Exploring COVID-19 Vaccines 'Safety Signal' Data on VigiAccess.org: A World Council for Health Report

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Abstract

Background:

The monitoring and analysis of adverse drug reactions (ADR's) play a pivotal role in ensuring drug safety. In the context of a public health emergency of international concern (PHEIC), and the roll out of experimental COVID-19 vaccines, the need for a comprehensive database and process to scrutinize ADRs is imperative.

Areas of uncertainty:

We aim to provide a broader understanding of ADRs associated with COVID-19 vaccines and their implications for public health given this has received attention worldwide.

Data sources:

This is the first in a series of scientific reports by the World Council for Health (WCH) delving into the COVID-19 vaccine data available on VigiAccess.org, which should be a valuable resource in this context.

Therapeutic Advances:

For all regions worldwide during the 26-month period, there were nearly 24 million reported adverse events (AEs), of which nearly 8 million were serious (SAEs). Over one million people experienced at least one SAE ranging from a combination of debilitating and life-threatening conditions and death. A total of 58,091 people were reported to have died in the dataset.

Conclusions:

Global authorities on the COVID-19 pandemic such as the World Health Organization (WHO), and the Uppsala Monitoring Centre (UMC) for global pharmacovigilance, need to liaise with health providers, government authorities and the public to investigate the COVID-19 vaccine safety signals. One-off vaccine damage payments of £120,000 for victims in the UK and schemes in other countries may be insufficient.

Whilst further investigation is needed to establish causation, based on the substantial numbers of deaths and SAEs associated with the COVID-19 vaccines on VigiAccess.org, the strategy of COVID-19 vaccination programmes worldwide should be reconsidered. Furthermore, these data will likely be significantly underreported given majority of cases were not self-reported and data would also be reported in other sources not captured by VigiAccess.

Introduction

The monitoring and analysis of adverse drug reactions (ADR's) play a pivotal role in ensuring drug safety. In the context of a public health emergency of international concern (PHEIC),[1] and the roll out of experimental COVID-19 vaccines,[2] the need for a comprehensive database and process to scrutinize ADRs is imperative.[3] VigiAccess.org[4] should be a valuable resource in this context.

What is VigiAccess.org?

VigiAccess.org[4] is an online database maintained by the Uppsala Monitoring Centre (UMC),[5] which serves as the global hub for pharmacovigilance (drug monitoring). As the World Health Organization's (WHO)[6] collaborating centre for international drug monitoring, the UMC curates ADR data from across the globe. VigiAccess.org[4] is part of Vigibase,[4] whose role is to analyse reports of suspected harm caused by medicines to identify 'safety signals'.[7]

In the wake of the ongoing global COVID-19 vaccination campaigns with new and experimental types of vaccines, VigiAccess.org[4] assumes unprecedented importance in identifying 'safety signals' related to the novel COVID-19 vaccines.

What is a Safety Signal?

WHO-UMC define a safety signal as: "*information on a new or known side effect that may be caused by a medicine and is typically generated from more than a single report of a suspected side effect. It's important to note that a signal does not indicate a direct causal relationship between a side effect and a medicine, but is essentially only a hypothesis that, together with data and arguments, justifies the need for further assessment*."[8]

WHO-UMC collaboration's role, if a signal appears to have been detected, is to further assess causality. Should a credible association between a side effect and a COVID-19 vaccine be determined, UMC's Vigibase[4] website states that it would be the UMC's role to communicate this information to the WHO Programme for International Drug Monitoring (PIDM).[9] The PIDM has 170 country members, and it appears to be up to country regulators to investigate further and decide if any action is required, such as providing a public alert or warning, or withdrawing a drug from the market.

