Analysis of COVID-19 vaccine death reports from the Vaccine Adverse Events Reporting System (VAERS) Database Interim Results and Analysis

Preprint · June 2021

DOI: 10.13140/RG.2.2.26987.26402

6 authors, including:

Scott Mclachlan
Queen Mary, University of London
57 PUBLICATIONS **275** CITATIONS
SEE PROFILE

Magda Osman
Queen Mary, University of London
158 PUBLICATIONS **1,807** CITATIONS
SEE PROFILE

Kudakwashe Dube
Massey University
75 PUBLICATIONS **404** CITATIONS
SEE PROFILE

Patience Penny Chiketero
Network Rail
1 PUBLICATION **0** CITATIONS
SEE PROFILE

Analysis of COVID-19 vaccine death reports from the Vaccine Adverse Events Reporting System (VAERS) Database

Interim Results and Analysis

Scott McLachlan, Magda Osman, Kudakwashe Dube, Patience Chiketero, Yvonne Choi, Norman Fenton

Risk and Information Management, Queen Mary University of London, UK
Birmingham Law School, University of Birmingham, UK
School of Biological and Chemical Sciences, Queen Mary University of London, UK
School of Fundamental Sciences, Massey University, NZ
Occupational Health and Wellbeing, Network Rail, UK
Health Informatics and Knowledge Engineering Research (HiKER) Group

Abstract

Clinically trained reviewers have undertaken a detailed analysis of a sample of the early deaths reported in VAERS (250 out of the 1644 deaths recorded up to April 2021). The focus is on the extent to which the reports enable us to understand whether the vaccine genuinely caused or contributed to the deaths. Contrary to claims that most of these reports are made by lay-people and are hence clinically unreliable, we identified health service employees as the *reporter* in at least 67%. The sample contains only people vaccinated early in the programme, and hence is made up primarily of those who are elderly or with significant health conditions. Despite this, there were only 14% of the cases for which a vaccine reaction could be ruled out as a contributing factor in their death.

Executive Summary

There have been multiple conflicting claims made about the safety of the COVID-19 vaccines that were rolled out world-wide from Dec 2020. However, there is no universally agreed system for reporting either deaths or serious side-effects for which these vaccines may have been the cause or a contributory factor, and hence, as a result, there are concerns about variability in the quality of reports and the credibility of the sources submitting them. Reports can be submitted by physicians involved in administering the vaccine or helping treat side effects that may have consequentially arisen, clinical and non-clinical health service employees, or pharmaceutical professionals involved in the investigation. Likewise, lay people, such the patient or their family and friends, may have submitted a report independently of medical carers. It has been suggested that a third category of submission may have been made by members of anti-vaccine, or other groups, motivated by ill-intent, who may exaggerate case numbers reported. Critics of safety reporting cite the fact that lay people, or those with malign intent, may form the bulk of reports and hence statistics on side effects must therefore be exaggerated because they come from non-credible sources. Set against this, research suggests that as few as 1% of the true adverse reactions ever get formally recorded.

In early April 2021 we downloaded the 2021 Vaccine Adverse Events Reporting System (VAERS) dataset with the aim to analyse these reports to determine the range and frequency of health problems potentially caused by the vaccines but also the quality of the reports, and by inference the credibility of the reporters lodging them. For each patient cited in a report, a clinically trained reviewer manually examines the report to determine its source and clinical credibility and to identify and record medical history, current illness, and symptoms. Each is then checked by a second reviewer. This process is ongoing, as there are 1644 deaths in the April VAERS deaths dataset that have been reported in patients who had recently received their first or second COVID-19 vaccination, and over 28,000 serious adverse events that did not result in death. This interim report presents the results of our analysis of the first 250 reported deaths that have been reviewed and coded by our team. We identified health service employees as the *reporter* in at least 67% of the reports, while pharmaceutical employees were identified as the reporter in a further 5%. Lay people were identifiable as the reporter in only 28% of the reports. This suggests an intention for clinical applicability and usefulness and goes some way towards addressing the common disclaimer that many VAERS reports are made by aggrieved family members and anti-vaxxers, both with an axe to grind. The sample is heavily biased because these were all people vaccinated very early in the programme when only the elderly, those with significant or chronic health conditions and frontline health service staff were being vaccinated. Yet, our analysis shows that the patients can be grouped into three main types: (i) those where the vaccine was most likely not a factor; (ii) those where the vaccine may have been a factor; and (iii) those where the vaccine was the most likely factor in their deaths. We found that in 34 of the 250 deaths (14%) a vaccine reaction could be ruled out as a contributing factor in their death; these were all patients either already bedridden and expected to die from a serious medical condition like lung cancer, or were described as at end of life or receiving palliative hospice care. For 203 of the 250 (81%) the vaccine may have been a factor in their death; however, many of these patients had one or more chronic or age-related comorbid conditions. Finally, for at least 13 of the 250 deaths (5%) the vaccine was the most likely cause of death; these patients had strong reactions soon after vaccination and died either on the same day, or during the next couple of days.

1. Introduction

> Amateur critics often like to dismiss anecdotes as 'unscientific', but this is wrong: anecdotes are weaker evidence than trials , but they are not without value and are often the first sign of a problem (or an unexpected benefit).
>
> Bad Pharma by Ben Goldacre, p189

In January 2020 the World Health Organisation (WHO) upgraded an outbreak of pneumonia cases which they said were caused by Sars-CoV-2 in China to global pandemic status (WHO, 2020). The development time for a vaccine candidate normally ranges from 3-6 months for an updated version of an already established jab such as last year's influenza vaccine, to three years for a completely new product (Plotkin, Robinson, Cunningham et al, 2017). Once testing in animal models is complete, taking perhaps another 1-2 years, testing the vaccine candidate in humans usually requires four phases of testing. Phase 1 involves a very small number of human subjects (20-40) with a focus on identifying any potentially life-threatening reactions and assessing immunogenicity, while Phase 4 involves collection of efficacy data from hundreds of thousands of people who have received the vaccine in its initial 2-3 years of community use (Dermody, DiMalo & Enquist, 2020). In total it takes anywhere from 5-8 years, or even as much as 15-20 years (Lanese, 2020), before a vaccine is licensed for community use, and several years beyond that before we have a complete picture of its safety and effectiveness.

While the WHO said in late February it did not believe a credible vaccine would be available in less than 18 months (Grenfell & Drew, 2020), pharmaceutical companies began the first human clinical testing of COVID-19 vaccines just three weeks later, even before most countries had felt any real impact from the disease (Le, Andreadakis, Roman et al, 2020). Much has been made about the accelerated pace with which COVID-19 vaccines were brought to market; including suggestions that animal testing and Phase 3 challenge trials were conducted following previously untested novel methods (Eyal, Lipsich & Smith, 2020; Lanese, 2020), or skipped altogether (Boodman, 2020; Lanese, 2020). (Magee, 2021) refuted claims of skipped animal testing but described that testing as using *defrosted embryos* and claimed that this form of animal testing *was* pivotal in the vaccine's rapid release. The implication is that animal model testing took place during the few weeks between publishing the SARS-CoV-2 DNA in late January 2020, which was a requirement before development of the mRNA vaccines could commence, and the first human trials that commenced only seven weeks later.

