9-Aug-2021

Re: Updated Report of UK Yellow Card data for COVID-19 vaccines up to 30th June 2021

Dr. June Raine, Medicines and Healthcare Products Regulatory Agency

cc.: **Dr. Sarah Branch**, MHRA Director of Vigilance and Risk Management of Medicines

cc.: Professor Anthony Harnden, JCVI Deputy Chair, University of Oxford

cc.: Committee on Human Medicines Chair and COVID-19 Vaccines Benefit Risk Expert Working Group **Professor Sir Munir Pirmohamed** MB ChB (Hons) PhD FRCP FRCP (Edin) FBPhS, FFPM (Hon) FMedSci, David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

cc.: Chemistry, Pharmacy and Standards Expert Advisory Group Chair, **Professor Yvonne Perrie** BSc Hons MRPharmS FAPS FSB PhD Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde

cc.: Clinical Trials, Biologicals and Vaccines Expert Advisory Group Chair, and COVID-19 Vaccines Safety Surveillance Methodologies Expert Working Group Chair **Dr Siraj Misbah** MBBS (Hons) MSc FRCP FRCPath, Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals & Chair of the Clinical Trials, Biologicals & Vaccines Expert Advisory Group (CTBVEAG) & Member of the Commission on Human Medicines (CHM)

cc.: Clinical Trials, Biologicals and Vaccines Expert Advisory Group Lay Representative and Patient Advocate, Mrs **Madeleine Wang** BA (Hons)

cc.: Infection Expert Advisory Group Chair and COVID-19 Therapeutics Expert Working Group Chair, **Professor Jonathan S Friedland** MA PhD FRCP FRCPE FRCPI FESCMID FMedSci Deputy Principal, St. George's, University of London

cc.: Infection Expert Advisory Group Lay Representative, **Ms Hilary A Shenton** CPFA. Retired Secretary to the School of Medicine, University of Sheffield

cc.: COVID-19 Therapeutics Expert Working Group and CHM Lay Representative, **Ms Susan Bradford**

cc.: Neurology, Pain and Psychiatry Expert Advisory Group Chair, **Professor Malcolm R Macleod** BSc MBChB MRCP PhD FRCP (Edin) Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

cc.: Paediatric Medicines Expert Advisory Group Chair, **Professor Steven Cunningham** MBChB PhD FRCPCH Professor of Paediatric Respiratory Medicine, University of Edinburgh and Honorary Consultant, Royal Hospital for Children and Young People, University of Edinburgh, Edinburgh

cc.: Paediatric Medicines Expert Advisory Group Lay Representative, **Ms Sara Payne** BA CPE LPC, Solicitor

cc.: Pharmacovigilance Expert Advisory Group Chair, **Professor Jamie Coleman** MD MA (Med Ed) FRCP FBPhS Professor in Medical Education/Consultant Clinical Pharmacologist, University of Birmingham

cc.: Pharmacovigilance Expert Advisory Group Lay Representative – Patient advocate, **Mrs Madeleine Wang**

EXECUTIVE SUMMARY

1. The MHRA has statutory responsibility for undertaking post-authorisation safety monitoring in the UK and **operating a transparent process**, summarising safety data to the public. It is required to **rapidly** detect new side-effects, a change in the nature of known side-effects, factors that increase the chance of having side-effects and **take any necessary action to minimise risk to individuals**, after weighing risks against expected benefits. Such actions can include **adding warnings** to product information, **restricting** or **suspending** the use of a product and **communicating** information to healthcare providers and patients.

2. By not providing age- and gender-stratified safety information, nor reporting deaths or reactions occurring within certain timeframes of vaccination (within 12 hours, 24 hours, 48 hours, 1 week, 2 weeks, etc.), the UK Government's Yellow Card system is **non-transparent** and not fit-for-purpose as an early warning system. These omissions in data collection and/or reporting mean that **basic conclusions about safety cannot be drawn**. Consequently, **the public and trial participants are not fully informed of the potential risks of taking a COVID-19 vaccine and are unable to give fully informed consent**. The public, healthcare workers and MHRA/CHM cannot rely on the system's reporting to reveal COVID-19 vaccine mortality and morbidity. A comprehensive overhaul of the Yellow Card system is required.

3. Clear safety signals can be discerned from data in safety surveillance systems in the US and EU:

- **Death reports per dose of COVID-19 vaccines are approx. 29 times higher than for influenza vaccines**.
- The high number and rate of death reports coupled with a **tight temporal relationship** to vaccination and the inability to rule out a vaccine reaction lends weight to a **causal relationship** between COVID-19 vaccination and death: in >65 year olds, 80% of a sample of death reports occurred within 1 week of vaccination.
- At 1 per 100,000 injections, rates of **allergic reactions are 10 times higher** with the Pfizer and Moderna COVID-19 vaccines than with other types of (non-COVID) vaccine.
- Males below the age of 65 years, but especially in **younger males i.e. 12-17 year olds, are at increased risk of myocarditis compared with females**.
- The European Medicines Agency has identified **Guillain-Barré Syndrome as a potential risk from the AstraZeneca COVID-19 vaccine** and is adding a warning to the product information to communicate to healthcare workers and patients that 'Vaccinated persons need to seek immediate medical attention if they develop weakness and paralysis in the extremities, possibly progressing to the chest and face, after vaccination with Vaxzevria, as these could be signs of Guillain-Barré Syndrome'.

4. Following Freedom of Information requests and analysis of public empirical evidence in the UK we can discern:

- **Death report rates per million doses are approximately 28 times higher for COVID-19 vaccines** than for influenza vaccines in the UK. This unfortunately does not support MHRA statements that the number of suspected adverse drug reactions so far is not unusual for an immunisation programme of this scale.

- The **COVID-19 vaccines may be responsible for the COVID-labelled mortality this past winter (at least 24,000 deaths) in England** and that **vaccines are ineffective in reducing mortality** (we observe more mortality not less two weeks after full vaccination). This number of deaths is clearly far higher than the 1,490 deaths reported to the Yellow Card system.
- **COVID-19 deaths per million population are significantly higher in the half of all countries globally with above average percentage of their population vaccinated** for COVID-19.
- Real world data (from Scotland and Israel) provide evidence of the **link between COVID-19 vaccination and increases in COVID-19 cases**. More cases are occurring than would have occurred without vaccination and most cases are occurring in the vaccinated. **Rather than vaccination protecting the vulnerable, therefore, in fact, the opposite is apparent**. Vaccine-associated enhanced disease, identified before rollout as a potential risk by MHRA, appears to be evident and needs further investigation.
- The **peaks in deaths within 28 days of vaccination** in Scotland **correspond to vaccination rates in persons 70 years and over having their first or second dose**.
- Calls for ambulances for **cardiac and respiratory arrest** and for **people falling unconscious/syncope** have increased above baseline since the shelf life for thawed vials of the Pfizer COVID-19 vaccine was increased from 5 to 31 days, following an MHRA decision, and since rollout started in under 30 year olds. Syncope is one of the pre-death symptoms noted by examination of USA death reports.

5. Our review of publicly reported data from the UK Government's Yellow Card system raises further concerns as follows, that warrant further investigation:

- Of the 1,490 death reports, there are 482 fatalities reported as 'death' or 'sudden death' **without a specific cause of death reported**. Sudden death would be most likely to occur from haemorrhagic, thrombo-embolic or ischaemic events. Without follow-up, **risks of specific events from the COVID-19 vaccines will be underestimated**.
- Rates of **anaphylaxis** with COVID-19 vaccines in the UK (Pfizer, Moderna and Astra-Zeneca vaccines) are estimated to be 1.5 per 100,000 injections. This rate is even higher than the (already high compared to previously used vaccines) estimate (1 per 100,000) in US for Pfizer and Moderna vaccines only.
- The many neurological reactions reported are suggestive of **neurodegenerative pathology**.
- The number and widespread location of pain reports, the reports of **Paroxysmal Extreme Pain Disorder** (PEPD) (excruciating pain that normally has onset in infancy or in utero, but which through a Freedom of Information request is identified as **occurring in adults**) and **large numbers of reports of PEPD-like symptoms** (e.g. loss of consciousness/syncope, flushing, eye pain, jaw pain) may be suggestive of spurious sodium channel depolarisation.
- The reactivation of latent viruses (e.g. herpes zoster/shingles) is strongly suggestive of **vaccine-induced immunocompromise**, as is the high number of immune-mediated conditions reported including Guillain-Barré Syndrome and Multiple Sclerosis. Compromised immunity post-vaccination may have contributed to the observed increases in SARS-CoV-2 infections post-vaccination.
- There have been 469 reports (and 3 fatalities) in the UK of infective or inflammatory cardiac conditions, including **myocarditis**, **endocarditis** and **pericarditis**. The UK public safety summaries do not indicate in how many of these individuals the reaction has resolved. From myocarditits reports

to the EU safety surveillance system we observe that nearly a **quarter of myocarditis cases are unresolved**.

- Although being identified by MHRA before vaccine rollout as a potential risk and being part of pharmacovigilance plans for monitoring, **Vaccine Associated Enhanced Disease and Vaccine Associated Enhanced Respiratory Disease appear not to have been publicly reported on in safety summaries**.

6. Risk-benefit balance decisions may have been based on invalid vaccine impact data: a **vaccine impact study** estimating deaths averted by the vaccines **was based on key assumptions that empirical evidence refutes**. **The risk-benefit balance of COVID-19 vaccines must be urgently re-assessed by MHRA/CHM/CHM EAGs** using real world empirical evidence and assuming use of known effective treatment protocols. To-date, risks from COVID-19 vaccines may be underestimated and expected benefits over-estimated.

Pending full **follow-up** of deaths, **investigation of vaccine safety and efficacy and of vaccine impact, and re-assessment of risk-benefit balance,** MHRA/CHM, in line with its statutory obligations, must **act to minimise risk to individuals** by:

- **Suspending** the COVID-19 vaccines rollout in all children and adults and any plans for booster vaccinations.
- **Suspending** enrolment in trials in UK of COVID-19 vaccines.
- **Communicating** to healthcare workers and the public the potential risk of Guillain-Barré Syndrome and the symptoms for which patients should seek immediate medical attention.
- **Communicating** to healthcare workers and the public known treatment protocols for COVID-19 (acute and long) and for post-vaccination side-effects, including Covid Vaccination (CoVAC) Syndrome, so that people can receive timely care.
- **Conducting** a complete overhaul of the Yellow Card system.

Dear Dr. Raine,

Re: Updated Report of UK Yellow Card data for COVID-19 vaccines up to 30th June 2021

Thank you for your letter of 22nd July 2021, in reply to our urgent report of 9th June 2021 regarding the Yellow Card data. We have updated our analysis with suspected adverse reactions (ADRs) to 30th June 2021, after nearly 45 million people have received their first dose, and 33 million both doses (compared to 39 million and 24 million, respectively, in our last report to 26th May 2021).

Thank you also for the links to the strategy from the Commission on Human Medicines (CHM) Expert Working Group on how monitoring of COVID-19 vaccine safety is being performed(1), and further information about CHM. In the strategy, we note:

- That MHRA is charged with operating a **transparent process** and providing regular **up-to-date summaries of the safety experience to the public**.
- The need to very quickly be able to establish if serious events that are **temporally related** to vaccination are merely coincidental association.
- That among the CHM responsibilities are 'advising on the impact of new safety issues on **the balance of risks and benefits** of licensed medicines – e.g. adding warnings, restricting or suspending use of a medicine'.
- That to assess whether there is continued benefit-risk balance, in addition to post-marketing safety of vaccines, **key further information is real world effectiveness and population impact** of the vaccines.
- That MHRA is required to **rapidly** detect, confirm, characterise and quantify any new risks – new side-effects, a change in the nature of known side-effects, factors that increase the chance of having side-effects - and **take any necessary action to minimise risk to individuals**, after weighing risks against expected benefits. Such action may include adding warnings, restricting **or suspending use of a medicine or sending communications to health care providers and patients**.
- That the means by which the strategy is effected include four main strands: 1) Enhanced passive surveillance via the Yellow Card system, 2) Data from a 20% sample of GP practices (CPRD Aurum Dataset), 3) Yellow Card Vaccine Monitor and 4) Epidemiological studies. The latter three means **would not however provide particularly rapid information**: the GP practice data relies on timely recording in GP IT systems of vaccinations given and of diagnoses for illness, which are likely delayed with vaccinations being given by external vaccination centres and patients finding it difficult to obtain appointments with their GP preventing/delaying diagnoses; the Yellow Card Vaccine Monitor, although important, is used in specific populations under-represented in trials, and will not encompass/generate data of relevance to the whole population; and epidemiological studies will only be applied to provide evidence about specific risks and will take time to conduct. Engaging with

academia[1] is noted as another means of monitoring safety by enabling the rapid conduct of epidemiological studies in OpenSAFELY17: we note however that they as yet have not published any vaccine safety studies on the associated website[2].

It would seem that from a strategic viewpoint, therefore, the most rapid system available currently is the Yellow Card system.

