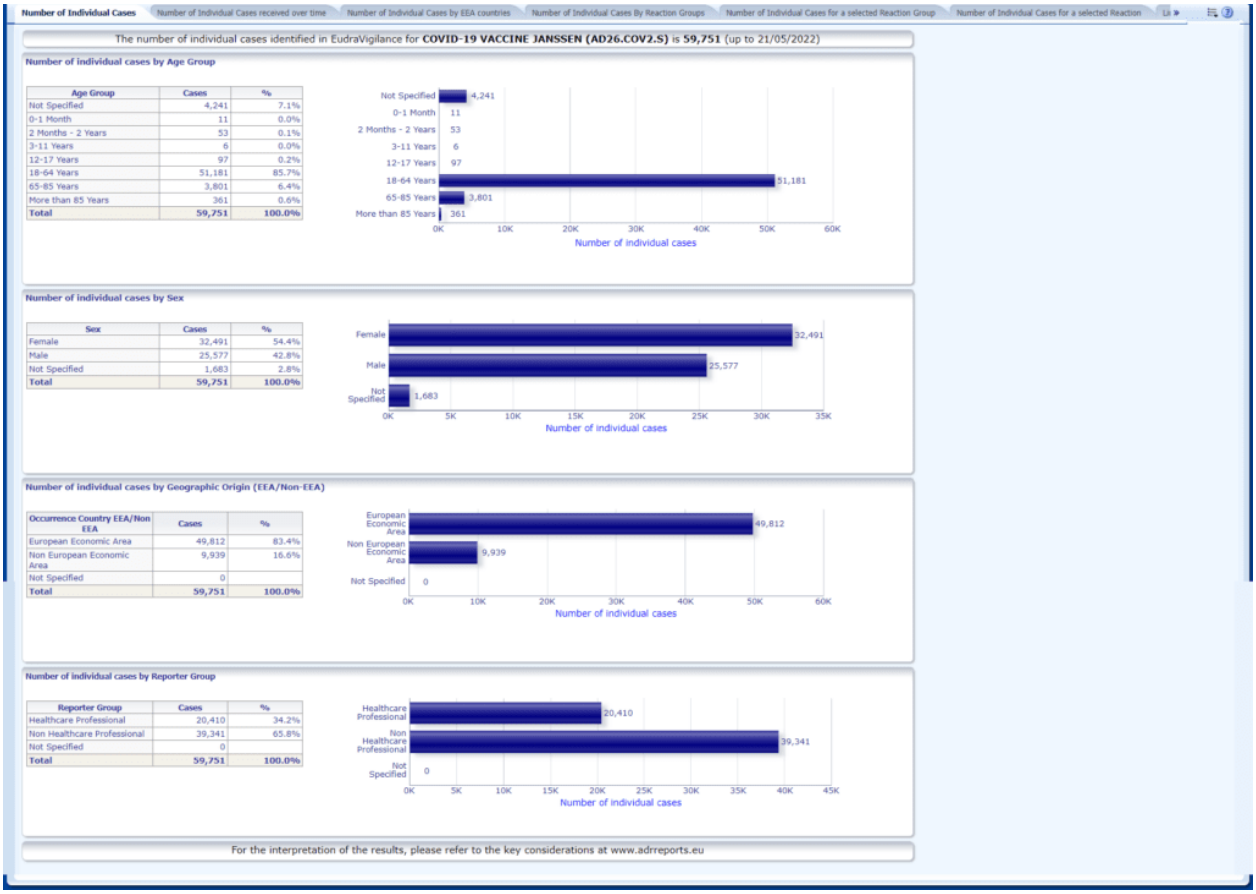
Discussion

The total number of individual adverse event cases identified in EudraVigilance are as follows: Covid-19 MRNA Vaccine Moderna – 294 772; Covid-19 MRNA Vaccine Pfizer-BioNTech (Tozinameran) – 956 913; Covid-19 Vaccine Astrazeneca – 488 769; Covid-19 Vaccine Janssen – 59 751; Covid-19 Vaccine Novavax – 756. The total number if individual adverse events cases identified for all Covid-19 vaccines on EudraVigilance is over 1.8 million.

There are over a thousand of cases reported in 0 – 2 years category, an age group for which the vaccines are not authorized. This potentially indicates infants and children are experiencing adverse events related to in-utero exposure, breastfeeding, and/or administered to individuals for whom the products are not authorized.

The total number of people vaccinated in EU/EEA countries is 341 628 772 or approximately 75.4% of the population.

Individual Cases of Adverse Events Identified in EudraVigilance for Measles Vaccines



Individual Cases of Adverse Events Identified in EudraVigilance for Covid-19 Vaccine Janssen

Source: *https://dap.ema.europa.eu/analytics/saw.dll?PortalPages&PortalPath=%2Fshared%2FPHV%20DAP%2F_portal%2FDAP&Action=Navigate&P0=1&P1=eq&P2=%22Line%20Listing%20Objects%22.%22Substance%20High%20Level%20Code%22&P3=1+25650*

Discussion

On the EudraVigilance database, the total number of individual adverse event reports are as follows: Measles, Mumps and Rubella Vaccine (LIVE) – 36 947; Measles Vaccine (LIVE) – 592; Measles and Rubella Vaccine (LIVE) – 116; Measles, Mumps, Rubella and Varicella Vaccine (LIVE) – 11 258. The total number of adverse events potentially relating to a vaccine containing a measles inoculation on EudraVigilance is 48 913.

In 2018, around 90% of European children were vaccinated for measles as part of measles, mumps, rubella vaccine.

Table 4: Contextual Data of Covid-19 and Measles Vaccine: EudraVigilance

# of	Covid-19 Vaccine	Measles Vaccine
Approximate Number of Individuals Vaccinated	341628772	673200000

# of	Covid-19 Vaccine	Measles Vaccine
Total number of Adverse Event Reports on EudraVigilance	1800000	48913

Discussion

Around 90% of Europeans have been immunized for Measles. Of the approximate 673.2 million individuals who have received the Measles Vaccine in Europe, there have been a total of 48 913 adverse event reports made on EudraVigilance.

Around 341 million European individuals have been vaccinated against Covid-19. From these, 1.8 million adverse event reports have been made on EudraVigilance.