Safety audits

The WHO provides guidance on pharmacovigilance practices, and regulatory bodies often have specific requirements for database management and reporting standards.[10] These standards emphasize the importance of routine audits, e.g. biannual audits, to maintaining the integrity of these databases. In the context of 'conditional' or 'emergency use' authorisation of any experimental interventions, as for the COVID-19 vaccines, it would be expected that such audits would be prioritised. A recent review suggests the evidence to date contraindicates further booster injections and suggests that, at a minimum, the mRNA injections (one type of Covid-19 vaccine available) should be removed from the childhood immunization program until proper safety and toxicological studies are conducted.[11]

This is the first in a series of scientific reports by the World Council for Health (WCH)[12] delving into the COVID-19 vaccine data available on VigiAccess.org.[4] The series aims to provide a broader understanding of ADRs associated with COVID-19 vaccines and their implications for public health. By utilising this WHO-UMC database, the aim is to contribute

to the ongoing discourse on whether COVID-19 vaccination programmes should be halted globally until further investigations have been conducted.

Methods

In December 2022, an application was submitted to the Uppsala Monitoring Centre (UMC) to access data on COVID-19 vaccines. This analysis focuses on the WHO-UMC VigiAccess.org data collected from December 1, 2020 to January 31, 2023 specifically examining adverse reactions/events associated with COVID-19 vaccines. This analysis aims to provide insights into the safety and implications of COVID-19 vaccinations based on the most comprehensive global data available through VigiAccess.org. This is particularly timely given recent discussions on excess deaths in parliaments and in the wider media.[13]

Data analysis

This first report in the WCH series summarises Adverse Events (AEs) and Serious Adverse Events (SAEs) (including deaths) by continent/region and age group and gender. It also examines time to onset of AEs from vaccination.

Results

In total, nearly 24 million AEs were reported from December 1, 2020 to January 31, 2023. On average, around five Adverse Events (AEs) were associated with each case. StataIC (StataCorp. 2023. Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC) was used to conduct all analyses which were reported descriptively.

AEs were most frequently notified and verified by professionals (67.8%) rather than self-reported which is more likely to be prone to reporting biases.[14,15] Of nearly 24 million individual AEs, 47.2% were notified by a consumer/non-health professional, 10.2% by a physician, 3% by a pharmacist, 0.2% by a lawyer, 7.1% by another health professional and it was unknown who notified the AE in 32.2% of cases.

As expected, notification from a professional was recorded to be higher in reported SAEs cases (74.2%), with 51.5% being notified by consumer/non-health professional and 16% being from a physician. The remaining notifications of SAEs were from lawyers (0.5%), pharmacists (1.6%) and other health professionals (4.7%).

For all regions worldwide during the 26-month period:

- 23,893,230 AEs were reported, of which 7,873,104 were SAEs.
- 1,042,732 individuals experienced at least one SAE ranging from a combination of debilitating and life-threatening conditions and death.
- 58,091 people were reported to have died.

Time to onset from vaccination

All Adverse Events (All AEs)

Half of 17.67 million reported adverse events (AEs) with time to onset data occurred within 24 hours of vaccination. The onset of 75% of AEs happened within three weeks, and over 95% occurred within one year.

Where pertinent data on onset were available, focusing on AEs with onset within a year (16.84 million AEs), the results remained robust, with half of the AEs occurring within 24 hours and 75% within two weeks (Interquartile range (IQR): 13 days).

The mean number of days to AE onset was 25.7 days (standard deviation (SD)=59.6). These data were skewed, indicating that most adverse events and reactions occurred shortly after vaccination. Notably, nearly 11.65 million AEs occurred within seven days, 13.85 million within 30 days and 14.62 million within 60 days of Covid vaccination.

All Serious Adverse Drug Events and Reactions (All SAEs)

Out of nearly 5.2 million AEs categorised as serious (SAEs) with available onset time data, half occurred within eight days. Specifically, almost 2.5 million SAEs occurred within seven days, 3.27 million within 30 days, and 3.57 million SAEs occurred within 60 days of Covid vaccination. The majority, totalling 4.77 million, took place within one year.

