Investigation into the Efficacy and Safety of Covid-19 Vaccines

Rick Bradford, 24 November 2021

Contents

0. Terminology....2
1. Safety – Evidence from Public Health Adverse Event Reports....3
1.1 Fatal Vaccine Events: Comparison of Covid-19 with Other Vaccines (UK)....3
1.2 Long-Term Effects: Usual Practice in Licencing Vaccines....4
2. Safety – Evidence from ONS Death Data....5
3. Licencing Trials: Safety and Efficacy Data....7
3.1 RRR Versus ARR....7
3.2 Vaccines' Mechanisms of Action....8
3.3 Evidence from Emergency Licencing Trials....9
3.3.1 Pfizer: Efficacy Against Infection....9
3.3.2 Pfizer Trial Deaths....10
3.3.3 Pfizer Trial Adverse Events....11
3.3.4 AstraZeneca: Efficacy Against Infection....13
3.3.5 AstraZeneca Trials' Adverse Events....14
4. Efficacy Implied by UK Public Health Data....15
4.1 Vaccine Efficacy Claimed by the HSA....17
5. Vaccination Risk-Benefit Analysis....19
Vaccine Benefit Against Hospitalisation per Year (cf. risk of a severe adverse vaccination reaction, estimated as 0.5% annually)....19
6. Supplementary Relevant Observations....20
6.1 The WHO and Booster Doses....20
6.2. Outpatient Treatment Protocol?....20
6.3. Vitamins D3 & K2....20
6.4 Spike Protein as a Mutagen....21
6.5 The Pharma Establishment's Questionable Integrity....21
7. Conclusions....22
Table 1: YCS Data for Covid and Non-Covid Vaccines Compared....26
Table 2: VAED Data Specific to Anaphylaxis and Guillain-Barré Syndrome....27
Table 3: Yellow Card Data for the Two Leading Covid-19 Vaccines....28
Table 4: Population of England by Age Range and Numbers Vaccinated by Week 37....29
Table 5: Vaccine Efficacy Implied by All-England Reported Cases in Weeks 37 through 40 (2021)....30

Table 6: Vaccine Efficacy Implied by All-England Reported Hospitalisations in Weeks 37 through 40 (2021) 30

Table 7: Vaccine Efficacy Implied by All-England Reported Deaths within 28 Days during Weeks 37-40 (2021) 31

Table 8: Vaccine Efficacy Implied by All-England Data for Weeks 42-45 (2021), from Ref.[22] 32

Table 9: Vaccine Efficacy, Weeks 41 and 45 Compared 33

Table 10: Vaccine Benefit Against Hospitalisation or Death: Absolute Risk Reduction, ARR, per 4 Week Period (Unvaccinated Rate Minus Double-Vaccinated Rate) 33

Appendix A: Investigation of Association of Vaccinations with Excess Deaths (England) ... 34

Appendix B: Investigation of Association of Vaccinations with Excess Deaths of 15-19 Year Olds (England) 37

Appendix C: Whole Population Versus Test-Negative Case Controlled Definitions of Vaccine Efficacy (Algebraic Formulae) 42

Appendix D: Discussion of VAERS/YCS Data 43

D.1 UK Vaccine Adverse Event Reporting System: "Yellow Card" Scheme 43

D.2 The Major Shortcoming of VAERS/YCS 43

D.3 Yellow Card Data at 7 October 2021 43

D.4 Under-reporting of Adverse Events 44

D.5 VAER Data for Other Vaccines before 2020 (US Data) 45

D.6 YCS Data for Influenza Vaccines in England before 2020 45

D.7 VAER Data Specific to Anaphylaxis and Guillain-Barré Syndrome 46

References 48

0. Terminology

"Risk"

I use "risk" at it appears to be used in medical literature, namely as essentially synonymous with the probability of an adverse event. Hence "risk reduction" refers to the reduction in the probability of an adverse event following a treatment of some kind. (The important distinction between absolute and relative risk reduction is addressed later).

People accustomed to deploying "risk" in the context of industrial safety, especially nuclear safety, will be more familiar with a definition in which risk is the product of the probability of the event and a numerical measure of the severity of the consequences of the event (so that a very improbable event with severe consequences might have the same risk as a far more probable event with less severe consequences). This formulation of risk is more appropriate in cost-benefit analysis and the implied decision-making process. However, it is not used here.

VAER(S)

Vaccine Adverse Event Reporting (System). In principle a generic term applicable to any such system in any country. However I shall use VAER(S) to refer to the system in the USA. The UK VAERS is the Yellow Card System which I shall refer to as such, or as YCS.

1. Safety – Evidence from Public Health Adverse Event Reports

In version 2 of this review I have relegated this discussion to Appendix D because, based on the rate of adverse reports from the vaccine trials, it is clear that the VAERS/YCS under-report so seriously as to be more misleading than helpful. However, Tables 1, 2 and 3 have been retained, as has the discussion on fatal adverse events, which follows next.

1.1 Fatal Vaccine Events: Comparison of Covid-19 with Other Vaccines (UK)

The Exposé has reported the response to a Freedom Of Information question in which the UK's Medicine and Healthcare product Regulatory Agency (MHRA) state that, excluding Covid-19 vaccinations, in the 20 years and 9 months between 1/1/01 to 25/8/21 there were 404 YCS reports which indicated fatal outcomes in the UK, Ref.15.

On the face of it the number of fatal YCS reports from Covid-19 vaccinations (a total of 1,698 as of the beginning of October 2021, or 1,752 by 10/11/21) looks worrisomely high compared to the accumulated total over 20 years from all other vaccines.

However, the volume of Covid-19 vaccinations which have been delivered since December 2020 is unprecedented. To compare the two sets of fatality statistics meaningfully we need to know how many other vaccinations have been delivered in the UK since 1/1/01.

Before the age of five, children are now given 12 different vaccinations, with a take-up rate of around 90%. With about 0.75M children per year group this is 8.1M vaccinations per year. However, not all these were given in year 2000/01, perhaps about half. So I estimate the number of vaccinations delivered in this age range over the last 20 years to be about 122M.

At ages 12 to 14, boys and girls now receive 4 different vaccinations, with a take-up of around 80%. With about 0.75M per year group this implies 2.4M vaccinations per year. However, the HPV vaccine (of which there are now 2 doses) was started for girls only in 2008, and has only just been rolled out to boys. Hence, there were only 1.2M vaccinations per year in this age group before 2008, and only 1.8M per year between 2008 and 2019. Hence over the last twenty years there have been about 24M vaccinations to adolescents.

In the 2019/20 influenza season 7.62 influenza vaccinations were delivered to people of 65 and over, plus 3.2M to people of all ages below 65. However, the rate of take-up by the over-65s has been increasing. The average number of seasonal influenza vaccinations to people of 65 and older since 2000/01 was about 6.6M, whilst to younger people the average over this period was about 2.6M. Hence, over the last 20 years the total influenza vaccinations was about 184M (132M to 65s and over, and 52M to the under 65s).

Finally there are vacation vaccinations for which I have no data and will ignore.

The total identified number of vaccinations over the last 20 years, excluding Covid vaccinations, is therefore 132M to people aged 65 and over, plus 198M to people of all ages below 65, most of which are to children and babies. The total is thus 330M.

The figure of 404 fatal VAERs thus relates to a death rate of 1.22 per million vaccinations across the entire age range prior to 2020. (If we assumed deaths were concentrated in the 65 and older age group, though I have no information to confirm this, then the death rate would be 3.06 per million vaccinations to those of 65 plus).

This non-Covid vaccine death rate compares with that from the combined Covid YCS reports to early October 2021 of 1,698 / 93.7M = 18.1 per million vaccinations. For the three Covid vaccines considered separately the death rate is 7.4 (Moderna) to 23.0 (AstraZeneca), Table 1. This currently covers all ages from adolescents onwards, though there is a skew to the older age groups in terms of percentage cover. Nevertheless, the fatal YCS data from other vaccines would suggest a death rate closer to 1.22 per million, and certainly less than 3 per million.

The FOI evidence published by The Exposé does seem to suggest that the death rate from Covid-19 vaccinations is 6 to 15 times greater than might have been expected, and up to 19 times more for AstraZeneca.

Sources used to derive the above estimates…

- Seasonal flu vaccine uptake in GP patients: monthly data, 2019 to 2020 - GOV.UK (www.gov.uk)
- Statistics » Child Immunisation (england.nhs.uk)
- The complete routine immunisation schedule from June 2020 (publishing.service.gov.uk)
- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/899423/PHE_Complete_Immunisation_Schedule_Jun2020_05.pdf
- https://www.gov.uk/government/publications/pneumococcal-polysaccharide-vaccine-ppv-vaccine-coverage-estimates
- https://www.gov.uk/government/collections/vaccine-uptake
- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/910604/hpr1520_shingles-vc-ann.pdf
- https://www.statista.com/statistics/281174/uk-population-by-age/

1.2 Long-Term Effects: Usual Practice in Licencing Vaccines

The potential for long term adverse health effects of the Covid-19 vaccines are a particular concern. Here “long term” might mean a few years, or several decades. Consequently, our current empirical knowledge of the long-term effects of the Covid-19 vaccines can be summarised succinctly and precisely as: zero.

There are two particular problems here. The first is that these vaccines were developed in unprecedented hast under the most extreme political and social/moral pressure – and, let us be blunt, there would also have been extreme commercial pressure acting on the development scientists from the management of the corporations doing the development. These pressures would also be felt throughout all the agencies tasked with vetting and licencing. In less than a

year, arguably as little as 9 months, the vaccines went from a standing start to being licenced for roll out to the whole population with few exceptions.

This contrasts with the observation by the College of Physicians of Philadelphia, whose History of Vaccines: Vaccine Development, Testing, and Regulation opens with the statement, "Vaccine development is a long, complex process, often lasting 10-15 years and involving a combination of public and private involvement".

That is one problem, and it would apply to any vaccine developed, tested and licenced for general use in such as short time. But there is another problem. Whilst mRNA based vaccines for influenza and rabies have been under development for years, as far as I am aware there has been no mRNA based vaccines rolled out to a national population before. And now we have one developed for a novel virus at breakneck speed rolled out to the whole world. The AstraZeneca vaccine is not mRNA based, but, like Pfizer, it too works by first causing the body to produce the Covid spike protein as an intermediary to antibody production.

The second major problem as regards the long-term is that the very novelty of these vaccines in terms of their mechanism makes a currently unanticipated response more likely (see also §6.4).

2. Safety – Evidence from ONS Death Data

Rather than using VAERS/YCS one can attempt to investigate any potential relationship between Covid vaccinations and deaths using the national death statistics published regularly by the ONS. Claims of such a relationship have been made. For example on 21 September 2021, The Exposé ran an article titled *Official data shows people who received a Covid-19 vaccine account for 70% of all-cause deaths during the first 6 months of 2021, with 20% occurring within 21 days of vaccination*.

The Exposé ran another story on 30 September 2021, *Investigation: Deaths among Teenagers have increased by 47% in the UK since they started getting the Covid-19 Vaccine according to official ONS data*. The theme was taken up by Will Jones in The Daily Sceptic the following day, *Deaths Among Teenagers Up 56% Since Vaccine Roll-Out Began* and reproduced in TCW.

Here I point out the inherent statistical difficulty in identifying a vaccine death signal from national ONS death data due to seeking a small signal against larger 'noise'. In Appendices A and B I present a specific rebuttal of the above two claims made by The Exposé.

To early October 2021, Table 1 identifies 1,698 fatal YCS reports. To a good approximation these deaths all relate to 2021, as very few vaccinations were carried out before January 2021. As discussed further below, the YCS will under-estimate the actual number of adverse events associated with vaccinations (actually massively so, as we shall see). However, one might argue that fatal cases will be less severely underreported, although one cannot be confident of that as it requires a medical professional, or a relative, associating the death with vaccination and taking the trouble to report it. For sake of argument, let us assume that the 1,698 fatal death reports might indicate, say, 7,000 actual vaccine-related deaths, i.e., roughly four times as many. I do not believe such a figure but use it only to illustrate the difficulty in identifying such a vaccination death signal against the background death count.

Before proceeding with my argument, it is appropriate at this point to make some observations to put the Covid death rate in perspective.

Figure 2 plots the number of deaths annually in England and Wales from 1950 to 2019. It has varied remarkably little, with increasing longevity and reducing death rates per 100,000 (Figure 3) being compensated by an increasing population. In 2019 there were 531,000 deaths in England and Wales. In 2020 this increased to 604,000, an excess of 73,000 between 2020 and 2019. This compares well with the total number of nominal Covid-19 deaths, based on deaths within 28 days of a positive test, which up to 31 December 2020 was 70,200 in England and Wales. (Based on Covid being mentioned on the death certificate the 2020 Covid death tally was 81,000 in England and Wales, suggesting this is an overestimate).

Figure 2

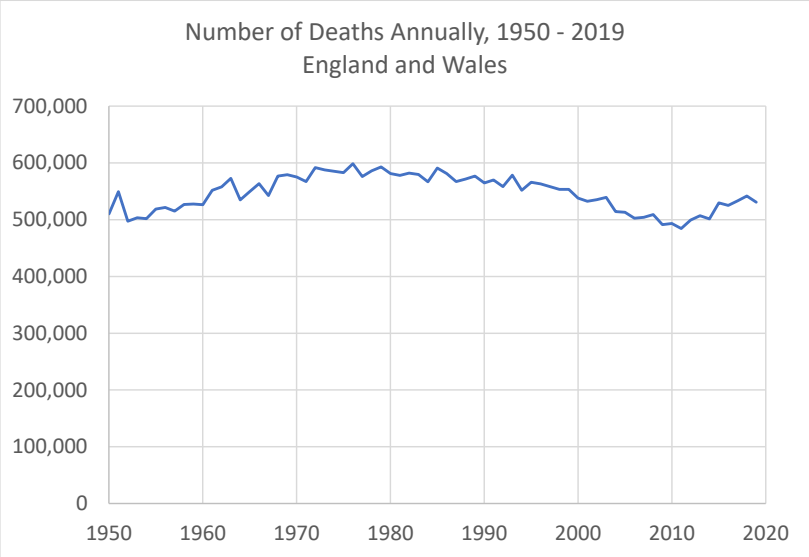
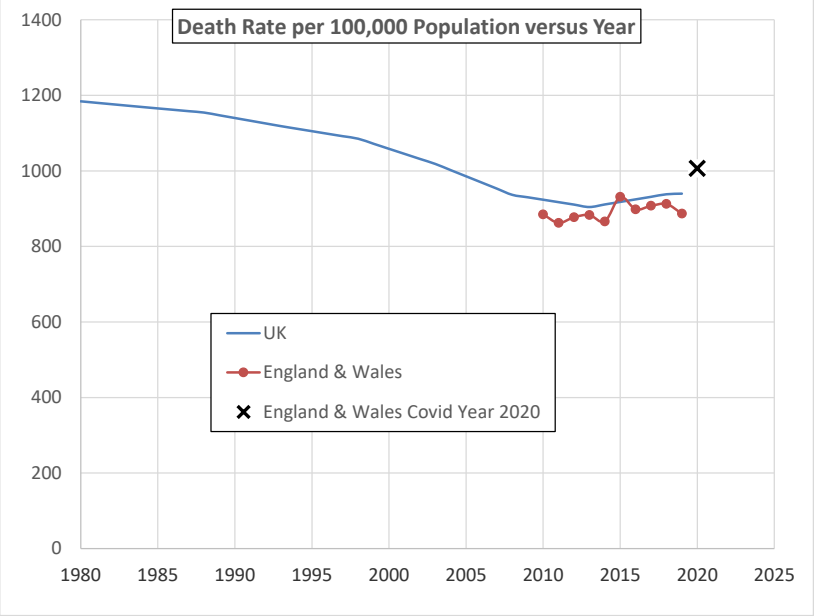


Figure 3



Thus total deaths in 2020, including Covid, were barely greater than in most years in the 1970s. In terms of death rate (per 100,000) that in 2020, including Covid, was 1,012 (see the

black cross in Figure 3). The death rate in every year before 2004 was larger than this. The death rate in 2015 to 2019 was about 900, so Covid appears to have caused an increase in death rate in 2020 of about 12.4%. It remains to be seen whether death rates will drop, perhaps to an all-time low, over the next 12 – 24 months, hence compensating for the recent increase.