The expedited approval of these vaccines, especially those using novel mRNA technology, has been a source of contention for clinical and lay people alike (Doshi, 2021; Mahase, 2020). Many argue that their novel technology should have warranted greater, not reduced, scrutiny (Doshi, 2021). Some even suggested Vaccine-Enhanced Respiratory Disease (VAERD) and vaccine excipient-related clotting would result from the new vaccines even before they were given emergency authorisation (Hotez, Corry, Strych et al, 2020). Indeed, some countries suspended use of the vaccines for exactly these reasons shortly after their vaccination programmes started (Dyer, 2021; Ostergaard, Schmidt, Horvath-Puho et al, 2021; Wise, 2021).

It is therefore unsurprising, that there has been great interest in the increasing number of reports of deaths, reactions and serious side-effects for which it is claimed the vaccine was the cause or a contributory factor. Unfortunately, there is no universally agreed system for reporting and so there can be great variability in the quality and number of reports. On the one hand there are those who claim that vaccine adverse event reports are primarily submitted by lay people such as the family and friends of the deceased or members of anti-vaccine groups. On the other hand, there are those who argue that as few as 1% of the true adverse reactions ever get formally recorded. Given that for a variety of reasons there is no other centralised recording of COVID-19 vaccine related events, these reports are the only source from which knowledge about patient outcomes may be drawn.

In early April 2021 we accessed and downloaded the dataset and accompanying documents from the US VAERS reporting system. Our objective is to perform an analysis of the reports to determine not just the range and frequency of health problems caused by the vaccines, but also the quality of the reports. Quality was assessed through analysis of the clinical information provided for each patient: whether it incorporates historic and current medical conditions, current medications, and details of the vaccination, onset of symptoms and the death events. This process is ongoing, as there are 1644 deaths in the dataset that have been reported in patients who had recently received their first or second COVID-19 vaccination, and over 28,000 serious adverse events, including severe tinnitus, inflammation of the heart muscle (myocarditis and pericarditis) and clots, that did not result in death. This interim report presents the results of our analysis of the first 250 reported deaths that have been reviewed and coded by our team.

The paper is structured as follows: In Section 2 we provide an overview of VAERS and compare it to the systems in other countries. In Section 3 we describe our detailed approach to the analysis and the interim results on the range and frequency of health problems caused by the COVID-19 vaccines. A discussion of the clinical results is provided in Section 4. In Section 5 we present the results of our analysis into the quality of reporting. In Section 6 we discuss what is generally known about the scale of COVID-19 vaccine deaths and adverse reactions compared to other vaccines. A discussion of the media narrative and 'fact checking' of VAERS is presented in Section 7, with conclusions and recommendation in Section 8.

2. Vaccine Adverse Events Reporting and Dissemination

Most countries operate some form of vaccine adverse event reporting system for post-licensure safety surveillance.

In the *United States of America* (USA) for several decades this function has been provided by the *Vaccine Adverse Events Reporting System* (VAERS) which is administered by the Food and Drug Administration (FDA) (Varricchio, Iskander, Ball et al, 2004). As shown in Figure 1a, significant and sometimes quite descriptive data is publicly available from the VAERS website that includes clinician's narrative notes along with medical history, current illnesses, medications and symptoms experienced by the patient. Figure 1b provides an example of a low-detail family reported incidence. Figure 1c is an example, discussed later, where the VAERS call centre employee (the *Recorder*) may have become the *Reporter* by imputing their own inferences and interpretations for whether the vaccine may or may not have been involved.

(a)

Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. Code was the result of PEA secondary to hypoxia (</= 85%), despite being on the vent, with PEEP 12, FiO2 of 100%, with acidosis. After 95 minutes of active resuscitation, the patient was found not responsive to painful stimuli. There was no palpable pulse. No spontaneous respirations. No heart or breath sounds by auscultation. Absence of pupillary light reflex.

(b)

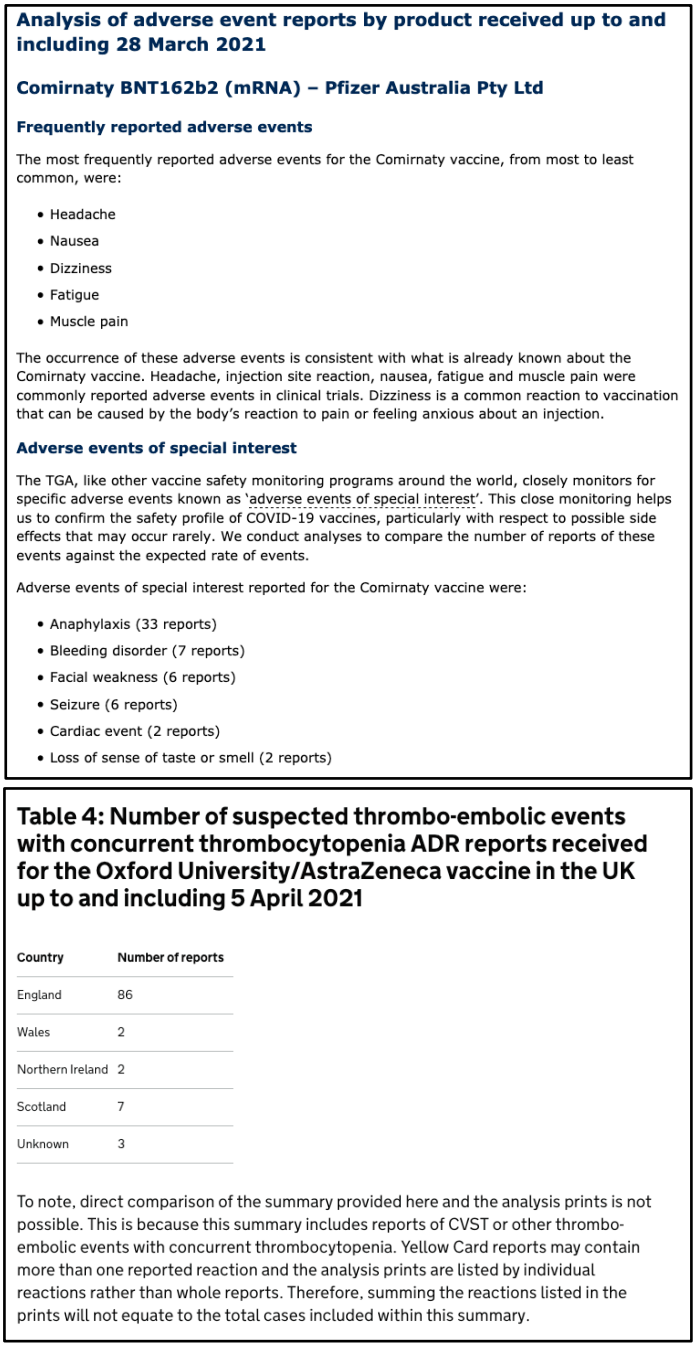
Pt called son to let him know he couldn't breath around 2 AM. Pts son showed up at his house 10 minutes later and ambulance arrived with in 20 minutes at 2:15