Comments

EudraVigilance data shows a number of individual case reports that are unprecedented on the database for any other pharmaceutical product or vaccine. Though the total number of adverse event reports cannot be compared directly with other products, this data must be considered given that Covid-19 vaccines are in general distribution, still in clinical trials, and must be scrutinized using all available evidence. Given that other similar products have been similarly widely distributed across Europe, **the magnitude of the disparity in total individual case reports for Covid-19 vaccines on EudraVigilance is cause for grave concern**.

In Table 4, we see 48 913 individual EudraVigilance reports linked in some way to the Measles vaccine of the approximate 673 million individuals who have received the vaccine in Europe. It is possible, however, that any amount of these might be attributable to other inoculations contained in the same vaccine. We see 1.8 million individual EudraVigilance reports associated with the Covid-19 vaccines of the approximate 341 million individuals who have received the vaccine. Correcting for the difference in the number of individuals who have received each vaccine, there is an over 70-fold increase in the number of individual adverse events reported to EudraVigilance for the Covid-19 vaccine. Given that Covid-19 vaccines are in clinical trials, **EudraVigilance Data is sufficient to establish an alarming safety signal for these products**.

The over 1000 reports of adverse events that occurred in children for whom the vaccine has not been authorized indicates the need for immediate and urgent action.

Given EudraVigilance's objectives–to gather information "on suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the EEA" that "enables the early detection of potential safety issues"–immediate and urgent action are required from all concerned European authorities.

UK Yellow Card Scheme

At a Glance

The UK Yellow Card scheme is run by the Medicines & Healthcare products Regulatory Agency (MHRA). The system collects and monitors data on adverse medical incidents or side effects relating to medical products such as medicines, vaccines, blood products, herbal products, and medical devices.

The scheme aims to “identify issues which might not have been previously known about,” and to “provide an early warning that the safety of a product may require more further investigation.” The MHRA states that it will “if necessary, take action to minimise risk and maximise benefit to the patients.”

How Reports are Made

Reports are made to the Yellow Card Scheme voluntarily by patients, parents, or caregivers and by healthcare professionals. Manufacturers are legally required to report problems with healthcare products to the MHRA.

Important Notes

- A report on the UK Yellow Card System implies a correlation between the vaccine and the adverse event, not the cause
- There is currently no Yellow Card data available for vaccines other than the Covid-19 vaccine
- The total numbers of adverse reactions for the Covid-19 vaccines are available in the weekly report supplied by the MHRA

The Data

Adverse Event Reports Received in the UK: Yellow Card Data

Total Number of Reports

Country	COVID-19 Pfizer/ BioNTech Vaccine	COVID-19 Vaccine AstraZeneca	COVID-19 Vaccine Moderna	Brand unspecified
England	133063	201976	30769	1008
Wales	8228	10854	2282	93
Northern Ireland	3009	2992	151	21
Scotland	12820	17480	3321	172

Source:
assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1076730/COVID-19_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_11.05.2022.pdf

Total Number of Individuals Who have Received a Vaccine by Country

Country	Number of doses
England	44841562

Country	Number of doses
Wales	2555948
Northern Ireland	1428240
Scotland	4511645

Source:
assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1076730/COVID-19_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_11.05.2022.pdf

Discussion

In the UK, over 53 million individuals have received at least one dose of the Covid-19 vaccine. The UK Yellow Card scheme currently documents over 450 000 reports of adverse reactions.

Yellow Card data for other vaccines is currently not available on the Yellow Card Website.

Interactive Drug Analysis Profile: Yellow Card Data for Paracetamol

Interactive Drug Analysis Profile

Overview

This Interactive Drug Analysis Profile (iDAP) displays an overview of all UK spontaneous suspected Adverse Drug Reactions (ADRs) reported through the Yellow Card Scheme. It is important to note that reported adverse reactions have not been proven to be related to the drug, and should not be interpreted as a list of known side effects. The MHRA encourages the use of Yellow Card data; however to ensure that it is interpreted in the correct way please refer to the guidance at the bottom of this page. Definitions and an explanation of terms used can also be found in the glossary page.