These AE data are mirrored by the individual case data. For individual cases with at least one SAE with available onset time data (n=943,542), over half occurred within one week and over 75% in little over two months. Nearly 482,680 individuals had a SAE within seven days, 642,135 within 30 days, and nearly 700,000 individuals had a SAE within 60 days of Covid vaccination.

All Deaths

Out of the 58,091 reported deaths, 39,852 were categorized as 'death' without any additional SAE. Among those with additional SAEs reported in association, these included conditions such as ‘caused/prolonged hospitalization’, ‘congenital anomaly/birth defect’, ‘disabling/incapacitating’, ‘life-threatening’, and other related conditions. The gender distribution among those who died showed that 42.1% were female, 46.6% were male, with gender unknown in the remaining 1.3%.

Notably, the majority of deaths occurred in individuals aged 45 years or older (68.9%), with the age unknown in 24.1% of reported deaths. Deaths among boys and girls aged 2 to 17 years accounted for 0.67% of the total (399 deaths). A small number of deaths (n=45) involved babies and toddlers aged less than 24 months, and it was unclear whether these deaths were attributed to the administration of the Covid vaccine to pregnant or nursing mothers or to the infants directly.

Table 1. Deaths And Serious Adverse Events In All Continents By Age Group

	SAEs (events)	**SAEs* (individuals)**	**SAEs Female/Male/Missing (individuals)**	**Deaths (individuals)**
0–27 days	1,744	266	123/111/32	25

28 days – 23 months	4,285	685	374/247/64	20
2–11 years	15,495	2,767	1,412/1,309/46	76
12–17 years	101,690	17,872	8,626/9,092/154	323
18–44 years	2,413,301	335,762	221,403/109,250/5,109	3,610
45–64 years	2,514,263	312,552	195,038/113,222/4,292	9,285
65–74 years	938,004	113,761	62,674/49,519/1,568	9,702
≥75 years	758,697	101,707	55,526/45,129/1,052	21,033
Age unknown	1,125,625	157,360	87,675/61,153/8,532	14,017
Total	**7,873,104**	**1,042,732**	**1,042,732**	**58,091**

* SAEs range from a combination of debilitating and life-threatening conditions and death

DEATHS AND SERIOUS ADVERSE EVENT DATA BY REGION

For the period under review (December 1, 2020 to January 31, 2023), summaries of VigiAccess.org[4] data for the COVID-19 vaccinations with regard to deaths and SAEs by region are as follows:

Table 2. Deaths and Serious Adverse Events By Region

Region	AEs (events)	SAE (events)	SAEs* (individuals)	Deaths (individuals)
Africa	555,875	33,799	7,730	750
Americas	8,002,545	2,301,922	306,154	36,951
Asia	943,435	67,842	18,866	4,382
Europe	13,752,007	5,349,718	687,156	14,837
Oceania	639,368	119,823	22,826	1,171
Total	**23,893,230**	**7,873,104**	**1,042,732**	**58,091**

* SAEs range from a combination of debilitating and life-threatening conditions and death

Deaths and SAEs by age group for each region is provided in Supplementary Tables S1-S5 in Appendix.

Discussion

Nearly 24 million AEs were reported during a 26-month period from December 2020. For all regions worldwide, nearly eight million of these cases were SAEs which were experienced by over one million individual people. Out of nearly 5.2 million SAEs with available onset time data, half occurred within eight days, with the majority (around 4.8 million) occurring within one year. These SAEs ranged from a combination of debilitating and life-threatening conditions and death. A total of 58,091 people were reported to have died, with a small number of these deaths (n=45) appearing to involve babies and toddlers aged less than 24 months.