(c)

patient passed away after receiving the Covid vaccine; This is a spontaneous report from a contactable nurse. An 81-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular into the right arm on 07Jan2021 at 0.3 mL, single for covid-19 immunization. There was no medical history and no concomitant medications. On 08Jan2021, the patient passed away after receiving the COVID vaccine. The patient died on 08Jan2021. An autopsy was not performed. Investigations indicate that unspecified labs were done, but nothing two weeks prior; no further details were provided. The patient received the first dose the day prior. The reporting nurse discussed it with the medical director, and he thought that he potentially passed away from the COVID vaccine. The relatedness of the event to the suspect vaccine was reported as related by the reporting nurse per The Agency. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the limited information available, it is medically not possible to make meaningful causality assessment, it is unlikely the vaccine could have contributed to the death of the patient based on the known safety profile. However case will be reevaluated when additional information is received during the follow-up The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Stated that the patient passed away after receiving the Covid vaccine

Figure 1: VAERS clinical narratives for patients who died within hours of receiving a COVID-19 vaccine where the reporter was: (a) a health service employee; (b) a family member of the deceased; and (c) where the VAERS call centre staff have included their own inferences.

In contrast, the publicly available data from the United Kingdom (UK), provided by the Medicines and Healthcare products Regulatory Authority (MHRA), and Australia (AUS), provided by the Therapeutic Goods Administration (TGA), is sparse. It consists in both cases of a simple list of symptoms and the frequency with which they have been reported. As shown in the examples in Figure 2, this data is provided with no information about the patients, clinical outcomes or vaccine batch numbers, and no ability to analyse and identify clusters that may present with serious consequences for individual patients, including death (Wise, 2021).



Analysis of adverse event reports by product received up to and including 28 March 2021

Comirnaty BNT162b2 (mRNA) – Pfizer Australia Pty Ltd

Frequently reported adverse events

The most frequently reported adverse events for the Comirnaty vaccine, from most to least common, were:

- Headache
- Nausea
- Dizziness
- Fatigue
- Muscle pain

The occurrence of these adverse events is consistent with what is already known about the Comirnaty vaccine. Headache, injection site reaction, nausea, fatigue and muscle pain were commonly reported adverse events in clinical trials. Dizziness is a common reaction to vaccination that can be caused by the body's reaction to pain or feeling anxious about an injection.

Adverse events of special interest

The TGA, like other vaccine safety monitoring programs around the world, closely monitors for specific adverse events known as 'adverse events of special interest'. This close monitoring helps us to confirm the safety profile of COVID-19 vaccines, particularly with respect to possible side effects that may occur rarely. We conduct analyses to compare the number of reports of these events against the expected rate of events.

Adverse events of special interest reported for the Comirnaty vaccine were:

- Anaphylaxis (33 reports)
- Bleeding disorder (7 reports)
- Facial weakness (6 reports)
- Seizure (6 reports)
- Cardiac event (2 reports)
- Loss of sense of taste or smell (2 reports)

Table 4: Number of suspected thrombo-embolic events with concurrent thrombocytopenia ADR reports received for the Oxford University/AstraZeneca vaccine in the UK up to and including 5 April 2021

Country	Number of reports
England	86
Wales	2
Northern Ireland	2
Scotland	7
Unknown	3

To note, direct comparison of the summary provided here and the analysis prints is not possible. This is because this summary includes reports of CVST or other thrombo-embolic events with concurrent thrombocytopenia. Yellow Card reports may contain more than one reported reaction and the analysis prints are listed by individual reactions rather than whole reports. Therefore, summing the reactions listed in the prints will not equate to the total cases included within this summary.

Figure 2: Vaccine Adverse Event data. Top: AUS (TGA, 2021) and Bottom: UK (MHRA, 2021)

3. Analysis of the VAERS data for COVID-19 Vaccines

In early April 2021 this team accessed and downloaded the raw 2021 VAERS dataset along with the corresponding Symptoms and Vaccine data from the VAERS website (https://vaers.hhs.gov/). Based on their consistent use of an anonymised patient identifier across all three datasets, we were able to aggregate them into a single dataset for analysis. For each patient a clinically trained reviewer manually examines the medical history, current illness, symptoms and clinician's narrative to identify and record individual medical conditions, symptoms of interest, and seeks to identify whether the Reporter is, for

example, a health service employee or family member. Each is then checked by a second reviewer who ensures the details have been correctly coded. This process is ongoing, as there are 1644 deaths in the dataset that have been reported in patients who had recently received their first or second COVID-19 vaccination, and over 28,000 serious adverse events that did not result in death.

This interim results paper presents information on the first 250 reported deaths that have been reviewed and coded by our team. Obviously, these results cannot be generalised as the sample is heavily biased - these were all people vaccinated very early in the programme when only the elderly, those with significant or chronic health conditions and frontline health service staff were being vaccinated.

Death by Age: As shown in Figure 3, unsurprisingly the 85+ age group accounts for the largest proportion of deaths (31.9%), almost double the next highest group, the 80-84 year olds (17.7%). In these two groups advanced age and collected co-morbid conditions tended to be described by clinical staff as most likely to have caused their death shortly after receiving the vaccine. However, the narrative notes contained numerous examples of deaths in vaccine recipients in these age groups who were still active and living in their own homes in the wider community, for example: 959568 who was found collapsed and unconscious by her husband less than 72 hours after receiving her COVID-19 vaccination, having suffered and almost immediately dying from a type of stroke known as a *cerebrovascular accident* (CVA), and 934373 who was found dead in an armchair in their lounge room by her husband in the early morning around 12 hours after receiving her COVID-19 vaccination.

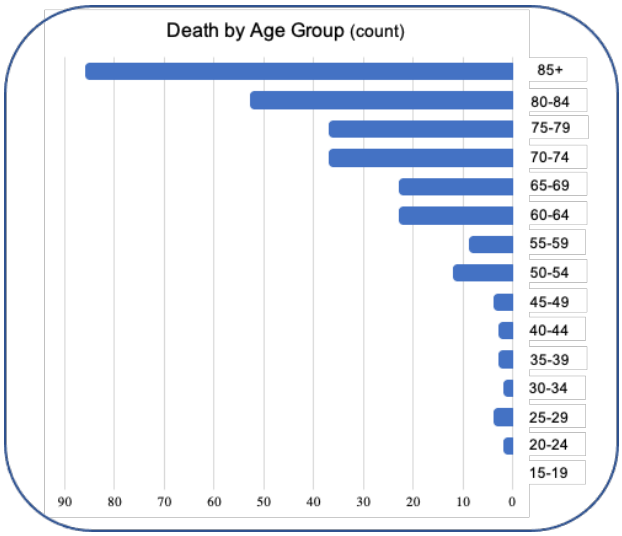


Figure 3: Death by Age Group

Much has been made in the media and academic literature about the need for protection and early vaccination of those aged 65 years and over. We believe this focus is the primary reason that 80% of the post-vaccination decedents reported are in this age group. Almost one-tenth (9%) expired within only 6 hours of their vaccination and 18% died in less than 12 hours. Over one third (36%) did not survive through to the following day.