You link also to data on the impact of the vaccination campaign in reducing infections and mortality. The report by Public Health England (PHE) and Cambridge University's Medical Research Council Biostatistics Unit covering data to 19 June 2021 infers reduction in mortality of 27,200 people as a result of the vaccination campaign(2). We note that a number of assumptions have been made in their analysis:

1) That the vaccine is assumed to reduce susceptibility to COVID-19, and to reduce mortality once infected. **We are unsure why such assumptions have been made when empirical evidence is available**, and in light of the CHM's recognition of the key importance of real world effectiveness data.

2) That in the no-vaccination scenario no other interventions are implemented to reduce incidence and mortality. **We are uncertain why such an assumption would be made when treatment protocols are available that are known to significantly reduce mortality and that have unparalleled safety profile**, e.g. ivermectin reduces mortality by 62% compared to no ivermectin, average risk ratio 0.38, 95% confidence interval 0.19–0.73; n = 2438; I2 = 49%; moderate-certainty evidence (3).

You indicated the importance of evaluating reports alongside evidence from other sources, so we discuss the updated Yellow Card data by reference to other pharmacovigilance sources, literature and analyses.

1. Death rates following COVID-19 vaccination are substantially higher than with previous vaccines

As of 14th July, there have been **1,490 deaths** reported post-vaccination with the COVID-19 vaccines. This constitutes 237 more deaths since our last report when we requested a halt to the rollout.

We are aware Yellow Card reports do not necessarily imply causality, as indicated in our previous report. The MHRA itself, however, states that the purpose of the Yellow Card system is to be an

[1] PHE and the Health Protection Research Unit in Immunisation at the London School of Hygiene and Tropical Medicine (LSHTM)
[2] https://www.opensafely.org/

early warning system that a medicine's safety may need further investigation[3] and, when urging doctors to report side-effects, you have been quoted as indicating that "There is no need to prove that the medicine caused the adverse reaction, just the suspicion is good enough".[4]

With **1,490 deaths** now reported post-vaccination with the COVID-19 vaccines, **these vaccines are clearly less safe than vaccines we have hitherto known**.

You suggest in your letter that 'some events may have happened coincidentally' and that this is 'particularly the case when millions of people are vaccinated'. The high number of death reports cannot unfortunately be explained by the large scale of rollout. If we compare death report rates following COVID-19 vaccines with those following influenza vaccines, data from the USA (Vaccine Adverse Event Reporting System (VAERS) and v-safe reports) suggests deaths per million vaccinations with the J&J COVID-19 vaccine in 2021 were 55-110 times greater than with influenza vaccine in the 2016-2019 time period (11.0 deaths per million with the former(4) vs 0.1-0.2 deaths per million with the latter).

The J&J vaccine is not used in the UK clearly. Following a Freedom of Information (FoI) request, data for COVID-19 vaccines used in the UK are also available. **Fatalities reported post-COVID-19 vaccine to MHRA are shown to be 169 times more in number than the average for fatalities reported to MHRA over the last 10 years for all other vaccines**[5]. When one considers that the number of seasonal influenza vaccinations given in adults between September 2019 and March 2020 in England was 11,974,864, i.e. approximately one sixth of the number of COVID-19 vaccinations given to-date, this would imply that the **rate of fatalities per dose administered in the UK was in the order of up to 28 times higher with the COVID-19 vaccines than with influenza vaccines**.[6]

Similar evidence is available from the USA: McLachlan et al. 2021(5) report that vaccine doses per VAERS death report for influenza vaccination were 7.3 million doses per death report in 2017, reducing to 2.3 million per death report in 2020, corresponding to an increase from 0.1 death reports per million doses in 2017 to 0.4 such reports per million doses in 2020. By contrast there were 7.4 death reports per million doses of COVID-19 vaccines reported to VAERS in the first three months of 2021(5). Comparing this rate to an average for influenza between 2017 and 2020 of 0.25 death reports per million doses, suggests, again that the **rate of fatalities per dose of COVID-19 vaccines in the USA is approximately 29 times that of influenza vaccines**. The authors estimated at the time of writing that if that trend continued at least 6,500 deaths could be reported by the end of 2021. We note that 6,985 deaths had already been reported to VAERS as of June 25th 2021.

[3] https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/
[4] https://www.theguardian.com/society/2006/may/12/health.medicineandhealth
[5] Source: Joel Smalley letter to his MP, appended to this letter, following a Freedom of Information request
[6] Assuming that fatality rates with influenza vaccines are similar to the average rate for other vaccines.

This seems not to concur unfortunately with the statement in your letter that 'the number…of suspected ADRs reported so far is not unusual for an immunisation programme of this scale'.

Comparing rates of death reports following the new COVID-19 vaccines to rates of death reported in previous vaccination campaigns provides information relevant to establishing a safety signal. Yet in response to another FoI request[7], when asked to provide evidence for your statement that the number and nature of Yellow Cards reported with the new COVID-19 vaccines was not unusual, your response was, "Prior to starting the COVID-19 vaccination programme, information from previous UK vaccination programmes was used to help the MHRA estimate the anticipated volume of Yellow Card reports. However, the incident numbers, including fatal reports from previous vaccination campaigns, are not being used as a comparative measure for the data in the summary report." **In so answering, not only has MHRA not provided the figures requested in this particular FoI request, but MHRA has also demonstrated that it is not operating a transparent system in preparing its summary report to the public.**

2. The tight temporal relationship between COVID-19 vaccination and death suggests causation

Although the Yellow Card system does not appear to systematically record the time since vaccination, the VAERS in the USA does. From that system it is apparent that sporadic event reporting is high in number, as in the UK, ***and*** **that there is a tight temporal relationship between COVID-19 vaccination and deaths**: 15% of deaths occurring within 24 hrs, 22% within 48 hrs and in 37% of deaths, the patient became unwell within 48 hrs of COVID-19 vaccination with an event that led to their death.

Further weight to causality is provided by a detailed analysis by clinically trained reviewers of a sample of VAERS death reports (n=250 out of the 1644 deaths in USA reported to April 2021, the majority of which (67%) were reported by healthcare professionals). The deaths analysed followed an almost equal number of Pfizer and Moderna COVID-19 vaccinations, and **91% of deaths occurred after administration of the first COVID-19 vaccine**. They reported that in only 14% of the deaths could a vaccine reaction be ruled out as a contributing factor in the death(5). **In 203/250 deaths (81%) the vaccine may have been a factor in the death, and in 13/250 deaths (5%) the vaccine was considered the most likely cause of death** as the death occurred either on the same day or within a couple of days of vaccination after a strong reaction soon after vaccination(5). They noted that in a **high number of vaccine recipients the description of their post-vaccine and pre-death symptoms included syncope (loss of consciousness, fainting**). In those aged 65 years and over, 9% died within only 6 hours of vaccination, 18% in <12 hours, 36% died before the following day, **50% died within 48 hours, 80% within 1 week**, 90% within 2 weeks and 100% within 4 weeks(5). The timecourse of emergence of deaths due to different causes has also been noted, with deaths due to allergic reactions occurring between 30 minutes and 4 days of receiving

[7] From Stephen Feldman

vaccination, deaths due to respiratory distress +/- pneumonia symptoms between days 2 and 9, and deaths due to a cardiac event (myocardial infarct, heart attack) occurring between days 5 and 14(5).

The high number of sporadic reports coupled with a tight temporal relationship and the inability to rule out a vaccine reaction lends weight to a causal relationship and provides a safety signal, warranting suspension of the COVID-19 vaccines pending an independent expert investigation.

- *Why is this clear safety signal not being acted upon by MHRA?*

Even if only 5% of the 1,490 deaths reported to MHRA to-date were causally linked to vaccination, this would mean 74 deaths. The last emergency use authorised vaccine in the UK, for swine flu, was suspended after 50 deaths.

In assessing the risk-benefit ratio, the MHRA and CHM may have considered that the number of deaths reported labelled as 'COVID-19' and the estimated deaths averted from the recent vaccine impact study(2) warranted continuation of the vaccine rollout. However, in the UK, there are serious concerns as to the validity of the case definition, the testing system, the operational test performance characteristics (or lack thereof), the analysis of PCR tests regarding cycle threshold used and number and location of primers/probes and of the recording of deaths(6), alongside concerns as to the validity of the assumptions used in the vaccine impact study. This brings into question the validity of the 'COVID' risk data and 'deaths averted by vaccines data' generated and subsequently used to inform risk-benefit calculations.

The risk-benefit ratio estimations need to be urgently revisited by MHRA/CHM/CHM Expert Advisory Groups (EAGs) and independent experts.

3. Deaths within 28 days of COVID-19 vaccination

With regard to our question of 'How many people have died within 28 days of vaccination?', your letter did not relate any specific numbers. We appreciate that the data reported to MHRA will not give the full picture of all deaths within 28 days of COVID-19 vaccination as not all reports will reach MHRA. However, of those that do, the system for monitoring post-vaccine safety data should be able to indicate, in a timely manner, time-to-event data, as these are **critical safety indicators, without which causality cannot be gauged**.

You have indicated that although the time since vaccination is not always provided in Yellow Card reports, for reports of fatalities, where permission is provided, the MHRA follows up in order to ascertain the length of time since the deceased received the vaccine. We would ask, therefore, of the 1,490 post-vaccination deaths reported via the Yellow Card system to-date;

- *For how many of these 1,490 deaths does MHRA have permission to follow up and how many has MHRA followed up*?
- *For how many of these 1,490 deaths does MHRA have the date of vaccination and date of death or date of onset of the event leading to death?*

You state in your letter of 22nd July 2021 that 'we have in place a proactive strategy to continually monitor the safety of COVID-19 vaccines, and through this strategy we are able to rapidly detect, confirm, and quantify any new risks and weigh these against the expected benefits.'

- *How can the risk associated with the COVID-19 vaccines be **rapidly** monitored by MHRA – or indeed by the CHM or its EAGs - when the date of vaccination is not readily available to enable deaths and suspected ADRs occurring within certain timeframes of vaccination to be made publicly available?*
- *Events occurring in close temporal relationship to vaccination lend weight to causality. How can MHRA assess causality without such critical information in a timely fashion?*
- *And, subsequently, how can people make an informed decision about whether or not taking a COVID-19 vaccine is right for them or their dependents without adequate, age- and gender-stratified and timely information about the potential risks? Age- and gender-stratified data and time-to-event data are not made available to the public currently, as should be the case in a transparent early warning system.*

We note that VAERS has a Standard Operating Procedure (SOP) for monitoring of ADR reports specifically for COVID-19 vaccines(7), which also highlights Adverse Events of Special Interest (AESIs) for follow-up. AESIs include death, COVID-19 disease, Guillain-Barré Syndrome, seizure, stroke, narcolepsy/cataplexy, anaphylaxis, vaccination during pregnancy, acute myocardial infarction, myopericarditis, coagulopathy (including thrombocytopenia, disseminated intravascular coagulopathy, and deep venous thrombosis), Kawasaki's disease, multisystemic inflammatory syndrome in children (MIS-C), multisystemic inflammatory syndrome in adults (MIS-A), transverse myelitis, Bells Palsy, and appendicitis. Table 1 indicates ADRs reported for these AESIs in the UK.

Table 1 - ADR reports to UK Yellow Card system (up to 21st July 2021 – Week 26) for Adverse Events of Special Interest identified in US VAERS Standard Operating Procedure for COVID-19 vaccines safety monitoring

AESI term	ADRs	Fatalities
Death	-	1,517
Acute myocardial infarction	89	13
Myocardial infarction	536	77
Anaphylaxis (anaphylactic shock/reaction)	1,194	4
Appendicitis (including appendicitis, noninfective appendicitis and appendicitis perforated)	67	0

AESI term	ADRs	Fatalities
Bell's palsy	879	0
Coagulopathy		
- Deep vein thrombosis (DVT)	1,299	10
- Disseminated intravascular coagulopathy (DIC)	19	2
- Thrombocytopenia (excluding immune thrombocytopenia)	1,018	7
COVID-19 disease (excluding asymptomatic COVID-19 and suspected COVID-19)	1,529	79
Guillain Barre Syndrome	407	2
Kawasaki's disease	0+	0
Multisystemic inflammatory syndrome (Systemic inflammatory response syndrome)	7	0
Myocarditis (incl. myocarditis, infectious myocarditis, viral myocarditis)	237	2
Pericarditis	281	1
Narcolepsy/catolepsy	24	0
Seizure (all types)	1,948	2
Stroke (excl. cerebral venous sinus thrombosis)	1,713	76
- cerebral venous sinus thrombosis	225	26
Transverse myelitis	102	0
Vaccination during pregnancy (exposure before/during pregancy, foetal/maternal/paternal)*	956	-

Abbreviations: AESI, adverse event of special interest; excl, excluding; incl., including

+ Note, however, that swollen lymph glands/lymphadenopathy, a symptom of Kawasaki's disease, was reported in 12,339 ADR reports and swollen tongue, another symptom, in 996 ADR reports.

* Spontaneous abortions were reported in 381 reports, of which 3 were fatal. There was also 1 haemorrhage in pregnancy reported.