Between 1st January 2021 and 15 October 2021 there have been a further 56,800 deaths attributed to Covid-19, based on a positive test within 28 days. Based on the average of years 2015 to 2019, by 15 October the number of (non-Covid) deaths that would be expected is 429,000. The total number of deaths to-date in 2021 is 485,800. These are the figures which represent the background 'noise' against which a potential vaccination signal of 1,698 deaths (or perhaps 7,000 deaths) must be identifiable. For the four possible combinations of numerator and denominator the signal is thus 3%, 12.3%, 0.4% or 1.4% of the background noise. The statistical difficulty of isolating any vaccination death signal from the background noise should now be apparent.

Appendices A and B present specific rebuttals of claims that have been made in The Exposé and elsewhere, but the above observations illustrate why the attempted was always doomed to failure.

3. Licencing Trials: Safety and Efficacy Data

3.1 RRR Versus ARR

Treatment for a disease is expected to reduce the risk of some adverse outcome. This is the "Risk Reduction" (RR) due to, or assumed to be due to, the treatment. Efficacy studies for a given treatment (in this case vaccination) generally report results in terms of RR.

Relative Risk Reduction (RRR) is the ***percentage*** by which risk is reduced by the treatment. Thus, if the risk (i.e., the probability) of the adverse outcome for an untreated person is R_u and the risk for a treated person is R_t then RRR = $1 - R_t/R_u$ (times 100 to express as a percentage).

In studies, the "Efficacy" of a treatment is generally identified with RRR, though they often do not make this clear.

Absolute Risk Reduction (ARR) is the amount by which risk is reduced by the treatment, i.e., ARR = $R_u - R_t$.

So ARR = $R_u \times$ RRR.

As an example, suppose the efficacy (=RRR) of a treatment is stated to be 80%. This means that a treated person has only one-fifth the probability (20%) of the adverse outcome that an untreated person has. But suppose the absolute risk for an untreated person (R_u) was only 1%. Then the treated person has an absolute risk of 0.2%, a reduction (ARR) of 0.8%.

There have been claims that the use of RRR as the definition of treatment efficacy is rather a subterfuge which disguises a possibly very small ARR.

However, both RRR and ARR are valid measures – but of different things.

RRR is the better measure of treatment efficacy.

However, RRR says nothing about the risk to an individual.

Even if the efficacy of a treatment (RRR) were 99%, and it was totally safe, there would be no point in taking the treatment if your absolute risk (R_u) was only one in a million anyway.

However, if your genetics or familial history mean you have a high susceptibility to a disease which may be rare in the general public, you will be interested in the RRR for a candidate treatment.

ARR is a poor measure of treatment efficacy because it depends upon external societal factors which determine the absolute risk, R_u. During an epidemic, R_u will vary by orders of magnitude depending upon the time in question. During the peak of an epidemic, R_u can become very large, whilst otherwise it may be extremely low. ARR varies along with R_u whereas RRR does not as RRR depends only upon the treatment, not the externalities (at least, ideally).

Note that the adverse outcome in question might be, (i) becoming infected, (ii) being hospitalised, (iii) dying, and all these will have different risks and different treatment efficacies.

3.2 Vaccines' Mechanisms of Action

From Ref.16: "The nucleoside-modified messenger RNA in COVID-19 mRNA Vaccine BNT162b2 (i.e., Pfizer) is formulated in lipid nanoparticles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19 disease."

In contrast, AstraZeneca is not mRNA based. From Ref.18: "It is a monovalent vaccine composed of a single recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector encoding the S glycoprotein of SARS-CoV-2 (i.e., the so-called "spike protein"). Following administration, the S glycoprotein of SARS-CoV-2 is expressed locally stimulating neutralising antibody and cellular immune responses."

Both these vaccines work by causing the body's natural machinery to produce the spike protein. The above quote implies that AstraZeneca produces spike protein "locally", i.e., near the injection site. This does not imply that the spike protein stays there, nor that the production of antibodies is local. The words for Pfizer make no mention of locality, and the same concern therefore applies.

I believe, but may be wrong, that conventional vaccines produce the antibodies locally, before the antibodies produced are transported around the body. This may be a key difference in action between Covid vaccines and conventional vaccines (but here I admit ignorance).

Moderna is an mRNA vaccine.

Now being trialled are saRNA vaccines. These "self-amplifying" vaccines self-replicate their mRNA. They are being targeted at booster shots. They raise even more concerns.

3.3 Evidence from Emergency Licencing Trials

3.3.1 Pfizer: Efficacy Against Infection

I take information on the Pfizer trials from Ref.16. Further details can be found in Ref.17 and Ref.21.

There were two efficacy trials, but Trial 1 involved only 60 subjects, so I will ignore it. Trial 2 subjects were drawn from United States, Europe, Turkey, South Africa and South America and involved 18,198 subjects given the vaccine and a control group of 18,325 people who were not.

- The trials started in late July'20 and nominally ended on 9th October'20 (however data continued to be gathered thereafter, see below);
- The control group was closely representative of the treatment group in demographics, age profile and comorbidity.
- The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19 disease;
- Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrolment were included. I find this rather baffling;
- Subjects received two doses of Pfizer vaccine, the second being between 19 and 42 days after the first;
- The surveillance period started from 7 days after the second dose.
- Confirmed cases were defined by one clinical symptom and a positive PCR test.

Figure 4a: Pfizer efficacy trial results from Ref.16 (Table 2): Data available at the time of licencing.

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS CoV-2 infection

Subgroup	COVID-19 mRNA Vaccine BNT162b2 N = 18,198 Cases n1 Surveillance time (n2)	Placebo N = 18,325 Cases n1 Surveillance time (n2)	Vaccine efficacy % (95% CI)
All participants (No confirmed cases were identified in adolescents 12 to 15 years of age)	8, 2.214 (17,411)	162, 2.222 (17,511)	95.0 (90.0, 97.9)
16 to 64 years	7, 1.706 (13,549)	143, 1.710 (13,618)	95.1 (89.6, 98.1)
65 years and older	1, 0.508 (3848)	119, 0.511 (3880)	94.7 (66.7, 99.9)
65 to 74 years	1, 0.406 (3074)	114, 0.406 (3095)	92.9 (53.1, 99.8)
75 years and older	0, 0.102 (774)	15, 0.106 (785)	100.0 (-13.1, 100.0)

Results are given in Figures 4a,b (above & below), taken from Ref.16. Ref.16 includes two Tables with Pfizer efficacy data against infection (i.e., being a "case"). I believe Figure 4a (Table 2) gives the data available at the time of licencing. Figure 4b (Table 3) includes far more data obtained by extending the surveillance period to 6 months after the second dose (and hence terminating around March 2021). I find Table 2 baffling as the numbers do not seem self-consistent. I suspect 162 should be 262.

Salient features of Table 2: At the time of licencing the trial data was woefully underpowered. In the 65 and older age range there was just 1 case in the treatment group and 119 in the control group. At the time of licencing the claim of efficacy for people 75 and older was not statistically significant at the 95% confidence level.

Figure 4b: Pfizer efficacy trial results from Ref.16 (Table 3), data 6 months after second dose (approx. 4 months after licencing and roll out to the public)

Table 3: Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup - participants without evidence of prior SARS-CoV-2 infection* prior to 7 days after Dose 2 – evaluable efficacy (7 days) population during the placebo controlled follow-up period

Subgroup	COVID 19 mRNA Vaccine Na=20,998 Cases n1b Surveillance time (n2d)	Na=21,096 Cases n1b Surveillance time (n2d)	Vaccine efficacy % (95% CI)
All participants	77, 6.247 (20,712)	850, 6.003 (20,713)	91.3 (89.0, 93.2)
16 to 64 years	70, 4.859 (15,519)	710, 4.654 (15,515)	90.6, (87.9, 92.7)
65 years and older	7, 1.233 (4,192)	124, 1.202 (4,226)	94.5 (88.3, 97.8)
65 to 74 years	6, 0.994 (3350)	98, 0.966 (3379)	94.1 (86.6, 97.9)
75 years and older	1, 0.239 (842)	26, 0.237 (847)	96.2 (76.9, 99.9)

Salient feature: with a far great amount of data available after 6 months, a good level of efficacy against infection is demonstrated by the trial, with significant efficacy (77% or better) at 95%CL in all age ranges. Ref.16 also gives the efficacy against severe Covid-19, seven days or more after the second dose, as 95% (BE), 71% (95%CL LB). We shall see later that this does not mesh well with UK public health experiential data.

3.3.2 Pfizer Trial Deaths

However Ref.16 does not quote an efficacy against death. Ref.[21] is the 6 month report (oddly still a preprint). The main report does not have death data either, but linking to the Supplementary Material on MedRxiv does reveal the death data. I reproduce Table S4 from the Supplementary Material below as Figure 4c.

Figure 4c: Pfizer trial, 6 month data (Ref.[21]): All-Cause Death Data

Reported Cause of Death[a]	BNT162b2 (N=21,926) n	Placebo (N=21,921) n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

So, from a pair of nearly-equal sized groups, the vaccinated group had 15 deaths and the unvaccinated 14 deaths. However, these data relate to the double-blinded period. When the trial double-blinded period was terminated, the control group received the vaccine. In the extended period after blinding had ended, five further patients died – all of whom had been vaccinated, either earlier or later. Quoting from Ref.[21] Supplementary Material,

"During the blinded, controlled period, 15 BNT162b2 and 14 placebo recipients died; during the open-label period, 3 BNT162b2 and 2 original placebo recipients who received BNT162b2 after unblinding died. None of these deaths were considered related to BNT162b2 by investigators."

(BNT162b2 being the Pfizer vaccine). The basis of the claim that none of "these deaths" was considered related to vaccination is not given. We shall see this claim does not sit well with the adverse event reports. On the face of it, the Pfizer trial involved more deaths of those vaccinated (20) than for those unvaccinated (14), though after blinding ended they were almost all vaccinated and so the comparability of group sizes and periods was compromised.

3.3.3 Pfizer Trial Adverse Events

Data on the adverse events reported during the Pfizer trial can be found in Ref.[21] Supplementary Material, Table S3, reproduced below as Figure 4d.

Figure 4d: Pfizer trial adverse events

Adverse Event	BNT162b2 (N[a]=21,926) n[b] (%)	Placebo (N[a]=21,921) n[b] (%)
Any event	6617 (30.2)	3048 (13.9)
Related[c]	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related[c,d]	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related[c]	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period. The population included all ≥16-year-old participants who received ≥1 dose of vaccine irrespective of follow-up time. a. N=number of participants in the specified group. This value is the denominator for the percentage calculations. b. n=Number of participants reporting ≥1 occurrence of the specified event category. For 'any event', n=number of participants reporting ≥1 occurrence of any event. c. Assessed by the investigator as related to investigational product. d. Shoulder injury related to vaccine administration, right axillary lymphadenopathy, and paroxysmal ventricular arrhythmia (as previously reported). Adverse events for 12–15-year-old participants were reported previously.[11]

Adverse event reports from this trial are a far better indication of the potential harms of the vaccine than VAER or YCS reports. Compared to the latter the advantages are,

- Because subjects know they are in a trial, and because adverse events are actually solicited from them by the trial staff, any under-reporting will be minimal, essentially nil;
- Clinic appraisal was used to identify serious conditions from minor conditions, which, as noted above, is difficult in VAERS/YCS due to the sheer volume (and because it requires medical knowledge, and ideally examination of the patient);
- The clinical appraisal also provides a judgment on whether the condition was truly related to the vaccination (double-blind, remember, so the clinician does not know which patients are the treated group);
- Most significantly of all, here we have a control group reporting adverse events under identical conditions and under double-blind conditions.

Salient points,

- The vaccinated group was subject to more than twice as many adverse events as the control group (30.2% cf 13.9%). This is ~20 times more frequent than the Yellow Card rate (2 x 0.8%, see Table1).
- Hence, adverse events can be attributed to 16.3% of two-dose vaccinations. Where judged clinically to be genuinely related to vaccination this figure is 17.9%;

- Adverse events reported by the vaccinated were far more likely to be judged as treatment-related (79%, 5241/6617) than were reports from the control group (43%, 1311/3048).
- The number of adverse events reported by the vaccinated and judged to be severe (262) exceeded the number of severe reports by the unvaccinated control (150). Using the method of Altman & Bland this suggests that there is 95% confidence that the vaccinated will be more likely to suffer severe adverse events than the unvaccinated. This rather important result went unremarked in the main text of the 6 month report, Ref.[21], and did not surface in the pre-licencing data, Ref.[16]. (Whether this implication of the trial data is borne out in the public health context is another matter).
- The best estimate of the risk of two-dose vaccination causing a ***severe*** adverse event is 0.5% (1.2% - 0.7%).
- Recall the 20 deaths in those vaccinated (cf. 14 unvaccinated) noted above, and recall that the Supplementary Material for Ref.[21] included the remark: "None of these deaths were considered related to BNT162b2 by investigators". This claim seems improbable in view of the observation that 79% of adverse events have been clinically judged as probably genuinely related to vaccination. Why should this suddenly become 0% in the context of deaths?

3.3.4 AstraZeneca: Efficacy Against Infection

I take information on the AstraZeneca efficacy trials from Ref.18 which was used as the basis for licencing but which describes the trials as "on-going". There were four trials, two in the UK, one in South Africa and one in Brazil. Data below are the pooled results.

- The studies excluded participants with history of anaphylaxis or angioedema; participants with severe and/or uncontrolled cardiovascular, gastrointestinal, liver, renal, endocrine/metabolic disease, and neurological illnesses; as well as those with immunosuppression;
- Participants had two doses of vaccine, between 2 and 26 weeks apart;
- 10.5% of participants were 56 to 69 years old and only 5.6% were aged 70 or older;
- Surveillance for emergence of illness started on day 15 after the second vaccine dose;
- The pooled trial is woefully under-powered, even worse than Pfizer;
- By the cut-off date of 7/12/20, the pooled trials included 332 cases, but only 131 were virologically confirmed. (Other cases were determined by adjudication committee on the basis of one symptom).
- The tabulated results (Figure 5) do not disaggregate by age, but the text notes, "The number of COVID-19 cases in participants ≥65 years old were too few to draw conclusions on efficacy".
- They go on to state that: "However, in this subpopulation, immunogenicity data are available; see below…... In the updated analysis, there were 12 cases in 1,383 participants (4 for COVID-19 Vaccine AstraZeneca vs 8 for control; VE = 51.9% [95% CI: -60.0, 85.5])". But note that this still gives a result consistent with zero vaccine efficacy in the 65 and older ages.

Figure 5: AstraZeneca efficacy trial results

Table 2: COVID-19 Vaccine AstraZeneca efficacy against COVID-19

Population	COVID-19 Vaccine AstraZeneca	COVID-19 Vaccine AstraZeneca	Control	Control	Vaccine efficacy % (CI)
———	N	Number of COVID-19 cases, n (%)	N	Number of COVID-19 cases, n (%)	———
Interim analysis (cut-off date: 4 November 2020)					
Primary (see above)	5,807	-	5,829	-	-
COVID-19 cases	-	30 (0.5)	-	101 (1.7)	70.4 (54.8, 80.6) (a)
Hospitalisations (b)	-	0	-	5 (0.1)	-
Severe disease (c)	-	0	-	1 (<0.1)	-
Updated analysis (cut-off date: 7 December 2020)					
Primary (see above)	8,597	-	8,581	-	-
COVID-19 cases	-	84 (1.0)	-	248 (2.9)	66.7 (57.4, 74.0) (d)
Hospitalisations (b)	-	0	-	9 (0.1)	100 (50.2, NE) (d)
Severe disease (c)	-	0	-	2 (<0.1)	-

3.3.5 AstraZeneca Trials' Adverse Events

Ref.[27] is the report on the four randomized controlled trials which underwrote licencing of the AstraZeneca vaccine. Data relates to the earlier cut-off of 4 November 2020, and hence to 5,807 participants in the group given the AstraZeneca vaccine, and 5,829 in a control group given the vaccine MenACWY which is a vaccine primarily for meningitis. Very little detail is provided for adverse events, the salient statement being,

"Serious adverse events occurred in 168 participants, 79 of whom received ChAdOx1 nCoV-19 (i.e., the AstraZeneca vaccine) and 89 of whom received MenACWY or saline control."