PARACETAMOL

- Single constituent brand names: ABDINE COLD RELIEF, ACCORD HEALTHCARE CO-CODAMOL, ACCORD HEALTHCARE PARACETAMOL, ACTAVIS GROUP PTC CO-CODAMOL, ACTAVIS GROUP PTC PARACETAMOL, ADOL, ANADIN PARACETAMOL, ASPAR PHARMS PARACETAMOL, BELL SONS PARACETAMOL, BOOTS COLD AND FLU RELIEF ALL IN ONE, BOOTS PARACETAMOL, BOOTS ULTRA COLD AND FLU RELIEF ALL IN ONE, BRAUN MELSUNGEN PARACETAMOL, CALPOL, CHELONIA HEALTHCARE PARACETAMOL, CO-OP PARACETAMOL, CRESCENT PHARMA PARACETAMOL, DAFALGAN, DISPROL, EDICT PARACETAMOL, EFFERALGAN, EXCEDRIN, FANNIN UK PARACETAMOL AND CAFFEINE, FEVERALL, FLUMED, FRESENIUS KABI PARACETAMOL, GALPHARM FLU-MAX ALL IN ONE CHESTY COUGH AND COLD, GALPHARM HEALTHCARE EXTRA POWER PAIN RELIEVER, GALPHARM HEALTHCARE PARACETAMOL, GLAXOSMITHKLINE CONSUMER HEALTHC UK PARACETAMOL AND CAFFEINE, HEALTHY IDEAS PARACETAMOL, HEDEX, LONARID MONO, M&A PHARMACHEM PARACETAMOL, MAX REMEDIES PARACETAMOL, MCNEIL PRODUCTS CALPOL SIX PLUS, MEDREICH PARACETAMOL, NEOLAB PARACETAMOL, NORIDEM ENTERPRISES PARACETAMOL, NOUMED LIFE SCIENCES PARACETAMOL, PALDESIC, PANADOL, PANALEVE, PANASORB, PARACETAMOL [not otherwise coded], PARACETS, PARAPAED, PERFALGAN, PINEWOOD LABS FEDRIL, PINEWOOD LABS JUNIOR PARACETAMOL, PINEWOOD LABS PARACETAMOL, Q-PANOL, RELONCHEM PARACETAMOL, ROSEMONT PHARMS PARACETAMOL, SAINSBURYS PARACETAMOL, STERLING HEALTH PARACETAMOL, SUSSEX PHARMS FLU STRENGTH HOT LEMON, THORNTON & ROSS PARACETAMOL, TRAMIL, TYLENOL, WILLIAM RANSOM PARACETAMOL, WOCKHARDT UK MAXIMUM FLU STRENGTH COLD CONTROL, WOCKHARDT UK PAIN RELIEF, WOCKHARDT UK PARACETAMOL, WRAFTON LABS PARACETAMOL, ZACTIPAR, ZENTIVA PHARMA UK PARACETAMOL
- Multiple constituent brand names: ACCORD-UK CO-CODAMOL, ACCORD-UK CO-DYDRAMOL, ACECODIN, ACTRON/ALKA-SELTZER XS, ALKA-SELTZER XS, ALPHARMA CO-PROXAMOL, ANADIN EXTRA, ASPAR PHARMS CO-CODAMOL, BEECHAMS ALL-IN-ONE, BEECHAMS COLD POWDERS, BEECHAMS COUGH AND COLD, BEECHAMS DAYTIME MULTI-SYMPTOM RELIEF, BEECHAMS FLU-PLUS, BEECHAMS FLU-PLUS HOT LEMON, BEECHAMS HOT BLACKCURRANT, BEECHAMS HOT LEMON, BEECHAMS MAX STRENGTH ALL IN ONE, BEECHAMS NIGHT-TIME COLD REMEDY, BEECHAMS POWDERS WITH PHENYLEPHRINE, BENYLIN DAY AND NIGHT COLD TREATMENT, BENYLIN FOR FLU LIQUID, BENYLIN FOUR FLU, BOOTS COLD AND FLU RELIEF, BOOTS COLD RELIEF, BOOTS DECONGESTANT WITH PARACETAMOL, BOOTS HOT LEMON COLD AND FLU RELIEF, BOOTS PAIN RELIEF, BOOTS PARACETAMOL AND CODEINE, BRISTOL LABS CO-CODAMOL, BRISTOL LABS PARACETAMOL, CELLTECH PHARMS CO-CODAMOL, CELLTECH PHARMS CO-PROXAMOL, CHRISTIES PARACETAMOL, CLARKES JUNIOR LEM-PLUS, CO-CODAMOL, CO-DYDRAMOL, CO-PROXAMOL, CODIPAR, CODOLIPRANE, COLDREX, CORICIDIN, DAY AND NIGHT NURSE, DAY NURSE, DF CO-DYDRAMOL, DI-GESIC, DIMOTAPP P, DISTALGESIC, DOMPERAMOL, DOZIC, DOZOL, DYPRACET, EP TABLETS, ETOVA-P, FEMERITAL, FEMINAX, FORTAGESIC, GALAKE, GALEN LTD (OLD 2) CO-CODAMOL, GALEN LTD CO-CODAMOL, GALPHARM HEALTHCARE PARACETAMOL PLUS, HEDEX EXTRA, JANSSEN-CILAG CO-CODAMOL, KAPAKE, LEMSIP, LEMSIP COLD AND FLU, LEMSIP JUNIOR, LEMSIP MAX, LEMSIP MAX ALL IN ONE, LEMSIP MAX COLD AND FLU CITRUS, LOBAK, M&A PHARMACHEM CO-CODAMOL, MCNEIL PRODUCTS CALCOLD, MEDISED, MEDISED INFANT, MEDREICH CO-CODAMOL, MERCURY PHARMS CO-CODAMOL, MIDRID, MIGRALEVE, MIGRALEVE PINK, MIGRALEVE YELLOW, MU-CRON, NEOLAB CO-CODAMOL, NEURODYNE, NIGHT NURSE, NIROLEX DAY COLD AND FLU COMFORT, NIROLEX NIGHT COLD AND FLU COMFORT, NON-DROWSY SUDAFED CONGESTION RELIEF, NORGESIC, NUROMOL, PAEDO-SED, PANADEINE, PANADEINE FORTE, PANADOL COLD TREATMENT, PANADOL EXTRA, PANADOL NIGHT PAIN, PANADOL PLUS, PARACETAMOL AND CODEINE PHOSPHATE, PARACETAMOL AND DIHYDROCODEINE, PARACODOL, PARAHYPON, PARAKE, PARAMAX, PARAMED MAX STRENGTH COLD AND FLU DAY AND NIGHT, PARAMED MAX STRENGTH SINUS RELIEF DAY AND NIGHT, PARAMOL, PHARMIDONE, PHOLCOLIX, PONTALSIC, PROPAIN, REGENT CO-PROXAMOL, RELACTON-C, REMEDEINE, RINUREL, SAFAPRYN, SAFAPRYN-CO, SAINSBURYS COLD RELIEF, SANOFI WINTHROP EXTRA PAIN RELIEF, SHAH CO-PROXAMOL, SINUTAB, SOLPADEINE, SOLPADEINE MAX, SOLPADEINE PLUS, SOLPADOL, SONALGIN, SSL INT PARACETAMOL CODEINE CAFFEINE & DOXYLAMINE COMPD, STERLING HEALTH CO-PROXAMOL, STERWIN COLD, SUDAFED MUCUS NOSE AND CHEST, SUDAFED SINUS, SUDAFED-CO, SYNDOL, TANDALGESIC, TEVA UK CO-CODAMOL, THORNTON & ROSS FLU RELIEF, TRAMACET, TRIOGESIC, TYLEX, UNIFLU, VEGANIN, VEGANIN AND ASPIRIN, VICKS COLDCARE, VICKS MEDINITE, VINCIGRIP, WALLIS LAB CO-CODAMOL, WOCKHARDT UK CO-CODAMOL, WOCKHARDT UK COLD RELIEF, WRAFTON LABS COLD RELIEF, WRAFTON LABS EXTRA POWER PAIN RELIEVER, WRAFTON LABS HEADACHE AND UPSET STOMACH RELIEF, WRAFTON LABS MAX STRENGTH SINUS RELIEF, WRAFTON LABS MAXIMUM STRENGTH COLD AND FLU, WRAFTON LABS PARACETAMOL PLUS, ZAPAIN, ZENTIVA PHARMA UK CO-CODAMOL, ZENTIVA PHARMA UK CO-DYDRAMOL

- Total number of reactions: 25158 - Total number of ADR reports: 9425
- Total number of serious ADR reports: 6329 - Total number of fatal ADR reports: 585
- Displays show a breakdown of all 9425 UK spontaneous reports received for PARACETAMOL.
- Reports processed up to: 31-Mar-2022