We note also the general Guidance for Industry from the FDA that discusses safety signals(8).

- *Please could you provide a copy of the MHRA's SOP for monitoring COVID-19 vaccine suspected ADRs, and indicate how follow-up of deaths and, if done, other AESIs, is conducted and in what timeframes?*

If the Yellow Card system cannot provide timely, age- and gender-stratified time-to-event information, as the VAERS in USA allows (notwithstanding other calls for VAERS to be improved also), we **must** ask ourselves, honestly and openly, the difficult question of whether the UK Yellow Card system is adequate in design and/or execution to satisfy its purpose – as an early warning system. The difference in transparency and content between the US and UK systems has been highlighted by McLachlan et al. 2021(5), who indicate that the sparsity of data in the UK system does not support meaningful research, nor allow basic conclusions to be drawn.

MHRA is not currently able through the Yellow Card System's set-up to operate a transparent process. A complete overhaul of the system is required.

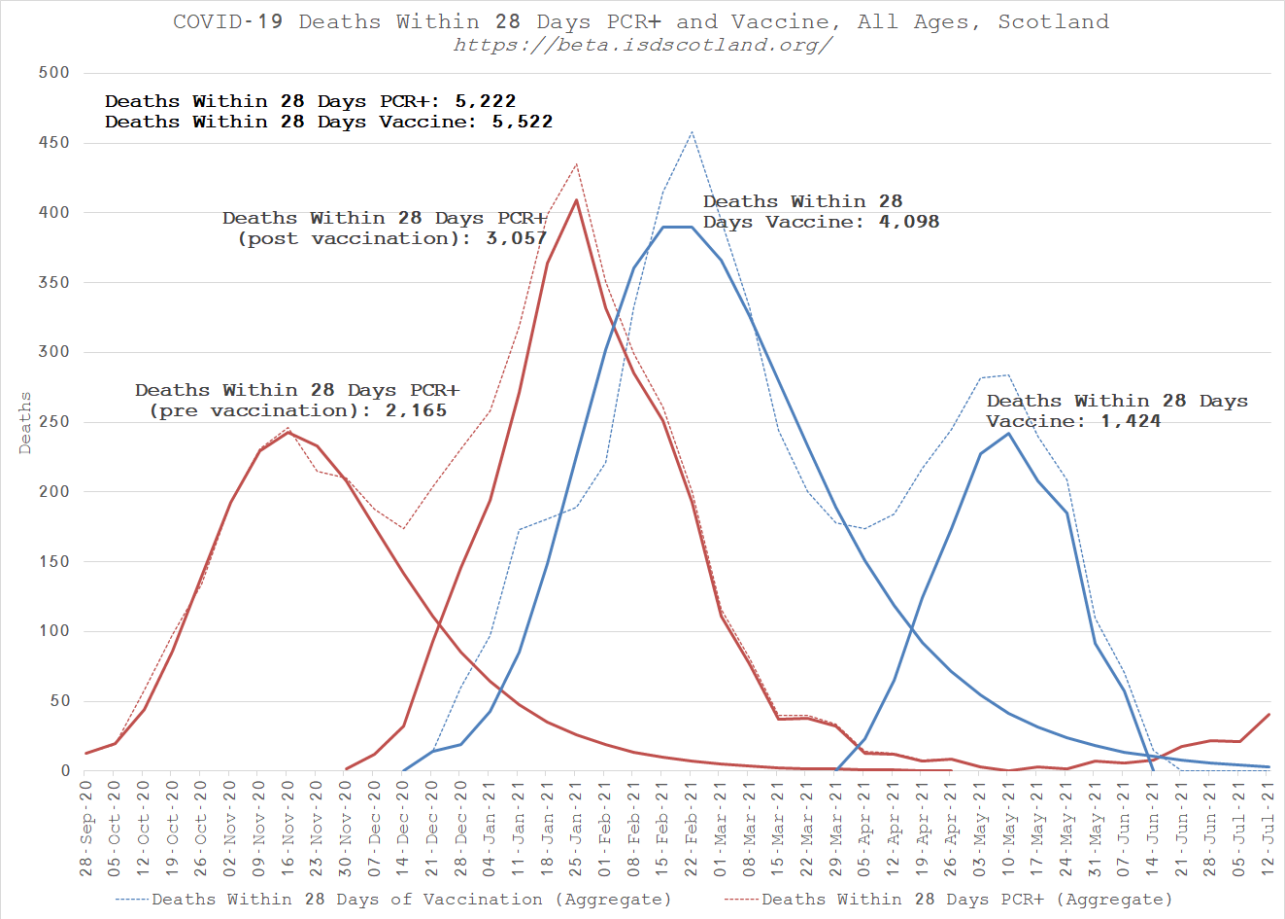
In the unprecendented situation faced, of large numbers of suspected ADR reports from products with only an Emergency Use Authorisation (EUA), it would be understandable that our country's systems might be strained beyond their usual capacity. **Acknowledging this threat to the system's ability to achieve its purpose would be both admirable and honourable, alongside action that mitigated public risk, namely suspending the rollout and EUAs pending further investigation and full follow-up of all deaths and AESIs.**

Scotland – deaths for any reason within 28 days of COVID-19 vaccination

Public Health Scotland (PHS), following FoI requests, has reported that **5,522** people have died for any reason within 28 days of COVID-19 vaccination in Scotland between 8th December 2020 and 11th June 2021 (Moderna COVID-19 vaccine 2; Pfizer vaccine 1877; Astra-Zeneca vaccine 3643)(9). Although providing a breakdown by date of death, the published report and associated spreadsheets still do not allow knowledge of deaths within different time frames of people having been administered a vaccine, so they preclude causality assessment. However, the below graph[8] shows that the number of deaths within 28 days of COVID-19 vaccines (n=5522(9) in blue) now exceeds those within 28 days of a PCR+ test that are ascribed to COVID (n=5,220) (Figure 1).

[8] Source: Data analyst Joel Smalley

Figure 1 – COVID-19 Deaths within 28 days of Positive PCR Test and within 28 days of COVID-19 Vaccine, Scotland



This graph elucidates a number of other phenomena:

1) Doctors[9] are reporting a COVID-like sickness emerging after receiving vaccine (deaths within 28 days PCR+ post-vaccination = 3,057 in the above graph), the distribution of which is very different from naturally occurring COVID infection (deaths within 28 days PCR+ pre-vaccination = 2,165). *See also next section discussing correlation between vaccination and occurrence of COVID cases.*

2) The peak of deaths within 28 days of the first dose of COVID-19 vaccines (blue line, 4,098 deaths) coincides with almost all persons 70 years and over having received their first dose (Figure 1a, page 9 of PHS 2021b (10)).

3) The peak of deaths within 28 days of the second dose of COVID-19 vaccines (blue line, 1,424 deaths) corresponds to almost all persons 70 years and over having received their second dose (Figure 1b, page 10 of PHS 2021b (10)).

[9] For example, Dr. Peter McCullough

These observations suggest that, although deaths for any reason within 28 days of COVID-19 vaccines up to 11th June 2021 did not appear to constitute excess mortality when compared to expected deaths according to previous years by PHS calculations(9), deaths within 28 days of COVID-19 vaccines do correlate with vaccines being received in those aged 70 years and above, with deaths increasing as vaccination proceeds in the >70s.

Furthermore, deaths for any reason within 28 days of COVID-19 vaccines do not appear to have been compared to deaths for any reason in the unvaccinated over the same time periods (i.e. from 8th December 2021) by PHS. The later PHS report comparing vaccinated (1 dose, 2 doses) and unvaccinated cohorts did so from 29th December 2020 onwards, meaning that deaths among the first (most elderly cohort receiving the first dose) vaccinated between 8th December and 29th December may not have been accounted for in this particular comparison(10). The selection of the 29th December 2020 date was based on efficacy grounds, i.e. with vaccination effect expected to occur three weeks after receipt of vaccination. The selection of this date is unhelpful when considering safety, however, as we know from the sample of deaths examined by McLachlan et al. 2021 that 90% of death reports in over 65 year olds died within 2 weeks of vaccination and 80% within 1 week(5).

Overall, this lack of transparency and lack of interrogation of the data by a number of different methods prevents adequate assessment of post-marketing surveillance of COVID-19 vaccines in Scotland.

England – deaths for any reason within 28 days of COVID-19 vaccination

We understand that Public Health England, in response to similar FoI requests, states that they do not hold the information on deaths within 28 days of COVID-19 vaccination.

Again, this demonstrates a lack of transparency and obfuscates adequate assessment of post-marketing surveillance of COVID-19 vaccines.

4. Independent expert analysis shows COVID-19 vaccines may be responsible for the COVID-labelled mortality this past winter, December 2020-March 2021

Mortality in England and Scotland has, however, been extensively and carefully analysed by age cohort by the independent data analyst, Joel Smalley. We append his analysis, sent as an open letter of 16th July 2021 to his Member of Parliament and provide key graphs below showing how deaths in 80+ year olds and care home cohorts track COVID-19 vaccination rates in each particular cohort (Figure 2 for England, Figure 3 for Scotland).

Figure 2 – COVID-19 Vaccinations and Deaths, in 80+ year olds, in Care Homes, and Overall, England

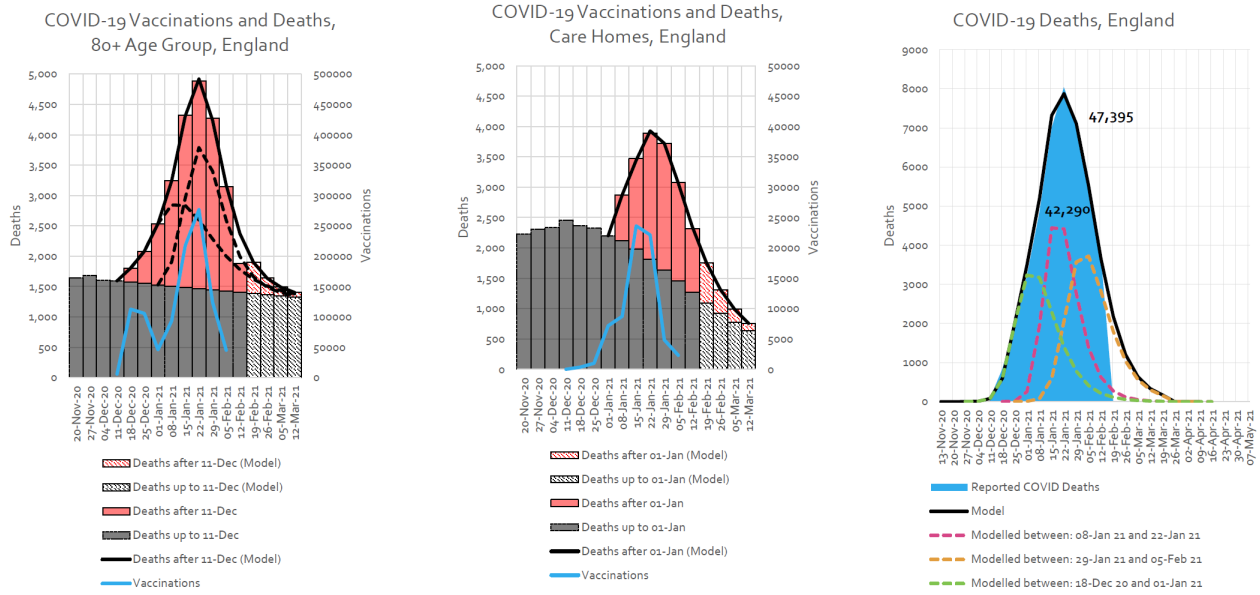
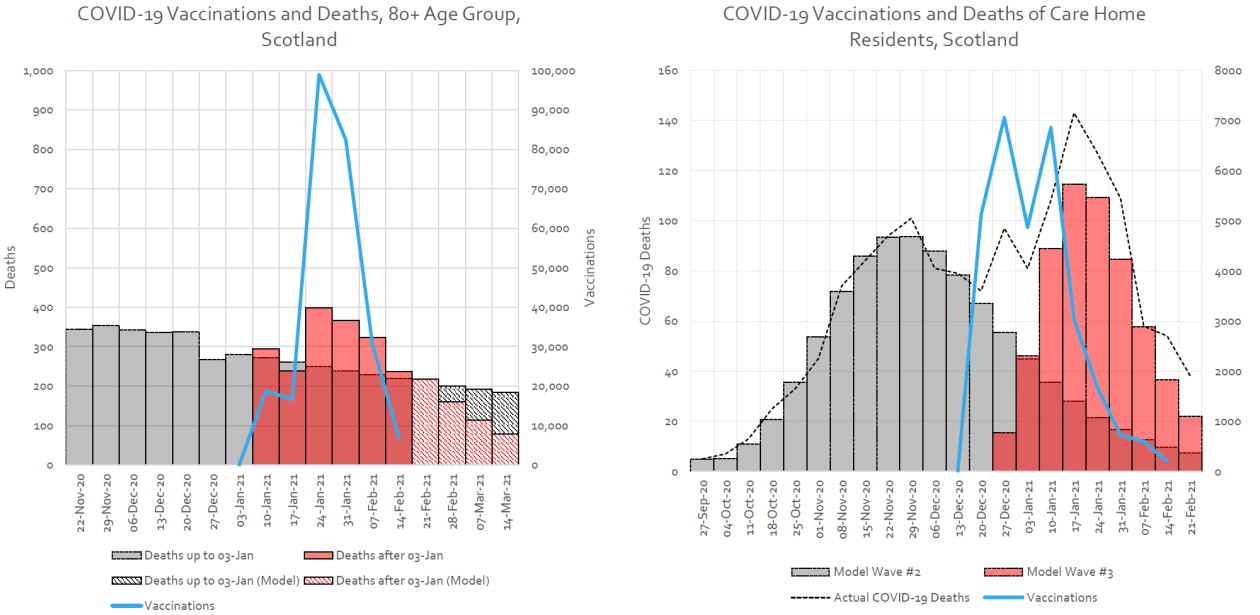


Figure 3 – COVID-19 Vaccinations and Deaths, in 80+ year olds and in Care Homes, Scotland



He indicates that the **'evidence in the public empirical data points towards COVID vaccines not only being ineffective in reducing mortality but also being responsible for the COVID-labelled mortality this past winter'**, and that, '**In England, the deaths reduced by COVID vaccines is zero. The deaths caused by COVID vaccines is at least 24,000**.'