However, only three cases of serious adverse events were judged to be vaccine related (one in the treatment group, one in the control group, and one undeclared). There was one fatal Covid-19 case (in the control group) and four deaths that were not from Covid and clearly were not vaccine related.

The above data indicate that 1.36% of people vaccinated with two doses of AstraZeneca with suffer serious events, (1.53% for the control), though the claim that all but three serious events were not vaccine related should be noted. Nevertheless, these compare with the Yellow Card data which indicates a YCS report rate of 0.5% per dose (or 1.0% for two doses). However, that refers to ***all*** adverse events, the overwhelming bulk of which would be minor. Consequently, as was the case for Pfizer, the trial data implies a far greater adverse

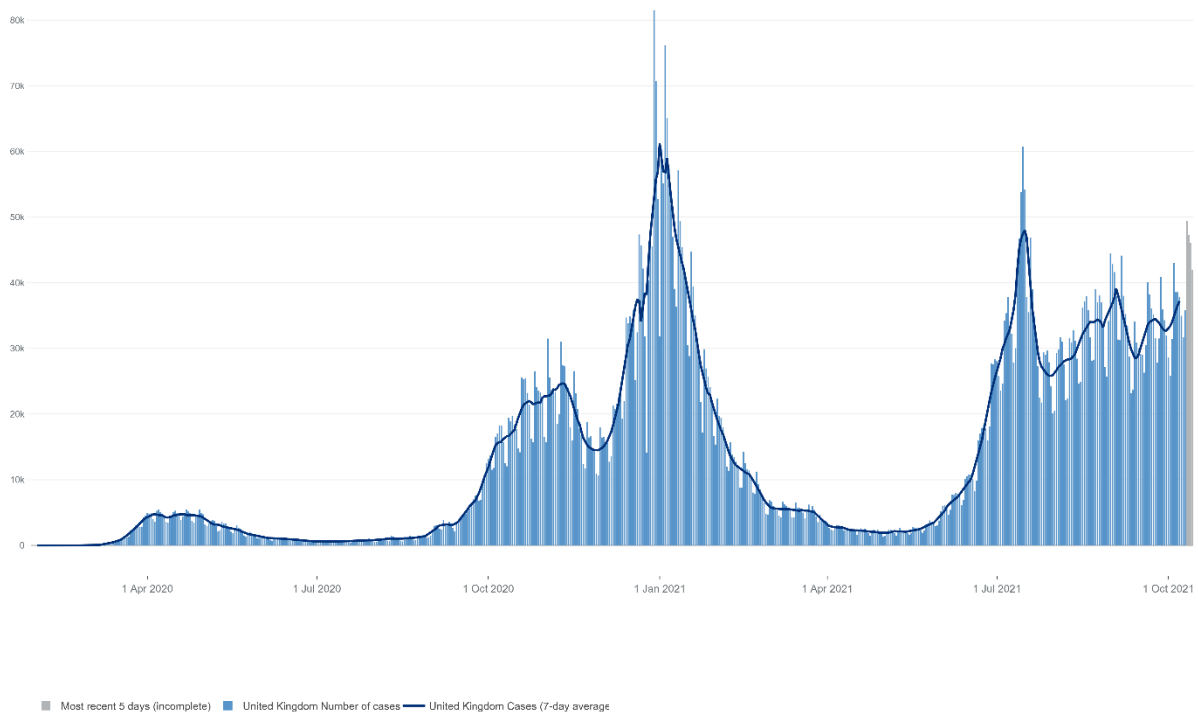
event rate than the Yellow Card data, again indicating that the latter are woefully under-reported.

The serious adverse event rate for AstraZeneca (1.36% of people) is comparable with Pfizer (1.2%). However, whereas Pfizer had a higher rate of serious adverse events than the control, AstraZeneca does not. Consequently one can only conclude, for AstraZeneca, that serious adverse events are no more common than for the meningitis vaccine MenACWY. Unfortunately that gives us no information for the serious adverse event rate for AstraZeneca when compared with an indisputably benign control (e.g., sterile saline). In the risk-benefit analysis, below, I shall assume for sake of argument that the serious adverse event rate attributable to the AstraZeneca vaccine is the same as Pfizer, i.e., 0.5%. Since they have comparable absolute rates this seems reasonable. However, this may be too conservative because only three of the AstraZeneca serious events were deemed vaccine related. Such conservatism is appropriate for a risk-benefit analysis.

4. Efficacy Implied by UK Public Health Data

By this time a better indication of vaccine efficacy is to be obtained from the population as a whole. Data on prevalence by vaccine status is taken from Ref.19, the UK Health Security Agency's vaccine surveillance report for week 41. The prevalence data in this edition relates to the four weeks 37 through 40. Data relates to England alone. This period runs from mid-August to mid-September and so is within the period of high case incidence, as shown by Figure 6 below.

Figure 6: Number of cases reported in UK against date (from here)



The numbers of cases, the numbers of hospitalisations, and the numbers of deaths over that 4 week period are given in Tables 2, 3 and 4 of Ref.19, broken down by age range and also by vaccination status. Five vaccination statuses are used: (i) not vaccinated, (ii) one dose of

vaccine within 20 days of specimen date; (iii) one dose of vaccine more than 20 days before specimen date; (iv) two doses of vaccine, the second being at least 14 days before specimen date; (v) unknown vaccination status. Here I shall confine attention to the comparison between (i) and (iv), i.e., double-vaccinated versus unvaccinated.

A shortcoming of the data in Ref.19 is that it does not disaggregate by vaccine type. This is potentially important as the licencing trials indicated AstraZeneca to be substantially less efficacious than Pfizer. I presume this information is within the complete datasets and that it is being monitored though not declared in Ref.19.

A crucial question arises in respect of the definitions of the denominators in the two key columns in Ref.19 Tables 2, 3, 4, namely "rates among persons vaccinated with 2 doses (per 100,000)" and "rates among persons not vaccinated (per 100,000)". Are the denominators the same in the two cases, i.e., does the 100,000 represent the whole population of England? Or, does the "rate among persons vaccinated with 2 doses (per 100,000)" mean the rate per 100,000 double-vaccinated people, whilst the "rate among persons not vaccinated (per 100,000)" mean the rate per 100,000 unvaccinated people? The latter is the case, though Ref.19 does not say so, and I have confirmed this by estimating the denominators independently myself. Details follow…

Internet sources can be used to find the population of England in the various age ranges required, as listed in Table 4. Ref.19 gives the percentage of vaccination coverage by age group. I use that at week 37, listed in Table 4 for both first and second vaccinations. Hence the numbers of people second vaccinated by week 37 are found as are the numbers not vaccinated at all at week 37 (Table 4).

Table 5 uses the case prevalence data for unvaccinated and double-vaccinated people from Table 2 of Ref.19 together with the denominators defined by my Table 4 to derive prevalence rates per 100,000 in each age range and compares these with what Ref.19 Table 2 gives for the rates. The agreement is pretty good and hence confirms this interpretation of the denominators. The implied vaccine efficacy is then found from 1 minus the ratio of the rates for double-vaccinated and unvaccinated people. Using my estimated rates or Ref.19's rates gives very similar results for the implied efficacy.

Table 5 confirms what Ref.19 states thus, "*in individuals aged greater than 30, the rate of a positive COVID-19 test is higher in vaccinated individuals compared to unvaccinated*". In terms of vaccine efficacy this means the efficacy is negative, i.e., vaccination apparently makes one more likely to become infected.

All that Ref.19 offers by way of explanation of this disconcerting result is this: "*This is likely to be due to a variety of reasons, including differences in the population of vaccinated and unvaccinated people as well as differences in testing patterns*".

This is hardly adequate, and it will not do to merely protest that "*the vaccination status of cases, inpatients and deaths is not the most appropriate method to assess vaccine effectiveness and there is a high risk of misinterpretation*". Actually it is a perfectly reasonable way to estimate vaccine efficacy, and has the advantage of statistical significance which is more than one can say about the licencing trials in the older age groups.

However, for this revised review, I have now looked at the week 46 report, Ref.[22]. This has more details of the sort of issues that might impact the reliability of the whole-population method for efficacy estimation. Moreover, the week 46 report gives references to the studies upon which the HSA's efficacy are based. In Appendix C I clarify how the two approaches differ.

An alternative explanation of the apparent doubling of the risk of infection in people twice-vaccinated of ages 30 – 80 is vaccine-induced enhanced susceptibility or antibody-dependent enhancement (ADE), which is a known phenomenon, e.g., see Ref.20 and may other sources.

On a happier note, for hospitalisation or death, my Tables 6 and 7 do indicate substantial vaccine efficacy, though this appears to diminish with age (details below and in those Tables). For week 45 the equivalent results are given in Tables 8 and 9.

4.1 Vaccine Efficacy Claimed by the HSA

Figure 7a: Vaccine efficacy claimed by HSA (Ref.19, Table 1) 2021 Week 41 Report

Outcome	Vaccine effectiveness*		
	Pfizer-BioNTech Cominarty	AstraZeneca Vaxzevria	Moderna Spikevax
Infection	75-85%	60-70%	
Symptomatic disease	80-90%	65-75%	90-99%
Hospitalisation	95-99%	90-99%	95-99%
Mortality	90-99%	90-95%	

High Confidence	Evidence from multiple studies which is consistent and comprehensive
Medium Confidence	Evidence is emerging from a limited number of studies or with a moderately level of uncertainty
Low Confidence	Little evidence is available at present and results are inconclusive

Figure 7b: Vaccine efficacy claimed by HSA (Ref.22, Table 1) 2021 Week 46 Report

Table 1. Summary of evidence on vaccine effectiveness against different outcomes Delta

Outcome	Vaccine effectiveness*		
	Pfizer-BioNTech Comirnaty	AstraZeneca Vaxzevria	Moderna Spikevax
Infection	75-85%	60-70%	
Symptomatic disease	80-90%	65-75%	90-99%
Hospitalisation	95-99%	90-99%	95-99%
Mortality	90-99%	90-95%	

The HSA reports prefer not to use whole-population data to deduce vaccine efficacy, instead citing reasons for it being potentially misleading. The basis of the vaccine efficacy claimed by the HSA at week 41, as reproduced in Figure 7a above, was obscure. However, at week 46 (Figure 7b) the HSA report states: "In order to estimate vaccine effectiveness against infection, repeat asymptomatic testing of a defined cohort of individuals is required. Studies have now reported on vaccine effectiveness against infection in healthcare workers, care home residents and the general population". The studies in question are Refs.[23,24].

These studies differ from the real-world data in that they use a "test-negative case–control design to estimate vaccine effectiveness". The dataset is drawn from the PCR testing programme, which is therefore a subset of the whole population defined by people who have symptoms. In the UK this will usually mean that the data is restricted to people who have had a positive cross-flow, self-administered test. The subsequent PCR test may then be positive or negative, and the vaccination status is then used to derive a relative risk for those infected (positive PCR) compared to the "control", i.e., the relative risk for those with a negative PCR.

Refs.[23,24] claim that the use of the test-negative case–control design "helps to control for biases related to exposure, health-seeking behaviour, access to testing, and case ascertainment", i.e., to overcome the shortcomings of a naïve usage of all the real-world data (in the HSA's opinion). But these studies, upon which HSA relies for its efficacy estimates, are less forthright about the obvious bias in their own dataset, namely that it relates only to individuals who have come forward for a PCR test. This is a rather glairing bias. It is reasonable to expect that unvaccinated individuals would be less likely to seek a PCR test, and, if so, this would explain the difference in the two estimates of efficacy.

In Appendix C I clarify in algebraic terms the difference between this "test-negative case-control" method of defining vaccine efficacy and the definition based on the real-world data used in my Tables 5 to 9. This clarifies why, if unvaccinated individuals are less likely to seek a PCR test, the HSA's method of estimation will result in a greater apparent vaccine efficacy – but that does not make it correct.

The whole-population results from my Tables 5 to 9, based on Refs.[19,22], are summarised below. Efficacies implied by this real-world data are substantially poorer than the HSA claims, Figures 7a,b. Moreover, whatever merits the HSA's disclaimers may have for infection, they are far less convincing in the context of hospitalisation or death.

Vaccine Efficacies Implied by Whole-Population Monitoring Data (smallest data from my Tables 5-9) (Combination of all vaccine types)

Ages	Infection	Hospitalisation	Death
< 60	Vaccine increases risk of infection above age 30, by up to about times two	>73%	>72%
60 – 69		70%	76%
70 - 79		64%	69%
80+		50%	57%

Hence, even against hospitalisation or death, the public health data suggest far lower efficacies than the HSA claims.

WARNING: The apparent age dependence of vaccine efficacy summarised above may actually be a surrogate for a waning efficacy over time – because the older age groups were vaccinated first. Hence, the efficacy against hospitalisation/death even in younger people

might drop to around 50%-60% over the next few months. Ref.[22] includes specific data on declining vaccine efficacy over time.

5. Vaccination Risk-Benefit Analysis

Here we are now interested in absolute risk, in order to judge risk-benefit for the individual (see §3.1).

VAERS/YCS data is essentially useless as a guide to risk because the degree of under-reporting is unknown but probably very high. Moreover, without detailed medical appraisal of the masses of data it is not clear how to identify serious adverse events from minor issues.

Consequently the trial data will be used to judge risk rather than VAERS/YCS data.

Moreover, we are interested in the potential for acquiring Covid-19 in its severe form as compared with the likelihood of a severe adverse reaction due to vaccination.

By concentrating on severe disease cf severe adverse events we bypass the contentious issue of vaccine efficacy against infection. If the whole population method is used, there is no benefit to vaccination and so risk-benefit does not arise.

For Pfizer the trial data implies that 0.5% of the double-vaccinated will suffer a severe adverse event which is attributable to the vaccination (see §3.3.3). For conservatism I assume the same for AstraZeneca. It looks like we are heading towards booster doses every 6 months, in which case it is reasonable to take this 0.5% figure as an annual absolute risk.

The annual benefit of the vaccination against being hospitalised (taken as a surrogate for severe disease) is obtained from Table 10 by multiplying by 13. Note that the whole population public health data must be used here as we need absolute risk based on the entire population. (The “test-negative case-control” data do not provide this absolute risk because they are based on the subset of the population obtaining PCR tests only).

The vaccination has benefit which outweighs the risk if the annual benefit (offset risk)exceeds 0.5%. The results of this risk-benefit analysis are…

Vaccine Benefit Against Hospitalisation per Year (cf. risk of a severe adverse vaccination reaction, estimated as 0.5% annually)

Age	Annual Probability of Vaccine Resulting in Avoidance of Hospitalisation	NNTV*	Risk-Benefit Favours Vaccination?
<18	0.04% - 0.07%	1,540 – 2,560	no
18 - 29	0.07% - 0.09%	1,100 – 1,540	no
30 - 39	0.10% - 0.17%	590 - 960	no
40 - 49	0.18% - 0.30%	334 - 549	no
50 - 59	0.27 – 0.53%	188 - 366	borderline
60 - 69	0.31% - 0.62%	160 - 320	borderline
70 - 79	0.44% - 0.86%	116 - 226	maybe
80+	0.49% - 1.29%	78 - 202	yes

*Number Needed To Vaccinate to avoid one hospitalisation (per year). Compare this with the rate of serious adverse vaccination effects of one per 200 people per year. This suggests that if NNTV exceeds 200 then vaccination does not have net benefit.

I emphasise that this risk-benefit analysis does not take account of any long-term risk, about which nothing reliable is currently known. That being the case it is a judgment, based on trust (or lack thereof), as to whether the above Table is relevant or not. For all but the oldest people it might be reasonable to conclude that an unknown risk is a poor gamble when set aside a relatively small offset risk (benefit). For those aged over 80, on the other hand, one could argue that there is no long term anyway.