Reset to Include All Reports | Display Printer Friendly Page

You may select a subset of reports using the filter options below:

Sex:
- Male
- Female
- Unknown

Age Group:
Youngest Age Group: 0-9
Oldest Age Group: 100+
- Unknown Age Group

Year Received:
Earliest Year Received: 1964
Latest Year Received: 2022

Reporter:
- Patient/Carer
- Healthcare Professional

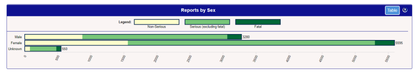
Report Submission:
- Direct to Agency
- Indirect via Industry

Route of Administration:
- (Select All)
- INTRAVENOUS
- ORAL USE
- UNKNOWN
- Routes with few reports

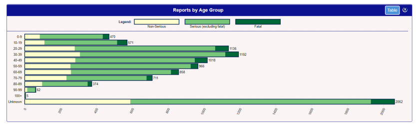
Seriousness:
- Fatal
- Serious (excluding fatal)
- Non-Serious

System Organ Class:
- (Select All)
- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Product issues
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

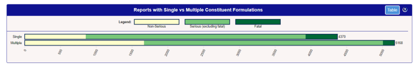
Reports by Sex



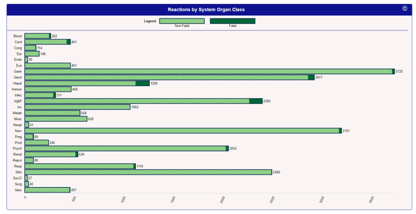
Reports by Age Group



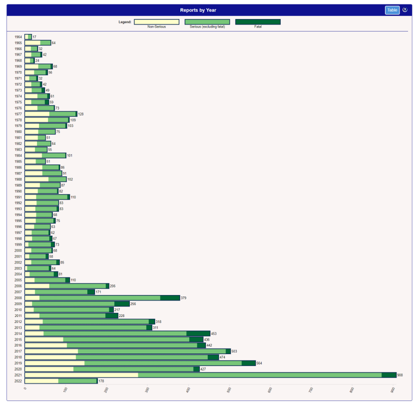
Reports with Single vs Multiple Constituent Formulations



Reactions by System Organ Class



Reports by Year



Reactions by MedDRA System Organ Class, High Level Group Term, High Level Term, and Preferred Term

Term (SOC, *HLGT*, HLT, PT)	Single active constituent		Multiple active constituents		Total reactions	
Expand All / Collapse All	All	Fatal	All	Fatal	All	Fatal
Blood and lymphatic system disorders	161	10	108	7	262	17
Cardiac disorders	252	26	224	15	461	40
Congenital, familial and genetic disorders	43	1	71	5	114	6
Ear and labyrinth disorders	45	0	102	0	146	0
Endocrine disorders	15	0	18	0	30	0
Eye disorders	185	2	284	0	461	2
Gastrointestinal disorders	1322	12	2473	14	3725	26
General disorders and administration site conditions	1346	44	1656	21	2917	64
Hepatobiliary disorders	1030	131	263	15	1256	140
Immune system disorders	253	1	218	0	468	1
Infections and infestations	236	23	87	2	311	25
Injury, poisoning and procedural complications	1971	108	523	30	2393	132
Investigations	697	1	415	1	1062	2
Metabolism and nutrition disorders	392	4	185	1	558	4
Musculoskeletal and connective tissue disorders	293	0	356	0	628	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	21	3	21	1	41	4
Nervous system disorders	1267	21	1991	6	3191	26
Pregnancy, puerperium and perinatal conditions	69	6	40	8	89	9
Product issues	132	0	108	0	240	0
Psychiatric disorders	764	20	1345	8	2052	28
Renal and urinary disorders	323	9	225	16	536	25
Reproductive system and breast disorders	30	0	61	0	88	0
Respiratory, thoracic and mediastinal disorders	563	11	575	12	1116	22
Skin and subcutaneous tissue disorders	1009	5	1492	0	2489	5
Social circumstances	6	0	22	0	27	0
Surgical and medical procedures	29	0	16	0	40	0
Vascular disorders	244	7	217	0	457	7
Total reactions	12698	445	13096	162	25158	585

Essential Context for Understanding this Interactive Drug Analysis Profile

Interactive Drug Analysis Profiles (IDAPs) contain complete listings of all suspected adverse drug reactions or side effects that have been reported to the MHRA via the Yellow Card Scheme for a particular drug substance. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies.

The data shown in these interactive profiles can be very useful in helping to identify possible medicine safety issues. However, this information does not present a complete overview of the potential side effects associated with specific medicines. Conclusions on the safety and risks of medicines cannot be made on the data shown in the Interactive Drug Analysis Profile alone.

For comprehensive information about the risks of particular medicines, you should refer to the patient information leaflet for the medicine, or ask your doctor, nurse or pharmacist.

When using the Interactive Drug Analysis Profile, you should remember that:

- The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the data in the Interactive Drug Analysis Profile. This is because we have limited information about how many people have taken the medicine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the adverse drug reaction. The existence of an adverse drug reaction report in the Interactive Drug Analysis Profile does not necessarily mean that the medicine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse drug reaction. Sometimes reactions can be part of the condition being treated rather than being caused by a medicine.
- Many factors have to be considered when assessing whether a medicine has caused a reported adverse drug reaction. When monitoring the safety of medicines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different medicines by comparing the numbers presented in the Interactive Drug Analysis Profiles. Reporting rates can be influenced by many factors including the seriousness of the adverse drug reactions, their ease of recognition and the extent of use of a particular product. Reporting can also be stimulated by promotion and publicity about a product.

If you are concerned about the medicine you are taking, you should contact your GP, the health professional who prescribed the medicine, your pharmacist or contact the NHS via the routes listed below.

- NHS 111 in England and Scotland on 111 (textphone 18001 111)
- NHS Direct Wales/Galw IECHYD Cymru on 0845 46 47 (textphone 0845 606 46 47)
- NHS Northern Ireland

You should not stop taking any prescribed medicine without first talking to your health professional.

Risks and benefits of medicines

For a medicine to be considered safe, the expected benefits of the medicine will be greater than the risk of suffering harmful reactions. It is important to note that most people take medicines without suffering any serious side effects.

All medicines can cause reactions. The patient information leaflet accompanying the medicine, or available from your pharmacist, lists the known side effects associated with the medicine. Healthcare professionals such as doctors and pharmacists can also provide this information. Information on side effects of medicines can be found on the NHS Choices website.