He indicates that the most plausible explanation is that **'vaccination increases the size of the susceptible/vulnerable population and is responsible for the majority of deaths in the winter Gompertz distribution' in England last winter**. Our analysis of the Yellow Card data, with over 65,000 immune system ADRs indicative of immunosuppression, supports this explanation, as do studies – including the original Pfizer study - reporting increased infections immediately post-vaccination.[10] Thus, the occurrence of antibody-dependent enhancement (ADE) or pathogenic priming, whereby disease is enhanced in the vaccinated, with the COVID-19 vaccines appears now to be evident.

We understand from MHRA's Product Assessment Report (PAR) of the Pfizer COVID-19 vaccine, BTN162b2(11), that this **vaccine-associated enhanced disease (VAED)** was already identified as an important potential risk[11], along with **vaccine associated enhanced respiratory disease** (VAERD), and that VAED and VAERD were earmarked for further investigation in the pharmacovigilance plan. Similar risks were identified and pharmacovigilance plans made in the PAR for the AstraZeneca COVID-19 vaccine(12).

- *Please provide a report on the investigations performed and results obtained under these pharmacovigilance plans to monitor VAED and VAERD in Pfizer and AstraZeneca Vaccines.*
- *Have Pfizer and AstraZeneca provided further information on VAED and VAERD? If not, why not, when they were identified as potential risks that should be monitored?*

We understand that these important questions have already been asked of the MHRA 24-Jun-2021[12] but that, six weeks on, the MHRA has still not provided answers. Dr. Engler notes in his email to MHRA that 'it is of grave concern that we may be starting to see some soft signals of the enhancement the MHRA itself raised as a concern', as 'double-vaccinated Covid patients are currently overrepresented in ICUs' seriously ill with COVID and 'a small but rising number of deaths are being observed in those fully vaccinated'. Dr. Engler further notes that 'the data is hard to interpret due to lack of age-stratification and other details'. **Again, this non-transparency in the Yellow Card system puts the public at risk.**

[10] https://www.bmj.com/content/372/bmj.n783/rr

[11] 'Vaccine associated enhanced disease (VAED) including Vaccine associated enhanced respiratory disease (VAERD) has been included as a potential risk. This is a theoretical risk which is relevant to all COVID-19 vaccines based on VAED having been seen in animal models for vaccines developed for SARS-CoV-1 (a similar but not identical virus to SARS- CoV-2, the virus responsible for COVID-19) and also seen in association with use of another respiratory virus vaccine, the Respiratory syncytial virus (RSV) vaccine. There is currently no evidence from non-clinical or clinical data of an association of VAED/VAERD with COVID-19 mRNA Vaccine BNT162b2; this potential risk will be further investigated as part of the pharmacovigilance plan of this vaccine.' 11. MHRA. Public Assessment Report. Authorisation for Temporary Supply. COVID-19 mRNA Vaccine BNT162b2 (BNT162b2 RNA) concentrate for solution for injection.; 2021a June.

[12] Email from Dr Jonathan Engler of 24-Jun-2021 to MHRACustomerServices@mhra.gov.uk with Subject heading 'CSC 56062 Vaccines for Covid19', which was reportedly passed on to MHRA's Vigilance Risk Management of Medicines experts.

- *Please could you indicate why MHRA is silent in relation to further data/analysis on these important safety issues?*
- *Please could you indicate why MHRA has not acted to suspend the COVID-19 vaccines – in line with its statutory obligation to minimise risk to individuals – when MHRA knows there is a potential risk of VAED and VAERD, when temporary authorisations of COVID-19 vaccines are dependent upon further risk evaluation under pharmacoviglance plans, and signals at macro- and on-the-ground levels suggest that the VAED/VAERD concerns could be valid?*

The evidence for claiming that the vaccines are ineffective in reducing mortality is provided by the fact that **we do not observe – in the empirical data - lower than expected mortality two weeks after full vaccination and that, in fact, more mortality is observed**, although on a smaller scale than after the first dose. From this empirical evidence we can see the error in the vaccination impact report(2) - that has no doubt underpinned risk-benefit calculations - that assumed that the vaccine would reduce susceptibility to COVID-19 and reduce mortality once infected.

In view of the evidence provided by this analysis, we would again urgently request that the COVID-19 vaccines be suspended pending investigation.

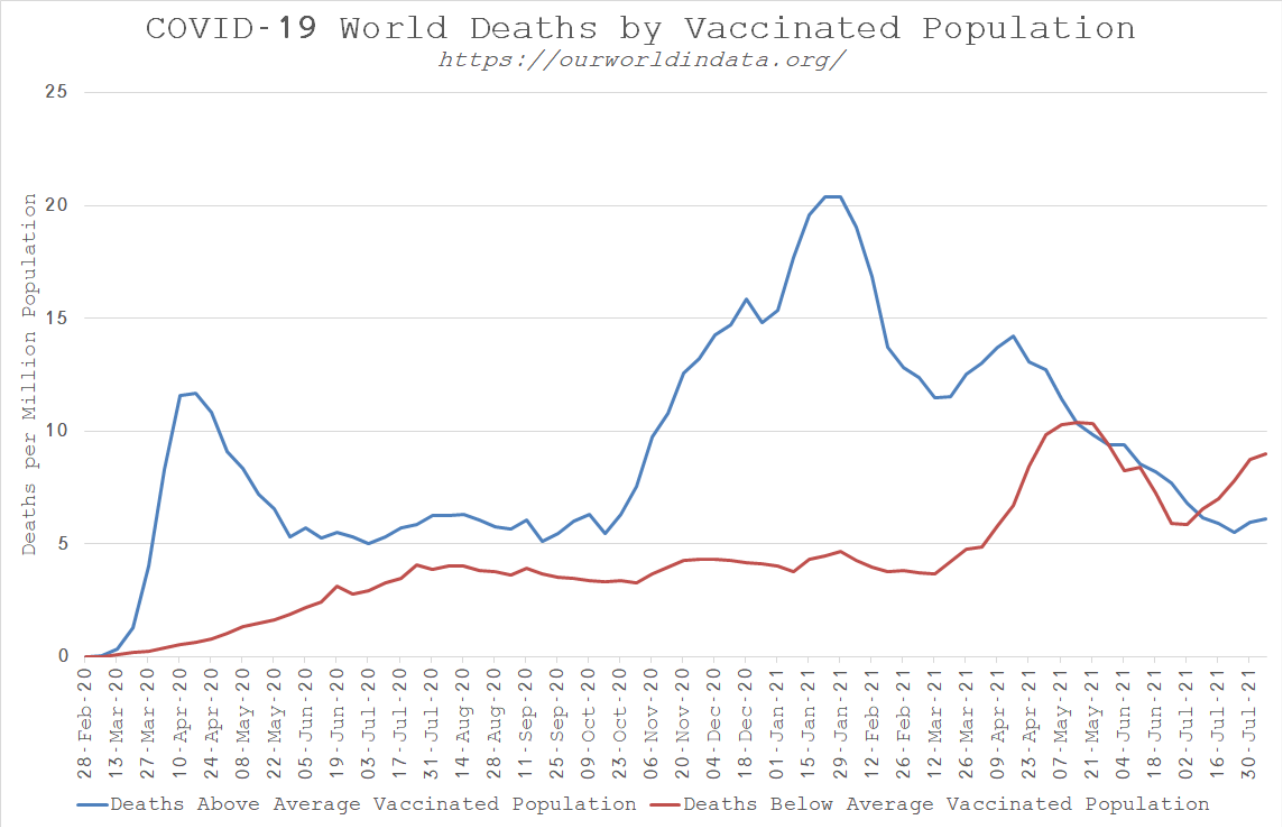
Further supportive evidence of vaccination being linked to higher death rates can be observed at the global level.

Figure 4 shows COVID-19 deaths per million before and after vaccinations aggregated across countries globally according to the percentages of their populations vaccinated[13]. The blue line series is aggregated death rates in the half of countries having above average vaccinated populations (before and after vaccination), the red line series that for those countries having below average vaccinated populations (before and after vaccination). As Joel Smalley points out[14]:

- COVID-19 death rates are significantly higher in those countries with above average vaccinated populations.
- In countries with below average vaccinated populations (red line) the death rate only spikes when the percentage of the population vaccinated exceeds 1% (i.e. from March 2021).

[13] Source: Joel Smalley
[14] Source: https://twitter.com/RealJoelSmalley/status/1424019692742656003?s=20

Figure 4 – Aggregated COVID-19 deaths per million globally according to the percentage of the population vaccinated for COVID



5. Increases in COVID 'cases' are linked to vaccination rollouts

Scotland

Many countries are reporting correlation between vaccination rates and COVID 'cases'.

If we examine these data for Scotland, the correlation between the 'recent increase in vaccination rate of 18-29 year olds and cases of all ages [or cases in 15-24 year olds] cannot be dismissed as coincidental'[15]. Figures 5 and 6 show this close correlation[16].

These data reflect reports from clinicians (e.g. leading cardiologist, Dr. Peter McCullough, MD, MPH, Professor of Medicine) of COVID-like illness occurring in people after their receiving COVID-19 vaccines.

[15] Source: Joel Smalley
[16] Source: Joel Smalley

Figure 5 – COVID-19 'Cases' in all age groups and Numbers Vaccinated (18-29 year olds), Scotland