Figure 4 highlights that 50% died in less than 48 hours after receiving their COVID-19 vaccination. This increases to 80% when we extend to the first week post-vaccination. A further 10% of deaths occurred in the second week, with the remaining 10% passing away during weeks 3 and 4. After receiving their COVID-19 vaccination, those people who were: (a) diagnosed or specifically described as having an *allergic reaction*, or whose symptoms strongly supported this diagnosis, died between 30 minutes and 4 days; (b) described as suffering from *respiratory distress*, with or without symptoms of *pneumonia*, died between days 2 and 9; and (c) diagnosed with or described as having a *cardiac event*, e.g.: *myocardial infarction* or *heart attack*, died between days 5 and 14.

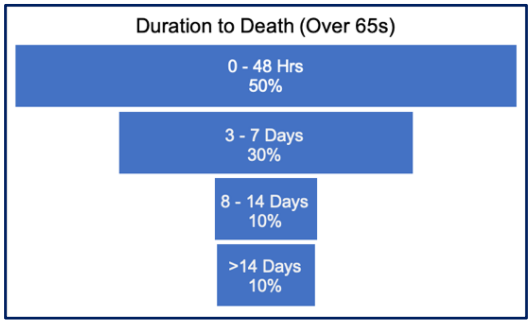


Figure 4: Duration from Vaccination to Death for the over-65s

Six decedents (921667, 921768, 943397, 944595, 956458 and 1092595) were identifiable from their narrative notes as staff in the current employ of healthcare provider organisations.

Pre-existing Conditions: Pre-existing or co-morbid conditions should always be critically appraised in any drug or vaccine study, but especially for these vaccines where issues of VAERD and clotting have been publicly raised, and because many of the VAERS reported deaths are blamed on the recipients underlying health status.

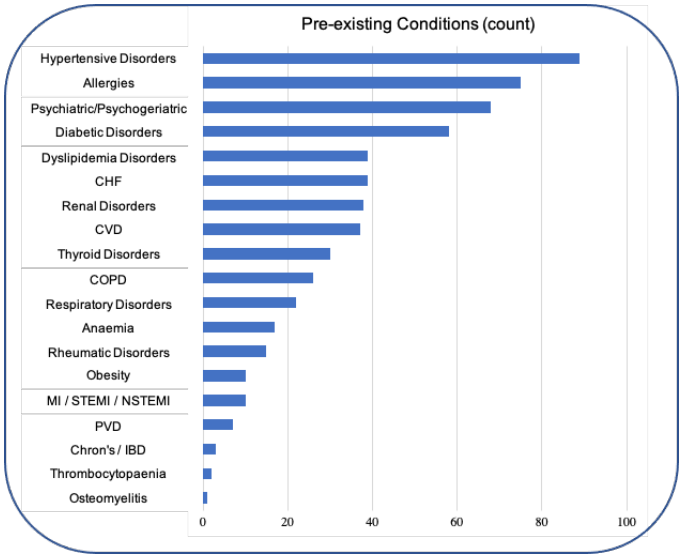


Figure 5: Pre-existing Conditions

Figure 5 shows that the most common single pre-existing condition were hypertensive disorders, or disorders of blood pressure (36%). The most common collective group were those we would normally

aggregate as *cardiac* or *heart conditions*, which were identified in the deaths of 35% of the reported vaccine recipients. These conditions include: *congestive heart failure* (CHF), *cardiovascular disease* (CVD), and *myocardial infarction* (MI) including ST-Elevation Myocardial Infarction (STEMI) and Non-ST-Elevation Myocardial Infarction (NSTEMI).

Almost one-third of all COVID-19 vaccine recipients had recorded food, drug or environmental allergies (30%). While 23% of the patients had a diabetic disorder, it was noted that for all but two whose diabetes was recent or sufficiently well controlled so as not to have resulted in co-morbidities at the time of vaccination, the rest were compounded by a hypertensive disorder along with either a chronic renal or thyroid condition; or an accumulation of all three.

Death by Vaccine Brand: Two vaccine brands had been administered to the 250 recipients in our interim results: Moderna and Pfizer\Biontech. Figure 3 shows that both vaccine brands were administered to an almost equal number of recipients. Eight reports failed to identify the manufacturer of the vaccine administered to the decedent.

We noted in the overall VAERS dataset that vaccine recipients were diversely located around the entire USA and they received doses from almost 200 different vaccine batches. However, there were eight vaccine batches in the overall VAERS dataset that were identified in relation to 30 or more recipients[1].

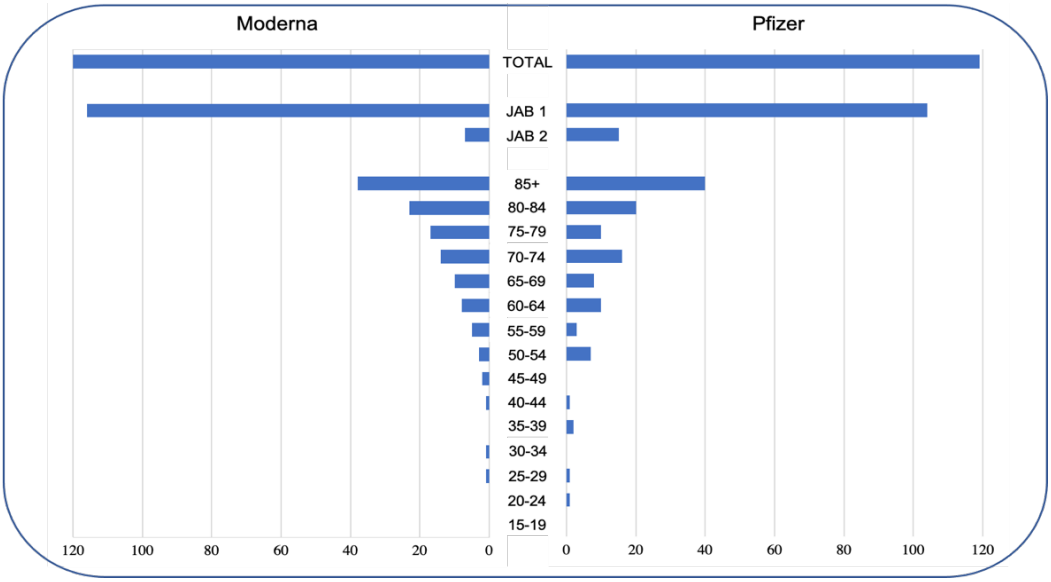


Figure 6: Deaths by Vaccine Brand

4. Discussion of clinical findings

The most significant incidental finding from our review of the symptoms and narrative provided in these reports was that while 8% directly report temporary (transient ischemic) to complete (ischemic) occlusive strokes and cerebral haemorrhage (ruptured aneurysm), many more report one or more clinical signs and symptoms consistent with clotting disorders without specifically identifying them as a potential cause of

