COVID-19 VACCINE ADVERSE EVENTS AROUND THE WORLD

WCH Covid-19 Vaccine Pharmacovigilance Report

Summary

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Approved by: WCH Health and Humanities Committee
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For the full report visit:
worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report
# Table of Contents

About World Council for Health 2  
What is this document? 3  
What is pharmacovigilance? 3  
Purpose of this report 4  
Method 4  
Why adverse event reporting matters for Covid-19 vaccines 5  
Findings: Number of adverse event reports 6  
Findings: Type of adverse event reports 12  
How many adverse events is too many? Precedent for recall 14  
Signal detected 16

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Pharmacovigilance is a pharmaceutical science, also known as drug safety. The goal of pharmacovigilance is to:

- collect, assess, and monitor data about adverse events;
- 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 including population data, studies, and industry reports. Pharmacovigilance databases containing adverse events are an inexpensive and accessible way to detect safety concerns around pharmaceutical products.

What is this document?

This document is a summary of the World Council for Health’s comprehensive Covid-19 Vaccine Pharmacovigilance Report prepared in May 2022. It is for all concerned citizens and clinicians. It summarises the alarming vaccine adverse events that are being observed in large numbers across several well-established pharmacovigilance databases around the world.

The report aims to establish whether or not there is a safety signal indicating a recall of Covid-19 vaccines.

What is pharmacovigilance?

Pharmacovigilance is a pharmaceutical science, also known as drug safety. The goal of pharmacovigilance is to:

- collect, assess, and monitor data about adverse events;
- 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 including population data, studies, and industry reports. Pharmacovigilance databases containing adverse events are an inexpensive and accessible way to detect safety concerns around pharmaceutical products.

How data are gathered:

The data examined in this report is sourced from adverse event reports documented on four well-established pharmacovigilance databases from around the world.
The purpose of this report:

This report aims to determine whether or not there are sufficient data on existing pharmacovigilance databases to indicate a recall of Covid-19 vaccines.

Method:

This report collates data on the following:

- the number of adverse events related to Covid-19 vaccines vs. other commonly administered vaccines;
- the types of adverse reactions linked to Covid-19 vaccines;
- the rate of adverse events that have been sufficient for product recall in the past.

From this data, we determine whether there is sufficient evidence to indicate a recall for Covid-19 vaccines.

The data we looked at:

- **VigiAccess Database**
  - World Health Organization (WHO)
  - VigiAccess is an initiative of the World Health Organization. It is an international database of reported potential adverse events related to medicinal products.

- **Vaccine Adverse Event Reporting System**
  - United States CDC and FDA
  - VAERS is managed by the US Centers for Disease Control and Prevention and Food and Drug Administration. It is an early warning system for safety concerns related to vaccines.

- **Eudravigilance**
  - European Medicines Agency
  - Eudravigilance is a database of suspected adverse drug reaction reports. It is used to evaluate, supervise, and monitor safety of medicines in the EU.

- **UK Yellow Card Scheme**
  - Medicines & Healthcare Products Regulatory Agency
  - The UK Yellow Card Scheme collects and monitors data on adverse medical incidents or side effects relating to medical products in the UK.

**Why adverse event reporting matters for Covid-19 vaccines:**

Traditionally, pharmacovigilance data from passive reporting systems are used to detect safety signals for rare adverse events that may have been missed in clinical trials. However, Covid-19 vaccines are unique in that:

- **Clinical trials are not completed.**
  - Phase 3 and Phase 4 clinical trials for Covid-19 injections are not complete. These phases of trials are designed to establish safety and efficacy and normally last from 10 - 15 years. **These products are being used on billions of people, including children, during their clinical trial phase, and the vast majority are not being monitored.** Their safety and efficacy is UNKNOWN.

- **6-month trial data showed more harm in the vaccinated group.**
  - In Pfizer’s largest clinical trial to date for these products, after 6 months:
    - there were 14 deaths in the placebo group and 20 deaths in the vaccine group;
    - there was a 300% increase in RELATED adverse events in the vaccine group.

- **Covid-19 products do not function like other vaccines.**
  - They do not prevent someone from contracting, spreading, or becoming ill with SARS-CoV-2.
  - Their effectiveness has waned significantly.
  - They are distributed throughout the entire body rather than staying in the arm the mRNA, which had never been used in humans prior to 2020, causes the body’s cells to produce harmful spike proteins for undetermined amounts of time.