In this context note §6.4, below, and also the recent indications of potential adverse effects of the spike protein on the heart, Refs.[38-41]. I have no idea where that one might end up – perhaps as a serious issue, perhaps as entirely a false alarm.

6. Supplementary Relevant Observations

6.1 The WHO and Booster Doses

As of 10 August 2021 the World Health Organisation's position on the need for booster doses of vaccine following the standard two-dose primary vaccination is as follows,

"To date, the evidence remains limited and inconclusive on any widespread need for booster doses following a primary vaccination series.", Ref.[28].

6.2. Outpatient Treatment Protocol?

Amazingly, at 23 November 2021, after 21 months of pandemic, the NHS still provides no treatment regimen for outpatients, Refs.[25,26]. Quote, "There is currently no specific treatment for coronavirus". Instead only paracetamol or ibuprofen are recommended, and this continues until such a time that you are so bad that A&E / hospitalisation is motivated. It is quite incredible that no attempt has been made to deploy safe drug options to minimise the number of cases reaching this severe stage. The denial of Ivermectin and Hydroxychloroquine is difficult to rationalise with valid, benign motives.

6.3. Vitamins D3 & K2

There is a large literature on the beneficial effects of vitamin D3 on the natural immune systems. Inverse correlations between serum vitamin D3 concentrations and Covid-19 mortality have been noted. Ref.[29] claims this relationship is causal, so that taking vitamin D3 supplements (preferably with vitamin K2 also) to boost serum levels to 50 ng/mL will be protective against Covid-19. (Normally a level of 20 ng/mL is regarded as sufficient, but a very large percentage of the UK population is below even that level). Their data suggests that boosting D3 level from 15 to 40 ng/mL offers 70% protection against Covid-19, and 50 ng/mL gives greater protection still. Hence, taking vitamin D3 supplements, with K2, in appropriate dosage, can be as effective a prophylactic as the Covid-19 vaccines if you were vitamin D deficient initially (and in winter in the UK 30% - 40% of the population are vitamin D deficient, even against the low standard of 20 ng/mL defined by avoidance of rickets, Ref.[36] – and a far larger percentage will have levels of below the optimal 50

ng/mL). Note that the authors of Ref.[29] do not present vitamin D3 as an alternative to vaccination, but as an addition.

6.4 Spike Protein as a Mutagen

All the Covid vaccines to-date cause production of the virus's spike protein as the key part of their mechanism. In attempting to address the potential harms caused by the spike protein we enter deep waters which I am not competent to negotiate (worryingly, I'm not convinced anyone is). However, one finding which is currently raising interest is the *in-vitro* discovery that the spike protein can enter the nucleus and impede the DNA repair mechanism. Some voices are claiming that safe vaccines should not be based on producing the full spike protein. The Abstract of Ref.[30] is,

"Severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) has led to the coronavirus disease 2019 (COVID–19) pandemic, severely affecting public health and the global economy. Adaptive immunity plays a crucial role in fighting against SARS–CoV–2 infection and directly influences the clinical outcomes of patients. Clinical studies have indicated that patients with severe COVID–19 exhibit delayed and weak adaptive immune responses; however, the mechanism by which SARS–CoV–2 impedes adaptive immunity remains unclear. Here, by using an in vitro cell line, we report that the SARS–CoV–2 spike protein significantly inhibits DNA damage repair, which is required for effective V(D)J recombination in adaptive immunity. Mechanistically, we found that the spike protein localizes in the nucleus and inhibits DNA damage repair by impeding key DNA repair protein BRCA1 and 53BP1 recruitment to the damage site. Our findings reveal a potential molecular mechanism by which the spike protein might impede adaptive immunity and underscore the potential side effects of full-length spike-based vaccines."

The implications are put in context in the video of Ref.[31].

6.5 The Pharma Establishment's Questionable Integrity

You can find opinions of any extremity, on any subject, on the internet and this means nothing. But what is one to think when an executive editor of the British Medical Journal, one of the world's most prestigious academic journals, publishes an article in the BMJ which states,

"Politicians and governments are suppressing science…. Science is being suppressed for political and financial gain. Covid-19 has unleashed state corruption on a grand scale, and it is harmful to public health." (Ref.[32]).

Can we just dismiss this under the general rubric of "conspiracy theory"? From the BMJ?

What are we to make of the staggeringly huge fines imposed on Big Pharma in the last couple of decades? Wiki currently lists 20 fines to Big Pharma in excess of $340 million, with five exceeding a billion dollars, Ref.[33]. Pfizer may have been pipped to the top spot by GlaxoSmithKline, though both have been fined approaching $3 billion in a single case. The size of these fines must, one presumes, reflect the seriousness of the offence. And the offences were not only civil, but also criminal. Pfizer's top fine to-date, in 2009, was for illegally promoting the use of four of its drugs. One of the offences was a felony violation for promoting off-label uses of Bextra, such as for pain relief after knee replacement surgery. At

the FDA's request, Pfizer pulled Bextra off the market in April 2005 because its risks, including a rare, sometimes fatal, skin reaction, outweighed its benefits. Moreover, Pfizer sales reps were distributing the drug, not only for unapproved conditions, but also at twice the approved dosage. (Ref.[34]).

That's the background, and then we read this whitleblower's account of data integrity issues with the Pfizer vaccine trials, Ref.[35]. A private research organisation, Ventavia Research Group, was contracted to carry out the trials. A regional director who was employed at the research organisation (Ventavia) claims that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson later contacted several former Ventavia employees who all left or were fired from the company. One of them stated that "everything that you complained about was spot on."

Are we looking here merely at a rather chaotic organisation, with poor QA but without bad motivation? Whatever the answer is to that, we read in Ref.[35], "In several cases Ventavia lacked enough employees to swab all trial participants who reported covid-like symptoms, to test for infection. Laboratory confirmed symptomatic covid-19 was the trial's primary endpoint, the employee noted. (An FDA review memorandum released in August this year states that across the full trial swabs were not taken from 477 people with suspected cases of symptomatic covid-19.)" That is a very large number, with the potential to make nonsense of the official reported Pfizer trial data.

Corporate crime in the pharmaceutical industry has a long history, see for example Ref.[37] from 1984.

Where does the truth lie? I don't know. But this is a sorry story to sit behind a medical procedure which large swathes of the world's population are coming under increasing coercion to accept, often against their wishes.

7. Conclusions

Safety: VAERS/YCS

[1] The Covid-19 vaccines have novel mechanisms of action, not previously used in a roll out to large populations. Also, they were developed and licenced under emergency legislation at breakneck speed. Empirical knowledge of potential long-term adverse effects is zero. This is my main concern, especially as regards universal deployment on younger people.

[2] Yellow Card reports are filed for fewer than 0.5% of AstraZeneca vaccinations and fewer than 0.3% of Pfizer vaccinations. All VAERS/YCS are known to under-report.

[3] The trial report for Pfizer (Ref.[21]) indicates that 30.2% of participants who received the vaccine made an adverse event report, indicating how seriously under-reported is the YCS data. Moreover, 79% of those reports were clinically assessed as probably related to vaccination.

[4] The trial report for Pfizer (Ref.[21]) indicates that 1.2% of participants who received the vaccine made an adverse event report for a severe condition. The trial report for AstraZeneca (Ref.[27]) indicates that 1.36% of participants who received the vaccine made an adverse event report for a serious condition. As severe/serious conditions will be a small proportion of total adverse events, these data further emphasis that the YCS under-reports to such a degree as to be more misleading than helpful.

[5] Ignoring this underreporting and taking YCS data at face value, the reported numbers of fatal YCS reports for all non-Covid vaccines in the UK since January 2001 obtained by FOI suggests that the death rate from Covid-19 vaccinations is 6 to 15 times greater than might have been expected, and up to 19 times more for AstraZeneca. The absolute rate is 7 to 23 per million (Table 1), but this may be seriously underreported (see above).

Safety: National Population Data

[6] Many claims have been made in news outlets, blogs, etc., that national-level (ONS) death statistics indicate an effect attributable to the Covid vaccines. Examples of such claims have been explicitly refuted in Appendices A and B. It is unlikely that a vaccine death signal will ever be discernible in national-level mortality data because the signal is probably too small compared with the noise.

[7] In England and Wales in 2020 the total number of nominal Covid-19 deaths, based on deaths within 28 days of a positive test, was 70,200 and this aligns well with the number of excess deaths in 2020 compared with 2019. To put the Covid death numbers in perspective, however, the death rate in 2020, including Covid, was below that in any year prior to 2004.

Safety: Trial Data

[8] The Pfizer trial resulted in 20 deaths of participants who had received the vaccine and 14 deaths of people who had not. The treatment and control groups were virtually the same size and comparable in demographics, age and comorbidities. However, after the blind period, the control group were given the vaccine. Five of the 20 deaths of vaccinated people occurred after the lifting of blinding.

[9] For the Pfizer trial, during the blinded period, two deaths in the control group, and one death in the vaccinated group, were attributed to Covid-19.

[10] Adverse event reporting from the Pfizer trial is considered a far better indication of the true extent and severity of adverse vaccine-related events than the YCS because the study conditions (including elicited information) will largely eliminate underreporting, clinical appraisal of reports give a reasonable indication of event severity and their likelihood of being genuinely vaccine related, and there is a control group for comparison.

[11] In the Pfizer trial, the vaccinated group was subject to more than twice as many adverse events as the control group (30.2% cf 13.9%). This is ~50 times more frequent than the Yellow Card reporting rate (2 x 0.3%, see Table1).

[12] Based on the Pfizer trial, after subtracting the adverse event rate for the control group, adverse events can be attributed to about 16% to 18% of two-dose vaccinations.

[13] For the Pfizer trial, the number of adverse events reported by the vaccinated and judged to be severe (262) exceeded the number of severe reports by the unvaccinated control (150). This suggests that there is 95% confidence that people vaccinated with Pfizer will be more likely to suffer severe adverse events than the unvaccinated. The best estimate of the risk of two-dose vaccination causing a ***severe*** adverse event is 0.5%.

[14] For the AstraZeneca trial, the serious adverse event reporting rate was 1.36% per double-vaccination. However: (i) this was less than the rate for the control group, although because the control group was given another vaccine (a meningitis vaccine) it is not clear what this implies; (ii) only three of the serious adverse events were clinically judged to be vaccine related. Unlike the Pfizer case, the AstraZeneca trial gives no indication of serious adverse events clearly linked to the AstraZeneca vaccine.

[15] In the AstraZeneca trial, there was only one fatal Covid-19 case (in the control group) and four deaths that were not from Covid and clearly were not vaccine related (one road traffic accident, one blunt force trauma, one homicide, and one fungal pneumonia).

Efficacy

[16] The licencing trials for Pfizer were woefully underpowered in the age range 65 and over, and even more so for those aged 75 and over. At the time of licencing, for ages 75 and over, the vaccine efficacy derived from then-available trial data was consistent with zero, a fact which has not surfaced in public discussions to the best of my knowledge (see Figure 4a). However, statistical significance was obtained later after accumulating more data (Figure 4b).

[17] The licensing trials for AstraZeneca are woefully under-powered, even worse than Pfizer. Other key observations are,

- The tabulated results in Ref.18 do not disaggregate by age, but the text notes, “The number of COVID-19 cases in participants ≥ 65 years old were too few to draw conclusions on efficacy”!!;
- Whilst Ref.18 goes on to state that “however, in this subpopulation, immunogenicity data are available” the results which follow are also statistically consistent with zero efficacy in the 65 and over age group;
- Staggeringly, it seems that the AstraZeneca trials did not provide a statistically significant basis for any non-zero efficacy for the 65 and over age group at the time of licencing.

[18] The above shortcomings in the trial efficacy data, and the questions over the safety data for Pfizer, suggests that these vaccines would not have been licenced when they were under normal conditions and were licenced then (Nov/Dec’20) only due to the prevailing emergency arrangements.

[19] The UK Health Security Agency (HSA) (Ref.19) does not use the whole-population when translating data on incidences for vaccinated and unvaccinated people into implied vaccine efficacy. Instead, they use studies based on a “test-negative case-control” methodology. Roughly this means, instead of using the whole population, only people who are symptomatic are used to derive efficacy. The difference between this approach and the use of the whole population is explained in Appendix C.

[20] Based on the whole population approach, the HSA incidence data imply that the likelihood of becoming a "case" (infected) is larger for double-vaccinated people over 30 than for the unvaccinated, by up to a factor of two (Tables 5 and 8).

[21] Based on the whole population approach, the HSA incidence data for people younger than 70 imply vaccine efficacy against hospitalisation or death of 70% or better (Tables 6, 7, 8, 9). This reduces for people aged 70 – 79, and reduces further to 50% - 57% for those aged 80 and over.

[22] The HSA's preferred "test-negative case-control" methodology yields substantially higher apparent vaccine efficacies: 90% to 99% for hospitalisation or death. It also indicates efficacy against infection, of 60% to 85%, in sharp contrast to the whole-population approach which indicates no efficacy at all (in fact disbenefit).

[23] The age effect apparent in Tables 6-9 is likely to be a surrogate for diminishing vaccine effectiveness over time. The HSA reports confirm such diminishing efficacy. The efficacy for younger people is also expected to decline over the next few months.

Vaccination Risk-Benefit Analysis

[24] A vaccination risk-benefit analysis has been provided, the results being age-dependent, as shown on Page 19. The risk is greater than the benefit for those under 50. The benefit is greater than the risk for those over 80. Between ages 50 and 80 the risk and benefit are comparable. This analysis ignores long term risk which is unknown though there are emerging concerns.

Miscellaneous Observations

[25] The WHO do not currently recommend booster vaccinations beyond the standard two doses.

[26] The NHS still makes no recommendation for treating Covid-19 outpatients in order to minimise ultimate hospitalisations. Safe and effective drug regimes (e.g., ivermectin) have been ignored. This is baffling. However, one notes that licencing the vaccines was dependent upon emergency arrangements, and these would be voided by an effective treatment regimen.

[27] There is evidence that supplementary vitamin D3 and K2 would be highly efficacious as a prophylactic against Covid-19, at the most bullish estimates comparable to vaccine efficacy. The NHS has not recommended that either.

[28] The whole picture as described here does not sit well with the increasing coercion to accept vaccination by people reluctant to do so.

Table 1: YCS Data for Covid and Non-Covid Vaccines Compared

Vaccine	Number of first doses (M)	Number of second doses (M)	Total number of doses	Number of Reports	Number of adverse events	YCS event rate per thousand doses	Report rate per thousand doses	YCS events per report	Deaths	Deaths per million vaccs
Covid-19 Vaccines (2020/2021)										
Pfizer[(1)]	22.5	19.6	42.1M	118,970	335,344	8.0	2.8	2.82	552	13.1
AstraZeneca[(2)]	24.9	24.0	48.9M	234,410	832,283	17.0	4.8	3.55	1126	23.0
Moderna[(2)]	1.5	1.2	2.7M	16,754	53,584	19.8	6.2	3.20	20	7.4
Non-Covid Vaccines (before 2020)										
All USA[(3)]			4 billion		476,000	0.12				
Influenza, England[(4)]			3,121,334		72,196	23.1		1.1		
Influenza, England[(5)]			5,473		116	21.2				
Influenza, England[(6)]			13,861		1,049	75.7				
All non-Covid vaccinations in UK 2001 to present			330M						404	1.22

[(1)]Reports to 29 September 2021, all adverse events

[(2)]Reports to 6 October 2021, all adverse events

[(3)]all licenced vaccines administered in the USA between 2006 and 2019, all adverse events

[(4)]Ref.11

[(5)]Ref.12 (not Fluarix Tetra)

[(6)]Ref.12 (Fluarix Tetra)

Table 2: VAED Data Specific to Anaphylaxis and Guillain-Barré Syndrome

Vaccine/Ref	Anaphylaxis			Guillain-Barré Syndrome		
	Doses, M	**Events**	**Rate per million**	**Doses**	**Events**	**Rate per million**
Covid-19 Vaccines (2020/2021)						
Pfizer[1]	42.1	491	11.7	42.1	53	1.3
AstraZeneca[2]	48.9	830	17.0	48.9	428	8.8
Moderna[2]	2.7	40	14.8	2.7	3	1.1
Non-Covid Vaccines (before 2020)						
Ref.2[3]			1 (3.8[4])			1 (3.8[4])
Ref.11 Influenza, England	3,121,334	495	158.6	3,121,334	266	85.2
Meases Ref.13 Ireland	[5]	7	120[5]	-		
HPV Ref.13 Ireland			1.4[5]			
None, UK[6]	-					10 to 35[7] per year

[1]Reports to 29 September 2021, all adverse events
[2]Reports to 6 October 2021, all adverse events
[3]Up to seven different vaccines, USA data
[4]After correcting for under-reporting
[5]Children under 16, denominators uncertain, rough estimate used. Statistics too small for reliability
[6]Ref.14, which finds no evidence of an increased risk of Guillain-Barré syndrome after seasonal influenza vaccine, the report rate post-vaccination being consistent with that without vaccination.
[7]This is the **annual** rate of GBS in the general UK population, not vaccine related. The lower rate is for under 20 year olds, the higher rate for those around 70.