[1] Pfizer\Biontech EL0140, EK9231, EL3249, EN5318 and Moderna 12L20A, 25J20A, 37K20A, 39K20A

death. Acute clotting disorders present from cerebral, pulmonary or abdominal embolism and the symptoms described post vaccination included: sudden severe headache (8), dizziness and light-headedness (16), sudden loss of balance or physical coordination with or without falls (38), difficulty walking (5), post-vaccination confusion with or without difficulty speaking or comprehending speech (11), sudden or unilateral weakness (33), sudden breathlessness or shortness of breath (39), coughing up blood (6), and sudden severe abdominal pain (4). Early non-acute signs and symptoms that may indicate the presence of deep vein thrombosis (DVT)[2] prior to presentation with acute embolism included pain (throbbing and cramping) in a leg which was reported by 2% of those who went on to describe some of the other more acute symptoms described above. Of the 22 patients where a stroke was explicitly identified, 20 (91%) had no mention of a pre-existing coagulative disorder, and 9 (41%) also had no mention of pre-existing hypertensive, arrhythmic cardiac disorders or an injury that might have otherwise explained the clotting event. There was no mention of a pre-existing clotting disorder for any of the 83 patients with one or more signs and symptoms of a possible clot event. While it is true that the patient histories and current illness descriptions present with variable quality and detail, this would not sufficiently explain away every instance.

The reviewers and authors include people trained in clinical nursing, a medical practitioner, health informaticians, a psychologist, a chartered mathematician, and a statistician. The reviewers generally commented on several common themes observed in the vaccine recipient patient data. First, the extremely high number of recipients who were reported as complaining of general weakness, tiredness, malaise and lethargy in the days after receiving COVID-19 vaccines. This is apparently a common theme in COVID-19 vaccine recipients and was even commented on in the notes on the website with the Australian summary statistics. Second, the similarly high number of recipients whose post-vaccination and pre-death symptoms included description of syncope (fainting, passing out or collapsing). We observed some description of collapse, syncope or fainting in the symptom or narrative notes of 6% of VAERS death reports reviewed. This observation is also generally consistent with a prior *Institute of Medicine* (IOM) report that said the VAERS evidence *convincingly supports* causal relationships between vaccine injection and syncope (Miller, Moro, Cano et al, 2015). Third, the majority (91%) of deaths are reported after administration of the first COVID-19 vaccination.

5. Results of our analysis into the quality of reporting

The reporting person (the *reporter*) and quality of clinical detail in the report varied considerably. The reporter ranged from a friend or family member of the deceased, through to clinicians, nurses, administrative employees of healthcare provider organisations, staff at vaccine deployment centres and in a small number of cases, staff from the pharmaceutical manufacturers who developed the vaccines. It was possible to identify that health service employees accounted for at least 67% (*n*=168) of the VAERS reports we evaluated, while pharmaceutical employees were identified as the reporter in a further 5% (*n*=12). While it is often suggested in the media that VAERS and Yellow Card reports are primarily the product of

[2] The USA CDC describe that half of all people with DVT have symptoms of swelling, pain, tenderness and localised redness of the skin at the affected part of the body. It also describes that such clots can become an acute *pulmonary embolus* (PE) without ever causing diagnosable signs and symptoms consistent with a DVT - https://www.cdc.gov/ncbddd/dvt/facts.html

lay people such as the family and friends of the deceased or members of anti-vaccine groups, this interim review found that lay people were involved in only 28% of the reports we reviewed. Finally, in 3% of cases the VAERS call centre employee (the *recorder*) appears to provide their own narrative or interpretation such that the recorder becomes, in effect, a reporter[3].

The majority of death reports in this interim dataset include some narrative description for the death event; whether a short clinical comment[4] or a more comprehensive narrative including elements of the patient's medical status prior to and/or post vaccination, similar in detail to that shown in Figure 1. On reading these it became apparent that some nursing or clinical staff felt it important to expressly distance vaccine administration from the resulting death. It was difficult to tell whether this was to avoid the negative mainstream media perceptions of being *vaccine hesitant* or *anti-vax*, to distract potential blame being levelled at the care organisation or healthcare provider who authorised and administered the vaccine, or was simply because they had an honest[5] belief in absolute vaccine infallibility. For 8 recipients[6], even absent evidence to support the assertion, it was reported categorically that the vaccine could not have had any causal relationship to the recipient's death. For 4 recipients[7] it was claimed, even in spite of evidence to the contrary, that COVID had caused their deaths because the vaccine had *insufficient time to save their lives*. For many of the elderly and infirm, the description of death often asserts a pre-existing or age-related condition as the more likely cause of death, including cancers and long-standing cardiac pathologies[8]. Also, for 12 recipients (5%) we are expressly told that one or more *negative* COVID-19 PCR test results were returned in the hours or days prior to the vaccine recipient's death. In spite of the fact that only 11 (4%) present with a test-confirmed and current COVID-19 infection, all 250 people in this interim collection were reported as COVID-19 deaths. This means that all, even those who received one or more negative test results, are erroneously counted in the officially reported national COVID-19 death tally.

6. Vaccine-related death reports 2017-2021

We downloaded and reviewed VAERS datasets for the years 2017-2021. Reports of possible vaccine-related deaths averaged 180 annually between 2017 and 2020 (Figure 7), but have risen more than 900% in just the first 3 months of 2021. Of the 1694 vaccine-related death reports recorded so far in 2021, 1644 (97%) relate to COVID-19 vaccines. Only 50 reports (3%) refer to a non-COVID-19 vaccine; with influenza (26%)

---

[3] E.g.: 940822 where the VAERS call centre staff member concludes on the basis of what they were told that *it is medically not possible to make meaningful causality assessment* and *it is unlikely the vaccine could have contributed to the death of the patient based on the known safety profile*.

[4] E.g.: 958322 whose record describes only that shortly after receiving his first Pfizer\Biontech vaccination the 62yo gentleman *began shaking and became unresponsive* and died later that same day; and 930466 whose narrative describes *fever, shortness of breath and chest pain that resulted in a heart attack a few hours after vaccination* as the progression of post-vaccination symptoms leading to an 82yo woman's death.

[5] and unsound

[6] VAERS-IDs: 917117, 917790, 917793, 924464, 926797, 935343, 964629 and 962714.

[7] VAERS-IDs: 917790, 937127, 937152 and 937186.

[8] E.g.: 924464 - lung cancer; 926797 - significant cardiac issues; 930487 - acute heart attack; 951518 - significant deterioration of physical and mental state due to psychogeriatric disease; 964629 - metastatic cancer; 932898 - cardiac arrest due to ongoing cardiac disease.

and zoster[9] (12%) vaccines most frequently identified, but almost half (48%) unspecified by the reporter. Figure 8 shows that the vaccines receiving the most attention overall during the 2017-2021 period were the influenza vaccines with a total of 203 reports during the five consecutive years - an average of 40 per year, but still far from the volume of COVID-19 reports recorded in just the first three months of 2021.