Monitoring the safety of medicines

Information collected through the Yellow Card Scheme is an important tool in helping the MHRA and CHM monitor the safety of medicines. Yellow Card reports of suspected adverse drug reactions are evaluated, together with additional sources of evidence such as worldwide literature, in order to identify previously unidentified hazards or side effects.

If a new side effect is identified, information is carefully considered in context of the overall side effect profile for the medicine, and how it compares with other medicines used to treat the same condition.

The MHRA will take action, if necessary, to ensure that the medicine is used in a way that minimises risk, while maximising patient benefit. Such changes may include, for example, restricting the indication, or special warnings and precautions. Rarely, a drug may need to be withdrawn from the market if the risk of side effects is considered to outweigh the benefits of treatment. Please see our How we monitor the safety of medicines section for further information.

Use of Yellow Card data for publication

If you wish to copy or circulate the information contained within an Interactive Drug Analysis Profile to anyone else, please ensure that a copy of these guidelines is also provided.

The MHRA and CHM encourage the use of data from the Yellow Card Scheme in research and for publication, but wish to ensure that the limitations of interpretation of the data are made clear.

If you propose to publish information based on Yellow Card data or Interactive Drug Analysis Profiles, the MHRA is most willing to provide advice on how the Yellow Card information might be best used and presented. The MHRA is also willing to provide feedback on manuscripts prior to publication. Please write to the Director, Vigilance and Risk Management of Medicines Division by email.

To download the comma-separated-values (CSV) data for PARACETAMOL, click here.

DAP version: 1.0.0
MedDRA version: 24.1
Report level: Substance

Yellow Card data for adverse reaction reports relating to paracetamol (acetaminophen)

Source: *info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000155768693.zip&agency=MHRA*

Discussion

Above is the Yellow Card data for adverse reaction reports relating to paracetamol (acetaminophen). Paracetamol is one of the most commonly used medications in the UK. Millions of individuals in the UK have taken this medication for several decades. The above report shows 25 158 reactions and 585 deaths associated with its use since 1964.

Comments

The Yellow Card Scheme shows over 450,000 yellow card reports related to the Covid-19 vaccines. Though the data for other vaccines is not available on the website, the data for paracetamol, a medication in widespread use for several decades in the UK, shows only a fraction of the reports (~25 000 since 1968) on the Yellow Card Scheme. Though these cannot be used in direct comparison, the magnitude of the disparity is cause for concern. Given that the Covid-19 products are still in clinical trials, all evidence should be used to assess their safety. **The UK Yellow Card data is sufficient to establish a safety signal for these products.**

Given the UK Yellow Card Scheme's objectives–to identify issues which might not have been previously known about and to provide an early warning that the safety of a product may require more further investigation and to take action to minimise risk and maximise benefit to the patients if necessary–immediate and urgent action are required.

Amount and Types of Adverse Events Reported: All Databases

What Kind of Adverse Events are Related to Covid-19 Vaccines?

There are a wide variety of adverse events reported on the databases examined in this report: WHO VigiAccess, CDC VAERS, EudraVigilance, and UK Yellow Card Reporting System. They range in severity from minor such as pain at the injection site to major events like cardiac arrest, strokes, myocarditis, and death.

Table 5: Common Types and Total Number of Adverse Events: VigiAccess, EudraVigilance, UK Yellow Card Scheme

Type of Event	VigiAccess as of May 25	EudraVigilance as of May 25	UK Yellow Card Scheme
Blood and Lymphatic Disorders	~ 176 000	~ 102 000	~ 27 000
Cardiac Disorders	~ 242 000	~ 127 000	~ 28 000
Gastrointestinal Disorders	~ 690 000	~ 344 000	~135 000
Infections and Infestations	~ 414 000	~ 220 000	~ 35 000

Type of Event	VigiAccess as of May 25	EudraVigilance as of May 25	UK Yellow Card Scheme
Injury, Poisoning, and Procedural Complications	~ 231 000	~ 64 000	~20 000
Investigations	~ 586 000***	~ 106 000	~ 20 000
Musculoskeletal and Connective Tissue Disorders	~ 1 007 000	~ 543 000	~ 175 000
Nervous System Disorders	~ 1 501 000	~ 746 000	~ 285 000
Psychiatric Disorders	~ 172 000	~ 64 000	~ 34 000
Reproductive System and Breast Disorders	~ 207 000	~ 139 000	~ 57 000
Respiratory, Thoracic and Mediastinal Disorders	~ 400 000	~ 136 000	~ 56 000
Skin and Subcutaneous Tissue Disorders	~ 477 000	~ 213 000	~ 101 000
Vascular Disorders	~ 193 000	~ 87 000	~ 23 000

*** *For this report, investigations were not considered.* ***

Discussion

Table 5 lists the most common reactions to Covid-19 vaccines by reaction group in VigiAccess, EudraVigilance, and UK Yellow Card Scheme.

In VigiAccess, the five most common reports by reaction group from most to least are as follows:

1. Nervous System Disorders – ~ 1 500 000
2. Musculoskeletal and Connective Tissue Disorder – ~ 1 000 000
3. Gastrointestinal Disorders – ~ 691 000
4. Skin and Subcutaneous Tissue Disorders – ~ 477 000
5. Vascular Disorder – ~193 000

In EudraVigilance, the five most common reports by reaction group from most to least are as follows:

1. Nervous System Disorders – ~ 746 000
2. Musculoskeletal and Connective Tissue Disorder – ~ 543 000
3. Gastrointestinal Disorders – ~ 344 000
4. Infections and Infestations – ~ 220 000
5. Skin and Subcutaneous Tissue Disorders – ~ 213 000

In UK Yellow Card Scheme, the five most common reports by reaction group from most to least are as follows:

1. Nervous System Disorders – ~ 285 000
2. Musculoskeletal and Connective Tissue Disorder – ~ 175 000
3. Gastrointestinal Disorders – ~ 135 000
4. Skin and Subcutaneous Tissue Disorders – ~ 101 000
5. Reproductive System and Breast Disorders – ~ 57 000

Common Covid-19 Vaccine Adverse Event Outcomes: VAERS

The Vaccine Adverse Event Reporting System (VAERS) Results

Covid-19 vaccine

Data current as of 05/20/2022

Request Form | Results | Map | Chart | Report | About

Dataset Documentation | Other Data Access | Help for Results | Printing Tips | Help with Exports

Save | Export | Reset

Quick Options | More Options

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Messages:

- **VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.**
- **These results are for 1,582,078 total events.**

Event Category	Events Reported	Percent (of 1,582,078)
Death	18,338	1.16%
Life Threatening	22,634	1.43%
Permanent Disability	27,115	1.71%
Congenital Anomaly / Birth Defect *	618	0.04%
Hospitalized	101,689	6.43%
Existing Hospitalization Prolonged	3,352	0.21%
Emergency Room / Office Visit **	186,719	11.80%
Emergency Room *	116,487	7.36%
Office Visit *	211,148	13.35%
None of the above	1,038,532	65.64%
Total	**1,726,632**	**109.14%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).
*** These values are only available from VAERS 2.0 Report Form, active 06/30/2017 to present.**
**** These value are only available from VAERS-1 Report Form, active 07/01/1990 to 06/29/2017.**

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Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information.