Table 3: Yellow Card Data for the Two Leading Covid-19 Vaccines

Event Condition	Pfizer[1]		Astra-Zenica[2]	
	Events	Fatalities	Events	Fatalities
Blood disorders	11,342	3	7,489	10
Cardiac disorders	5,734	98	9,520	171
Congenital disorders	63	0	95	1
Ear disorders	4,602	0	9,994	0
Endocrine disorders	223	0	401	0
Eye disorders	5,562	0	14,087	0
Gastrointestinal disorders	31,083	16	79,193	14
General disorders	83,606	187	250,367	388
Hepatic disorders	156	1	472	8
Immune system disorders	1,697	2	3036	5
Infections	7,902	88	18,628	97
Injuries	5,216	1	8,813	1
Investigations	4,181	3	10,978	1
Metabolic disorders	1,850	2	8,718	3
Muscle & tissue disorders	40,047	0	100,340	1
Neoplasms	239	5	447	8
Nervous system disorders	57,975	55	176,914	196
Pregnancy conditions	517	15	298	6
null	91	0	172	1
Psychiatric disorders	6,970	1	17,468	7
Renal & urinary disorders	915	7	2,600	5
Reproductive & breast disorders	21,797	1	18,730	0
Respiratory disorders	14,352	51	28,070	134
Skin disorders	23,303	1	51,214	0
Social circumstances	191	0	400	0
Surgical & medical procedures	369	1	779	0
Vascular disorders	5,360	14	13,060	69
TOTAL events	**335,344**	**552**	**832,283**	**1126**
Total reports	**118,970**	**552**	**234,410**	**1126**

[1]Covid-19, reports to 29 September 2021

[2]Covid-19, reports to 6 October 2021

Table 4: Population of England by Age Range and Numbers Vaccinated by Week 37

ages	Population (M)	Percentage vaccinated once only	Percentage vaccinated twice	Number not vaccinated x100,000	Number vaccinated twice x100,000
<18	12.0	7.8%	1.6%	111	1.92
18 - 29	9.06	65%	51%	31.7	46.2
30 - 39	7.39	69%	61%	22.9	45.1
40 - 49	8.23	78%	75%	18.1	61.7
50 - 59	6.84	88%	85%	8.2	58.1
60 - 69	6.06	92%	89%	4.85	53.9
70 - 79	3.97	95%	93%	2.0	36.9
80+	2.57	95%	93%	1.29	23.9
Total/Average	**56.1**	**36%**	**58%**	**20M**	**33M**

Table 5: Vaccine Efficacy Implied by All-England Reported Cases in Weeks 37 through 40 (2021)

ages	Cases in the unvaccinated	Cases in those double vaccinated ≥14 days earlier	Rates among persons not vaccinated (per 100,000)		Rates among persons vaccinated with 2 doses (per 100,000		Implied vaccine efficacy against infection	
			My estimate	Ref.19	My estimate	Ref.19	My estimate	Ref.19
<18	311,199	654	2,814	2,671	341	277	88%	90%
18 - 29	20,547	22,053	648	605	477	403	26%	33%
30 - 39	20,532	48,232	897	710	1069	824	-19%	-16%
40 - 49	11,729	89,546	648	696	1451	1456	-124%	-109%
50 - 59	4,998	63,929	610	489	1100	903	-80%	-85%
60 - 69	1,694	33,486	349	314	621	589	-78%	-88%
70 - 79	622	20,916	311	253	567	452	-82%	-79%
80+	375	9,365	291	299	392	365	-35%	-22%

Table 6: Vaccine Efficacy Implied by All-England Reported Hospitalisations in Weeks 37 through 40 (2021)

ages	Numbers of unvaccinated hospitalised	Numbers of the double vaccinated hospitalised	Rates for people not vaccinated (per 100,000)		Rates for persons vaccinated with 2 doses (per 100,000)		Implied vaccine efficacy against hospitalisation	
			My estimate	Ref.19	My estimate	Ref.19	My estimate	Ref.19
<18	386	1	3.5	3.3	0.5	0.4	86%	88%
18 - 29	186	48	5.9	5.5	1.0	0.9	83%	84%
30 - 39	293	121	12.8	10.1	2.7	2.1	79%	79%
40 - 49	317	281	17.5	18.8	4.6	4.6	74%	76%
50 - 59	263	370	32.1	25.7	6.4	5.2	80%	80%
60 - 69	177	477	36.5	32.8	8.9	8.4	76%	74%
70 - 79	126	779	63.0	51.2	21.1	16.8	67%	67%
80+	94	957	72.9	74.8	40.0	37.3	45%	50%

Table 7: Vaccine Efficacy Implied by All-England Reported Deaths within 28 Days during Weeks 37-40 (2021)

ages	Numbers of deaths of people unvaccinated	Numbers of deaths of people double vaccinated	Rates for people not vaccinated (per 100,000)		Rates for persons vaccinated with 2 doses (per 100,000)		Implied vaccine efficacy against death	
			My estimate	Ref.19	My estimate	Ref.19	My estimate	Ref.19
<18	3	0	0.03	0.0	0.0	0.0	-	-
18 - 29	12	6	0.4	0.4	0.1	0.1	75%	75%
30 - 39	22	6	1.0	0.8	0.1	0.1	90%	88%
40 - 49	33	27	1.8	2.0	0.4	0.4	78%	80%
50 - 59	101	88	12.3	9.9	1.5	1.2	88%	88%
60 - 69	109	241	22.5	20.2	4.5	4.2	80%	79%
70 - 79	116	589	58.0	47.2	16.0	12.7	72%	73%
80+	161	1179	124.8	128.1	49.3	45.9	60%	64%

Table 8: Vaccine Efficacy Implied by All-England Data for Weeks 42-45 (2021), from Ref.[22]

COVID-19 vaccine surveillance report – week 46

Table 6. Unadjusted rates of COVID-19 infection, hospitalisation and death in vaccinated and unvaccinated populations.

Please note that the following table should be read in conjunction with pages 14-16 of this report, and the footnotes provided on page 22.

	Cases reported by specimen date between week 42 and week 45 2021		Cases presenting to emergency care (within 28 days of a positive test) resulting in overnight inpatient admission, by specimen date between week 42 and week 45 2021		Death within 28 days of positive COVID-19 test by date of death between week 42 and week 45 2021		Death within 60 days of positive COVID-19 test by date of death between week 42 and week 45 2021	
	Unadjusted rates among persons vaccinated with 2 doses (per 100,000)[1,2]	Unadjusted rates among persons not vaccinated (per 100,000)[1,2]	Unadjusted rates among persons vaccinated with 2 doses (per 100,000)[2]	Unadjusted rates among persons not vaccinated (per 100,000)[2]	Unadjusted rates among persons vaccinated with 2 doses (per 100,000)[2]	Unadjusted rates among persons not vaccinated (per 100,000)[2]	Unadjusted rates among persons vaccinated with 2 doses (per 100,000)[2]	Unadjusted rates among persons not vaccinated (per 100,000)[2]
Under 18	531.2	2,301.2	0.0	4.6	0.0	0.1	0.0	0.1
18-29	713.2	805.2	1.4	8.4	0.0	0.3	0.0	0.3
30-39	1,314.9	948.7	4.1	16.9	0.2	0.9	0.2	1.1
40-49	2,043.5	929.5	8.5	31.2	0.7	2.6	0.9	3.2
50-59	1,442.9	689.6	12.4	53.0	1.6	9.8	2.1	11.9
60-69	1,061.1	495.4	20.5	68.0	6.5	27.3	7.8	33.5
70-79	660.9	420.9	37.1	103.0	17.2	60.4	20.3	65.5
≥80	383.2	417.9	58.7	157.9	56.5	140.1	66.6	155.5

Table 9: Vaccine Efficacy, Weeks 41 and 45 Compared

Age	Efficacy against hospitalisation		Efficacy against death by day 28		Efficacy against death day 60
	Week 41	Week 45	Week 41	Week 45	Week 45
<18	88%	100%	-	100%	100%
18 - 29	84%	83%	75%	100%	100%
30 - 39	79%	76%	88%	78%	82%
40 - 49	76%	73%	80%	73%	72%
50 - 59	80%	77%	88%	84%	82%
60 - 69	74%	70%	79%	76%	77%
70 - 79	67%	64%	73%	72%	69%
80+	50%	63%	64%	60%	57%

Table 10: Vaccine Benefit Against Hospitalisation or Death: Absolute Risk Reduction, ARR, per 4 Week Period (Unvaccinated Rate Minus Double-Vaccinated Rate)

Age	Benefit against hospitalisation		Benefit against death by day 28		Benefit against death day 60
	Week 41	Week 45	Week 41	Week 45	Week 45
<18	0.003%	0.005%	0	0.0001%	0.0001%
18 - 29	0.005%	0.007%	0.0003%	0.0003%	0.0003%
30 - 39	0.008%	0.013%	0.0007%	0.0007%	0.0009%
40 - 49	0.014%	0.023%	0.002%	0.002%	0.002%
50 - 59	0.021%	0.041%	0.008%	0.008%	0.010%
60 - 69	0.024%	0.048%	0.016%	0.021%	0.026%
70 - 79	0.034%	0.066%	0.035%	0.043%	0.045%
80+	0.038%	0.099%	0.082%	0.084%	0.089%

Appendix A: Investigation of Association of Vaccinations with Excess Deaths (England)

This Appendix is essentially a rebuttal of the attempt to identify a vaccination death signal made in The Exposé on 21/9/21: *Official data shows people who received a Covid-19 vaccine account for 70% of all-cause deaths during the first 6 months of 2021, with 20% occurring within 21 days of vaccination*.

The approach taken is ill-conceived as it is based on total deaths, not excess deaths. As the large majority of older people have been vaccinated it is inevitable that most deaths will be of vaccinated people, which proves nothing.

Here I look at excess deaths to see if there is indeed any association with vaccination status or vaccination timeline. "Excess deaths" are defined as the difference between 2021 deaths and the average od deaths in the 5 years 2015 to 2019 (pre-Covid). "Non-Covid excess deaths" means excess deaths minus deaths attributed to Covid.

Figure A.1 plots vaccinations per week against non-Covid excess deaths per week (covering mid-December'20 to September'21). There is no obvious relationship. The (Pearson) correlation coefficient is small and negative.

Figure A.1

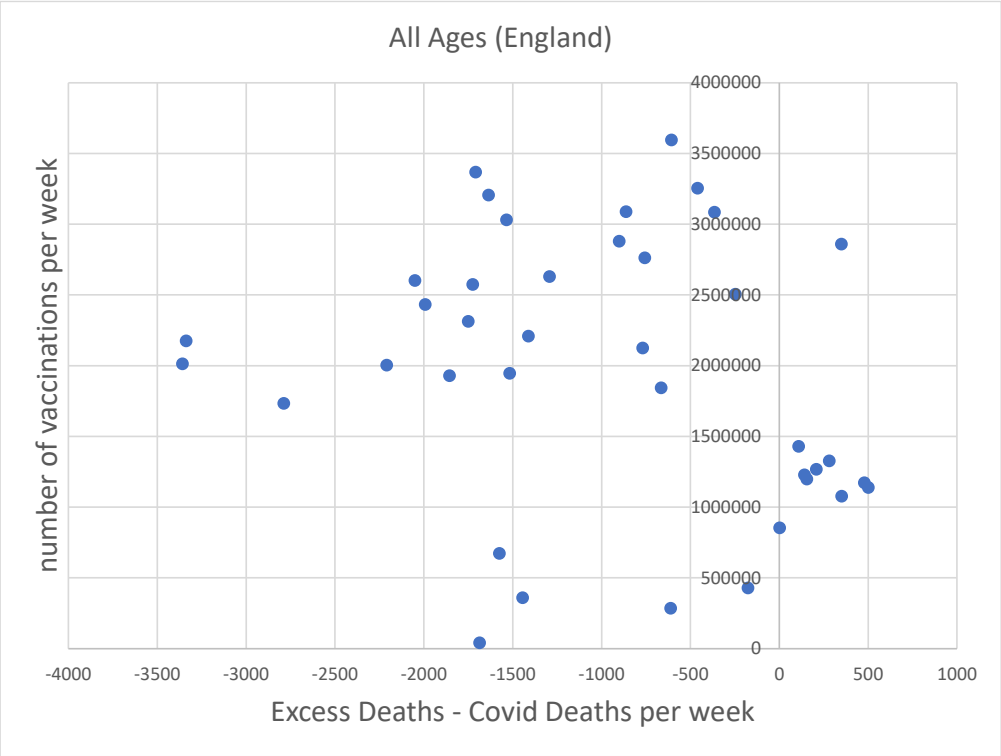
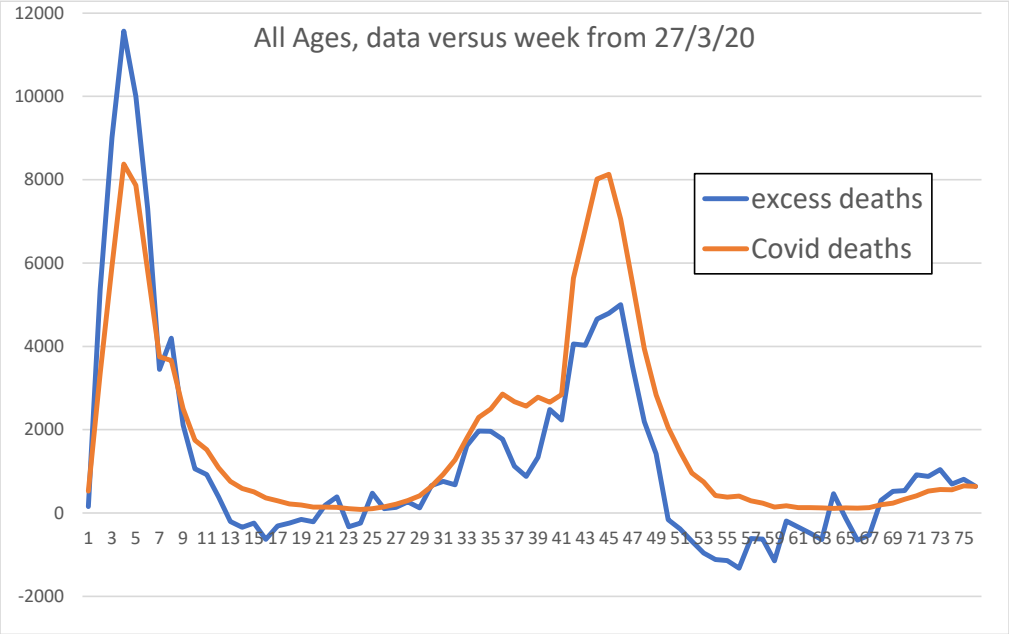