Strengths and limitations of the VigiAccess.org data

The majority of AEs and SAEs were confirmed by a professional rather than self-reported, which can be prone to reporting biases.[14,15] The obvious strength of this analysis is that it utilises a very large and important dataset and highlights the potential harms associated with Covid-19 vaccination. It counters the assertions that these vaccines are 'safe' and should prompt an investigation into safety signals and some of the serious injuries and deaths that have been reported. As with any vaccination or medicinal product, informed consent and choice are important, especially considering potential alternative options with no significant side effects.[16]

While the VigiAccess[4] data on COVID-19 vaccines (with 5,286,822 people in the dataset reporting at least one AE), offers valuable insights, it is difficult to determine any causation beyond the apparent safety signals and any association with some of the AEs.[8,16,18] However, considering the context that approximately 14 billion doses have been given and 5.55 billion people had received at least one COVID-19 vaccine dose by January 2024,[19] these data potentially represent one ADR report per 1,000 people vaccinated. Thus, although the reports are not indicative of causation, these data may highlight the need for further analysis and follow up reports.

In the absence of further investigation, and without knowing the denominators associated with the total number of people with a vaccination for Covid-19, indirect comparisons with other vaccines such as tetanus can put the VigiAccess.org data into perspective. Estimating the number of doses of the tetanus vaccine administered since 1967 (the year when tetanus vaccine ADRs were first reported to VigiAccess.org) is challenging due to variations in global vaccination programs, changes in immunization schedules, and incomplete historical records. However, the WHO has been actively promoting tetanus vaccination for decades.[20,21] Considering the widespread use of tetanus vaccination in routine immunization programs, emergency responses, and various public health initiatives globally (e.g., tetanus)[22] it is reasonable to suggest that billions of doses of the tetanus vaccine have been administered since its introduction. To be protected throughout life, WHO recommends that an individual receives at least six doses (3 primary plus 3 booster doses) of tetanus-toxoid-containing vaccines, with primary doses being encouraged as early as six weeks of age.[20] In January 2024, the reports associated with the tetanus vaccine to date numbered less than 17,000, including a total of 34 deaths.[4] Thus, the contrast in VigiAccess.org ADR data for the COVID-19 vaccines and other long-standing vaccines such as the tetanus vaccine, suggests further investigation of the Covid-19 vaccination programme is warranted.

Under-reporting

Numerous studies have highlighted the tendency of healthcare professionals to underreport AEs, leading to a substantial gap between the actual occurrence of ADRs and their representation in official databases. A landmark study conducted by Hazell and Shakir in 2006, titled "Under-reporting of adverse drug reactions: a systematic review," concluded that less than 10% of ADRs are reported.[23] Factors contributing to under-reporting include time constraints, lack of awareness, uncertainty about causality, and concerns about professional liability. Self-reported outcomes by people with an AE would help address the issue of a decline in reporting of suspected ADRs,[24] but would be offset by any data being potentially prone to reporting biases, a criticism that could be levelled at the yellow card scheme.[25]

Whilst the WHO acknowledges the issue of under-reporting and advocates for the strengthening of pharmacovigilance systems,[26] this conduct needs to extend to a thorough safety audit of its own Covid-19 database. If the problem of under-reporting is recognised in relation to the COVID-19 data, signals had been identified from February 2021 since 100,000 ADR cases were already reported to VigiAccess.org at this stage. Therefore, this may have been substantially more given these data were likely to have been under-reported, especially at that early stage of the COVID-19 vaccination roll out.

Governance and Covid-19

The WHO has informed the international COVID-19 vaccination policy. The organization is partially funded by government contributions from across the globe and is heavily dependent on voluntary contributions from industry and corporate foundations. These voluntary contributions comprise more than 80% of the WHO's annual income.[27] Transparency is therefore important. Given the scope for potential conflicts of interest, the WHO-UMC collaboration should present the results of the safety signals demonstrated in the analyses presented in this paper and conduct further investigations. This would then encourage individual governments to explore reports of their own safety datasets.