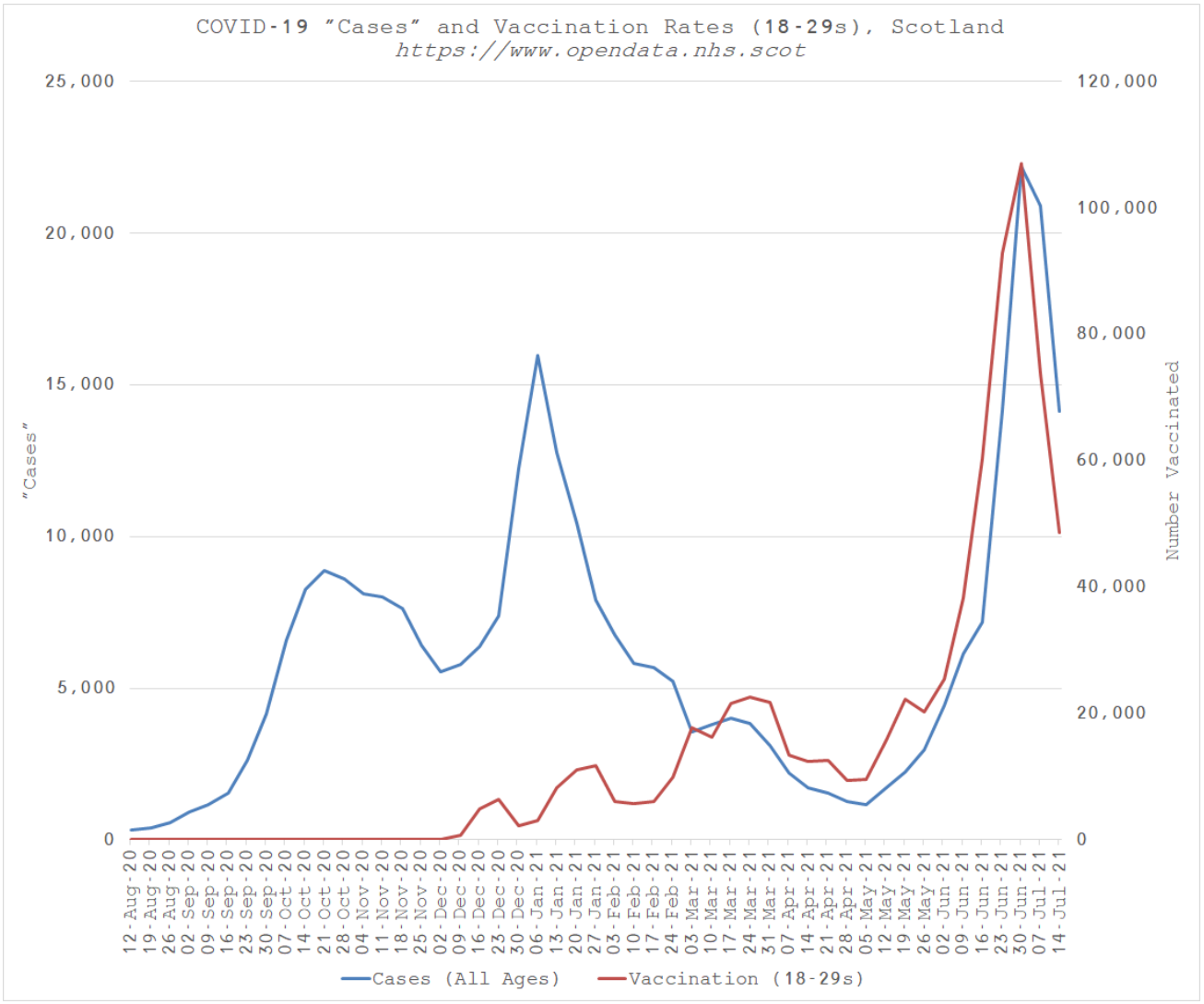
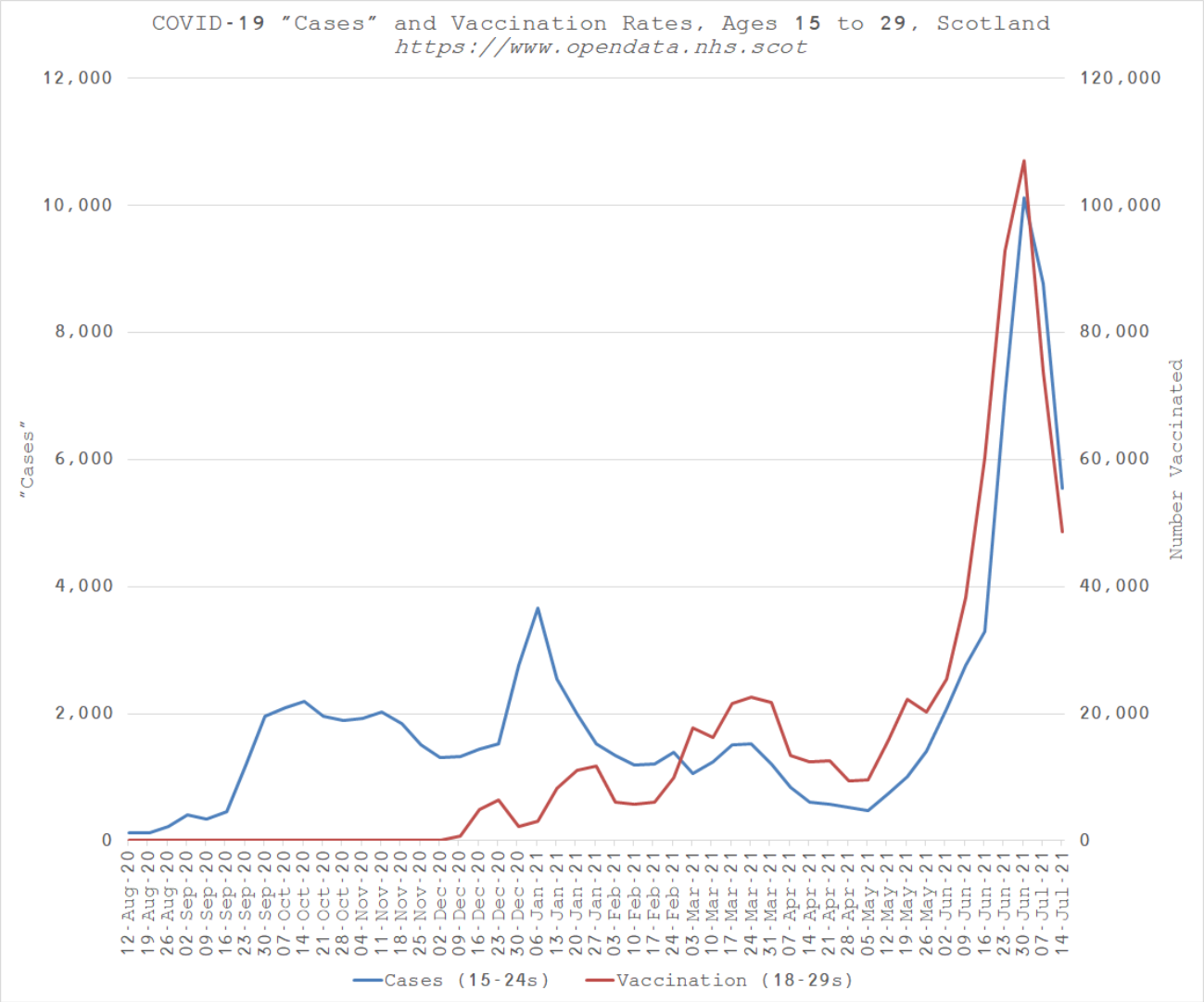


Figure 6 – COVID-19 'Cases' in 15-24 year olds and Numbers Vaccinated (18-29 year olds), Scotland



Israel – irrefutable evidence of link between vaccination rollout and increase in COVID

All vaccination in Israel is with the Pfizer/BioNTech vaccine. These data are from Joel Smalley, independent data analyst[17].

Figure 7 shows COVID-19 cases in the over 60s in Israel. The modelled observed COVID-19 cases (solid black line) is fitted to the observed data using a simple model assuming exponential decay. The fewest series between 21-Nov-2020 and 29-May-2021 was 3 (dotted lines). The first of these represents the modelled cases with natural COVID, the second cases from the first dose with the

[17] https://twitter.com/RealJoelSmalley/status/1422941794476699651?s=20

Pfizer/BioNTech vaccine (rollout started 19-Dec-2021 in Israel) and the third series cases from the second dose.

Figure 7 – COVID-19 cases in over 60 year olds in Israel

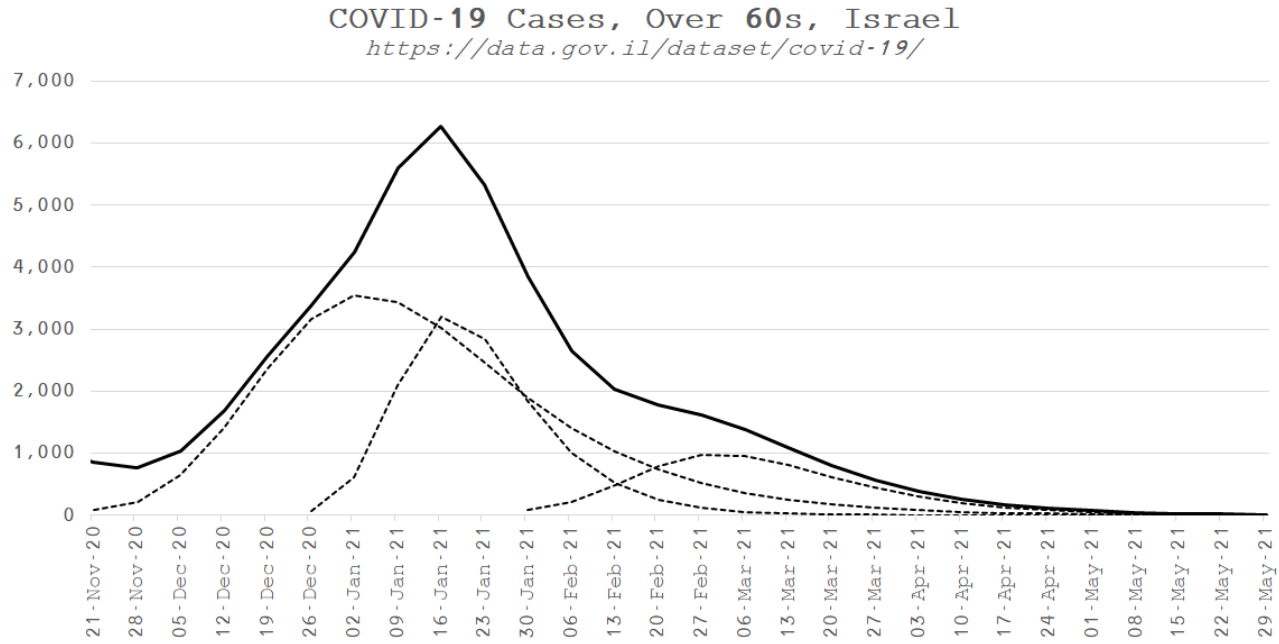


Figure 8 below shows the modelled first series (dotted line) and observed case data (solid line) for the unvaccinated.

Figure 8 – Modelled and observed COVID-19 cases in over 60 year olds in Israel in unvaccinated

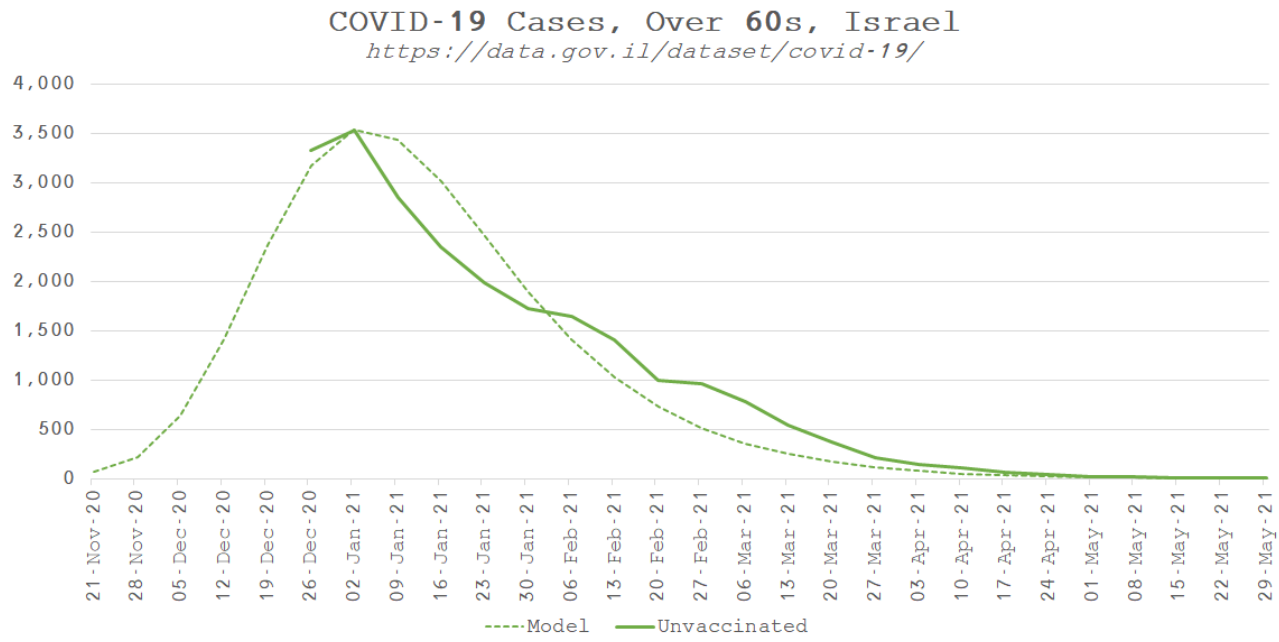


Figure 9 below shows the modelled second and third series (dotted lines) and observed case data (solid line) for the vaccinated for their first and second doses.