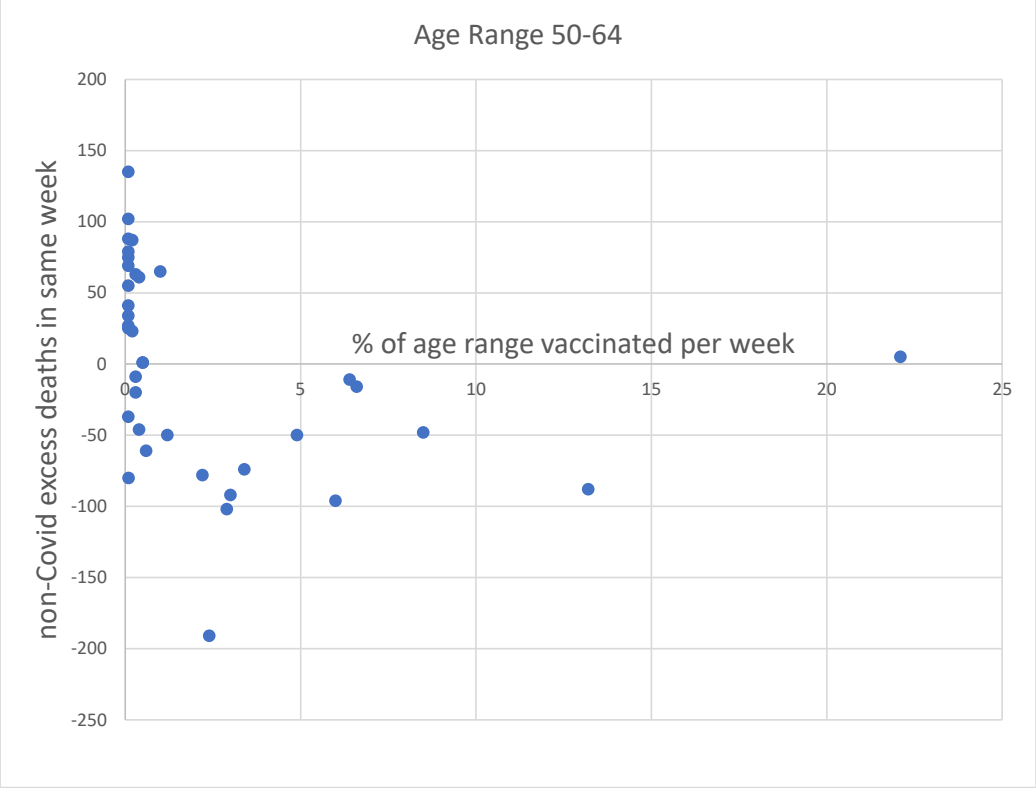
Figure A.2 plots the nominal Covid-19 deaths against week from March 2020 and compares with the excess deaths. This shows that the nominal Covid deaths exceed the excess deaths for most of the time since the first peak. So, there are no non-Covid excess deaths to explain since spring 2020. This illustrates that seeking a vaccine death signal based on "all ages" deaths is impossible as there is no non-Covid excess death data to work with.

Figure A.2:



As an attempt to circumvent this problem, I also looked at the data for a specific age range, namely 50-64. Figure A.4 plots vaccinations per week for this age range against non-Covid excess deaths per week in this age range (covering mid-December'20 to September'21). There is again no obvious relationship, most of the non-Covid excess death data are again negative, and the (Pearson) correlation coefficient is small and negative.

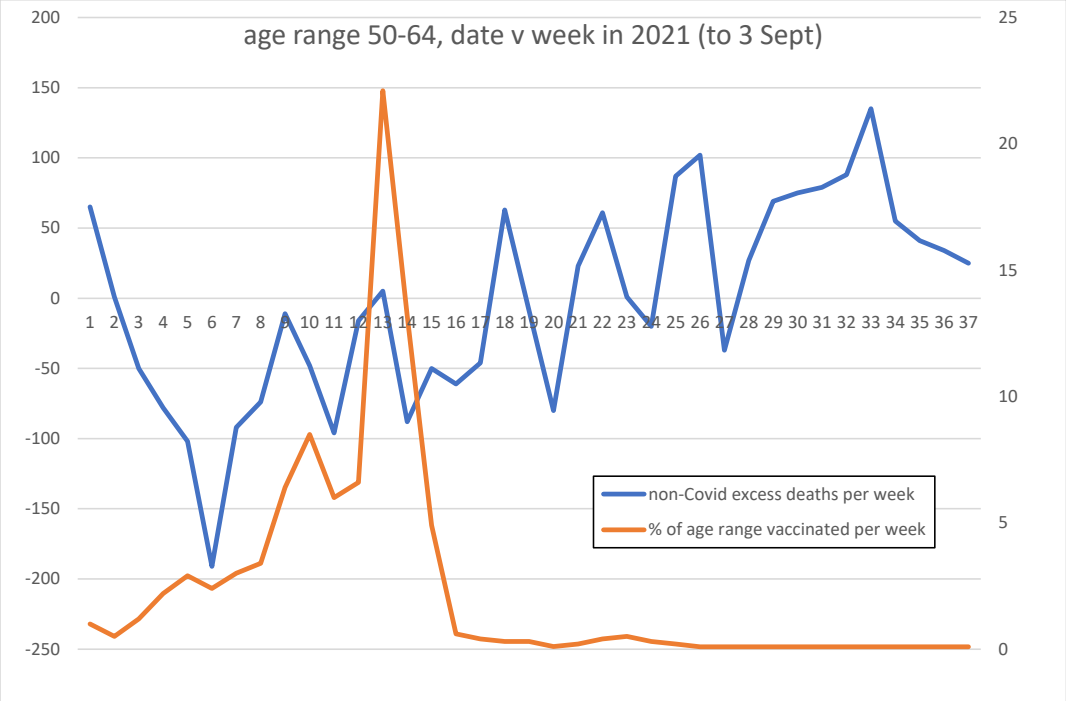
Figure A.4



Finally, Figure A.5 plots against week both the percentage of the 50-64 age range vaccinated per week and the non-Covid excess deaths per week in this age range (from January'21 to September'21). I thought the positive "non-Covid excess death signal" over the last few months in this age range might show a relationship with vaccination - but it doesn't.

One might argue that if fatal vaccination effects were delayed by 10 to 20 weeks, then you could argue that Figure A.5 shows an association. The weakness of this argument is that it is irrefutable: if one is basing the argument on coincidence of timing and one allows oneself the freedom to assume an arbitrary delay of one's own choosing, then any pair of curves can provide an "explanation". At this point one is in the hands of long-term investigations in which epidemiological techniques reliant upon a control group are the only feasible methodology.

Figure A.5



Key sources used in this Appendix

https://coronavirus.data.gov.uk/details/vaccinations?areaType=nation&areaName=England

https://app.powerbi.com/view?r=eyJrIjoiYmUwNmFhMjYtNGZhYS00NDk2LWFlMTAtOTg0OGNhNmFiNGM0IiwidCI6ImVlNGUxNDk5LTRhMzUtNGIyZS1hZDQ3LTVmM2NmOWRlODY2NiIsImMiOjh9

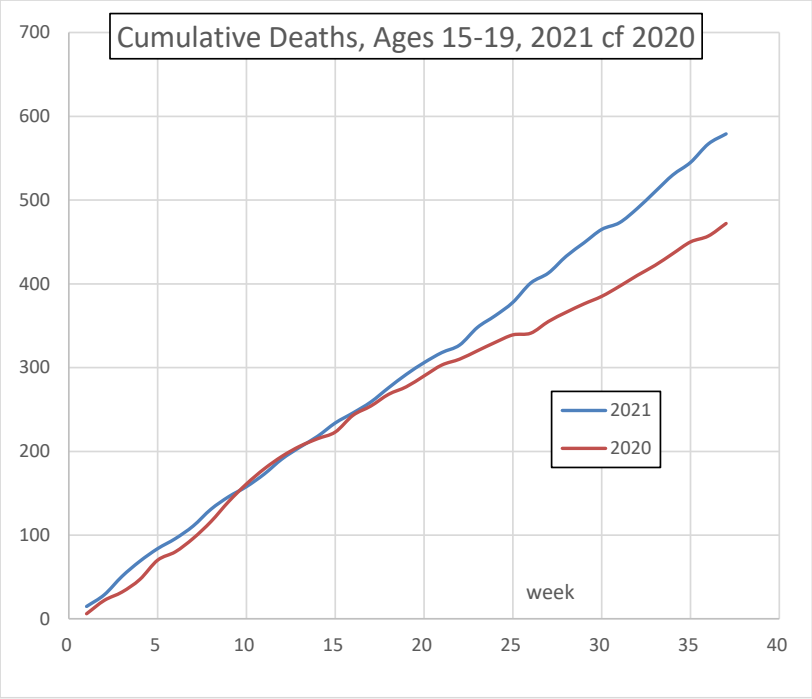
Appendix B: Investigation of Association of Vaccinations with Excess Deaths of 15-19 Year Olds (England)

This Appendix is a rebuttal of the attempt to establish a link between vaccinations and deaths specific to the 15-19 year old age group made by The Exposé on 30 September 2021, *Investigation: Deaths among Teenagers have increased by 47% in the UK since they started getting the Covid-19 Vaccine according to official ONS data* and taken up by Will Jones in The Daily Sceptic the following day, *Deaths Among Teenagers Up 56% Since Vaccine Roll-Out Began*.

At first glance they appear to have a valid case. On closer inspection, however, the claims fall apart. It's an object lesson in extracting meaning from data and the need to attack claims from different perspectives.

The claims stem from data taken from the ONS's Weekly provisional figures on deaths registered in England and Wales when it had data to 17 September 2021. From those data the following comparison between the cumulative deaths in 2020 and 2021 of 15 to 19 year olds can be plotted against week (up to week 37 for both years). Will Jones provides this Figure, which is correct.

Figure B.1



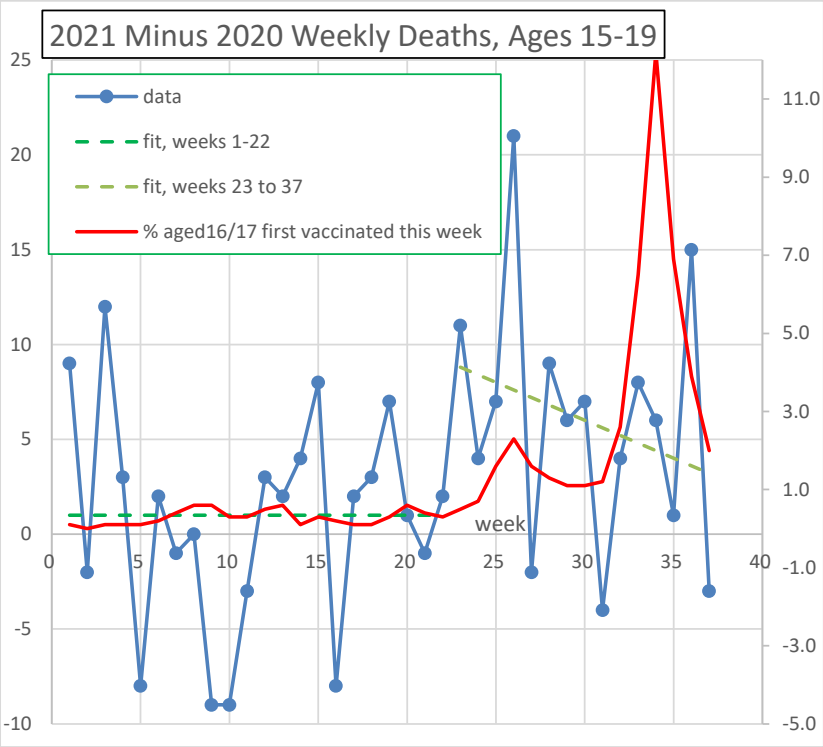
The claims of a link with vaccination hinge upon an apparent coincidence of timing, the two curves above diverging after around week 23, which, it is claimed, was when vaccinations of this age group started to take off.

The claim is implicitly that there is a distinction between the ***excess*** death rates before and after week 23, where "excess deaths" means the excess of 2021 deaths over 2020. To investigate this claim with more statistical rigour I regressed the weekly excess death data separately before and after week 23. There is indeed a clearly distinct trend in the two

periods, as shown by the green dashed lines in Figure 2. The red curve is the number of (first) vaccinations in this age group per week, which shows the claimed coincidence of timing.

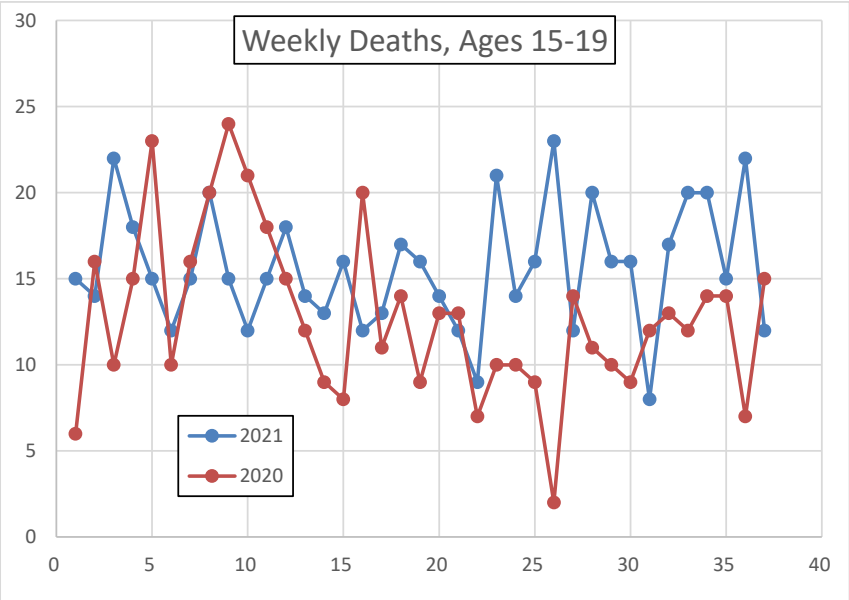
So, at first sight I seemed to be looking at a genuine signal of vaccination being related to excess deaths in the 15 – 19 age group.

Figure B.2*: *This would be a smoking gun if one were not sufficiently critical



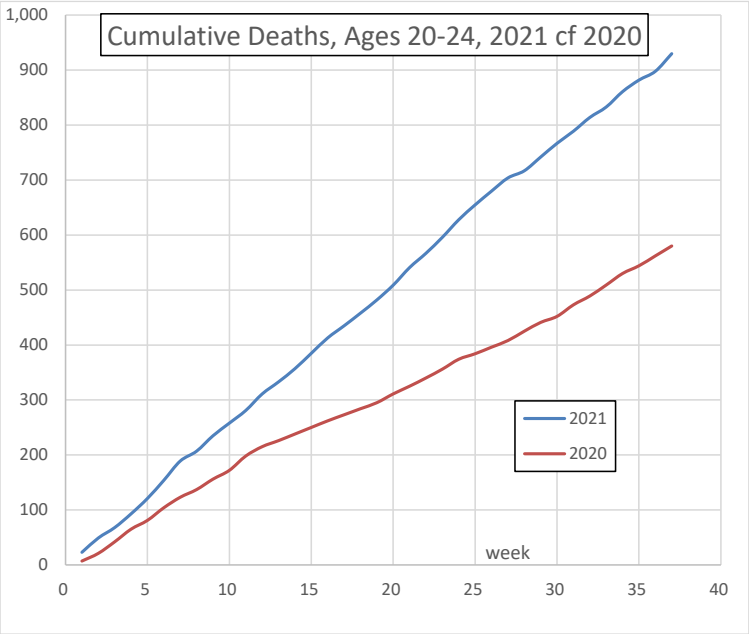
But the story begins to fall apart when one looks at the weekly deaths, comparing 2020 with 2021, Figure 3. The excess deaths from week 23 are related more to a downward blip in 2020 than an abnormal increase in 2021. This cannot be aligned with vaccinations.