**Safe treatments are available.**

Covid-19 can be mitigated and treated with safe, established drugs including antivirals, anticoagulants, and immune therapies.
Findings:

Total number of adverse events

Summary:

The total number of adverse events related to Covid-19 vaccines on VigiAccess, VAERS, Eudravigilance, and UK Yellow Card Scheme is unprecedented in each database. The magnitude of disparity in the number of adverse events compared to other commonly administered vaccines and therapies is sufficient to indicate an alarming safety signal for these products.

Findings:

Number of adverse events

WHO VigiAccess

VigiAccess shows a number of adverse events that is unprecedented on the database for any other pharmaceutical product or vaccine. When we compare it to the Tuberculosis vaccine, for example, which has been administered to more people than any other vaccine, we see the following:

- 37,000 adverse event reports for Tuberculosis vaccine since 1968;
- over 4,000,000 adverse event reports for Covid-19 vaccine since 2020.

For the full report visit:

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Findings:
Number of adverse events (cont.)

Over 50% of total reports in the VAERS database since 1990 are related to the Covid-19 vaccine. There is a 10-fold difference in the number of adverse event reports for the MMR vaccine compared to the Covid-19 vaccine, 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. There are over 1,700 reports of adverse events on VAERS of children at ages for whom the vaccine was not authorised. In addition, VAERS data show an alarming spike in death reports in 2021 and 2022.

Currently of the over 37,000 deaths reported to VAERS since 1990, 27,968 are related to Covid-19 products.

Average number of deaths on VAERS 1990 - 2020:

Risk of death | VAERS – flu vaccine vs. Covid-19 vaccine:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th># of vaccinations</th>
<th>Number of deaths</th>
<th>Risk of death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flu</td>
<td>167,447,642</td>
<td>33</td>
<td>1 in 5,074,171</td>
</tr>
<tr>
<td>Covid-19</td>
<td>173,335,886</td>
<td>5770</td>
<td>1 in 30,041</td>
</tr>
</tbody>
</table>

Risk of dying from COVID-19 vaccine is 169 times greater than flu vaccine

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

Findings:
Number of adverse events (cont.)

EudraVigilance data shows a number of individual case reports that is unprecedented on the database for any other pharmaceutical product or vaccine. When comparing it to the measles vaccine there is a 70-fold increase in the number of events reported to EudraVigilance. There are 48,913 individual EudraVigilance reports linked in someway 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. There are 1.8 million individual EudraVigilance reports associated with the Covid-19 vaccines of the approximate 341 million individuals who have received the vaccine.

Total Number Adverse Events on EudraVigilance – common vaccines:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Approximate number who have been vaccinated</th>
<th>Total number of adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>All measles vaccines</td>
<td>673,200,000</td>
<td>48,913</td>
</tr>
<tr>
<td>All polio vaccines</td>
<td>673,200,000</td>
<td>8982</td>
</tr>
<tr>
<td>All influenza vaccines</td>
<td>unknown</td>
<td>44,618</td>
</tr>
<tr>
<td>Covid-19</td>
<td>341,628,772</td>
<td>1,800,000</td>
</tr>
</tbody>
</table>

Source: https://www.adrreports.eu/
Findings: Number of adverse events (cont.)

Of the 53 million people who have been vaccinated for Covid-19 in the UK, the Yellow Card Scheme shows over 450,000 yellow card reports related to the Covid-19 vaccines. Comparing this to the data for paracetamol, a medication that has been in widespread general use for several decades, there are only a fraction of the reports (~25,000 since 1968) on the Yellow Card Scheme. The data for other vaccines is not available on the Yellow Card Website.

Total number adverse events on Yellow Card scheme—common medicines vs. Covid-19 vaccine:

<table>
<thead>
<tr>
<th>Product</th>
<th>Total number of adverse events</th>
<th>Reports since</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paracetamol</td>
<td>25,158</td>
<td>1968</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>16,690</td>
<td>1969</td>
</tr>
<tr>
<td>Diphenhydramine (Benadryl)</td>
<td>2165</td>
<td>1964</td>
</tr>
<tr>
<td>Covid-19 vaccine</td>
<td>450,000</td>
<td>2020</td>
</tr>
</tbody>
</table>

Source: https://yellowcard.mhra.gov.uk/idaps

Findings: Number of adverse events (cont.)

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

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

Total number adverse events per pharmacovigilance database:

![TOTAL Adverse Events per Pharmacovigilance Database](https://yellowcard.mhra.gov.uk/idaps)
Findings:
Types of adverse events

Summary:
The most common types of adverse events on these databases are:

- Nervous system disorders
- Musculoskeletal and connective tissue disorders
- Gastrointestinal disorders
- Anaphylaxis
- Venous thromboembolism
- Myocarditis/pericarditis
- Convulsions/seizures

There are over 50,000 reports of death related to Covid-19 vaccines on these databases.