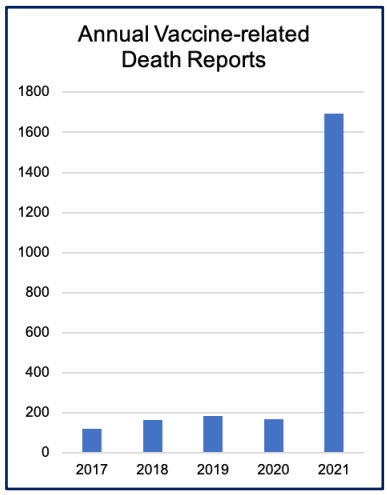


Figure 7: Annual vaccine-related death reports in VAERS (2017-2021)

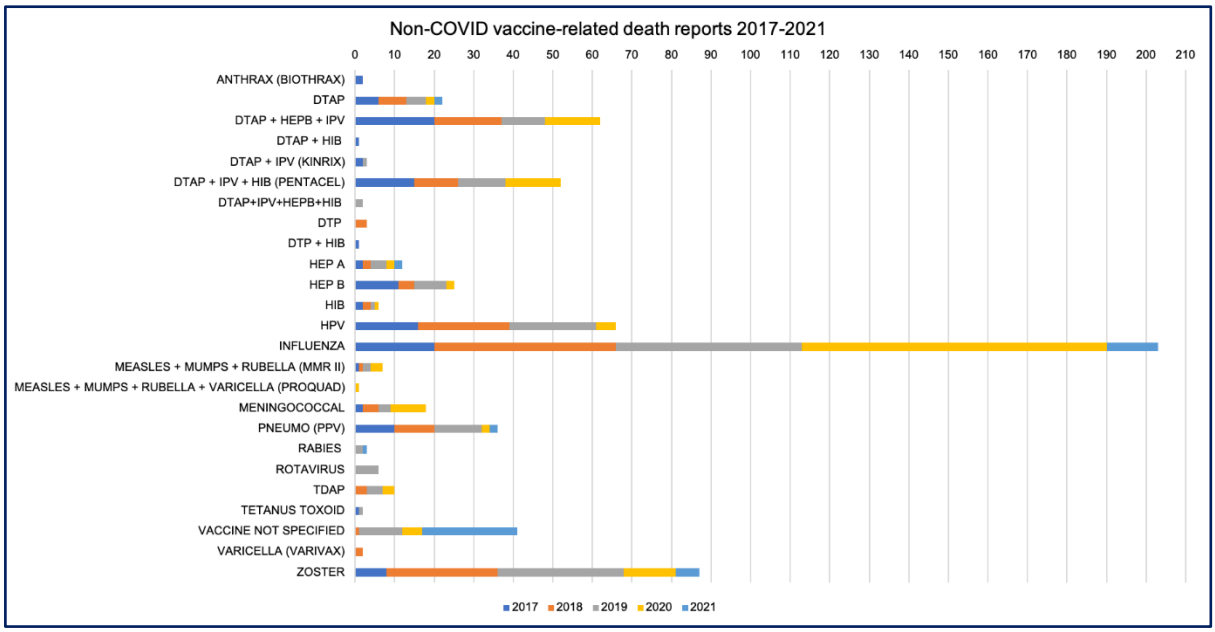


Figure 8: Non-COVID vaccine-related death reports (2017-2021)

[9] Herpes Zoster is more commonly known as *shingles* and is a reactivation, in adults, of the childhood varicella *chicken pox* virus. Several studies have confirmed that infection with chicken pox during childhood produces a significant degree of life-long immunity that is preventative for shingles in later life, and that universal childhood vaccination for chicken pox (which actively prevents infection with the natural chicken pox virus) has resulted in a dramatic increase in moderate to severe shingles diagnoses for middle aged and older adults.

In order to identify the scale of increase in vaccine adverse event reporting for the COVID-19 vaccines we must consider the number of doses administered per each VAERS death report, and the number of reports per million vaccinations administered in the same population for other vaccines. We collected data[10] for the total number of influenza vaccinations administered during the 2017-2020 period from the USA's *Centres for Disease Control* (CDC), and COVID-19 vaccination doses administered in the USA during the first three months of 2021 from the USA Department of Health's COVID Dashboard. These data are shown in Figure 9. We found that as the number of doses of influenza vaccine being administered annually was increasing (from 146mil in 2017 to 174.5mil in 2020), the number of VAERS reports suggesting a link between influenza vaccination and a vaccination-temporal death also increased. Overall and represented by the orange line in Figure 9, the number of doses administered per VAERS death report dropped from 7.3mil/report in 2017, to 2.3mil/report in 2020. This equates to an increase from 0.1 to 0.4 reports per million doses administered between the years 2017 and 2020 which is indicated by the blue line in Figure 10.

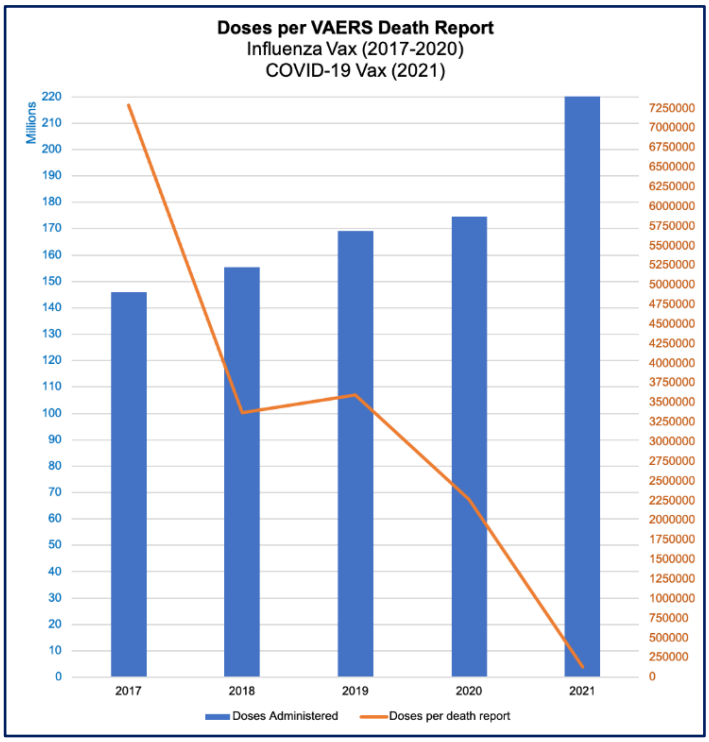


Figure 9: Doses Administered per VAERS Death Report (2017-2020)

[10] https://www.cdc.gov/flu/prevent/vaccine-supply-historical.htm

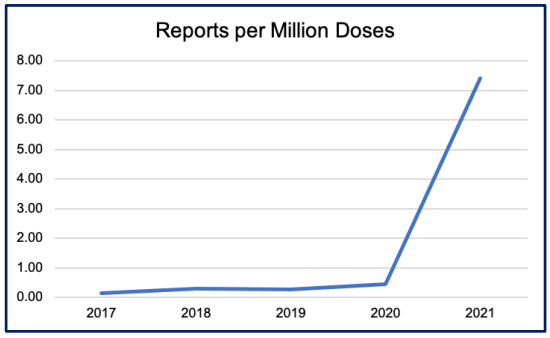


Figure 10: VAERS Death reports per million doses administered

In stark contrast, for COVID-19 vaccines there is one VAERS death report for each 135,000 administered doses (orange line in Figure 9). This represents a staggering 1677% increase in VAERS death reporting for COVID-19 vaccines, or as shown by the blue line in Figure 10, an increase of 7 reports per million doses administered in just the first three months of 2021. If this reporting trend continues, there could be at least 6500 individual VAERS death reports by the end of 2021, which would represent a 3400% increase in reports compared to the last five years.