In excess of five million COVID-19 vaccine adverse drug reactions were reported by individuals on the WHO-UMC pharmacovigilance system to date, including in excess of 58,000 deaths. However, there is still a widespread assertion that Covid-19 vaccines are unequivocally 'safe', not least from the WHO.[28,29] This raises doubts about the adequacy of the WHO-UMC's current pharmacovigilance process. This questions whether Vigibase[4] has adequately disseminated the analysis pertaining to the VigiAccess[4] data and if the conclusions with respect to the potential safety signals have been communicated to the WHO Programme for International Drug Monitoring (PIDM). This is particularly relevant given the safety of Covid-19 vaccines is such an important topic and is forming major discussion across parliaments worldwide and considering continued excess deaths post pandemic.[30]

Conclusions

Many global authorities on the COVID-19 pandemic need to fully investigate the potential association with COVID-19 vaccines and the apparent safety signals shown in our analyses. The WHO and the UMC for global pharmacovigilance should alert the 194 WHO member states, health providers and the public to the COVID-19 vaccine safety signals and reconsider their future recommendations.

Whilst further investigation is needed to establish causation, based on the substantial numbers of deaths and SAEs associated with the COVID-19 vaccines on VigiAccess.org, the COVID-19 vaccination programmes worldwide need reconsideration of the recommendations in current use, in children, pregnant women and adults. Our analyses suggest that an urgent enquiry is required to further examine safety audits, especially those required by law and particularly in light of the potential for the future expansion of power for public health emergencies of international concern (PHEICs).[1]

WHO and UMC should consider conducting a transparent pharmacovigilance audit of COVID-19 vaccine data and make it readily available in the public domain. One-off vaccine damage payments of £120,000 for victims in the UK[31] and schemes in other countries may be insufficient. Safety audits of all national and international pharmacovigilance databases, with respect to the COVID-19 vaccine data are urgently needed. These should be conducted by independent scientists and scientific groups with no financial conflicts of interest. Until this is conducted, and given the substantial number of people who have experienced AEs from a Covid-19 vaccine, sources may continue to question the safety associated with the COVID-19 vaccination programmes and its necessity. All government regulatory agencies should ensure sufficient staff to conduct follow up of all ADR reports, prioritising those with SAEs and deaths reported. It would be advantageous to engage with scientists and health care professionals with experience in the area who have observed patients with various conditions potentially linked to the Covid vaccines.

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Contributions of authors

Lawrie and Bryant contributed equally to the completion of the manuscript. Bryant conducted the statistical analyses of the dataset.

Conflicts of interest

The authors have no conflicts of interest to declare. The World Council for Health (WCH) is a international grassroots organization committed to advancing health and well-being on a worldwide scale. With a mission to educate about the root cause of disease and promote an integrated approach to health, the World Council for Health serves as a dynamic platform for collaboration among healthcare professionals, researchers, policymakers and the public. Grounded in the principles of transparency, accountability, and innovation, the World Council for Health is dedicated to shaping a healthier future for communities around the world.

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Appendix

1. Africa

- AEs: 555,875
- SAEs: 33,799
- Individuals with at least one SAE: 7,730
- Reported deaths: 750

Table S1. Deaths and Serious Adverse Events in Africa by Age Group

	SAEs (events)	SAEs* (individuals)	SAEs Female/Male/Missing (individuals)	Deaths (individuals)
0–27 days	226	55	20/35/0	1
28 days – 23 months	172	46	23/23/0	3
2–11 years	155	47	21/25/1	0
12–17 years	475	118	62/55/1	7
18–44 years	13,720	3,354	1,756/1,553/45	81
45–64 years	10,208	1,995	1,101/869/25	213
65–74 years	3,554	711	336/371/4	191
≥75 years	2,085	516	265/244/7	206
Age unknown	3,204	888	410/366/112	48
Total	**33,799**	**7,730**	**7,730**	**750**

* SAEs range from a combination of debilitating and life-threatening conditions and death

2. Americas

- AEs: 8,002,545
- SAEs: 2,301,922
- Individuals with at least one SAE: 306,154
- Reported deaths: 36,951