Figure B.3



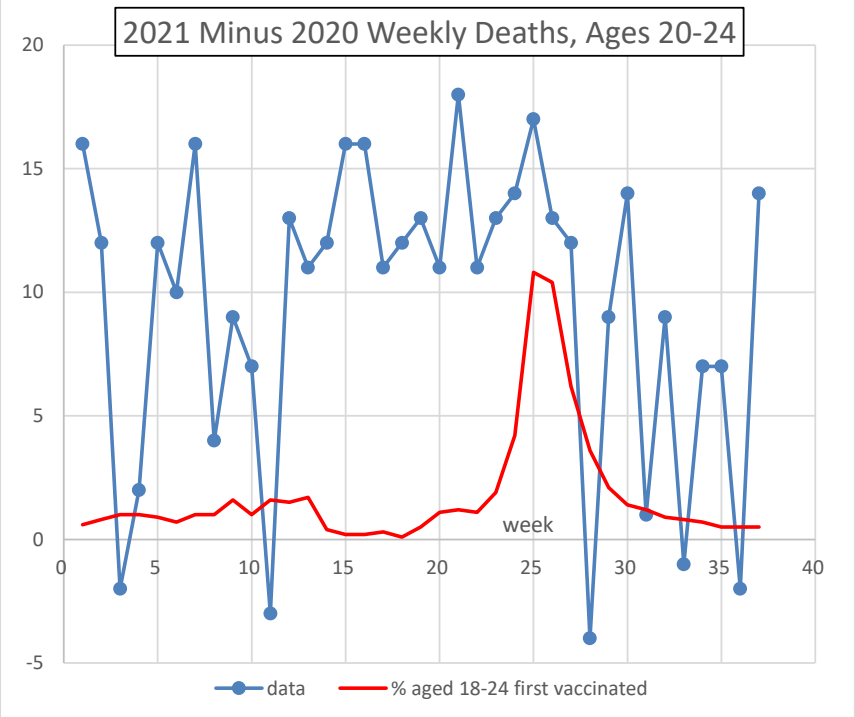
If there is a vaccination signal in the 15-19 age group one would expect one also in the 20-24 age group. The cumulative deaths, up to week 37, in 2020 and 2021 in this age range are shown in Figure 4. The excess 2021 deaths are even more marked than for the 15-19 age group (Fig.1).

Figure B.4



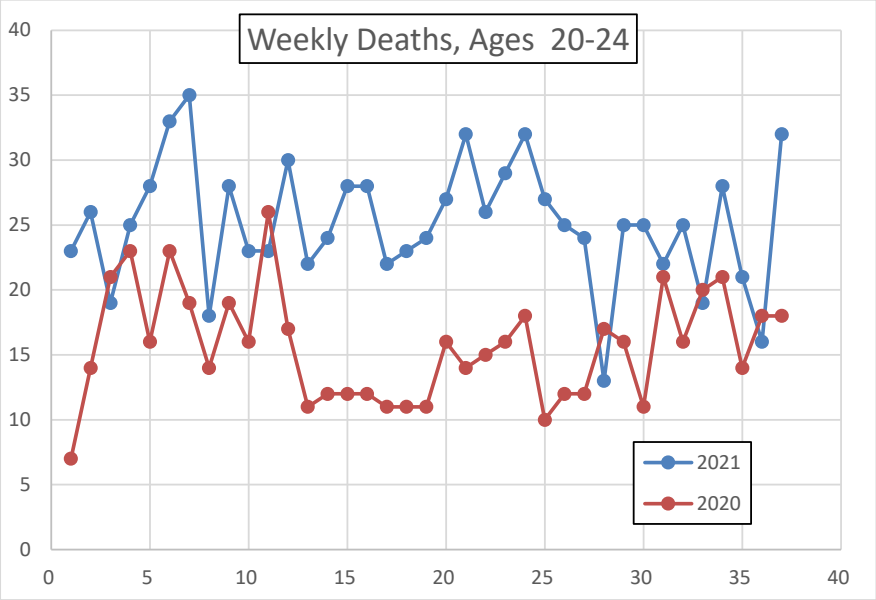
So, question: does the excess death data in the 20-24 age group also align with vaccinations as regards timing? Answer: no. Figure 5 plots the weekly excess deaths in comparison with the weekly (first) vaccinations.

Figure B. 5



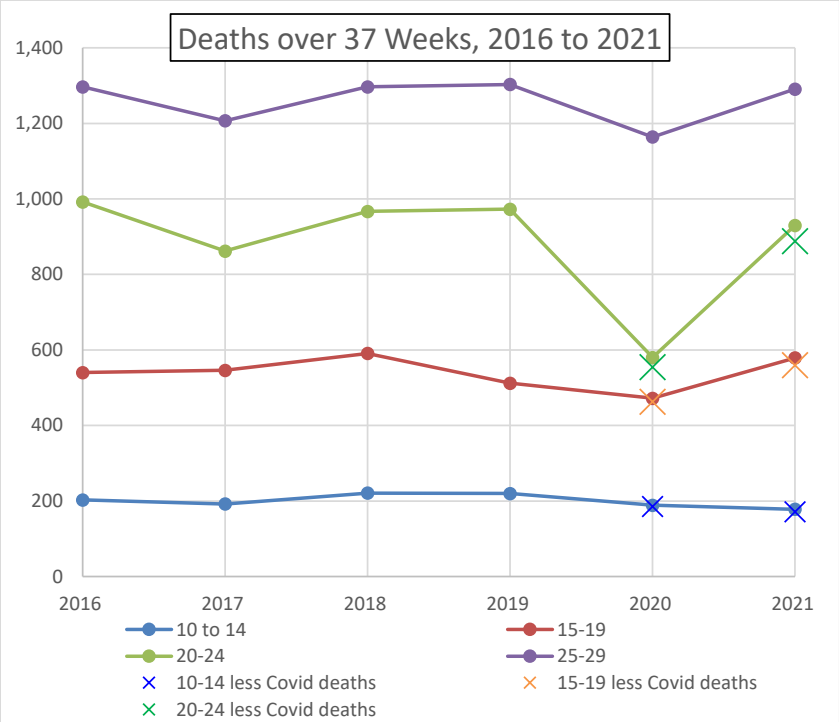
Just as for the 15-19 age group, the excess deaths in the 20-24 age group comes about primarily because of an abnormally low death rate in 2020, not an abnormally high death rate in 2021, Figure 6, which undermines the link with vaccination…

Figure B.6



This observation shows up clearly in the total deaths over the first 37 weeks of each year, shown in Figure 7. It is 2020 which is abnormal, not 2021.

Figure B.7



Covid Deaths: The alert will spot that Covid deaths should strictly be subtracted from the data before attempting to isolate a vaccination signal. I have re-run all the above stats doing just that. The number of Covid deaths at these ages is too small to make any difference.

Conclusions for Appendix B

[1] There is no signal of vaccination-induced deaths in the 15-19 or 20-24 age groups apparent in the currently available datasets.

[2] There were unexplained ***reduced*** deaths among these age groups, especially 20-24, in 2020 compared with earlier years. [Part of this might be reduced road accident deaths, due to lockdowns and home working, which would normally account for about 175 deaths of 20-24 year olds per year. But this does not account for the whole death reduction of ~400 in 2020].

Appendix C: Whole Population Versus Test-Negative Case Controlled Definitions of Vaccine Efficacy (Algebraic Formulae)

Here I give in algebraic form the two different definitions of vaccine efficacy; that using the whole population (my Tables 5 to 9) versus the HSA's preferred "test-negative case controlled" definition. (The latter leads to the HSA's far greater claimed efficacy than implied directly by public health data, Tables 5-9).

The quantities below may relate to any desired outcome measure: infection, hospitalisation or death. They may also relate to any specific age range, or all ages. The term "vaccinated" means double-vaccinated with any of the approved vaccines. "Unvaccinated" means having had no vaccinations.

N_0^{vac} = total vaccinated in the population

N_p^{vac} = number of vaccinated people with the outcome measure (a positive PCR test, or hospitalisation, or death)

N_{p+n}^{vac} = number of vaccinated people who were PCR tested

N_0^{unvac} = total unvaccinated in the population

N_p^{unvac} = number of unvaccinated people with the outcome measure (a positive PCR test, or hospitalisation, or death)

N_{p+n}^{unvac} = number of unvaccinated people who were PCR tested

Note that, $N_{p+n}^{vac} < N_0^{vac}$ and $N_{p+n}^{unvac} < N_0^{unvac}$. It is this fact that leads to the very different estimated efficacies.

Whole-population rates defined as: $\frac{N_p^{vac}}{N_0^{vac}}$ (vaccinated) or $\frac{N_p^{unvac}}{N_0^{unvac}}$ (unvaccinated)

So whole-population vaccine efficacy is $1 - \frac{N_p^{vac}}{N_p^{unvac}} \cdot \frac{N_0^{unvac}}{N_0^{vac}}$ (1)

Test-negative case controlled rates defined as: $\frac{N_p^{vac}}{N_{p+n}^{vac}}$ (vaccinated) or $\frac{N_p^{unvac}}{N_{p+n}^{unvac}}$ (unvaccinated)

So the test-negative case controlled vaccine efficacy is $1 - \frac{N_p^{vac}}{N_p^{unvac}} \cdot \frac{N_{p+n}^{unvac}}{N_{p+n}^{vac}}$ (2)

The latter definition is independent of the total population size, taking as the denominators in the definition of the rates the number of people who have had a PCR test, though it might be negative or positive.

One might expect the unvaccinated to be less assiduous in getting a PCR test than the vaccinated, in which case N_{p+n}^{unvac} will be a smaller proportion of N_0^{unvac} than N_{p+n}^{vac} is of N_0^{vac}. In other words, $\frac{N_{p+n}^{unvac}}{N_{p+n}^{vac}} < \frac{N_0^{unvac}}{N_0^{vac}}$ and hence the efficacy based on the "test-negative case controlled" definition will be larger than the efficacy based on using the whole population in the denominators of the rates.

Appendix D: Discussion of VAERS/YCS Data

D.1 UK Vaccine Adverse Event Reporting System: "Yellow Card" Scheme

As far as I have been able to determine, the Yellow Card system does not specify a timescale after vaccination within which a report must be filed, nor does it restrict who can file the report.

Reports are filed purely on the basis of a subjective suspicion of a possible association with the vaccination. This suggests that the timescale issue is key, though individuals will differ as regards what timescale is considered sufficiently short to raise suspicion. Some people might be suspicious only if the adverse condition occurs within hours, whilst other people might be suspicious if it occurs after a few days or even a week of the vaccination. One might guess that a delay of over a week would fail to arouse suspicion in many people.

At the risk of stating an obvious, but rather important fact, reports of fatalities cannot be filed by the person in question. This may impact under-reporting of fatalities in particular. On the other hand, the seriousness of fatalities may encouraging a better reporting rate, it's difficult to say.

D.2 The Major Shortcoming of VAERS/YCS

Potentially the most important shortcoming of any VAERS/YCSwill be effects which are delayed beyond the timescale at which any suspicion would arise naturally. Thus anything beyond a few weeks is unlikely to be identified, and in particularly, the potential for chronic conditions to arise far later – perhaps years later – is entirely beyond a VAERS system to detect at all. Such long-term impacts can only be identified epidemiologically, and this requires unvaccinated control groups.

Western Governments are currently applying gradually increasing coercion to achieve 100% vaccination coverage across all age groups, even for pregnant women and even in children for whom the risk of Covid-19 is almost zero. Successful resistance by a control group is scientifically essential. It is difficult to rationalise this behaviour by Governments as herd immunity does not require anything close to 100% immunity. Suspicions of nefarious motivations naturally arise when Government policies appear to have no basis in reason, and even, in this case, to be contrary to scientific desirability. Suspicions then alight on "cover up" and financial gain, though group-think and incompetence are always strong contenders.

D.3 Yellow Card Data at 7 October 2021

Yellow Card data are reported weekly, the latest being found at https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting#yellow-card-reports. For the two leading vaccines (Pfizer and AstraZeneca) the YCS data as it was at the time of writing are summarised in Table 3 by major health category.

Another of the shortcomings of a VAERS/YCS is that the low-bar on reporting is set by individuals themselves. Most people expect some minor reaction from a vaccination. This is recognised by the above report which states that effects lasting just a few days like injection-site tenderness or pain, headache, fatigue, myalgia, malaise, pyrexia (fever), chills, arthralgia,

and nausea occur in "more than 1 in 10 people". Actually this is a wild underestimate. The clinical trials of AstraZeneca, Ref.18, found that these minor effects were far more common. Quote, "The most frequently reported adverse reactions were injection site tenderness (63.8%), injection site pain (54.3%), headache (52.7%), fatigue (53.0%), myalgia (43.9%), malaise (44.4%), pyrexia (includes feverishness (33.5%) and fever ≥38°C (7.6%)), chills (32.2%), arthralgia (26.6%) and nausea (22.2%)".

Some people do choose to raise a Yellow Card for such common reactions, but only an extremely small percentage. For example, despite the above incidence data, only 0.5% of AstraZeneca vaccinations have resulted in a Yellow Card report (and, for Pfizer, 0.3%).

D.4 Under-reporting of Adverse Events

VAERS/YCS will inevitably be subject to under-reporting, even when the severity of the adverse event is clearly reportable. But what is the extent of the under-reporting?

The best summary I have found is from the US system, Ref.1, which cites Ref.2 as the source of the bulk of its data. (None of the underreporting data relate to Covid-19 vaccines). Ref.2 investigated underreporting of anaphylaxis resulting from seven different vaccines and its data indicate a median reporting rate of 24%. Ref.2 also investigated the under-reporting of Guillain-Barré syndrome resulting from three different vaccines, and its data suggest a median reporting rate of 22%. The range of results was very large, from 12% to 76%.

A 2013 study, Ref.3, indicated that only 71% of healthcare professionals in the USA were aware of VAERS. Of those healthcare professionals who had identified at least one AEFI (Adverse Event Following Immunisation) only 17% indicated they had ever reported to VAERS, though the more serious events were more likely to be reported.

A 1995 study, Ref.4, investigated four vaccines. For two vaccines the VAERS reporting rate for seizures (a serious event) was 24% and 37%. However, for minor conditions like rash the reporting rate could be less than 1%, whilst for thrombocytopenia (insufficient platelet production potentially resulting in nosebleeds, bleeding gums, blood in urine, heavy menstrual periods or bruising) reporting rates were not more than 5% and possibly less than 1%.

The above findings indicate that under-reporting of serious conditions might be by a factor of about 4, whilst under-reporting of the most minor conditions is so great that the VAERS data is rather meaningless in this category.

However, there are a number of problems involved in assuming these estimates of under-reporting apply to Covid-19 vaccines in the UK,

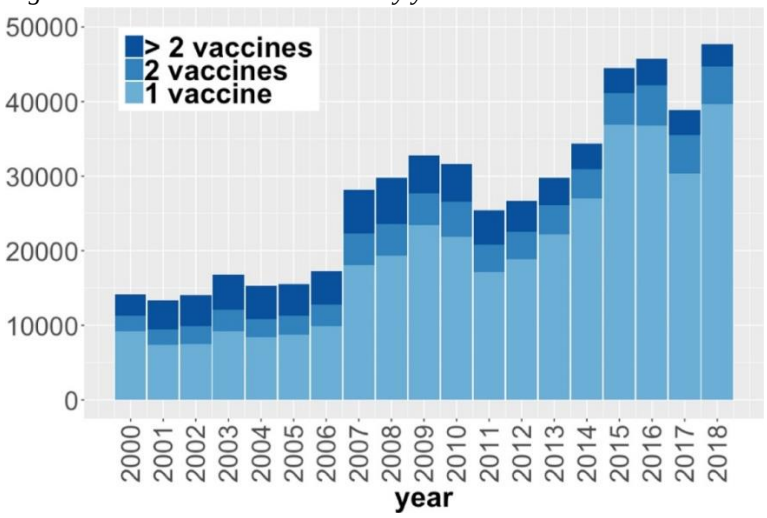
- Reading across from USA data to the UK may be invalid;
- Covid-19 has presented unique social conditions that may affect the likelihood of reporting (e.g., widespread suspicion of the vaccines might encourage reporting);
- Most importantly, it is not clear if data for non-fatal conditions can be assumed as applicable for fatal conditions, bearing in mind that the person reporting cannot then be the person affected, unlike many/most of the non-fatal reports.
- Most importantly, the vaccine trials indicate a far higher adverse event rate, rendering the VAERS/YCS next to useless as regards absolute rates.