Findings:
Types of adverse events

The majority of adverse events reported to all databases are serious in nature, with nervous system disorders being the most commonly reported. There are over 50,000 reported deaths linked to Covid-19 vaccines. Pharmacovigilance databases such as VigiAccess, EudraVigilance, VAERS, and UK Yellow Card Scheme rely on passive reporting from healthcare providers, pharmaceutical companies, and individuals, and are known to be vastly underreported.

Most common AE reports by reaction group:

<table>
<thead>
<tr>
<th>Database</th>
<th>Nervous system disorders</th>
<th>Musculoskeletal and connective tissue disorders</th>
<th>Gastrointestinal disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>VigiAccess</td>
<td>1,500,000</td>
<td>1,000,000</td>
<td>691,000</td>
</tr>
<tr>
<td>EudraVigilance</td>
<td>746,000</td>
<td>543,000</td>
<td>344,000</td>
</tr>
<tr>
<td>UK Yellow Card</td>
<td>285,000</td>
<td>175,000</td>
<td>135,000</td>
</tr>
</tbody>
</table>

Most common reports VAERS, Covid-19 vaccine:
1. Arthritis and arthralgia/joint pain
2. Anaphylaxis
3. Venous thromboembolism
4. Myocarditis/pericarditis
5. Stroke and convulsions/seizures

Number of deaths reported by database—Covid-19 vaccine:

<table>
<thead>
<tr>
<th>Database</th>
<th>Number of Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>VigiAccess</td>
<td>22,000</td>
</tr>
<tr>
<td>VAERS</td>
<td>28,000</td>
</tr>
<tr>
<td>EudraVigilance</td>
<td>800</td>
</tr>
<tr>
<td>UK Yellow Card</td>
<td>2100</td>
</tr>
</tbody>
</table>

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How many adverse events is too many?

Precedent for drug and vaccine recall

Summary:
The 1976 mass vaccination campaign was halted after a series of adverse event reports including 53 deaths. The polio vaccine was recalled in less than 1 year after 10 reported deaths. The Covid-19 vaccine, with over 28,000 associated reports of death on VAERS alone, has not been recalled.

There is sufficient evidence to indicate a recall of Covid-19 vaccines.

How many adverse events is too many?

Given that Covid-19 vaccine development was rushed and that they are still in clinical trials, it is imperative to consider how pharmacovigilance data may be used to assess their safety, efficacy, and the case for their continued use.

Precedent from other pharmaceutical products suggests that the data are sufficient to indicate a recall of Covid-19 vaccines.

The 1976 swine flu

In February 1976, 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. 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.

When reports emerged of suspected adverse reactions, including heart attacks, Guillain-Barré syndrome and 53 reported deaths, citizens began doubt the safety of the vaccine. Coupled with the fact the pandemic did not materialise as predicted, the government halted the mass vaccination programme on December 16.

Major drug and vaccine recalls in history:

![Graph showing reported deaths for major drug/vaccine recalls](source: https://vaersanalysis.info/2022/05/14/vaers-summary-for-covid-19-vaccines-through-5-6-2022/)

Source: https://vaersanalysis.info/2022/05/14/vaers-summary-for-covid-19-vaccines-through-5-6-2022/
Signal detected: Covid-19 product recall indicated

Unprecedented numbers of adverse events

• 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.

Serious adverse events and death

Data from VigiAccess, VAERS, EudraVigilance, and UK Yellow Card Scheme reveal that the most common reports related to Covid-19 vaccines are:

- Nervous System Disorders
- Musculoskeletal and Connective Tissue Disorders
- Gastrointestinal Disorders
- Anaphylaxis
- Venous Thromboembolism
- Myocarditis/Pericarditis
- Convulsions/Seizures

There are over 50,000 reports of death related to Covid-19 vaccines.

Precedent for product recall

• Adverse events are underreported.
• Covid-19 products were developed quickly and administered to large populations while still in Phase 3 clinical trials.
• Data from VAERS and the FDA Adverse Event Reporting System (FAERS) reveals that the polio vaccine was recalled in less than 1 year after 10 reported deaths, the vaccine was recalled in less than 1 year after 53 reported deaths. The Covid-19 vaccines, with over 28,000 associated reports of death, have not been recalled after two years.

For the full report visit: worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report
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