Table S2. Deaths and Serious Adverse Events in Americas by Age Group

	SAEs (events)	SAEs* (individuals)	SAEs Female/Male/Missing (individuals)	Deaths (individuals)
0–27 days	44	16	10/4/2	3
28 days – 23 months	734	124	51/70/3	9
2–11 years	8,573	1,149	556/590/3	47
12–17 years	46,562	5,576	2,294/3,275/7	189
18–44 years	423,092	57,604	36,162/21,354/88	1771
45–64 years	473,228	59,812	34,226/25,520/66	4,667
65–74 years	280,269	32,510	16,100/16,392/18	5,540
≥75 years	286,211	41,657	21,195/20,437/25	11,949
Age unknown	783,209	107,706	57,698/49,453/555	12,776
Total	**2,301,922 events**	**306,154 people**	**306,154 people**	**36,951 people**

* SAEs range from a combination of debilitating and life-threatening conditions and death

3. Asia

- AEs: 943,435
- SAEs: 67,842
- Individuals with at least one SAE: 18,866
- Reported deaths: 4,382

Table S3. Deaths and Serious Adverse Events in Asia by age group

	SAEs (events)	SAEs* (individuals)	SAEs Female/Male/Missing (individuals)	Deaths (individuals)
0–27 days	0	0	0/0/0	0
28 days – 23 months	13	5	1/3/1	0
2–11 years	594	204	102/100/2	16
12–17 years	2,306	690	366/323/1	69
18–44 years	27,334	7,113	4,178/2,899/36	792
45–64 years	19,144	5,444	2,545/2,879/20	1,552
65–74 years	8,791	2,548	1,113/1,426/9	993
≥75 years	7,421	2,192	1,148/1,031/13	831
Age unknown	2,239	670	278/229/163	129
Total	**67,842**	**18,866**	**18,866**	**4,382**

* SAEs range from a combination of debilitating and life-threatening conditions and death

4. Europe

- AEs: 13,752,007
- SAEs: 5,349,718
- Individuals with at least one SAE: 687,156

- Reported deaths: 14,837

Table S4. Deaths and Serious Adverse Events in Europe by Age Group

	SAEs (events)	SAEs* (individuals)	SAEs Female/Male/Missing (individuals)	Deaths (individuals)
0–27 days	1,468	193	92/72/29	21
28 days – 23 months	3,345	502	297/145/60	8
2–11 years	5,540	1,246	680/529/37	8
12–17 years	49,165	10,890	5,674/5,076/140	52
18–44 years	1,905,883	259,701	174,546/80,465/4,690	902
45–64 years	1,973,585	238,920	153,142/81,743/4,035	2,633
65–74 years	632,294	75,532	43,834/30,215/1,483	2,749
≥75 years	451,496	54,812	31,564/22,279/969	7,497
Age unknown	326,942	45,360	27,676/10,223/7,461	967
Total	**5,349,718**	**687,156**	**687,156**	**14,837**

* SAEs range from a combination of debilitating and life-threatening conditions and death

5. Oceania

- AEs: 639,368
- SAEs: 119,823
- Individuals with at least one SAE: 22,826
- Reported deaths: 1,171

Table S5. Deaths and Serious Adverse Events in Oceania by Age Group

	SAEs (events)	SAEs (individuals)	SAEs Female/Male/Missing (individuals)	Deaths (individuals)
0–27 days	6	2	1/0/1	0
28 days – 23 months	21	8	2/6/0	0
2–11 years	633	121	53/65/3	5
12–17 years	3182	598	230/363/5	6
18–44 years	43,272	7,990	4,761/2,979/250	64
45–64 years	38,098	6,381	4,024/2,211/146	220
65–74 years	13,096	2,460	1,291/1,115/54	229
≥75 years	11,484	2,736	1,354/1,138/38	550
Age unknown	10,031	2,530	1,613/882/241	97
Total	**119,823**	**22,826**	**22,826**	**1,171**

* SAEs range from a combination of debilitating and life-threatening conditions and death