Figure 9 – Modelled and observed COVID-19 cases in over 60 year olds in Israel in the vaccinated

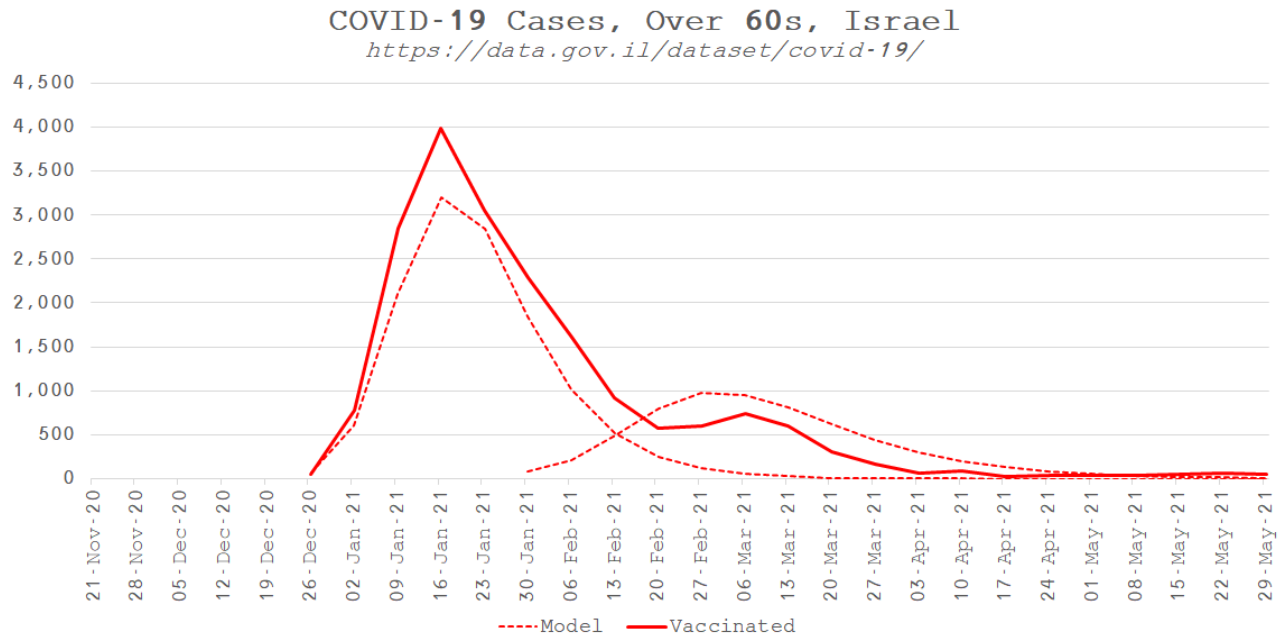


Figure 10 below shows there have been approximately 19,000 more cases than we would have expected if there had been no vaccinations.

Figure 10 – Modelled and observed COVID-19 cases in over 60 year olds in Israel in the unvaccinated (green) and vaccinated doses 1 and 2 (red)

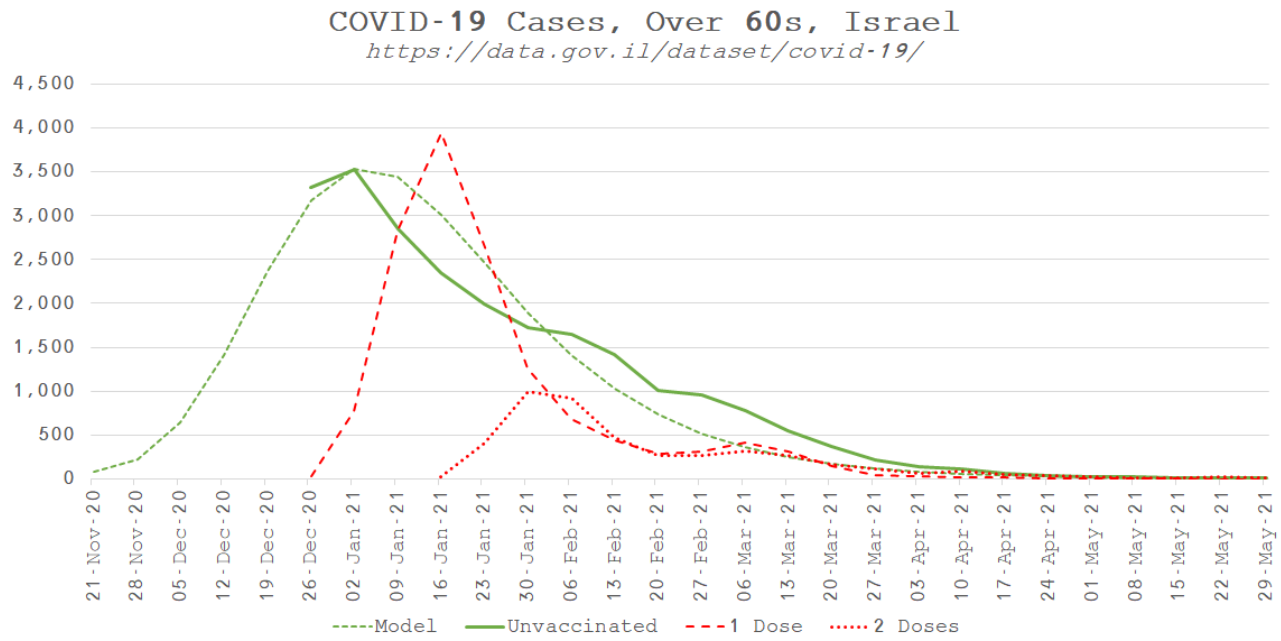
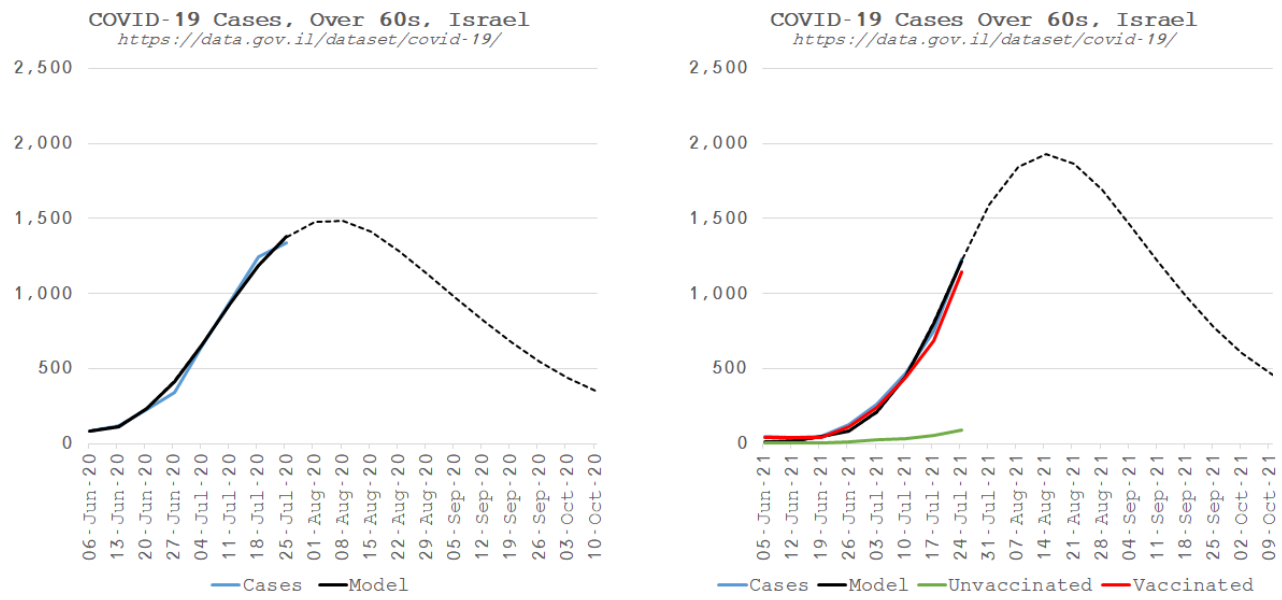


Figure 11 below indicates how this increase in cases last winter following vaccination has not resulted, unfortunately, with fewer cases later on and that, comparing the series starting in June 2021 with the same period last year, it is likely that there will be approximately 10% more cases overall and most cases are occurring in the vaccinated. The vaccine trials never claimed to reduce transmission.[18] The data from Israel show that there are more, not fewer, cases overall, following vaccination, so rather than vaccination protecting the vulnerable, in fact, the opposite is apparent.

[18] 'The vaccine trials have not been designed to measure reduction in transmission risk from infected vaccinated individuals to susceptible contacts': https://www.ecdc.europa.eu/sites/default/files/documents/Risk-of- transmission-and-reinfection-of-SARS-CoV-2-following-vaccination.pdf

Figure 11 – Modelled (black line) and observed COVID-19 cases (blue) in over 60 year olds in Israel in the unvaccinated (green) and vaccinated (red) in the June-October period in 2021 vs 2020



Overall the case fatality rate (CFR) in over 60s in Israel for the December 2020-May 2021 period is 6.6%, slightly higher than the 6.3% observed from data prior to November 2020. With the increased cases, however, this suggests vaccines are directly responsible for an additional 1,200 deaths out of a total of approximately 3,000.

6. Immune system reported ADRs (infections, inflammation, immune system, allergic responses)

To 30th June, a total of **65,312 ADRs and 197 fatalities** fell into this category (Table 2), compared with 54,870 ADRs and 171 fatalities as of 26th May. This represents a further 10,442 immune system ADR reports and a further 26 fatalities since our last report.

Allergic responses to the vaccines comprised 29,956 ADRs and 5 fatalities to 30th June (compared with 25,270 ADRs and 4 fatalities up to May 26th). Klimek et al. 2021(13) have reviewed how the contents of COVID-19 vaccines differ from other types of vaccine and highlighted the allergic potential of liposomes, polyethylene glycol, tromethamine/trometamol, and mRNA. They indicate that anaphylaxis with the Pfizer and Moderna vaccines is occurring at a rate of approximately 1 per 100,000 injections and that this is approximately 10-fold higher than with other types of (non-COVID-19) vaccines(13). In the UK Yellow Card data, there have been 1,194 cases of anaphylaxis (4 fatalities), equating to approximately **1.5 cases of anaphylaxis per 100,000 injections**.

Many 'INFECTION' category ADRs indicated the occurrence of re-activation of latent viruses, including herpes zoster or shingles (2,499 ADRs as of July 7th vs 1,827 such ADRs May 26th) and opthalmic herpes zoster (13 ADRs). This is strongly suggestive of vaccine-induced immune-compromise. Reactivation of herpes zoster and opthalmic herpes zoster has also been observed after the Pfizer COVID-19 vaccine in a case series from Israel(14).

Also suggestive of vaccine-induced immunocompromise is the high number of immune-mediated conditions reported, including Guillain-Barré Syndrome (391 ADRs, 2 fatalities), and Multiple Sclerosis (142 ADRs, 1 fatality).

There have been 469 reports of infective or inflammatory cardiac conditions, including **myocarditis** (205 ADRs, 2 fatalities), **endocarditis** (8 ADRs) and **pericarditis** (256 ADRs, 1 fatality). A leading cardiologist, Dr. McCullough, has voiced concern about ongoing cardiac injury with very high troponin levels in young people with myocarditis, that are remaining high for at least 2 months[19], suggestive of ongoing cardiac injury [personal communication, meeting of experts 21-Jul-2021]. Currently, the government report[20] states that 'These reports are extremely rare, and the events are typically mild with individuals recovering within a short time with standard treatment and rest.'

- *Please can you confirm that each of these yellow card reports of individuals with post-vaccination myocarditis and pericarditis have been followed up and for how long?*
- *In addition, please can you confirm how many of these individuals have recovered fully and the status of those who have not fully recovered?*

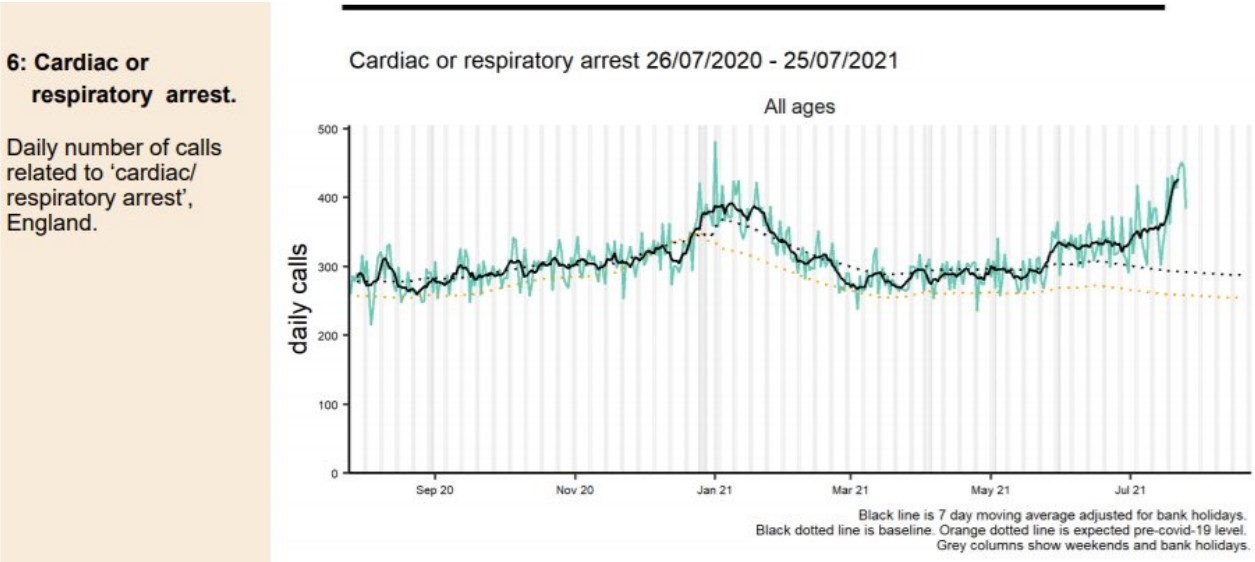
In the Eudravigilance safety surveillance system, there have been 1034 reports of myocarditis alone with the Pfizer COVID-19 vaccine, 23 (2.2%) of which have been fatal and 244 of which (23.6%) have not resolved. In the 12-17 year age group, 95% of reports (88/93) have been in males; in 18-64 year olds 70% (539/774) are males and in 65 years and over 54% (60/112) are males. From these data it is clear that males (<65 years but particularly in the <18 year age group) are particularly affected by myocarditis, and this could be due to higher expression levels of ACE2 receptors in men than in women(15).