Data contains VAERS reports processed as of 05/20/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information.

Under Title 21, Code of Federal Regulations Section 600.80, a serious event is defined with any of the following outcomes: Death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

Values of Event Category field vary in their availability over time due to changes in the reporting form. The "Emergency Room/Office Visit" value was avaliable only for events reported using the VAERS-1 form, active 07/01/1990 to 06/29/2017. The "Congenital Anomaly/Birth Defect", "Emergency Room", and "Office Visit" values are available only for events reported using the VAERS 2.0 form, active 06/30/2017 to present. These changes must be considered when evaluating count of events for these categories.

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation for more information.

Query Date: May 30, 2022 12:39:32 PM

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Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 05/20/2022, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on May 30, 2022 12:39:32 PM

Top | Options | Notes | Citation | Query Criteria

Query Criteria:

Title: Covid-19 vaccine
State / Territory: The United States/Territories/Unknown
Group By: Event Category
Show Totals: True
Show Zero Values: False

Content source: CDC WONDER

Common Covid-19 Vaccine Adverse Event Outcomes: VAERS

Source: *wonder.cdc.gov/*

Table 6: Common Covid-19 Reactions by Type: VAERS

Reaction	Number of Reports on VAERS
Myocarditis/Pericarditis	22,000
Heart Attacks	6,400
Guillain-Barre	2,600
Thrombocytopenia	6,000
Stroke	16,000
Convulsions/Seizures	16,000
Convulsions/Seizures	16,000
Anaphylaxis	49,000
Bell's Palsy	15,000
Venous Thromboembolism	25,000
Arthritis and Arthralgia/Joint Paint	78,000
Death	28,000

Source: vaersanalysis.info/2022/05/14/vaers-summary-for-covid-19-vaccines-through-5-6-2022/

Discussion

Over 54% of adverse events reported to VAERS are attributed to the Covid-19 vaccine including death, life-threatening injury, permanent disability, congenital anomalies/birth defects, hospitalizations, emergency room visits, doctor's office visits, and others.

Table 6 lists some of the most commonly reported reactions on VAERS to the Covid-19 vaccine. These are (from most to least):

1. Arthritis and Arthralgia/Joint Paint
2. Anaphylaxis
3. Venous Thromboembolism
4. Myocarditis/Pericarditis
5. Stroke
6. Convulsions/Seizures

There are over 28 000 deaths, over 75% of all deaths reported to VAERS since 1990, associated with the Covid-19 vaccine.

Comments

Table 7: 3 Most Common Reports by Reaction Group: VigiAccess, EudraVigilance, and UK Yellow Card

Database	Nervous System Disorders	Musculoskeletal and Connection Tissue Disorders
VigiAccess	1 500 000	1 000 000
EudraVigilance	746 000	543 000
UK Yellow Card	285 000	175 000

Nervous System Disorders, Musculoskeletal and Connective Tissue Disorders, and

Gastrointestinal Disorders are the 3 most commonly reported reaction groups on VigiAccess, EudraVigilance, and UK Yellow Card Scheme.

Arthritis and Arthralgia/Joint Pain, Anaphylaxis, Venous Thromboembolism, Myocarditis/Pericarditis, Stroke and Convulsions/Seizures are some of the most commonly reported adverse events on VAERS.

The following number of reports involving death related to Covid-19 vaccines are as follows:

Table 8: Number of Deaths Reported by Database: Covid-19 Vaccines

VigiAccess	EudraVigilance	UK Yellow Card	VAERS
~ 22 000	~ 800	~ 2100	~ 28 000

How Many Adverse Events is Too Many?

Active vs. Passive Surveillance

Pharmacovigilance databases such as VigiAccess, EudraVigilance, VAERS, and UK Yellow Card Scheme **rely on passive reporting** from healthcare providers, pharmaceutical companies, and individuals.

Passive reporting or passive surveillance of adverse events means that the onus of reporting falls on the individual (and/or their healthcare provider) who received a vaccine or other pharmaceutical product. If an adverse event is noted, the individual or healthcare provider may voluntarily report.

Active reporting or active surveillance of adverse events means that a pharmaceutical company or healthcare body is actively collecting adverse event reports through careful and comprehensive monitoring procedures.

Adverse Events on Pharmacovigilance Databases are Under-Reported

Passive surveillance, such as the pharmacovigilance databases studied in this report, result in significantly less adverse event reports than active surveillance reporting. In a study comparing active and passive surveillance of adverse events, 8.8% of those under active surveillance reported and adverse event, while only 0.1% of those under passive surveillance reported an adverse event. That is an 88 fold difference in the number of reports for that particular study. The WHO also notes that passive surveillance "makes it difficult to ensure completeness and timeliness of data collection." Studies of new pharmaceutical products normally require active surveillance of adverse events during the clinical trial phase. The number of adverse events documented during active surveillance is universally higher than what is passively reported to pharmacovigilance databases later. **The actual number of adverse events that occurred in temporal relation to Covid-19 vaccines would be much higher than is revealed by the data in these pharmacovigilance databases.**

As stated earlier in this report, an adverse event report is not indicative that the vaccine caused an event, simply that it was related. However, the likelihood that a product caused an adverse event increases as the time between administration of a product and the adverse event decreases. **VAERS data reveals a close temporal relationship between the administration of the Covid-19 vaccine and the subsequent adverse event with a majority of adverse events happening within just 2 days of receiving the vaccine**. **This indicates a more likely causal relationship.**

The Unique Case of Covid-19 Vaccines

Operation Warp Speed

When Covid-19 emerged as a novel virus in 2019, little was known about its virulence and what its impacts would be on the general population. Early models overestimated the morbidity and mortality of the illness, and, as a result, "Operation Warp Speed" was introduced to accelerate the development of a vaccine and other therapeutics for the novel virus. Several government agencies collaborated to develop, study, manufacture, and distribute Covid-19 vaccines. Operation Warp Speed meant that vaccine studies were accelerated and that the products were pushed to market while still in clinical trials.