7. The media narrative and "Fact checking"

During early May television reports, such as one made by Tucker Carlson on FOX News[11], suggested we should consider the number of adverse event and death reports being recorded in the VAERS database for COVID vaccines when deciding whether young and healthy people who are not otherwise at risk from COVID-19 should even receive these medications. Tucker asks a number of simple but relevant questions in regards to the social, political and potentially legal coercion being used to promote the taking of COVID vaccines: "How many people have died after taking COVID vaccines?", "what *are* the potential risks from taking these vaccinations?" and "what do we really know *about* the potential risks from taking these vaccinations?". These are all questions that should be asked when considering whether to take any medication; whether that medication is an antidepressant, statin, or even a vaccine. Carlson's thesis was that when we consider the dramatic rise in adverse event and death reports for COVID vaccines, as supported by our analysis in this work, the situation for COVID vaccines is demonstrably worse than for any other commonly administered large-volume vaccine like those administered for influenza in our example in Figure 9. Carlson goes to great pains to carefully point out that it is the VAERS data itself that shows that more deaths have been reported for COVID-19 vaccines than any other vaccine during the last 15 years, and that what he is calling for is simply some level of government and independent scrutiny to assess whether the increased VAERS reports are indicative of a problem. He also provides discussion on the alternate viewpoints proposed by others that seek to explain away some of the excessively high number of deaths in the over-65 age group: for example, that it could be coincidence, or may be wholly expected, that some elderly recipients died shortly after receiving COVID injections. In any event, the questions being asked here are those which are normally asked of any new medication. They are important and necessary and should not be waved away simply by virtue of an application of the term 'vaccine'.

[11] https://video.foxnews.com/v/6252794642001#sp=show-clips

Health professionals are expected to warn patients regarding likely and possible side effects for any drug or clinical intervention. They cannot perform this important and critical task and enable our ability to provide *informed consent* in circumstances where that data is not being collected or analysed, or where discussion of side effects and outcomes is being stifled or branded as *misinformation* in the public arena.

Self-titled *fact checkers* and journalists in the mainstream media immediately discredited Carlson's (and other's) narratives where the VAERS data was concerned. They imputed that VAERS was a *breeding-ground for anti-vaccine misinformation* and pointed to the twitter posts of generalist doctors as vaccine *experts* that rejected Carlson's VAERS death claims[12] by claiming all the deaths were *coincidence* and asserting unproven facts about ongoing death rates, and without also pointing out that the same *expert* in a subsequent post acknowledges that VAERS data was used to identify the clotting issue with the Johnson & Johnson COVID-19 vaccine[13] (McCarthy, 2021). It is incredible to decry VAERS as rubbish self-reported nonsense when that data suggests something that goes against your particular views, while also suggesting it provides data that was relevant or helpful in other circumstances. Other journalists directed readers to VAERS' own disclaimers and the fact that anyone can report an adverse reaction to VAERS to say that *any number of its reports have nothing to do with the vaccine* and assert that this also means *the vaccines haven't been linked to* or *did not cause* the deaths (Dunlop, 2021; Dupuy, 2021; Walsh, 2021). It would also be factual to say that they haven't been disconnected or disproved as potentially causal in the deaths either. However, not one journalist paused to acknowledge this opposing truth. Several *fact checkers* acknowledge that some people experience allergic reactions to the vaccines, and say the VAERS data shows this most often occurs within 30 minutes of administration (Jaramillo, 2021). They also report that these serious adverse reactions occur in only *2 to 5 people per million vaccinated*, which would be only 0.0005% (Jaramillo, 2021). The language and intonation used by these *fact checkers* is strongly opposed to any idea that an allergic reaction, or *anaphylaxis*, to a vaccine could lead to death. They describe use of VAERS data in any way that might suggest these vaccines might result in even a single allergic reaction that causes death as *misuse*, and *misinformation* - even though our analysis shows that a vaccine allergic reaction is the most likely cause for the symptoms and patient outcomes described for at least 13 of the 250 deaths reviewed in this work (5%), who in each case strongly reacted either shortly after receiving the injection or within the first 4 hours, and died between 30 minutes and 4 days later.

It should be noted that many of the self-titled *fact checkers* are simply mainstream media journalists and other online content creators and opinion-makers[14]. They often name and shame those who speak out against a particular policy or public narrative for not having qualifications appropriate to the scientific or medical content in discussion (Jaramillo, 2021), while also providing what they claim are scientific or medical *facts* from a soapbox similarly absent of any relevant inculcation (Noorchashm, 2021). Either way,

---

[12] https://twitter.com/Craig_A_Spencer/status/1390113877128531970?s=20

[13] https://twitter.com/Craig_A_Spencer/status/1390115599204896768?s=20

[14] This is certainly the case for most who post at https://www.factcheck.org, including the prolific *fact check* poster *Catalina Jaramillo,* a pre-COVID NPR reporter who berates others who do not present with scientific or medical qualifications while hiding behind her journalism major with aspirations in the domains of environmental issues and public policy but entirely lacking qualifications in immunology or medical science to support her own opposing viewpoints. The same is also true at https://factcheck.afp.com where career journalists and digital verification editors like *W.G. Dunlop* dispense personal opinion under the banner of COVID *fact checking* on a range of highly technical medical topics for which they possess no training or relevant qualifications (https://www.linkedin.com/in/w-g-dunlop-aa867920)

we believe the *fact checkers* should be treated with the same degree of scepticism and distrust they recommend we employ when reading any of the sources which they so strongly disprove of.

8. Conclusions

This report presented information derived from analysis of the first 250 COVID-19 vaccine related deaths reported in the VAERS database. While interim in nature, there are sufficient reports of reasonable quality, with 72% authored by health service employees, to support further analysis to potentially answer any number of hypothetical questions. Because the sample is heavily biased - being made up only of those vaccinated early, namely the elderly, those with significant or chronic health conditions and frontline health service staff – the clinical results are not generalisable. But there are some important findings. that the only patients where a vaccine allergic reaction be ruled out as contributing to death were 34 (14%) who were all either already bedridden, at end of life, and expected to die anyway from a serious comorbid like lung cancer or were on palliative hospice care. We also found that for at least 13 of the 250 deaths (5%), a vaccine allergic reaction was indisputably the most likely direct cause for the symptoms and patient outcomes described. Our ongoing work will continue to process all 1644 reported deaths before going on to review the almost 28,000 significant adverse event reports. We are seeking to identify and investigate relationships in the data between different singular and grouped pre-existing conditions and the COVID-19 vaccines, and to further code the narrative clinician's notes to determine whether answers can be found to the public hypotheses surrounding their continued use and role, if any, in the events that have been reported. Our work has also highlighted the vast difference in transparency and content between the data provided by the USA and that of the UK and Australia. The quantity and quality of data provided by the USA VAERS dataset is capable of supporting meaningful research, while the sparsity of data provided by the UK and Australia doesn't even allow the most basic of conclusions to be drawn. Public pressure should be directed towards the governments of the UK and Australia to provide greater granularity of data similar to that of the USA.