An **increase in cardiac or respiratory arrests** can be observed from National Ambulance Syndromic Surveillance (NASS) system reports of daily calls (Figure 12)(16). The COVID-19 vaccine rollout started 8th December 2020. Calls for cardiac or respiratory arrest start to increase approximately 1 week after rollout begins, reflecting McLachlan's observations of deaths due to a cardiac event (myocardial infarct, heart attack) occurring between days 5 and 14 following a first dose(5). A

[19] Troponin levels 40-50 ng/mL and not coming down for prolonged period (e.g. 2 months) in young people with myocarditis (Upper Limit of Normal is 0.5 ng/mL at Dr. McCullough's laboratory).
[20] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

further concerning **rise in cardiac or respiratory arrest calls** above baseline levels has been ongoing since May 21st 2021 approximately (Figure 12).

Figure 12 – National Ambulance Syndromic Surveillance (NASS) system reports of daily calls for cardiac or respiratory arrest, England



This happens to correspond to the issuance by NHS England on 20 May 2021 of the notification of the change to shelf life of the Pfizer COVID-19 vaccine, allowing the thawed vial to be stored at 2-8°C for 31 days, rather than the 5 days limit that had up to that date been applied(17). **This followed MHRA's amendment to the Conditions of Authorisation of the Pfizer vaccine**. This also corresponds to the rollout starting in younger adults, aged under 30 years old. It would, therefore, be of relevance to examine the age- and gender-distribution of both the NASS cardiac or respiratory arrest calls data(16) and of ADR reports to the Yellow Card system, as if the increase since late May is mainly in younger males (as opposed to females) it could be suggestive of an ACE2 receptor mediated effect. If there were no difference in the proportion of calls/reports to young men and women, it might be more indicative of a blanket effect due to the change in shelf-life amendment.

That the age- and gender-stratified data are not readily available from the Yellow Card system highlights the risk to the public that a non-transparent system represents.

The rollout, particularly to younger age groups should be halted and the Pfizer COVID-19 vaccine shelf-life amendment reversed pending investigation.

7. Bleeding, clotting and ischaemic reported ADRs

To 30th June 2021, a total of **25,253 bleeding, clotting and ischaemic suspected ADRs** have been reported, of which 964 were fatal (Table 3). In the 5 weeks since our last report there have been 11,487 such reports and 108 fatalities.

Bleeding, clotting and ischaemic ADRs were the most common cause of post-vaccination fatalities.

The most common Yellow Card categories affected by these sorts of ADRs were general disorders (**death for unspecified reason 482**), the nervous system (183 fatalities, mainly from brain bleeds and clots), respiratory (with 115 fatalities, mainly from pulmonary thromboembolism) and cardiac categories (104 fatalities).

- *The most common cause of sudden death is a cardiovascular event. Have these deaths with unspecified reason been followed up to establish the likely cause?*

8. Pain reported ADRs

To 30th June 2021 there have been 291,159 pain ADRs (6 fatalities), including muscle and tissue disorders, nervous system disorders, migraine and headache (Table 4).

9. Neurological suspected ADRs

To 30th June 2021 reports included 12,727 suspected neurological ADRs, including 2,485 ADRs (2 fatalities) involving seizures and 2,926 ADRs involving some form of paralysis, palsy including Bell's palsy or other neuropathy or Guillain-Barré Syndrome. Sensory disturbances were reported in 6,604 ADRs, including high numbers of eye (4,858 ADRs) and ear disorders. There have been 438 reports of blindness[21]. Searches for encephalopathy, dementia, ataxia, spinal muscular atrophy, delirium, Parkinson or dystonia resulted in 706 reports, the vast majority in the psychiatric disorders Yellow Card category (Table 5).

Crossing of the blood-brain barrier and neurodegenerative pathology is suggested by the reactions reported. Preclinical data demonstrate the crossing of the blood-brain barrier by the S1 subunit of the spike protein when injected intravenously(18).

The European Medicines Agency has recently published a safety update report from the Pharmacovigilance Risk Assessment Committee (PRAC) on the AstraZeneca COVID-19 vaccine(19), in which they state 'Vaccinated persons need to seek immediate medical attention if they develop

[21] To July 21st 2021

weakness and paralysis in the extremities, possibly progressing to the chest and face, after vaccination with Vaxzevria, as these could be signs of Guillain-Barré Syndrome', and they indicate the product information will be updated in the Warnings and Precautions section to alert healthcare professionals and people taking the vaccine of this potential risk.

- *Will MHRA take action to warn healthcare providers and people in the UK of the potential risk of Guillain-Barré Syndrome with the AstraZeneca COVID-19 vaccine?*

One further case of **Paroxysmal Extreme Pain Disorder** (PEPD) has been reported since our last report, bringing the total to 12 cases, all following the Astra-Zeneca COVID-19 vaccine.

PEPD results from a gene mutation causing sodium channel abnormalities and excruciating pain episodes. It is an extremely rare inherited neuropathic condition, having been definitively described in only 77 patients from 15 families worldwide(20, 21). In light of this, 12 cases being reported since the COVID-19 vaccine rollout started in the UK and 12 for the Astra-Zeneca COVID-19 vaccine in the European Medicines Agency's Eudravigilance database (an additional 2 cases compared to the time of our last report) would appear highly unusual. The onset of PEPD is reported normally to be in early infancy, often on the first day of life or in utero(21), yet the European COVID-19 vaccine pharmacovigilance data shows that the PEPD cases being reported are occurring in adults (9/12 cases – for the other 3 cases the age was not specified).

PEPD may, however, be underdiagnosed normally due to its ability to mimic other syndromes and syncopes(22). Common symptoms of PEPD include transient loss of consciousness with asystole, vasodilatation (flushing) and cyanosis(22). Other signs and symptoms include limb swelling, apnoea and pupillary changes, and eye and jaw pain(23) as well as non-epileptic tonic seizures and constipation, the latter brought on by fear of the pain(21). We would like to draw your attention to the frequency with which these symptoms have been reported post-COVID-19 vaccination[22]: loss of consciousness 1,465; syncope 4,104; vasodilatation 133; flushing 1,033; cyanosis 137 (including 1 neonatal); limb swelling 9; apnoea 53 (including 1 infantile apnoea); pupillary deformity 1; periorbital or eye pain 3,986; jaw pain 847; constipation 624. Furthermore, the frequency with which pain in general has been reported (291,159 pain ADRs) may suggest that the COVID-19 vaccines are spuriously affecting sodium channel depolarisation, as occurs in this rare genetic disorder of PEPD. In a FoI request to the MHRA, it was confirmed that the cases reported to the Yellow Card system in UK have also occurred in adults.

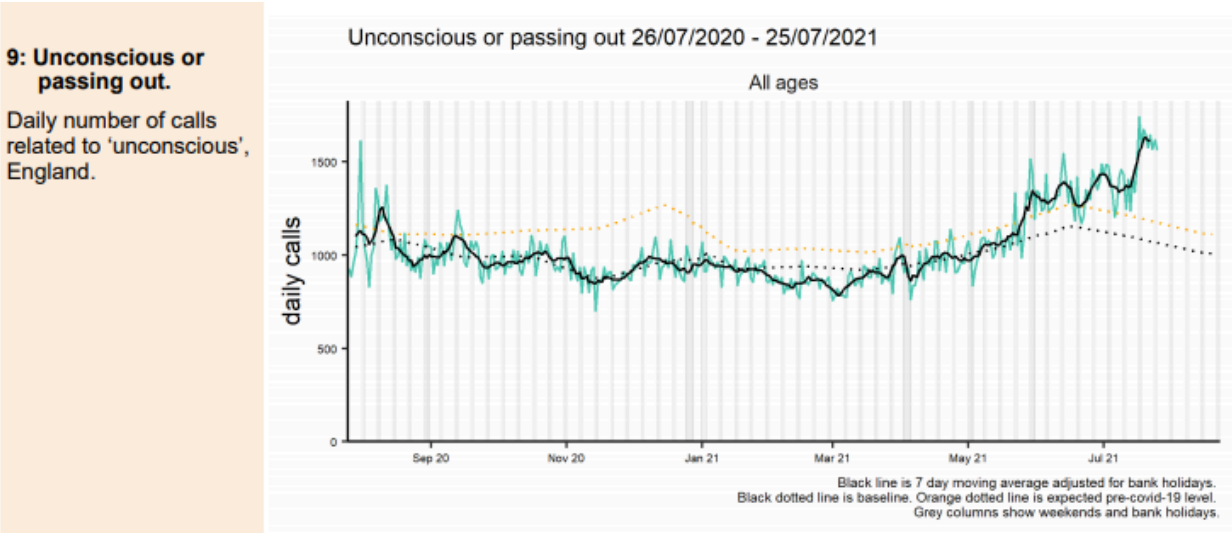
- *Since drawing these unusual reports to the attention of the MHRA, have these individuals been followed up?*

The large numbers of syncope/loss of consciousness reported to MHRA reflect the discussion of McLachlan et al. 2021(5) already mentioned, in which they observed from their detailed analysis

[22] Up to 14-Jul-2021

of VAERS death reports that **descriptions of patients' post-vaccine and pre-death symptoms included syncope**. The NASS bulletin(16) also lists 'Unconscious/passing out' as one of the syndromic indicators with 11,335 calls in the week and that these are above baseline levels. Their data also shows that 'Unconscious/passing out' calls have increased alarmingly since May 21st, 2021 (Figure 13):

Figure 13 – National Ambulance Syndromic Surveillance (NASS) system reports of daily calls for people being 'Unconscious or Passing out', England



The very large number of neurological ADRs, adult-occurring cases of the usually very rare and infancy-onset PEPD and the reports of PEPD-like symptoms provides a safety signal warranting suspension of COVID-19 vaccines pending investigation.

10. Reproductive system disorders

Up to 30th June 2021, there were a high number of Reproductive System ADRs (9,184, Table 6), including 258 ADRs reported related to the male reproductive system and 8,926 ADRs for the female reproductive system, mainly in the 'reproductive and breast disorders' category. This will be the subject of a separate report.

Conclusion

As noted in the CHM's Expert Working Group report on COVID-19 vaccine safety surveillance(1), **MHRA has statutory responsibility for undertaking post-authorisation safety monitoring in the UK.** We ask the MHRA **to take action as follows, in line with its statutory obligation to minimise**

risk to individuals, pending full investigation of vaccine safety and efficacy **and re-assessment of risk-benefit ratios** by MHRA/CHM/CHM EAGs and independent experts using real world empirical evidence and assuming use of known effective treatment protocols:

- **Suspend the COVID-19 vaccines immediately in all children** so plans to vaccinate children aged 12 & over are cancelled, incl. imminent plans in those at higher risk of COVID-19, who would be most vulnerable to vaccine side-effects, and plans in 16-17 year olds.
- **Suspend** the use of COVID-19 vaccines in all adults
- **Suspend enrolment** in trials in UK of COVID-19 vaccines
- **Communicate to healthcare workers and vaccine recipients** the potential risk of Guillain-Barré Syndrome with the AstraZeneca COVID-19 vaccine and that 'Vaccinated persons need to seek immediate medical attention if they develop weakness and paralysis in the extremities, possibly progressing to the chest and face, after vaccination, as these could be signs of Guillain-Barré Syndrome'.
- **Communicate to healthcare workers and vaccine recipients** known treatment protocols for COVID-19 (acute and long) and for post-vaccination side-effects, including Covid Vaccination (CoVAC) Syndrome, so that people can receive timely care. We have collated health guidance from international clinical expert groups on managing these conditions, which we can share with you for distribution.
- **Postpone** any EUA assessment of booster vaccinations
- **Conduct a comprehensive overhaul** of the UK's Yellow Card system

We thank the UK Freedom Project[23] for their assistance with data extraction, Joel Smalley for sharing his graphs and analyses and Dr. Jonathan Engler and Dr. Stephen Feldman for sharing the correspondence they have had with MHRA. We remain at your service to assist further.

Yours sincerely,

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Epidemica Ltd., UK

[23] www.ukfreedomproject.org

[24] Please note that EbMC Squared CiC is a Community Interest Company that conducts research mandated by the public and funded by public donations. We have no conflicts of interest and do not engage in industry-funded work.

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Appendix I – Updated analysis of Yellow Card data (methods)

In this latest update to 30th June 2021, we have again searched the Yellow Card reports using pathology-specific key words to group the data according to the following five broad, clinically relevant categories. After running each search, we entered the results into an Excel spreadsheet, excluding ADRs that were clearly irrelevant or appeared in duplicate.