D.5 VAER Data for Other Vaccines before 2020 (US Data)

According to the US Centres for Disease Control (CDC), in the 14 years from 2006 to 2019 over 4 billion doses of vaccines covered by US regulations were distributed in the US, Ref.6. That corresponds to an average of 286 million vaccinations per year in the USA. That figure has credibility when compared with the number of vaccinations for influenza alone in the USA. Coverage of annual 'flu vaccinations is about 50% across the whole age range, Ref.7, and hence accounts for half the 330 million population, i.e., 165 million vaccinations per year for 'flu alone.

Annual VAERs data for the USA can be downloaded from Ref.8. (In passing we note that the large size of the file in 2021 is related to the abnormally large number of vaccinations due to Covid-19 in 2021). In 2019 there were 48,443 VAERs. However, the number has been increasing, as shown by Figure 1 taken from Ref.10. The average number of VAERs per year in the USA between years 2006 and 2019 was 34,000. Hence, dividing by 286 gives a VAER rate of 119 per million vaccinations (i.e., 0.12 per thousand).

Figure 1: Total VAERs in the USA by year



D.6 YCS Data for Influenza Vaccines in England before 2020

(1) Ref.11

848,375 unique individuals were identified between 2010 and 2018, between them they received 3,121,334 seasonal influenza vaccinations. Overall, the median age of vaccine recipients was 67 years. This is expected, reflecting the national guidance that patients >65 years old be routinely offered influenza vaccination. Adverse Events of Interest (AEI) were restricted to those identified via medical appointments within 7 days of the vaccination.

No AEIs were recorded for 418,346 participants, who had in total received 2,308,812 vaccinations.

A total of 1,488,870 GP consultations by 430,029 unique individuals (50.7% of all participants) for influenza vaccine surveillance conditions were identified across all years of this study. These individuals had received a total of 812,522 vaccinations. Of this group, 79,260 consultations by 65,141 unique individuals (7.7% of all participants) occurred within 7 days of influenza vaccination.

The total number of AEIs reported (in the 7 day period) by these 65,141 individuals (based on Tables 2, 3, 4 of Ref.11) was 72,196. The average number of AEIs per individual was thus 1.11. (Using the figure for consultations instead gives an upper bound of 1.22).

The conditions for which consultation was sought were grouped according to the EMA category of surveillance condition and shown in Table 2. The most common recorded AEI occurring in the week following vaccination were myalgia, cough, rash and headache however AEIs were observed in every category, including potentially fatal conditions such as anaphylaxis (n = 495) and Guillain-Barré Syndrome (n = 266).

The 7 days following vaccination show a consistently elevated RI (relative incidence) of between 1·9 and 2·6 in all years studied with an upward trend in the magnitude of this effect. The periods between 8 and 14 days, and 15 and 45 days have RIs fractionally elevated over baseline but to a far lesser degree than in the 0–7 day period.

The total AEIs within 1 week (72,196) divided by the total number of vaccinations (3,121,334) is thus an AEI rate per influenza vaccination of 23.1 per thousand.

The rates for anaphylaxis and Guillain-Barré syndrome were 159 and 85 per million vaccinations respectively.

(2) Ref.12

This paper reports the weekly and cumulative incidence of pre-defined adverse events of interest (AEI) occurring within 7 days post-vaccination. 19,334 participants (19.8%) received influenza vaccination, of whom 13,861 (71.7%) received Fluarix Tetra. A total of 1,049 participants receiving Fluarix Tetra reported AEIs. A total of 62 individuals reported an AEI with a known brand of non-GSK influenza vaccine and 54 with an unknown brand.

I interpret the above data to indicate an average AEI rate of 21.2 per thousand for non-Fluarix-Tetra (i.e., 62 + 54 divided by 19,334 - 13861), but a rate of 76 per thousand for Fluarix-Tetra (i.e., 1049 / 13,861).

Table 1 summarises the YCS event rates per vaccination for the Covid vaccines in the UK compared with non-Covid vaccines prior to 2020 based on the above sources. Unfortunately the USA and UK data for non-Covid vaccines are wildly different, which I have been unable to explain.

The UK event reporting rate for Covid vaccines is two orders of magnitude larger than the USA reporting rate for non-Covid vaccines. This is disconcerting. However, the UK event reporting rate for Covid vaccines is less than the rates for UK influenza vaccines. Based on this, and the many years experience with influenza vaccines, I conclude that the overall reporting rate for the Covid vaccines is within expectation.

D.7 VAER Data Specific to Anaphylaxis and Guillain-Barré Syndrome

After correcting for under-reporting, Ref.2 indicated the true rate of anaphylaxis or Guillain-Barré syndrome from US data was an average of 3.8 per million doses for the seven vaccines studied (corresponding to around 1 VAER per million doses for each of these disorders).

Ref.13 (Ireland) suffers from very low statistics and uncertain denominators, but quotes rough estimates of anaphylaxis in children under 16 of 120 per million for a univalent measles vaccine but only 1.4 per million for a bivalent HPV vaccine.

Ref.14 examines the incidence of Guillain-Barré syndrome (GBS) following influenza vaccination with the incidence unrelated to vaccination and finds no significance difference. The annual rate of GBS in the UK was reported as between ~10 per million for people under 20 up to a maximum of 35 per million for 70 year olds. It is difficult to compare such an annual incidence rate with YCS data because the latter are not explicitly time related. However it does put the latter in perspective as it suggests that rates of 10 to 35 per million doses of vaccine are only comparable with the 'natural' annual risk of GBS.

Table 2 compares the Yellow Card report rates for anaphylaxis or Guillain-Barré syndrome after Covid vaccinations with the above report rates for other vaccines. The Covid vaccines have a report rate for these serious conditions an order of magnitude higher than the US data for other vaccines, but an order of magnitude lower than data for other vaccines from England and Ireland.

References

[1] Shin Jie Yong, *Underreporting and Post-Vaccine Deaths in the Vaccine Adverse Event Reporting System (VAERS) Explained*, 17 July 2021. https://medium.com/microbial-instincts/underreporting-and-post-vaccine-deaths-in-vaccine-adverse-event-reporting-system-vaers-explained-14fe22b2a65f

[2] Elaine R.Miller, Michael M.McNeil, Pedro L.Moro, Jonathan Duffy and John R.Su (2020). *The reporting sensitivity of the Vaccine Adverse Event Reporting System (VAERS) for anaphylaxis and for Guillain-Barré syndrome*. Vaccine 38(47), 7458-7463. November 2020. https://doi.org/10.1016/j.vaccine.2020.09.072

[3] Michael M.McNeil, Rongxia Li, Susanne Pickering, Theresa M.Real, Philip J.Smith and Michael R.Pemberton (2013). *Who is unlikely to report adverse events after vaccinations to the Vaccine Adverse Event Reporting System (VAERS)?* Vaccine 31(24) 2673-2679, May 2013. https://doi.org/10.1016/j.vaccine.2013.04.009

[4] Steven Rosenthal and Robert Chen (1995). *The Reporting Sensitivities of Two Passive Surveillance Systems for Vaccine Adverse Events*. Am J Public Health. 1995 December; 85(12): 1706–1709. http://doi.org/10.2105/ajph.85.12.1706

[5] Yellow Card data reported for Pfizer vaccine at 29 September 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1023928/COVID-19_mRNA_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_29.09.2021_final.pdf

[6] Health Services & Resources Administration (USA), National Vaccine Injury Compensation Program Monthly Statistics Report to 31 Dec.2019. https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf

[7] Centres for Disease Control & Prevention. Flu Vaccination Coverage, United States, 2019–20 Influenza Season. https://www.cdc.gov/flu/fluvaxview/coverage-1920estimates.htm?web=1&wdLOR=cE0357A09-0DA4-4F7F-A62D-1DF599A33629

[8] Vaccine Adverse Event Reporting System. Annual Data Files. https://vaers.hhs.gov/data/datasets.html

[9] Ren, JJ., Sun, T., He, Y. *et al.* A statistical analysis of vaccine-adverse event data. *BMC Med Inform Decis Mak* **19,** 101 (2019). https://doi.org/10.1186/s12911-019-0818-8

[10] Lili Zhao, Sunghun Lee, Rongxia Li, Edison Ong, Yongqun He and Gary Freed (2020). Improvement in the Analysis of Vaccine Adverse Event Reporting System Database. Stat Biopharm Res. 2020; 12(3): 303–310 (April 2020). http://doi.org/10.1080/19466315.2020.1764862

[11] Joe W Cross, Mark Joya, Christopher McGee, Oluwafunmi Akinyemi, Piers Gatenby and Simonde Lusignan (2020). Adverse events of interest vary by influenza vaccine type and brand: Sentinel network study of eight seasons (2010–2018). Vaccine 38(22) 3869-3880, 8 May 2020. https://doi.org/10.1016/j.vaccine.2020.03.034

[12] Simon de Lusignan, Filipa Ferreira, Silvia Damaso, Rachel Byford, Sameera Pathirannehelage, Anne Yeakey, Ivelina Yonova, Anne Schuind and Gael Dos Santos.

Enhanced passive surveillance of influenza vaccination in England, 2016−2017: an observational study using an adverse events reporting card. Human Vaccines & Immunotherapeutics (2019) 15(5), 1048-1059. https://doi.org/10.1080/21645515.2019.1565258

[13] Michel Erlewyn-Lajeunesse, Linda P Hunt, Paul T Heath and Adam Finn (2012). *Anaphylaxis as an adverse event following immunisation in the UK and Ireland. Disease in Childhood*. 97(6) 487-490, 23 January 2012. http://dx.doi.org/10.1136/archdischild-2011-301163

[14] Julia Stowe, Nick Andrews, Lesley Wise and Elizabeth Miller (2009). Investigation of the Temporal Association of Guillain-Barré Syndrome With Influenza Vaccine and Influenza-like Illness Using the United Kingdom General Practice Research Database. American Journal of Epidemiology, 169(3), 382–388, February 2009. https://doi.org/10.1093/aje/kwn310

[15] THE EXPOSÉ, September 25, 2021. UK Medicine Regulator confirms there have been four times as many deaths due to the Covid-19 Vaccines in 8 months than deaths due to all other Vaccines combined in 20 years. https://theexpose.uk/2021/09/25/uk-medicine-regulator-confirms-there-have-been-four-times-as-many-deaths-due-to-the-covid-19-vaccines-in-8-months-than-deaths-due-to-all-other-vaccines-combined-in-20-years/

[16] Medicines & Healthcare products Regulatory Agency (MHRA). Decision: Information for Healthcare Professionals on COVID-19 Vaccine Pfizer/BioNTech (Regulation 174). Updated 27 September 2021. https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine

[17] Pfizer, Press Release 10 December 2020. *Pfizer and BioNTech Announce Publication of Results from Landmark Phase 3 Trial of BNT162b2 COVID-19 Vaccine Candidate in The New England Journal of Medicine.* https://www.businesswire.com/news/home/20201210005703/en/

[18] Medicines & Healthcare products Regulatory Agency (MHRA). Decision: Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca (Regulation 174). Updated 9 September 2021. https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca-regulation-174

[19] UK Health Security Agency. COVID-19 vaccine surveillance report Week 41 (2021). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1025358/Vaccine-surveillance-report-week-41.pdf

[20] W Huisman, B E E Martina, G F Rimmelzwaan, R A Gruters and A D M E Osterhaus. Vaccine-induced enhancement of viral infections. Vaccine 27(4):505-12, Jan 22, 2009. http://doi.org/10.1016/j.vaccine.2008.10.087.

[21] Stephen J. Thomas, et al. (2021). Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine (Pfizer). Preprint posted on MedRxiv July 28, 2021. https://doi.org/10.1101/2021.07.28.21261159. See also the Supplementary Material linked from the doi, and also here.

[22] UK Health Security Agency. COVID-19 vaccine surveillance report Week 46 (2021). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1034383/Vaccine-surveillance-report-week-46.pdf

[23] Nick Andrews, et al. (2021). Vaccine effectiveness and duration of protection of Comirnaty, Vaxzevria and Spikevax against mild and severe COVID-19 in the UK. MedRxiv 21 September 2021. https://doi.org/10.1101/2021.09.15.21263583

[24] Jamie Lopez Bernal. (27 April 2021). Effectiveness of the Pfizer-BioNTech and Oxford-AstraZeneca vaccines on covid-19 related symptoms, hospital admissions, and mortality in older adults in England: test negative case-control study. BMJ 2021;373:n1088. http://doi.org/10.1136/bmj.n1088

[25] NHS. (11 November 2021). How to look after yourself at home if you have coronavirus (COVID-19). https://www.nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/how-to-treat-symptoms-at-home/

[26] NHS. (accessed 23/11/21). Corona Virus Covid-19: Clinical/medical management. https://www.england.nhs.uk/coronavirus/secondary-care/management-confirmed-coronavirus-covid-19/clinical-medical-management/

[27] Merryn Voysey et al. (9 January 2021). Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. The Lancet Vol 397, 99-111. https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2932661-1

[28] World Health Organisation. (10 August 2021). Interim statement on COVID-19 vaccine booster doses. https://www.who.int/news/item/10-08-2021-interim-statement-on-covid-19-vaccine-booster-doses

[29] Lorenz Borsche, Bernd Glauner and Julian von Mendel. (2021). COVID-19 Mortality Risk Correlates Inversely with Vitamin D3 Status, and a Mortality Rate Close to Zero Could Theoretically Be Achieved at 50 ng/mL 25(OH)D3: Results of a Systematic Review and Meta-Analysis. Nutrients **13** (2021) 3596. https://doi.org/10.3390/nu13103596

[30] Hui Jang and Ya-Fang Mei. (2021). SARS–CoV–2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination In Vitro. *Viruses* **2021**, *13*(10), 2056 (October 2021); https://doi.org/10.3390/v13102056

[31] Merogenomics. (12 November 2021). https://www.youtube.com/watch?v=4Unt03UBhbU

[32] Kamran Abbasi. (13 November 2020). Covid-19: politicisation, "corruption," and suppression of science. BMJ 2020; 371 doi: https://doi.org/10.1136/bmj.m4425

[33] Wikipedia. (24/11/21). List of largest pharmaceutical settlements

[34] Rita Rubin. (3 September 2009). Pfizer fined $2.3 billion for illegal marketing in off-label drug case. USA TODAY. https://abcnews.go.com/Business/pfizer-fined-23-billion-illegal-marketing-off-label/story?id=8477617

[35] Paul D Thacker. (2 November 2021). Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial. BMJ 2021;375:n2635 https://doi.org/10.1136/bmj.n2635

[36] Judy More. (March 2016). Prevention of vitamin D deficiency. British Journal of Family Medicine.

[37] John Braithwaite. (1984). Corporate Crime in the Pharmaceutical Industry. Routledge & Kegan Paul.

[38] GBNews, 25/11/21. Covid: Report reveals increase in risk of heart attack following the mRNA COVID vaccine. Covid: Report reveals increase in risk of heart attack following the mRNA COVID vaccine - YouTube

[39] Steven R Gundry, (8/11/21). Abstract 10712: Mrna COVID Vaccines Dramatically Increase Endothelial Inflammatory Markers and ACS Risk as Measured by the PULS Cardiac Test: a Warning. *Circulation*. 2021;144:A10712. https://www.ahajournals.org/doi/abs/10.1161/circ.144.suppl_1.10712

[40] John Campbell (25/11/21). Heart risk after vaccines. https://www.youtube.com/watch?v=LEBGl8MVE-c

[41] Elisa Avolio et al (2021). The SARS-CoV-2 Spike protein disrupts human cardiac pericytes function through CD147-receptor-mediated signalling: a potential non-infective mechanism of COVID-19 microvascular disease. bioRxiv 20 July 2021.