ALL Covid-19 Vaccines are in Phase 3 Trials

On August 23, 2021, the US Food and Drug Administration (FDA) approved the first Covid-19 vaccine. Many other countries health authorities followed suit soon after. Prior to that, the vaccines were administered to billions of people under emergency use authorization. Many people understood that 'approval' meant that vaccines were no longer experimental. That is not true. **ALL Covid-19 vaccines, including those that are approved, are still in Phase 3 clinical trials.**

What are Phase 3 Clinical Trials?

According to the FDA, Phase 3 trials:

- Involve 300 – 3000 volunteers
- Last 1 to 4 years
- Are designed to establish efficacy and monitor adverse reactions
- 25 – 30% of products will make it to the next phase of clinical trials

The efficacy and safety of Covid-19 vaccines has, therefore, not been established. In addition, the number of volunteers recruited for Phase 3 trials of this product is highly unusual.

What are Phase 4 Clinical Trials?

According to the FDA, Phase 4 trials:

- Involve several thousand volunteers
- Last 10 – 15 years
- Are designed to establish safety and efficacy

Covid-19 vaccines have not yet entered Phase 4 trials.

The 1967 Swine Flu: A Case of a Rushed Mass Vaccination Campaign

In February 1967, an investigation was launched into the mysterious death of an American Private who died during a basic training exercise. CDC tests revealed that Private David Lewis had contracted a strain of swine flu. Subsequently 11 other soldiers tested positive for the virus while hundreds of others tested positive for antibodies. Alarming headlines appeared in newspapers across the country, and, the CDC Director, citing a "strong possibility" of a pandemic, recommended an unprecedented plan of mass vaccination of US citizens.

Though no further evidence emerged that the virus was problematic, the CDC and then President Gerald Ford adopted a 'better safe than sorry' approach, and began a mass vaccination campaign for the swine flu. When reports emerged of suspected adverse reactions, including heart attacks, Guillain-Barre syndrome and 53 reported deaths, citizens began doubt the safety of the vaccine. Coupled with the fact the pandemic did not materialize as predicted, the government halted the mass vaccination program on December 16.

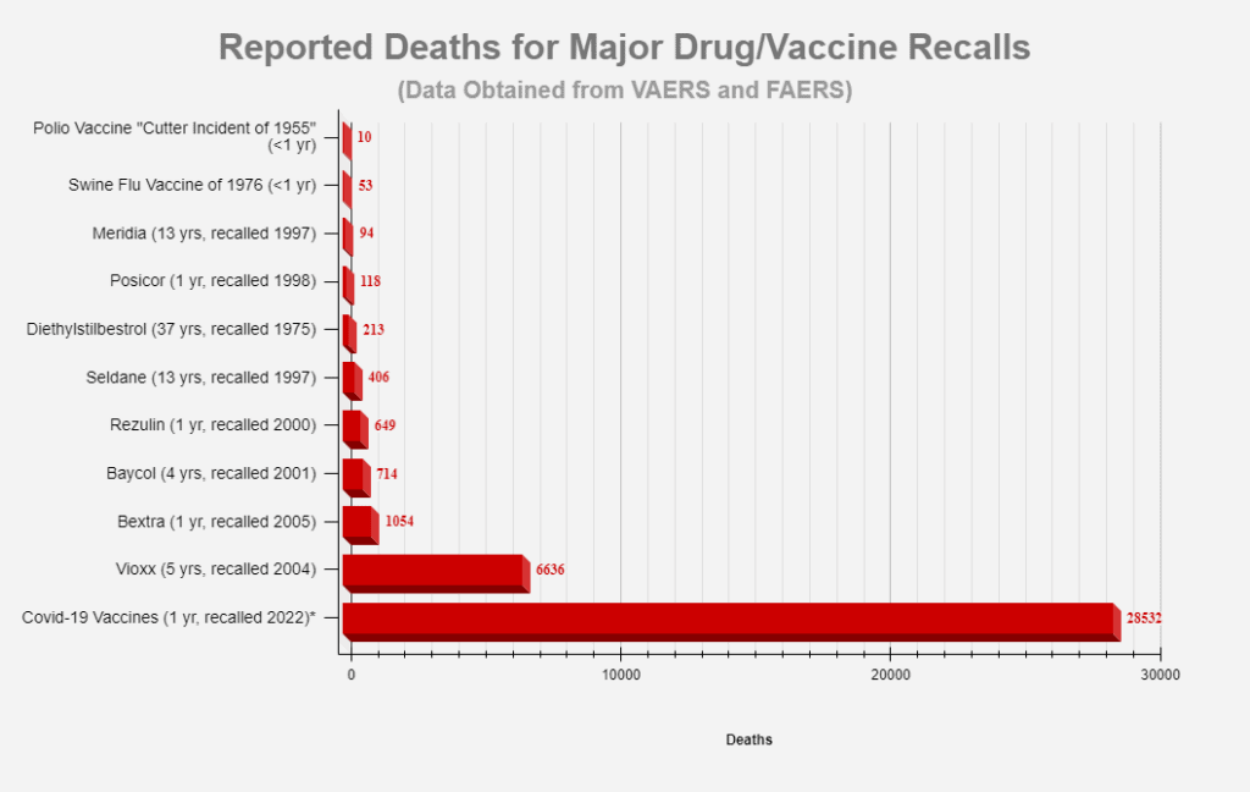
Key Lessons from the 1967 Swine Flu

Though the landscape of 2022 is very different, the following key insights from the mass swine flu vaccination campaign should be highlighted:

- It is essential for scientists and policy makers to re-evaluate information derived from early models as real-time information emerges about a suspected pandemic
- A 'better safe than sorry' approach is confounded by the issue that the evidence does not yet exist to make the statement that a rushed vaccination is *safer* than exposure to a virus about which little is known
- Reports of as few as 50 deaths linked to the swine flu vaccination were enough to shut down the program completely
- Natural immunity must be considered
- Responses to any suspected pandemic must align with the best available evidence about the nature of the threat and not be guided by politics, media, and emotions of the general public

Major Drug and Vaccine Recalls in History

When a concerning number of adverse events or deaths is noticed in pharmacovigilance reports, governing bodies may recall a previously authorized or approved product. The following graph shows the number of deaths reported to VAERS or FAERS before a product was recalled.