A. Immune System ADRs
B. Bleeding, Clotting and Ischaemic ADRs
C. 'Pain' ADRs
D. Neurological ADRs
E. Reproductive System ADRs

A. Immune System Adverse Drug Reactions (Infection, Inflammation, Autoimmune, Allergic) (Table 2)

We used the following SEARCH TERMS to identify immune system ADRs: INFECTION (category), immune system (category), -itis; immun, multiple sclerosis, lupus, myasthenia, pernicious, diabetes, Addison, Crohn's, Coeliac, Graves, alopecia, amyloidosis, antiphospholipid, angioedema, Behcet's, pemphigoid, psoriasis, aplasia, sarcoidosis, scleroderma, thrombocytopenia, vitiligo, Miller Fisher, Guillain-Barre; allerg*, urticaria, rash, eczema, asthma, **anaphylac***.

B. Bleeding, Clotting and Ischaemic Adverse Drug Reactions (Table 3)

We used the following SEARCH TERMS to identify bleeding, clotting and ischaemic ADRs. Terms not searched in our last report are in bold: haemorrhage, bleed, haemo*, **epistaxis,** thrombo*, emboli*, coag*, death, **occlus,** ischaem*, infarct*, angina, stroke, cerebrovascular, CVA. As previously, we included the term 'death' in this search group, as this term accounted for many reported fatalities (482) without specific details. Given the large number of fatalities without a specific cause of death, we considered that ADRs reported in this way, in particular as 'sudden death', would be most likely to occur from haemorrhagic, thrombo-embolic or ischaemic events. Given the seriousness of this ADR, we considered it justifiable to do this pending clarification of the cause of death in these 482 people.

C. 'Pain' Adverse Drug Reactions (Table 4)

We used the following SEARCH TERMS to identify pain ADRs: pain, -algia, **headache, migraine**.

D. Neurological Adverse Drug Reactions (Table 5)

In addition to examining ADRs in the **NERVOUS SYSTEM DISORDERS (category),** we used the following SEARCH TERMS to identify neurological ADRs specifically involving paralysis, neurological degeneration, and convulsive ADRs as follows**: (paralysis), palsy, paresis, neuropathy, incontinence, Guillain-Barre, Miller Fisher, multiple sclerosis; (neurodegeneration) encephalopathy, dementia, ataxia, spinal muscular atrophy, delirium, Parkinson; (seizure), convuls, seizure, fit, -lepsy**

E. Reproductive System Adverse Drug Reactions (Table 6)

Search terms included those for the male reproductive system - **Testic , testes, scrotal, penile, epididym, prostate, 'breast cancer male', balanitis, sperm, 'infertility male', erection, semen (excluding basement), gynaecomastia, 'male sexual dysfunction'** – and for the female reproductive system and pregnancy - **Breast cancer (excluding male), lactation, mastitis, breast abcess, genital herpes, genital abscess, endometritis, Infertility (excluding male), oophoritis, menopaus*, menstrua*, vaginal, vulval, vulvo, cervix, ovarian, pelvis, genital, sexual dysfunction excluding male, uterine, fallopian, exposures associated with pregnancy, delivery and lactation** (Category).

Table 2. Immune System Adverse Drug Reactions (up to 30th June 2021 – Week 23)

SEARCH terms	Inflammation (-itis), infection	Immun, immune system +	Allerg, asthma, eczema, urticaria, rash, anaphylac	
Yellow Card Category	All ADRs (Fatal)	All ADRs (Fatal)	All ADRs (Fatal)	**Total Week 23 All ADRs (Fatal)**
Blood disorders	132 (0)	1272 (12)		**1404 (12)**
Cardiac disorders	297 (2)	1 (0)		**298 (2)**
Congenital disorders	2 (0)	5 (0)		**7 (0)**
Ear disorders	13 (0)	1 (0)		**14 (0)**
Endocrine disorders	28 (0)	20 (0)		**48 (0)**
Eye disorders	234 (0)	6 (0)	69 (0)	**309 (0)**
Gastrointestinal disorders	746 (4)	142 (0)		**888 (4)**
General disorders	1161 (0)		976 (0)	**2137 (0)**
Hepatic disorders	57 (1)	9 (0)		**66 (1)**
Immune system disorders		2580 (0)	1612 (4)	**4192 (4)**
Infections	22823 (158)	7 (0)	163 (0)	**22993 (158)**
Injuries	41 (0)	5 (0)	1 (0)	**47 (0)**
Investigations	1 (0)	29 (0)	2 (0)	**32 (0)**
Metabolic disorders		204 (1)		**204 (1)**
Muscle & tissue disorders	1985 (0)	65 (0)		**2050 (0)**
Neoplasms	1 (0)			**1 (0)**
Nervous system disorders	255 (0)	572 (6)		**827 (6)**
Pregnancy conditions		11 (0)		**11 (0)**
Psychiatric disorders		2 (0)		**2 (0)**
Renal & urinary disorders	42 (1)	3 (0)		**45 (1)**
Reproductive & breast disorders	29 (0)		9 (0)	**38 (0)**
Respiratory disorders	84 (2)	5 (0)	834 (0)	**923 (2)**
Skin disorders	566 (0)	1338 (0)	26287 (1)	**28191 (1)**
Surgical & medical procedures		269 (2)	3 (0)	**272 (2)**
Vascular disorders	306 (3)	7 (0)		**313 (3)**
Grand Total	**28803 (171)**	**6553 (21)**	**29956 (5)**	**65312 (197)**

Abbreviations: ADR, adverse drug reaction

+ Multiple sclerosis, lupus, myasthenia, pernicious, diabetes, Addison, Coeliac, Graves, alopecia, amyloidosis, antiphospholipid, angioedema, Behcet's, pemphigoid, psoriasis, aplasia, sarcoidosis, scleroderma, thrombocytopenia, vitiligo, Miller Fisher, Guillain-Barre, Crohn

Table 3. Bleeding, Clotting and Ischaemic Adverse Drug Reactions (up to 30th June 2021 – Week 23)

SEARCH terms	Death	Haemorrhage, bleed, haemo, epistaxis	Ischaem, infarct, angina, stroke, cerebrovascular, CVA	Thrombo, emboli, coag	Occlus	
Yellow Card Category	All ADRs (Fatal)	All ADRs (Fatal)	All ADRs (Fatal)	All ADRs (Fatal)	All ADRs (Fatal)	**Total Week 23 All ADRs (Fatal)**
Blood disorders		40 (0)	13 (0)	166 (4)		**219 (4)**
Cardiac disorders		9 (5)	863 (94)	27 (5)	2 (0)	**901 (104)**
Congenital disorders		2 (0)				**2 (0)**
Ear disorders		22 (0)				**22 (0)**
Endocrine disorders		13 (0)		1 (0)		**14 (0)**
Eye disorders		298 (0)	15 (0)	19 (0)	120 (0)	**452 (0)**
Gastrointestinal disorders		671 (5)	47 (4)	40 (1)	1 (0)	**759 (10)**
General disorders	484 (482)	61 (0)		3 (0)	1 (0)	**549 (482)**
Hepatic disorders		3 (0)	3 (1)	87 (5)	0 (0)	**93 (6)**
Infections		1 (0)		11 (0)		**12 (0)**
Injuries		28 (1)	14 (0)	4 (0)	1 (0)	**47 (1)**
Investigations		44 (0)	3 (0)	197 (0)		**244 (0)**
Metabolic disorders		1 (0)				**1 (0)**
Muscle & tissue disorders		6 (0)				**6 (0)**
Neoplasms		1 (0)		3 (0)		**4 (0)**
Nervous system disorders		434 (81)	2196 (67)	385 (35)	11 (0)	**3026 (183)**
Pregnancy conditions	6 (1)	2 (0)		54 (0)		**62 (1)**
Psychiatric disorders	18 (0)					**18 (0)**
Renal & urinary disorders		80 (1)	15 (1)	13 (0)	4 (0)	**112 (2)**
Reproductive & breast disorders		8625 (0)		2 (0)		**8627 (0)**

SEARCH terms	Death	Haemorrhage, bleed, haemo, epistaxis	Ischaem, infarct, angina, stroke, cerebrovascular, CVA	Thrombo, emboli, coag	Occlus	
Respiratory disorders		2931 (1)	17 (1)	1701 (113)	1 (0)	**4650 (115)**
Skin disorders		80 (0)				**80 (0)**
Social circumstances	1 (0)					**1 (0)**
Surgical & medical procedures				7 (0)		**7 (0)**
Vascular disorders		1627 (3)	76 (2)	3607 (51)	35 (0)	**5345 (56)**
Grand Total	**509 (483)**	**14979 (97)**	**3262 (170)**	**6327 (214)**	**176 (0)**	**25253 (964)**

Abbreviations: ADR, adverse drug reaction; CVA, cerebrovascular accident

Table 4. Pain Adverse Drug Reactions (up to 30th June 2021 – Week 23)

SEARCH terms	Pain, -algia, headache, migraine
Yellow Card Category	**Total (Fatal)**
Blood disorders	**1546 (0)**
Congenital disorders	**17 (0)**
Ear disorders	**2558 (0)**
Endocrine disorders	**15 (0)**
Eye disorders	**3894 (0)**
Gastrointestinal disorders	**13271 (0)**
General disorders	**41296 (2)**
Hepatic disorders	**79 (0)**
Injuries	**23 (0)**
Muscle & tissue disorders	**105566 (0)**
Neoplasms	**2 (0)**
Nervous system disorders	**111984 (4)**
Pregnancy conditions	**3 (0)**
Psychiatric disorders	**1 (0)**
Renal & urinary disorders	**1162 (0)**
Reproductive & breast disorders	**1407 (0)**
Respiratory disorders	**7085 (0)**
Skin disorders	**1118 (0)**
Vascular disorders	**132 (0)**
Grand Total	**291159 (6)**

Table 5. Neurological Adverse Drug Reactions (up to 30th June 2021 – Week 23)

SEARCH terms	Convuls, seizure, fit, -lepsy	Paralysis, palsy, paresis, neuropathy, incontinence, Guillain-Barre, Miller Fisher, multiple sclerosis	Speech, taste, smell, olfactory, blind, sight, visual, vision, deaf, hearing	Encephalopathy, dementia, ataxia, spinal muscular atrophy, delirium, Parkinson, dystonia	
Yellow Card Category	All ADRs (Fatal)	All ADRs (Fatal)	All ADRs (Fatal)	All ADRs (Fatal)	**Total Week 23 All ADRs (Fatal)**
Congenital disorders	1 (0)	6 (0)	3 (0)	2 (0)	**12 (0)**
Ear disorders			698 (0)		**698 (0)**
Eye disorders		22 (0)	4858 (0)		**4880 (0)**
Gastrointestinal disorders		59 (0)			**59 (0)**
Investigations		2 (0)	3 (0)		**5 (0)**
Nervous system disorders	2479 (2)	2588 (0)	877 (0)	165 (0)	**6109 (2)**
Pregnancy conditions			15 (0)		**15 (0)**
Psychiatric disorders			120 (0)	539 (0)	**659 (0)**
Renal & urinary disorders		249 (0)			**249 (0)**
Social circumstances			30 (0)		**30 (0)**
Surgical & medical procedures	5 (0)				**5 (0)**
Grand Total	**2485 (2)**	**2926 (0)**	**6604 (0)**	**706 (0)**	**12721 (2)**

Abbreviations: ADR, adverse drug reaction

Table 6. Reproductive System Adverse Drug Reactions (up to 30th June 2021 – Week 23)

SEARCH terms	Testic , testes, scrotal, penile, epididym, prostate, 'breast cancer male', balanitis, sperm, 'infertility male', erection, semen (excluding basement), gynaecomastia, 'male sexual dysfunction'	Breast cancer (excluding male), lactation, mastitis, breast abcess, genital herpes, genital abscess, endometritis, Infertility (excluding male), oophoritis, menopaus*, menstrua*, vaginal, vulval, vulvo, cervix, ovarian, pelvis, genital, sexual dysfunction excluding male, uterine, fallopian, exposures associated with pregnancy, delivery and lactation (Category)	
Yellow Card Category	All ADRs (Fatal)	All ADRs (Fatal)	**Total (Fatal)**
Congenital disorders	2 (0)	24 (0)	**26 (0)**
Injuries	2 (0)	2 (0)	**4 (0)**
Investigations	4 (0)	9 (0)	**13 (0)**
Neoplasms	15 (0)	119 (0)	**134 (0)**
Nervous system disorders		2 (0)	**2 (0)**
Pregnancy conditions		9 (0)	**9 (0)**
Psychiatric disorders		2 (0)	**2 (0)**
Renal & urinary disorders	1 (0)		**1 (0)**
Reproductive & breast disorders	127 (0)	8676 (0)	**8803 (0)**
Skin disorders	106 (0)		**106 (0)**
Social circumstances		76 (0)	**76 (0)**
Surgical & medical procedures	1 (0)	7 (0)	**8 (0)**
Grand Total	**258 (0)**	**8926 (0)**	**9184 (0)**

Abbreviations: ADR, adverse drug reaction

Appendix II – Letter from Joel Smalley to his MP

Please see the attachment