References

Blume-Kohout, M. E., & Sood, N. (2013). Market size and innovation: Effects of Medicare Part D on pharmaceutical research and development. *Journal of public economics*, *97*, 327-336.

Boodman, E. (2020). Researchers rush to test coronavirus vaccine in people without knowing how well it works in animals. *Stat News*. Sourced from: https://www.statnews.com/2020/03/11/researchers-rush-to-start-moderna-coronavirus-vaccine-trial-without-usual-animal-testing/

Dermody, T. S., DiMaio, D., & Enquist, L. W. (2020). Vaccine Safety, Efficacy, and Trust Take Time. *Annual Review of Virology*, *8*.

Doshi, P. (2021). Pfizer and Moderna's "95% effective" vaccines—we need more details and the raw data. *The BMJ Opinion*.

Dunlop, W.G. (2021). Tucker Carlson misrepresents government data on COVID-19 vaccines. Last accessed: May 9th. Sourced from: https://abcnews.go.com/Health/wireStory/explainer-activists-target-cdc-vaccine-tracking-system-77563630

Dupuy, B. (2021). Explainer: How activists target CDC vaccine tracking system. Last accessed: May 7th. Sourced from: https://factcheck.afp.com/tucker-carlson-misrepresents-government-data-COVID-19-vaccines

Dyer, O. (2021). COVID-19: EMA defends AstraZeneca vaccine as Germany and Canada halt rollouts. *The BMJ Opinion*. https://doi.org/10.1136/bmj.n883

Eyal, N., Lipsitch, M., & Smith, P. G. (2020). Human challenge studies to accelerate coronavirus vaccine licensure. *The Journal of infectious diseases*, *221*(11), 1752-1756.

Grenfell, R. & Drew, T. (2020). Here's why the WHO says a coronavirus vaccine is 18 months away. Sourced from: https://theconversation.com/heres-why-the-who-says-a-coronavirus-vaccine-is-18-months-away-131213

Hotez, P. J., Corry, D. B., Strych, U., & Bottazzi, M. E. (2020). COVID-19 vaccines: neutralizing antibodies and the alum advantage. *Nature Reviews Immunology*, *20*(7), 399-400.

Jaramillo, C. (2021) Viral posts misuse VAERS data to make false claims about COVID-19 vaccines. Sourced from: https://www.factcheck.org/2021/03/scicheck-viral-posts-misuse-vaers-data-to-make-false-claims-about-COVID-19-vaccines/

Kennedy, R. (2019). CDC Recommended vaccine Schedule 1986 vs 2019. Sourced from: https://childrenshealthdefense.org/child-health-topics/known-culprit/vaccines-culprit/cdc-recommended-vaccine-schedule-1986-vs-2019/

Kremer, M., & Snyder, C. M. (2003). *Why are drugs more profitable than vaccines?* (No. w9833). National Bureau of Economic Research. Sourced from: https://www.nber.org/system/files/working_papers/w9833/w9833.pdf

Lanese, N. (2020) Researchers fast-track coronavirus vaccine by skipping key animal testing first. *LiveScience*. Sourced from: https://www.livescience.com/coronavirus-vaccine-trial-no-animal-testing.html

Le, T., Andreadakis, Z., Kumar, A., Roman, R., Tollefsen, S., Saville, M., & Mayhew, S. (2020). The COVID-19 vaccine development landscape. *Nature Reviews*. Sourced from: https://www.nature.com/articles/d41573-020-00073-5

Magee, C. (2021). Top 10 COVID-19 Vaccine Myths. *Understanding Animal Research*. Sourced from: https://www.understandinganimalresearch.org.uk/news/communications-media/top-10-COVID-19-vaccine-myths/

Mahase, E. (2020). COVID-19: Vaccine trials need more transparency to enable scrutiny and earn public trust, say experts. *bmj*, *371*.

McCarthy, B. (2021). Tucker Carlson's misleading claim about deaths after COVID-19 vaccine. Last accessed: May 6th. Sourced from: https://www.politifact.com/factchecks/2021/may/06/tucker-carlson/tucker-carlsons-misleading-claim-about-deaths-afte/

MHRA, (2021). Coronavirus vaccine - weekly summary Yellow Card reporting - 15 April 2021. Sourced from: https://www.gov.uk/government/publications/coronavirus-COVID-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

Miller, E. R., Moro, P. L., Cano, M., & Shimabukuro, T. T. (2015). Deaths following vaccination: what does the evidence show?. *Vaccine*, *33*(29), 3288-3292.

Noorchashm, H. (2021) Fact-checking factcheck.org's Ms. Catalina Jaramillo: Part 1. Last accessed: May 5th. Sourced from: https://noorchashm.medium.com/fact-checking-factcheck-orgs-ms-catalina-jaramillo-b69ebebb9996

Østergaard, S. D., Schmidt, M., Horváth-Puhó, E., Thomsen, R. W., & Sørensen, H. T. (2021). Thromboembolism and the Oxford–AstraZeneca COVID-19 vaccine: side-effect or coincidence?. *The Lancet*. https://doi.org/10.1016/S0140-6736(21)00762-5

Plotkin, S., Robinson, J. M., Cunningham, G., Iqbal, R., & Larsen, S. (2017). The complexity and cost of vaccine manufacturing–an overview. *Vaccine*, *35*(33), 4064-4071.

TGA, (2021) COVID-19 Vaccine weekly safety report - 07-04-2021. Sourced from: https://www.tga.gov.au/periodic/COVID-19-vaccine-weekly-safety-report-07-04-2021

Varricchio, F., Iskander, J., Destefano, F., Ball, R., Pless, R., Braun, M. M., & Chen, R. T. (2004). Understanding vaccine safety information from the vaccine adverse event reporting system. *The Pediatric infectious disease journal*, *23*(4), 287-294.

Walsh, J. (2021). Tucker Carlson says vaccine-related deaths may be abnormally high - but vaccines haven't been linked to deaths. Last accessed: May 5th. Sourced from: https://www.forbes.com/sites/joewalsh/2021/05/05/tucker-carlson-says-vaccine-related-deaths-may-be-abnormally-high---but-vaccines-havent-been-linked-to-deaths/

WHO, (2020). WHO COVID Timeline. Sourced from: https://www.who.int/news/item/27-04-2020-who-timeline---COVID-19

Wise, J. (2021). COVID-19: European countries suspend use of Oxford-AstraZeneca vaccine after reports of blood clots. *The BMJ Opinion*. https://doi.org/10.1136/bmj.n699

Wouters, O. J. (2020). Lobbying expenditures and campaign contributions by the pharmaceutical and health product industry in the United States, 1999-2018. *JAMA internal medicine*, *180*(5), 688-697.

Yin, W. (2008). Market incentives and pharmaceutical innovation. *Journal of Health Economics*, *27*(4), 1060-1077.