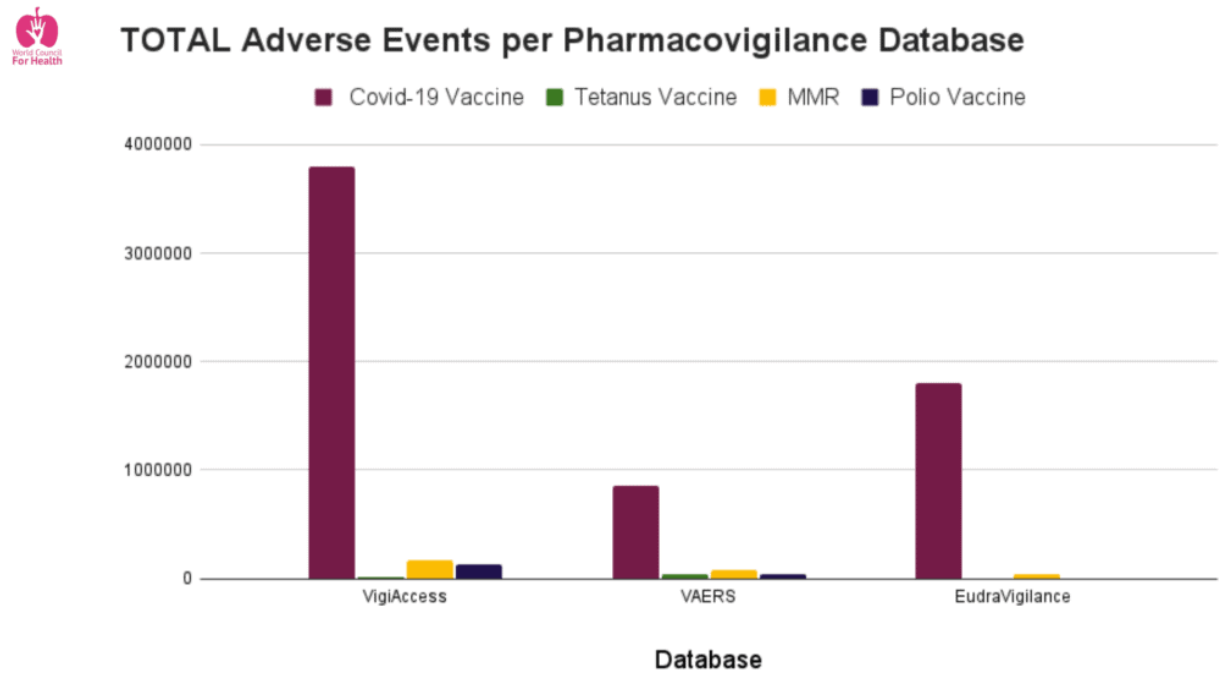
From VAERS Analysis

Source: *vaersanalysis.info/2022/05/14/vaers-summary-for-covid-19-vaccines-through-5-6-2022/*

The Polio Vaccine was recalled in less than 1 year after 10 reported deaths, the Swine Flu Vaccine was recalled in less than 1 year after 53 reported deaths. The Covid-19 vaccine, with over 28 000 associated reports of death, has not been recalled.

Signal Detected

Table 9: Total Adverse Events per Pharmacovigilance Database



Total Adverse Events per Pharamacovigilance Database

****Yellow Card data excluded****

Discussion

Across all databases, Covid-19 vaccines show an alarming number of adverse events and death reports when compared to other commonly administered vaccines.

Comments

There is concerning safety signal regarding Covid-19 vaccines detected on all databases examined in this report.

Conclusion

This report sought to look at pharmacovigilance data from VigiAcess, VAERS, EudraVigilance, and UK Yellow Card for Covid-19 vaccines. The aim was to determine if the data on these databases was sufficient to establish a safety signal about these products. We conclude the following:

Data from Pharmacovigilance Databases about Covid-19 Vaccines vs. Other Commonly Administered Vaccines and Pharmaceutical Products

- All pharmacovigilance databases examined in this report reveal a number of adverse events reports linked to Covid-19 vaccines that are between ten times and 169 times more than what is observed in other commonly administered products
- There are several thousand reports of adverse events in children for whom the Covid-19 product has not been approved

There is sufficient evidence on all pharmacovigilance databases examined in this report to establish a concerning safety signal about Covid-19 vaccines.

Data about the Types of Adverse Reaction Reports Linked to Covid-19 Vaccines

- Data from WHO VigiAccess, EudraVigilance, and UK Yellow Card Scheme reveal that the majority of adverse events reports related to Covid-19 vaccines are: Nervous System Disorders, Musculoskeletal and Connective Tissue Disorders and Gastrointestinal Disorders
- Data from VAERS reveal that the majority of adverse event reports related to Covid-19 vaccines are: Arthritis and Arthraligia, Anaphylaxis, Venous Thromboembolism, Myocarditis/Pericarditis, Stroke, and Convulsions/Seizures
- Eudravigilance reports 1200 deaths linked to Covid-19 vaccines. UK Yellow Card reports 2100 deaths linked to Covid-19 vaccines. VAERS reports 28 000 deaths linked to Covid-19 vaccines

The types of adverse reaction reports linked to Covid-19 products are serious in nature.

Data about the Rate of Adverse Events that is Sufficient for Product Recall

- Pharmacovigilance databases, such as those examined in this report, rely on passive surveillance. Adverse events are underreported
- Covid-19 products are unique in that they were developed quickly and administered to large populations while still in Phase 3 clinical trials
- In 1967, the American government rushed a mass vaccination campaign for swine flu. Information emerged about the nature of the virus and adverse reactions linked to the vaccine, and the campaign was halted in less than a year
- Data from VAERS and FAERS reveals that The Polio Vaccine was recalled in less than 1 year after 10 reported deaths, the Swine Flu Vaccine was recalled in less than 1 year after 53 reported deaths. The Covid-19 vaccine, with over 28 000 associated reports of death, has not been recalled after two years

There is sufficient evidence of adverse events relating to Covid-19 vaccines to indicate that a product recall is immediately necessary.

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